UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K

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

For the Fiscal Year Ended December 31, 2019

OR

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

Commission File Number: 001-31918

IDERA PHARMACEUTICALS, INC.

(Exact name of Registrant as specified in its charter)

Delaware	**04-3072298**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
505 Eagleview Blvd., Suite 212 **Exton, Pennsylvania** (Address of principal executive offices)	**19341** (Zip Code)

(484) 348-1600

(Registrant's telephone number, including area code)

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

Title of Each Class:	Trading Symbol	Name of Each Exchange on Which Registered
Common Stock, $.001 par value	**IDRA**	**Nasdaq Capital Market**

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 ☑

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

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

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

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

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

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

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant was $63.6 million based on the last sale price of the registrant's common stock as reported on the Nasdaq Capital Market on June 28, 2019 (the last business day of the registrant's most recently completed second fiscal quarter).

As of February 15, 2020, the registrant had 30,538,478 shares of common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement for its 2020 annual meeting of stockholders are incorporated by reference into Part III of this Form 10-K where indicated. Such definitive proxy statement will be filed with the U.S. Securities and Exchange Commission within 120 days after the year ended December 31, 2019.

IDERA PHARMACEUTICALS, INC.
FORM 10-K

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Unless the context otherwise indicates, references in this Annual Report on Form 10-K to "Idera," "the Company," "we," "us" and "our" refer to Idera Pharmaceuticals, Inc.

IMO® and Idera® are our trademarks. All other trademarks and service marks appearing in this Annual Report on Form 10-K are the property of their respective owners.

Unless otherwise indicated, all share and per share amounts, including the exercise or conversion price of any of our securities, reflect, as applicable, the occurrence of a 1-for-8 reverse split of our common stock that occurred on July 27, 2018.

NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K ("Form 10-K") and the documents we incorporate by reference contain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). All statements, other than statements of historical fact, included or incorporated in this report regarding our strategy, future operations, collaborations, intellectual property, cash resources, financial position, future revenues, projected costs, prospects, plans and objectives of management are forward-looking statements. The words "believes," "anticipates," "estimates," "plans," "expects," "intends," "may," "could," "should," "potential," "likely," "projects," "continue," "will," "schedule," "would" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. We cannot guarantee that we actually will achieve the plans, intentions or expectations disclosed in our forward-looking statements and you should not place undue reliance on our forward-looking statements. These forward-looking statements involve known and unknown risks, uncertainties, and other factors, which may be beyond Idera's control, and which may cause the actual results, performance, or achievements of the Company to be materially different from future results, performance, or achievements expressed or implied by such forward-looking statements.

There are a number of important factors that could cause our actual results to differ materially from those indicated or implied by forward-looking statements. These important factors include those set forth below under Part I, Item 1A "Risk Factors." These factors and the other cautionary statements made in this Annual Report on Form 10-K and the documents we incorporate by reference should be read as being applicable to all related forward-looking statements whenever they appear in this Annual Report on Form 10-K and the documents we incorporate by reference.

In addition, any forward-looking statements represent our estimates only as of the date that this Annual Report on Form 10-K is filed with the Securities and Exchange Commission ("SEC") and should not be relied upon as representing our estimates as of any subsequent date. All forward-looking statements included in this Annual Report on Form 10-K are made as of the date hereof, and are expressly qualified in their entirety by this cautionary notice. We do not assume any obligation to update any forward-looking statements. We disclaim any intention or obligation to update or revise any forward-looking statement, whether as a result of new information, future events or otherwise, except as may be required by law.

PART I.

Item 1. Business.

Overview

We are a clinical-stage biopharmaceutical company with a business strategy focused on the clinical development, and ultimately the commercialization, of drug candidates for both oncology and rare disease indications characterized by small, well-defined patient populations with serious unmet medical needs. Our current focus is on our Toll-like receptor, or TLR, agonist, tilsotolimod (IMO-2125), for oncology. We believe we can develop and commercialize targeted therapies on our own. To the extent we seek to develop drug candidates for broader disease indications, we have entered into and may explore additional collaborative alliances to support development and commercialization.

TLRs are key receptors of the immune system and play a role in innate and adaptive immunity. As a result, we believe TLRs are potential therapeutic targets for the treatment of a broad range of diseases. Using our chemistry-based platform, we designed both TLR agonists and antagonists to act by modulating the activity of targeted TLRs. A TLR agonist is a compound that stimulates an immune response through the targeted TLR. A TLR antagonist is a compound that inhibits an immune response by blocking the targeted TLR.

Our current TLR-targeted clinical-stage drug candidate, tilsotolimod, is an agonist of TLR9. We are currently developing tilsotolimod, via intratumoral injection, for the treatment of anti-PD1 refractory metastatic melanoma in combination with ipilimumab, an anti-CTLA4 antibody marketed as Yervoy® by Bristol-Myers Squibb Company (“BMS”) in a Phase 3 registration trial. We are also evaluating intratumoral tilsotolimod in combination with nivolumab, an anti-PD1 antibody marketed as Opdivo® by BMS, and ipilimumab for the treatment of multiple solid tumors in a multicohort Phase 2 trial.

Clinical Development

Tilsotolimod (IMO-2125)

Tilsotolimod (IMO-2125) is a synthetic phosphorothioate oligonucleotide that acts as a direct agonist of TLR9 to stimulate the innate and adaptive immune systems. Tilsotolimod is being developed for administration via intratumoral injection in combination with systemically administered checkpoint inhibitors for the treatment of various solid tumors, including (i) anti-PD1 refractory metastatic melanoma in combination with ipilimumab, (ii) microsatellite stable (“MSS”) colorectal cancer (“CRC”) in combination with nivolumab and ipilimumab, and (iii) squamous cell carcinoma of the head and neck (“SCCHN”) in combination with ABBV-368 and other combinations. We refer to our tilsotolimod development program as the ILLUMINATE development program. See additional information under the heading “Collaborative Alliances” for information on the development of tilsotolimod in collaboration with AbbVie for patients with SCCHN.

Advancements in cancer immunotherapy have included the approval and late-stage development of multiple checkpoint inhibitors, which are therapies that target mechanisms by which tumor cells evade detection by the immune system. Despite these advancements, many patients fail to respond to these therapies. For instance, approximately 50% of patients with melanoma fail to respond to therapy with approved checkpoint inhibitors. Current published data suggests that the lack of response to checkpoint inhibition is related to a non-immunogenic tumor microenvironment. We believe TLR9 agonists may be useful in melanoma and other solid tumor types that are refractory to anti-PD1 treatment due, in part, to low mutation load and low dendritic cell infiltration. Because TLR9 agonists, such as tilsotolimod, stimulate the immune system, we believe there is a scientific rationale to evaluate the combination of intratumoral injection of tilsotolimod with checkpoint inhibitors. Specifically, we believe intratumoral injection of tilsotolimod activates a local immune response in the injected tumor, which may complement the effect of the systemically administered checkpoint inhibitors. Currently, there is minimal immunotherapy benefit, post chemotherapy, for patients with SCCHN and are no approved immunotherapy options for patients with MSS-CRC.

In studies conducted in our laboratories, intratumoral injection of TLR9 agonists, such as tilsotolimod, has potentiated the antitumor activity of multiple checkpoint inhibitors in preclinical tumor models. We believe these data support evaluation of combination regimens including the combination of a TLR9 agonist, such as tilsotolimod, with one or more checkpoint inhibitors for the treatment of cancer.

Melanoma

Melanoma is a cancer that begins in a type of skin cell called melanocytes. While melanoma is one of the least common types of skin cancer, it has a poor prognosis when not detected and treated early. As is the case in many forms of cancer, melanoma becomes more difficult to treat once the disease has spread, or metastasized, beyond the skin to other parts of the body. According to the American Cancer Society, approximately 100,000 people in the United States will be diagnosed with invasive melanoma this year. In recent years, pioneering immunotherapies known as checkpoint inhibitors have changed the treatment of advanced melanoma and have become the standard of care, with anti-PD-1 agents being the most commonly used immunotherapy in the first-line setting. These agents work by increasing the ability of the body's immune system to help detect and fight cancer cells. However, due to primary or acquired resistance mechanisms that exclude or inhibit anti-tumor immune cells, as many as 60% of patients do not benefit from this type of therapy, and up to one-third of initial responders develop resistance to the therapy and ultimately experience disease progression. Today, these refractory patients are left with few options for further treatment, paving the way for novel investigational therapies such as tilsotolimod.

We are currently developing tilsotolimod for use in combination with checkpoint inhibitors for the treatment of patients with anti-PD1 refractory metastatic melanoma. Tilsotolimod has received Orphan Drug Designation for the treatment of melanoma Stages IIb to IV and Fast Track designation for the treatment of anti-PD1 refractory metastatic melanoma in combination with ipilimumab therapy from the U.S. Food and Drug Administration ("FDA").

ILLUMINATE-301 - Phase 3 Trial of Tilsotolimod (IMO-2125) in Combination with Ipilimumab in Patients with Anti-PD1 Refractory Metastatic Melanoma

In the first quarter of 2018, we initiated a Phase 3 trial of the tilsotolimod–ipilimumab combination in patients with anti-PD1 refractory metastatic melanoma, which we refer to as ILLUMINATE-301. This trial will compare the results of the tilsotolimod–ipilimumab combination to those of ipilimumab alone in a 1:1 randomization. This trial originally targeted a sample size of 308 patients and was expected to be conducted at up to 110 sites worldwide. The family of primary endpoints of the trial are overall response rate ("ORR") by RECIST v1.1 and median overall survival ("OS"). We believe positive results in either of the primary endpoints could lead to approval in the United States. Key secondary endpoints include ORR by immune-related RECIST, durable response rate, median time to response, median progression free survival ("PFS") and patient-reported outcomes using a validated scale.

Following feedback from the ILLUMINATE-301 Steering Committee and global melanoma and immunology experts, we elected to make several modifications to the ILLUMINATE-301 trial design which better reflect the current treatment landscape in anti-PD-1 refractory melanoma and increase the probability of success in the trial. We are currently targeting a median OS improvement over ipilimumab alone of greater than or equal to 4.6 months, compared to 6.6 months originally targeted, and an ORR improvement of 10 percentage points over ipilimumab alone, compared to 20 percentage points originally targeted. Accordingly, the target effect size or hazard ratio has been adjusted to 0.71 from 0.63. In order to maintain statistical power, the sample size was increased to 454 patients from the original target sample size of 308 patients. We solicited feedback from the FDA and they did not object to these changes. We have also received approval from other global health authorities related to these changes. In March 2020, we completed target enrollment for ILLUMINATE-301.

As discussed below under the heading "Collaborative Alliances," in May 2018, we entered into a clinical trial collaboration and supply agreement with BMS under which BMS has agreed to supply YERVOY® (ipilimumab), at its cost and for no charge to us, for use in ILLUMINATE-301, including for the increase in sample size.

ILLUMINATE-204 - Phase 1/2 Trial of Tilsotolimod (IMO-2125) in Combination with Ipilimumab or Pembrolizumab in Patients with Anti-PD1 Refractory Metastatic Melanoma

In December 2015, we initiated a Phase 1/2 clinical trial to assess the safety and efficacy of intratumoral tilsotolimod in combination with ipilimumab, in patients with metastatic melanoma (refractory to treatment with a PD1 inhibitor, also referred to as anti-PD1 refractory), which we refer to as ILLUMINATE-204. We subsequently amended the trial protocol to include an additional treatment arm to study the combination of tilsotolimod with pembrolizumab, an anti-PD1 antibody marketed as Keytruda® by Merck & Co., Inc., in the same patient population. The Phase 2 expansion of our ILLUMINATE-204 trial closed for enrollment in February 2019 with a total of 52 patients dosed at 8 mg tilsotolimod in combination with ipilimumab, 49 of which are evaluable for safety and efficacy.

In this clinical trial, tilsotolimod is administered intratumorally into a selected tumor lesion at weeks 1, 2, 3, 5, 8, 11, 17, 23 and 29, for a total of nine doses, together with the standard dosing regimen of ipilimumab or pembrolizumab, administered intravenously. For patients who lack superficially accessible disease for injection, tilsotolimod is administered via injection into deep lesions, such as liver metastases, using interventional radiology guidance.

The trial was initiated at The University of Texas, MD Anderson Cancer Center ("MD Anderson") under the strategic research alliance we entered into with MD Anderson in June 2015, and additional sites were added through the fourth quarter of 2018. The primary objectives of the Phase 1 portion of the trial include characterizing the safety of the combinations and determining the recommended Phase 2 dose. A secondary objective of the Phase 1 portion of the trial is describing the antitumor activity of tilsotolimod when administered intratumorally in combination with ipilimumab or pembrolizumab. Objectives of the Phase 2 portion of the trial are to determine the objective response rate to the combinations using immune-related response criteria ("irRC") and RECIST v1.1 criteria. Additional objectives of the Phase 2 portion of the trial include determination of median PFS and median OS, and to continue to characterize the safety of the combinations. In the Phase 1 portion of the trial, serial biopsies were taken of selected injected and non-injected tumor lesions pre- and post-24 hours of the first dose of tilsotolimod, as well as at 8 and 13 weeks, to assess immune changes and response assessments. In the Phase 2 portion of the trial, biopsies were optional.

Ipilimumab Arm

In the Phase 1 portion of the ipilimumab arm of our Phase 1/2 clinical trial of tilsotolimod, escalating doses of tilsotolimod ranging from 4 mg through 32 mg were evaluated in a total of 18 patients, all but one who had progressed on nivolumab or pembrolizumab prior to enrollment in the trial. The combination of tilsotolimod and ipilimumab was generally well-tolerated at all dose levels studied. In April 2017, we completed tilsotolimod dose escalation and, based on the safety and efficacy data and data from translational immune parameters, selected the 8 mg dose level as the recommended dose level for the Phase 2 portion of the ipilimumab arm of the trial.

In April 2017, we initiated enrollment in the Phase 2 portion of the ipilimumab arm of our Phase 1/2 clinical trial of tilsotolimod with the 8 mg dose of intratumoral tilsotolimod. The Phase 2 portion of the trial utilizes a two-stage design to evaluate the objective response rate of tilsotolimod in combination with ipilimumab, compared to historical data for ipilimumab alone in the anti-PD1 refractory metastatic melanoma population. Based on the responses observed, the trial advanced with the expansion of the ipilimumab-tilsotolimod combination arm of ILLUMINATE-204 at the recommended Phase 2 dose of 8 mg tilsotolimod.

The Phase 2 ipilimumab-tilsotolimod combination arm of the ILLUMINATE-204 trial closed for enrollment in February 2019 with a total of 52 patients dosed at the recommended Phase 2 dose. As of August 5, 2019, of the 49 subjects evaluable for efficacy, 13 had a response representing a best overall response rate of 27%. Of the 13 responders, four were unconfirmed responses. Additionally, 36 of the 49 patients achieved stable disease or better, representing a disease control rate of 74%. Durable responses (>6 months) were observed in 5 of 9 confirmed responses per RECIST v1.1. Median overall survival (OS) had not yet been reached (min/max: 1.6 months/35 months).

We subsequently examined the four unconfirmed responders (of the 13 responders noted above) out of the 49 subjects evaluable for efficacy. As of October 23, 2019, two subjects were confirmed per RECIST v1.1 criteria, one remained unconfirmed, and one experienced disease progression. As for disease control, 35 of the 49 patients achieved stable disease or better (71%). Durable responses (greater than six months) were observed in five of 10 confirmed responses per RECIST v1.1 criteria who were evaluable for durability. The safety profile observed is consistent with previously reported results.

Other key findings from the trial include data demonstrating a systemic antitumor effect on distant uninjected tumors in patients who received tilsotolimod in combination with ipilimumab. Also, data showing clinical responses were observed in patients whose tumors had low HLA-ABC expression before treatment was started. Since HLA-ABC expression is required for ipilimumab antitumor activity (Rodig, 2018), evidence of clinical responses in patients with low HLA-ABC expression supports the contribution of tilsotolimod's mechanism of action to overcome resistance to ipilimumab in tumors with this HLA-ABC expression profile. This information suggests that tilsotolimod has the potential to enhance the overall response rate compared to that expected with ipilimumab alone.

Pembrolizumab Arm

In the Phase 1 portion of the pembrolizumab arm of our Phase 1/2 clinical trial of tilsotolimod, we evaluated escalating doses of tilsotolimod ranging from 8 mg through 32 mg.

We completed enrollment with a total of 9 patients dosed with the combination therapy in the 8 mg, 16 mg and 32 mg dosing cohorts in the Phase 1 dose escalation portion of the pembrolizumab arm of the trial. As of January 16, 2020, one patient who was treated at the 16 mg dose experienced a complete response by RECIST v1.1 criteria and has completed the study.

Refractory Solid Tumors

ILLUMINATE-101 - Phase 1b Trial of Intratumoral Tilsotolimod (IMO-2125) Monotherapy in Patients with Refractory Solid Tumors

In March 2017, we initiated a Phase 1b dose escalation trial of intratumoral tilsotolimod as a single agent in multiple tumor types, which we refer to as ILLUMINATE-101. In this trial, intratumoral tilsotolimod was administered on days 1, 8 and 15 of cycle 1 and on day 1 of each subsequent 21-day cycle, up to 17 cycles, for a total of 19 doses. We completed enrollment of a total of 38 patients in four dose-escalation cohorts at doses of 8mg (cohort 1, n=11), 16mg (cohort 2, n=8), 23mg (cohort 3, n=10) and 32mg (cohort 4, n=9). There were no dose-limiting toxicities observed and tilsotolimod appeared to be generally well-tolerated at each of the dose levels tested. We also completed enrollment of 16 patients in a melanoma expansion cohort, which utilized a Simon's optimal two-stage design, to assess whether tilsotolimod as a single agent (8mg dose) has any statistically relevant clinical activity, as demonstrated for objective response according to RECIST v1.1 criteria, in patients with metastatic melanoma who have progressed on or after treatment with a PD-(L)1 inhibitor. The study was completed in October 2019.

At the European Society for Medical Oncology Congress in September 2019, we provided an update on ILLUMINATE-101, noting that as of July 1, 2019, a total of 54 patients had been dosed, including 38 patients in the dose-evaluation portion of the trial and 16 patients in the melanoma dose-expansion cohort. Of the 45 evaluable patients, 33% (n=15) had a best response stable disease. Duration of stable disease ranged from 1.5 to 12 months from the start of treatment, with stable disease ongoing for two patients. There were no correlations between dose and efficacy observed.

An additional purpose of this study was to obtain tumor biopsies to assess the effect of tilsotolimod on the tumor microenvironment in multiple types of solid tumors and inform the expansion of the development program beyond melanoma. Translational research in ILLUMINATE-101 demonstrated that tilsotolimod increased dendritic cell activation and upregulated MHC class II and IFN-α signaling, which suggests improved antigen presentation, and is similar to that observed and previously reported in the tumor biopsies from the ILLUMINATE-204 melanoma subjects. This observation provided additional rationale to expand the tilsotolimod clinical development program to additional solid tumors.

Other Solid Tumors

Advancements in cancer immunotherapy have included the approval and late-stage development of multiple checkpoint inhibitors, as single agents or in combination, for other solid tumors including, among others, dMMR/MSI-H colorectal cancer ("CRC") and squamous cell carcinoma of the head and neck ("SCCHN").

Nivolumab administered as monotherapy or in combination with ipilimumab has demonstrated benefit and is approved for the treatment of dMMR/MSI-H mCRC. However, in a previously treated microsatellite stable ("MSS") CRC patient population, nivolumab + ipilimumab combination therapy did not produce objective responses. MSS-CRC has been shown to be highly immunosuppressive. Moreover, the tumor microenvironment in MSS-CRC has been shown to keep dendritic cells in an immature state. Given tilsotolimod's mechanism of action of activating dendritic cells, it may serve a complementary function to nivolumab and ipilimumab within the immunosuppressive tumor microenvironment ("TME") of MSS-CRC patients.

We believe, based on internally conducted commercial research and information published by the American Cancer Society and other references, that annually in the United States, approximately 140,000 people are diagnosed with CRC, of which 85% are MSS, and that approximately 50,000 deaths are attributed to CRC. Additionally, we believe that annually in the United States, approximately 64,000 people are diagnosed with SCCHN and there are approximately 14,000 deaths attributed to SCCHN. We also believe that, in 2018, approximately 200,000 patients in the United States with various tumor types have been treated with an anti-PD-1/anti-PD-L1 therapy. Approximately 87% of these patients may progress after treatment and therefore may benefit from alternative therapies.

Squamous cell carcinoma is the most frequent malignant tumor of the head and neck region and develops from the mucosal linings of the upper aerodigestive tract. Although the majority of patients present with loco-regional disease, more than 50% will succumb to recurrent or metastatic disease despite aggressive therapy with surgery, radiation, and/or chemotherapy. Relapsed or metastatic SCCHN ("RM-SCCHN") is currently an incurable disease with a poor prognosis and the mortality rate of patients presenting with advanced disease remains high. Recently, the results from prospectively conducted trials employing the immune-modulating antibodies nivolumab and pembrolizumab following chemotherapy heralded a new era of treatment for RM-SCCHN. Patients responding to these agents have seen durable responses and in controlled studies an overall survival benefit has been demonstrated for the anti-PD-1 antibodies versus standard of care chemotherapy. The challenge remains to increase the percentage of patients responding to these treatments, which currently ranges from 13% to 23% depending on the line of therapy.

ILLUMINATE-206 - Phase 2 Trial of Tilsotolimod (IMO-2125) in Combination with Nivolumab and Ipilimumab for the treatment of Solid Tumors

In December 2018, we submitted an IND application to the FDA to evaluate tilsotolimod administered intratumorally, in combination with nivolumab and ipilimumab in a Phase 2, multicohort study of multiple solid tumors. The basis for this study is supported by data generated from our ILLUMINATE-101 and ILLUMINATE-204 trials, which suggest the mechanism of action for tilsotolimod may be tumor-type agnostic and potentially beneficial in combination with checkpoint modulation in a variety of tumor types. In January 2019, we received notification from the FDA that the study may proceed and initiated the Phase 2, open-label, global, multicohort study for the treatment of specific solid tumors in September 2019. We refer to this study as ILLUMINATE-206.

Each cohort in this study is designed to be conducted in two parts. The purpose of the first part (Part 1) is for signal finding and utilizes a Simon's minimax two-stage design in a single-arm. The primary objective of Part 1 is to evaluate the efficacy (measured by ORR based on RECIST v1.1) of intratumoral tilsotolimod in combination with nivolumab and ipilimumab. Secondary objectives of Part 1 include safety, tolerability, immunogenicity and translational data evaluations. Based on the data from Part 1 of each cohort, expansion of a cohort may be conducted as Part 2. Part 2 objectives will be determined after the decision is made to initiate Part 2 of a given cohort. The start and end of the study will be independent for each cohort.

The ILLUMINATE-206 cohorts are as follows:

- MSS-CRC Cohort (currently underway): Relapsed/refractory MSS-CRC in immunotherapy-naïve patients treated with tilsotolimod in combination with nivolumab and ipilimumab; and
- RM-SCCHN Cohort (currently being evaluated): RM-SCCHN in PD-1-refractory patients treated with tilsotolimod in combination with nivolumab and ipilimumab.

We initiated ILLUMINATE-206 beginning with the MSS-CRC Cohort. An initial group of ten patients were enrolled to evaluate the safety of administering the combination of tilsotolimod, nivolumab and ipilimumab. Within Part 1 of the MSS-CRC Cohort, approximately 65 patients may be enrolled pending data from the signal-finding stage. See information on our clinical trial and supply agreement with AbbVie under the heading "Collaborative Alliances" which discusses the development of tilsotolimod in combination with ABBV-368 and other combinations for the treatment of SCCHN.

As discussed below under the heading "Collaborative Alliances," in March 2019, we entered into a clinical trial collaboration and supply agreement with BMS, under which BMS has agreed to manufacture and supply YERVOY® (ipilimumab) and OPDIVO® (nivolumab), at its cost and for no charge to us, for use in ILLUMINATE-206.

Discontinued Programs

In July 2018, following an analysis of our gene-silencing technology platform and our research portfolio, we decided to suspend our rare disease and discovery programs as part of our overall strategy to more narrowly focus our capital resources on the development and commercialization of tilsotolimod.

IMO-8400 for Rare Diseases

We had been developing IMO-8400, an antagonist of TLR7, TLR8 and TLR9, for the treatment of rare diseases, and dermatomyositis was our lead clinical target. In December 2015, we initiated a Phase 2, randomized, double-blind, placebo-controlled clinical trial designed to assess the safety, tolerability and treatment effect of IMO-8400 in adult patients with dermatomyositis. In June 2018, we reported that the trial did not meet its primary endpoint of statistically significant change from baseline in the Cutaneous Dermatomyositis Disease Area and Severity Index (CDASI) activity score versus placebo. As a result, in July 2018, we made a decision to discontinue this clinical program upon completion of final close-out activities.

In April 2019, we out-licensed IMO-8400 to a privately-held biopharmaceutical company. See Note 10 of the notes to our financial statements in this Annual Report on Form 10-K for additional information.

Agreement with Abbott Molecular

We are party to a development and commercialization agreement with Abbott Molecular, Inc. (“Abbott”), which we entered into in May 2014, in connection with our prior IMO-8400 clinical development program for the treatment of certain genetically defined forms of B-cell lymphoma, including our Phase 1/2 clinical trial in patients with diffuse large B-cell lymphoma (“DLBCL”) harboring the MYD88 L265P oncogenic mutation. The agreement provided for the development and subsequent commercialization, by Abbott, of an in vitro companion diagnostic test utilizing polymerase chain reaction technology to identify with high sensitivity and specificity the presence in tumor biopsy samples of the oncogenic mutation referred to scientifically as MYD88 L265P. In September 2016, we suspended all clinical development of IMO-8400 for B-cell lymphomas. While we have maintained our relationship with Abbott under the agreement, we are permitted to terminate the agreement upon 90 days written notice to Abbott and, under circumstances specified in the agreement, payment of a termination fee and wind-down costs. The parties also may terminate the agreement based on uncured material breaches by or the bankruptcy or insolvency of the other party, and each party has the right to terminate the agreement in the event of specified permanent injunctions based on infringement of third-party intellectual property rights.

IMO-9200 for Autoimmune Disease

We had developed a second novel synthetic oligonucleotide antagonist of TLR7, TLR8, and TLR9, IMO-9200, as a drug candidate for potential use in selected autoimmune disease indications. In 2015, we completed a Phase 1 clinical trial of IMO-9200 in healthy subjects as well as additional preclinical studies of IMO-9200 for autoimmune diseases. In 2015, we determined not to proceed with the development of IMO-9200 because the large autoimmune disease indications for which IMO-9200 had been developed did not fit within the strategic focus of our company. In November 2016, we entered into an exclusive license and collaboration agreement with Vivelix Pharmaceuticals, Ltd. (“Vivelix”), granting Vivelix worldwide rights to develop and market IMO-9200 for non-malignant gastrointestinal disorders, which agreement we refer to as the Vivelix Agreement. On November 4, 2018, Vivelix notified us that they decided to terminate ongoing development activities related to IMO-9200. Subsequently, on March 4, 2019, we mutually agreed to terminate the Vivelix Agreement.

Other Rare Disease and Discovery Programs

Collaboration with GlaxoSmithKline Intellectual Property Development Limited

In November 2015, we entered into a collaboration and license agreement with GlaxoSmithKline Intellectual Property Development Limited (“GSK”) to license, research, develop and commercialize pharmaceutical compounds from our nucleic acid chemistry technology for the treatment of selected targets in renal disease, which agreement we refer to as the GSK Agreement. In connection with the GSK Agreement, GSK provided an initial target for us to identify a potential population of development candidates to address such target under a mutually agreed upon research plan. Prior to suspending our rare disease and discovery programs, and the wind-

down of such discovery operations, we created multiple development candidates to address the initial target designated by GSK. Until November 2019, the expiration of the collaboration term, GSK had the right to designate one development candidate in its sole discretion, from the population of identified candidates, to move forward into clinical development. However, GSK did not designate any candidate for development during the collaboration term. If such designation had occurred, GSK would have been solely responsible for the development and commercialization activities for that designated development candidate.

The GSK Agreement also provided GSK with the option to select up to two additional targets at any time during the first two years of the agreement, for further research under mutually agreed upon research plans. Upon selecting additional targets, GSK then had the option to designate one development candidate for each additional target, at which time GSK would have sole responsibility to develop and commercialize each such designated development candidate. GSK did not select any additional targets for research through the expiry of the option period.

Under the terms of the GSK Agreement, we received a $2.5 million upfront, non-refundable, non-creditable cash payment upon the execution of the GSK Agreement. Additionally, we were initially eligible to receive a total of up to approximately $100 million in license, research, clinical development and commercialization milestone payments under the GSK agreement, of which $9 million of these milestone payments would have been payable by GSK upon the identification of the additional targets, the completion of current and future research plans and the designation of development candidates and $89 million would have been payable by GSK upon the achievement of clinical milestones and commercial milestones. As a result of GSK not designating a development candidate during the collaboration term, we are no longer eligible to receive any additional license, research, clinical development and commercialization milestone payments, or any royalty payments, pursuant to the GSK Agreement.

Collaborative Alliances

Our current alliances include collaborations with AbbVie Inc. (“AbbVie”) and BMS. In addition to our current alliances, we may seek to enter into additional collaborative alliances to support development and commercialization of our TLR agonists and antagonists.

Collaboration with AbbVie

Effective August 27, 2019, we entered into a clinical trial collaboration and supply agreement with AbbVie, a global, research-based biopharmaceutical company, to conduct a clinical study to evaluate the efficacy and safety of combinations of an OX40 agonist (ABBV-368), tilsotolimod, nab-paclitaxel and/or an anti-programmed cell death 1 (PD-1) antagonist (ABBV-181), which we refer to as the AbbVie Agreement. Under the AbbVie Agreement, we will provide a clinical trial supply of tilsotolimod to AbbVie and AbbVie will sponsor, fund and conduct the study entitled “A Phase 1b, Multicenter, Open-Label Study to Determine the Safety, Tolerability, Pharmacokinetics, and Preliminary Efficacy of ABBV-368 plus Tilsotolimod and Other Therapy Combinations in Subjects with Recurrent/Metastatic Head and Neck Squamous Cell Carcinoma” (the, “AbbVie Study”). We have agreed to manufacture and supply tilsotolimod at its cost and for no charge to AbbVie, for use in the AbbVie Study.

Collaboration with Bristol-Meyers Squibb

Effective May 18, 2018, we entered into a clinical trial collaboration and supply agreement with BMS (the “May 2018 BMS Agreement”) to clinically evaluate the combination of tilsotolimod with BMS’s therapy YERVOY® (ipilimumab). Under the May 2018 BMS Agreement, we will sponsor, fund and conduct our ongoing global, open-label, multicenter Phase 3 clinical trial of tilsotolimod in combination with YERVOY® entitled “A Randomized Phase 3 Comparison of IMO-2125 with Ipilimumab versus Ipilimumab Alone in Patients with Anti-PD-1 Refractory Melanoma” in accordance with an agreed-upon protocol, which we refer to as ILLUMINATE-301. Under the May 2018 BMS Agreement, BMS granted us a non-exclusive, non-transferrable, royalty-free license (with a right to sublicense) under its intellectual property to use YERVOY® in ILLUMINATE-301 and has agreed to manufacture and supply YERVOY®, at its cost and for no charge to us, for use in ILLUMINATE-301.

Effective March 11, 2019, we entered into a second clinical trial collaboration and supply agreement with BMS (the "March 2019 BMS Agreement") to clinically evaluate the combination of tilsotolimod with BMS's therapy YERVOY® (ipilimumab) and OPDIVO® (nivolumab). Under the March 2019 BMS Agreement, we will sponsor, fund and conduct a Phase 2, open-label, global, multicenter, multicohort study of intratumoral tilsotolimod in combination with YERVOY® and OPDIVO® entitled "Study of Tilsotolimod in Combination with Nivolumab and Ipilimumab For the Treatment of Solid Tumors" in accordance with an agreed-upon protocol, which we refer to as ILLUMINATE-206. Under the March 2019 BMS Agreement, BMS granted us a non-exclusive, non-transferrable, royalty-free license (with a right to sublicense) under its intellectual property to use YERVOY® and OPDIVO® in ILLUMINATE-206 and has agreed to manufacture and supply YERVOY® and OPDIVO®, at its cost and for no charge to us, for use in ILLUMINATE-206.

Academic and Research Collaborations

We have entered into research collaborations with scientists at leading academic research institutions. These research collaborations allow us to augment our internal research capabilities and obtain access to specialized knowledge and expertise. In general, our research collaborations may require us to supply compounds and pay various amounts to support the research. Under these research agreements, if a collaborator, solely or jointly with us, creates any invention, we may own exclusively such invention, have an automatic paid-up, royalty-free non-exclusive license or have an option to negotiate an exclusive, worldwide, royalty-bearing license to such invention. Inventions developed solely by our scientists in connection with research collaborations are owned exclusively by us. These collaborative agreements are non-exclusive and may be terminated with limited notice.

Research and Development Expenses

We are committed to redefining the treatment of certain cancers and rare diseases and have historically dedicated a significant portion of our resources to our efforts on the discovery and development of our drug candidates. For the years ended December 31, 2019, 2018 and 2017, we spent approximately $34.9 million, $41.8 million, and $50.7 million, respectively, on research and development activities. We plan to continue to invest in research and development, primarily with respect to our clinical trials of tilsotolimod. Accordingly, we anticipate a significant portion of our operating expenses will continue to be related to clinical development in 2020 and beyond.

Patents, Proprietary Rights and Trade Secrets

Our success depends in part on our ability to obtain and maintain proprietary protection for our drug candidates, technology and know-how, to operate without infringing the proprietary rights of others and to prevent others from infringing our proprietary rights. We use a variety of methods to seek to protect our proprietary position, including filing U.S. and foreign patent applications related to our proprietary technology, inventions and improvements that are important to the development of our business. We also rely on trade secrets, know-how, continuing technological innovation, and in-licensing opportunities to develop and maintain our proprietary position.

We have devoted and continue to devote a substantial amount of our resources into establishing intellectual property protection for:

- Novel chemical entities that function as agonists of TLR3, TLR7, TLR8 or TLR9;
- Novel chemical entities that function as antagonists of TLR7, TLR8 or TLR9; and
- Composition and use of our nucleic acid chemistry compounds to treat and prevent a variety of diseases.

On November 5, 2019, the U.S. Patent and Trademark Office issued to us U.S. Patent No. 10,463,686 entitled "Immune Modulation With TLR9 Agonists For Cancer Treatment," which includes tilsotolimod. The patent includes 24 claims directed to methods of treating melanoma with intratumoral administration of tilsotolimod in combination with certain immune checkpoint inhibitor therapies, including inhibitors of the CTLA-4 and PD-1/PD-L1 pathways. The patent is expected to expire in September 2037.

As of February 15, 2020, we owned approximately 53 U.S. patents and patent applications and about 184 patents and patent applications throughout the rest of the world for our TLR-targeted immune modulation technologies. These patents and patent applications include claims covering the chemical compositions of matter and methods of use of our IMO compounds, such as IMO-8400, IMO-9200 and tilsotolimod (IMO-2125), as well as other compounds. These patents and patent applications (if granted) expire at various dates ranging from 2020 to 2037. With respect to IMO-8400, we have six issued U.S. patents that cover the chemical composition of matter of IMO-8400 and certain methods of its use, the latest of which expires in 2031. With respect to IMO-9200, we have nine issued U.S. patents that cover the chemical composition for IMO-9200 and methods of its use, the latest of which expires in 2034. With respect to tilsotolimod, we have an issued U.S. patent that covers the chemical composition of matter of tilsotolimod that will expire in 2024 and additional patents that cover methods of its use, the latest of which will expire in 2037. We have pending applications in the United States and outside of the United States that cover methods of treatment or use of tilsotolimod, which, if granted, will expire between 2035 and 2039.

Because patent applications in the United States and many foreign jurisdictions are typically not published until 18 months after filing, or in some cases not at all, and because publications of discoveries in the scientific literature often lag behind actual discoveries, neither we nor our licensors can be certain that we or they were the first to make the inventions claimed in issued patents or pending patent applications, or that we or they were the first to file for protection of the inventions set forth in these patent applications.

Litigation may be necessary to defend against or assert claims of infringement, to enforce patents issued to us, to protect trade secrets or know-how owned by us, or to determine the scope and validity of the proprietary rights of others or to determine the appropriate term for an issued patent. In addition, the United States Patent and Trademark Office ("USPTO") may declare interference proceedings to determine the priority of inventions with respect to our patent applications or reexamination or reissue proceedings to determine if the scope of a patent should be narrowed. Litigation or any of these other proceedings could result in substantial costs to and diversion of effort by us, even if the eventual outcome is favorable to us, and could have a material adverse effect on our business, financial condition and results of operations. These efforts by us may not be successful.

The term of individual patents depends upon the legal term for patents in the countries in which they are obtained. In most countries, including the United States, the patent term is 20 years from the earliest filing date of a non-provisional patent application. In the United States, a patent's term may be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the USPTO in examining and granting a

patent, or may be shortened if a patent is terminally disclaimed over an earlier filed patent. The term of a patent that covers a drug, biological product or medical device approved pursuant to a pre-market approval may also be eligible for patent term extension when FDA approval is granted, provided statutory and regulatory requirements are met. The length of the patent term extension is related to the length of time the drug is under regulatory review while the patent is in force. The Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Act, permits a patent term extension of up to five years beyond the expiration date set for the patent. Patent extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent applicable to each regulatory review period may be granted an extension and only those claims reading on the approved drug are extended. Similar provisions are available in Europe and other foreign jurisdictions to extend the term of a patent that covers an approved drug.

We may rely, in some circumstances, on trade secrets and confidentiality agreements to protect our technology. Although trade secrets are difficult to protect, wherever possible, we use confidential disclosure agreements to protect the proprietary nature of our technology. We regularly implement confidentiality agreements with our employees, consultants, scientific advisors, and other contractors and collaborators. However, there can be no assurance that these agreements will not be breached, that we will have adequate remedies for any breach, or that our trade secrets and/or proprietary information will not otherwise become known or be independently discovered by competitors. To the extent that our employees, consultants or contractors use intellectual property owned by others in their work for us, disputes may also arise as to the rights in related or resulting know-how and inventions.

Manufacturing

We do not currently own or operate manufacturing facilities for the production of clinical or commercial quantities of any of our drug candidates. We currently rely and expect to continue to rely on other companies for the manufacture of our drug candidates for preclinical and clinical development. We source our bulk drug manufacturing requirements from a limited number of contract manufacturers through the issuance of work orders on an as-needed basis. We currently do not have any long-term supply contracts. We depend and will continue to depend on our contract manufacturers to manufacture our drug candidates in accordance with current Good Manufacturing Practices (“cGMP”) regulations for use in clinical trials. We will ultimately depend on contract manufacturers for the manufacture of our products for commercial sale, if and when our drug candidates are approved. Contract manufacturers are subject to extensive governmental regulation.

Competition

The biotechnology and pharmaceutical industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. We are currently developing tilsotolimod (IMO-2125), our TLR agonist drug candidate, for the treatment by intratumoral injection of multiple oncology indications in combination with checkpoint inhibitors. There are many other companies, both public and private, that are actively engaged in discovery, development, and commercializing products and technologies that may compete with our drug candidate, tilsotolimod, including TLR-targeted compounds as well as non-TLR-targeted therapeutics.

Immuno-oncology, which utilizes a patient's own immune system to combat cancer, is currently an active area of research for biotechnology and pharmaceutical companies. Interest in immuno-oncology is driven by efficacy data in cancers with historically bleak outcomes and the potential to achieve a cure or functional cure for some patients. As such, we expect that our efforts in this field will be competitive with a wide variety of different approaches. Any one of these competitive approaches may result in the development of novel technologies that are more effective, safer or less costly than any that we are developing.

We are aware of other companies developing TLR agonists as well as other mechanisms of action that are focused on stimulating the immune response. These companies include, but are not limited to, Aduro Biotech, Inc., BioLineRx Ltd., Checkmate Pharmaceuticals, Inc., Dynavax Technologies Corporation, Exicure, Inc., Gilead Sciences Inc., GlaxoSmithKline plc, Hoffmann-La Roche Ltd., Innate Immunotherapeutics Ltd., Mologen AG VentiRx Pharmaceuticals Inc., Nektar Therapeutics, and Telormedix S.A.. Additionally, we are aware of other companies developing non-TLR therapies in our patient populations including, but not limited to OncoSec Immunotherapies, Iovance Biotherapeutics, Lytix Biopharma and Takara Bio.

We recognize that other companies, including large pharmaceutical companies, may be developing or have plans to develop products and technologies that may compete with ours. Many of our competitors have substantially greater financial, technical, and human resources than we have. In addition, many of our competitors have significantly greater experience than we have in undertaking preclinical studies and human clinical trials of new pharmaceutical products, obtaining FDA and other regulatory approvals of products for use in health care and manufacturing, and marketing and selling approved products. Our competitors may discover, develop or commercialize products or other novel technologies that are more effective, safer or less costly than any that we are developing. Our competitors may also obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours.

We anticipate that the competition with our drug candidate, tilsotolimod, and technologies will be based on a number of factors including product efficacy, safety, availability, and price. The timing of market introduction of tilsotolimod and competitive products will also affect competition among products. We expect the relative speed with which we can develop tilsotolimod, complete the clinical trials and approval processes, and supply commercial quantities of the products to the market to be important competitive factors. Our competitive position will also depend upon our ability to attract and retain qualified personnel, to obtain patent protection or otherwise develop proprietary products or processes, protect our intellectual property, and to secure sufficient capital resources for the period between technological conception and commercial sales.

Risks related to our competitors and our competitive position are discussed in further detail in the section entitled "Risk Factors" of this Annual Report on Form 10-K.

Government Regulation

Government authorities in the United States, at the federal, state and local level, and in other countries and jurisdictions, including the European Union, extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, marketing, pricing, post-approval monitoring and reporting, and import and export of pharmaceutical products. The processes for obtaining regulatory approvals in the United States and in foreign countries and jurisdictions, along with subsequent compliance with applicable statutes and regulations and other regulatory authorities, require the expenditure of substantial time and financial resources.

Review and Approval of Drugs in the United States

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act ("FDCA") and associated implementing regulations. The failure to comply with the FDCA and other applicable U.S. requirements at any time during the product development process, approval process or after approval may subject an applicant and/or sponsor to a variety of administrative or judicial sanctions, including refusal by the FDA to approve pending applications, withdrawal of an approval, imposition of a clinical hold, issuance of warning letters and other types of letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement of profits, or civil or criminal investigations and penalties brought by the FDA and the Department of Justice, or the DOJ, or other governmental entities, including state agencies.

An applicant seeking approval to market and distribute a new drug product in the United States must typically undertake the following:

- completion of preclinical laboratory tests, animal studies and formulation studies in compliance with the FDA's good laboratory practice ("GLP") regulations;
- submission to the FDA of an IND, which must take effect before human clinical trials may begin in the United States;
- approval by an independent institutional review board ("IRB"), representing each clinical site before each clinical trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with good clinical practices ("GCP") to establish the safety and efficacy of the proposed drug product for each indication;
- preparation and submission to the FDA of a new drug application ("NDA");
- review of the product candidate by an FDA advisory committee, where appropriate or if applicable;
- satisfactory completion of one or more FDA inspections of the manufacturing facility or facilities at which the product, or components thereof, are produced to assess compliance with cGMP requirements and to assure that the facilities, methods and controls are adequate to preserve the product's identity, strength, quality and purity;
- satisfactory completion of FDA audits of clinical trial sites to assure compliance with GCPs and the integrity of the clinical data;
- payment of user fees and securing FDA approval of the NDA; and
- compliance with any post-approval requirements, including Risk Evaluation and Mitigation Strategies ("REMS") where applicable, and post-approval studies required by the FDA.

Preclinical Studies

Before an applicant begins testing a product candidate with potential therapeutic value in humans, the product candidate enters the preclinical testing stage. Preclinical studies include laboratory evaluation of the purity and stability of the manufactured drug substance or active pharmaceutical ingredient and the formulated drug or drug product, as well as in vitro and animal studies to assess the safety and activity of the drug for initial testing in humans and to establish a rationale for therapeutic use. The conduct of preclinical studies is subject to federal regulations and requirements, including GLP regulations. The results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and plans for clinical studies, among other things, are submitted to the FDA as part of an IND. Additional preclinical testing, such as animal tests of reproductive adverse events and carcinogenicity, may continue after the IND is submitted.

Human Clinical Studies in Support of an NDA

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with GCP requirements, which include, among other things, the requirement that all research subjects provide their informed consent in writing before their participation in any clinical trial. Clinical trials are conducted under written study protocols detailing, among other things, the objectives of the study, inclusion and exclusion criteria, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. A protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND. An IND is an exemption from the FDCA that allows an unapproved product candidate to be shipped in interstate commerce for use in an investigational clinical trial and a request for FDA authorization to administer such investigational product to humans. An IND automatically becomes effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions related to a proposed clinical trial and places the trial on clinical hold or partial clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin.

Typically, the FDA will require one IND for early development studies where the sponsor is uncertain of the indication or dosage form of the proposed product, where the drug is being developed for closely related indications within a single review division at FDA, or where there are multiple closely-related routes of administration using the same dosage formulation. On the other hand, multiple INDs may be required where there are two or more unrelated conditions being developed or where multiple dosage forms are being extensively investigated or where multiple routes of administration are being evaluated.

In addition to the foregoing IND requirements, an IRB representing each institution participating in the clinical trial must review and approve the plan for any clinical trial before it commences at that institution, and the IRB must conduct continuing review and reapprove the study at least annually. The IRB must review and approve, among other things, the study protocol and informed consent information to be provided to study subjects. An IRB must operate in compliance with FDA regulations. Information about certain clinical trials must be submitted within specific timeframes to the National Institutes of Health for public dissemination on their ClinicalTrials.gov website.

Additionally, some trials are overseen by an independent group of qualified experts organized by the trial sponsor, known as a data monitoring committee (“DMC”). This group provides recommendations as to whether a trial should move forward at designated check points based on access that only the group maintains to available data from the study. Suspension or termination of development during any phase of clinical trials can occur if it is determined that the participants or patients are being exposed to an unacceptable health risk. Other reasons for suspension or termination may be made by us based on evolving business objectives and/or competitive climate.

Human clinical trials are typically conducted in three sequential phases, which may overlap or be combined:

Phase 1: The drug is initially introduced into healthy human subjects or patients with the target disease (e.g. cancer) or condition and tested for safety, dosage tolerance, absorption, metabolism, distribution, excretion and, if possible, to gain an early indication of its effectiveness and to determine optimal dosage.

Phase 2: The drug is administered to a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage.

Phase 3: The drug is administered to an expanded patient population, generally at geographically dispersed clinical trial sites, in well-controlled clinical trials to generate enough data to statistically evaluate the efficacy and safety of the product for approval, to establish the overall risk-benefit profile of the product, and to provide adequate information for the labeling of the product.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and more frequently if serious adverse events occur. In addition, IND safety reports must be submitted to the FDA for any of the following: serious and unexpected suspected adverse reactions; findings from other studies or animal or in vitro testing that suggest a significant risk in humans exposed to the drug; and any clinically important increase in the case of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, or at all. Furthermore, the FDA, the sponsor or the data monitoring committee for a clinical trial may suspend or terminate the clinical trial at any time on various grounds, including a finding that the research subjects are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution, or an institution it represents, if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients. The FDA will typically inspect one or more clinical sites to assure compliance with GCP and the integrity of the clinical data submitted.

Section 505(b)(2) NDAs

NDAs for most new drug products are based on two full clinical studies which must contain substantial evidence of the safety and efficacy of the proposed new product. These applications are submitted under Section 505(b)(1) of the FDCA. The FDA is, however, authorized to approve an alternative type of NDA under Section 505(b)(2) of the FDCA. This type of application allows the applicant to rely, in part, on the FDA's previous findings of safety and efficacy for a similar product, or published literature. Specifically, Section 505(b)(2) applies to NDAs for a drug for which the investigations made to show whether or not the drug is safe for use and effective in use and relied upon by the applicant for approval of the application "were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted."

Thus, Section 505(b)(2) authorizes the FDA to approve an NDA based on safety and effectiveness data that were not developed by the applicant. NDAs filed under Section 505(b)(2) may provide an alternate and potentially more expeditious pathway to FDA approval for new or improved formulations or new uses of previously approved products. If the Section 505(b)(2) applicant can establish that reliance on the FDA's previous approval is scientifically appropriate, the applicant may eliminate the need to conduct certain preclinical or clinical studies of the new product. The FDA may also require companies to perform additional studies or measurements to support the change from the approved product. The FDA may then approve the new drug candidate for all or some of the label indications for which the referenced product has been approved, as well as for any new indication sought by the Section 505(b)(2) applicant.

Submission of an NDA to the FDA

Assuming successful completion of required clinical testing and other requirements, the results of the preclinical and clinical studies, together with detailed information relating to the product's chemistry, manufacture, controls and proposed labeling, among other things, are submitted to the FDA as part of an NDA requesting approval to market the drug product for one or more indications. Under federal law, the submission of most NDAs is subject to an application user fee, which for federal fiscal year 2019 is $2,588,478 for an application requiring clinical data. The sponsor of an approved NDA is also subject to an annual program fee, which for fiscal year 2019 is $309,915. Exceptions or waivers for these fees exist for a small company (fewer than 500 employees, including employees and affiliates) satisfying certain requirements and products with orphan drug designation for a particular indication are not subject to a fee provided there are no other intended uses in the NDA.

The FDA conducts a preliminary review of an NDA within 60 calendar days of its receipt and strives to inform the sponsor by the 74th day after the FDA's receipt of the submission to determine whether the application is sufficiently complete to permit substantive review. The FDA may request additional information rather than accept an NDA for filing. In this event, the application must be resubmitted with the additional information. The resubmitted application is also subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review.

The FDA has agreed to specified performance goals in the review process of NDAs. Under the agreement, 90% of applications seeking approval of New Molecular Entities ("NMEs"), are meant to be reviewed within ten months from the date on which the FDA accepts the NDA for filing, and 90% of applications for NMEs that have been designated for "priority review" are meant to be reviewed within six months of the filing date. For applications seeking approval of drugs that are not NMEs, the ten-month and six-month review periods run from the date that the FDA receives the application. The review process may be extended by the FDA for three additional months to consider new information or clarification provided by the applicant to address an outstanding deficiency identified by the FDA following the original submission.

Before approving an NDA, the FDA typically will inspect the facility or facilities where the product is or will be manufactured. These pre-approval inspections cover all facilities associated with an NDA submission, including drug component manufacturing (such as active pharmaceutical ingredients), finished drug product manufacturing, and control testing laboratories. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP.

In addition, as a condition of approval, the FDA may require an applicant to develop a REMS. REMS use risk minimization strategies beyond the professional labeling to ensure that the benefits of the product outweigh the potential risks. To determine whether a REMS is needed, the FDA will consider the size of the population likely to use the product, seriousness of the disease, expected benefit of the product, expected duration of treatment, seriousness of known or potential adverse events, and whether the product is a new molecular entity. REMS can include medication guides, physician communication plans for healthcare professionals, and elements to assure safe use, or ETASU. ETASU may include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring, and the use of patient registries. The FDA may require a REMS before approval or post-approval if it becomes aware of a serious risk associated with use of the product. The requirement for a REMS can materially affect the potential market and profitability of a product.

The FDA is required to refer an application for a novel drug to an advisory committee or explain why such referral was not made. Typically, an advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates and provides a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Fast Track, Breakthrough Therapy and Priority Review Designations

The FDA is authorized to designate certain products for expedited review if they are intended to address an unmet medical need in the treatment of a serious or life-threatening disease or condition. These programs are fast track designation, breakthrough therapy designation and priority review designation.

Specifically, the FDA may designate a product for fast track review if it is intended, whether alone or in combination with one or more other drugs, for the treatment of a serious or life-threatening disease or condition, and it demonstrates the potential to address unmet medical needs for such a disease or condition. For fast track products, sponsors may have greater interactions with the FDA and the FDA may initiate review of sections of a fast track product's NDA before the application is complete. This rolling review may be available if the FDA determines, after preliminary evaluation of clinical data submitted by the sponsor, that a fast track product may be effective. The sponsor must also provide, and the FDA must approve, a schedule for the submission of the remaining information and the sponsor must pay applicable user fees. However, the FDA's time period goal for reviewing a fast track application does not begin until the last section of the NDA is submitted. In addition, the fast track designation may be withdrawn by the FDA if the FDA believes that the designation is no longer supported by data emerging in the clinical trial process.

Second, in 2012, Congress enacted the Food and Drug Administration Safety and Innovation Act ("FDASIA"). This law established a new regulatory scheme allowing for expedited review of products designated as "breakthrough therapies." A product may be designated as a breakthrough therapy if it is intended, either alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing

therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The FDA may take certain actions with respect to breakthrough therapies, including holding meetings with the sponsor throughout the development process; providing timely advice to the product sponsor regarding development and approval; involving more senior staff in the review process; assigning a cross-disciplinary project lead for the review team; and taking other steps to design the clinical trials in an efficient manner.

Third, the FDA may designate a product for priority review if it is a drug that treats a serious condition and, if approved, would provide a significant improvement in safety or effectiveness. The FDA determines, on a case-by-case basis, whether the proposed drug represents a significant improvement when compared with other available therapies. Significant improvement may be illustrated by evidence of increased effectiveness in the treatment of a condition, elimination or substantial reduction of a treatment-limiting drug reaction, documented enhancement of patient compliance that may lead to improvement in serious outcomes, and evidence of safety and effectiveness in a new subpopulation. A priority designation is intended to direct overall attention and resources to the evaluation of such applications, and to shorten the FDA's goal for taking action on a marketing application from ten months to six months.

Accelerated Approval Pathway

The FDA may grant accelerated approval to a drug for a serious or life-threatening condition that provides meaningful therapeutic advantage to patients over existing treatments based upon a determination that the drug has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit. The FDA may also grant accelerated approval for such a condition when the product has an effect on an intermediate clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality ("IMM"), and that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. Drugs granted accelerated approval must meet the same statutory standards for safety and effectiveness as those granted traditional approval.

For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. Surrogate endpoints can often be measured more easily or more rapidly than clinical endpoints. An intermediate clinical endpoint is a measurement of a therapeutic effect that is considered reasonably likely to predict the clinical benefit of a drug, such as an effect on IMM. The FDA has limited experience with accelerated approvals based on intermediate clinical endpoints, but has indicated that such endpoints generally may support accelerated approval where the therapeutic effect measured by the endpoint is not itself a clinical benefit and basis for traditional approval, if there is a basis for concluding that the therapeutic effect is reasonably likely to predict the ultimate clinical benefit of a drug.

The accelerated approval pathway is most often used in settings in which the course of a disease is long and an extended period of time is required to measure the intended clinical benefit of a drug, even if the effect on the surrogate or intermediate clinical endpoint occurs rapidly. Thus, accelerated approval has been used extensively in the development and approval of drugs for treatment of a variety of cancers in which the goal of therapy is generally to improve survival or decrease morbidity and the duration of the typical disease course requires lengthy and sometimes large trials to demonstrate a clinical or survival benefit.

The accelerated approval pathway is usually contingent on a sponsor's agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the drug's clinical benefit. As a result, a drug candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of Phase 4 or post-approval clinical trials to confirm the effect on the clinical endpoint. Failure to conduct required post-approval studies, or confirm a clinical benefit during post-marketing studies, would allow the FDA to withdraw the drug from the market on an expedited basis. All promotional materials for drug candidates approved under accelerated regulations are subject to prior review by the FDA.

The FDA's Decision on an NDA

On the basis of the FDA's evaluation of the NDA and accompanying information, including the results of the inspection of the manufacturing facilities, the FDA may issue an approval letter or a complete response letter. An

approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional testing or information in order for the FDA to reconsider the application. If and when those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA, the FDA will issue an approval letter. The FDA has committed to reviewing such resubmissions in two or six months depending on the type of information included. Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

If the FDA approves a product, it may limit the approved indications for use for the product, require that contraindications, warnings or precautions be included in the product labeling, require that post-approval studies, including Phase 4 clinical trials, be conducted to further assess the drug's safety after approval, require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution restrictions or other risk management mechanisms, including REMS, which can materially affect the potential market and profitability of the product. The FDA may prevent or limit further marketing of a product based on the results of post-market studies or surveillance programs. After approval, many types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further testing requirements and FDA review and approval.

Post-Approval Requirements

Drugs manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to recordkeeping, periodic reporting, product sampling and distribution, advertising and promotion and reporting of adverse experiences with the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There also are continuing, annual user fee requirements for any marketed products and the establishments at which such products are manufactured, as well as new application fees for supplemental applications with clinical data.

In addition, drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and state agencies, and are subject to periodic unannounced inspections by the FDA and these state agencies for compliance with cGMP requirements. Changes to the manufacturing process are strictly regulated and often require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting and documentation requirements upon the sponsor and any third-party manufacturers that the sponsor may decide to use. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance.

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, suspension of the approval, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or holds on post-approval clinical trials;
- refusal of the FDA to approve pending NDAs or supplements to approved NDAs, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates the marketing, labeling, advertising and promotion of prescription drug products placed on the market. This regulation includes, among other things, standards and regulations for direct-to-consumer advertising, communications regarding unapproved uses, industry-sponsored scientific and educational activities, and promotional activities involving the Internet and social media. Promotional claims about a drug's safety or effectiveness are prohibited before the drug is approved. After approval, a drug product generally may not be promoted for uses that are not approved by the FDA, as reflected in the product's prescribing information. In the United States, health care professionals are generally permitted to prescribe drugs for such uses not described in the drug's labeling, known as off-label uses, because the FDA does not regulate the practice of medicine. However, FDA regulations impose rigorous restrictions on manufacturers' communications, prohibiting the promotion of off-label uses. It may be permissible, under very specific, narrow conditions, for a manufacturer to engage in nonpromotional, non-misleading communication regarding off-label information, such as distributing scientific or medical journal information.

If a company is found to have promoted off-label uses, it may become subject to adverse public relations and administrative and judicial enforcement by the FDA, the DOJ, or the Office of the Inspector General of the Department of Health and Human Services, as well as state authorities. This could subject a company to a range of penalties that could have a significant commercial impact, including civil and criminal fines and agreements that materially restrict the manner in which a company promotes or distributes drug products. The federal government has levied large civil and criminal fines against companies for alleged improper promotion, and has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed.

In addition, the distribution of prescription pharmaceutical products is subject to the Prescription Drug Marketing Act ("PDMA"), and its implementing regulations, as well as the Drug Supply Chain Security Act ("DSCA"), which regulate the distribution and tracing of prescription drug samples at the federal level, and set minimum standards for the regulation of drug distributors by the states. The PDMA, its implementing regulations and state laws limit the distribution of prescription pharmaceutical product samples and the DSCA imposes requirements to ensure accountability in distribution and to identify and remove counterfeit and other illegitimate products from the market.

Abbreviated New Drug Applications for Generic Drugs

In 1984, with passage of the Hatch-Waxman Amendments to the FDCA, Congress authorized the FDA to approve generic drugs that are the same as drugs previously approved by the FDA under the NDA provisions of the statute. To obtain approval of a generic drug, an applicant must submit an abbreviated new drug application, or ANDA, to the agency. In support of such applications, a generic manufacturer may rely on the preclinical and clinical testing previously conducted for a drug product previously approved under an NDA, known as the reference listed drug ("RLD").

Specifically, in order for an ANDA to be approved, the FDA must find that the generic version is identical to the RLD with respect to the active ingredients, the route of administration, the dosage form, and the strength of the drug. At the same time, the FDA must also determine that the generic drug is "bioequivalent" to the innovator drug. Under the statute, a generic drug is bioequivalent to a RLD if "the rate and extent of absorption of the drug do not show a significant difference from the rate and extent of absorption of the listed drug."

Upon approval of an ANDA, the FDA indicates whether the generic product is "therapeutically equivalent" to the RLD in its publication "Approved Drug Products with Therapeutic Equivalence Evaluations," also referred to as the "Orange Book." Physicians and pharmacists consider a therapeutic equivalent generic drug to be fully substitutable for the RLD. In addition, by operation of certain state laws and numerous health insurance programs, the FDA's designation of therapeutic equivalence often results in substitution of the generic drug without the knowledge or consent of either the prescribing physician or patient.

Under the Hatch-Waxman Amendments, the FDA may not approve an ANDA until any applicable period of non-patent exclusivity for the RLD has expired. The FDCA provides a period of five years of non-patent data exclusivity for a new drug containing a new chemical entity. For the purposes of this provision, a new chemical entity ("NCE"), is a drug that contains no active moiety that has previously been approved by the FDA in any other NDA. An active moiety is the molecule or ion responsible for the physiological or pharmacological action of the drug substance. In cases where such exclusivity has been granted, an ANDA may not be filed with the FDA until the

expiration of five years unless the submission is accompanied by a Paragraph IV certification, in which case the applicant may submit its application four years following the original product approval. The FDCA also provides for a period of three years of exclusivity if the NDA includes reports of one or more new clinical investigations, other than bioavailability or bioequivalence studies, that were conducted by or for the applicant and are essential to the approval of the application. This three-year exclusivity period often protects changes to a previously approved drug product, such as a new dosage form, route of administration, combination or indication.

The FDA must establish a priority review track for certain generic drugs, requiring the FDA to review a drug application within eight (8) months for a drug that has three (3) or fewer approved drugs listed in the Orange Book and is no longer protected by any patent or regulatory exclusivities, or is on the FDA's drug shortage list. The new legislation also authorizes FDA to expedite review of ''competitor generic therapies'' or drugs with inadequate generic competition, including holding meetings with or providing advice to the drug sponsor prior to submission of the application.

Hatch-Waxman Patent Certification and the 30-Month Stay

Upon approval of an NDA or a supplement thereto, NDA sponsors are required to list with the FDA each patent with claims that cover the applicant's product or an approved method of using the product. Each of the patents listed by the NDA sponsor is published in the Orange Book. When an Abbreviated New Drug Application ("ANDA"), or 505(b)(2) applicant files its application with the FDA, the applicant is required to certify to the FDA concerning any patents listed for the reference product in the Orange Book, except for patents covering methods of use for which the ANDA applicant is not seeking approval.

Specifically, the applicant must certify with respect to each patent that:

- the required patent information has not been filed;
- the listed patent has expired;
- the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or
- the listed patent is invalid, unenforceable or will not be infringed by the new product.

A certification that the new product will not infringe the already approved product's listed patents or that such patents are invalid or unenforceable is called a Paragraph IV certification. If the applicant does not challenge the listed patents or indicates that it is not seeking approval of a patented method of use, the application will not be approved until all the listed patents claiming the referenced product have expired (other than method of use patents involving indications for which the ANDA applicant is not seeking approval).

If the ANDA or 505(b)(2) applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA and patent holders once the ANDA or 505(b)(2) application has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days after the receipt of a Paragraph IV certification automatically prevents the FDA from approving the ANDA or 505(b)(2) application until the earlier of 30 months after the receipt of the Paragraph IV notice, expiration of the patent, or a decision in the infringement case that is favorable to the ANDA applicant.

Pediatric Studies and Exclusivity

Under the Pediatric Research Equity Act of 2003, an NDA or supplement thereto must contain data that are adequate to assess the safety and effectiveness of the drug product for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. With enactment of the FDASIA in 2012, sponsors must also submit pediatric study plans prior to the assessment data. Those plans must contain an outline of the proposed pediatric study or studies the applicant plans to conduct, including study objectives and design, any deferral or waiver requests, and other information required by regulation. The applicant, the FDA, and the FDA's internal review committee must then

review the information submitted, consult with each other, and agree upon a final plan. The FDA or the applicant may request an amendment to the plan at any time.

For drugs intended to treat a serious or life-threatening disease or condition, the FDA must, upon the request of an applicant, meet to discuss preparation of the initial pediatric study plan or to discuss deferral or waiver of pediatric assessments. In addition, FDA will meet early in the development process to discuss pediatric study plans with sponsors and FDA must meet with sponsors by no later than the end-of-phase 1 meeting for serious or life-threatening diseases and by no later than ninety (90) days after FDA's receipt of the study plan.

The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults, or full or partial waivers from the pediatric data requirements. Additional requirements and procedures relating to deferral requests and requests for extension of deferrals are contained in the FDASIA. Unless otherwise required by regulation, the pediatric data requirements do not apply to products with orphan designation.

Pediatric exclusivity is another type of non-patent marketing exclusivity in the United States and, if granted, provides for the attachment of an additional six months of marketing protection to the term of any existing regulatory exclusivity, including the non-patent and orphan exclusivity. This six-month exclusivity may be granted if an NDA sponsor submits pediatric data that fairly respond to a written request from the FDA for such data. The data do not need to show the product to be effective in the pediatric population studied; rather, if the clinical trial is deemed to fairly respond to the FDA's request, the additional protection is granted. If reports of requested pediatric studies are submitted to and accepted by the FDA within the statutory time limits, whatever statutory or regulatory periods of exclusivity or patent protection cover the product are extended by six months. This is not a patent term extension, but it effectively extends the regulatory period during which the FDA cannot approve another application.

Orphan Drug Designation and Exclusivity

Under the Orphan Drug Act, the FDA may designate a drug product as an "orphan drug" if it is intended to treat a rare disease or condition (generally meaning that it affects fewer than 200,000 individuals in the United States, or more in cases in which there is no reasonable expectation that the cost of developing and making a drug product available in the United States for treatment of the disease or condition will be recovered from sales of the product). A company must request orphan product designation before submitting an NDA. If the request is granted, the FDA will disclose the identity of the therapeutic agent and its potential use. Orphan product designation does not convey any advantage in or shorten the duration of the regulatory review and approval process, although it does convey certain advantages such as tax benefits and exemption from PDUFA fees.

If a product with orphan status receives the first FDA approval for the disease or condition for which it has such designation or for a select indication or use within the rare disease or condition for which it was designated, the product generally will receive orphan product exclusivity. Orphan product exclusivity means that the FDA may not approve any other applications for the same product for the same indication for seven years, except in certain limited circumstances. Competitors may receive approval of different products for the indication for which the orphan product has exclusivity and may obtain approval for the same product but for a different indication. If a drug or drug product designated as an orphan product ultimately receives marketing approval for an indication broader than what was designated in its orphan product application, it may not be entitled to exclusivity.

Orphan drug exclusivity will not bar approval of another product under certain circumstances, including if a subsequent product with the same drug for the same condition is shown to be clinically superior to the approved product on the basis of greater efficacy or safety, or providing a major contribution to patient care, or if the company with orphan drug exclusivity is not able to meet market demand. This is the case despite an earlier court opinion holding that the Orphan Drug Act unambiguously required the FDA to recognize orphan exclusivity regardless of a showing of clinical superiority.

Patent Term Restoration and Extension

A patent claiming a new drug product may be eligible for a limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, which permits a patent restoration of up to five years for patent term lost during product development and the FDA regulatory review. The restoration period granted is typically one-half the time between the effective date of an IND and the submission date of an NDA, plus the time

between the submission date of an NDA and the ultimate approval date. Patent term restoration cannot be used to extend the remaining term of a patent past a total of 14 years from the product's approval date. Only one patent applicable to an approved drug product is eligible for the extension, and the application for the extension must be submitted prior to the expiration of the patent in question. A patent that covers multiple drugs for which approval is sought can only be extended in connection with one of the approvals. The USPTO reviews and approves the application for any patent term extension or restoration in consultation with the FDA.

The 21st Century Cures Act

On December 13, 2016, President Obama signed the 21st Century Cures Act (the "Cures Act") into law. The Cures Act is designed to modernize and personalize healthcare, spur innovation and research, and streamline the discovery and development of new therapies through increased federal funding of particular programs. It authorizes increasing funding for FDA to spend on innovation projects. The new law also amends the Public Health Service Act to reauthorize and expand funding for the National Institutes of Health. The Act establishes the NIH Innovation Fund to pay for the cost of development and implementation of a strategic plan, early stage investigators and research. It also charges NIH with leading and coordinating expanded pediatric research. Further, the Cures Act directs the Centers for Disease Control and Prevention to expand surveillance of neurological diseases.

With amendments to the FDCA and the Public Health Service Act, Title III of the Cures Act seeks to accelerate the discovery, development, and delivery of new medicines and medical technologies. To that end, and among other provisions, the Cures Act reauthorizes the priority review voucher program for certain drugs intended to treat rare pediatric diseases; creates a new priority review voucher program for drug applications determined to be material threat medical countermeasure applications; revises the FDCA to streamline review of combination product applications; requires FDA to evaluate the potential use of "real world evidence" to help support approval of new indications for approved drugs; provides a new "limited population" approval pathway for antibiotic and antifungal drugs intended to treat serious or life-threatening infections; and authorizes FDA to designate a drug as a "regenerative advanced therapy," thereby making it eligible for certain expedited review and approval designations.

Review and Approval of Drug Products in the European Union

In order to market any product outside of the United States, a company must also comply with numerous and varying regulatory requirements of other countries and jurisdictions regarding quality, safety and efficacy and governing, among other things, clinical trials, marketing authorization, commercial sales and distribution of drug products. Whether or not it obtains FDA approval for a product, the company would need to obtain the necessary approvals by the comparable foreign regulatory authorities before it can commence clinical trials or marketing of the product in those countries or jurisdictions. The approval process ultimately varies between countries and jurisdictions and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries and jurisdictions might differ from and be longer than that required to obtain FDA approval. Regulatory approval in one country or jurisdiction does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country or jurisdiction may negatively impact the regulatory process in others.

Clinical Trial Approval in the EU

Pursuant to the European Clinical Trials Directive, a system for the approval of clinical trials in the European Union has been implemented through national legislation of the member states. Under this system, an applicant must obtain approval from the competent national authority of a European Union member state in which the clinical trial is to be conducted. Furthermore, the applicant may only start a clinical trial after a competent ethics committee has issued a favorable opinion. Clinical trial application must be accompanied by an investigational medicinal product dossier with supporting information prescribed by the European Clinical Trials Directive and corresponding national laws of the member states and further detailed in applicable guidance documents. In April 2014, the EU adopted a new Clinical Trials Regulation, which will be directly applicable to and binding without the need for any national implementing legislation. Under the new coordinated procedure for the approval of clinical trials, the sponsor of a clinical trial will be required to submit a single application for approval of a clinical trial to a reporting EU Member State (RMS) through an EU Portal. The submission procedure will be the same irrespective of whether the clinical trial is to be conducted in a single EU Member State or in more than one EU Member State.

The Clinical Trials Regulation also aims to streamline and simplify the rules on safety reporting for clinical trials. The Regulation was published on June 16, 2014 but is not expected to apply until 2019.

Orphan Drug Designation and Exclusivity

Regulation 141/2000 provides that a drug shall be designated as an orphan drug if its sponsor can establish: that the product 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 Community when the application is made, or that the product is intended for the diagnosis, prevention or treatment of a life-threatening, seriously debilitating or serious and chronic condition in the European Community and that without incentives it is unlikely that the marketing of the drug in the European Community would generate sufficient return to justify the necessary investment. For either of these conditions, the applicant must demonstrate that there exists no satisfactory method of diagnosis, prevention or treatment of the condition in question that has been authorized in the European Community or, if such method exists, the drug will be of significant benefit to those affected by that condition.

Regulation 847/2000 sets out criteria and procedures governing designation of orphan drugs in the EU. Specifically, an application for designation as an orphan product can be made any time prior to the filing of an application for approval to market the product. Marketing authorization for an orphan drug leads to a ten-year period of market exclusivity. This period may, however, be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for orphan drug designation, for example because the product is sufficiently profitable not to justify market exclusivity. Market exclusivity can be revoked only in very selected cases, such as consent from the marketing authorization holder, inability to supply sufficient quantities of the product, demonstration of “clinically relevant superiority” by a similar medicinal product, or, after a review by the Committee for Orphan Medicinal Products, requested by a member state in the fifth year of the marketing exclusivity period (if the designation criteria are believed to no longer apply). Medicinal products designated as orphan drugs pursuant to Regulation 141/2000 shall be eligible for incentives made available by the European Community and by the member states to support research into, and the development and availability of, orphan drugs.

Pharmaceutical Coverage, Pricing and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of products approved by the FDA and other government authorities. Sales of products will depend, in part, on the extent to which the costs of the products will be covered by third-party payors, including government health programs in the United States such as Medicare and Medicaid, commercial health insurers and managed care organizations. The process for determining whether a payor will provide coverage for a product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the product once coverage is approved. Third-party payors are increasingly challenging the prices charged, examining the medical necessity, and reviewing the cost-effectiveness of medical products and services and imposing controls to manage costs. Third-party payors may also limit coverage to specific products on an approved list, or formulary, which might not include all of the approved products for a particular indication.

In order to secure coverage and reimbursement for any product that might be approved for sale, a company may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of the product, in addition to the costs required to obtain FDA or other comparable regulatory approvals. A payor’s decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Third-party reimbursement may not be sufficient to maintain price levels high enough to realize an appropriate return on investment in product development.

The containment of healthcare costs also has become a priority of federal, state and foreign governments and the prices of drugs have been a focus in this effort. Governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit a company’s revenue generated from the sale of any approved products. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which a company or its collaborators receive marketing approval, less favorable coverage

policies and reimbursement rates may be implemented in the future. In the European Union, pricing and reimbursement schemes vary widely from country to country. Some countries provide that drug products may be marketed only after a reimbursement price has been agreed. Some countries may require the completion of additional studies that compare the cost-effectiveness of a particular drug candidate to currently available therapies, or so-called health technology assessments, in order to obtain reimbursement or pricing approval. For example, the European Union provides options for its member states to restrict the range of drug products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. European Union member states may approve a specific price for a drug product or may instead adopt a system of direct or indirect controls on the profitability of the company placing the drug product on the market. Other member states allow companies to fix their own prices for drug products, but monitor and control company profits. The downward pressure on health care costs in general, particularly prescription drugs, has become intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross-border imports from low-priced markets exert competitive pressure that may reduce pricing within a country. Any country that has price controls or reimbursement limitations for drug products may not allow favorable reimbursement and pricing arrangements.

Healthcare Law and Regulation

Healthcare providers, physicians and third-party payors play a primary role in the recommendation and prescription of drug products that are granted marketing approval. Arrangements with providers, consultants, third-party payors and customers are subject to broadly applicable fraud and abuse and other healthcare laws and regulations. Such restrictions under applicable federal and state healthcare laws and regulations, include the following:

- the federal Anti-Kickback Statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made, in whole or in part, under a federal healthcare program such as Medicare and Medicaid;

- the federal False Claims Act imposes civil penalties, and provides for civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government, with potential liability including mandatory treble damages and significant per-claim penalties, currently set at $5,500 to $11,000 per false claim;

- the federal Health Insurance Portability and Accountability Act of 1996 (“HIPAA”), imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and their respective implementing regulations, including the Final Omnibus Rule published in January 2013, also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;

- the federal false statements statute prohibits 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;

- the federal transparency requirements under the Health Care Reform Law, known as the federal Physician Payments Sunshine Act, require manufacturers of drugs, devices, biologics and medical supplies to report to the Centers for Medicare & Medicaid Services (“CMS”) within the Department of Health and Human Services information related to payments and other transfers of value to physicians and teaching hospitals and physician ownership and investment interests held by physicians and their immediate family members; and

- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers.

Some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to report information related to payments to physicians and other health care providers or marketing expenditures. State and foreign laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Healthcare Reform in the United States

A primary trend in the United States healthcare industry and elsewhere is cost containment. There have been a number of federal and state proposals during the last several years regarding the pricing of pharmaceutical and biopharmaceutical products, limiting coverage and reimbursement for drugs and other medical products, government control and other changes to the healthcare system in the United States.

By way of example, the United States and state governments continue to propose and pass legislation designed to reduce the cost of healthcare. In March 2010, the United States Congress enacted the Patient Protection and Affordable Care Act (the "PPACA") which, among other things, includes changes to the coverage and payment for products under government health care programs. Among the provisions of the PPACA of importance to potential drug candidates are:

- an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs, although this fee would not apply to sales of certain products approved exclusively for orphan indications;

- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to certain individuals with income at or below 133% of the federal poverty level, thereby potentially increasing a manufacturer's Medicaid rebate liability;

- expanded manufacturers' rebate liability under the Medicaid Drug Rebate Program by increasing the minimum rebate for both branded and generic drugs and revising the definition of "average manufacturer price" ("AMP") for calculating and reporting Medicaid drug rebates on outpatient prescription drug prices and extending rebate liability to prescriptions for individuals enrolled in Medicare Advantage plans;

- addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected;

- expanded the types of entities eligible for the 340B drug discount program;

- established the Medicare Part D coverage gap discount program by requiring manufacturers to provide a point-of-sale-discount off the negotiated price of applicable brand drugs to eligible beneficiaries during their coverage gap period as a condition for the manufacturers' outpatient drugs to be covered under Medicare Part D;

- established a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research;

- established the Independent Payment Advisory Board ("IPAB") which has authority to recommend certain changes to the Medicare program to reduce expenditures by the program that could result in reduced payments for prescription drugs. However, the IPAB implementation has been not been clearly defined. The PPACA provided that under certain circumstances, IPAB recommendations will become law unless Congress enacts legislation that will achieve the same or greater Medicare cost savings; and

- established the Center for Medicare and Medicaid Innovation within CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending. Funding has been allocated to support the mission of the Center for Medicare and Medicaid Innovation from 2011 to 2019. Other legislative changes have been proposed and adopted since the PPACA was enacted. These changes include the Budget Control Act of 2011, which, among other things, led to aggregate reductions to Medicare payments to providers of up to 2% per fiscal year that started in 2013 and will stay in effect through 2024 unless additional Congressional action is taken, and the American Taxpayer Relief Act of 2012, which, among other things, reduced Medicare payments to several types of providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for any of our product candidates for which we may obtain regulatory approval or the frequency with which any such product candidate is prescribed or used. Further, there have been several recent U.S. congressional inquiries and proposed state and federal legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the costs of drugs under Medicare and reform government program reimbursement methodologies for drug products.

These healthcare reforms, as well as other healthcare reform measures that may be adopted in the future, may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment methodologies and additional downward pressure on the price for any approved product and/or the level of reimbursement physicians receive for administering any approved product. Reductions in reimbursement levels may negatively impact the prices or the frequency with which products are prescribed or administered. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. Since enactment of the PPACA, there have been numerous legal challenges and Congressional actions to repeal and replace provisions of the law. In May 2017, the U.S. House of Representatives passed legislation known as the American Health Care Act of 2017. Thereafter, the Senate Republicans introduced and then updated a bill to replace the PPACA known as the Better Care Reconciliation Act of 2017. The Senate Republicans also introduced legislation to repeal the PPACA without companion legislation to replace it, and a “skinny” version of the Better Care Reconciliation Act of 2017. In addition, the Senate considered proposed healthcare reform legislation known as the Graham-Cassidy bill. None of these measures was passed by the U.S. Senate.

The Trump Administration has also taken executive actions to repeal or delay implementation of the PPACA. In January 2017, President Trump signed an Executive Order directing federal agencies with authorities and responsibilities under the PPACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the PPACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. In October 2017, the President signed a second Executive Order allowing for the use of association health plans and short-term health insurance, which may provide fewer health benefits than the plans sold through the PPACA exchanges. At the same time, the Administration announced that it will discontinue the payment of cost-sharing reduction (“CSR”) payments to insurance companies until Congress approves the appropriation of funds for such CSR payments. The loss of the CSR payments is expected to increase premiums on certain policies issued by qualified health plans under the PPACA. A bipartisan bill to appropriate funds for CSR payments was introduced in the Senate, but the future of that bill is uncertain.

With enactment of the Tax Cuts and Jobs Act of 2017, which was signed by the President on December 22, 2017, Congress repealed the “individual mandate.” The repeal of this provision, which requires most Americans to carry a minimal level of health insurance, will become effective in 2019. According to the Congressional Budget Office, the repeal of the individual mandate will cause 13 million fewer Americans to be insured in 2027 and premiums in insurance markets may rise. Additionally, on January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain PPACA-mandated fees, including the so-called “Cadillac” tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices. The Congress will likely consider other legislation to replace elements of the PPACA, during the next Congressional session.

Further, there have been several recent U.S. congressional inquiries and proposed federal and proposed and enacted state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the costs of drugs under Medicare and reform government program reimbursement methodologies for drug products. At the federal level, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. At the state level, individual states are increasingly aggressive in passing legislation and implementing 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 some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional health care authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other health care programs. These measures could reduce the ultimate demand for our products, once approved, or put pressure on our product pricing.

Information About Our Executive Officers

See Part III, Item 10. “Directors, Executive Officers and Corporate Governance” for information relating to our executive officers.

Employees

As of February 15, 2020, we employed 36 individuals, 22 of whom are engaged in research and development activities and six of whom hold a Ph.D., M.D., or equivalent degree. None of our employees are covered by a collective bargaining agreement, and we consider relations with our employees to be good.

Corporate Information

We were incorporated in Delaware in 1989 and our office headquarters is located at 505 Eagleview Boulevard, Suite 212, Exton, Pennsylvania 19341.

Information Available on the Internet

Our internet address is www.iderapharma.com. The contents of our website are not part of this Annual Report on Form 10-K and our internet address is included in this document as an inactive textual reference. We make available free of charge through our web site our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to these reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act as soon as reasonably practicable after we electronically file or furnish such materials to the SEC. The SEC maintains an internet site at www.sec.gov containing reports, proxies and information statements and other information regarding issuers that file electronically with the SEC.

Item 1A. Risk Factors.

RISK FACTORS

Investing in our securities involves a high degree of risk. You should carefully consider the risks and uncertainties described below in addition to the other information included or incorporated by reference in this Annual Report on Form 10-K before purchasing our common stock. Our business, financial condition and results of operations could be materially and adversely affected by any of these and currently unknown risks or uncertainties. In that case, the market price of our common stock could decline, and you may lose all or part of your investment in our securities.

Risks Relating to Our Financial Results and Need for Financing

We will need additional financing, which may be difficult to obtain on terms attractive to us or at all. Our failure to obtain necessary financing or doing so on unattractive terms could result in the termination of our operations and the sale and license of our assets or otherwise adversely affect our research and development programs and other operations.

We had cash, cash equivalents and investments of approximately $42.8 million at December 31, 2019, inclusive of the $6.2 million contingently refundable option fee received in connection with the December 2019 Securities Purchase Agreement. We believe, based on our current operating plan, our existing cash, cash equivalents and investments on hand as of December 31, 2019, excluding the $6.2 million contingently refundable option fee and including interest income and cash received through February 2020 from the ATM Agreement and LPC Purchase Agreement, both of which are discussed below within Item 7 of this Annual Report on Form 10-K, will enable us to fund our operations into the first quarter of 2021. Specifically, we believe our available funds will be sufficient to enable us to perform the following:

(i) Complete and disclose results from:

a) our Phase 1/2 clinical trial of tilsotolimod in combination with ipilimumab and pembrolizumab in anti-PD1 refractory melanoma (ILLUMINATE-204); and

b) the Phase 1b monotherapy clinical trial of tilsotolimod in multiple refractory tumor types (ILLUMINATE-101);

(ii) continue to execute on our ongoing Phase 3 clinical trial of tilsotolimod in combination with ipilimumab for the treatment of anti-PD1 refractory metastatic melanoma (ILLUMINATE-301), including announcement of top-line ORR and other preliminary data;

(iii) initiate and complete enrollment in the signal-finding stage of Part I of our Phase 2 study of tilsotolimod in combination with nivolumab and ipilimumab for the treatment of MSS-CRC (ILLUMINATE-206), pending results from the initial group of ten patients enrolled to evaluate safety;

(iv) fund certain investigator initiated clinical trials of tilsotolimod; and

(v) maintain our current level of general and administrative expenses in order to support the business.

We expect that we will need to raise additional funds in order to complete our ongoing clinical trials of tilsotolimod and to continue to fund our operations. We are seeking and expect to continue to seek additional funding through collaborations, the sale or license of assets or financings of equity or debt securities. We believe that the key factors that will affect our ability to obtain funding are:

(i) the results of our clinical development activities in our tilsotolimod program or any other drug candidates we develop on the timelines anticipated;

(ii) the cost, timing, and outcome of regulatory reviews;

(iii) competitive and potentially competitive products and technologies and investors' receptivity to tilsotolimod or any other drug candidates we develop and the technology underlying them in light of competitive products and technologies;

(iv) the receptivity of the capital markets to financings by biotechnology companies generally and companies with drug candidates and technologies similar to ours specifically;

(v) the receptivity of the capital markets to any in-licensing, product acquisition or other transaction we may enter into; and

(vi) our ability to enter into additional collaborations with biotechnology and pharmaceutical companies and the success of such collaborations.

In addition, increases in expenses or delays in clinical development may adversely impact our cash position and require additional funds or cost reductions.

Financing may not be available to us when we need it or may not be available to us on favorable or acceptable terms or at all. We could be required to seek funds through collaborative alliances or through other means that may require us to relinquish rights to some of our technologies, drug candidates or drugs that we would otherwise pursue on our own. In addition, if we raise additional funds by issuing equity securities, our then existing stockholders may experience dilution. The terms of any financing may adversely affect the holdings or the rights of existing stockholders. An equity financing that involves existing stockholders may cause a concentration of ownership. 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, and are likely to include rights that are senior to the holders of our common stock. Any additional debt or equity financing may contain terms which are not favorable to us or to our stockholders, such as liquidation and other preferences, or liens or other restrictions on our assets. As discussed in Note 14 to the financial statements appearing elsewhere in this Annual Report on Form 10-K, additional equity financings may also result in cumulative changes in ownership over a three-year period in excess of 50% which would limit the amount of net operating loss and tax credit carryforwards that we may utilize in any one year.

If we are unable to obtain adequate funding on a timely basis or at all, we will be required to terminate, modify or delay clinical trials of tilsotolimod, or relinquish rights to portions of our technology, drug candidates and/or products.

We have incurred substantial losses and expect to continue to incur losses. We will not be successful unless we reverse this trend.

As of December 31, 2019, we had an accumulated deficit of $720.9 million. Since January 1, 2001, we have primarily been involved in the development of our TLR pipeline. From January 1, 2001 to December 31, 2019, we incurred losses of $460.7 million. We incurred losses of $260.2 million prior to December 31, 2000, during which time we were primarily involved in the development of earlier generation antisense technology. These losses, among other things, have had and will continue to have an adverse effect on our stockholders' equity, total assets and working capital.

We have never had any products of our own available for commercial sale and have received no revenues from the sale of drugs. As of December 31, 2019, substantially all of our revenues have been from collaborative and license agreements. We have devoted substantially all of our efforts to research and development, including clinical trials, and have not completed development of any drug candidates. Because of the numerous risks and uncertainties associated with developing drugs, we are unable to predict the extent of any future losses, whether or when any of our drug candidates will become commercially available, or when we will become profitable, if at all. We expect to incur substantial operating losses in future periods.

Risks Relating to Our Business, Strategy and Industry

We are depending heavily on the development of our lead TLR-targeted drug candidate, tilsotolimod, in our immuno-oncology program. If we terminate the development of this program or are unable to successfully develop and commercialize tilsotolimod or any other drug candidate, or experience significant delays in doing so, our business may be materially harmed.

We have invested a significant portion of our time and financial resources in the development of TLR-targeted clinical-stage drug candidates as part of our immuno-oncology and rare disease programs. In the future, we intend to continue to invest a significant portion of our time and financial resources in the development of our lead TLR-

targeted candidate, tilsotolimod, in our immuno-oncology program. For instance, we are conducting (i) a Phase 1/2 clinical trial of tilsotolimod, administered intratumorally, in combination with ipilimumab or pembrolizumab in patients with anti-PD1 refractory metastatic melanoma, (ii) a Phase 2 clinical trial of tilsotolimod in combination with nivolumab and ipilimumab for the treatment of MSS-CRC tumor types, (iii) a Phase 3 clinical trial of tilsotolimod, administered intratumorally, in combination with ipilimumab in patients with anti-PD1 refractory metastatic melanoma, and (iv) a Phase 1b trial of tilsotolimod, administered intratumorally, as a monotherapy in patients with refractory solid tumors.

We anticipate that our ability to generate product revenues will depend heavily on the successful development and commercialization of our TLR drug candidate, tilsotolimod.

Our ability to generate future milestone and royalty revenues under our current collaboration with GSK, and under any other collaboration that we enter into with respect to our other programs, will depend on the development and commercialization of the drug candidates being developed under the collaborations.

We have entered into and may in the future continue to seek to enter into collaborative alliances with pharmaceutical companies to advance our TLR agonists and antagonist candidates and with respect to additional applications of our nucleic acid chemistry technology program, which we suspended internally in 2018. Should we in the future seek to do so, we may not be able to enter into such agreements on attractive terms or at all.

Our ability to successfully develop and commercialize potential drug candidates will depend on our ability to overcome these recent challenges and on several factors, including the following:

- the drug candidates demonstrating activity in clinical trials;
- the drug candidates demonstrating an acceptable safety profile in nonclinical toxicology studies and during clinical trials;
- timely enrollment in clinical trials of drug candidates, which may be slower than anticipated, potentially resulting in significant delays;
- satisfying conditions imposed on us and/or our collaborators by the FDA or equivalent foreign regulatory authorities regarding the scope or design of clinical trials;
- the ability to demonstrate to the satisfaction of the FDA, or equivalent foreign regulatory authorities, the safety and efficacy of the drug candidates through current and future clinical trials;
- timely receipt of necessary marketing approvals from the FDA and equivalent foreign regulatory authorities;
- the ability to combine our drug candidates and the drug candidates being developed by our collaborators and any other collaborators safely and successfully with other therapeutic agents;
- achieving and maintaining compliance with all regulatory requirements applicable to the products;
- establishment of commercial manufacturing arrangements with third-party manufacturers;
- the ability to secure orphan drug exclusivity for our drug candidates either alone or in combination with other products;
- the successful commercial launch of the drug candidates, assuming FDA approval is obtained, whether alone or in combination with other products;
- acceptance of the products as safe and effective by patients, the medical community, and third-party payors;
- competition from other companies and their therapies;
- changes in treatment regimens;
- favorable market conditions in which to raise additional capital;
- the strength of our intellectual property portfolio in the United States and abroad; and
- a continued acceptable safety and efficacy profile of the drug candidates following marketing approval.

We are developing tilsotolimod in combination with other immuno-modulatory compounds and chemotherapeutic agents and our efforts may not be successful or result in any approved and marketable products.

Tilsotolimod is being developed for administration via intratumoral injection in combination with systemically administered checkpoint inhibitors for the treatment of various solid tumors, including (i) anti-PD1 refractory metastatic melanoma in combination with ipilimumab, (ii) microsatellite stable colorectal cancer in combination with nivolumab and ipilimumab, and (iii) squamous cell carcinoma of the head and neck in combination with ABBV-368 and other therapy combinations. While we have evaluated the safety profile of tilsotolimod as a single agent via intratumoral injection in previous trials, and as marketed products the safety profiles of ipilimumab and nivolumab are each known, the safety profile of the combination of tilsotolimod with ipilimumab and/or nivolumab are still being evaluated. Further, we recently entered into the AbbVie Agreement under which AbbVie will conduct a clinical study to evaluate the efficacy and safety of combinations of an OX40 agonist (ABBV-368), tilsotolimod, nab-paclitaxel and/or an anti-programmed cell death 1 (PD-1) antagonist (ABBV-181).These factors may result in participating subjects experiencing serious adverse events or undesirable side effects or exposure to unacceptable health risks requiring us or AbbVie to suspend or terminate any clinical trials which are being conducted with tilsotolimod and other therapeutic agents.

If we experience delays or difficulties in the enrollment of patients in clinical trials, our receipt of necessary regulatory approvals could be delayed or prevented.

We may not be able to initiate or continue clinical trials for our drug candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or similar regulatory authorities outside the United States. Additionally, because there are a limited number of patients with dermatomyositis, or other rare diseases having indications for which we may determine to develop our TLR antagonists, our ability to enroll eligible patients in any clinical trials for these indications may be limited or may result in slower enrollment than we anticipated. In addition, some of our competitors have ongoing clinical trials for drug candidates that treat the same indications as our drug candidates, and patients who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors' drug candidates.

Patient enrollment can be affected by other factors, including the:

- severity of the disease under investigation;
- eligibility criteria for the trial in question;
- perceived risks and benefits of the TLR-targeted drug candidates under study;
- efforts to facilitate timely enrollment in clinical trials;
- availability of competing clinical trials or other therapies;
- patient referral practices of physicians;
- ability to monitor patients adequately during and after treatment; and
- proximity and availability of clinical trial sites for prospective patients.

Our inability to enroll a sufficient number of patients for our clinical trials would result in significant delays and could require us to abandon one or more clinical trials altogether. Enrollment delays in our clinical trials may result in increased development costs for our drug candidates, which would cause the value of our company to decline and limit our ability to obtain additional financing.

If our clinical trials are unsuccessful, or if they are delayed or terminated, we may not be able to develop and commercialize our drug candidates.

In order to obtain regulatory approvals for the commercial sale of our drug candidates, we are required to complete extensive clinical trials in humans to demonstrate the safety and efficacy of our drug candidates. Clinical trials are lengthy, complex, and expensive processes with uncertain results. We may not be able to complete any clinical trial of a potential product within any specified time period. Moreover, clinical trials may not show our potential products to be both safe and efficacious. The FDA or other equivalent foreign regulatory agencies may not allow us to complete these trials or commence and complete any other clinical trials.

The results from preclinical testing of a drug candidate that is under development may not be predictive of results that will be obtained in human clinical trials. In addition, the results of early human clinical trials may not be predictive of results that will be obtained in larger scale, advanced stage clinical trials.

Furthermore, interim results of a clinical trial do not necessarily predict final results, and failure of any of our clinical trials can occur at any stage of testing. Companies in the biotechnology and pharmaceutical industries, including companies with greater experience in preclinical testing and clinical trials than we have, have suffered significant setbacks in clinical trials, even after demonstrating promising results in earlier trials. Moreover, effects seen in nonclinical studies, even if not observed in clinical trials, may result in limitations or restrictions on clinical trials. Numerous unforeseen events may occur during, or as a result of, preclinical testing, nonclinical testing or the clinical trial process that could delay or inhibit the ability to receive regulatory approval or to commercialize drug products.

Other companies developing drugs targeted to TLRs have experienced setbacks in clinical trials. These setbacks may result in enhanced scrutiny by regulators or institutional review boards (“IRBs”) of clinical trials of our drug candidates, including our TLR-targeted drug candidates, which could result in regulators or IRBs prohibiting the commencement of clinical trials, requiring additional nonclinical studies as a precondition to commencing clinical trials or imposing restrictions on the design or scope of clinical trials that could slow enrollment of trials, increase the costs of trials or limit the significance of the results of trials. Such setbacks could also adversely impact the desire of investigators to enroll patients in, and the desire of patients to enroll in, clinical trials of our drug candidates.

Other events that could delay or inhibit conduct of our clinical trials include:

- regulators or IRBs may not authorize us to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- nonclinical or clinical data may not be readily interpreted, which may lead to delays and/or misinterpretation;
- our nonclinical tests, including toxicology studies, or clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional nonclinical testing or clinical trials or we may abandon projects that we expect may not be promising;
- the rate of enrollment or retention of patients in our clinical trials may be lower than we expect;
- we might have to suspend or terminate our clinical trials if the participating subjects experience serious adverse events or undesirable side effects or are exposed to unacceptable health risks;
- regulators or IRBs may hold, suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements, issues identified through inspections of manufacturing or clinical trial operations or clinical trial sites, or if, in their opinion, the participating subjects are being exposed to unacceptable health risks;
- regulators may hold or suspend our clinical trials while collecting supplemental information on, or clarification of, our clinical trials or other clinical trials, including trials conducted in other countries or trials conducted by other companies;
- we, along with our collaborators and subcontractors, may not employ, in any capacity, persons who have been debarred under the FDA's Application Integrity Policy, or similar policy under foreign regulatory authorities. Employment of such debarred persons, even if inadvertent, may result in delays in the FDA's or foreign equivalent's review or approval of our drug candidates, or the rejection of data developed with the involvement of such person(s);
- we or our contract manufacturers may be unable to manufacture sufficient quantities of our drug candidates for use in clinical trials;
- the cost of our clinical trials may be greater than we currently anticipate making continuation and/or completion improbable; and
- our drug candidates may not cause the desired effects or may cause undesirable side effects or our drug candidates may have other unexpected characteristics.

We do not know whether clinical trials will begin as planned, will need to be restructured or will be completed on schedule, if at all. Significant clinical trial delays also could allow our competitors to bring products to market before we do and impair our ability to commercialize our drug candidates.

Delays in commencing clinical trials of potential products could increase our costs, delay any potential revenues, and reduce the probability that a potential product will receive regulatory approval.

Our drug candidates and our collaborators' drug candidates will require preclinical and other nonclinical testing and extensive clinical trials prior to submission of any regulatory application for commercial sales. In conducting clinical trials, we cannot be certain that any planned clinical trial will begin on time, if at all. Delays in commencing clinical trials of potential products could increase our drug candidate development costs, delay any potential revenues, reduce the potential length of patent exclusivity and reduce the probability that a potential product will receive regulatory approval.

Commencing clinical trials may be delayed for a number of reasons, including delays in:

- manufacturing sufficient quantities of drug candidate that satisfy the required quality standards for use in clinical trials;
- demonstrating sufficient safety to obtain regulatory approval for conducting a clinical trial;
- reaching an agreement with any collaborators on all aspects of the clinical trial;
- reaching agreement with contract research organizations, if any, and clinical trial sites on all aspects of the clinical trial;
- resolving any objections from the FDA or any regulatory authority on an IND or proposed clinical trial design;
- obtaining additional financing;
- obtaining IRB approval for conducting a clinical trial at a prospective site; and
- enrolling patients in order to commence the clinical trial.

The technologies on which we rely are unproven and may not result in any approved and marketable products.

Our technologies or therapeutic approaches are relatively new and unproven. We have focused our efforts on the research and development of RNA- and DNA-based compounds, or oligonucleotides, targeted to TLRs. Neither we nor any other company have obtained regulatory approval to market such TLR-targeted drug candidates as therapeutic drugs, and no such products currently are being marketed. The results of preclinical studies with TLR-targeted compounds may not be indicative of results that may be obtained in clinical trials, and results we have obtained in the clinical trials we have conducted to date may not be predictive of results in subsequent large-scale clinical trials. Further, the chemical and pharmacological properties of RNA- and DNA-based compounds targeted to TLRs may not be fully recognized in preclinical studies and small-scale clinical trials, and such compounds may interact with human biological systems in unforeseen, ineffective or harmful ways that we have not yet identified.

Moreover, only five nucleic acid-based therapeutics have been approved by the FDA for marketing in the United States since 1998 and are currently being marketed. As such, oligonucleotides as a chemical class of drug candidates have limited precedence for successful late-stage development and regulatory approval.

As a result of these factors, we may never succeed in obtaining regulatory approval to market any product. Furthermore, the commercial success of any of our drug candidates for which we may obtain marketing approval from the FDA or other regulatory authorities will depend upon their acceptance by patients, the medical community, and third-party payors as clinically useful, safe, and cost-effective. In addition, if products being developed by our competitors have negative clinical trial results or otherwise are viewed negatively, the perception of our technologies and market acceptance of our drug candidates could be impacted negatively.

Our setbacks with respect to our TLR-targeted compounds, together with the setbacks experienced by other companies developing oligonucleotides-based compounds and TLR-targeted compounds, may result in a negative perception of our technology and our TLR-targeted compounds, impact our ability to obtain marketing approval of

these drug candidates and adversely affect acceptance of our technology and our TLR-targeted compounds by patients, the medical community and third-party payors.

Our efforts to educate the medical community on our potentially unique approaches may require greater resources than would be typically required for products based on conventional technologies or therapeutic approaches. The safety, efficacy, convenience, and cost-effectiveness of our drug candidates as compared to competitive products will also affect market acceptance.

We face substantial competition, which may result in others discovering, developing or commercializing drugs before or more successfully than us.

We are currently developing tilsotolimod (IMO-2125), our TLR agonist drug candidate, for the treatment by intratumoral injection of multiple oncology indications in combination with checkpoint inhibitors. In the immune-oncology environment, there are many other companies, public and private, that are actively engaged in discovery, development, and commercializing products and technologies that may compete with our drug candidate and program, including TLR-targeted compounds as well as non-TLR-targeted therapeutics.

Immuno-oncology, which utilizes a patient's own immune system to combat cancer, is currently an active area of research for biotechnology and pharmaceutical companies. Interest in immuno-oncology is driven by efficacy data in cancers with historically bleak outcomes and the potential to achieve a cure or functional cure for some patients. As such, we expect that our efforts in this field will be competitive with a wide variety of different approaches. Any one of these competitive approaches may result in the development of novel technologies that are more effective, safer or less costly than any that we are developing.

We are aware of other companies developing TLR agonists as well as other mechanisms of action that are focused on stimulating the immune response. These companies include, but are not limited to, Aduro Biotech, Inc., BioLineRx Ltd., Checkmate Pharmaceuticals, Inc., Dynavax Technologies Corporation, Exicure, Inc., Gilead Sciences Inc., GlaxoSmithKline plc, Hoffmann-La Roche Ltd., Innate Immunotherapeutics Ltd., Mologen AG VentiRx Pharmaceuticals Inc., Nektar Therapeutics, and Telormedix S.A. Additionally, we are aware of other companies developing non-TLR therapies in our patient populations including, but not limited to OncoSec Immunotherapies, Iovance Biotherapeutics, Lytix Biopharma and Takara Bio.

Some potentially competitive products have been in development or commercialized for years, in some cases by large, well established pharmaceutical companies. Many of the marketed products have been accepted by the medical community, patients, and third-party payors. Our ability to compete may be affected by the previous adoption of such products by the medical community, patients, and third-party payors. Additionally, in some instances, insurers and other third-party payors seek to encourage the use of generic products, which makes branded products, such as is planned for our drug candidates upon commercialization, potentially less attractive, from a cost perspective, to buyers.

We recognize that other companies, including large pharmaceutical companies, may be developing or have plans to develop products and technologies that may compete with ours. Many of our competitors have substantially greater financial, technical, and human resources than we have. In addition, many of our competitors have significantly greater experience than we have in undertaking preclinical studies and human clinical trials of new pharmaceutical products, obtaining FDA and other regulatory approvals of products for use in health care and manufacturing, and marketing and selling approved products. Our competitors may discover, develop or commercialize products or other novel technologies that are more effective, safer or less costly than any that we are developing. Our competitors may also obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours.

We anticipate that the competition with our drug candidates and technologies will be based on a number of factors including product efficacy, safety, availability, and price. The timing of market introduction of our drug candidates and competitive products will also affect competition among products. We expect the relative speed with which we can develop products, complete the clinical trials and approval processes, and supply commercial quantities of the products to the market to be important competitive factors. Our competitive position will also depend upon our ability to attract and retain qualified personnel, to obtain patent protection or otherwise develop proprietary products or processes, protect our intellectual property, and to secure sufficient capital resources for the period between technological conception and commercial sales.

We face risks related to health epidemics and other outbreaks of communicable diseases, which could significantly disrupt our operations and may materially and adversely affect our business and financial condition.

Our business could be adversely impacted by the effects of the coronavirus or other epidemics. In December 2019, a novel strain of the coronavirus (COVID-19) emerged in China and the virus has now spread to several other countries, including Europe and the U.S., and infections have been reported globally. The extent to which the coronavirus impacts our operations will depend on future developments, which are highly uncertain and cannot be predicted at this time, and include the duration, severity and scope of the outbreak and the actions taken to contain or treat the coronavirus outbreak. The continued spread of the coronavirus globally could materially and adversely impact our operations including without limitation, our clinical trial operations, regulatory approval and the timing thereof, the operations of our collaboration partners, travel, employee health and availability which may have a material and adverse impact on our business, financial condition and results of operations. For example, with respect to our ILLUMINATE-301 trial, the coronavirus outbreak could impact our ability to obtain results if trial participants are unable to travel to and from clinical sites for administration of the therapies and/or for scans or testing pursuant to the ILLUMINATE-301 trial protocol; deliver clinical trial supplies to clinical trial sites; conduct the trial if clinical trial sites close; and produce accurate results if the pandemic is found to impact trial endpoints.

In addition, a significant outbreak of coronavirus could result in widespread global health crisis that could adversely affect global economies and financial markets resulting in an economic downturn that could affect future revenue and operating results.

Risks Related to Human Capital Management

The loss of key personnel, especially our principal executive officer, could delay or prevent us from achieving our objectives.

Our success is highly dependent on the retention of principal members of our technical and management staff, including our President and Chief Executive Officer, Mr. Vincent Milano.

We are a party to an employment agreement with Mr. Milano, which is terminable upon 15 days prior written notice at the election of either party and immediately in the event of a termination for cause (as defined therein). We do not carry key man life insurance for Mr. Milano.

Competition for technical and management personnel is intense in our industry, and we may not be able to sustain our operations or grow if we are unable to attract and retain key personnel.

Our future growth will require hiring a number of qualified technical and management personnel. Accordingly, recruiting and retaining such personnel in the future will be critical to our success. There is intense competition from other companies and research and academic institutions for qualified personnel in the areas of our activities. If we are not able to continue to attract and retain, on acceptable terms, the qualified personnel necessary for the continued development of our business, we may not be able to sustain our operations or growth.

Because we are a small biopharmaceutical-focused company with limited resources, we may be unable to attract and retain qualified personnel; the termination of relationships with key management, consulting and scientific personnel or the inability to recruit and retain additional personnel could prevent us from developing our technologies, conducting clinical trials and/or obtaining financing.

We are a small company and we rely heavily on third parties and outside consultants to conduct many important functions. As of December 31, 2019, we had 36 full-time employees. We may require additional experienced executive, accounting, legal, administrative and other personnel from time to time in the future. Also, because of the specialized scientific nature of our business, our ability to develop products and to compete with our current and future competitors largely depends upon our ability to attract, retain and motivate highly-qualified managerial, consulting and scientific personnel. If we are unable to retain the services of one or more of the principal members of senior management, consultants or other key employees, our ability to implement our business strategy could be materially harmed. We face intense competition for qualified employees and consultants from biopharmaceutical companies, research organizations and academic institutions. Attracting, retaining or replacing these personnel on acceptable terms may be difficult and time-consuming given the high demand in our industry for similar personnel. There is intense competition for qualified personnel in the areas of our activities, and we cannot assure you that we will be able to continue to attract and retain the qualified personnel necessary for the development of our business.

Risks Related to Regulatory Approval and Marketing of Our Drug Candidates and Other Legal Compliance Matters

Even if we complete the necessary preclinical studies and clinical trials, the marketing approval process is expensive, time-consuming and uncertain and may prevent us from obtaining approvals for the commercialization of some or all of our drug candidates. As a result, we cannot predict when or if we, or any future collaborators, will obtain marketing approval to commercialize a drug candidate.

Our drug candidates and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, marketing, promotion, sale and distribution, export and import are subject to extensive regulation by the FDA and comparable foreign regulatory authorities, whose laws and regulations may differ from country to country. We are not permitted to market our drug candidates in the United States or in other countries until we, or any future collaborators, receive approval of an NDA from the FDA or marketing approval from applicable regulatory authorities outside of the United States.

All of the drug candidates that we are developing, or may develop in the future, will require additional research and development, extensive preclinical studies, nonclinical testing, clinical trials, and regulatory approval prior to any commercial sales. This process is lengthy, often taking a number of years, is uncertain, and is expensive. Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish the drug candidate's safety and purity. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the regulatory authorities.

Since our inception, we have conducted, or collaborated with others to conduct, clinical trials of a number of compounds and for a number of disease indications.

The FDA and other regulatory authorities may not approve any of our potential products for any indication.

We may need to address a number of technological challenges in order to complete development of our drug candidates. Moreover, these products may not be effective in treating any disease or may prove to have undesirable or unintended side effects, unintended alteration of the immune system over time, toxicities or other characteristics that may preclude our obtaining regulatory approval or prevent or limit commercial use. In addition, changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application. The FDA and comparable authorities in other countries have substantial discretion in the approval process and may refuse to accept any application or may decide that our data is insufficient for approval and require additional preclinical, clinical or other studies. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent marketing approval of a drug candidate.

Any delay in obtaining or failure to obtain required approvals could materially adversely affect our ability or that of any collaborators we may have to generate revenue from the particular drug candidate, which likely would result in significant harm to our financial position and adversely impact our stock price.

Our failure to obtain marketing approval in foreign jurisdictions would prevent our drug candidates from being marketed abroad, and any approval we are granted for our drug candidates in the United States would not assure approval of drug candidates in foreign jurisdictions.

In order to market and sell our drugs in the European Union and many other jurisdictions, we, and any future collaborators, must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The marketing approval process outside of the United States generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside of the United States, it is required that the drug be approved for reimbursement before the drug can be approved for sale in that country. We, and any future collaborators, may not obtain approvals from regulatory authorities outside of the United States on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside of the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA.

Additionally, on June 23, 2016, the electorate in the United Kingdom ("U.K.") voted in favor of leaving the European Union ("E.U."), commonly referred to as Brexit. On March 29, 2017, the U.K. formally notified the E.U. of its intention to withdraw pursuant to Article 50 of the Lisbon Treaty and began to negotiate the terms of its withdrawal and outline the future relationship between the U.K. and E.U. upon exit, which occurred on January 31, 2020. Following the U.K.'s departure, there is now a transition period during which existing arrangements will remain in place until the end of 2020, allowing detailed discussions on the future relationship between the U.K. and the E.U. to take place.

The potential impact on our future results of operations and liquidity resulting from Brexit remains unclear. The actual effects of Brexit will depend upon many factors and significant uncertainty remains with respect to the future relationship between the U.K. and the E.U. The final outcome of the discussions during the transition period may impact certain business operations, such as forcing us to restrict or delay efforts to develop or seek regulatory approval in the U.K. and/or E.U., including the approval and supply of our drug candidates. Such delays in obtaining, or an inability to obtain, any marketing approvals, as a result of Brexit or otherwise, would prevent us from commercializing our drug candidates in the U.K. and/or the E.U. and restrict our ability to generate revenue in these jurisdictions which may impact our ability to achieve and sustain profitability which may significantly and materially harm our business.

Even if we, or any future collaborators, obtain marketing approvals for our drug candidates, the terms of approvals and ongoing regulation of our drugs may limit how we, or they, manufacture and market our drugs, which could materially impair our ability to generate revenue.

Once marketing approval has been granted, an approved drug and its manufacturer and marketer are subject to ongoing review and extensive regulation. We, and any future collaborators, must therefore comply with requirements concerning advertising and promotion for any of our drug candidates for which we or they obtain marketing approval. Promotional communications with respect to prescription drugs are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the drug's approved labeling. Thus, we, and any future collaborators, may not be able to promote any drugs we develop for indications or uses for which they are not approved.

In addition, manufacturers of approved drugs and those manufacturers' facilities are required to comply with extensive FDA requirements, including ensuring that quality control and manufacturing procedures conform to cGMPs, which include requirements relating to quality control and quality assurance as well as the corresponding maintenance of records and documentation and reporting requirements. We, our contract manufacturers, our future collaborators and their contract manufacturers could be subject to periodic unannounced inspections by the FDA to monitor and ensure compliance with cGMPs.

Accordingly, assuming we, or our future collaborators, receive marketing approval for one or more of our drug candidates, we, and our future collaborators, and our and their contract manufacturers will continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production, product surveillance and quality control.

If we, and our future collaborators, are not able to comply with post-approval regulatory requirements, we, and our future collaborators, could have the marketing approvals for our drugs withdrawn by regulatory authorities and our, or our future collaborators', ability to market any future drugs could be limited, which could adversely affect our ability to achieve or sustain profitability. Further, the cost of compliance with post-approval regulations may have a negative effect on our operating results and financial condition.

Moreover, legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our drug candidates, if any, may be. In addition, increased scrutiny by the United States Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us and any collaborators to more stringent product labeling and post-marketing testing and other requirements.

Any of our drug candidates for which we, or our future collaborators, obtain marketing approval in the future could be subject to post-marketing restrictions or withdrawal from the market and we, and our future collaborators, may be subject to substantial penalties if we, or they, fail to comply with regulatory requirements or if we, or they, experience unanticipated problems with our drugs following approval.

Any of our drug candidates for which we, or our future collaborators, obtain marketing approval in the future, as well as the manufacturing processes, post-approval studies and measures, labeling, advertising and promotional activities for such drug, among other things, will be subject to continual requirements of and review by the FDA and other regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, registration and listing requirements, requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, requirements regarding the distribution of samples to physicians and recordkeeping. Even if marketing approval of a drug candidate is granted, the approval may be subject to limitations on the indicated uses for which the drug may be marketed or to the conditions of approval, including the requirement to implement a Risk Evaluation and Mitigation Strategy, which could include requirements for a restricted distribution system.

The FDA may also impose requirements for costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of a drug. The FDA and other agencies, including the DOJ, closely regulate and monitor the post-approval marketing and promotion of drugs to ensure that they are manufactured, marketed and distributed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA imposes stringent restrictions on manufacturers' communications regarding off-label use and if we, or our future collaborators, do not market any of our drug candidates for which we, or they, receive marketing approval for only their approved indications, we, or they, may be subject to warnings or enforcement action for off-label marketing. Violation of the FDCA and other statutes, including the False Claims Act, relating to the promotion and advertising of prescription drugs may lead to investigations or allegations of violations of federal and state health care fraud and abuse laws and state consumer protection laws.

In addition, later discovery of previously unknown adverse events or other problems with our drugs or their manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may yield various results, including:

- litigation involving patients taking our drug;
- restrictions on such drugs, manufacturers or manufacturing processes;
- restrictions on the labeling or marketing of a drug;
- restrictions on drug distribution or use;
- requirements to conduct post-marketing studies or clinical trials;

- warning letters or untitled letters;
- withdrawal of the drugs from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of drugs;
- fines, restitution or disgorgement of profits or revenues;
- suspension or withdrawal of marketing approvals;
- damage to relationships with any potential collaborators;
- unfavorable press coverage and damage to our reputation;
- refusal to permit the import or export of drugs;
- drug seizure; or
- injunctions or the imposition of civil or criminal penalties.

Under the CURES Act and the Trump Administration's regulatory reform initiatives, the FDA's policies, regulations and guidance may be revised or revoked and that could prevent, limit or delay regulatory approval of our drug candidates, which would impact our ability to generate revenue.

In December 2016, the 21st Century Cures Act, or Cures Act, was signed into law. The Cures Act, among other things, is intended to modernize the regulation of drugs and spur innovation, but its ultimate implementation is unclear. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability, which would adversely affect our business, prospects, financial condition and results of operations.

We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. For example, certain policies of the Trump administration may impact our business and industry. Namely, the Trump administration has taken several executive actions, including the issuance of a number of Executive Orders, that could impose significant burdens on, or otherwise materially delay, the FDA's ability to engage in routine regulatory and oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. An under-staffed FDA could result in delays in the FDA's responsiveness or in its ability to review submissions or applications, issue regulations or guidance, or implement or enforce regulatory requirements in a timely fashion or at all. Moreover, on January 30, 2017, President Trump issued an Executive Order, applicable to all executive agencies, including the FDA, which requires that for each notice of proposed rulemaking or final regulation to be issued in fiscal year 2017, the agency shall identify at least two existing regulations to be repealed, unless prohibited by law. These requirements are referred to as the "two-for-one" provisions. This Executive Order includes a budget neutrality provision that requires the total incremental cost of all new regulations in the 2017 fiscal year, including repealed regulations, to be no greater than zero, except in limited circumstances. For fiscal years 2018 and beyond, the Executive Order requires agencies to identify regulations to offset any incremental cost of a new regulation and approximate the total costs or savings associated with each new regulation or repealed regulation. In interim guidance issued by the Office of Information and Regulatory Affairs within OMB on February 2, 2017, the administration indicates that the "two-for-one" provisions may apply not only to agency regulations, but also to significant agency guidance documents. In addition, on February 24, 2017, President Trump issued an executive order directing each affected agency to designate an agency official as a "Regulatory Reform Officer" and establish a "Regulatory Reform Task Force" to implement the two-for-one provisions and other previously issued executive orders relating to the review of federal regulations, however it is difficult to predict how these requirements will be implemented, and the extent to which they will impact the FDA's ability to exercise its regulatory authority. If these executive actions impose constraints on the FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted.

We may not be able to obtain or maintain orphan drug exclusivity for applications of our TLR drug candidates.

Regulatory authorities in some jurisdictions, including the United States and Europe, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals in the United States.

Generally, if a product with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes the European Medicines Agency, or EMA, or the FDA from approving another marketing application for the same drug for the same indication for that exclusivity period. The applicable period is seven years in the United States and ten years in Europe. The European exclusivity period can be reduced to six years if a drug no longer meets the criteria for orphan drug designation or if the drug is sufficiently profitable such that market exclusivity is no longer justified. Orphan drug exclusivity may be lost if the FDA or EMA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition.

In June 2017, the FDA granted us orphan drug designation for tilsotolimod for the treatment of melanoma Stages IIb to IV. However, there can be no assurance that we will obtain orphan drug designation or exclusivity for any other disease indications for which we develop tilsotolimod, or for our other drug candidates. Even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs can be approved for the same condition. Even after an orphan drug is approved, the FDA can subsequently approve the same drug for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care.

On August 3, 2017, Congress passed the FDA Reauthorization Act of 2017, or FDARA. FDARA, among other things, codified the FDA's pre-existing regulatory interpretation, to require that a drug sponsor demonstrate the clinical superiority of an orphan drug that is otherwise the same as a previously approved drug for the same rare disease in order to receive orphan drug exclusivity. The new legislation reverses prior precedent holding that the Orphan Drug Act unambiguously requires that the FDA recognize the orphan exclusivity period regardless of a showing of clinical superiority. The FDA may further reevaluate the Orphan Drug Act and its regulations and policies. We do not know if, when, or how the FDA may change the orphan drug regulations and policies in the future, and it is uncertain how any changes might affect our business. Depending on what changes the FDA may make to its orphan drug regulations and policies, our business could be adversely impacted.

A fast track designation by the FDA may not actually lead to a faster development or regulatory review or approval process, and does not increase the likelihood that drug candidates will receive marketing approval.

We intend to seek fast track designation for some applications of our drug candidates. If a drug is intended for the treatment of a serious or life-threatening condition and the drug demonstrates the potential to address unmet medical needs for this condition, the drug sponsor may apply for FDA fast track designation. The FDA has broad discretion whether or not to grant this designation, so even if we believe a particular drug candidate is eligible for this designation, we cannot assure you that the FDA would decide to grant it.

In November 2017, the FDA granted us fast track designation for tilsotolimod for the treatment of anti-PD1 refractory metastatic melanoma in combination with ipilimumab therapy. However, even with fast track designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may withdraw fast track designation if it believes that the designation is no longer supported by data from our clinical development program.

A breakthrough therapy designation by the FDA for any application of our drug candidates may not lead to a faster development or regulatory review or approval process, and it does not increase the likelihood that those drug candidates will receive marketing approval.

We may seek a breakthrough therapy designation for some applications of our drug candidates. A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For drugs and biologics that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Drugs designated as breakthrough therapies by the FDA are also eligible for accelerated approval.

Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe an application of one of our drug candidates meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of a breakthrough therapy designation for a drug candidate may not result in a faster development process, review or approval compared to drugs considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of our drug candidates qualify as breakthrough therapies, the FDA may later decide that the products no longer meet the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

If we are required by the FDA to obtain approval of a companion diagnostic in connection with and as a condition to approval of a drug candidate, and we do not obtain or we experience delays in obtaining FDA approval of a diagnostic device, we will not be able to commercialize the drug candidate and our ability to generate revenue will be materially impaired.

According to FDA guidance, if the FDA determines that a companion diagnostic device is essential to the safe and effective use of a novel therapeutic product or indication, the FDA generally will not approve the therapeutic product or new therapeutic product indication if the companion diagnostic is not also approved or cleared for that indication. Under the Federal Food, Drug, and Cosmetic Act, companion diagnostics are regulated as medical devices and the FDA has generally required companion diagnostics intended to select the patients who will respond to cancer treatment to obtain Premarket Approval, or a PMA. The PMA process, including the gathering of clinical and preclinical data and the submission to and review by the FDA, involves a rigorous premarket review during which the applicant must prepare and provide the FDA with reasonable assurance of the device's safety and effectiveness and information about the device and its components regarding, among other things, device design, manufacturing and labeling. PMA approval is not guaranteed and may take considerable time, and the FDA may ultimately respond to a PMA submission with a not approvable determination based on deficiencies in the application and require additional clinical trial or other data that may be expensive and time-consuming to generate and that can substantially delay approval.

We do not have experience or capabilities in developing or commercializing diagnostics and plan to rely on third parties or collaborators to perform these functions. Companion diagnostics are subject to regulation by the FDA and similar regulatory authorities outside the United States as medical devices and require separate regulatory approval prior to commercialization.

If we, or any third parties that we engage to assist us or any of our collaborators, are unable to successfully develop companion diagnostics for our TLR antagonist drug candidates that require a companion diagnostic, or experience delays in doing so:

- the development of such TLR antagonist drug candidates may be adversely affected if we are unable to appropriately select patients for enrollment in our clinical trials;
- such TLR antagonist drug candidates may not receive marketing approval if their safe and effective use depends on a companion diagnostic; and

- we may not realize the full commercial potential of any TLR antagonist drug candidate that receives marketing approval if, among other reasons, we are unable to appropriately identify patients with the specific oncogenic mutation targeted by such TLR antagonist drug candidate.

If any of these events were to occur, our business would be harmed, possibly materially.

We have only limited experience in regulatory affairs and our drug candidates are based on new technologies; these factors may affect our ability or the time we require to obtain necessary regulatory approvals.

We have only limited experience in filing the applications necessary to obtain regulatory approvals. Moreover, the products that result from our research and development programs will likely be based on new technologies and new therapeutic approaches that have not been extensively tested in humans. The regulatory requirements governing these types of products may be more rigorous than for conventional drugs. As a result, we may experience a longer regulatory process in connection with obtaining regulatory approvals of any product that we develop.

We may experience difficulties and delays in manufacturing certain of our drug candidates.

We may, in the future, experience difficulties and delays inherent in manufacturing our products, such as (i) failure by us or any of our vendors or suppliers to comply with Current Good Manufacturing Practices and other applicable regulations and quality assurance guidelines that could lead to manufacturing shutdowns, product shortages and delays in product manufacturing; (ii) delays related to the construction of new facilities or the expansion of existing facilities, including those intended to support future demand for our products; and (iii) other manufacturing or distribution problems including changes in manufacturing production sites and limits to manufacturing capacity due to regulatory requirements, changes in types of products produced, or physical limitations that could impact continuous supply. In addition, we could experience difficulties or delays in manufacturing our products caused by natural disasters, such as hurricanes. Manufacturing difficulties can result in product shortages, leading to lost sales and reputational harm to us.

Our relationships with healthcare providers and physicians and third-party payors will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

Healthcare providers, physicians and third party payors will play a primary role in the recommendation and prescription of any drugs for which we obtain marketing approval. Our future arrangements with third party payors, healthcare providers and physicians may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute any drugs for which we obtain marketing approval. These include the following:

- Anti-Kickback Statute—the federal healthcare anti-kickback statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation or arranging of, any good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid;
- False Claims Act—the federal False Claims Act imposes criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for, among other things, knowingly presenting, or causing to be presented false or fraudulent claims for payment by a federal healthcare program or making a false statement or record material to payment of a false claim or avoiding, decreasing or concealing an obligation to pay money to the federal government, with potential liability including mandatory treble damages and significant per-claim penalties, currently set at $5,500 to $11,000 per false claim;
- Privacy laws such as HIPAA—the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters, and, as amended by the Health Information Technology for Economic and Clinical Health Act and its implementing regulations, also imposes obligations, including mandatory contractual terms and technical safeguards, with respect to maintaining the privacy, security and transmission of individually identifiable health information;

- Transparency Requirements—federal laws require applicable manufacturers of covered drugs to report payments and other transfers of value to physicians and teaching hospitals; and
- Analogous State and Foreign Laws—analogous state and foreign fraud and abuse laws and regulations, such as state anti-kickback and false claims laws, can apply to sales or marketing arrangements and claims involving healthcare items or services and are generally broad and are enforced by many different federal and state agencies as well as through private actions.

Some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures. State and foreign laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not pre-empted by HIPAA, thus complicating compliance efforts.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion of products from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

Current and future legislation may increase the difficulty and cost for us and any collaborators to obtain marketing approval of our drug candidates and may affect the prices we, or they, may obtain.

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could, among other things, prevent or delay marketing approval of our drug candidates, restrict or regulate post-approval activities and affect our ability, or the ability of any collaborators, to profitably sell any products for which we, or they, obtain marketing approval. We expect that current laws, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we, or any collaborators, may receive for any approved products.

For example, in March 2010, President Obama signed into law the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively the PPACA. Among the provisions of the PPACA of potential importance to our business and our drug candidates are the following:

- an annual, non-deductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program;
- expansion of healthcare fraud and abuse laws, including the civil False Claims Act and the federal Anti-Kickback Statute, new government investigative powers and enhanced penalties for noncompliance;
- a Medicare Part D coverage gap discount program, in which manufacturers must agree to offer point-of-sale discounts off negotiated prices;
- extension of manufacturers' Medicaid rebate liability;
- expansion of eligibility criteria for Medicaid programs;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- new requirements to report certain financial arrangements with physicians and teaching hospitals;

- a new requirement to annually report drug samples that manufacturers and distributors provide to physicians; and
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

In addition, other legislative changes have been proposed and adopted since the PPACA was enacted. These changes include the Budget Control Act of 2011, which, among other things, led to aggregate reductions to Medicare payments to providers of up to 2% per fiscal year that started in 2013 and, due to subsequent legislative amendments to the statute, will stay in effect through 2025 unless additional congressional action is taken, and the American Taxpayer Relief Act of 2012, which, among other things, reduced Medicare payments to several types of providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for any of our drug candidates for which we may obtain regulatory approval or the frequency with which any such drug candidate is prescribed or used. Further, there have been several recent U.S. congressional inquiries and proposed state and federal legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the costs of drugs under Medicare and reform government program reimbursement methodologies for drug products.

We expect that these healthcare reforms, as well as other healthcare reform measures that may be adopted in the future, may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment methodologies and additional downward pressure on the price that we receive for any approved product and/or the level of reimbursement physicians receive for administering any approved product we might bring to market. Reductions in reimbursement levels may negatively impact the prices we receive or the frequency with which our products are prescribed or administered. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors.

The Trump Administration has also taken a number of executive actions to repeal or delay implementation of the PPACA. Most recently, the Tax Cuts and Jobs Act of 2017 repealed the “individual mandate.” The repeal of this provision, which requires most Americans to carry a minimal level of health insurance, became effective in 2019. According to the Congressional Budget Office, the repeal of the individual mandate will cause 13 million fewer Americans to be insured in 2027 and premiums in insurance markets may rise.

We will continue to evaluate the effect that the PPACA and its possible repeal and replacement could have on our business. It is possible that repeal and replacement initiatives, if enacted into law, could ultimately result in fewer individuals having health insurance coverage or in individuals having insurance coverage with less generous benefits. While the timing and scope of any potential future legislation to repeal and replace PPACA provisions is highly uncertain in many respects, it is also possible that some of the PPACA provisions that generally are not favorable for the research-based pharmaceutical industry could also be repealed along with PPACA coverage expansion provisions Accordingly, such reforms, if enacted, could have an adverse effect on anticipated revenue from drug candidates that we may successfully develop and for which we may obtain marketing approval and may affect our overall financial condition and ability to develop commercialize drug candidates.

The costs of prescription pharmaceuticals in the United States has also been the subject of considerable discussion in the United States, and members of Congress and the Administration have stated that they will address such costs through new legislative and administrative measures. The pricing of prescription pharmaceuticals is also subject to governmental control outside the United States. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost effectiveness of our drug candidates to other available therapies. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our ability to generate revenues and become profitable could be impaired. In the European Union, similar political, economic and regulatory developments may affect our ability to profitably commercialize our products. In addition to continuing pressure on prices and cost containment measures, legislative developments at the European Union or member state level may result in significant additional requirements or obstacles that may increase our operating costs.

Moreover, legislative and regulatory proposals have also been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical drugs. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our drug candidates, if any, may be. In addition, increased scrutiny by Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us and any future collaborators to more stringent drug labeling and post-marketing testing and other requirements.

Laws and regulations governing any international operations we may have in the future may preclude us from developing, manufacturing and selling certain drug candidates outside of the United States and require us to develop and implement costly compliance programs.

We are subject to numerous laws and regulations in each jurisdiction outside the United States in which we operate. The creation, implementation and maintenance of international business practices compliance programs is costly and such programs are difficult to enforce, particularly where reliance on third parties is required.

The FCPA prohibits any U.S. individual or business from paying, offering, authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with certain accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations. The anti-bribery provisions of the FCPA are enforced primarily by the DOJ. The SEC is involved with enforcement of the books and records provisions of the FCPA.

Compliance with the FCPA and other anti-bribery laws is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the pharmaceutical industry, because, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered foreign officials. Certain payments to hospitals in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions.

Various laws, regulations and executive orders also restrict the use and dissemination outside of the United States, or the sharing with certain non-U.S. nationals, of information classified for national security purposes, as well as certain products and technical data relating to those products. Our expansion outside of the United States, has required, and will continue to require, us to dedicate additional resources to comply with these laws, and these laws may preclude us from developing, manufacturing, or selling certain drugs and drug candidates outside of the United States, which could limit our growth potential and increase our development costs. The failure to comply with laws governing international business practices may result in substantial penalties, including suspension or debarment from government contracting. Violation of the FCPA and other anti-bribery laws can result in significant civil and criminal penalties. Indictment alone under the FCPA can lead to suspension of the right to do business with the U.S. government until the pending claims are resolved. Conviction of a violation of the FCPA can result in long-term disqualification as a government contractor. The termination of a government contract or relationship as a result of our failure to satisfy any of our obligations under laws governing international business practices would have a negative impact on our operations and harm our reputation and ability to procure government contracts. The SEC also may suspend or bar issuers from trading securities on U.S. exchanges for violations of the FCPA's accounting provisions.

Governments outside of the United States tend to impose strict price controls, which may adversely affect our revenues from the sales of drugs, if any.

In some countries, particularly the countries of the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a drug. To obtain reimbursement or pricing approval in some countries, we, or our future collaborators, may be required to conduct a clinical trial that compares the cost-effectiveness of our drug to other available therapies. If reimbursement of our drugs is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be materially harmed.

If we fail 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 our business.

We are 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. Our operations involve the use of hazardous and flammable materials, including chemicals and biological and radioactive materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our 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.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or commercialization efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Our employees may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements, which could cause significant liability for us and harm our reputation.

We are exposed to the risk of employee fraud or other misconduct, including intentional failures to comply with FDA regulations or similar regulations of comparable foreign regulatory authorities, provide accurate information to the FDA or comparable foreign regulatory authorities, comply with manufacturing standards we have established, comply with federal and state healthcare fraud and abuse laws and regulations and similar laws and regulations established and enforced by comparable foreign regulatory authorities, report financial information or data accurately or disclose unauthorized activities to us. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and 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 governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws, standards or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of significant fines or other sanctions.

We depend on information technology, infrastructure and data to conduct our business. Any significant disruption could have a material adverse effect on our business.

We are dependent upon information technology, infrastructure and data. Computer systems, including ours and those of our suppliers, partners and service providers, contain sensitive confidential information or intellectual property. Computer systems are vulnerable to service interruption or destruction, cyber-attacks (both malicious and random) and other natural or man-made incidents or disasters, which may be prolonged or go undetected. Such events and attacks are increasing in their frequency, sophistication and intensity, and have become increasingly difficult to detect. A significant or large-scale interruption of our information technology could adversely affect our ability to manage and keep our operations running efficiently and effectively. An incident that results in a wider or sustained disruption to our business or products could have a material adverse effect on our business, financial condition and results of operations.

Likewise, data privacy or security breaches by employees or others may pose a risk that sensitive data, including our intellectual property, trade secrets or personal information of our employees, patients or other business partners may be exposed to unauthorized persons or to the public. There can be no assurance that our efforts, or the efforts of our partners and vendors, will prevent service interruptions, or identify breaches in our systems, that could adversely affect our business and operations and/or result in the loss of critical or sensitive information, which could result in financial, legal, business or reputational harm to us. In addition, our liability insurance may not be sufficient in type or amount to cover us against claims related to security breaches, cyberattacks and other related breaches.

Risks Relating to Collaborators

Our existing collaborations and any collaborations we enter into in the future may not be successful.

Historically, an important element of our business strategy has included entering into collaborative alliances with corporate collaborators, primarily large pharmaceutical companies, for the development, commercialization, marketing, and distribution of some of our drug candidates. Our current collaboration and/or license agreements, as more fully described within Item 1 of this Annual Report on Form 10-K, or any collaborations we may enter into in the future, may not be successful. The success of our collaborative alliances, if any, will depend heavily on the efforts and activities of our collaborators. Our existing collaborations and any potential future collaborations have risks, including the following:

- our collaborators may control the development of the drug candidates being developed with our technologies and compounds including the timing of development;
- our collaborators may control the development of the companion diagnostic to be developed for use in conjunction with our drug candidates including the timing of development;
- our collaborators may control the public release of information regarding the developments, and we may not be able to make announcements or data presentations on a schedule favorable to us;
- disputes may arise in the future with respect to the ownership of or right to use technology and intellectual property developed with our collaborators;
- disagreements with our collaborators could delay or terminate the research, development or commercialization of products, or result in litigation or arbitration;
- we may have difficulty enforcing the contracts if any of our collaborators fail to perform;
- our collaborators may terminate their collaborations with us, which could make it difficult for us to attract new collaborators or adversely affect the perception of us in the business or financial communities;
- our collaboration agreements are likely to be for fixed terms and subject to termination by our collaborators in the event of a material breach or lack of scientific progress by us;
- our collaborators may have the first right to maintain or defend our intellectual property rights and, although we would likely have the right to assume the maintenance and defense of our intellectual

property rights if our collaborators do not, our ability to do so may be compromised by our collaborators' acts or omissions;

- our collaborators may challenge our intellectual property rights or utilize our intellectual property rights in such a way as to invite litigation that could jeopardize or invalidate our intellectual property rights or expose us to potential liability;
- our collaborators may not comply with all applicable regulatory requirements, or may fail to report safety data in accordance with all applicable regulatory requirements;
- our collaborators may change the focus of their development and commercialization efforts. Pharmaceutical and biotechnology companies historically have re-evaluated their priorities following mergers and consolidations, which have been common in recent years in these industries. The ability of our drug candidates to reach their potential could be limited if our collaborators decrease or fail to increase spending relating to such drug candidates;
- our collaborators may under fund or not commit sufficient resources to the testing, marketing, distribution or development of our drug candidates; and
- our collaborators may develop alternative products either on their own or in collaboration with others, or encounter conflicts of interest or changes in business strategy or other business issues, which could adversely affect their willingness or ability to fulfill their obligations to us.

Given these risks, it is possible that any collaborative alliance into which we enter may not be successful. Collaborations with pharmaceutical companies and other third parties often are terminated or allowed to expire by the other party. For example, in March 2019, we mutually agreed to terminate the Vivelix Agreement. Additionally, in November 2019, the collaboration term of the GSK Agreement expired. The termination or expiration of our current collaboration agreements or any other collaboration agreement that we enter into in the future may adversely affect us financially and could harm our business reputation.

If we are unable to establish additional collaborative alliances, our business may be materially harmed.

Collaborators provide the necessary resources and drug development experience to advance our compounds in their programs. We have entered into and expect to continue to seek to enter into collaborative alliances with pharmaceutical companies to advance our TLR agonist and antagonist candidates and with respect to additional applications of our nucleic acid chemistry technology research program. Upfront payments and milestone payments received from collaborations help to provide us with the financial resources for our internal research and development programs. Our internal programs are focused on developing TLR-targeted drug candidates for the potential treatment of certain rare diseases and in our immuno-oncology program and on nucleic acid chemistry drug candidates. We believe that additional resources will be required to advance compounds in all of these areas. If we do not reach agreements with additional collaborators in the future, we may not be able to obtain the expertise and resources necessary to achieve our business objectives, our ability to advance our compounds will be jeopardized and we may fail to meet our business objectives.

We may have difficulty establishing additional collaborative alliances, particularly with respect to our TLR-targeted drug candidates and technology. For example, potential collaborators may note that our prior TLR collaborations with Vivelix, Novartis and with Merck KGaA have been terminated. Potential collaborators may also be reluctant to establish collaborations with respect to tilsotolimod (IMO-2125) or IMO-9200, given our prior setbacks with respect to these drug candidates. We also face, and expect to continue to face, significant competition in seeking appropriate collaborators.

Even if a potential partner were willing to enter into a collaborative alliance with respect to our TLR-targeted compounds or technology or our nucleic acid chemistry technology, the terms of such a collaborative alliance may not be on terms that are favorable to us. Moreover, collaborations are complex and time consuming to negotiate, document, and implement. We may not be successful in our efforts to establish and implement collaborations on a timely basis.

Risks Relating to Intellectual Property

If we are unable to obtain and maintain patent protection for our discoveries, the value of our technology and products will be adversely affected.

Our patent positions, and those of other drug discovery companies, are generally uncertain and involve complex legal, scientific, and factual questions. Our ability to develop and commercialize drugs depends in significant part on our ability to:

- obtain and maintain valid and enforceable patents;
- obtain licenses to the proprietary rights of others on commercially reasonable terms;
- operate without infringing upon the proprietary rights of others;
- prevent others from infringing on our proprietary rights; and
- protect our trade secrets.

We do not know whether any of our currently pending patent applications or those patent applications that we license will result in the issuance of any patents. Our issued patents and those that may be issued in the future, or those licensed to us, may be challenged, invalidated, held unenforceable, narrowed in the course of a post-issuance proceeding or circumvented, and the rights granted thereunder may not provide us proprietary protection or competitive advantages against competitors with similar technology. Moreover, intellectual property laws may change and negatively impact our ability to obtain issued patents covering our technologies or to enforce any patents that issue. Because of the extensive time required for development, testing, and regulatory review of a potential product, it is possible that, before any of our products can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thus reducing any advantage provided by the patent.

Because patent applications in the United States and many foreign jurisdictions are typically not published until 18 months after filing, or in some cases not at all, and because publications of discoveries in the scientific literature often lag behind actual discoveries, neither we nor our licensors can be certain that we or they were the first to make the inventions claimed in issued patents or pending patent applications, or that we or they were the first to file for protection of the inventions set forth in these patent applications.

As of February 15, 2020, we owned approximately 53 U.S. patents and patent applications and approximately 184 patents and patent applications throughout the rest of the world for our TLR-targeted immune modulation technologies. These patents and patent applications include claims covering the chemical compositions of matter and methods of use of our IMO compounds, such as IMO-8400, IMO-9200 and tilsotolimod (IMO-2125), as well as other compounds. These patents and patent applications (if granted) expire at various dates ranging from 2020 to 2037. With respect to IMO-8400, we have six issued U.S. patents that cover the chemical composition of matter of IMO-8400 and certain methods of its use, the latest of which will expire in 2031. With respect to IMO-9200, we have nine issued U.S. patents that cover the chemical composition for IMO-9200 and methods of its use, the latest of which will expire in 2034. With respect to tilsotolimod, we have an issued U.S. patent that covers the chemical composition of matter of tilsotolimod that expires in 2024 and additional patents covering methods of its use, the latest of which will expire in 2037. We have pending applications in the United States and outside of the United States that cover methods of treatment or use of tilsotolimod, which, if granted, will expire between 2035 and 2039.

Third parties may own or control patents or patent applications and require us to seek licenses, which could increase our development and commercialization costs, or prevent us from developing or marketing products.

Although we have many issued patents and pending patent applications in the United States and other countries, we may not have rights under certain third-party patents or patent applications related to our compounds under development. Third parties may own or control these patents and patent applications in the United States and abroad. In particular, we are aware of certain third-party U.S. patents that contain claims related to immunostimulatory polynucleotides and their use to stimulate an immune response, as well as to antisense technology. Although we do not believe any of our TLR or antisense compounds under development infringe any valid claim of these patents, we cannot be assured that the holder of such patents would not seek to assert such

patents against us or, if the holder did, that the courts would not interpret the claims of such patents more broadly than we believe appropriate and determine that we are in infringement of such patents. In addition, there may be other patents and patent applications related to our current or future drug candidates of which we are not aware. Therefore, in some cases, in order to develop, manufacture, sell or import some of our drug candidates, we or our collaborators may choose to seek, or be required to seek, licenses under third-party patents issued in the United States and abroad or under third-party patents that might issue from U.S. and foreign patent applications. In such an event, we would be required to pay license fees or royalties or both to the licensor. If licenses are not available to us on acceptable terms, we or our collaborators may not be able to develop, manufacture, sell or import these products, or may be delayed in doing so. Either of these results could have a material adverse effect on our business.

We may become involved in expensive patent litigation or other proceedings, which could result in our incurring substantial costs and expenses or substantial liability for damages, require us to stop our development and commercialization efforts or result in our patents being invalidated, interpreted narrowly or limited.

There has been substantial litigation and other proceedings regarding patent and other intellectual property rights in the biotechnology industry. We may become a party to various types of patent litigation or other proceedings regarding intellectual property rights from time to time even under circumstances where we are not practicing and do not intend to practice any of the intellectual property involved in the proceedings.

In addition to litigation, we may become involved in patent office proceedings, including oppositions, reexaminations, supplemental examinations and inter partes reviews involving our patents or the patents of third parties. We may initiate such proceedings or have such proceedings brought against us. An adverse determination in any such proceeding, or in litigation, could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products 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 drug candidates. An adverse determination in a proceeding involving a patent in our portfolio could result in the loss of protection or a narrowing in the scope of protection provided by that patent.

The cost to us of any patent litigation or other proceeding, even if resolved in our favor, could be substantial. Some of our competitors may be able to sustain the cost of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. If any patent litigation or other proceeding is resolved against us, we or our collaborators may be enjoined from developing, manufacturing, selling or importing our drugs without a license from the other party and we may be held liable for significant damages. We may not be able to obtain any required license on commercially acceptable terms or at all. In a patent office proceeding, such as an opposition, reexamination or inter partes review, our patents may be narrowed or invalidated.

Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace. Patent litigation and other proceedings may also absorb significant management time.

Our intellectual property may be infringed by a third party.

Third parties may infringe one or more of our issued patents or trademarks. We cannot predict if, when or where a third party may infringe one or more of our issued patents or trademarks. To counter infringement, we may be required to file infringement claims, which can be expensive and time-consuming. Moreover, there is no assurance that we would be successful in a court of law in proving that a third party is infringing one or more of our issued patents or trademarks. Any claims we assert against perceived infringers could also provoke these parties to assert counterclaims against us, alleging that we infringe their intellectual property. In addition, in a patent infringement proceeding, a court may decide that a patent of ours is invalid or unenforceable, in whole or in part, construe the patent’s claims narrowly and/or 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, any of which may adversely affect our business. Even if we are successful in proving in a court of law that a third party is infringing one or more of our issued patents or trademarks there can be no assurance that we would be successful in halting their infringing activities, for example, through a permanent injunction, or that we would be fully or even partially financially compensated for any harm to our business. We may be forced to enter into a license or other agreement with the

infringing third party at terms less profitable or otherwise commercially acceptable to us than if the license or agreement were negotiated under conditions between those of a willing licensee and a willing licensor.

Additionally, we may not become aware of a third-party infringer within legal timeframes for compensation or at all, thereby possibly losing the ability to be compensated for any harm to our business. Such a third party may be operating in a foreign country where the infringer is difficult to locate and/or the intellectual property laws may be more difficult to enforce. Some third-party infringers may be able to sustain the costs of complex infringement litigation more effectively than we can because they have substantially greater resources. Any inability to stop third-party infringement could result in loss in market share of some of our products or even lead to a delay, reduction and/or inhibition of the development, manufacture or sale of certain products by us. There is no assurance that a product produced and sold by a third-party infringer would meet our or other regulatory standards or would be safe for use. Such third-party infringer products could irreparably harm the reputation of our products thereby resulting in substantial loss in market share and profits.

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

We employ individuals who were previously employed at other biotechnology or pharmaceutical companies. We may be subject to claims that the we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information of our employees' former employers or other third parties. We may also be subject to claims that former employers or other third parties have an ownership interest in our patents. Litigation may be necessary to defend against these claims. There is no guarantee of success in defending these claims, and if we do not prevail, we could be required to pay substantial damages and could lose rights to important intellectual property. Even if we are successful, litigation could result in substantial cost and be a distraction to our management and other employees.

Risks Relating to Product Manufacturing, Marketing and Sales, and Reliance on Third Parties

Because we have limited manufacturing experience, and no manufacturing facilities or infrastructure, we are dependent on third-party manufacturers to manufacture drug candidates for us. If we cannot rely on third-party manufacturers, we will be required to incur significant costs and devote significant efforts to establish our own manufacturing facilities and capabilities.

We have limited manufacturing experience and no manufacturing facilities, infrastructure or clinical or commercial scale manufacturing capabilities. In order to continue to develop our drug candidates, apply for regulatory approvals, and ultimately commercialize products, we need to develop, contract for or otherwise arrange for the necessary manufacturing capabilities.

We currently rely upon third parties to produce material for nonclinical and clinical testing purposes and expect to continue to do so in the future. We also expect to rely upon third parties to produce materials that may be required for the commercial production of our drug candidates, if approved. Our current and anticipated future dependence upon others for the manufacture of our drug candidates may adversely affect our future profit margins and our ability to develop drug candidates and commercialize any drug candidates on a timely and competitive basis. We currently do not have any long-term supply contracts.

There are a limited number of manufacturers that operate under the FDA's cGMP regulations capable of manufacturing our drug candidates. As a result, we may have difficulty finding manufacturers for our drug candidates with adequate capacity for our needs. If we are unable to arrange for third-party manufacturing of our drug candidates on a timely basis, or to do so on commercially reasonable terms, we may not be able to complete development of our drug candidates or market them.

Reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured drug candidates ourselves, including:

- reliance on the third party for regulatory compliance and quality assurance;
- the possibility of breach of the manufacturing agreement by the third party because of factors beyond our control;
- the possibility of termination or nonrenewal of the agreement by the third party, based on its own business priorities or otherwise, at a time that is costly or inconvenient for us;
- the potential that third-party manufacturers will develop know-how owned by such third party in connection with the production of our drug candidates that becomes necessary for the manufacture of our drug candidates; and
- reliance upon third-party manufacturers to assist us in preventing inadvertent disclosure or theft of our proprietary knowledge.

Any contract manufacturers with which we enter into manufacturing arrangements will be subject to ongoing periodic, unannounced inspections by the FDA, or foreign equivalent, and corresponding state and foreign agencies or their designees to ensure compliance with cGMP requirements and other governmental regulations and corresponding foreign standards. Any failure by our third-party manufacturers to comply with such requirements, regulations or standards could lead to a delay in the conduct of our clinical trials, or a delay in, or failure to obtain, regulatory approval of any of our drug candidates. Such failure could also result in sanctions being imposed, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, product seizures or recalls, imposition of operating restrictions, total or partial suspension of production or distribution, or criminal prosecution.

Additionally, contract manufacturers may not be able to manufacture our drug candidates at a cost or in quantities necessary to make them commercially viable. As of January 1, 2020, our third-party manufacturers have met our manufacturing requirements, but we cannot be assured that they will continue to do so. Furthermore, changes in the manufacturing process or procedure, including a change in the location where the drug substance or drug product is manufactured or a change of a third-party manufacturer, may require prior FDA review and approval in accordance with the FDA's cGMP and New Drug Application/biologics license application regulations. Contract manufacturers may also be subject to comparable foreign requirements. This review may be costly and time-consuming and could delay or prevent the launch of a drug candidate. The FDA or similar foreign regulatory agencies at any time may also implement new standards, or change their interpretation and enforcement of existing standards for manufacture, packaging or testing of products. If we or our contract manufacturers are unable to comply, we or they may be subject to regulatory action, civil actions or penalties.

We have no experience selling, marketing or distributing products and no internal capability to do so.

If we receive regulatory approval to commence commercial sales of any of our drug candidates, we will face competition with respect to commercial sales, marketing, and distribution. These are areas in which we have no experience. To market any of our drug candidates directly, we would need to develop a marketing and sales force with technical expertise and with supporting distribution capability. In particular, we would need to recruit experienced marketing and sales personnel. Alternatively, we could engage a pharmaceutical or other healthcare company with an existing distribution system and direct sales force to assist us. However, to the extent we entered into such arrangements, we would be dependent on the efforts of third parties. If we are unable to establish sales and distribution capabilities, whether internally or in reliance on third parties, our business would suffer materially.

If third parties on whom we rely for clinical trials do not perform as contractually required or as we expect, we may not be able to obtain regulatory approval for or commercialize our drug candidates and our business may suffer.

We do not have the ability to independently conduct the clinical trials required to obtain regulatory approval for our drug candidates. We depend on independent clinical investigators, contract research organizations, and other third-party service providers in the conduct of the clinical trials of our drug candidates and expect to continue to do so. We expect to contract with contract research organizations for future clinical trials. We rely heavily on these parties for successful execution of our clinical trials, but do not control many aspects of their activities. We are responsible for ensuring that each of our clinical trials is conducted in accordance with the general

investigational plan and protocols for the trial. Moreover, the FDA and foreign regulatory agencies require us to comply with certain standards, commonly referred to as good clinical practices, and applicable regulatory requirements, for conducting, recording, and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity, and confidentiality of clinical trial participants are protected. Our reliance on third parties that we do not control does not relieve us of these responsibilities and requirements. Third parties may not complete activities on schedule, or at all, or may not conduct our clinical trials in accordance with regulatory requirements or our stated protocols. If these third parties fail to carry out their obligations, we may need to enter into new arrangements with alternative third parties. This could be difficult, costly or impossible, and our preclinical studies or clinical trials may need to be extended, delayed, terminated or repeated, and we may not be able to obtain regulatory approval in a timely fashion, or at all, for the applicable drug candidate, or to commercialize such drug candidate being tested in such studies or trials. If we seek to conduct any of these activities ourselves in the future, we will need to recruit appropriately trained personnel and add to our research, clinical, quality and corporate infrastructure.

The commercial success of any drug candidates that we may develop will depend upon the degree of market acceptance by physicians, patients, third-party payors, and others in the medical community.

Any products that we ultimately bring to the market, if they receive marketing approval, may not gain market acceptance by physicians, patients, third-party payors or others in the medical community. For example, current cancer treatments like chemotherapy and radiation therapy are well-established in the medical community, and doctors may continue to rely on these treatments. If our products do not achieve an adequate level of acceptance, we may not generate product revenue and we may not become profitable. The degree of market acceptance of our products, if approved for commercial sale, will depend on a number of factors, including:

- the prevalence and severity of any side effects, including any limitations or warnings contained in the product's approved labeling;
- the efficacy and potential advantages over alternative treatments;
- the ability to offer our drug candidates for sale at competitive prices;
- relative convenience and ease of administration;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength of marketing and distribution support and the timing of market introduction of competitive products; and
- publicity concerning our products or competing products and treatments.

Even if a potential product displays a favorable efficacy and safety profile, market acceptance of the product will not be known until after it is launched. Our efforts to educate patients, the medical community, and third-party payors on the benefits of our drug candidates may require significant resources and may never be successful. Such efforts to educate the marketplace may require more resources than are required by conventional technologies marketed by our competitors.

If we are unable to obtain adequate reimbursement from third-party payors for any products that we may develop or acceptable prices for those products, our revenues and prospects for profitability will suffer.

Most patients rely on Medicare, Medicaid, private health insurers, and other third-party payors to pay for their medical needs, including any drugs we may market. If third-party payors do not provide adequate coverage or reimbursement for any products that we may develop, our revenues and prospects for profitability will suffer. Congress enacted a limited prescription drug benefit for Medicare recipients in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. While the program established by this statute may increase demand for our products if we were to participate in this program, our prices will be negotiated with drug procurement organizations for Medicare beneficiaries and are likely to be lower than we might otherwise obtain. Non-Medicare third-party drug procurement organizations may also base the price they are willing to pay on the rate paid by drug procurement organizations for Medicare beneficiaries or may otherwise negotiate the price they are willing to pay.

A primary trend in the United States healthcare industry is toward cost containment. In addition, in some foreign countries, particularly the countries of the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take six months or longer after the receipt of regulatory marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost effectiveness of our drug candidates or products to other available therapies. The conduct of such a clinical trial could be expensive and result in delays in commercialization of our drug candidates. These further clinical trials would require additional time, resources, and expenses. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our prospects for generating revenue, if any, could be adversely affected and our business may suffer.

In March 2010, the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act became law. These health care reform laws are intended to broaden access to health insurance; reduce or constrain the growth of health care spending, especially Medicare spending; enhance remedies against fraud and abuse; add new transparency requirements for health care and health insurance industries; impose new taxes and fees on certain sectors of the health industry; and impose additional health policy reforms. Among the new fees is an annual assessment on makers of branded pharmaceuticals and biologics, under which a company's assessment is based primarily on its share of branded drug sales to federal health care programs. Such fees could affect our future prospects for profitability. Although it is too early to determine the effect of the health care legislation on our future prospects for profitability and financial condition, the law appears likely to continue the pressure on pharmaceutical pricing, especially under the Medicare program, and may also increase our regulatory burdens and operating costs.

Third-party payors are challenging the prices charged for medical products and services, and many third-party payors limit reimbursement for newly-approved health care products. These third-party payors may base their coverage and reimbursement on the coverage and reimbursement rate paid by carriers for Medicare beneficiaries. Furthermore, many such payors are investigating or implementing methods for reducing health care costs, such as the establishment of capitated or prospective payment systems. Cost containment pressures have led to an increased emphasis on the use of cost-effective products by health care providers. In particular, third-party payors may limit the indications for which they will reimburse patients who use any products that we may develop. Cost control initiatives could limit the price we might establish for products that we or our current or future collaborators may develop or sell, which would result in lower product revenues or royalties payable to us.

We face a risk of product liability claims and may not be able to obtain insurance.

Our business exposes us to the risk of product liability claims that is inherent in the manufacturing, testing, and marketing of human therapeutic drugs. We face an inherent risk of product liability exposure related to the testing of our drug candidates in human clinical trials and will face an even greater risk if we commercially sell any products. Regardless of merit or eventual outcome, liability claims and product recalls may result in:

- decreased demand for our drug candidates and products;
- damage to our reputation;
- regulatory investigations that could require costly recalls or product modifications;
- withdrawal of clinical trial participants;
- costs to defend related litigation;
- substantial monetary awards to clinical trial participants or patients, including awards that substantially exceed our product liability insurance, which we would then have to pay using other sources, if available, and would damage our ability to obtain liability insurance at reasonable costs, or at all, in the future;
- loss of revenue;
- the diversion of management's attention away from managing our business; and
- the inability to commercialize any products that we may develop.

Although we have product liability and clinical trial liability insurance that we believe is adequate, this insurance is subject to deductibles and coverage limitations. We may not be able to obtain or maintain adequate protection against potential liabilities. If we are unable to obtain insurance at acceptable cost or otherwise protect against potential product liability claims, we will be exposed to significant liabilities, which may materially and adversely affect our business and financial position. These liabilities could prevent or interfere with our commercialization efforts.

If we breach our agreements with third parties or if there is a dispute concerning any of our agreements with third parties, our business could be materially harmed.

Our agreements with third parties impose on us various obligations, as described throughout Item 1 of this Annual Report on Form 10-K. If we fail to comply with such obligations, or a counterparty to our agreements believes that we have failed to comply with such obligations, we may be sued and the costs of the resulting litigation could materially harm our business. Additionally, disputes may arise under these agreements, including with respect to the interpretation of such agreements and fee redeterminations or renegotiations thereof. These disputes may lead to litigation, termination of the agreement, or amendments that change our rights under the agreement, which could materially affect our financial position and materially harm our business.

Risks Relating to Ownership of Our Common Stock

Our corporate governance structure, including provisions in our certificate of incorporation and by-laws and Delaware law, may prevent a change in control or management that stockholders may consider desirable.

Section 203 of the Delaware General Corporation Law and our certificate of incorporation and by-laws contain provisions that might enable our management to resist a takeover of our company or discourage a third party from attempting to take over our company. These provisions include:

- a classified board of directors;
- limitations on the removal of directors;
- limitations on stockholder proposals at meetings of stockholders;
- the inability of stockholders to act by written consent or to call special meetings; and
- the ability of our board of directors to designate the terms of and issue new series of preferred stock without stockholder approval.

In addition, Section 203 of the Delaware General Corporation Law imposes restrictions on our ability to engage in business combinations and other specified transactions with significant stockholders. These provisions could have the effect of delaying, deferring or preventing a change in control of us or a change in our management that stockholders may consider favorable or beneficial. These provisions could also discourage proxy contests and make it more difficult for you and other stockholders to elect directors and take other corporate actions. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock.

We have three significant securityholders. If these securityholders choose to act together, they could exert substantial influence over our business. In addition, in connection with any merger, consolidation or sale of all or substantially all of our assets, they would be entitled to receive consideration in excess of their reported beneficial ownership of our common stock.

As of February 15, 2020, Baker Bros. Advisors LP, and certain of its affiliated funds (collectively, “Baker Brothers”) held 4,608,786 shares of our common stock, warrants to purchase up to 2,708,812 shares of our common stock at an exercise price of $0.08 per share, warrants to purchase 2,368,400 shares of our common stock at an exercise price of $1.52 per share and 23,684 shares of our Series B1 preferred stock convertible into 2,368,400 shares of our common stock. As of February 15, 2020, Baker Brothers beneficially owned 15.1% of our outstanding common stock, which excludes all convertible securities as a result of certain beneficial ownership limitations. Under the terms of the warrants issued to Baker Brothers and the December 2019 Securities Purchase Agreement (as defined below) related to the securities issued in connection with the 2019 Private Placement, Baker Brothers is not permitted to convert or exercise any common stock equivalents to the extent that such

conversion or exercise would result in Baker Brothers (and its affiliates) beneficially owning more than 4.99% of the number of shares of our common stock outstanding immediately after giving effect to the issuance of shares of common stock issuable upon conversion or exercise of such securities. Baker Brothers has the right to increase this beneficial ownership limitation in its discretion on 61 days' prior written notice to us, provided that in no event is Baker Brothers permitted to convert or exercise such securities to the extent that such exercise would result in Baker Brothers (and its affiliates) beneficially owning more than 19.99% of the number of shares of our common stock outstanding immediately after giving effect to the issuance of shares of common stock issuable upon conversion or exercise of such securities. The information in this paragraph is based on a Schedule 13G filed with the SEC on September 6, 2019 and information provided to us by Baker Brothers. On February 9, 2015, we entered into a registration rights agreement with Baker Brothers, pursuant to which we agreed to file registration statements to register for resale the shares of our common stock, including shares issuable upon the exercise of the warrants, held by Baker Brothers. Additionally, on December 23, 2019, concurrently with the execution of the December 2019 Securities Purchase Agreement, we entered into a registration rights agreement with Baker Brothers, pursuant to which we agreed, following demand by Baker Brothers, to file with the SEC a registration statement on Form S-3 covering the resale of the shares of common stock issuable upon conversion of the Series B Preferred Stock or exercise of the Series B Warrants (defined below) (as applicable) as promptly as reasonably practicable following such demand, and in any event within 60 days of such demand.

As of February 15, 2020, entities affiliated with Pillar Invest Corporation (the “Pillar Investment Entities”) held 3,221,317 shares of our common stock, constituting 10.5% of our outstanding common stock, and beneficially owned 10.6% of our outstanding common stock. The information in this paragraph is based on a Schedule 13D/A filed with the SEC on July 25, 2019, a Form 3 filed with the SEC on August 5, 2019 and Form 4’s filed with the SEC on November 8, 2019 and February 26, 2020.

As of February 15, 2020, Castellina Ventures Ltd. (“Castellina”) held 2,137,638 shares of our common stock, constituting 7.0% of our outstanding common stock. The information in this paragraph is based on a Schedule 13G filed with the SEC on September 4, 2018.

If any of our significant security holders acted together, they could be able to exert substantial influence over our business. This concentration of voting power could delay, defer or prevent a change of control, entrench our management and the board of directors or delay or prevent a merger, consolidation, takeover or other business combination involving us on terms that other stockholders may desire. In addition, conflicts of interest could arise in the future between us, on the one hand, and either of our significant securityholders on the other hand, concerning potential competitive business activities, business opportunities, the issuance of additional securities and other matters.

Although there are contractual limitations on the beneficial ownership of Baker Brothers, if Baker Brothers were to exercise their warrants for common stock or convert their preferred stock, and/or choose to act together with any of our other significant security holders, they could be able to exert substantial influence over our business. This concentration of voting power could delay, defer or prevent a change of control, entrench our management and the board of directors or delay or prevent a merger, consolidation, takeover or other business combination involving us on terms that other stockholders may desire. In addition, conflicts of interest could arise in the future between us, on the one hand, and either or all of our significant securityholders on the other hand, concerning potential competitive business activities, business opportunities, the issuance of additional securities and other matters.

Furthermore in the event of a sale of our company, whether by merger, sale of all or substantially all of our assets or otherwise, Baker Brothers would be entitled to receive, with respect to each share of common stock issuable upon conversion of preferred stock or exercise of warrants then held by them and without regard to the beneficial ownership limitations imposed on the conversion or exercise of such securities, the same amount and kind of securities, cash or property as they would have been entitled to receive if such securities had been converted into or exercised for shares of our common stock immediately prior to such sale of our company. Because Baker Brothers would receive this sale consideration with respect to preferred stock and warrants not included in their reported beneficial ownership of our common stock, in the event of a sale of our company, they would be entitled to receive a significantly larger portion of the total proceeds distributable to the holders of our securities than is represented by their reported beneficial ownership of our common stock.

Our stock price has been and may in the future be extremely volatile. In addition, because our common stock has historically been traded at low volume levels, our investors' ability to trade our common stock may be limited. As a result, investors may lose all or a significant portion of their investment.

Our stock price has been and may in the future be volatile. During the period from January 1, 2019 to February 15, 2020, the closing sales price of our common stock ranged from a high of $4.19 per share to a low of $1.45 per share. The stock market has also experienced periods of significant price and volume fluctuations and the market prices of biotechnology companies in particular have been highly volatile, often for reasons that have been unrelated to the operating performance of particular companies. The market price for our common stock may be influenced by many factors, including:

- our cash resources;
- timing and results of nonclinical studies and clinical trials of our drug candidates or those of our competitors;
- the regulatory status of our drug candidates;
- failure of any of our drug candidates, if approved, to achieve commercial success;
- the success of competitive products or technologies;
- regulatory developments in the United States and foreign countries;
- our success in entering into collaborative agreements;
- developments or disputes concerning patents or other proprietary rights;
- the departure of key personnel;
- our ability to maintain the listing of our common stock on The Nasdaq Capital Market (“Nasdaq”) or an alternative national securities exchange;
- variations in our financial results or those of companies that are perceived to be similar to us;
- the terms of any financing consummated by us;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors and issuance of new or changed securities analysts' reports or recommendations; and
- general economic, industry, and market conditions.

In addition, our common stock has historically been traded at low volume levels and may continue to trade at low volume levels. As a result, any large purchase or sale of our common stock could have a significant impact on the price of our common stock and it may be difficult for investors to sell our common stock in the market without depressing the market price for the common stock or at all.

As a result of the foregoing, investors may not be able to resell their shares at or above the price they paid for such shares. Investors in our common stock must be willing to bear the risk of fluctuations in the price of our common stock and the risk that the value of their investment in our stock could decline.

If securities analysts do not publish research reports about our business or if they downgrade us or our sector, the price of our common stock could decline.

The trading market for our common stock will depend in part on research reports that industry or financial analysts publish about the us and our business. If analysts downgrade us or other research analysts downgrade the industry in which we operate or the stock of any of our competitors, the price of our common stock may decline. Additionally, we currently only have six analysts covering our stock. We lack the potential benefit that coverage by other analysts may provide.

Our financial statements, including our balance sheets and statements of operations and comprehensive loss, are subject to quarterly changes related to the revaluation our warrant and future tranche right liabilities.

In accordance with ASC Topic 480, *Liabilities-Distinguishing from Equity* and/or ASC Topic 815, *Accounting for Derivative Instruments and Hedging Activities*, our outstanding Series B1 convertible preferred shares are accounted for as temporary equity and related warrants and future tranche rights issued in connection with our December 2019 Private Placement are accounted for as liabilities at fair value. Accordingly, the associated warrant and future tranche right liabilities are re-measured at each reporting period with changes in fair value recorded in earnings. The process of determining the fair value of the warrants and future tranche rights requires complex models and the development of significant and subjective estimates that may, and are likely to, change over the duration of the instrument with related changes in internal and external market factors. As a result, our financial statements and results of operations may fluctuate quarterly, based on factors, such as the trading value of our common stock and certain assumptions, which are outside of our control. The liabilities and accounting line items associated with our warrant and future tranche right liabilities on our balance sheet and statement of operations are non-cash items, and the inclusion of such items in our financial statements may materially affect the outcome of our quarterly and annual results, even though such items are non-cash and do not affect the cash we have available for operations. Investors should take such accounting matters and other non-cash items into account when comparing our quarter-to-quarter and year-to-year operating results and financial statements.

We completed a private placement of our Series B1 preferred stock in December 2019 and are contingently obligated to sell shares of Series B2, Series B3 and Series B4 preferred stock and warrants to the extent Baker Brothers exercise its option to purchase these securities pursuant to the December 2019 Securities Purchase Agreement. If we are required to redeem shares of Series B1, Series B2, Series B3 or Series B4 preferred stock, or in the event the we do not receive required shareholder approval and the option fee we received pursuant to the December 2019 Securities Purchase Agreement is required to be returned to Baker Brothers, our cash position will be negatively impacted. In addition, we may not have sufficient funds to redeem such shares of preferred stock.

Pursuant to the December 2019 Securities Purchase Agreement, we issued 23,684 shares of Series B1 preferred stock in connection with our December 2019 private placement and are contingently obligated to issue 98,685 shares of Series B2 preferred stock, 82,814 shares of Series B3 preferred stock and 82,418 shares of Series B4 preferred stock and accompanying warrants exercisable for either common stock or Series B1 preferred stock, to the extent Baker Brothers exercise its option to purchase these securities pursuant to the December 2019 Securities Purchase Agreement. We received a $6.2 million contingently refundable option fee pursuant to the December 2019 Securities representing $0.125 for each share of our common stock underlying (i) the Series B2 preferred stock and accompanying warrants, (ii) the Series B3 preferred stock and accompanying warrants and (iii) Series B4 preferred stock and accompanying warrants, issuable in the transaction. In the event we do not receive the required shareholder approval to increase our authorized shares of common stock in an amount sufficient to cover the conversion of Series B2, Series B3 and Series B4 preferred stock and warrants on or prior to December 31, 2020, the option fee shall be returned to Baker Brothers within five business days after such date. Although the Board recommends the stockholders support the proposal to increase the authorized shares, there can be no assurance that such approval will be obtained.

Further, subject to the terms of the Certificate of Designations, Preferences and Rights of Series B1 Convertible Preferred Stock, Series B2 Convertible Preferred Stock, Series B3 Convertible Preferred Stock and Series B4 Convertible Preferred Stock of the Company, on or after the five-year anniversary of the applicable initial issuance date of each such series of preferred stock, and to the extent that the holder’s redemption rights with regard to such series of preferred stock are not lost upon our achievement of certain criteria regarding our stock price and ILLUMINATE-301 on or before the two-year anniversary date of the applicable initial issuance date, some or all of our outstanding shares of such series of preferred stock may be redeemable at the option of the holder at a redemption price of $152.00 per share of Series B1 and Series B2 preferred stock and $182.00 per share of Series B3 and Series B4 preferred stock, upon delivery of an irrevocable written notice to us. If a holder of preferred stock requests redemption, we will be required to redeem such shares of preferred stock, subject to certain provisions regarding insufficient funds. We may be unable to redeem such preferred stock if restrictions under applicable law or contractual obligations prohibit such redemption. For example, Delaware law provides that a redemption on capital stock may only be paid from “surplus” or, if there is no “surplus,” from a corporation’s net profits for the then-current or the preceding fiscal year. Unless we operate profitably, our ability to redeem the preferred stock would require the availability of adequate “surplus,” which is defined as the excess, if any, of our net assets (total assets less total liabilities) over our capital. To date, we have operated at a loss. To the extent a

Series B preferred stockholder exercises its redemption rights when it is eligible to do so, and if we do not have sufficient "surplus" under Delaware law at that time, we would be unable to effect such redemption. If we do have sufficient "surplus" to effect such redemption at that time, our available cash will be negatively impacted and our ability to use the net proceeds from this offering could be substantially limited. In addition, such reduction in our available cash could decrease the trading price of our common stock.

The issuance or sale of shares of our common stock, or rights to acquire shares of our common stock, including the issuance of our securities pursuant to the December 2019 Securities Purchase Agreement, could depress the trading price of our common stock.

Under the terms of the December 2019 Securities Purchase Agreement, the private placement transaction consists of four separate tranches. In the first tranche, we issued and sold 23,684 shares of Series B1 preferred stock, at a purchase price of $152 per share and a conversion price of $1.52 per share, and related warrants to purchase up to 2,368,400 shares of common stock (or, if the holder elects to exercise the warrants for shares of Series B1 preferred stock, 23,684 shares of Series B1 preferred stock), at an exercise price of $1.52 per share (or, if the holder elects to exercise the warrants for shares of Series B1 Preferred Stock, $152 per Series B1 preferred share). In addition, we agreed to issue and sell the following securities in future tranches: (i) tranche 2 consists of 98,685 shares of Series B2 preferred stock, at a purchase price of $152 per share and a conversion price of $1.52 per share, and related warrants to purchase up to 9,868,500 shares of common stock (or, if the holder elects to exercise the warrants for shares of Series B1 preferred stock, 98,685 shares of Series B1 preferred stock), at an exercise price of $1.52 per share (or, if the holder elects to exercise the warrants for Series B1 preferred stock, $152 per Series B1 preferred share); (ii) tranche 3 consists of 82,418 shares of Series B3 preferred stock, at a purchase price of $182 per share and a conversion price of $1.82 per share, and related warrants to purchase up to 6,593,440 shares of common stock (or, if the holder elects to exercise the warrants for shares of Series B1 preferred stock, 65,934 shares of Series B1 preferred stock), at an exercise price of $1.82 per share (or, if the holder elects to exercise the warrants for Series B1 preferred stock, $182 per Series B1 preferred share); and (iii) tranche 4 consists of 82,418 shares of Series B4 preferred stock, at a purchase price of $182 per share and a conversion price of $1.82 per share, and related warrants to purchase up to 6,593,440 shares of common stock (or, if the holder elects to exercise the warrants for shares of Series B1 preferred stock, 65,934 shares of Series B1 preferred stock), at an exercise price of $1.82 per share (or, if the holder elects to exercise the warrants for Series B1 preferred stock, $182 per Series B1 preferred share), for additional gross proceeds of up to $87.6 million, each tranche to occur at such investors' discretion. However, if at any time following the closing date of tranche 3 our common stock has achieved a closing price on the Nasdaq Capital Market of at least $7.60 for twenty (20) days out of any thirty (30) consecutive day period, we may elect to terminate Baker Brothers' right to purchase shares in tranche 4 that were not issued and sold prior to such date.

In addition, we may conduct future offerings of our common stock, preferred stock or other securities that are convertible into or exercisable for our common stock to finance our operations or fund acquisitions, or for other purposes. If (i) we issue shares of common stock pursuant to the conversion or exercise of the securities issuable under the December 2019 Securities Purchase Agreement, (ii) we issue additional shares of our common stock or rights to acquire shares of our common stock in other future transactions, (iii) any of our existing stockholders sells a substantial amount of our common stock, or (iv) the market perceives that such issuances or sales may occur, then the trading price of our common stock may significantly decrease. In addition, our issuance of additional shares of common stock will dilute the ownership interests of our existing common stockholders.

Certain investors in the December 2019 private placement will have the ability to control or significantly influence certain business decisions.

Pursuant to the terms of the December 2019 Securities Purchase Agreement, subject to certain conditions, Baker Brothers have consent rights over certain significant matters of the Company's business. These include decisions to (i) issue or authorize equity securities that rank equal or senior to the Series B1, Series B2, Series B3 and Series B4 preferred stock with respect to liquidation preference, (ii) incur any indebtedness in excess of $1,000,000 , in the aggregate, outside the ordinary course of business (other than the refinancing of the Company's existing term debt), (iii) sell, transfer or otherwise dispose of tilsotolimod (such approval not to be reasonably withheld), (iv) license tilsotolimod in the United States or the European Union (in each case such approval not to be unreasonably withheld), or (v) pay any dividends. As a result, Baker Brothers will have significant influence over certain matters affecting our business.

Because we do not intend to pay dividends on our common stock, investor returns will be limited to any increase in the value of our stock.

We have never declared or paid any cash dividends on our common stock. We currently intend to retain all available funds and any future earnings to support our operations and finance the growth and development of our business and do not anticipate declaring or paying any cash dividends on our common stock for the foreseeable future. Additionally, the December 2019 Securities Purchase Agreement, more fully described below, contains negative covenants which restricts our ability to pay dividends on our equity securities. Any return to stockholders will therefore be limited to the appreciation of their stock, if any.

Item 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

We lease approximately 11,000 square feet of office space located in Exton, Pennsylvania. The lease was to expire on May 31, 2020, subject to a five-year renewal option. In December 2019, we elected to exercise the five-year renewal option which extended the lease through May 31, 2025. We may terminate the lease at any point as long as we remain a member of the landlord's group and require a space with more square footage. We have specified rights to sublease this facility.

Item 3. Legal Proceedings.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II.

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Market Information

Our common stock is listed under the symbol "IDRA" on the Nasdaq.

Holders of Record

As of February 15, 2020, we had approximately 57 common stockholders of record registered on our books, excluding shares held through banks and brokers.

Dividends

We have never declared or paid cash dividends on our common stock, and we do not expect to pay any cash dividends on our common stock in the foreseeable future. The declaration and payment of dividends in the future, of which there can be no assurance, will be determined by our board of directors in light of conditions then existing, including earnings, financial condition, capital requirements and other factors. In addition, the December 2019 Securities Purchase Agreement, more fully described below, contains negative covenants which restricts our ability to pay dividends on our equity securities.

Securities Authorized for Issuance Under Equity Compensation Plans

The following table provides information as of December 31, 2019 regarding total shares subject to outstanding stock options, warrants and rights and total additional shares available for issuance under our existing equity incentive and employee stock purchase plans. In addition, from time to time, we grant "inducement grants" pursuant to Nasdaq Listing Rule 5635(c)(4).

Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights (a)	Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights (b)	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column (a)) (c)
Equity compensation plans approved by stockholders (1)	4,020,292	$ 11.67	2,622,581
Equity compensation plans not approved by stockholders (2)	393,750	$ 26.76	—
Total	4,414,042	$ 13.08	2,622,581

(1) Consists of our: 2008 Stock Incentive Plan; 2013 Stock Incentive Plan and 2017 Employee Stock Purchase Plan. Amounts in column (a) include stock options and unvested restricted stock units outstanding. Shares are available for future issuance only under our 2013 Stock Incentive Plan and 2017 Employee Stock Purchase Plan.

(2) Consists of stock options issued as inducement grants as of December 31, 2019. These stock options are generally subject to the same terms and conditions as those awarded pursuant to the plans approved by our stockholders.

Recent Sales of Unregistered Securities

The following is a summary of transactions by us involving sales of our securities that were not registered under the Securities Act during the year ended December 31, 2019.

December 2019 Private Placement

On December 23, 2019, we filed a current report on Form 8-K reporting a private placement transaction pursuant to a Securities Purchase Agreement, dated as of December 23, 2019, by and between us and certain institutional investors (the "December 2019 Securities Purchase Agreement"). For additional information regarding the transaction, see Note 7 to the financial statements included in this report.

Concurrent with the private placement, we amended outstanding warrants initially issued on May 7, 2013, September 30, 2013 and February 10, 2014 to remove expiration date. Following the amendment, these warrants will not expire.

Issuer Purchases of Equity Securities

We did not repurchase any of our equity securities during the year ended December 31, 2019.

Item 6. Selected Financial Data.

The following selected financial data are derived from our financial statements. The data should be read in conjunction with Management's Discussion and Analysis of Financial Condition and Results of Operations and the financial statements, related notes, and other financial information included elsewhere in this Annual Report on Form 10-K.

	Year Ended December 31,				
	2019	2018	2017	2016	2015
	(In thousands, except per share data)				
Statement of Operations and Comprehensive Loss Data:					
Alliance revenue	$ 1,448	$ 662	$ 902	$ 16,199	$ 249
Operating expenses:					
Research and development	34,853	41,841	50,653	39,824	33,699
General and administrative	12,481	15,420	15,588	15,132	15,396
Merger-related costs, net	—	1,245	1,128	—	—
Restructuring costs	181	3,112	—	—	—
Total operating expenses	47,515	61,618	67,369	54,956	49,095
Loss from operations	(46,067)	(60,956)	(66,467)	(38,757)	(48,846)
Other income (expense):					
Interest income	1,150	1,089	574	415	357
Interest expense	—	(11)	(50)	(80)	(105)
Warrant revaluation expense	(598)	—	—	—	—
Future tranche right revaluation expense	(10,964)	—	—	—	—
Foreign currency exchange (loss) gain	(36)	(3)	(41)	33	39
Net loss	$ (56,515)	$ (59,881)	$ (65,984)	$ (38,389)	$ (48,555)
Deemed dividend related to December 2019 Private Placement (1)	(28,043)	—	—	—	—
Net loss applicable to common stockholders	$ (84,558)	$ (59,881)	$ (65,984)	$ (38,389)	$ (48,555)
Net loss per share applicable to common stockholders - basic and diluted	$ (2.96)	$ (2.25)	$ (3.35)	$ (2.41)	$ (0.42)
Weighted-average number of common shares used in computing net loss per common share applicable to common stockholders - basic and diluted (2)	28,545	26,601	19,675	15,950	14,387
Comprehensive loss:					
Net loss	(56,515)	(59,881)	(65,984)	(38,389)	(48,555)
Other comprehensive income (loss):					
Unrealized income (loss) on available-for-sale securities	—	—	17	117	(117)
Total other comprehensive income (loss)	—	—	17	117	(117)
Comprehensive loss	$ (56,515)	$ (59,881)	$ (65,967)	$ (38,272)	$ (48,672)
Balance Sheet Data:					
Cash, cash equivalents and investments	$ 42,793	$ 71,431	$ 112,629	$ 109,014	$ 87,157
Working capital	(8,249)	63,789	106,512	101,691	56,427
Total assets	47,489	73,023	118,417	113,231	92,276
Note payable	—	—	209	501	762
Accumulated deficit	(720,890)	(664,375)	(604,494)	(538,470)	(500,081)
Total stockholders' equity (deficit)	(11,168)	63,994	107,695	103,349	83,582

(1) See Note 7 to the financial statements appearing elsewhere in this Form 10-K.

(2) Computed on the basis described in Note 17 to the financial statements appearing elsewhere in this Annual Report on Form 10-K.

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our audited financial statements and the related notes appearing elsewhere in this Annual Report on Form 10-K.

Overview

We are a clinical-stage biopharmaceutical company with a business strategy focused on the clinical development, and ultimately the commercialization, of drug candidates for both oncology and rare disease indications characterized by small, well-defined patient populations with serious unmet medical needs. Our current focus is on our Toll-like receptor, or TLR, agonist, tilsotolimod (IMO-2125), for oncology. We believe we can develop and commercialize targeted therapies on our own. To the extent we seek to develop drug candidates for broader disease indications, we have entered into and may explore additional collaborative alliances to support development and commercialization.

TLRs are key receptors of the immune system and play a role in innate and adaptive immunity. As a result, we believe TLRs are potential therapeutic targets for the treatment of a broad range of diseases. Using our chemistry-based platform, we have designed both TLR agonists and antagonists to act by modulating the activity of targeted TLRs. A TLR agonist is a compound that stimulates an immune response through the targeted TLR. A TLR antagonist is a compound that inhibits an immune response by blocking the targeted TLR.

Our current TLR-targeted clinical-stage drug candidate, tilsotolimod, is an agonist of TLR9. We are currently developing tilsotolimod, via intratumoral injection, for the treatment of anti-PD1 refractory metastatic melanoma in combination with ipilimumab, an anti-CTLA4 antibody marketed as Yervoy® by BMS, in a Phase 3 trial. We are also evaluating intratumoral tilsotolimod in combination with nivolumab, an anti-PD1 antibody marketed as Opdivo® by BMS, and ipilimumab for the treatment of multiple solid tumors in a Phase 2 trial.

Termination of Merger Agreement

On January 21, 2018, we entered into an Agreement and Plan of Merger, or the Merger Agreement, with BioCryst Pharmaceuticals, Inc. ("BioCryst"). The board of directors of each of Idera and BioCryst unanimously approved the Merger Agreement and the transactions contemplated thereby and the required regulatory approvals were received. However, the proposed merger was subject to approval by the stockholders of Idera and BioCryst, and satisfaction of other customary closing conditions, as specified in the Merger Agreement. At a special meeting of BioCryst stockholders held on July 10, 2018, BioCryst's stockholders voted against the adoption of the Merger Agreement. Following such vote and in accordance with the terms of the Merger Agreement, BioCryst terminated the Merger Agreement on July 10, 2018. In accordance with the Merger Agreement, BioCryst paid us a fixed expense reimbursement amount of $6 million in connection with the termination of the Merger Agreement.

Corporate Consolidation and Wind-down of Discovery Operations

In July 2018, following an analysis of our gene-silencing technology platform and our research portfolio, we suspended our rare disease and discovery programs, including our nucleic acid chemistry research program, as part of our overall strategy to focus on the development and commercialization of tilsotolimod. In connection with this focused strategy, we closed our operating facility in Cambridge, Massachusetts and consolidated our operations to our Exton, Pennsylvania location. We also eliminated a total of 18 employee positions, primarily in the area of discovery, representing approximately 40% of our employee base.

For further details on our clinical development programs, collaborative alliances and other information about our business that impacts our financial condition and results of operations, see *Item 1. Business.*

Critical Accounting Policies and Estimates

This management's discussion and analysis of financial condition and results of operations is based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. On an ongoing basis, management evaluates its estimates and judgments, including those related to revenue recognition, stock-based compensation and research and development prepayments, accruals and related expenses. Management bases its estimates and judgments on historical experience and on various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

We regard an accounting estimate or assumption underlying our financial statements as a "critical accounting estimate" where:

- the nature of the estimate or assumption is material due to the level of subjectivity and judgment necessary to account for highly uncertain matters or the susceptibility of such matters to change; and

- the impact of the estimates and assumptions on financial condition or operating performance is material.

While our significant accounting policies are described in more detail in Note 2 to our financial statements appearing elsewhere in this Annual Report on Form 10-K, we believe the following accounting policies to be most critical to the judgments and estimates used in the preparation of our financial statements.

Research and Development Prepayments, Accruals and Related Expenses

As part of the process of preparing our financial statements, we are required to estimate our accrued and prepaid expenses for research and development activities performed by third parties, including Clinical Research Organizations ("CROs") and clinical investigators. These estimates are made as of the reporting date of the work completed over the life of the individual study in accordance with agreements established with CROs and clinical trial sites. Some CROs invoice us on a monthly basis, while others invoice upon achievement of milestones and the expense is recorded as services are rendered. We determine the estimates of research and development activities incurred at the end of each reporting period through discussion with internal personnel and outside service providers as to the progress or stage of completion of trials or services, as of the end of each reporting period, pursuant to contracts with clinical trial centers and CROs and the agreed upon fee to be paid for such services. We periodically confirm the accuracy of our estimates with the service providers and make adjustments if necessary. Clinical trial site costs related to patient enrollments are recorded as patients are entered into the trial.

Stock-Based Compensation

We recognize all share-based payments to employees and directors as expense in our statements of operations and comprehensive loss based on their fair values. We record compensation expense over an award's requisite service period, or vesting period, based on the award's fair value at the date of grant. Our policy is to charge the fair value of stock options as an expense, adjusted for forfeitures, on a straight-line basis over the vesting period, which is generally four years for employees and one year for directors.

We use the Black-Scholes option pricing model to estimate the fair value of stock option grants. The Black-Scholes option pricing model relies on a number of key assumptions to calculate estimated fair values, including assumptions as to average risk-free interest rate, expected dividend yield, expected life and expected volatility. For the assumed risk-free interest rate, we use the U.S. Treasury security rate with a term equal to the expected life of the option. Our assumed dividend yield of zero is based on the fact that we have never paid cash dividends to common stockholders and have no present intention to pay cash dividends. We use an expected option life based on actual experience. Our assumption for expected volatility is based on the actual stock-price volatility over a period equal to the expected life of the option.

If factors change and we employ different assumptions for estimating stock-based compensation expense in future periods, or if we decide to use a different valuation model, the stock-based compensation expense we recognize in future periods may differ significantly from what we have recorded in the current period and could materially affect our operating income (loss), net income (loss) and earnings (loss) per share. It may also result in a lack of comparability with other companies that use different models, methods and assumptions. The Black-Scholes option pricing model was developed for use in estimating the fair value of traded options that have no vesting restrictions and are fully transferable. These characteristics are not present in our option grants. Although the Black-Scholes option pricing model is widely used, existing valuation models, including the Black-Scholes option pricing model, may not provide reliable measures of the fair values of our stock-based compensation.

Warrant and Future Tranche Right Liabilities and Related Revaluation Income (Expense)

We entered into the December 2019 Securities Purchase Agreement, as more fully described in Note 7 to our financial statements appearing elsewhere in this Annual Report on Form 10-K, pursuant to which we issued shares of convertible preferred stock with detachable warrants. Additionally, the December 2019 Securities Purchase Agreement contains call options on redeemable preferred shares with warrants (conditionally exercisable for shares that are puttable), which we refer to as future tranche rights.

We determined that these warrants and future tranche rights represent freestanding financial instruments and account for both the warrants and future tranche rights as liabilities, which requires the measurement of the fair value of the liability at the time of issuance and recording changes as a charge to current earnings at each reporting period, which is included in Warrant Liability Revaluation Expense and/or Future Tranche Right Liability Revaluation Expense in the Company's statements of operations and comprehensive loss.

Warrant Liability. We use an option pricing model to value our liability-classified warrants. Inherent in the valuation model are assumptions related to volatility, risk-free interest rate, expected term, dividend rate, and other scenarios (i.e. probability of complex features of the warrants being triggered). Due to the nature of and inputs in the model used to assess the fair value of the warrants, it is not abnormal to experience significant fluctuations during each remeasurement period.

Future Tranche Right Liability. We use both a binomial lattice model and a Monte Carlo simulation to value the future tranche rights. We selected these models as we believe they are reflective of all significant assumptions that market participants would likely consider in negotiating the transfer of the future tranche rights. Such assumptions include, among other inputs, stock price volatility, risk-free rates, redemption and early exercise assumptions, cancellation and conversion assumptions, and the potential for future adjustment of the conversion price due to a future dilutive financing. Due to the nature of and inputs in the model used to assess the fair value of the future tranche rights, it is not abnormal to experience significant fluctuations during each remeasurement period.

Results of Operations

Years ended December 31, 2019, 2018 and 2017

Alliance Revenue

Alliance revenues consist of revenue generated through collaborative research, development and/or commercialization agreements and other out-licensing arrangements. The terms of these agreements may include payment to us of one or more of the following: nonrefundable, up-front license fees; research, development and commercial milestone payments; and other contingent payments due based on the activities of the counterparty or the reimbursement by licensees of costs associated with patent maintenance.

Alliance revenue for the years ended December 31, 2019, 2018 and 2017 was comprised of the following:

	Year Ended December 31, (in thousands)			% Change		
($ in thousands)	2019	2018	2017	2019 vs. 2018	2018 vs. 2017	
Out-license arrangement	$ 1,447	$ —	$ —	100%	0%	(1)
GSK collaboration	—	517	863	-100%	-40%	(2)
Vivelix collaboration	—	56	14	-100%	300%	(3)
Other	1	89	25	-99%	256%	(4)
Total Alliance revenue	$ 1,448	$ 662	$ 902	119%	-27%	

(1) Alliance revenue for the year ended December 31, 2019 totaled $1.4 million and primarily related to the out-licensing of certain non-core technology to Licensee during the second quarter of 2019.

(2) GSK collaboration revenues for each of the years ended December 31, 2018 and 2017 primarily relate to the recognition of a $2.5 million upfront payment received in connection with the execution of the GSK Agreement in November 2015, which was initially recorded as deferred revenue. We recognized this deferred revenue as revenue on a straight-line basis over the anticipated performance period under the GSK Agreement. The decrease in GSK collaboration revenues during 2018, as compared to 2017, was primarily due to a change that we made during the second quarter of 2017 with respect to our anticipated performance period under our collaboration with GSK from the original estimate of 27 months to an updated estimate of 36 months, which we accounted for on a prospective basis. Such performance period concluded in the fourth quarter of 2018. Accordingly, no such revenues were recognized during 2019. See Part I, Item 1, "Business —Collaborative Alliances" of this Form 10-K for additional details regarding our collaboration with GSK and Note 10 to the financial statements appearing elsewhere in this Annual Report on Form 10-K for information on the related accounting treatment.

(3) Vivelix collaboration revenues for each of the years ended December 31, 2018 and 2017 reflect the reimbursement for certain research activities we performed under the Vivelix Agreement, which was terminated on March 4, 2019. No such services were performed during 2019. See Part I, Item 1, "Business —Collaborative Alliances" of this Form 10-K for additional details regarding our collaboration with Vivelix and Note 10 to the financial statements appearing elsewhere in this Annual Report on Form 10-K for information on the related accounting treatment.

(4) Other revenues are comprised of amounts earned in connection with collaborations which are not material to our current operations nor expected to be material in the future, including reimbursements by licensees of costs associated with patent maintenance.

Research and Development Expenses

For each of our research and development programs, we incur both direct and indirect expenses. We track direct research and development expenses by program, which include third party costs such as contract research, consulting and clinical trial and manufacturing costs. We do not allocate indirect research and development expenses, which may include regulatory, laboratory (equipment and supplies), personnel, facility and other overhead costs (including depreciation and amortization), to specific programs.

In the table below, research and development expenses are set forth in the following categories which are discussed beneath the table:

	Year Ended December 31, (in thousands)			% Change	
($ in thousands)	**2019**	**2018**	**2017**	**2019 vs 2018**	**2018 vs 2017**
IMO-2125 external development expense	$ 25,494	$ 23,388	$ 10,930	9%	114% (1)
IMO-8400 external development expense	45	2,647	8,484	-98%	-69%(2)
Other drug development expense	9,314	10,732	16,682	-13%	-36%(3)
Basic discovery expense	—	5,074	8,980	-100%	-43%(4)
Severance and option modification expense	—	—	5,577	0%	-100%(5)
Total research and development expenses	$ 34,853	$ 41,841	$ 50,653	-17%	-17%

(1) *IMO-2125 External Development Expenses.* These expenses include external expenses that we have incurred in connection with the development of tilsotolimod as part of our immuno-oncology program. These external expenses include payments to independent contractors and vendors for drug development activities conducted after the initiation of tilsotolimod clinical development in immuno-oncology, but exclude internal costs such as payroll and overhead expenses. We commenced clinical development of tilsotolimod as part of our immuno-oncology program in July 2015 and from July 2015 through December 31, 2019 we incurred approximately $65.2 million in tilsotolimod external development expenses as part of our immuno-oncology program, including costs associated with the preparation for and conduct of the ongoing Phase 1/2 clinical trial to assess the safety and efficacy of tilsotolimod in combination with ipilimumab and with pembrolizumab in patients with metastatic melanoma (ILLUMINATE-204), the preparation and conduct of our ongoing Phase 1b clinical trial of tilsotolimod monotherapy in patients with refractory solid tumors (ILLUMINATE-101), the preparation for, initiation and conduct of our ongoing Phase 3 clinical trial of tilsotolimod in combination with ipilimumab in patients with metastatic melanoma (ILLUMINATE-301), the preparation for our Phase 2 clinical trial of tilsotolimod in combination with nivolumab and ipilimumab for the treatment of solid tumor (ILLUMINATE-206), and the manufacture of additional drug substance for use in our clinical trials and additional nonclinical studies.

The increases in our IMO-2125 external development expenses in 2019 as compared to 2018 was primarily due to increases in costs incurred with contract research organizations to support our ongoing ILLUMINATE-301 trial, which we initiated in the first quarter of 2018, and ILLUMINATE-206, which we initiated in the second quarter of 2019. The increase was partially offset by decreased expenses related to ILLUMINATE-101 and ILLUMINATE-204 trials.

The increases in our IMO-2125 external development expenses in 2018 as compared to 2017 was primarily due to increases in costs incurred with contract research organizations to support (i) our ongoing ILLUMINATE-301 trial, which we initiated in the first quarter of 2018, (ii) our ongoing ILLUMINATE-101 trial, which we initiated in March 2017, and (iii) our ongoing ILLUMINATE-204 trial, which we initiated in December 2015.

Going forward, we expect ongoing IMO-2125 external development expenses to be significant as our focus in 2020 continues to be on the clinical development of tilsotolimod (IMO-2125). See additional information under the heading “Financial Condition, Liquidity and Capital Resources” regarding our future funding requirements.

(2) *IMO-8400 External Development Expenses.* These expenses include external expenses that we have incurred in connection with IMO-8400 since October 2012, when we commenced clinical development of IMO-8400. These external expenses include payments to independent contractors and vendors for drug development activities conducted after the initiation of IMO-8400 clinical development but exclude internal costs such as payroll and overhead expenses. Since October 2012, we incurred approximately $45.4 million in IMO-8400 external development expenses through December 31, 2019, including costs associated with our Phase 1 clinical trial in healthy subjects; our Phase 2 clinical trial in patients with psoriasis, our Phase 1/2 clinical trial in patients with Waldenström's macroglobulinemia and our Phase 1/2 clinical trial in patients with diffuse large B-cell lymphoma ("DLBCL") harboring the MYD88 L265P oncogenic mutation, which we discontinued in September 2016; our Phase 2 clinical trial in patients with dermatomyositis, which we determined in July 2018 to discontinue upon completion of final close-out activities; the manufacture of drug substance for use in our clinical trials; and expenses associated with our collaboration with Abbott Molecular for the development of a companion diagnostic for identification of patients with DLBCL harboring the MYD88 L265P oncogenic mutation. In July 2018, we terminated further development of IMO-8400. As a result, we expect IMO-8400 external development expenses to be insignificant in future periods.

The decrease in our IMO-8400 external development expenses in 2019 as compared to 2018 was due to the decision to discontinue all development of IMO-8400 in July 2018.

The decrease in our IMO-8400 external development expenses in 2018, as compared to 2017, was primarily due to costs incurred during the 2017 period on clinical development of IMO-8400 for B-cell lymphomas, including our trials in Waldenström's macroglobulinemia and DLBCL harboring the MYD88 L265P oncogenic mutation, which we did not incur in 2018 as a result of our decision in September 2016 to discontinue development of IMO-8400 for treatment of B-cell lymphomas and focus on the development of IMO-8400 for the treatment of dermatomyositis, which was subsequently discontinued in July 2018.

(3) *Other Drug Development Expenses.* These expenses include external expenses associated with preclinical development of identified compounds in anticipation of advancing these compounds into clinical development, including IDRA-008. In addition, these expenses include internal costs, such as payroll and overhead expenses, associated with preclinical development and products in clinical development. The external expenses associated with preclinical compounds include payments to contract vendors for manufacturing and the related stability studies, preclinical studies, including animal toxicology and pharmacology studies, and professional fees. Other drug development expenses also include costs associated with compounds that were previously being developed but are not currently being developed. In July 2018, we suspended further preclinical research. As a result, we expect other drug development expenses to be lower in future periods.

The decrease in other drug development expenses in 2019, as compared to 2018, was primarily due to a decrease in internal employee and facility overhead related costs, as we suspended preclinical research activities in July 2018 and focused on the development of our clinical drug candidates.

The decrease in other drug development expenses in 2018, as compared to 2017, was primarily due to a decrease in internal employee and facility overhead related costs and external costs of preclinical programs, including related toxicology studies, bulk drug manufacturing and awareness and education programs, as we suspended preclinical research activities in July 2018 and focused on the development of our clinical drug candidates.

(4) *Basic Discovery Expenses.* These expenses include our internal and external expenses relating to our discovery efforts with respect to our TLR-targeted programs, including agonists and antagonists of TLR3, TLR7, TLR8 and TLR9, and our nucleic acid chemistry research programs. These expenses reflect charges for laboratory supplies, external research, and professional fees, as well as payroll and overhead expenses. In July 2018, we suspended all internal discovery programs. As a result, there were no basic discovery expenses in 2019.

The decrease in basic discovery expenses in 2018, as compared to 2017, was primarily due to decreases in employee-related costs, lab supplies and facility overhead expenses as a result of our

restructuring initiatives, including the suspension of all internal discovery programs and closing of our Cambridge, Massachusetts facility.

(5) *Severance and Option Modification Expenses.* The expenses incurred during 2017 relate to charges for severance benefits provided pursuant to a separation agreement entered into in April 2017 in connection with the resignation of our former President of Research, effective May 31, 2017. Of the $5.6 million incurred, $1.3 million relates to severance pay in the form of salary continuation payments which was paid over a two-year period through May 31, 2019 and a pro-rated 2017 bonus payment, and $4.3 million relates to non-cash stock-based compensation expense resulting from modifications to previously issued stock option awards. No such expenses were incurred in 2018 or 2019.

General and Administrative Expenses

General and administrative expenses consist primarily of payroll, stock-based compensation expense, consulting fees and professional legal fees associated with our patent applications and maintenance, our corporate regulatory filing requirements, our corporate legal matters, and our business development initiatives. For the years ended December 31, 2019, 2018 and 2017, general and administrative expenses totaled $12.5 million, $15.4 million, and $15.6 million, respectively.

General and administrative expenses decreased by approximately $2.9 million, or 19.1%, in 2019, as compared to 2018. The decreases were primarily due to lower facility-related costs as a result of cost savings realized in connection with the closing of our Cambridge, Massachusetts facility post-restructuring in July 2018 and lower investor relations costs.

General and administrative expenses decreased by approximately $0.2 million, or 1.1%, in 2018, as compared to 2017, primarily due to lower employee related costs, partially offset by facility related costs incurred at our Cambridge, Massachusetts facility post-restructuring in July 2018.

Merger-related Costs, net

Merger-related costs, net consists of charges and, where applicable, credits for transaction and integration-related professional fees, employee retention, and other incremental costs directly related to these activities, which are offset by merger termination fees.

Merger-related costs, net for the years ended December 31, 2018 and 2017 amounted to a net charge of $1.2 million and $1.1 million, respectively. The 2018 period was comprised of $7.2 million of expenses incurred in connection with the transactions contemplated by the Merger Agreement, including legal and professional fees, partially offset by a $6.0 million fixed expense reimbursement received in connection with the termination of the Merger Agreement. No such costs were incurred during 2019.

Restructuring Costs

Restructuring costs consist primarily of severance and related benefit costs related to workforce reductions, contract termination and wind-down costs and asset impairments.

Restructuring costs for the years ended December 31, 2019 and 2018 totaled $0.2 million and $3.1 million, respectively, and resulted from our decision in July 2018 to wind-down our discovery operations, reduce the workforce in Cambridge, Massachusetts that supported such operations, and close our Cambridge facility. No such costs were incurred during 2017.

Interest Income

Interest income for the years ended December 31, 2019, 2018 and 2017 totaled $1.2 million, $1.1 million, and $0.6 million, respectively. The year-over-year increases were primarily due to an increase in average investment balances, including money market funds classified as cash equivalents as a result of our decision to invest more cash in interest earning money market accounts in 2018.

Amounts may fluctuate from period to period due to changes in average investment balances, including money market funds classified as cash equivalents, and composition of investments.

Interest Expense

Interest expense for each of the years ended December 31, 2018 and 2017 totaled less than $0.1 million and related to interest incurred on the outstanding balance of our note payable, which was paid off in June 2018. Accordingly, no such costs were incurred during 2019.

Warrant Revaluation Expense

During the year ended December 31, 2019, we recorded non-cash expense of approximately $0.6 million for warrant revaluation charges associated with the revaluation of our liability-classified warrants subsequent to their December 2019 issuance in connection with the 2019 Private Placement. Due to the nature of and inputs in the model used to assess the fair value of our outstanding warrants, it is not abnormal to experience significant fluctuations during each remeasurement period. These fluctuations may be due to a variety of factors, including changes in our stock price and changes in estimated stock price volatility over the remaining life of the warrants. Warrant revaluation expense for 2019 was driven primarily by an increase in our stock price. No such expense was incurred during 2018 or 2017.

Future Tranche Right Revaluation Expense

During the year ended December 31, 2019, we recorded non-cash future tranche right revaluation expense of approximately $11.0 million related to the change in fair value of the future tranche right liability (right to purchase preferred stock and warrants to an investor at future dates) subsequent to their December 2019 issuance in connection with the 2019 Private Placement. Due to the nature of and inputs in the model used to assess the fair value of the future tranche rights, it is not abnormal to experience significant fluctuations during each remeasurement period. These fluctuations may be due to a variety of factors, including changes in our stock price and changes in estimated stock price volatility over the remaining estimated lives of the future tranche rights. Future tranche right revaluation expense for 2019 was driven primarily by an increase in our stock price. No such expense was incurred during 2018 or 2017.

Net Loss and Net Loss Attributable to Common Stockholders

As a result of the factors discussed above, our net loss was $56.5 million, $59.9 million, and $66.0 million for the years ended December 31, 2019, 2018 and 2017, respectively. For the year ended December 31, 2019, net loss attributable to common stockholders was $84.6 million, a difference of $28.0 million compared to net loss for the same period due to a deemed dividend related to the excess fair value provided to Baker Brothers in connection with the December 2019 Private Placement. See Note 7 for additional details. For the years ended December 31, 2018 and 2017, net loss was the same as net loss attributable to common stockholders.

Net Operating Loss Carryforwards

In December 2017, the Tax Cuts and Jobs Act ("TCJA") was signed into law. Among other things, the TCJA permanently lowered the corporate federal income tax rate to 21% from the existing maximum rate of 35%, effective for tax years including or commencing January 1, 2018. Certain provisions from the Tax Reform Act of 1986 were not impacted by TCJA, such as those limiting the amount of net operating loss carryforwards ("NOLs") and tax credit carryforwards that companies may utilize in any one year in the event of changes in ownership as defined by Section 382 of the Internal Revenue Code.

We have completed several financings since the effective date of the Tax Reform Act of 1986, which as of December 31, 2019, have resulted in ownership changes that will significantly limit our ability to utilize our net operating loss and tax credit carryforwards. In December 2017, we completed a study which determined that ownership changes had occurred. The federal and state net operating loss and tax credit carryforwards and related deferred tax assets discussed below and included in Note 14 to the financial statements appearing elsewhere in this Annual Report on Form 10-K have been adjusted to reflect the limitations that resulted from this study. The Company continues to monitor equity activity and potential ownership changes.

As of December 31, 2019, we had cumulative federal and state NOLs of approximately $295.8 million and $290.2 million available to reduce federal and state taxable income, respectively. As a result of TCJA, federal net operating losses incurred for taxable years beginning after January 1, 2018 have an unlimited carryforward period, but can only be utilized to offset 80% of taxable income in future taxable periods. Of the $295.8 million of federal NOLs, $98.4 million have an unlimited carryforward and the remaining NOLs are still subject to expiration through 2037. State NOLs are still subject to expiration according to the laws of each respective jurisdiction. We file state tax returns in Massachusetts and Pennsylvania whereby both jurisdictions impose a 20-year carryforward period. All $290.2 million of state NOLs expire through 2039, with the first year of expiration being 2032 for $21.0 million of Massachusetts NOLs. In addition, at December 31, 2019, we had cumulative federal and state tax credit carryforwards of $21.6 million and $1.9 million, respectively, available to reduce federal and state income taxes, respectively, which expire through 2039 and 2034, respectively, for federal and state purposes.

Financial Condition, Liquidity and Capital Resources

Financial Condition

As of December 31, 2019, we had an accumulated deficit of $720.9 million. To date, substantially all of our revenues have been from collaboration and license agreements and we have received no revenues from the sale of commercial products. We have devoted substantially all of our efforts to research and development, including clinical trials, and we have not completed development of any commercial products. Our research and development activities, together with our selling, general and administrative expenses, are expected to continue to result in substantial operating losses for the foreseeable future. These losses, among other things, have had and will continue to have an adverse effect on our stockholders' equity, total assets and working capital. Because of the numerous risks and uncertainties associated with developing drug candidates, and if approved, commercial products, we are unable to predict the extent of any future losses, whether or when any of our drug candidates will become commercially available or when we will become profitable, if at all.

Liquidity and Capital Resources

Overview

We require cash to fund our operating expenses and to make capital expenditures. Historically, we have funded our cash requirements primarily through the following:

(i) sale of common stock, preferred stock and warrants;

(ii) exercise of warrants;

(iii) debt financing, including capital leases;

(iv) license fees, research funding and milestone payments under collaborative and license agreements; and

(v) interest income.

We filed a shelf registration statement on Form S-3 on August 10, 2017, which was declared effective on September 8, 2017. Under this registration statement, we may sell, in one or more transactions, up to $250.0 million of common stock, preferred stock, depository shares and warrants. As of February 15, 2020, we may sell up to an additional $107.5 million of securities under this registration statement, which has been reduced for the full contractual amounts provided for under our Common Stock Purchase Agreement with Lincoln Park Capital Fund LLC (the "LPC Purchase Agreement") and our "At-The-Market" Equity Program pursuant to a Equity Distribution Agreement with JMP Securities LLC (the "ATM Agreement"), both of which are more fully described in Note 8 of the notes to our financial statements included in this Annual Report on Form 10-K.

In addition to the potential funding under the LPC Purchase Agreement and ATM Agreement, the December 2019 Securities Purchase Agreement, more fully described in Note 7 to the financial statements appearing elsewhere in this Annual Report on Form 10-K, provides for up to $97.7 million aggregate gross proceeds at the sole discretion of the Baker Brothers, of which $10.1 million was received in December 2019. Assuming Baker Brothers exercises their rights under the agreement and no other forms of external funding, we expect the proceeds could fund operations beyond an NDA filing for tilsotolimod.

See Notes 7 and 8 to the financial statements appearing elsewhere in this Annual Report on Form 10-K for additional information regarding our recent equity financings and common stock warrant activity.

Funding Requirements

We had cash, cash equivalents and investments of approximately $42.8 million at December 31, 2019, inclusive of the $6.2 million contingently refundable option fee received in connection with the December 2019 Securities Purchase Agreement. We believe based on our current operating plan, our existing cash, cash equivalents and investments on hand as of December 31, 2019, excluding the $6.2 million contingently

refundable option fee and including interest income and cash received through February 2020 from the ATM Agreement and LPC Purchase Agreement, will enable us to fund our operations into the first quarter of 2021. Specifically, we believe our available funds will be sufficient to enable us to perform the following:

(i) Complete and disclose results from:

a) our Phase 1/2 clinical trial of tilsotolimod in combination with ipilimumab and pembrolizumab in anti-PD1 refractory melanoma (ILLUMINATE-204); and

b) the Phase 1b monotherapy clinical trial of tilsotolimod in multiple refractory tumor types (ILLUMINATE-101);

(ii) continue to execute on our ongoing Phase 3 clinical trial of tilsotolimod in combination with ipilimumab for the treatment of anti-PD1 refractory metastatic melanoma (ILLUMINATE-301), including announcement of top-line ORR and other preliminary data;

(iii) initiate and complete enrollment in the signal-finding stage of Part I of our Phase 2 study of tilsotolimod in combination with nivolumab and ipilimumab for the treatment of MSS-CRC (ILLUMINATE-206), pending results from the initial group of ten patients enrolled to evaluate safety;

(iv) fund certain investigator initiated clinical trials of tilsotolimod; and

(v) maintain our current level of general and administrative expenses in order to support the business.

We expect that we will need to raise additional funds in order to complete our ongoing clinical trials of tilsotolimod and to continue to fund our operations. We are seeking and expect to continue to seek additional funding through collaborations, the sale or license of assets or financings of equity or debt securities. We believe that the key factors that will affect our ability to obtain funding are:

(i) the results of our clinical development activities in our tilsotolimod program or any other drug candidates we develop on the timelines anticipated;

(ii) the cost, timing, and outcome of regulatory reviews;

(iii) competitive and potentially competitive products and technologies and investors' receptivity to tilsotolimod or any other drug candidates we develop and the technology underlying them in light of competitive products and technologies;

(iv) the receptivity of the capital markets to financings by biotechnology companies generally and companies with drug candidates and technologies similar to ours specifically;

(v) the receptivity of the capital markets to any in-licensing, product acquisition or other transaction we may enter into; and

(vi) our ability to enter into additional collaborations with biotechnology and pharmaceutical companies and the success of such collaborations.

In addition, increases in expenses or delays in clinical development may adversely impact our cash position and require additional funds or cost reductions.

Financing may not be available to us when we need it or may not be available to us on favorable or acceptable terms or at all. Additionally, Baker Brothers may not exercise their right to purchase convertible preferred stock or exercise warrants in connection with the December 2019 Securities Purchase Agreement and, while the Board recommends the stockholders support the proposal to increase the authorized shares, in the event we do not receive the required shareholder approval provided for in the December 2019 Purchase Agreement, the $6.2 million option fee we received is required to be returned to Baker Brothers. We could be required to seek funds through collaborative alliances or through other means that may require us to relinquish rights to some of our technologies, drug candidates or drugs that we would otherwise pursue on our own. In addition, if we raise additional funds by issuing equity securities, our then existing stockholders may experience dilution. The terms of any financing may adversely affect the holdings or the rights of existing stockholders. An equity financing that involves existing stockholders may cause a concentration of ownership. 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, and are likely to include rights that are senior to the holders of our common stock. Any additional debt or equity financing may contain terms which are not

favorable to us or to our stockholders, such as liquidation and other preferences, or liens or other restrictions on our assets. As discussed in Note 14 to the financial statements appearing elsewhere in this Annual Report on Form 10-K, additional equity financings may also result in cumulative changes in ownership over a three-year period in excess of 50% which would limit the amount of net operating loss and tax credit carryforwards that we may utilize in any one year.

If we are unable to obtain adequate funding on a timely basis or at all, we will be required to terminate, modify or delay our clinical trials of tilsotolimod, or relinquish rights to portions of our technology, drug candidates and/or products.

Cash Flows

The following table presents a summary of the primary sources and uses of cash for the years ended December 31, 2019, 2018 and 2017:

	Year Ended December 31,		
(in thousands)	**2019**	**2018**	**2017**
Net cash provided by (used in):			
Operating activities	$ (44,498)	$ (51,916)	$ (55,259)
Investing activities	(2,402)	215	28,064
Financing activities	15,488	10,192	59,157
Increase (decrease) in cash, cash equivalents and restricted cash	**$ (31,412)**	**$ (41,509)**	**$ 31,962**

Operating Activities. The net cash used in operating activities for all periods presented consists primarily of our net losses adjusted for non-cash charges and changes in components of working capital. The decrease in cash used in operating activities for the year ended December 31, 2019, as compared to 2018, was primarily due to decreases in cash outflows related to our prior discovery and other development programs, lower costs resulting from the closure of our Cambridge, Massachusetts office, and no 2019 merger-related costs, partially offset by increased cash outflows related to our current IMO-2125 development program. The decrease in cash used in operating activities for the year ended December 31, 2018, as compared to 2017, was primarily due to decreases in cash outflows related to our discovery and development programs, including payments to contract research organizations, partially offset by merger-related costs.

Investing Activities. Cash provided by investing activities primarily consisted of the following amounts relating to our investments in available-for-sale securities and purchases and disposals of property and equipment:

- for the year ended December 31, 2019, proceeds from the maturity of available-for-sale securities of $42.1 million was fully offset by the purchase of $44.5 million of available-for-sale securities;
- for the year ended December 31, 2018, proceeds of $0.3 million from the sale of property and equipment, partially offset by purchases of less than $0.1 million of property and equipment; and
- for the year ended December 31, 2017, proceeds from the maturity of available-for-sale securities of $28.3 million, partially offset by the purchase of $0.2 million of property and equipment.

Financing Activities. Cash provided by financing activities primarily consisted of the following amounts raised in connection with the following transactions:

- for the year ended December 31, 2019, $15.4 million in aggregate net proceeds from financing arrangements consisting of $10.1 million received pursuant to the December 2019 Securities Purchase Agreement, $3.7 million received pursuant to the LPC Purchase Agreement and $1.6 million received under the ATM Agreement, plus an additional $0.1 million in proceeds from employee stock purchases under our 2017 Employee Stock Purchase Plan (“2017 ESPP”);
- for the year ended December 31, 2018, $10.2 million in aggregate proceeds from the exercise of common stock options and warrants and $0.2 million in proceeds from employee stock purchases under our 2017 ESPP, partially offset by $0.2 million in payments made on our previously outstanding note payable; and

- for the year ended December 31, 2017, net proceeds of $53.8 million from our follow-on underwritten public offering of our common stock in October 2017, excluding less than $0.1 million of costs that were unpaid at December 31, 2017, and $5.7 million in aggregate net proceeds from employee stock purchases under our 2017 ESPP and the exercise of common stock options and warrants.

Contractual Obligations

As of December 31, 2019, our contractual commitments and the effects such commitments are expected to have on our liquidity and cash flows in future periods were as follows:

	Payments Due by Period				
(in thousands)	**Total**	**Less than 1 year**	**1 - 3 years**	**3 - 5 years**	**More than 5 years**
Operating leases	$ 1,245	$ 217	$ 453	$ 475	$ 100
Total	$ 1,245	$ 217	$ 453	$ 475	$ 100

Our only material lease commitments relate to our facility in Exton, Pennsylvania, which expires on May 31, 2025.

Off-Balance Sheet Arrangements

As of December 31, 2019, we had no off-balance sheet arrangements.

New Accounting Pronouncements

New accounting pronouncements are discussed in Note 2 in the Notes to the Financial Statements in this Annual Report on Form 10-K.

Item 7A. Quantitative and Qualitative Disclosures about Market Risk.

As of December 31, 2019, all material assets and liabilities are in U.S. dollars, which is our functional currency.

We maintain investments in accordance with our investment policy. The primary objectives of our investment activities are to preserve principal, maintain proper liquidity to meet operating needs and maximize yields. Although our investments are subject to credit risk, our investment policy specifies credit quality standards for our investments and limits the amount of credit exposure from any single issue, issuer or type of investment. We regularly review our investment holdings in light of the then current economic environment. At December 31, 2019, all of our invested funds were invested in money market funds classified in cash and cash equivalents on the accompanying balance sheet and commercial paper classified in short-term investments on the accompanying balance sheet.

Based on a hypothetical ten percent adverse movement in interest rates, the potential losses in future earnings, fair value of risk sensitive financial instruments, and cash flows are immaterial, although the actual effects may differ materially from the hypothetical analysis.

Item 8. Financial Statements and Supplementary Data.

All financial statements required to be filed hereunder are filed as listed under Item 15(a) of this Annual Report on Form 10-K and are incorporated herein by this reference.

Quarterly Operating Results (Unaudited)

The following table presents the unaudited statement of operations and comprehensive loss data for each of the eight quarters in the period ended December 31, 2019. The information for each of these quarters is unaudited, but has been prepared on the same basis as the audited financial statements appearing elsewhere in this Annual Report on Form 10-K. In our opinion, all necessary adjustments, consisting only of normal recurring adjustments, have been made to present fairly the unaudited quarterly results when read in conjunction with the audited financial statements and the notes thereto appearing elsewhere in this document. These operating results are not necessarily indicative of the results of operations that may be expected for any future period.

	Three months ended							
	Dec. 31, 2019	Sep. 30, 2019	Jun. 30, 2019	Mar. 31, 2019	Dec. 31, 2018	Sep. 30, 2018	Jun. 30, 2018	Mar. 31, 2018
	(In thousands, except per share data)							
Statement of Operations and Comprehensive Loss Data:								
Alliance revenue	$ —	$ —	$ 1,448	$ —	$ 99	$ 145	$ 163	$ 255
Operating expenses:								
Research and development	8,368	8,359	10,024	8,102	8,929	8,860	10,664	13,388
General and administrative	3,420	3,023	2,895	3,143	3,571	3,984	4,216	3,649
Merger-related costs, net	—	—	—	—	—	(3,836)	1,583	3,498
Restructuring costs	—	5	45	131	95	3,017	—	—
Total operating expenses	11,788	11,387	12,964	11,376	12,595	12,025	16,463	20,535
Loss from operations	(11,788)	(11,387)	(11,516)	(11,376)	(12,496)	(11,880)	(16,300)	(20,280)
Other income (expense):								
Interest income	158	249	339	404	330	277	271	211
Interest expense	—	—	—	—	—	—	(4)	(7)
Warrant revaluation expense	(598)	—	—	—	—	—	—	—
Future tranche right revaluation expense	(10,964)	—	—	—	—	—	—	—
Foreign currency exchange gain (loss)	(40)	5	1	(2)	16	(2)	2	(19)
Net loss	$ (23,232)	$ (11,133)	$ (11,176)	$ (10,974)	$ (12,150)	$ (11,605)	$ (16,031)	$ (20,095)
Deemed dividend related to December 2019 Private Placement (1)	(28,043)	—	—	—	—	—	—	—
Net loss applicable to common stockholders	$ (51,275)	$ (11,133)	$ (11,176)	$ (10,974)	$ (12,150)	$ (11,605)	$ (16,031)	$ (20,095)
Net loss per share applicable to common stockholders - basic and diluted	$ (1.76)	$ (0.39)	$ (0.39)	$ (0.40)	$ (0.45)	$ (0.43)	$ (0.59)	$ (0.81)
Weighted-average number of common shares used in computing net loss per share applicable to common stockholders - basic and diluted (2)	29,177	28,847	28,461	27,676	27,183	27,175	27,133	24,880
Comprehensive loss:								
Net loss	$ (23,232)	$ (11,133)	$ (11,176)	$ (10,974)	$ (12,150)	$ (11,605)	$ (16,031)	$ (20,095)
Other comprehensive income (loss):								
Unrealized gain (loss) on available-for-sale securities	(1)	(1)	—	2	—	—	—	—
Total other comprehensive income (loss)	(1)	(1)	—	2	—	—	—	—
Comprehensive loss	$ (23,233)	$ (11,134)	$ (11,176)	$ (10,972)	$ (12,150)	$ (11,605)	$ (16,031)	$ (20,095)

(1) See Note 7 to the financial statements appearing elsewhere in this Form 10-K.

(2) Computed on the basis described in Note 17 to the financial statements appearing elsewhere in this Form 10-K.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

None.

Item 9A. Controls and Procedures.

Disclosure Controls and Procedures

Our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of December 31, 2019. In designing and evaluating our disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and our management necessarily applied its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on this evaluation, our principal executive officer and principal financial officer concluded that as of December 31, 2019, our disclosure controls and procedures were (1) designed to ensure that material information relating to us is made known to our principal executive officer and principal financial officer by others, particularly during the period in which this report was prepared, and (2) effective, in that they provide reasonable assurance that information required to be disclosed by us in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms.

Internal Control over Financial Reporting

a) ***Management's Annual Report on Internal Control over Financial Reporting***

Our management, with the participation of our principal executive officer and principal financial officer, is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is defined in Rule 13a-15(f) and 15d-15(f) promulgated under the Exchange Act as a process designed by, or under the supervision of, the Company's principal executive and principal financial officers and effected by the Company's board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles and includes those policies and procedures that:

- Pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of the assets of the Company;

- Provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the Company are being made only in accordance with authorizations of management and directors of the Company; and

- Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the Company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Management assessed the effectiveness of our internal control over financial reporting as of December 31, 2019. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in *Internal Control — Integrated Framework* (2013).

Based on its assessment, management believes that, as of December 31, 2019, the Company's internal control over financial reporting is effective based on those criteria.

Ernst & Young LLP, our independent registered public accounting firm, has issued an attestation report on the effectiveness of our internal control over financial reporting as of December 31, 2019. This report appears immediately below.

b) Attestation Report of the Registered Public Accounting Firm

Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of Idera Pharmaceuticals, Inc.

Opinion on Internal Control over Financial Reporting

We have audited Idera Pharmaceuticals, Inc.'s internal control over financial reporting as of December 31, 2019, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (the COSO criteria). In our opinion, Idera Pharmaceuticals, Inc. (the Company) maintained, in all material respects, effective internal control over financial reporting as of December 31, 2019, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the balance sheets of Idera Pharmaceuticals, Inc. as of December 31, 2019 and 2018, and the related statements of operations and comprehensive loss, redeemable preferred stock and stockholders' equity (deficit) and cash flows for each of the three years in the period ended December 31, 2019, and the related notes and our report dated March 11, 2020 expressed an unqualified opinion thereon that included an explanatory paragraph regarding the Company's ability to continue as a going concern.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Annual Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the 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 audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects.

Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control Over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance

with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ ERNST & YOUNG LLP

Philadelphia, Pennsylvania
March 11, 2020

c) Changes in Internal Control over Financial Reporting.

No change in our internal control over financial reporting occurred during the fourth quarter of the fiscal year ended December 31, 2019 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

None.

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 the 2020 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days of the fiscal year ended December 31, 2019.

We have adopted a written code of business conduct and ethics that applies to our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. We have posted a current copy of the Code of Business Conduct and Ethics in the "Investors — Corporate Governance" section of our website, which is located at www.iderapharma.com. We intend to satisfy the disclosure requirements under Item 5.05 of Form 8-K regarding an amendment to, or waiver from, a provision of our code of business conduct and ethics by posting such information on our website at www.iderapharma.com.

Item 11. Executive Compensation.

The information required by this item is incorporated by reference to our Proxy Statement for the 2020 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days of the fiscal year ended December 31, 2019.

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 the 2020 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days of the fiscal year ended December 31, 2019.

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 the 2020 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days of the fiscal year ended December 31, 2019.

Item 14. Principal Accountant Fees and Services.

The information required by this item is incorporated by reference to our Proxy Statement for the 2020 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission within 120 days of the fiscal year ended December 31, 2019.

PART IV.

Item 15. Exhibits and Financial Statement Schedules.

(a) (1) *Financial Statements.*

(2) We are not filing any financial statement schedules as part of this Annual Report on Form 10-K because they are not applicable or the required information is included in the financial statements or notes thereto.

(3) The list of Exhibits filed as a part of this Annual Report on Form 10-K is set forth on the Exhibit Index below.

(b) The list of Exhibits filed as a part of this Annual Report on Form 10-K is set forth on the Exhibit Index below.

(c) None.

Exhibit Index

Exhibit Number	Description	Incorporated by Reference to			
		Form	SEC File No.	Exhibit(s)	Filing Date
1.1	Equity Distribution Agreement, dated November 26, 2018, by and between Idera Pharmaceuticals, Inc. and JMP Securities LLC	8-K	001-31918	1.1	November 26, 2018
2.1	Agreement and Plan of Merger, dated as January 21, 2018, by and among Idera Pharmaceuticals, Inc., BioCryst Pharmaceuticals, Inc., Nautilus Holdco, Inc., Island Merger Sub, Inc. and Boat Merger Sub, Inc.	8-K	001-31918	2.1	January 22, 2018
3.1	Restated Certificate of Incorporation of Idera Pharmaceuticals, Inc., as amended.	10-Q	001-31918	3.1	August 2, 2018
3.2	Amended and Restated Bylaws of Idera Pharmaceuticals, Inc.	10-K	001-31918	3.2	March 7, 2018
3.3	Certificate of Designations, Preferences and Rights of Series B1 Convertible Preferred Stock, Series B2 Convertible Preferred Stock, Series B3 Convertible Preferred Stock and Series B4 Convertible Preferred Stock of the Company	8-K	001-31918	3.1	December 23, 2019
4.1	Specimen Certificate for shares of Common Stock, $.001 par value, of Idera Pharmaceuticals, Inc.	S-1	33-99024	4.1	December 8, 1995
4.2	Form of Warrant issued in May 2013 to purchasers in Idera Pharmaceuticals, Inc.'s registered public offering on Idera Pharmaceuticals, Inc.'s registration statement on Form S-1 (File No. 333-187155)	10-Q	001-31918	10.5	May 15, 2013
4.3	Form of Warrant issued in September 2013 to purchasers in Idera Pharmaceuticals, Inc.'s registered public offering on Idera Pharmaceuticals, Inc.'s registration statement on Form S-3 (File No. 333-191073)	8-K	001-31918	4.1	September 26, 2013
4.4	Form of Warrant issued in February 2014 to purchasers in Idera Pharmaceuticals, Inc.'s registered public offering on Idera Pharmaceuticals, Inc.'s registration statement on Form S-3 (File No. 333-191073)	8-K	001-31918	4.1	February 5, 2014
4.5	Registration Rights Agreement, dated as of March 4, 2019, by and between Idera Pharmaceuticals, Inc. and Lincoln Park Capital Fund, LLC	10-K	001-31918	4.5	March 6, 2019
4.6	Form of Warrant issued in December 2019 to purchasers in Idera Pharmaceuticals, Inc. private placement transaction	8-K	001-31918	4.1	December 23, 2019
4.7	Unit Purchase Agreement by and among Idera Pharmaceuticals, Inc. and certain persons and entities listed therein, dated April 1, 1998	10-K	000-27352	10.39	April 1, 2002

Exhibit Number	Description	Incorporated by Reference to			
		Form	SEC File No.	Exhibit(s)	Filing Date
4.8	Registration Rights Agreement, dated March 24, 2006, by and among Idera Pharmaceuticals, Inc. and the Investors named therein	8-K	001-31918	10.2	March 29, 2006
4.9	Registration Rights Agreement, dated February 9, 2015, among Idera Pharmaceuticals, Inc. and the Selling Stockholders named therein	8-K	001-31918	4.1	February 9, 2015
4.10	Amendment to the Registration Rights Agreement, dated January 21, 2018, by and among Idera Pharmaceuticals, Inc., 667, L.P., Baker Brothers Life Sciences, L.P. and 14159, L.P.	8-K	001-31918	10.1	January 22, 2018
4.11*	Registration Rights Agreement, dated December 23, 2019, by and among Idera Pharmaceuticals, Inc. and certain investors named therein				
4.12*	Voting Agreement, dated as of December 23, 2019, by and among Idera Pharmaceuticals, Inc. and certain investors named therein				
4.13*	Warrant Amendment Agreement, dated as of December 23, 2019, by and among Idera Pharmaceuticals, Inc. and certain holders of warrants named therein				
4.14*	Description of the Idera Pharmaceuticals, Inc. Securities Registered Under Section 12 of the Securities Exchange Act of 1934				
10.1†	2005 Stock Incentive Plan, as amended	10-Q	001-31918	10.4	August 14, 2006
10.2†	2008 Stock Incentive Plan, as amended	8-K	001-31918	99.2	June 17, 2011
10.3†	2013 Stock Incentive Plan, as amended	8-K	001-31918	10.1	June 13, 2014
10.4†	Amendment to 2013 Stock Incentive Plan, as amended	8-K	001-31918	10.1	June 11, 2015
10.5†	Amendment to 2013 Stock Incentive Plan, as amended	8-K	001-31918	10.1	June 9, 2017
10.6†	Amendment to 2013 Stock Incentive Plan, as amended	DEF14A	001-31918	Appendix A	April 25, 2019
10.7†	2017 Employee Stock Purchase Plan	8-K	001-31918	10.2	June 9, 2017
10.8†	Amendment to 2017 Employee Stock Purchase Plan	DEF14A	001-31918	Appendix C	April 25, 2019
10.9	Policy on Treatment of Stock Options in the Event of Retirement, approved April 28, 2014	10-Q	001-31918	10.1	August 12, 2014
10.10†	Form of Incentive Stock Option Agreement Granted Under the 2008 Stock Incentive Plan	8-K	001-31918	10.2	June 10, 2008

Exhibit Number	Description	Incorporated by Reference to			
		Form	SEC File No.	Exhibit(s)	Filing Date
10.11†	Form of Nonstatutory Stock Option Agreement Granted Under the 2008 Stock Incentive Plan	8-K	001-31918	10.3	June 10, 2008
10.12†	Form of Nonstatutory Stock Option Agreement (Non-Employee Directors) Granted Under the 2008 Stock Incentive Plan	8-K	001-31918	10.4	June 10, 2008
10.13†	Form of Restricted Stock Agreement Under the 2008 Stock Incentive Plan	8-K	001-31918	10.5	June 10, 2008
10.14†	Form of Incentive Stock Option Agreement granted under the 2013 Stock Incentive Plan	8-K	001-31918	10.2	July 29, 2013
10.15†	Form of Nonstatutory Stock Option Agreement granted under the 2013 Stock Incentive Plan	8-K	001-31918	10.3	July 29, 2013
10.16†	Form of Nonstatutory Stock Option Agreement (Non-Employee Directors) granted under the 2013 Stock Incentive Plan	8-K	001-31918	10.4	July 29, 2013
10.17†	Form of Inducement Stock Option Award – Nonstatutory Stock Option Agreement	10-Q	001-31918	10.1	November 6, 2015
10.18†	Form of Restricted Stock Agreement under the 2013 Stock Incentive Plan	10-Q	001-31918	10.3	August 8, 2019
10.19†	Separation Agreement and Release of Claims dated April 18, 2017 between Idera Pharmaceuticals, Inc. and Sudhir Agrawal	10-Q	001-31918	10.1	August 7, 2017
10.20†	Scientific Advisor Agreement effective June 1, 2017 by and between Idera Pharmaceuticals, Inc. and Sudhir Agrawal	10-K	001-31918	10.30	March 7, 2018
10.21†	Consulting Services Agreement, dated October 31, 2018, by and between Idera Pharmaceuticals, Inc. and Louis J. Arcudi, III	8-K	001-31918	99.1	November 2, 2018
10.22†	Separation Agreement and Release, dated October 31, 2018, by and between Idera Pharmaceuticals, Inc. and Louis J. Arcudi, III	8-K	001-31918	99.2	November 2, 2018
10.23†	Employment Letter Agreement, dated December 1, 2014, by and between Idera Pharmaceuticals, Inc. and Vincent Milano	10-K	001-31918	10.24	March 12, 2015
10.24†	Amendment to Employment Agreement, dated January 10, 2020, by and between the Company and Vincent J. Milano	8-K	001-31918	10.1	January 15, 2020
10.25†	Form of Vincent J. Milano Restricted Stock Unit Agreement	8-K	001-31918	10.2	January 15, 2020
10.26†	Employment Letter, dated January 26, 2015, by and between Idera Pharmaceuticals, Inc. and Clayton Fletcher	10-Q	001-31918	10.1	May 11, 2015
10.27†	Employment Offer Letter, dated October 15, 2015, by and between Idera Pharmaceuticals, Inc. and John J. Kirby	10-K	001-31918	10.26	March 6, 2019

Exhibit Number	Description	Incorporated by Reference to			
		Form	SEC File No.	Exhibit(s)	Filing Date
10.28†	Employment Letter, dated November 11, 2015 by and between Idera Pharmaceuticals, Inc. and Joanna Horobin	10-K	001-31918	10.35	March 7, 2018
10.29†	Employment Letter, dated February 2, 2017, by and between Idera Pharmaceuticals, Inc. and Jonathan Yingling	10-K	001-31918	10.36	March 7, 2018
10.30†	Amendment to Severance and Change of Control Agreement, dated January 27, 2020, by and between the Company and Dr. Jonathan Yingling	8-K	001-31918	10.1	January 27, 2020
10.31†	Employment Offer Letter, dated August 20, 2018, by and between Idera Pharmaceuticals, Inc. and Bryant D. Lim	10-Q	001-31918	10.1	November 6, 2018
10.32†	Employment Offer Letter, dated June 26, 2019, by and between Idera Pharmaceuticals, Inc. and Elizabeth Tarka	10-Q	001-31918	10.4	August 8, 2019
10.33†	Form of Director and Officer Indemnification Agreement	10-Q	001-31918	10.1	May 4, 2017
10.34†	Form of Executive Severance and Change of Control Agreement	10-Q	001-31918	10.2	May 4, 2017
10.35††	Development and Commercialization Agreement, dated May 1, 2014, by and between Abbott Molecular Inc. and Idera Pharmaceuticals, Inc.	10-Q	001-31918	10.3	August 12, 2014
10.36††	License Agreement, dated November 28, 2016, by and between Idera Pharmaceuticals, Inc. and Vivelix Pharmaceuticals, Ltd.	10-K	001-31918	10.56	March 15, 2017
10.37††	Clinical Trial Collaboration and Supply Agreement, by and between Idera Pharmaceuticals, Inc. and Bristol-Myers Squibb Company, dated May 18, 2018	10-Q	001-31918	10.1	August 2, 2018
10.38††	Clinical Trial Collaboration and Supply Agreement, by and between Idera Pharmaceuticals, Inc. and Bristol-Myers Squibb Company, dated March 11, 2019	10-Q	001-31918	10.1	May 2, 2019
10.39††	Clinical Trial Collaboration and Supply Agreement, effective August 27, 2019, by and between AbbVie Inc. and Idera Pharmaceuticals, Inc.	10-Q	001-31918	10.1	November 6, 2019
10.40	Lease Agreement dated March 31, 2015, between Idera Pharmaceuticals, Inc. and 505 Eagleview Boulevard Associates, L.P.	10-K	001-31918	10.45	March 7, 2018
10.41	First Amendment dated September 23, 2015 to Lease Agreement dated March 31, 2015 between Idera Pharmaceuticals, Inc. and 505 Eagleview Boulevard Associates, L.P.	10-K	001-31918	10.46	March 7, 2018
10.42*	Second Amendment dated January 13, 2020 to Lease Agreement dated March 31, 2015 between Idera Pharmaceuticals, Inc. and 505 Eagleview Boulevard Associates, L.P.				

Exhibit Number	Description	Incorporated by Reference to			
		Form	SEC File No.	Exhibit(s)	Filing Date
10.47	Purchase Agreement, dated as of March 4, 2019, by and between Idera Pharmaceuticals, Inc. and Lincoln Park Capital Fund, LLC	10-K	001-31918	10.37	March 6, 2019
10.48	Securities Purchase Agreement, dated December 23, 2019, by and among the institutional investors named therein	8-K	001-31918	10.1	December 23, 2019
23.1*	Consent of Independent Registered Public Accounting Firm				
31.1*	Certification of Chief Executive Officer pursuant to Exchange Act Rules 13a-14 and 15d-14, as adopted pursuant to Section 302 of Sarbanes-Oxley Act of 2002				
31.2*	Certification of Chief Financial Officer pursuant to Exchange Act Rules 13a-14 and 15d-14, as adopted pursuant to Section 302 of Sarbanes-Oxley Act of 2002				
32.1*	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002				
32.2*	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002				
101.INS	XBRL Instance Document				
101.SCH	XBRL Taxonomy Extension Schema				
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document				
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document				
101.LAB	XBRL Taxonomy Extension Labels Linkbase Document				
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document				

* Filed or furnished, as applicable, herewith.

† Management contract or compensatory plan or arrangement required to be filed as an Exhibit to the Annual Report on Form 10-K.

†† In accordance with Item 601(b)(10) of Regulation S-K, portions of this exhibit have been omitted in order for them to remain confidential.

Item 16. Form 10-K Summary.

Not applicable.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, on this 11th day of March 2020.

Idera Pharmaceuticals, Inc.

By: /S/ VINCENT J. MILANO
Vincent J. Milano
President and
Chief Executive Officer

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/ VINCENT J. MILANO Vincent J. Milano	President, Chief Executive Officer and Director (Principal Executive Officer)	March 11, 2020
/S/ JOHN J. KIRBY John J. Kirby	Chief Financial Officer (Principal Financial and Accounting Officer)	March 11, 2020
/S/ JAMES A. GERAGHTY James A. Geraghty	Chairman of the Board of Directors	March 11, 2020
/S/ CRISTINA CSIMMA Cristina Csimma, Pharm. D., M.H.P.	Director	March 11, 2020
/S/ MICHAEL DOUGHERTY Michael Dougherty	Director	March 11, 2020
/S/ MARK GOLDBERG Mark Goldberg, M.D.	Director	March 11, 2020
/S/ MAXINE GOWEN Maxine Gowen, Ph.D.	Director	March 11, 2020
/S/ HOWARD H. PIEN Howard H. Pien	Director	March 11, 2020
/S/ CAROL A. SCHAFER Carol A. Schafer	Director	March 11, 2020

IDERA PHARMACEUTICALS, INC.

INDEX TO FINANCIAL STATEMENTS
December 31, 2019

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and the Board of Directors of Idera Pharmaceuticals, Inc.

Opinion on the Financial Statements

We have audited the accompanying balance sheets of Idera Pharmaceuticals, Inc. (the Company) as of December 31, 2019 and 2018, and the related statements of operations and comprehensive loss, redeemable preferred stock and stockholders' equity (deficit) and cash flows for each of the three years in the period ended December 31, 2019, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2019 and 2018, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2019, in conformity with U.S. generally accepted accounting principles.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2019, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) and our report dated March 11, 2020 expressed an unqualified opinion thereon.

The Company's Ability to Continue as a Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has suffered recurring losses from operations, has a working capital deficiency, and has stated that substantial doubt exists about the Company's ability to continue as a going concern. Management's evaluation of the events and conditions and management's plans regarding these matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits. We are a public accounting firm registered with the 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. 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 supporting 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.

/s/ ERNST & YOUNG LLP

We have served as the Company's auditor since 2002.

Philadelphia, Pennsylvania
March 11, 2020

IDERA PHARMACEUTICALS, INC.
BALANCE SHEETS

(In thousands, except per share amounts)	December 31, 2019	December 31, 2018
ASSETS		
Current assets:		
Cash and cash equivalents	$ 40,019	$ 71,431
Short-term investments	2,774	—
Prepaid expenses and other current assets	3,475	1,376
Total current assets	46,268	72,807
Property and equipment, net	97	207
Operating lease right-of-use asset	1,054	—
Other assets	70	9
Total assets	$ 47,489	$ 73,023
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	$ 457	$ 1,134
Accrued expenses	7,461	7,884
Operating lease liability	163	—
Future tranche right liability	46,436	—
Total current liabilities	54,517	9,018
Warrant liability, long-term	3,241	—
Operating lease liability, net of current portion	899	—
Other liabilities	—	11
Total liabilities	58,657	9,029
Commitments and contingencies (Note 13)		
Preferred stock, $0.01 par value, Authorized — 5,000 shares:		
Series B1 redeemable convertible preferred stock (Note 7); Designated — 278 shares, Issued and outstanding — 24 and 0 shares at December 31, 2019 and December 31, 2018, respectively	—	—
Stockholders' equity (deficit)		
Preferred stock, $0.01 par value, Authorized — 5,000 shares:		
Series A convertible preferred stock; Designated — 1,500 shares, Issued and outstanding — 1 share	—	—
Common stock, $0.001 par value, Authorized — 70,000 shares; Issued and outstanding — 29,672 and 27,188 at December 31, 2019 and December 31, 2018, respectively	30	27
Additional paid-in capital	709,692	728,342
Accumulated deficit	(720,890)	(664,375)
Total stockholders' equity (deficit)	(11,168)	63,994
Total liabilities and stockholders' equity (deficit)	$ 47,489	$ 73,023

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

IDERA PHARMACEUTICALS, INC.
STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(In thousands, except per share amounts)	Year Ended December 31, 2019	2018	2017
Alliance revenue	$ 1,448	$ 662	$ 902
Operating expenses:			
Research and development	34,853	41,841	50,653
General and administrative	12,481	15,420	15,588
Merger-related costs, net	—	1,245	1,128
Restructuring costs	181	3,112	—
Total operating expenses	47,515	61,618	67,369
Loss from operations	(46,067)	(60,956)	(66,467)
Other income (expense):			
Interest income	1,150	1,089	574
Interest expense	—	(11)	(50)
Warrant revaluation expense	(598)	—	—
Future tranche right revaluation expense	(10,964)	—	—
Foreign currency exchange loss	(36)	(3)	(41)
Net loss	$ (56,515)	$ (59,881)	$ (65,984)
Deemed dividend related to December 2019 Private Placement (see Note 7)	(28,043)	—	—
Net loss attributable to common stockholders	$ (84,558)	$ (59,881)	$ (65,984)
Net loss per share applicable to common stockholders - basic and diluted (Note 17)	$ (2.96)	$ (2.25)	$ (3.35)
Weighted-average number of common shares used in computing net loss per share applicable to common stockholders - basic and diluted	28,545	26,601	19,675
Comprehensive loss:			
Net loss	$ (56,515)	$ (59,881)	$ (65,984)
Other comprehensive income (loss):			
Unrealized gain on available-for-sale securities	—	—	17
Total other comprehensive income	—	—	17
Comprehensive loss	$ (56,515)	$ (59,881)	$ (65,967)

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

IDERA PHARMACEUTICALS, INC.
STATEMENTS OF REDEEMABLE PREFERRED STOCK AND STOCKHOLDER'S EQUITY (DEFICIT)

(In thousands, except per share amounts)	Series B1 Preferred Number of Shares	Series B1 Preferred $0.001 Par Value	Common Stock Number of Shares	Common Stock $0.001 Par Value	Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive (Loss)/Income	Total Stockholders' Equity
Balance, December 31, 2016	—	$ —	18,633	$ 18	$ 641,818	$ (538,470)	$ (17)	$ 103,349
Cumulative effect from adoption of new accounting standard (Note 2)	—	—	—	—	40	(40)	—	—
Sale of common stock, net of issuance costs	—	—	4,792	5	53,741	—	—	53,746
Issuance of common stock under employee stock purchase plan	—	—	22	—	253	—	—	253
Exercise of common stock options and warrants	—	—	996	1	5,443	—	—	5,444
Issuance of common stock for services	—	—	10	—	150	—	—	150
Stock-based compensation	—	—	—	—	10,720	—	—	10,720
Unrealized gain on marketable securities	—	—	—	—	—	—	17	17
Net loss	—	—	—	—	—	(65,984)	—	(65,984)
Balance, December 31, 2017	—	$ —	24,453	$ 24	$ 712,165	$ (604,494)	$ —	$ 107,695
Issuance of common stock under employee stock purchase plan	—	—	25	—	243	—	—	243
Issuance of common stock upon exercise of common stock options and warrants	—	—	2,702	3	10,163	—	—	10,166
Issuance of common stock for services rendered	—	—	8	—	97	—	—	97
Stock-based compensation	—	—	—	—	5,674	—	—	5,674
Net loss	—	—	—	—	—	(59,881)	—	(59,881)
Balance, December 31, 2018	—	$ —	27,188	$ 27	$ 728,342	$ (664,375)	$ —	$ 63,994
Sale of common stock, net of issuance costs	—	—	2,068	3	5,295	—	—	5,298
Sale of redeemable convertible preferred stock	23,684	—	—	—	—	—	—	—
Deemed dividend related to December 2019 Private Placement (Note 7)	—	—	—	—	(28,043)	—	—	(28,043)
Issuance of commitment shares (Note 8)	—	—	270	—	—	—	—	—
Issuance of common stock under employee stock purchase plan	—	—	61	—	121	—	—	121
Issuance of common stock upon exercise of warrants	—	—	38	—	3	—	—	3
Issuance of common stock for services rendered	—	—	47	—	129	—	—	129
Stock-based compensation expense	—	—	—	—	3,845	—	—	3,845
Net loss	—	—	—	—	—	(56,515)	—	(56,515)
Balance, December 31, 2019	23,684	$ —	29,672	$ 30	$ 709,692	$ (720,890)	$ —	$ (11,168)

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

IDERA PHARMACEUTICALS, INC.
STATEMENTS OF CASH FLOWS

(In thousands)	Year Ended December 31, 2019	2018	2017
Cash Flows from Operating Activities:			
Net loss	$ (56,515)	$ (59,881)	$ (65,984)
Adjustments to reconcile net loss to net cash used in operating activities:			
Stock-based compensation	3,845	5,674	10,720
Warrant liability revaluation expense	598	—	—
Future tranche right liability revaluation expense	10,964	—	—
Issuance of common stock for services rendered	129	97	150
Accretion of discounts and premiums on investments	(372)	—	94
Depreciation and amortization expense	120	432	746
(Gain) Loss on disposal or impairment of property and equipment	(10)	477	—
Changes in operating assets and liabilities:			
Prepaid expenses and other assets	(2,160)	2,717	(1,962)
Accounts payable, accrued expenses, and other liabilities	(1,105)	(866)	1,674
Deferred revenue	—	(566)	(697)
Other	8	—	—
Net cash used in operating activities	(44,498)	(51,916)	(55,259)
Cash Flows from Investing Activities:			
Purchases of available-for-sale securities	(44,502)	—	—
Proceeds from maturity of available-for-sale securities	42,100	—	28,270
Proceeds from the sale of property and equipment	11	290	—
Purchases of property and equipment	(11)	(75)	(206)
Net cash (used in) provided by investing activities	(2,402)	215	28,064
Cash Flows from Financing Activities:			
Proceeds from private placement	10,072	—	—
Proceeds from common stock financings, net	5,298	—	53,763
Proceeds from employee stock purchases	121	243	253
Proceeds from exercise of common stock options and warrants	3	10,166	5,444
Payments on note payable	—	(209)	(292)
Payments on capital leases	(6)	(8)	(11)
Net cash provided by financing activities	15,488	10,192	59,157
Net (decrease) increase in cash, cash equivalents and restricted cash	(31,412)	(41,509)	31,962
Cash, cash equivalents and restricted cash, beginning of period	71,431	112,940	80,978
Cash, cash equivalents and restricted cash, end of period	$ 40,019	$ 71,431	$ 112,940
Supplemental disclosure of cash flow information:			
Cash paid for interest	$ —	$ 9	$ 42
Increase to right-of-use asset at adoption of ASC 842 and upon lease reassessment	$ 1,236	$ —	$ —
Increase to lease liability at adoption of ASC 842 and upon lease reassessment	$ 1,236	$ —	$ —
Supplemental disclosure of non-cash financing and investing activities:			
Non-cash property additions	$ —	$ —	$ 150
Accrued financing transaction costs	$ 165	$ 101	$ 17

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

IDERA PHARMACEUTICALS, INC.

NOTES TO FINANCIAL STATEMENTS
December 31, 2019

Note 1. Business and Organization

Business Overview

Idera Pharmaceuticals, Inc. ("Idera" or the "Company"), a Delaware corporation, is a clinical-stage biopharmaceutical company with a business strategy focused on the clinical development, and ultimately the commercialization, of drug candidates for both oncology and rare disease indications characterized by small, well-defined patient populations with serious unmet medical needs. The Company's current focus is on its Toll-like receptor, or TLR, agonist, tilsotolimod (IMO-2125), for oncology. The Company believes it can develop and commercialize targeted therapies on its own. To the extent the Company seeks to develop drug candidates for broader disease indications, it has entered into and may explore additional collaborative alliances to support development and commercialization.

Liquidity and Financial Condition

As of December 31, 2019, the Company had an accumulated deficit of $720.9 million and a cash, cash equivalents and short-term investments balance of $42.8 million, which includes the $6.2 million contingently refundable option fee received in connection with the 2019 Private Placement, as more fully described in Note 7. The Company expects to incur substantial operating losses in future periods and will require additional capital as it seeks to advance tilsotolimod and any future drug candidates through development to commercialization. The Company does not expect to generate product revenue, sales-based milestones or royalties until the Company successfully completes development of and obtains marketing approval for tilsotolimod or other future drug candidates, either alone or in collaboration with third parties, which the Company expects will take a number of years. In order to commercialize tilsotolimod and any future drug candidates, the Company needs to complete clinical development and comply with comprehensive regulatory requirements. The Company is subject to a number of risks and uncertainties similar to those of other companies of the same size within the biotechnology industry, such as uncertainty of clinical trial outcomes, uncertainty of additional funding and history of operating losses.

The Company believes, based on management's current operating plan, that its existing balance of cash, cash equivalents and short-term investments on hand as of December 31, 2019, excluding the $6.2 million contingently refundable Option Fee (Note 7) and including interest income and cash received through February 2020 from the ATM Agreement (Note 8) and the LPC Purchase Agreement (Note 8), will be sufficient to fund operations into the first quarter of 2021. Management's operating plan which underlies the analysis of the Company's ability to continue as a going concern involves the estimation of the amount and timing of future cash inflows and outflows. Actual results could vary from the operating plan. The Company follows the provisions of Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") Topic 205-40, *Presentation of Financial Statements—Going Concern*, which requires management to assess the Company's ability to continue as a going concern within one year after the date the financial statements are issued. The Company's balance of cash, cash equivalents and short-term investments on hand as of December 31, 2019, excluding the $6.2 million contingently refundable option fee (Note 7), is not sufficient to fund operations for the one-year period after the date the financial statements are issued. As a result, there is substantial doubt about the Company's ability to continue as a going concern through the one-year period from the date these financial statements are issued. Management's plans that are intended to mitigate this risk include raising additional capital through the Company's December 2019 Securities Purchase Agreement (Note 7), Common Stock Purchase Agreement (Note 8), "At-The-Market" Equity Program (Note 8), or additional financing or strategic transactions. Management's plans may also include the possible deferral of certain operating expenses unless additional capital is received. The Company has and will continue to evaluate available alternatives to extend its operations beyond the one-year period after the date the financial statements are issued.

Note 1. Business and Organization (Continued)

Reverse Stock Split

As further described in Note 8, on July 27, 2018, the Company effected a 1-for-8 reverse stock split of the Company's outstanding shares of common stock, as authorized at a special meeting. All share and per share amounts of common stock, preferred stock, options and warrants in the accompanying financial statements and notes thereto have been retroactively adjusted for all periods presented to reflect the reverse stock split.

Note 2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying financial statements have been prepared in accordance with U.S. generally accepted accounting principles ("GAAP").

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates, judgements, and assumptions that affect the reported amounts of assets, liabilities, equity, revenues and expenses, and related disclosure of contingencies in the accompanying financial statements and these notes. In addition, management's assessment of the Company's ability to continue as a going concern involves the estimation of the amount and timing of future cash inflows and outflows. On an ongoing basis, the Company evaluates its estimates, judgments and methodologies. The Company bases its estimates on historical experience and on various other assumptions that are believed to be reasonable. Actual results could differ materially from those estimates.

Segment Information

Operating segments are defined as components of an enterprise in 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 assessing performance. The Company views its operations and manages its business as one operating segment, which is the business of developing novel therapeutics for oncology and rare diseases.

Financial Instruments

The fair value of the Company's financial instruments is determined and disclosed in accordance with the three-tier fair value hierarchy specified in Note 3. The Company is required to disclose the estimated fair values of its financial instruments. As of December 31, 2019 and 2018, the Company's financial instruments consisted of cash, cash equivalents, short-term investments, receivables, and warrant and future tranche right liabilities. The estimated fair values of these financial instruments approximate their carrying values as of December 31, 2019 and 2018. As of December 31, 2019, the Company did not have any other derivatives, hedging instruments or other similar financial instruments.

Concentration of Credit Risk

Financial instruments that subject the Company to credit risk primarily consist of cash, cash equivalents and investments. The Company's credit risk is managed by investing in highly rated money market instruments, certificates of deposit, corporate bonds, commercial paper and debt securities. Due to these factors, no significant additional credit risk is believed by management to be inherent in the Company's assets. As of December 31, 2019, all of the Company's cash and cash equivalents were held at two financial institutions.

Cash and Cash Equivalents

The Company considers all highly liquid investments with maturities of 90 days or less when purchased to be "cash equivalents." Cash and cash equivalents at December 31, 2019 and 2018 consisted of cash and money market funds.

Note 2. Summary of Significant Accounting Policies (Continued)

Property and Equipment

Property and equipment is carried at acquisition cost less accumulated depreciation, subject to review for impairment whenever events or changes in circumstances indicate that the carrying amount of the asset may not be recoverable as described further under the heading "Impairment of Long-Lived Assets" below. The cost of normal, recurring, or periodic repairs and maintenance activities related to property and equipment are expensed as incurred. The cost for planned major maintenance activities, including the related acquisition or construction of assets, is capitalized if the repair will result in future economic benefits.

Depreciation and amortization are computed using the straight-line method based on the estimated useful lives of the related assets. Laboratory and other equipment are depreciated over three to five years. Leasehold improvements are amortized over the remaining lease term or the related useful life, if shorter.

When an asset is disposed of, the associated cost and accumulated depreciation is removed from the related accounts on the Company's balance sheet with any resulting gain or loss included in the Company's statement of operations.

Operating Lease Right-of-use Asset and Lease Liability

The Company accounts for leases under ASC Topic 842, *Leases*. The Company determines if an arrangement is a lease at inception. Operating leases are included in long-term right-of-use assets and current and long-term lease liabilities within the Company's balance sheets. Right-of-use ("ROU") assets represent the Company's right to use an underlying asset for the lease term and lease liabilities represent the Company's obligation to make lease payments arising from the lease. Operating lease right-of-use assets and liabilities are recognized at commencement date based on the present value of lease payments over the lease term. As most of the Company's leases do not provide an implicit rate, the Company uses its incremental borrowing rates, which are the rates incurred to borrow on a collateralized basis over a similar term, an amount equal to the lease payments in a similar economic environment. Lease expense for lease payments is recognized on a straight-line basis over the lease term. The right-of-use assets are tested for impairment according to ASC 360. Leases with an initial term of 12 months or less are not recorded on the balance sheet and are recognized as lease expense on a straight-line basis over the lease term.

In December 2019, the Company determined it was reasonably certain that it would exercise its five-year renewal option to extend its Exton, PA office lease, which was scheduled to expired in May 2020. As a result of this determination, the renewal option was included in the lease term and the Company recorded an incremental ROU asset and lease liability of $1.0 million as of December 31, 2019, the date this determination was made. Subsequently, in January 2020, the Company exercised its option to renew and extend the lease term for a period of five years from June 1, 2020 through May 31, 2025.

Impairment of Long-Lived Assets

In accordance with ASC 360-10-35, *Impairment or Disposal of Long-Lived Assets*, the Company reviews its long-lived assets and identifiable finite-lived intangible assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable (i.e. impaired). Once an impairment is determined, the actual impairment recognized is the difference between the carrying amount and the fair value (less costs to sell for assets to be disposed of) as estimated using one of the following approaches: income, cost and/or market. Fair value using the income approach is determined primarily using a discounted cash flow model that uses the estimated cash flows associated with the asset or asset group under review, discounted at a rate commensurate with the risk involved. Fair value utilizing the cost approach is determined based on the replacement cost of the asset reduced for, among other things, depreciation and obsolescence. Fair value, utilizing the market approach, benchmarks the fair value against the carrying amount.

Note 2. Summary of Significant Accounting Policies (Continued)

Warrant Liability

The Company accounts for stock warrants as either equity instruments, liabilities or derivative liabilities in accordance with ASC 480, *Distinguishing Liabilities from Equity* (ASC 480) and/or ASC 815, *Derivatives and Hedging* (ASC 815), depending on the specific terms of the warrant agreement. Freestanding warrants for shares that are potentially redeemable, whereby the Company may be required to transfer assets (e.g. cash or other assets) outside of its control, are classified as liabilities. Liability-classified warrants are recorded at their estimated fair values at each reporting period until they are exercised, terminated, reclassified or otherwise settled. Changes in the estimated fair value of liability-classified warrants are recorded in Warrant Revaluation Income (Expense) in the Company's statements of operations and comprehensive loss. Equity classified warrants are recorded within additional paid-in capital at the time of issuance and not subject to remeasurement. For additional discussion on warrants, see Note 8.

Future Tranche Right Liability

In connection with the Company's 2019 Private Placement, as more fully described in Note 7, the Company entered into the December 2019 Securities Purchase Agreement, which contains call options on redeemable preferred shares with warrants (conditionally exercisable for shares that are puttable). The Company determined that these call options represent freestanding financial instruments and accounts for the options as a liabilities ("Future Tranche Right Liability") under ASC 480, which requires the measurement of the fair value of the liability at the time of issuance and recording changes as a charge to current earnings at each reporting period, which is included in Future Tranche Right Liability Revaluation Expense in the Company's statements of operations and comprehensive loss.

Preferred Stock

The Company applies ASC 480 when determining the classification and measurement of its preferred stock. Preferred shares subject to mandatory redemption are classified as liability instruments and are measured at fair value. Conditionally redeemable preferred shares (including preferred shares that feature redemption rights that are either within the control of the holder or subject to redemption upon the occurrence of uncertain events not solely within the Company's control) are classified as temporary equity. At all other times, preferred shares are classified as stockholders' equity.

Accretion of redeemable convertible preferred stock includes the accretion of the Company's Series B redeemable convertible preferred stock to its stated value. The carrying value of the Series B redeemable convertible preferred stock is being accreted to redemption value using the effective interest method, from the date of issuance to the earliest date the holders can demand redemption.

Redeemable Preferred Stock Issued with Other Freestanding Instruments

The Company considers guidance within ASC 470-20, *Debt* (ASC 470), ASC 480, and ASC 815 when accounting for a redeemable equity instrument issued with other freestanding instruments (e.g. detachable warrants and future tranche right liabilities), such as in the December 2019 Private Placement. In circumstances in which redeemable convertible preferred stock is issued with freestanding liability-classified instruments, the proceeds from the issuance of the convertible preferred stock are first allocated to those instruments at their full estimated fair value. The remaining proceeds, as further reduced by discounts created by the bifurcation of embedded derivatives and/or beneficial conversion features, if any, are allocated to the redeemable equity instrument.

See Note 7 for additional discussion on the Company's accounting for the 2019 Private Placement.

Note 2. Summary of Significant Accounting Policies (Continued)

Revenue Recognition

The Company recognizes revenue in accordance with ASC Topic 606, *Revenue from Contracts with Customers* ("ASC 606'), which applies to all contracts with customers, except for contracts that are within the scope of other standards, such as leases, insurance, collaboration arrangements and financial instruments. In accordance with ASC 606, the Company recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that the Company determines are within the scope of ASC Topic 606, it performs the following five steps:

(i) identify the contract(s) with a customer;

(ii) identify the performance obligations in the contract;

(iii) determine the transaction price;

(iv) allocate the transaction price to the performance obligations in the contract; and

(v) recognize revenue when (or as) the entity satisfies a performance obligation.

The Company only applies the five-step model to contracts when it determines that it is probable it will collect the consideration to which it is entitled in exchange for the goods or services it transfers to the customer. At contract inception, once the contract is determined to be within the scope of ASC 606, the Company assesses the goods or services promised within each contract and determines those that are performance obligations, and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

Amounts received prior to satisfying the revenue recognition criteria are recognized as deferred revenue in the Company's balance sheet. Amounts expected to be recognized as revenue within the 12 months following the balance sheet date are classified as current portion of deferred revenue. Amounts not expected to be recognized as revenue within the 12 months following the balance sheet date are classified as deferred revenue, net of current portion.

Alliance Revenues

The Company's revenues have primarily been generated through collaborative research, development and/or commercialization agreements. The terms of these agreements may include payment to the Company of one or more of the following: nonrefundable, up-front license fees; research, development and commercial milestone payments; and other contingent payments due based on the activities of the counterparty or the reimbursement by licensees of costs associated with patent maintenance. Each of these types of revenue are recorded as Alliance revenues in the Company's statements of operations.

In determining the appropriate amount of revenue to be recognized as it fulfills its obligations under each of its agreements, the Company performs the following steps:

(i) identification of the promised goods or services in the contract;

(ii) determination of whether the promised goods or services are performance obligations including whether they are distinct in the context of the contract;

(iii) measurement of the transaction price, including the constraint on variable consideration;

(iv) allocation of the transaction price to the performance obligations; and

(v) recognition of revenue when (or as) the Company satisfies each performance obligation.

Note 2. Summary of Significant Accounting Policies (Continued)

See Note 10, “Collaboration and License Agreements” for additional details regarding the Company’s collaboration arrangements.

As part of the accounting for these arrangements, the Company allocates the transaction price to each performance obligation on a relative stand-alone selling price basis. The stand-alone selling price may be, but is not presumed to be, the contract price. In determining the allocation, the Company maximizes the use of observable inputs. When the stand-alone selling price of a good or service is not directly observable, the Company estimates the stand-alone selling price for each performance obligation using assumptions that require judgment. Acceptable estimation methods include, but are not limited to: (i) the adjusted market assessment approach, (ii) the expected cost plus margin approach, and (iii) the residual approach (when the stand-alone selling price is not directly observable and is either highly variable or uncertain). In order for the residual approach to be used, the Company must demonstrate that (a) there are observable stand-alone selling prices for one or more of the performance obligations and (b) one of the two criteria in ASC 606-10-32-34(c)(1) and (2) is met. The residual approach cannot be used if it would result in a stand-alone selling price of zero for a performance obligation as a performance obligation, by definition, has value on a stand-alone basis.

An option in a contract to acquire additional goods or services gives rise to a performance obligation only if the option provides a material right to the customer that it would not receive without entering into that contract. Factors that the Company considers in evaluating whether an option represents a material right include, but are not limited to: (i) the overall objective of the arrangement, (ii) the benefit the collaborator might obtain from the arrangement without exercising the option, (iii) the cost to exercise the option (e.g. priced at a significant and incremental discount) and (iv) the likelihood that the option will be exercised. With respect to options determined to be performance obligations, the Company recognizes revenue when those future goods or services are transferred or when the options expire.

The Company’s revenue arrangements may include the following:

Up-front License Fees: If a license is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenues from nonrefundable, up-front fees allocated to the license when the license is transferred to the licensee and the licensee is able to use and benefit from the license. For licenses that are bundled with other promises, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from non-refundable, up-front fees. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition.

Milestone Payments: At the inception of an agreement that includes research and development milestone payments, the Company evaluates whether each milestone is considered probable of being achieved and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within the control of the Company or the licensee, such as regulatory approvals, are not considered probable of being achieved until those approvals are received. The transaction price is then allocated to each performance obligation on a relative stand-alone selling price basis, for which the Company recognizes revenue as or when the performance obligations under the contract are satisfied. At the end of each subsequent reporting period, the Company re-evaluates the probability of achievement of such milestones and any related constraint, and if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect Alliance revenues and earnings in the period of adjustment.

Research and Development Activities: If the Company is entitled to reimbursement from its collaborators for specified research and development activities or the reimbursement of costs associated with patent maintenance, the Company determines whether such funding would result in Alliance revenues or an offset to research and development expenses. Reimbursement of patent maintenance costs are recognized during the period in which the related expenses are incurred as Alliance revenues in the Company’s statements of operations.

Note 2. Summary of Significant Accounting Policies (Continued)

Royalties: If the Company is entitled to receive sales-based royalties from its collaborator, including milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, the Company recognizes revenue at the later of (i) when the related sales occur, provided the reported sales are reliably measurable, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). To date, the Company has not recognized any royalty revenue resulting from any of its collaboration and license arrangements.

Manufacturing Supply and Research Services: Arrangements that include a promise for future supply of drug substance, drug product or research services at the licensee's discretion are generally considered as options. The Company assesses if these options provide a material right to the licensee and if so, they are accounted for as separate performance obligations. If the Company is entitled to additional payments when the licensee exercises these options, any additional payments are recorded in Alliance revenues when the licensee obtains control of the goods, which is upon delivery, or as the services are performed.

The Company receives payments from its licensees based on schedules established in each contract. Upfront payments and fees are recorded as deferred revenue upon receipt, and may require deferral of revenue recognition to a future period until the Company performs its obligations under these arrangements. Amounts are recorded as accounts receivable when the Company's right to consideration is unconditional. The Company does not assess whether a contract has a significant financing component if the expectation at contract inception is such that the period between payment by the licensees and the transfer of the promised goods or services to the licensees will be one year or less.

Research and Development Expenses

All research and development expenses are expensed as incurred. Research and development expenses are comprised of costs incurred in performing research and development activities, including drug development trials and studies, drug manufacturing, laboratory supplies, external research, payroll including stock-based compensation and overhead. Nonrefundable advance payments for goods or services to be received in the future for use in research and development activities are deferred and capitalized. The capitalized amounts are expensed as the related goods are accepted by the Company or the services are performed. As of December 31, 2019 and 2018, the Company recorded approximately $2.8 million and $0.6 million as prepaid research and development, respectively, which is included within prepaid expenses and other current assets in the accompanying balance sheets.

Stock-Based Compensation

The Company accounts for stock-based compensation using ASC 718, *Compensation – Stock Compensation* ("ASC 718"), or ASC 505-50, *Equity – Equity Based Payments to Non-Employees*, as applicable. The Company accounts for stock-based awards to employees and non-employee directors using the fair value based method to determine compensation expense for all arrangements where shares of stock or equity instruments are issued for compensation. In addition, the Company accounts for stock-based compensation to other non-employees in accordance with the accounting guidance for equity instruments that are issued to entities or persons other than employees.

The Company recognizes all share-based payments to employees and directors as expense in the statements of operations and comprehensive loss based on their fair values. The Company records compensation expense on a straight-line basis over an award's requisite service period, or vesting period, based on the award's fair value at the date of grant. Vesting is generally four years for employees and one year for directors. The Company uses a Black-Scholes option-pricing model to determine the fair value of each option grant as of the date of grant for expense incurred. The Black-Scholes option pricing model requires inputs for risk-free interest rate, dividend yield, expected stock price volatility and expected term of the options. See Note 12, "Stock-based Compensation" for additional details.

Note 2. Summary of Significant Accounting Policies (Continued)

Prior to the adoption of Accounting Standards Update ("ASU") 2016-09, *Compensation - Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting* ("ASU 2016-09"), ASC 718 required forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differed from those estimates. However, ASU 2016-09 allows an entity to elect as an accounting policy upon adoption either to continue to estimate the total number of awards for which the requisite service period will not be rendered or to account for forfeitures when they occur. In connection with the adoption of this ASU in the first quarter of 2017, the Company made an accounting policy election to account for forfeitures as they occur and applied this change in accounting policy on a modified retrospective basis, resulting in less than a $0.1 million reduction in Additional paid-in capital and an increase in Accumulated deficit as of January 1, 2017, to reflect the cumulative effect of previously estimated forfeitures. See the caption "Cumulative effect from adoption of new accounting standard" within the accompanying statements of redeemable preferred stock and stockholders' equity (deficit).

Merger-related Costs, net

On January 21, 2018, the Company, BioCryst Pharmaceuticals, Inc., a Delaware corporation ("BioCryst"), Nautilus Holdco, Inc., a Delaware corporation and a direct, wholly owned subsidiary of BioCryst ("Holdco"), Island Merger Sub, Inc., a Delaware corporation and a direct, wholly owned subsidiary of Holdco, and Boat Merger Sub, Inc., a Delaware corporation and a direct, wholly owned subsidiary of Holdco, entered into an Agreement and Plan of Merger (the "Merger Agreement"). The board of directors of each of Idera and BioCryst unanimously approved the Merger Agreement and the transactions contemplated thereby and the required regulatory approvals were received. However, the proposed merger was subject to approval by the stockholders of Idera and BioCryst, and satisfaction of other customary closing conditions, as specified in the Merger Agreement. At a special meeting of BioCryst stockholders held on July 10, 2018, BioCryst's stockholders voted against the adoption of the Merger Agreement. Following such vote and in accordance with the terms of the Merger Agreement, BioCryst terminated the Merger Agreement. In accordance with the Merger Agreement, BioCryst paid the Company a fixed expense reimbursement amount of $6 million in July 2018 in connection with the termination of the Merger Agreement. The fixed expense reimbursement amount is included in "Merger-related costs, net" in the accompanying statements of operations.

Merger-related costs, net includes amounts related to the transactions contemplated under the Merger Agreement, including charges incurred for transaction and integration-related professional fees, employee retention costs, and other incremental costs directly related to the potential merger; less the $6 million fixed expense reimbursement termination fee, which was received by the Company in July 2018.

Restructuring Costs

Restructuring charges are primarily comprised of severance costs related to workforce reductions, contract termination and wind-down costs and asset impairments. In accordance with ASC 420, *Exit or Disposal Cost Obligations*, the Company recognizes restructuring charges when the liability has been incurred, except for one-time employee termination benefits that are incurred over time. Generally, one-time employee termination benefits (i.e. severance costs) are accrued at the date management has committed to a plan of termination and employees have been notified of their termination dates and expected severance payments. Other costs will be recorded as incurred. Asset impairment charges have been, and will be, recognized when management has concluded that the assets have been impaired in accordance with ASC 360-10-35, *Impairment or Disposal of Long-Lived Assets*, or other applicable authoritative guidance. See Note 11 for additional details.

Income Taxes

An asset and liability approach is used for financial accounting and reporting for income taxes. Deferred income taxes arise from temporary differences between income tax and financial reporting and principally relate to recognition of revenue and expenses in different periods for financial and tax accounting purposes and are measured using currently enacted tax rates and laws. In addition, a deferred tax asset can be generated by a net operating loss carryover. If it is more likely than not that some portion or all of a deferred tax asset will not be realized, a valuation allowance is recognized.

Note 2. Summary of Significant Accounting Policies (Continued)

In the event the Company is charged interest or penalties related to income tax matters, the Company would record such interest as interest expense and would record such penalties as other expense in the Statements of Operations. No such charges have been incurred by the Company. For each of the years ended December 31, 2019, 2018 and 2017, the Company had no uncertain tax positions. See Note 14, "Income Taxes" for additional details.

Net Loss per Common Share applicable to Common Stockholders

Basic and diluted net loss per common share applicable to common stockholders is computed using the weighted average number of shares of common stock outstanding during the period. The diluted loss per share calculation gives effect to dilutive stock options, warrants, convertible preferred stock and other potentially dilutive common stock equivalents outstanding during the period. Diluted loss per share is based on the if-converted method or the treasury stock method, as applicable, and includes the effect from the potential issuance of common stock, such as shares issuable pursuant to the conversion of convertible preferred stock and the exercise of stock options and warrants, assuming the exercise of all "in-the-money" common stock equivalents based on the average market price during the period. Common stock equivalents have been excluded where their inclusion would be anti-dilutive. Diluted net loss per common share applicable to common stockholders is the same as basic net loss per common share applicable to common stockholders for each of the three years in the period ended December 31, 2019 as the effects of the Company's potential common stock equivalents are antidilutive (see Note 17).

Comprehensive Income (Loss)

Comprehensive income (loss) is defined as the change in equity of a business enterprise during a period from transactions and other events and circumstances from non-owner sources. Comprehensive income (loss) for the years ended December 31, 2019, 2018 and 2017 is comprised of reported net income (loss) and any change in net unrealized gains and losses on investments in available-for-sale securities during each year, which is included in "Accumulated other comprehensive income" on the accompanying balance sheets. In accordance with ASC Topic 220, *Comprehensive Income*, the Company has elected to present the components of net income and other comprehensive income as one continuous statement.

New Accounting Pronouncements

Recently Adopted Accounting Pronouncements

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)* ("ASU 2016-02"). ASU 2016-02 requires organizations that lease assets, with lease terms of more than 12 months, to recognize on the balance sheet the assets and liabilities for the rights and obligations created by those leases. Consistent with GAAP, the recognition, measurement and presentation of expenses and cash flows arising from a lease by a lessee will depend primarily on its classification as a finance or operating lease. However, unlike the previous standard, which required only capital leases to be recognized on the balance sheet, ASU 2016-02 requires both types of leases to be recognized on the balance sheet. This guidance was applicable to the Company's fiscal year beginning January 1, 2019, and the Company adopted ASU 2016-02 in the first quarter of 2019 using the alternative modified retrospective transition method, which allowed the Company to apply the new lease standard to the beginning of the 2019 period and did not require adjusting comparative period financial information. Additionally, the Company elected the package of practical expedients to not reassess prior conclusions related to contracts containing leases, lease classification and initial direct costs. As a result of adopting ASU 2016-02, the primary impact on the Company's financial statements was the recognition of a right-of-use asset and corresponding liability of approximately $0.3 million on its balance sheet as of January 1, 2019 related to its existing Exton, PA facility operating lease.

In June 2018, the FASB issued ASU No. 2018-07, *Compensation – Stock Compensation (Topic 718)* ("ASU 2018-07"). ASU 2018-07 simplifies the accounting for nonemployee share-based payment transactions and was adopted by the Company in the first quarter of 2019. The adoption of this ASU did not have a material impact on the Company's financial statements.

Note 2. Summary of Significant Accounting Policies (Continued)

Recently Issued (Not Yet Adopted) Accounting Pronouncements

In June 2016 the FASB issued ASU No. 2016-13, *Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*. This standard requires that credit losses be reported using an expected losses model rather than the incurred losses model that is currently used, and establishes additional disclosures related to credit risks. For available-for-sale debt securities with unrealized losses, this standard now requires allowances to be recorded instead of reducing the amortized cost of the investment. This standard will be effective for the Company on January 1, 2020. The Company is currently evaluating the potential impact that this standard may have on our financial position and results of operations but does not expect the impact of this standard to be material.

In August 2018, the FASB issued ASU No. 2018-13, *Disclosure Framework - Changes to the Disclosure Requirements for Fair Value Measurement* ("ASU 2018-13"), which amends ASC 820, *Fair Value Measurement*. ASU 2018-13 modifies the disclosure requirements for fair value measurements by removing, modifying, or adding certain disclosures. The ASU is effective for annual periods, including interim periods within those annual periods, beginning after December 15, 2019, with early adoption permitted for removed or modified disclosures, and delayed adoption of the additional disclosures until their effective date. The Company is currently evaluating the effect that the ASU will have on its financial statements and related disclosures but does not expect the impact of this amendment to be material.

Note 3. Fair Value Measurements

Assets and Liabilities Measured at Fair Value on a Recurring Basis

The Company applies the guidance in ASC 820, *Fair Value Measurement*, to account for financial assets and liabilities measured on a recurring basis. Fair value is measured at the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. As such, fair value is a market-based measurement that is determined based on assumptions that market participants would use in pricing an asset or liability.

The Company uses a fair value hierarchy, which distinguishes between assumptions based on market data (observable inputs) and an entity's own assumptions (unobservable inputs). The guidance requires that fair value measurements be classified and disclosed in one of the following three categories:

- Level 1: Unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities;
- Level 2: Quoted prices in markets that are not active or inputs which are observable, either directly or indirectly, for substantially the full term of the asset or liability;
- Level 3: Prices or valuation techniques that require inputs that are both significant to the fair value measurement and unobservable (i.e., supported by little or no market activity).

Determining which category an asset or liability falls within the hierarchy requires significant judgment. The Company evaluates its hierarchy disclosures each reporting period. There were no transfers between Level 1, 2 and 3 during the years ended December 31, 2019, 2018 and 2017.

Note 3. Fair Value Measurements (Continued)

The table below presents the assets and liabilities measured and recorded in the financial statements at fair value on a recurring basis at December 31, 2019 and 2018 categorized by the level of inputs used in the valuation of each asset and liability.

	December 31, 2019			
(In thousands)	**Total**	**Level 1**	**Level 2**	**Level 3**
Assets				
Cash	$ 250	$ 250	$ —	$ —
Money market funds	39,769	39,769	—	—
Short-term investments – commercial paper	2,774	—	2,774	—
Total assets	$ 42,793	$ 40,019	$ 2,774	$ —
Liabilities				
Warrant liability	$ 3,241	$ —	$ —	$ 3,241
Future tranche right liability	46,436	—	—	46,436
Total liabilities	$ 49,677	$ —	$ —	$ 49,677

	December 31, 2018			
(In thousands)	**Total**	**Level 1**	**Level 2**	**Level 3**
Assets				
Cash	$ 8,446	$ 8,446	$ —	$ —
Money market funds	61,177	61,177	—	—
Other cash equivalents – commercial paper	1,808	—	1,808	—
Total assets	$ 71,431	$ 69,623	$ 1,808	$ —
Total liabilities	$ —	$ —	$ —	$ —

The Level 1 assets consist of money market funds, which are actively traded daily. The Level 2 assets consist of commercial paper whose fair value may not represent actual transactions of identical securities. The fair value of commercial paper is generally determined based on the relationship between the investment's discount rate and the discount rates of the same issuer's commercial paper available in the market which may not be actively traded daily. Since these fair values may not be based upon actual transactions of identical securities, they are classified as Level 2.

Changes in Level 3 Liabilities Measured at Fair Value on a Recurring Basis

Warrant Liability and Future Tranche Right Liability

The reconciliation of the Company's warrant and future tranche right liability measured at fair value on a recurring basis using unobservable inputs (Level 3) is as follows:

(In thousands)	**Warrant Liability**	**Derivative Liability**
Balance at December 31, 2018	$ —	$ —
Issuance of redeemable preferred stock and warrants [1]	2,643	35,472
Change in the fair value of liability	598	10,964
Balance at December 31, 2019	$ 3,241	$ 46,436

(1) Represents fair value of freestanding warrants and the future tranche right related to the December 2019 Private Placement on the issuance date.

Note 3. Fair Value Measurements (Continued)

Assumptions Used in Determining Fair Value of Liability-Classified Warrants

The Company utilizes an option pricing model to value its liability-classified warrants. Inherent in the valuation model are assumptions related to volatility, risk-free interest rate, expected term, dividend rate, and other scenarios (i.e. probability of complex features of the warrants being triggered).

The fair value of the warrants has been estimated with the following weighted-average assumptions:

	December 23, 2019	December 31, 2019
Risk-free interest rate	1.82%	1.79%
Expected dividend yield	—	—
Expected term (years)	7.00	6.98
Expected volatility	80%	80%
Exercise price (per share)	$ 1.52	$ 1.52

Assumptions Used in Determining Fair Value of Future Tranche Rights

The Company utilizes a binomial lattice model to value the Series B2 (tranche 2) and B3 (tranche 3) tranches and a Monte Carlo simulation to value the Series B4 (tranche 4) future tranche rights. The Company selected these models as it believes they are reflective of all significant assumptions that market participants would likely consider in negotiating the transfer of the Future Tranche Rights. Such assumptions include, among other inputs, stock price volatility, risk-free rates, redemption and early exercise assumptions, cancellation and conversion assumptions, and the potential for future adjustment of the conversion price due to a future dilutive financing.

The estimated fair value of the Future Tranche Rights is determined using Level 2 and Level 3 inputs. Significant inputs and assumptions used in the valuation models are as follows:

	December 23, 2019	December 31, 2019
Risk-free interest rate for warrants	1.82%	1.82%
Risk-free interest rate for preferred stock	1.86% - 1.89%	1.84% - 1.88%
Expected dividend yield	—	—
Expected term (years) of call option on preferred stock	1.18 - 2.18	1.16 - 2.16
Expected term (years) of warrants	8.18 - 9.18	8.16 - 9.16
Expected volatility	80%	80%
Exercise price (per share) for common stock equivalent for preferred stock and warrant	$ 1.52 - 1.82	$ 1.52 - 1.82

As of December 23, 2019 and December 31, 2019, the Company deemed it probable that shareholder approval would be obtained, on or prior to December 31, 2020, with respect to increasing the Company's authorized shares of common stock in an amount sufficient to cover the conversion of all potential convertible securities issuable upon exercise of the Future Tranche Rights. See Note 7 for further details on the such required shareholder approval.

Note 4. Investments

The Company's available-for-sale investments at fair value consisted of the following at December 31, 2019:

	December 31, 2019			
(In thousands)	Cost	Gross Unrealized (Losses)	Gross Unrealized Gains	Estimated Fair Value
Short-term investments – commercial paper	$ 2,774	$ —	$ —	$ 2,774
Total short-term investments	2,774	—	—	2,774
Total investments	$ 2,774	$ —	$ —	$ 2,774

The Company had no realized gains or losses from the sale of investments in available-for-sale securities in the year ended December 31, 2019. There were no losses or other-than-temporary declines in value included in "Interest income" on the Company's statements of operations and comprehensive loss for any securities for the year ended December 31, 2019.

Note 5. Property and Equipment

At December 31, 2019 and 2018, net property and equipment at cost consisted of the following:

(In thousands)	December 31, 2019	December 31, 2018
Leasehold improvements	$ 107	$ 104
Equipment and other	764	767
Total property and equipment, at cost	871	871
Less: Accumulated depreciation and amortization	774	664
Property and equipment, net	$ 97	$ 207

Depreciation and amortization expense on property and equipment was approximately $0.1 million, $0.4 million, and $0.7 million in 2019, 2018 and 2017, respectively.

During the year ended December 31, 2018, the Company recorded asset impairments related to its property equipment in the amount of $0.5 million in connection with restructuring activities more fully described in Note 11. No impairment charges were recognized during the years ended December 31, 2019 or 2017.

Note 6. Accrued Expenses

At December 31, 2019 and 2018, accrued expenses consisted of the following:

(In thousands)	December 31, 2019	December 31, 2018
Payroll and related costs	$ 2,179	$ 1,962
Clinical and nonclinical trial expenses	4,199	3,958
Professional and consulting fees	859	605
Restructuring expenses	113	1,147
Other	111	212
Total accrued expenses	$ 7,461	$ 7,884

Included in accrued Payroll and related costs as December 31, 2018 is $0.7 million of salary continuation severance benefits which was paid in equal installments through October 31, 2019 to former executives.

Note 7. Redeemable Convertible Preferred Stock

December 2019 Private Placement

On December 23, 2019, the Company entered into a Securities Purchase Agreement (the "December 2019 Securities Purchase Agreement") with institutional investors affiliated with Baker Brothers (the "Purchasers"), an existing shareholder and related party as more fully described in Note 16, under which the Company sold 23,684 shares of Series B1 convertible preferred stock ("Series B1 Preferred Stock") and warrants to purchase 2,368,400 shares of the Company's common stock at an exercise price of $1.52 per share (or, if the holder elects to exercise the warrants for shares of Series B1 Preferred Stock, 23,684 shares of Series B1 Preferred Stock at an exercise price of $152 per share) for aggregate gross proceeds of $3.9 million (the "Initial Closing").

In addition, we have agreed to sell to the Purchasers, at their option and subject to certain conditions including stockholder approval to increase the Company's authorized shares of common stock, shares of Series B2 convertible preferred stock ("Series B2 Preferred Stock"), Series B3 convertible preferred stock ("Series B3 Preferred Stock") and Series B4 convertible preferred stock ("Series B4 Preferred Stock) and accompanying warrants to purchase common stock (or preferred stock at the election of the holder) over a 21-month period after stockholder approval is received (the "Future Tranche Rights") as follows:

Future Tranche Rights	Preferred Shares	Price Per Share	Aggregate Purchase Price
Tranche 2 (Series B2) [1]	98,685	$ 152	$ 15,000,120
Tranche 3 (Series B3) [2]	82,418	$ 182	15,000,076
Tranche 4 (Series B4) [2]	82,418	$ 182	15,000,076
Total	263,521		$ 45,000,272

(1) Accompanied by related warrants to purchase up to 9,868,500 shares of the Company's common stock (or, if the holder elects to exercise the warrants for shares of Series B1 Preferred Stock, 98,685 shares of Series B1 Preferred Stock), at an exercise price of $1.52 per share (or, if the holder elects to exercise the warrants for Series B1 Preferred Stock, $152 per share of Series B1 Preferred Stock).

(2) Accompanied by related warrants to purchase up to 6,593,440 shares of the Company's common stock (or, if the holder elects to exercise the warrants for shares of Series B1 Preferred Stock, 65,934 shares of Series B1 Preferred Stock), at an exercise price of $1.82 per share (or, if the holder elects to exercise the warrants for Series B1 Preferred Stock, $182 per share of Series B1 Preferred Stock).

As consideration for the Future Tranche Rights, the Company received aggregate gross proceeds of $6.2 million (the "Option Fee"). In the event the Company does not receive the required shareholder approval to increase the Company's authorized shares of common stock in an amount sufficient to cover the conversion of all potential convertible securities issuable under the December 2019 Securities Purchase Agreement on or prior to December 31, 2020, the Option Fee shall be returned to the Purchasers. The Board recommends the stockholders support the proposal to increase the authorized shares.

The purchase and sale of the securities issuable under tranches 2, 3 and 4 may occur in two or more separate closings, each to be conducted at the Purchasers' discretion. The right of the Purchasers to purchase Series B2, Series B3 and Series B4 Preferred Stock will expire 9 months, 15 months, and 21 months following shareholder approval, respectively. However, the Purchasers' right to purchase securities under tranches 3 and 4 is contingent on the purchase of all of the securities in each preceding tranche right. In the event the Purchaser's do not purchase all of the securities in a given tranche, their right to purchase shares in future tranches terminates and any outstanding warrants issued under the December 2019 Securities Purchase Agreement would terminate. Additionally, the Company has the right to decline the Series B4 Preferred Stock investment if its common stock trades at $7.60 for 20 days out of 30 days subsequent to the closing of the Series B3 Preferred Stock investment.

In addition to the aggregate gross proceeds received from the Initial Closing and the Option Fee, the Company is eligible to receive aggregate gross proceeds of up to an additional $87.6 million under the December 2019 Securities Purchase Agreement.

Note 7. Redeemable Convertible Preferred Stock (Continued)

Accounting Considerations

The Company determined that the Series B1 Preferred Stock, the accompanying Series B1 warrants, and each of the Future Tranche Rights represented a freestanding financial instrument. The warrants and the Future Tranche Rights are liability classified as the underlying shares are potentially redeemable and such redemption is deemed to be outside of the Company's control. The $10.1 million in gross proceeds received in December 2019 was allocated to the Series B1 warrants and the Future Tranche Rights based on their estimated fair values of $2.6 million and $35.5 million, respectively. The excess fair value of $28.0 million over the gross proceeds received of $10.1 million was recorded as a deemed dividend to Baker Brothers, an existing significant shareholder. Costs in connection with the December 2019 Securities Purchase Agreement were expensed as incurred.

Due to the redeemable nature of the Series B1 Preferred Stock, the Series B1 Preferred Stock has been classified as temporary equity. While the Series B1 Preferred Stock is not currently redeemable, it will become redeemable either on (i) the fifth anniversary of the initial issue date, or December 23, 2024, provided that certain events (the "Redemption Loss Events") do not occur first or (ii) upon a liquidation or deemed liquidation event, provided that certain events (the "Liquidation Loss Events") do not occur first. The Company cannot assess the probability of whether the Redemption Loss Events will occur prior to the fifth anniversary of the initial issue date, if ever, as certain factors triggering such events are outside the control of the Company. Accordingly, the carrying value of the Series B1 Preferred Stock is being accreted to its redemption value as of December 31, 2019. In the event the holders of the Series B1 Preferred Stock lose their right to request redemption, the Series B Preferred Stock will no longer be accreted to its redemption value until redemption upon a liquidation event is deemed probable. For the year ended December 31, 2019, accretion was de minimis.

Note 8. Stockholders' Equity

Preferred Stock

The Restated Certificate of Incorporation, as amended, of the Company permits its board of directors to issue up to 5,000,000 shares of preferred stock, par value $0.01 per share, in one or more series, to designate the number of shares constituting such series, and fix by resolution, the powers, privileges, preferences and relative, optional or special rights thereof, including liquidation preferences and dividends, and conversion and redemption rights of each such series.

As of December 31, 2019, the Company has designated the following class of preferred stock:

- Series A: 1,500,000 authorized shares of Series A Convertible Preferred Stock
- Series B1: 277,921 authorized shares of Series B1 Redeemable Convertible Preferred Stock
- Series B2: 98,685 authorized shares of Series B2 Redeemable Convertible Preferred Stock
- Series B3: 82,814 authorized shares of Series B3 Redeemable Convertible Preferred Stock
- Series B4: 82,814 authorized shares of Series B4 Redeemable Convertible Preferred Stock

Note 8. Stockholders' Equity (Continued)

Series A Convertible Preferred Stock. The dividends on the Series A convertible preferred stock ("Series A Preferred Stock") are payable semi-annually in arrears at the rate of 1% per annum, at the election of the Company, either in cash or additional duly designated, fully paid and nonassessable shares of Series A Preferred Stock. In the event of liquidation, dissolution or winding up of the Company, after payment of debts and other liabilities of the Company, the holders of the Series A Preferred Stock then outstanding will be entitled to a distribution of $1 per share out of any assets available to shareholders. The Series A Preferred Stock is non-voting. All remaining shares of Series A Preferred Stock rank, as to payment upon the occurrence of any liquidation event, senior to the Company's common stock. Shares of Series A Preferred Stock are convertible, in whole or in part, at the option of the holder into fully paid and nonassessable shares of common stock at $272.00 per share, subject to adjustment. As of December 31, 2019 and 2018, there were 655 shares of Series A Preferred Stock outstanding.

Series B1, B2, B3 and B4 Convertible Preferred Stock. Holders of Series B1 Preferred Stock, Series B2 Preferred Stock, Series B3 Preferred Stock and Series B4 Preferred Stock (collectively, the "B1/B2/B3/B4 Preferred Stock") are entitled to the amount of dividends, if and when declared, as would be payable to holders of common stock on an "as converted" basis (e.g. participating dividends). Until the applicable Transition Date (defined below), in the event of a liquidation event or deemed liquidation event, after payment of debts and other liabilities of the Company, the holders of the Series B1/B2/B3/B4 Preferred Stock then outstanding will be entitled to a distribution equal to the then applicable stated value per share of the Series B1/B2/B3/B4 Preferred Stock. Additionally, until the applicable Transition Date (defined below), at any time on or after the date that is the fifth (5th) anniversary of the initial issue date of the applicable series of preferred stock, all or any portion of the preferred stock is redeemable at the option of the holder at a redemption price of $152.00 per share (for Series B1 and Series B2 Preferred Stock) and $182.00 per share (for Series B3 and Series B4 Preferred Stock). The "Transition Date" means:

a) With respect to the Series B1 Preferred Stock, the first date following December 23, 2021, on which each of the Conditions (as defined below) is met (the "Series B1 Transition Date"); and

b) With respect to the Series B2 Preferred Stock, Series B3 Preferred Stock and Series B4 Preferred Stock, the first date following the two-year anniversary of the applicable series of preferred stock's initial issue date, on which each of the Conditions (as defined below) is met (the "Series B2 Transition Date").

The "Conditions" shall mean: (a) the closing price of the Company's common stock has been equal to or exceeded the price that is equal to three times (3x) the applicable series of preferred stock's conversion price ($1.52 for Series B1 Preferred Stock and B2 Preferred Stock; $1.82 for Series B3 Preferred Stock and Series B4 Preferred Stock) for 180 calendar days; (b) the 50-day average trading volume of the Company's common stock is greater than 500,000 shares (subject to adjustment for any stock dividend, stock split, stock combination or other similar transaction); and (c) the presentation by the Company at an appropriate medical conference of the "Overall Survival" data as defined in its ILLUMINATE-301 study protocol.

The Series B1/B2/B3/B4 Preferred Stock is non-voting and rank, as to payment upon the occurrence of any liquidation event, senior to the Company's common stock. Shares of Series B1 Preferred Stock and Series B2 Preferred Stock are convertible, in whole or in part, at the option of the holder into fully paid and nonassessable shares of common stock at $1.52 per share, subject to adjustment. Shares of Series B2 Preferred Stock and Series B3 Preferred Stock are convertible, in whole or in part, at the option of the holder into fully paid and nonassessable shares of common stock at $1.82 per share, subject to adjustment. As more fully described in Note 7, the Company's outstanding Series B1 Preferred Stock is classified in temporary equity, outside of stockholders' equity as of December 31, 2019. No shares of Series B2 Preferred Stock, Series B3 Preferred Stock or Series B4 Preferred Stock are outstanding as of December 31, 2019.

Note 8. Stockholders' Equity (Continued)

Common Stock

On June 20, 2018, the Company's stockholders approved an amendment to the Company's Restated Certificate of Incorporation, as amended, to effect a reverse stock split of the Company's outstanding shares of common stock at a ratio within a range from 1-for-4 to 1-for-8 and set the number of authorized shares of the Company's common stock at a number determined by calculating the product of 280,000,000 (previous number of authorized shares) multiplied by two times (2x) the reverse stock split ratio. On July 27, 2018, the Company implemented a 1-for-8 reverse split of its issued and outstanding shares of common stock (the "Reverse Split"), and set the number of its authorized shares of common stock to 70,000,000. The Reverse Split became effective on July 27, 2018 at 5:00 p.m., Eastern Time, and the Company's common stock began trading on the Nasdaq Capital Market on a Reverse Split-adjusted basis at the opening of trading on July 30, 2018. As of a result of the Reverse Split, every eight shares of the Company's issued and outstanding common stock were combined into one share of its common stock, except to the extent that the Reverse Split resulted in any of the Company's stockholders owning a fractional share, which was settled in cash. In connection with the Reverse Split, there was no change in the nominal par value per share of $0.001. The Reverse Split did not change the number of authorized shares or par value of the Company's preferred stock.

Common Stock Authorized

As of December 31, 2019, the Company had 70,000,000 shares of common stock authorized of which 25,066,074 shares of common stock were reserved for the issuance upon the exercise of outstanding warrants and options to purchase common stock, outstanding restricted stock units, the conversion of Series A and Series B1 convertible preferred stock, shares required to be reserved under the LPC Purchase Agreement (defined below), and shares available for grant under the Company's 2013 Stock Incentive Plan and shares available for purchase under the Company's 2017 Employee Stock Purchase Plan.

Put Shares

Pursuant to the terms of a unit purchase agreement dated as of May 5, 1998, the Company issued and sold a total of 149,960 shares of common stock (the "Put Shares") at a price of $128.00 per share. Under the terms of the unit purchase agreement, the initial purchasers (the "Put Holders") of the Put Shares have the right (the "Put Right") to require the Company to repurchase the Put Shares. The Put Right may not be exercised by any Put Holder unless: (1) the Company liquidates, dissolves or winds up its affairs pursuant to applicable bankruptcy law, whether voluntarily or involuntarily; (2) all of the Company's indebtedness and obligations, including without limitation the indebtedness under the Company's then outstanding notes, has been paid in full; and (3) all rights of the holders of any series or class of capital stock ranking prior and senior to the common stock with respect to liquidation, including without limitation the Series A convertible preferred stock, have been satisfied in full. The Company may terminate the Put Right upon written notice to the Put Holders if the closing sales price of its common stock exceeds $256.00 per share for the twenty consecutive trading days prior to the date of notice of termination. Because the Put Right is not transferable, in the event that a Put Holder has transferred Put Shares since May 5, 1998, the Put Right with respect to those shares has terminated. As a consequence of the Put Right, in the event the Company is liquidated, holders of shares of common stock that do not have Put Rights with respect to such shares may receive smaller distributions per share upon the liquidation than if there were no Put Rights outstanding.

As of December 31, 2019, the Company has repurchased or received documentation of the transfer of 49,993 Put Shares and 4,472 of the Put Shares continued to be held in the name of Put Holders. The Company cannot determine at this time what portion of the Put Rights of the remaining 95,494 Put Shares have terminated.

Note 8. Stockholders' Equity (Continued)

Equity Financings

Common Stock Purchase Agreement

On March 4, 2019, the Company entered into a Purchase Agreement with Lincoln Park Capital Fund, LLC ("Lincoln Park"), pursuant to which, upon the terms and subject to the conditions and limitations set forth therein, Lincoln Park has committed to purchase an aggregate of $35.0 million of shares of Company common stock from time to time at the Company's sole discretion (the "LPC Purchase Agreement"). As consideration for entering into the LPC Purchase Agreement, the Company issued 269,749 shares of Company common stock to Lincoln Park as a commitment fee (the "Commitment Shares"). The closing price of the Company's common stock on March 4, 2019 was $2.84 and the Company did not receive any cash proceeds from the issuance of the Commitment Shares. During the year ended December 31, 2019, the Company sold 1,535,848 shares pursuant to the LPC Purchase Agreement, resulting in net proceeds of $3.7 million.

"At-The-Market" Equity Program

In November 2018, the Company entered into a Equity Distribution Agreement (the "ATM Agreement") with JMP Securities LLC ("JMP") pursuant to which the Company may issue and sell shares of its common stock having an aggregate offering price of up to $50.0 million (the "Shares") through JMP as its agent. Subject to the terms and conditions of the ATM Agreement, JMP will use its commercially reasonable efforts to sell the Shares from time to time, based upon the Company's instructions, by methods deemed to be an "at the market offering" as defined in Rule 415(a)(4) promulgated under the Securities Act of 1933, as amended, or if specified by the Company, by any other method permitted by law, including but not limited to in negotiated transactions. The Company has no obligation to sell any of the Shares, and the Company or JMP may at any time suspend sales under the ATM Agreement or terminate the ATM Agreement. JMP is entitled to a fixed commission of 3.0% of the gross proceeds from Shares sold. During the year ended December 31, 2019, the Company sold 532,700 Shares pursuant to the ATM Agreement resulting in net proceeds, after deduction of commissions and other offering expenses, of $1.6 million. No Shares were sold pursuant to the ATM Agreement during 2018.

October 2017 Follow-on Underwritten Public Offering

On October 30, 2017, the Company closed a follow-on underwritten public offering, in which it sold 4,166,666 shares of common stock at a price to the public of $12.00 per share for aggregate gross proceeds of $50.0 million ("2017 Offering"). On November 1, 2017, the Company sold an additional 625,000 shares of common stock pursuant to the exercise in full of the underwriters' 30-day option to purchase additional shares of the Company's common stock at the public offering price less the underwriting discount. The net proceeds to the Company from the 2017 Offering, including the exercise by the underwriters of their option to purchase additional shares and after deducting underwriters' discounts and commissions and other offering costs and expenses, were approximately $53.7 million. Baker Brothers, which is affiliated with two of the Company's directors, participated in the 2017 Offering and purchased 1,000,000 shares of the Company's common stock at the price offered to the public.

Note 8. Stockholders' Equity (Continued)

Common Stock Warrants

In connection with various financing transactions, the Company has issued warrants to purchase shares of the Company's common stock and preferred stock. The Company accounts for common stock and preferred stock warrants as equity instruments or liabilities, depending on the specific terms of the warrant agreement. See Note 2 for further details on accounting policies related to the Company's warrants.

The following table summarizes outstanding warrants to purchase shares of the Company's common stock and/or preferred stock as of December 31, 2019 and 2018:

	Number of Shares			
Description	December 31, 2019	December 31, 2018	Weighted-Average Exercise Price	Expiration Date
Liability-classified Warrants				
December 2019 Series B1 warrants [1]	2,368,400	—	$ 1.52	Dec 2026
	2,368,400	—		
Equity-classified Warrants				
May 2013 warrants	1,949,754	1,977,041	$ 0.08	None [2]
September 2013 warrants	514,756	521,997	$ 0.08	None [2]
February 2014 warrants	266,006	269,844	$ 0.08	None [2]
	2,730,516	2,768,882		
Total outstanding	5,098,916	2,768,882		

(1) The Series B1 warrants are exercisable for either common stock (exercise price of $1.52) or Series B1 Convertible Preferred Stock (exercise price of $152) at the discretion of the warrant holder.

(2) In connection with December 2019 Private Placement, the expiration date on these warrants was amended to be indefinite.

The table below is a summary of the Company's warrant activity for the year ended December 31, 2019.

	Number of Warrants	Weighted-Average Exercise Price
Outstanding at December 31, 2018	2,768,882	$ 0.08
Issued [1]	2,368,400	1.52
Exercised	(38,366)	0.08
Expired	—	—
Outstanding at December 31, 2019	5,098,916	$ 0.75

(1) During the year ended December 31, 2019, certain related parties were issued warrants as more fully described in Note 16.

Note 9. Alliance Revenue

Alliance revenue for the years ended December 31, 2019, 2018 and 2017 represents revenue from contracts with customers accounted for in accordance with ASC Topic 606. For the years ended December 31, 2019, 2018 and 2017, Alliance revenue in the accompanying statements of operations and comprehensive loss is comprised of the following:

(In thousands)	2019	2018	2017
Out-license arrangement [1]	$ 1,447	$ —	$ —
GSK collaboration [2]	—	517	863
Vivelix collaboration [3]	—	56	14
Other [4]	1	89	25
Total Alliance revenue	$ 1,448	$ 662	$ 902

(1) For the year ended December 31, 2019, the Company recognized Alliance revenues of $1.4 million under the Licensee Agreement, as more fully described in Note 10, primarily related to the transfer of the IMO-8400 License and IMO-8400 drug product.

(2) For the years ended December 31, 2018 and 2017, revenue recognized primarily relates to the amortization of the $2.5 million upfront, non-refundable, non-creditable cash payment received upon the execution of the GSK Agreement, as more fully described in Note 10, which was recognized as revenue on a straight-line basis over the estimated 36-month research plan period, which approximated the timing in which performance obligations were satisfied. No such revenue was recognized during 2019. Revenue recognized for the year ended December 31, 2017 also includes an additional $0.1 million related to additional research services performed in connection with the GSK Agreement.

(3) For each of the years ended December 31, 2018 and 2017, revenue recognized relates to reimbursements for research services performed in connection with the Vivelix Agreement, as more fully described in Note 10.

(4) For all periods presented, revenue recognized relates to collaborations which are not material to the Company's current operations nor expected to be material in the future, including reimbursements by licensees of costs associated with patent maintenance.

During each of the years ended December 31, 2018 and 2017, the Company recognized Alliance revenues of $0.6 million and $0.7 million, respectively, as a result of changes in the contract liability balances associated with its contracts with customers. Such revenue recognized was included in the contract liability balance at the beginning of each respective period.

See Note 10 for additional details regarding the Company's collaboration arrangements.

Note 10. Collaboration and License Agreements

Option and License Agreement with Licensee

In April 2019, the Company entered into an amended and restated option and license agreement with a privately-held biopharmaceutical company ("Licensee"), pursuant to which the Company granted Licensee (i) exclusive worldwide rights to develop and market IMO-8400 for the treatment, palliation and diagnosis of all diseases, conditions or indications in humans (the "IMO-8400 License"), (ii) an exclusive right and license to develop IMO-9200 in accordance with certain IMO-9200 pre-option exercise protocols (the "IMO-9200 Option Period License"), and (iii) an exclusive option, exercisable at Licensee's discretion, to obtain the exclusive worldwide rights to develop and market IMO-9200 for the treatment, palliation and diagnosis of all diseases, conditions or indications in humans (the "IMO-9200 Option") (collectively, the "Licensee Agreement"). In connection with the Licensee Agreement, the Company transferred certain drug material to Licensee for Licensee's use in development activities. Licensee is solely responsible for the development and commercialization of IMO-8400 and, if Licensee exercises the IMO-9200 Option, Licensee would be solely responsible for the development and commercialization of IMO-9200.

Note 10. Collaboration and License Agreements (Continued)

Under the terms of the Licensee Agreement, the Company received upfront, non-refundable fees totaling approximately $1.4 million and ownership of 10% of Licensee's outstanding common stock, subject to future adjustment, for granting Licensee the IMO-8400 License, the IMO-9200 Option Period License and transfer of related drug materials. In addition, the Company is eligible to receive a $1 million non-refundable fee upon Licensee exercising the IMO-9200 Option ("Option Fee") and is entitled to certain sub-licensing payments on sublicense revenue received by Licensee, if any. The Company may also be eligible for certain development and sales-based milestone payments and royalties on global net sales for any future products. The Company does not anticipate the receipt of any of the future milestones or royalties in the short term, if ever.

The Company concluded that the contract counterparty, Licensee, is a customer and accounted for the Licensee Agreement in accordance with ASC 606. As of December 31, 2019, the total transaction price of the contract was $1.4 million, which excluded the Option Fee and all development and sales milestones as all such payments were fully constrained. Additionally, as of December 31, 2019, there were no remaining performance obligations under the Licensee Agreement. The Company re-evaluates its performance obligations and transaction price in each reporting period and as uncertain events are resolved or other changes in circumstances occur.

As disclosed above, in connection with the Licensee Agreement, the Company owns 10% of Licensee's outstanding common stock, subject to future adjustment. The Company evaluated the guidance in ASC Topic 321, *Investments-Equity Securities*, and elected to account for the investment using the measurement alternative as the equity securities are without a readily determinable fair value, and the arrangement does not result in Idera having control or significant influence over Licensee. Accordingly, the securities are measured at cost, less any impairment, plus or minus changes resulting from observable price changes and are recorded in Other assets at a value of less than $0.1 million in the accompanying balance sheets. As of December 31, 2019, the Company considered the cost of the investment to not exceed the fair value of the investment and did not identify any observable price changes.

See Note 9 for details on revenue recognized in connection with the Company's collaboration with Licensee for each of the years ended December 31, 2019, 2018 and 2017.

Collaboration with Vivelix

In November 2016, the Company entered into an exclusive license and collaboration agreement with Vivelix Pharmaceuticals, Ltd. ("Vivelix") pursuant to which the Company granted Vivelix worldwide rights to develop and market IMO-9200 for non-malignant gastrointestinal disorders and certain back-up compounds to IMO-9200 (the "Vivelix Agreement"). Under the terms of the Vivelix Agreement, Vivelix was solely responsible for the development and commercialization of IMO-9200 and any designated back-up compounds. In connection with the Vivelix Agreement, Idera also transferred certain drug material to Vivelix for Vivelix's use in its development activities. Additionally, Vivelix could request that the Company create, characterize and perform research on back-up compounds.

At the effective date of the Vivelix Agreement, Baker Bros. Advisors LP and certain of its affiliated funds (collectively "Baker Brothers") beneficially owned approximately 7.0% of the Company's outstanding common stock and affiliates of Baker Brothers constituted two of the four directors on the board of directors of Vivelix and two of the seven directors on the board of directors of the Company.

Under the terms of the Vivelix Agreement, the Company received an upfront, non-refundable fee of $15 million related to the license granted for IMO-9200 and back-up compounds to IMO-9200, which was recognized at the inception of the Vivelix Agreement in the fourth quarter of 2016. Additionally, the Company was eligible for future IMO-9200 related development, regulatory and sales milestone payments and sales-based royalties. However, on March 4, 2019, the Company and Vivelix mutually agreed to terminate the Vivelix Agreement. Accordingly, the Company is no longer eligible to receive any future milestone or royalty-based payments and all rights previously granted to Vivelix with respect to IMO-9200 and certain back-up compounds to IMO-9200 reverted back to the Company.

See Note 9 for details on revenue recognized in connection with the Company's collaboration with Vivelix for each of the years ended December 31, 2019, 2018 and 2017.

Note 10. Collaboration and License Agreements (Continued)

Collaboration with GSK

In November 2015, the Company entered into a collaboration and license agreement with GSK to license, research, develop and commercialize pharmaceutical compounds from the Company's nucleic acid chemistry technology for the treatment of selected targets in renal disease (the "GSK Agreement"). In connection with the GSK Agreement, GSK identified an initial target for the Company to attempt to identify a potential population of development candidates to address such target under a mutually agreed upon research plan. Prior to the wind-down of its discovery operations as more fully described in Note 10, the Company created multiple development candidates to address the initial target designated by GSK. Until November 2019, the expiration of the collaboration term, GSK had the right to designate one development candidate in its sole discretion, from the population of identified candidates, to move forward into clinical development. However, GSK did not designate any candidate for development during the collaboration term. If such designation had occurred, GSK would have been solely responsible for the development and commercialization activities of that designated development candidate.

The GSK Agreement also provided GSK with the option to select up to two additional targets at any time during the first two years of the GSK agreement, for further research under mutually agreed upon research plans. Upon selecting additional targets, GSK then had the option to designate one development candidate for each additional target, at which time GSK would have sole responsibility to develop and commercialize each such designated development candidate. GSK did not select any additional targets for research through expiry of the option period.

Under the terms of the GSK Agreement, the Company received a $2.5 million upfront, non-refundable, non-creditable cash payment upon the execution of the GSK Agreement. Additionally, the Company was initially eligible to receive a total of up to approximately $100 million in license, research, clinical development and commercialization milestone payments, of which $9 million of these milestone payments would have been payable by GSK upon the identification of the additional targets, the completion of current and future research plans and the designation of development candidates and $89 million would have been payable by GSK upon the achievement of clinical milestones and commercial milestones. As a result of GSK not designating a development candidate during the collaboration term, the Company is no longer eligible to receive any additional license, research, clinical development and commercialization milestone payments, or any royalty payments.

See Note 9 for details on revenue recognized in connection with the Company's collaboration with GSK for each of the years ended December 31, 2019, 2018 and 2017.

Collaboration with Abbott Molecular Inc.

In May 2014, the Company entered into a development and commercialization agreement with Abbott Molecular, Inc. ("Abbott Molecular") for the development of an in vitro companion diagnostic intended to be used in the Company's prior clinical development programs to treat certain genetically defined forms of B-cell lymphoma with IMO-8400. The agreement provided for the development and subsequent commercialization by Abbott Molecular of a companion diagnostic test utilizing polymerase chain reaction technology to identify with high sensitivity and specificity the presence in tumor biopsy samples of the oncogenic mutation referred to scientifically as MYD88 L265P. Under the agreement, Abbott Molecular was primarily responsible for developing and obtaining regulatory approvals for the companion diagnostic in accordance with an agreed development plan and regulatory plan and for making the companion diagnostic test commercially available in accordance with an agreed commercialization plan. Abbott Molecular would retain all proceeds from commercialization of the companion diagnostic test, if any. In September 2016, the Company suspended internal clinical development of IMO-8400 for B-cell lymphomas. While the Company has maintained its relationship with Abbott, the Company is permitted to terminate the agreement upon 90 days written notice to Abbott Molecular and, under circumstances specified in the agreement, payment of a termination fee and wind-down costs. The parties also may terminate the agreement based on uncured material breaches by or the bankruptcy or insolvency of the other party, and each party has the right to terminate the agreement in the event of specified permanent injunctions based on infringement of third party intellectual property rights.

Note 10. Collaboration and License Agreements (Continued)

The Company incurred approximately $0.4 million, and $0.8 million in expenses under the Abbott Molecular agreement during the years ended December 31, 2018 and 2017, respectively, related to funding Abbott Molecular's development of the companion diagnostic test. No such costs were incurred during 2019.

Note 11. Restructuring Costs

In July 2018, the Company determined to wind-down its discovery operations, reduce the workforce in Cambridge, Massachusetts that supports such operations, and close its Cambridge facility. In connection with the reduction-in-workforce, 18 positions were being eliminated, primarily in the area of discovery, representing approximately 40% of the Company's employees. Of the 18 positions eliminated, 15 were effective July 31, 2018 with the remaining effective during the first half of 2019. The Company completed the consolidation of its operations to its Exton, Pennsylvania location in the third quarter of 2018.

Total restructuring-related charges incurred through December 31, 2019 totaled $3.3 million and were comprised of (i) one-time termination costs in connection with the reduction in workforce, including severance, benefits and related costs, of approximately $2.8 million; (ii) contract termination costs of approximately $0.2 million in connection with the early lease termination for the Cambridge facility; and (iii) non-cash asset impairments of approximately $0.7 million, inclusive of $0.5 million of fixed asset impairments and $0.2 million in write-offs of facility-related prepaid expenses; offset by (iv) a non-cash gain of approximately $0.4 million related to the write-off of the remaining deferred rent liability associated with the Cambridge facility lease.

The following summarizes restructuring-related activity for the years ended December 31, 2019 and 2018:

(in thousands)	Employee Severance and Benefits	Contract Termination Costs	Asset Impairments	Total
Accrued restructuring balance as of December 31, 2017	$ —	$ —	$ —	$ —
Charges incurred (1)	2,635	225	674	3,534
Cash payments	(1,380)	(225)	—	(1,605)
Non-cash settlements	(24)	—	(674)	(698)
Adjustments	(84)	—	—	(84)
Accrued restructuring balance as of December 31, 2018	$ 1,147	$ —	$ —	$ 1,147
Charges incurred	181	—	—	181
Cash payments	(1,215)	—	—	(1,215)
Accrued restructuring balance as of December 31, 2019	$ 113	$ —	$ —	$ 113

(1) Excludes $0.4 million gain due to the write-off of the remaining deferred rent liability associated with the termination of the Cambridge, Massachusetts facility lease.

As of December 31, 2019, the entire accrued restructuring balance is classified as a current liability and included in "Accrued expenses" in the accompanying balance sheets. See Note 6.

Note 12. Stock-based Compensation

As of December 31, 2019, the only equity compensation plans from which the Company may currently issue new awards are the Company's 2013 Stock Incentive Plan (as amended to date, the "2013 Plan") and 2017 Employee Stock Purchase Plan (the "2017 ESPP"), each as more fully described below.

Equity Incentive Plans

2013 Stock Incentive Plan

The Company's board of directors adopted the 2013 Plan, which was approved by the Company's stockholders effective July 26, 2013. Amendments to the 2013 Plan were approved by the Company's stockholders in June 2014, June 2015, June 2017 and June 2019. The 2013 Plan is intended to further align the interests of the Company and its stockholders with its employees, including its officers, non-employee directors, consultants and advisers by providing equity-based incentives. The 2013 Plan allows for the issuance of incentive stock options intended to qualify under Section 422 of the Internal Revenue Code, non-statutory stock options, stock appreciation rights, restricted stock awards, restricted stock units, other stock-based awards and performance awards. The total number of shares of common stock authorized for issuance under the 2013 Plan is 5,653,057 shares of the Company's common stock, plus such additional number of shares of common stock (up to 868,372 shares) as is equal to the number of shares of common stock subject to awards granted under the Company's 2005 Stock Incentive Plan or 2008 Stock Incentive Plan (the "2008 Plan"), to the extent such awards expire, terminate or are otherwise surrendered, canceled, forfeited or repurchased by the Company at their original issuance price pursuant to a contractual repurchase right.

As of December 31, 2019, options to purchase a total of 3,459,693 shares of common stock and 193,625 restricted stock units were outstanding and up to 2,301,240 shares of common stock remained available for grant under the 2013 Plan. The Company has not made any awards pursuant to other equity incentive plans, including the 2008 Plan, since the Company's stockholders approved the 2013 Plan. As of December 31, 2019, options to purchase a total of 366,974 shares of common stock were outstanding under the 2008 Plan.

In addition, as of December 31, 2019, non-statutory stock options to purchase an aggregate of 393,750 shares of common stock were outstanding that were issued outside of the 2013 Plan to certain employees in 2017, 2015 and 2014 pursuant to the Nasdaq inducement grant exception as a material component of new hires' employment compensation.

Employee Stock Purchase Plans

1995 Employee Stock Purchase Plan

The Company's 1995 Employee Stock Purchase Plan (the "1995 ESPP"), as amended, provided for the issuance of up to 62,500 shares of common stock to participating employees of the Company or its subsidiaries. The 1995 ESPP was terminated effective August 31, 2017 as a result of the adoption by the Company's board of directors and approval of shareholders of the 2017 Employee Stock Purchase Plan (the "2017 ESPP"), as described below.

2017 *Employee Stock Purchase Plan*

The Company's board of directors adopted the 2017 ESPP which was approved by the Company's stockholders and became effective June 7, 2017. An amendment to the 2017 ESPP was approved by the Company's stockholders in June 2019. The 2017 ESPP is intended to qualify as an "employee stock purchase plan" as defined in Section 423 of the Internal Revenue Code, and is intended to encourage our employees to become stockholders of ours, to stimulate increased interest in our affairs and success, to afford employees the opportunity to share in our earnings and growth and to promote systematic savings by them. The total number of shares of common stock authorized for issuance under the 2017 ESPP is 412,500 shares of common stock, subject to adjustment as described in the 2017 ESPP. Participation is limited to employees that would not own 5% or more of the total combined voting power or value of the stock of the Company after the grant. As of December 31, 2019, 321,341 shares remained available for issuance under the 2017 ESPP.

Note 12. Stock-based Compensation (Continued)

Stock Purchase Plan Administration

The 1995 ESPP provided for and 2017 ESPP provides for offerings to employees to purchase common stock with offerings beginning on dates determined by the compensation committee of the board of directors or on the first business day thereafter. Each offering begins a "plan period" during which payroll deductions are to be made and held for the purchase of common stock at the end of the plan period. The compensation committee may, at its discretion, choose a plan period of 12 months or less for subsequent offerings and/or choose a different commencement date for offerings. During each plan period participating employees may elect to have a portion of their compensation, ranging from 1% to 10% of compensation as defined by the plan, withheld and used for the purchase of common stock at the end of each plan period. The purchase price is equal to 85% of the lower of the fair market value of a share of common stock on the first trading date of each plan period or the fair market value of a share of common stock on the last trading day of the plan period, and is limited by participant to $25,000 in fair value of common stock per year as well as other quarterly plan limitations as defined by each plan.

For the years ended December 31, 2019, 2018 and 2017, the Company issued 60,953, 24,824, and 21,869 shares of common stock, respectively, under the Company's employee stock purchase plans and recognized $0.1 million, $0.1 million, and $0.2 million, respectively, in related stock-based compensation expense.

Accounting for Stock-based Compensation

The Company recognizes non-cash compensation expense for stock-based awards under the Company's equity incentive plans over an award's requisite service period, or vesting period, using the straight-line attribution method, based on their grant date fair value, determined using the Black-Scholes option-pricing model. The fair value of the discounted purchases made under the Company's 2015 ESPP and 2017 ESPP is calculated using the Black-Scholes option-pricing model. The fair value of the look-back provision plus the 15% discount is recognized as compensation expense over each plan period.

Total stock-based compensation expense attributable to stock-based payments made to employees and directors and employee stock purchases included in operating expenses in the Company's statements of operations for the years ended December 31, 2019, 2018 and 2017 was as follows:

(in thousands)	2019	2018	2017
Stock-based compensation:			
Research and development			
Employee Stock Purchase Plans	$ 36	$ 71	$ 96
Equity Incentive Plans (1)	1,312	1,780	6,398
	$ 1,348	$ 1,851	$ 6,494
General and administrative			
Employee Stock Purchase Plans	$ 20	$ 48	$ 63
Equity Incentive Plans	2,477	3,751	4,163
	$ 2,497	$ 3,799	$ 4,226
Restructuring costs			
Equity Incentive Plans	$ —	$ 24	$ —
	$ —	$ 24	$ —
Total stock-based compensation expense	$ 3,845	$ 5,674	$ 10,720

(1) The 2017 charge includes approximately $4.3 million of additional stock-based compensation recognized as a result of modifications to previously issued stock option awards in connection with the resignation of an executive.

During the years ended December 31, 2019, 2018 and 2017, the weighted average fair market value of stock options granted was $1.64, $7.00, and $8.08, respectively.

Note 12. Stock-based Compensation (Continued)

Assumptions Used in Determining Fair Value of Stock Options

Inherent in the Black-Scholes option-pricing model are the following assumptions:

Volatility. The Company estimates stock price volatility based on the Company's historical stock price performance over a period of time that matches the expected term of the stock options.

Risk-free interest rate. The risk-free interest rate is based on the U.S. Treasury yield curve in effect at the time of grant commensurate with the expected term assumption.

Expected term. The expected term of stock options granted is based on an estimate of when options will be exercised or cancelled in the future.

Dividend rate. The dividend rate is based on the historical rate, which the Company anticipates will remain at zero.

Forfeitures. The Company accounts for forfeitures when they occur. Ultimately, the actual expense recognized over the vesting period will be for only those shares that vest. See Note 2.

The fair value of each option award at the date of grant was estimated using the Black-Scholes option pricing model. All options granted during the three years in the period ended December 31, 2019 were granted at exercise prices equal to the fair market value of the common stock on the dates of grant**.**

The following weighted average assumptions apply to the options to purchase 1,279,016, 1,136,874, and 527,039 shares of common stock granted to employees and directors during the years ended December 31, 2019, 2018 and 2017, respectively:

	2019	2018	2017
Average risk-free interest rate	2.1%	2.5%	1.7%
Expected dividend yield	—	—	—
Expected lives (years)	3.7	3.7	4.0
Expected volatility	84%	74%	86%
Weighted average exercise price (per share)	$ 2.75	$ 12.63	$ 12.96

All options granted during the year ended December 31, 2019 and 2018 were granted at exercise prices equal to the fair market value of the common stock on the dates of grant**.**

Stock Option Activity

The following table summarizes stock option activity for the year ended December 31, 2019.

($ in thousands, except per share data)	Stock Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life (in years)	Aggregate Intrinsic Value
Outstanding at December 31, 2018	3,304,531	$ 18.41	6.6	$
Granted	1,279,016	2.75		
Exercised	—	—		
Forfeited	(143,874)	12.95		
Expired	(219,256)	31.29		
Outstanding at December 31, 2019 (1)	4,220,417	$ 13.08	6.6	$ —
Exercisable at December 31, 2019	2,292,157	$ 19.20	4.7	$ —

(1) Includes both vested stock options as well as unvested stock options for which the requisite service period has not been rendered but that are expected to vest based on achievement of a service condition.

Note 12. Stock-based Compensation (Continued)

The fair value of options that vested during the year ended December 31, 2019 was $4.7 million. As of December 31, 2019, there was $5.2 million of unrecognized compensation cost related to unvested options, which the Company expects to recognize over a weighted average period of 2.5 years.

Restricted Stock Activity

The following table summarizes restricted stock activity for the year ended December 31, 2019:

($ in thousands, except per share data)	Number of Shares	Weighted-Average Grant Date Fair Value
Nonvested shares at December 31, 2018	—	$ —
Granted	194,550	3.14
Cancelled	(925)	3.14
Vested	—	—
Nonvested shares at December 31, 2019	193,625	$ 3.14

As of December 31, 2019, there was $0.5 million of unrecognized compensation cost related to the restricted stock units, which is expected to be recognized over a weighted average period of 3.0 years.

Note 13. Commitments and Contingencies

Lease Commitments

As of December 31, 2019, the Company's leased assets consisted of its office headquarters in Exton, Pennsylvania. Prior to the September 30, 2018 termination date, the Company also leased a facility in Cambridge, Massachusetts. During 2019, 2018 and 2017, rent expense, including real estate taxes, was $0.3 million, $1.7 million, and $2.4 million, respectively. The leases are classified as operating leases.

Future minimum commitments as of December 31, 2019 under the Company's lease agreements are approximately:

December 31,	Operating Leases *(in thousands)*
2020	$ 217
2021	224
2022	229
2023	235
2024	240
2025	100
	$ 1,245

The Company entered into the Exton, Pennsylvania facility lease on April 1, 2015, which was subsequently amended on September 23, 2015 to include additional space. We currently lease approximately 11,000 square feet of office space at our Exton facility. The lease expires on May 31, 2025 as a result of the Company's election to exercise its five-year renewal option.

Note 14. Income Taxes

In December 2017, the Tax Cuts and Jobs Act ("TCJA") was signed into law. Among other things, the TCJA permanently lowers the corporate federal income tax rate to 21% from the existing maximum rate of 35%, effective for tax years including or commencing January 1, 2018. As a result of the reduction of the corporate federal income tax rate to 21%, GAAP required companies to revalue their deferred tax assets and deferred tax liabilities as of the date of enactment, with the resulting tax effects accounted for in the reporting period of enactment. This revaluation resulted in a provision of $27.6 million to income tax expense and a corresponding reduction in the valuation allowance for the year ended December 31, 2017. As a result, there was no impact to the Company's statement of operations and comprehensive loss for the year ended December 31, 2017 as a result of reduction in tax rates.

The Company's preliminary estimate of the TCJA and the remeasurement of its deferred tax assets and liabilities was subject to the finalization of management's analysis related to certain matters, such as developing interpretations of the provisions of the TCJA, changes to certain estimates and the filing of the Company's tax returns. The final determination of the TCJA and the remeasurement of the Company's deferred assets and liabilities was completed during 2018, within one year from the enactment of the TCJA, as additional information became available. There were no changes to management's analysis of the effects of TCJA originally performed as of December 31, 2017.

Certain provisions from the Tax Reform Act of 1986 were not impacted by TCJA, such as those limiting the amount of net operating loss carryforwards ("NOLs") and tax credit carryforwards that companies may utilize in any one year in the event of changes in ownership, as defined by Section 382 of the Internal Revenue Code. The Company has completed several financings since the effective date of the Tax Reform Act of 1986, which as of December 31, 2019, have resulted in ownership changes that will significantly limit the Company's ability to utilize its net operating loss and tax credit carryforwards. In December 2017, the Company completed a study which determined that ownership changes had occurred. The federal and state net operating loss and tax credit carryforwards and related deferred tax assets shown in the table below have been adjusted to reflect the limitations that resulted from this study. The Company continues to monitor equity activity and potential ownership changes.

As of December 31, 2019, the Company had cumulative federal and state NOLs of approximately $295.8 million and $290.2 million available to reduce federal and state taxable income, respectively. As a result of TCJA, federal net operating losses incurred for taxable years beginning after January 1, 2018 have an unlimited carryforward period, but can only be utilized to offset 80% of taxable income in future taxable periods. Of the $295.8 million of federal NOLs, $98.4 million have an unlimited carryforward and the remaining NOLs are still subject to expiration through 2037. State NOLs are still subject to expiration according to the laws of each respective jurisdiction. The Company files state tax returns in Massachusetts and Pennsylvania whereby both jurisdictions impose a 20-year carryforward period. All $290.2 million of state NOLs expire through 2039, with the first year of expiration being 2032 for $21.0 million of Massachusetts NOLs. In addition, at December 31, 2019, the Company had cumulative federal and state tax credit carryforwards of $21.6 million and $1.9 million, respectively, available to reduce federal and state income taxes, respectively, which expire through 2039 and 2034, respectively, for federal and state purposes.

As of December 31, 2019 and 2018, the components of the deferred tax assets are approximately as follows:

	2019	2018
	(In thousands)	
Operating loss carryforwards	$ 81,403	$ 70,509
Tax credit carryforwards	23,072	18,514
Lease liabilities	308	—
Other	7,994	8,627
Total deferred tax assets	112,777	97,650
Right-of-use asset	(306)	—
Valuation allowance	(112,471)	(97,650)
Net deferred tax assets	$ —	$ —

Note 14. Income Taxes (Continued)

The Company has provided a full valuation allowance for its deferred tax asset due to the uncertainty surrounding the ability to realize these assets.

The difference between the U.S. federal corporate tax rate and the Company's effective tax rate for the years ended December 31, 2019, 2018 and 2017 is as follows:

	2019	2018	2017
Expected federal income tax rate	(21.0)%	(21.0)%	(34.0)%
Expiring credits and NOLs	—	1.0	—
Change in valuation allowance	26.2	37.9	0.9
Federal and state credits	(8.1)	(7.4)	(6.9)
State income taxes, net of federal benefit	(4.7)	(9.7)	(3.7)
Permanent differences	4.8	0.5	2.4
Rate change related to TCJA	—	—	41.9
Other	2.8	(1.3)	(0.6)
Effective tax rate	0.0 %	0.0 %	0.0 %

The Company applies ASC 740-10, *Accounting for Uncertainty in Income Taxes, an interpretation of ASC 740*. ASC 740-10 clarifies the accounting for uncertainty in income taxes recognized in financial statements and requires the impact of a tax position to be recognized in the financial statements if that position is more likely than not of being sustained by the taxing authority. The Company had no unrecognized tax benefits resulting from uncertain tax positions at December 31, 2019 and 2018.

The Company has not conducted a study of its research and development tax credit carryforwards. Such a study might result in an adjustment to the Company's research and development credit carryforwards, however, until a study is completed and any adjustment is known, no amounts are being presented as an uncertain tax position under ASC 740-10. A full valuation allowance has been provided against the Company's research and development credits and, if an adjustment is required, this adjustment would be offset by an adjustment to the valuation allowance. Thus, there would be no impact to the statements of operations and comprehensive loss if an adjustment was required.

The Company files income tax returns in the U.S. federal, Massachusetts and Pennsylvania jurisdictions. The Company is no longer subject to tax examinations for years before 2016, except to the extent that it utilizes NOLs or tax credit carryforwards that originated before 2016. The Company does not believe there will be any material changes in its unrecognized tax positions over the next 12 months. The Company has not incurred any interest or penalties. In the event that the Company is assessed interest or penalties at some point in the future, they will be classified in the statements of operations and comprehensive loss as general and administrative expense.

Note 15. Employee Benefit Plan

The Company has an employee benefit plan under Section 401(k) of the Internal Revenue Code. The plan allows employees to make contributions up to a specified percentage of their compensation. Under the plan, the Company matches a portion of the employees' contributions up to a defined maximum. Prior to August 2018, the Company historically contributed up to 3% of employee base salary, by matching 50% of the first 6% of annual base salary contributed by each employee. Effective August 2018, the Company began contributing up to 5% of employee base salary, by matching 100% of the first 5% of annual base salary contributed by each employee. Approximately $0.3 million, $0.2 million and $0.3 million of 401(k) benefits were charged to operating expenses for the years ended December 31, 2019, 2018 and 2017, respectively.

Note 16. Related Party Transactions

Baker Brothers

Julian C. Baker, a member of the Company's Board until his resignation in September 2018, is a principal of Baker Bros. Advisors, LP. Additionally, Kelvin M. Neu, a member of Company's Board until his resignation in June 2019, is an employee of Baker Bros. Advisors, LP. As of December 31, 2019, Baker Bros. Advisors, LP and certain of its affiliated funds (collectively, "Baker Brothers") held sole voting power with respect to an aggregate of 4,608,786 shares of the Company's common stock, representing approximately 16% of the Company's outstanding common stock.

During 2019, Baker Brothers purchased shares of the Company's Series B1 Preferred Stock and accompanying warrants to purchase common stock in connection with the 2019 Private Placement, as more fully described in Note 7. Concurrent with the 2019 Private Placement, the Company amended the warrants initially issued to Baker Brothers and other holders on May 7, 2013, September 30, 2013 and February 10, 2014 to remove expiration date. Following the amendment, these warrants will not expire.

During 2018, Baker Brothers exercised warrants to purchase 2,700,791 shares of the Company's common stock at an exercise price of $3.76 per share for a total exercise price of approximately $9.5 million.

During 2017, Baker Brothers purchased shares of the Company's common stock in connection with underwritten public offerings of shares of the Company's common stock as more fully described in Note 8.

As of December 31, 2019, Baker Brothers held warrants to purchase up to 2,708,812 shares of the Company's common stock at an exercise price of $0.08 per share, warrants to purchase up to 2,368,400 shares of the Company's common stock (or, if Baker Brothers elects to exercise the warrants for shares of Series B1 Preferred Stock, 23,684 shares of Series B1 Preferred Stock), at an exercise price of $1.52 per share (or, if Baker Brothers elects to exercise the warrants for shares of Series B1 Preferred Stock, $152 per Series B1 Preferred Warrant Share.

Pillar Investment Entities

Youssef El Zein, a member of the Company's board of directors until his resignation in October 2017, is a director and controlling stockholder of Pillar Invest Corporation ("Pillar Invest"), which is the general partner of Pillar Pharmaceuticals I, L.P., Pillar Pharmaceuticals II, L.P. ("Pillar II"), Pillar Pharmaceuticals III, L.P. ("Pillar III"), Pillar Pharmaceuticals IV, L.P. ("Pillar IV") and Pillar Pharmaceuticals V, L.P. ("Pillar V"), Pillar Pharmaceuticals 6 L.P. and Pillar Partners Foundation L.P. (collectively, the "Pillar Investment Entities"). As of December 31, 2019, the Pillar Investment Entities own approximately 11% of the Company's common stock.

During 2018, Participations Besancon, an investment fund advised by Pillar Invest having no affiliation with Mr. El Zein, exercised warrants to purchase 150,000 shares of the Company's common stock at an exercise price of $3.76 per share for a total exercise price of approximately $0.6 million.

During 2017, Pillar II exercised 629,257 warrants to purchase shares of the Company's common stock at a total exercise price of approximately $3.5 million and Besancon exercised 364,752 warrants to purchase shares of the Company's common stock at a total exercise price of approximately $1.9 million. The warrant exercise prices had been established at the time that the warrants were purchased.

Board Fees Paid in Stock

Pursuant to the Company's director compensation program, in lieu of director board and committee fees of approximately $0.1 million incurred during each of the years ended December 31, 2019, 2018 and 2017, respectively, the Company issued 53,985, 13,654, and 7,867 shares of common stock, respectively, to certain of its directors. Director board and committee fees are paid in arrears and the number of shares issued was calculated based on the market closing price of the Company's common stock on the issuance date.

Note 17. Net Loss per Common Share Applicable to Common Stockholders

Net loss applicable to common stockholders represents net loss adjusted for deemed dividends related to the December 2019 Private Placement, as more fully described in Note 7. Basic and diluted net loss per common share applicable to common stockholders is calculated by dividing net loss applicable to common stockholders by the weighted-average number of shares of common stock outstanding during the period, without consideration of common stock equivalents. The Company's potentially dilutive securities, which include outstanding stock option awards, unvested restricted stock units, common stock warrants, convertible preferred stock and securities underlying the Future Tranche Rights (see Note 7), are considered to be common stock equivalents and are only included in the calculation of diluted net loss per share when their effect is dilutive. For the years ended December 31, 2019, 2018 and 2017, diluted net loss per common share applicable to common stockholders was the same as basic net loss per common share applicable to common stockholders as the effects of the Company's potential common stock equivalents are antidilutive.

Total antidilutive securities that were excluded from the calculation of diluted net loss per share applicable to common stockholders, due to their anti-dilutive effect, were 61,289,079, 6,075,339, and 8,145,188 as of December 31, 2019, 2018 and 2017, respectively. Such antidilutive securities consisted of stock options, unvested restricted stock units, convertible preferred stock, warrants and securities underlying Future Tranche Rights as December 31, 2019, and consisted of stock options, convertible preferred stock and warrants as of December 31, 2018 and 2017.

Note 18. Subsequent Events

The Company considers events or transactions that occur after the balance sheet date but prior to the issuance of the financial statements to provide additional evidence relative to certain estimates or to identify matters that require additional disclosure.

Proceeds from Sale of Common Stock

"At-The-Market" Equity Program

During the period January 1, 2020 through March 11, 2020, the Company sold 403,983 shares of its common stock pursuant to the ATM Agreement, as more fully described in Note 8, resulting in net proceeds after deduction of commissions of $0.6 million.

Common Stock Purchase Agreement

During the period January 1, 2020 through March 11, 2020, the Company sold 450,000 shares of its common pursuant to the LPC Purchase Agreement, as more fully described in Note 8, resulting in net proceeds of $0.8 million.

Exhibit 4.11

Execution Copy

REGISTRATION RIGHTS AGREEMENT

This Registration Rights Agreement (this "Agreement") is made as of December 23, 2019, by and between Idera Pharmaceuticals, Inc., a Delaware corporation (the "Company"), and the persons listed on the attached Schedule A who are signatories to this Agreement (collectively, the "Investors"). Unless otherwise defined herein, capitalized terms used in this Agreement have the respective meanings ascribed to them in Section 1.

RECITALS

WHEREAS, the Company and the Investors wish to provide for certain arrangements with respect to the registration of the Registrable Securities (as defined below) by the Company under the Securities Act (as defined below).

NOW, THEREFORE, in consideration of the mutual promises and covenants set forth herein, and other consideration, the receipt and adequacy of which are hereby acknowledged, the parties hereto agree as follows:

Section 1.
Definitions

1.1. Certain Definitions. In addition to the terms defined elsewhere in this Agreement, as used in this Agreement, the following terms have the respective meanings set forth below:

(a) "Board" shall mean the Board of Directors of the Company.

(b) "Commission" shall mean the Securities and Exchange Commission or any other federal agency at the time administering the Securities Act.

(c) "Common Stock" shall mean the common stock of the Company, par value $0.001 per share.

(d) "Exchange Act" shall mean the Securities Exchange Act of 1934, as amended, or any similar successor federal statute and the rules and regulations thereunder, all as the same shall be in effect from time to time.

(e) "Other Securities" shall mean securities of the Company, other than Registrable Securities (as defined below).

(f) "Person" shall mean any individual, partnership, corporation, company, association, trust, joint venture, limited liability company, unincorporated organization, entity or division, or any government, governmental department or agency or political subdivision thereof.

(g) "Registrable Securities" shall mean the shares of Common Stock and any Common Stock issued or issuable upon the exercise or conversion of any other securities (whether equity,

debt or otherwise) of the Company now owned or hereafter acquired by any of the Investors. Registrable Securities shall cease to be Registrable Securities upon the earliest to occur of the following events: (i) such Registrable Securities have been sold pursuant to an effective Registration Statement; (ii) such Registrable Securities have been sold by the Investors pursuant to Rule 144 (or other similar rule), (iii) at any time after any of the Investors become an affiliate of the Company, such Registrable Securities may be resold by the Investor holding such Registrable Securities without limitations as to volume or manner of sale pursuant to Rule 144; or (iv) ten (10) years after the date of this Agreement. For purposes of this definition, in order to determine whether an Investor is an "affiliate" (as such term is defined and used in Rule 144, and including for determining whether volume or manner of sale limitations of Rule 144 apply) the parties will assume that all convertible securities (whether equity, debt or otherwise) have been converted into Common Stock.

(h) The terms "register," "registered" and "registration" shall refer to a registration effected by preparing and filing a Registration Statement in compliance with the Securities Act, and such Registration Statement becoming effective under the Securities Act.

(i) "Registration Expenses" shall mean all expenses incurred by the Company in effecting any registration pursuant to this Agreement, including, without limitation, all registration, qualification, and filing fees, printing expenses, escrow fees, fees and disbursements of counsel for the Company, up to $50,000 of reasonable legal expenses of one special counsel for Investors (if different from the Company's counsel and if such counsel is reasonably approved by the Company) in connection with the preparation and filing of the Resale Registration Shelf (as defined below), and up to $50,000 of reasonable legal expenses of one special counsel for Investors (if different from the Company's counsel and if such counsel is reasonably approved by the Company) per underwritten public offering, blue sky fees and expenses, and expenses of any regular or special audits incident to or required by any such registration, but shall not include Selling Expenses.

(j) "Registration Statement" means any registration statement of the Company filed with, or to be filed with, the SEC under the Securities Act, including the related prospectus, amendments and supplements to such registration statement, including pre- and post-effective amendments, and all exhibits and all material incorporated by reference in such registration statement as may be necessary to comply with applicable securities laws other than a registration statement (and related prospectus) filed on Form S-4 or Form S-8 or any successor forms thereto.

(k) "Rule 144" shall mean Rule 144 as promulgated by the Commission under the Securities Act, as such rule may be amended from time to time, or any similar successor rule that may be promulgated by the Commission.

(l) "Securities Act" shall mean the Securities Act of 1933, as amended, or any similar successor federal statute and the rules and regulations thereunder, all as the same shall be in effect from time to time.

(m) "Selling Expenses" shall mean all underwriting discounts and selling commissions applicable to the sale of Registrable Securities, the fees and expenses of any legal counsel (except as provided in the definition of "Registration Expenses") and any other advisors any of

the Investors engage and all similar fees and commissions relating to the Investors' disposition of the Registrable Securities.

Section 2.
Resale Registration Rights

2.1. Resale Registration Rights.

(a) Following demand by any Investor, the Company shall file with the Commission a Registration Statement on Form S-3 (except if the Company is not then eligible to register for resale the Registrable Securities on Form S-3, in which case such registration shall be on another appropriate form in accordance with the Securities Act) covering the resale of the Registrable Securities by the Investors (the "Resale Registration Shelf"), and the Company shall file such Resale Registration Shelf as promptly as reasonably practicable following such demand, and in any event within sixty (60) days of such demand. Such Resale Registration Shelf shall include a "final" prospectus, including the information required by Item 507 of Regulation S-K of the Securities Act, as provided by the Investors in accordance with Section 2.7. Notwithstanding the foregoing, before filing the Resale Registration Shelf, the Company shall furnish to the Investors a copy of the Resale Registration Shelf and afford the Investors an opportunity to review and comment on the Resale Registration Shelf. The Company's obligation pursuant to this Section 2.1(a) is conditioned upon the Investors providing the information contemplated in Section 2.7.

(b) The Company shall use its reasonable best efforts to cause the Resale Registration Shelf and related prospectuses to become effective as promptly as practicable after filing. The Company shall use its reasonable best efforts to cause such Registration Statement to remain effective under the Securities Act until the earlier of the date (i) all Registrable Securities covered by the Resale Registration Shelf have been sold or may be sold freely without limitations or restrictions as to volume or manner of sale pursuant to Rule 144 or (ii) all Registrable Securities covered by the Resale Registration Shelf otherwise cease to be Registrable Securities pursuant to the definition of Registrable Securities. The Company shall promptly, and within two (2) business days after the Company confirms effectiveness of the Resale Registration Shelf with the Commission, notify the Investors of the effectiveness of the Resale Registration Shelf.

(c) Notwithstanding anything contained herein to the contrary, the Company shall not be obligated to effect, or to take any action to effect, a registration pursuant to Section 2.1(a):

(i) if the Company has and maintains an effective Registration Statement on Form S-3ASR that provides for the resale of an unlimited number of securities by selling stockholders (a "Company Registration Shelf");

(ii) during the period forty-five (45) days prior to the Company's good faith estimate of the date of filing of a Company Registration Shelf; or

(iii) if the Company has caused a Registration Statement to become effective pursuant to this Section 2.1 during the prior twelve (12) month period.

(d) If the Company has a Company Registration Shelf in place at any time in which the Investors make a demand pursuant to Section 2.1(a), the Company shall file with the Commission, as promptly as practicable, and in any event within fifteen (15) business days after such demand, a "final" prospectus supplement to its Company Registration Shelf covering the resale of the Registrable Securities by the Investors (the "Prospectus"); provided, however, that the Company shall not be obligated to file more than one Prospectus pursuant to this Section 2.1(d) in any six month period to add additional Registrable Securities to the Company Registration Shelf that were acquired by the Investors other than directly from the Company or in an underwritten public offering by the Company. The Prospectus shall include the information required under Item 507 of Regulation S-K of the Securities Act, which information shall be provided by the Investors in accordance with Section 2.7. Notwithstanding the foregoing, before filing the Prospectus, the Company shall furnish to the Investors a copy of the Prospectus and afford the Investors an opportunity to review and comment on the Prospectus.

(e) Deferral and Suspension. At any time after being obligated to file a Resale Registration Shelf or Prospectus, or after any Resale Registration Shelf has become effective or a Prospectus filed with the Commission, the Company may defer the filing of or suspend the use of any such Resale Registration Shelf or Prospectus, upon giving written notice of such action to the Investors with a certificate signed by the Principal Executive Officer of the Company stating that in the good faith judgment of the Board, the filing or use of any such Resale Registration Shelf or Prospectus covering the Registrable Securities would be seriously detrimental to the Company or its stockholders at such time and that the Board concludes, as a result, that it is in the best interests of the Company and its stockholders to defer the filing or suspend the use of such Resale Registration Shelf or Prospectus at such time. The Company shall have the right to defer the filing of or suspend the use of such Resale Registration Shelf or Prospectus for a period of not more than one hundred twenty (120) days from the date the Company notifies the Investors of such deferral or suspension; provided that the Company shall not exercise the right contained in this Section 2.1(e) more than once in any twelve month period. In the case of the suspension of use of any effective Resale Registration Shelf or Prospectus, the Investors, immediately upon receipt of notice thereof from the Company, shall discontinue any offers or sales of Registrable Securities pursuant to such Resale Registration Shelf or Prospectus until advised in writing by the Company that the use of such Resale Registration Shelf or Prospectus may be resumed. In the case of a deferred Prospectus or Resale Registration Shelf filing, the Company shall provide prompt written notice to the Investors of (i) the Company's decision to file or seek effectiveness of the Prospectus or Resale Registration Shelf, as the case may be, following such deferral and (ii) in the case of a Resale Registration Shelf, the effectiveness of such Resale Registration Shelf. In the case of either a suspension of use of, or deferred filing of, any Resale Registration Shelf or Prospectus, the Company shall not, during the pendency of such suspension or deferral, be required to take any action hereunder (including any action pursuant to Section 2.2 hereof) with respect to the registration or sale of any Registrable Securities pursuant to any such Resale Registration Shelf, Company Registration Shelf or Prospectus.

(f) Other Securities. Subject to Section 2.2(e) below, any Resale Registration Shelf or Prospectus may include Other Securities, and may include securities of the Company being sold for the account of the Company; provided such Other Securities are excluded first from such Registration Statement in order to comply with any applicable laws or request from any Government Entity, Nasdaq or any applicable listing agency. For the avoidance of doubt, no

Other Securities may be included in an underwritten offering pursuant to Section 2.2 without the consent of the Investors.

2.2. Sales and Underwritten Offerings of the Registrable Securities.

(a) Notwithstanding any provision contained herein to the contrary, the Investors, collectively, shall and subject to the limitations set forth in this Section 2.2, be permitted one underwritten public offering per calendar year, but no more than three underwritten public offerings in total, to effect the sale or distribution of Registrable Securities.

(b) If the Investors intend to effect an underwritten public offering pursuant to a Resale Registration Shelf or Company Registration Shelf to sell or otherwise distribute Registrable Securities, they shall so advise the Company and provide as much notice to the Company as reasonably practicable (and in any event not less than fifteen (15) business days prior to the Investors' request that the Company file a prospectus supplement to a Resale Registration Shelf or Company Registration Shelf).

(c) In connection with any offering initiated by the Investors pursuant to this Section 2.2 involving an underwriting of shares of Registrable Securities, the Investors shall be entitled to select the underwriter or underwriters for such offering, subject to the consent of the Company, such consent not to be unreasonably withheld, conditioned or delayed.

(d) In connection with any offering initiated by the Investors pursuant to this Section 2.2 involving an underwriting of shares of Registrable Securities, the Company shall not be required to include any of the Registrable Securities in such underwriting unless the Investors (i) enter into an underwriting agreement in customary form with the underwriter or underwriters, (ii) accept customary terms in such underwriting agreement with regard to representations and warranties relating to ownership of the Registrable Securities and authority and power to enter into such underwriting agreement and (iii) complete and execute all questionnaires, powers of attorney, custody agreements, indemnities and other documents as may be requested by such underwriter or underwriters. Further, the Company shall not be required to include any of the Registrable Securities in such underwriting if (Y) the underwriting agreement proposed by the underwriter or underwriters contains representations, warranties or conditions that are not reasonable in light of the Company's then-current business or (Z) the underwriter, underwriters or the Investors require the Company to participate in any marketing, road show or comparable activity that may be required to complete the orderly sale of shares by the underwriter or underwriters.

(e) If the total amount of securities to be sold in any offering initiated by the Investors pursuant to this Section 2.2 involving an underwriting of shares of Registrable Securities exceeds the amount that the underwriters determine in their sole discretion is compatible with the success of the offering, then the Company shall be required to include in the offering only that number of such securities, including Registrable Securities (subject in each case to the cutback provisions set forth in this Section 2.2(e)), that the underwriters and the Company determine in their sole discretion shall not jeopardize the success of the offering. If the underwritten public offering has been requested pursuant to Section 2.2(a) hereof, the number of shares that are entitled to be included in the registration and underwriting shall be allocated in the following manner: (a) first,

shares of Company equity securities that the Company desires to include in such registration shall be excluded and (b) second, Registrable Securities requested to be included in such registration by the Investors shall be excluded. To facilitate the allocation of shares in accordance with the above provisions, the Company or the underwriters may round down the number of shares allocated to any of the Investors to the nearest 100 shares.

2.3. Fees and Expenses. All Registration Expenses incurred in connection with registrations pursuant to this Agreement shall be borne by the Company. All Selling Expenses relating to securities registered on behalf of the Investors shall be borne by the Investors.

2.4. Registration Procedures. In the case of each registration of Registrable Securities effected by the Company pursuant to Section 2.1 hereof, the Company shall keep the Investors advised as to the initiation of each such registration and as to the status thereof. The Company shall use its reasonable best efforts, within the limits set forth in this Section 2.4, to:

(a) prepare and file with the Commission such amendments and supplements to such Registration Statement and the prospectuses used in connection with such Registration Statement as may be necessary to keep such Registration Statement effective and current and comply with the provisions of the Securities Act with respect to the disposition of all securities covered by such Registration Statement;

(b) furnish to the Investors such numbers of copies of a prospectus, including preliminary prospectuses, in conformity with the requirements of the Securities Act, and such other documents as the Investors may reasonably request in order to facilitate the disposition of Registrable Securities;

(c) use its reasonable best efforts to register and qualify the Registrable Securities covered by such Registration Statement under such other securities or blue sky laws of such jurisdictions in the United States as shall be reasonably requested by the Investors, provided that the Company shall not be required in connection therewith or as a condition thereto to qualify to do business or to file a general consent to service of process in any such states or jurisdictions;

(d) in the event of any underwritten public offering, and subject to Section 2.2(d), enter into and perform its obligations under an underwriting agreement, in usual and customary form, with the managing underwriter of such offering and take such other usual and customary action as the Investors may reasonably request in order to facilitate the disposition of such Registrable Securities;

(e) notify the Investors at any time when a prospectus relating to a Registration Statement covering any Registrable Securities is required to be delivered under the Securities Act of the happening of any event as a result of which the prospectus included in such Registration Statement, as then in effect, includes an untrue statement of a material fact or omits to state a material fact required to be stated therein or necessary to make the statements therein not misleading in the light of the circumstances then existing. The Company shall use its reasonable best efforts to amend or supplement such prospectus in order to cause such prospectus not to include any untrue statement of a material fact or omit to state a material fact required to

be stated therein or necessary to make the statements therein not misleading in the light of the circumstances then existing;

(f) provide a transfer agent and registrar for all Registrable Securities registered pursuant to such Registration Statement and, if required, a CUSIP number for all such Registrable Securities, in each case not later than the effective date of such registration;

(g) if requested by an Investor, use reasonable best efforts to cause the Company's transfer agent to remove any restrictive legend from any Registrable Securities, within two business days following such request;

(h) cause to be furnished, at the request of the Investors, on the date that Registrable Securities are delivered to underwriters for sale in connection with an underwritten offering pursuant to this Agreement, (i) an opinion, dated such date, of the counsel representing the Company for the purposes of such registration, in form and substance as is customarily given to underwriters in an underwritten public offering, addressed to the underwriters, and (ii) a letter or letters from the independent certified public accountants of the Company, in form and substance as is customarily given by independent certified public accountants to underwriters in an underwritten public offering, addressed to the underwriters; and

(i) cause all such Registrable Securities included in a Registration Statement pursuant to this Agreement to be listed on each securities exchange or other securities trading markets on which Common Stock is then listed.

2.5. The Investors Obligations.

(a) Discontinuance of Distribution. The Investors agree that, upon receipt of any notice from the Company of the occurrence of any event of the kind described in Section 2.4(e) hereof, the Investors shall immediately discontinue disposition of Registrable Securities pursuant to any Registration Statement covering such Registrable Securities until the Investors' receipt of the copies of the supplemented or amended prospectus contemplated by Section 2.4(e) hereof or receipt of notice that no supplement or amendment is required and that the Investors' disposition of the Registrable Securities may be resumed. The Company may provide appropriate stop orders to enforce the provisions of this Section 2.5(a).

(b) Compliance with Prospectus Delivery Requirements. The Investors covenant and agree that they shall comply with the prospectus delivery requirements of the Securities Act as applicable to them or an exemption therefrom in connection with sales of Registrable Securities pursuant to any Registration Statement filed by the Company pursuant to this Agreement.

(c) Notification of Sale of Registrable Securities. The Investors covenant and agree that they shall notify the Company following the sale of Registrable Securities to a third party as promptly as reasonably practicable, and in any event within thirty (30) days, following the sale of such Registrable Securities.

2.6. Indemnification.

(a) To the extent permitted by law, the Company shall indemnify the Investors, and, as applicable, their officers, directors, and constituent partners, legal counsel for each Investor and each Person controlling the Investors, with respect to which registration, related qualification, or related compliance of Registrable Securities has been effected pursuant to this Agreement, and each underwriter, if any, and each Person who controls any underwriter within the meaning of the Securities Act against all claims, losses, damages, or liabilities (or actions in respect thereof) to the extent such claims, losses, damages, or liabilities arise out of or are based upon (i) any untrue statement (or alleged untrue statement) of a material fact contained in any prospectus or other document (including any related Registration Statement) incident to any such registration, qualification, or compliance, or (ii) any omission (or alleged omission) to state therein a material fact required to be stated therein or necessary to make the statements therein not misleading, or (iii) any violation or alleged violation by the Company of the Securities Act, the Exchange Act, any state securities law, or any rule or regulation promulgated under the Securities Act, the Exchange Act or any state securities law applicable to the Company and relating to action or inaction required of the Company in connection with any such registration, qualification, or compliance; and the Company shall pay as incurred to the Investors, each such underwriter, and each Person who controls the Investors or underwriter, any legal and any other expenses reasonably incurred in connection with investigating or defending any such claim, loss, damage, liability, or action; provided, however, that the indemnity contained in this Section 2.6(a) shall not apply to amounts paid in settlement of any such claim, loss, damage, liability, or action if settlement is effected without the consent of the Company (which consent shall not unreasonably be withheld); and provided, further, that the Company shall not be liable in any such case to the extent that any such claim, loss, damage, liability, or expense arises out of or is based upon any violation by such Investor of the obligations set forth in Section 2.5 hereof or any untrue statement or omission contained in such prospectus or other document based upon written information furnished to the Company by the Investors, such underwriter, or such controlling Person and stated to be for use therein.

(b) To the extent permitted by law, each Investor (severally and not jointly) shall, if Registrable Securities held by such Investor are included for sale in the registration and related qualification and compliance effected pursuant to this Agreement, indemnify the Company, each of its directors, each officer of the Company who signs the applicable Registration Statement, each legal counsel and each underwriter of the Company’s securities covered by such a Registration Statement, each Person who controls the Company or such underwriter within the meaning of the Securities Act against all claims, losses, damages, and liabilities (or actions in respect thereof) arising out of or based upon (i) any untrue statement (or alleged untrue statement) of a material fact contained in any such Registration Statement, or related document, or (ii) any omission (or alleged omission) to state therein a material fact required to be stated therein or necessary to make the statements therein not misleading, or (iii) any violation or alleged violation by such Investor of Section 2.5 hereof, the Securities Act, the Exchange Act, any state securities law, or any rule or regulation promulgated under the Securities Act, the Exchange Act or any state securities law applicable to such Investor and relating to action or inaction required of such Investor in connection with any such registration and related qualification and compliance, and shall pay as incurred to such persons, any legal and any other expenses reasonably incurred in connection with investigating or defending any such claim, loss,

damage, liability, or action, in each case only to the extent that such untrue statement (or alleged untrue statement) or omission (or alleged omission) is made in (and such violation pertains to) such Registration Statement or related document in reliance upon and in conformity with written information furnished to the Company by such Investor and stated to be specifically for use therein; provided, however, that the indemnity contained in this Section 2.6(b) shall not apply to amounts paid in settlement of any such claim, loss, damage, liability, or action if settlement is effected without the consent of such Investor (which consent shall not unreasonably be withheld); provided, further, that such Investor's liability under this Section 2.6(b) (when combined with any amounts such Investor is liable for under Section 2.6(d)) shall not exceed such Investor's net proceeds from the offering of securities made in connection with such registration.

(c) Promptly after receipt by an indemnified party under this Section 2.6 of notice of the commencement of any action, such indemnified party shall, if a claim in respect thereof is to be made against an indemnifying party under this Section 2.6, notify the indemnifying party in writing of the commencement thereof and generally summarize such action. The indemnifying party shall have the right to participate in and to assume the defense of such claim; provided, however, that the indemnifying party shall be entitled to select counsel for the defense of such claim with the approval of any parties entitled to indemnification, which approval shall not be unreasonably withheld; provided further, however, that if either party reasonably determines that there may be a conflict between the position of the Company and the Investors in conducting the defense of such action, suit, or proceeding by reason of recognized claims for indemnity under this Section 2.6, then counsel for such party shall be entitled to conduct the defense to the extent reasonably determined by such counsel to be necessary to protect the interest of such party. The failure to notify an indemnifying party promptly of the commencement of any such action, if prejudicial to the ability of the indemnifying party to defend such action, shall relieve such indemnifying party, to the extent so prejudiced, of any liability to the indemnified party under this Section 2.6, but the omission so to notify the indemnifying party shall not relieve such party of any liability that such party may have to any indemnified party otherwise than under this Section 2.6.

(d) If the indemnification provided for in this Section 2.6 is held by a court of competent jurisdiction to be unavailable to an indemnified party with respect to any loss, liability, claim, damage, or expense referred to therein, then the indemnifying party, in lieu of indemnifying such indemnified party hereunder, shall contribute to the amount paid or payable by such indemnified party as a result of such loss, liability, claim, damage, or expense in such proportion as is appropriate to reflect the relative fault of the indemnifying party on the one hand and of the indemnified party on the other in connection with the statements or omissions that resulted in such loss, liability, claim, damage, or expense as well as any other relevant equitable considerations. The relative fault of the indemnifying party and of the indemnified party shall be determined by reference to, among other things, whether the untrue or alleged untrue statement of a material fact or the omission to state a material fact relates to information supplied by the indemnifying party or by the indemnified party and the parties' relative intent, knowledge, access to information, and opportunity to correct or prevent such statement or omission. In no event, however, shall (i) any amount due for contribution hereunder be in excess of the amount that would otherwise be due under Section 2.6(a) or Section 2.6(b), as applicable, based on the limitations of such provisions and (ii) a Person guilty of fraudulent misrepresentation (within the

meaning of the Securities Act) be entitled to contribution from a Person who was not guilty of such fraudulent misrepresentation.

(e) Notwithstanding the foregoing, to the extent that the provisions on indemnification and contribution contained in the underwriting agreement entered into in connection with an underwritten public offering are in conflict with the foregoing provisions, the provisions in the underwriting agreement shall control; provided, however, that the failure of the underwriting agreement to provide for or address a matter provided for or addressed by the foregoing provisions shall not be a conflict between the underwriting agreement and the foregoing provisions.

(f) The obligations of the Company and the Investors under this Section 2.6 shall survive the completion of any offering of Registrable Securities in a Registration Statement under this Agreement or otherwise.

2.7. Information. The Investors shall furnish to the Company such information regarding the Investors and the distribution proposed by the Investors as the Company may reasonably request and as shall be reasonably required in connection with any registration referred to in this Agreement. The Investors agree to, as promptly as practicable (and in any event prior to any sales made pursuant to a prospectus), furnish to the Company all information required to be disclosed in order to make the information previously furnished to the Company by the Investors not misleading. The Investors agree to keep confidential the receipt of any notice received pursuant to Section 2.4(e) and the contents thereof, except as required pursuant to applicable law. Notwithstanding anything to the contrary herein, the Company shall be under no obligation to name the Investors in any Registration Statement if the Investors have not provided the information required by this Section 2.7 with respect to the Investors as a selling securityholder in such Registration Statement or any related prospectus.

2.8. Rule 144 Requirements. With a view to making available to the Investors the benefits of Rule 144 promulgated under the Securities Act and any other rule or regulation of the Commission that may at any time permit the Investors to sell Registrable Securities to the public without registration, the Company agrees to use its reasonable best efforts to:

(a) make and keep public information available, as those terms are understood and defined in Rule 144 under the Securities Act at all times after the date hereof;

(b) file with the Commission in a timely manner all reports and other documents required of the Company under the Securities Act and the Exchange Act;

(c) prior to the filing of the Registration Statement or any amendment thereto (whether pre-effective or post-effective), and prior to the filing of any prospectus or prospectus supplement related thereto, to provide the Investors with copies of all of the pages thereof (if any) that reference the Investors; and

(d) furnish to any Investor, so long as the Investor owns any Registrable Securities, forthwith upon request (i) a written statement by the Company that it has complied with the reporting requirements of Rule 144, (ii) a copy of the most recent annual or quarterly report of the Company and such other reports and documents so filed by the Company, and (iii) such other

information as may be reasonably requested by an Investor in availing itself of any rule or regulation of the Commission which permits an Investor to sell any such securities without registration.

Section 3.
Miscellaneous

3.1. Amendment. No amendment, alteration or modification of any of the provisions of this Agreement shall be binding unless made in writing and signed by each of the Company and the Investors.

3.2. Injunctive Relief. It is hereby agreed and acknowledged that it shall be impossible to measure in money the damages that would be suffered if the parties fail to comply with any of the obligations herein imposed on them and that in the event of any such failure, an aggrieved Person shall be irreparably damaged and shall not have an adequate remedy at law. Any such Person shall, therefore, be entitled (in addition to any other remedy to which it may be entitled in law or in equity) to injunctive relief, including, without limitation, specific performance, to enforce such obligations, and if any action should be brought in equity to enforce any of the provisions of this Agreement, none of the parties hereto shall raise the defense that there is an adequate remedy at law.

3.3. Notices. All notices required or permitted under this Agreement must be in writing and sent to the address or facsimile number identified below. Notices must be given: (a) by personal delivery, with receipt acknowledged; (b) by facsimile followed by hard copy delivered by the methods under clause (c) or (d); (c) by prepaid certified or registered mail, return receipt requested; or (d) by prepaid reputable overnight delivery service. Notices shall be effective upon receipt. Either party may change its notice address by providing the other party written notice of such change. Notices shall be delivered as follows:

If to the Investors: At such Investor's address as set forth on Schedule A hereto

If to the Company: Idera Pharmaceuticals, Inc.
505 Eagleview Blvd., Suite 212
Exton, Pennsylvania 19341
Attn: Chief Financial Officer
Attn: General Counsel

with a copy to: Morgan, Lewis & Bockius LLP
1701 Market Street
Philadelphia, Pennsylvania 19103-2921
Attn: Joanne R. Soslow, Esq.

3.4. Governing Law; Jurisdiction; Venue; Jury Trial.

(a) This Agreement shall be governed by, and construed in accordance with, the law of the State of New York without giving effect to any choice or conflict of law provision or rule

(whether of the State of New York or any other jurisdiction) that would cause the application of the laws of any jurisdiction other than the State of New York.

(b) Each of the Company and the Investors irrevocably and unconditionally submits, for itself and its property, to the nonexclusive jurisdiction of the courts of the State of New York sitting in the Borough of Manhattan, New York and of the United States District Court of the Southern District of New York, and any appellate court from any thereof, in any action or proceeding arising out of or relating to this Agreement and the transactions contemplated herein, or for recognition or enforcement of any judgment, and each of the Company and the Investors irrevocably and unconditionally agrees that all claims in respect of any such action or proceeding may be heard and determined in such New York state court or, to the fullest extent permitted by applicable law, in such federal court. Each of the Company and the Investors hereto agrees that a final judgment in any such action or proceeding shall be conclusive and may be enforced in other jurisdictions by suit on the judgment or in any other manner provided by law.

(c) Each of the Company and the Investors irrevocably and unconditionally waives, to the fullest extent permitted by applicable law, any objection that it may now or hereafter have to the laying of venue of any action or proceeding arising out of or relating to this Agreement and the transactions contemplated herein in any court referred to in Section 3.4(b) hereof. Each of the Company and the Investors hereby irrevocably waives, to the fullest extent permitted by applicable law, the defense of an inconvenient forum to the maintenance of such action or proceeding in any such court.

(d) EACH OF THE COMPANY AND THE INVESTORS HEREBY IRREVOCABLY WAIVES, TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, ANY RIGHT IT MAY HAVE TO A TRIAL BY JURY IN ANY LEGAL PROCEEDING DIRECTLY OR INDIRECTLY ARISING OUT OF OR RELATING TO THIS AGREEMENT OR THE TRANSACTIONS CONTEMPLATED HEREBY (WHETHER BASED ON CONTRACT, TORT OR ANY OTHER THEORY). EACH OF THE COMPANY AND THE INVESTORS (A) CERTIFIES THAT NO REPRESENTATIVE, AGENT OR ATTORNEY OF ANY OTHER PERSON HAS REPRESENTED, EXPRESSLY OR OTHERWISE, THAT SUCH OTHER PERSON WOULD NOT, IN THE EVENT OF LITIGATION, SEEK TO ENFORCE THE FOREGOING WAIVER AND (B) ACKNOWLEDGES THAT EACH OF THE COMPANY AND THE INVESTORS HAS BEEN INDUCED TO ENTER INTO THIS AGREEMENT BY, AMONG OTHER THINGS, THE MUTUAL WAIVERS AND CERTIFICATIONS IN THIS SECTION.

3.5. Successors, Assigns and Transferees. Any and all rights, duties and obligations hereunder shall not be assigned, transferred, delegated or sublicensed by any party hereto without the prior written consent of the other party; provided, however, that the Investors shall be entitled to transfer Registrable Securities to one or more of their affiliates and, solely in connection therewith, may assign their rights hereunder in respect of such transferred Registrable Securities, in each case, so long as such Investor is not relieved of any liability or obligations hereunder, without the prior consent of the Company. Any transfer or assignment made other than as provided in the first sentence of this Section 3.5 shall be null and void. Subject to the foregoing and except as otherwise provided herein, the provisions of this Agreement shall inure to the benefit of, and be binding upon, the successors, permitted assigns, heirs, executors and

administrators of the parties hereto. The Company shall not consummate any recapitalization, merger, consolidation, reorganization or other similar transaction whereby stockholders of the Company receive (either directly, through an exchange, via dividend from the Company or otherwise) equity (the "Other Equity") in any other entity (the "Other Entity") with respect to Registrable Securities hereunder, unless prior to the consummation thereof, the Other Entity assumes, by written instrument, the obligations under this Agreement with respect to such Other Equity as if such Other Equity were Registrable Securities hereunder.

3.6. Entire Agreement. This Agreement, together with any exhibits hereto, constitute the entire agreement between the parties relating to the subject matter hereof and all previous agreements or arrangements between the parties, written or oral, relating to the subject matter hereof are superseded.

3.7. Waiver. No failure on the part of either party hereto to exercise any power, right, privilege or remedy under this Agreement, and no delay on the part of either party hereto in exercising any power, right, privilege or remedy under this Agreement, shall operate as a waiver thereof; and no single or partial exercise of any such power, right, privilege or remedy shall preclude any other or further exercise thereof or of any other power, right, privilege or remedy.

3.8. Severability. If any part of this Agreement is declared invalid or unenforceable by any court of competent jurisdiction, such declaration shall not affect the remainder of the Agreement and the invalidated provision shall be revised in a manner that shall render such provision valid while preserving the parties' original intent to the maximum extent possible.

3.9. Titles and Subtitles. The titles and subtitles used in this Agreement are used for convenience only and are not to be considered in construing or interpreting this Agreement. All references in this Agreement to sections, paragraphs and exhibits shall, unless otherwise provided, refer to sections and paragraphs hereof and exhibits attached hereto.

3.10. Counterparts. This Agreement may be executed in any number of counterparts, each of which shall be enforceable against the parties that execute such counterparts (including by facsimile or other electronic means), and all of which together shall constitute one instrument.

3.11. Term and Termination. The Investors' rights to demand the registration of the Registrable Securities under this Agreement, as well as the Company's obligations hereunder other than pursuant to Section 2.6 hereof, shall terminate automatically once all Registrable Securities cease to be Registrable Securities pursuant to the terms of this Agreement.

[*Remainder of Page Intentionally Left Blank; Signature Page Follows*]

IN WITNESS WHEREOF, the parties hereto have executed this Registration Rights Agreement effective as of the day, month and year first above written.

IDERA PHARMACEUTICALS, INC.

By: /s/ Vincent J. Milano
Name: Vincent J. Milano
Title: Chief Executive Officer

IN WITNESS WHEREOF, the parties hereto have executed this Registration Rights Agreement effective as of the day, month and year first above written.

667, L.P.

By: BAKER BROS. ADVISORS LP, management company and investment adviser to **667, L.P.**, pursuant to authority granted to it by Baker Biotech Capital, L.P., general partner to 667, L.P., and not as the general partner.

By: /s/ Scott L. Lessing
Scott L. Lessing
President

BAKER BROTHERS LIFE SCIENCES, L.P.

By: BAKER BROS. ADVISORS LP, management company and investment adviser to **Baker Brothers Life Sciences, L.P**., pursuant to authority granted to it by Baker Brothers Life Sciences Capital, L.P., general partner to Baker Brothers Life Sciences, L.P., and not as the general partner.

By: /s/ Scott L. Lessing
Scott L. Lessing
President

Schedule A

The Investors

667, L.P.
BAKER BROTHERS LIFE SCIENCES, L.P.

Exhibit 4.12

Execution Copy

VOTING AGREEMENT

THIS VOTING AGREEMENT (this "**Agreement**") is entered into as of December 23, 2019, by and among the investors who are signatories hereto (each, an "**Investor**" and collectively, the "**Investors**") and Idera Pharmaceuticals, Inc., a Delaware corporation (the "**Company**"). Capitalized terms used herein but not otherwise defined shall have the meaning given to them in the Purchase Agreement (as defined below).

BACKGROUND

The execution and delivery of this Agreement by the Investors is a material inducement to the willingness of the Company to enter into that certain Securities Purchase Agreement, dated as of the date hereof (the "**Purchase Agreement**"), by and among the Company and the Investors, pursuant to which, subject to the terms and conditions set forth in the Purchase Agreement, the Investors may purchase Securities.

In consideration of the promises and the covenants and agreements set forth in the Purchase Agreement and in this Agreement, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto hereby agree as follows:

1. Shares Subject to this Agreement. The Investors each agree to hold all shares of voting capital stock of the Company registered in their respective names or beneficially owned by them and/or over which they exercise voting control as of the date of this Agreement and any other shares of voting capital stock of the Company legally or beneficially held or acquired by them after the date hereof or over which they exercise voting control (the "**Shares**") subject to, and to vote the Shares in accordance with, the provisions of this Agreement.

2. Agreement to Vote Shares.

(a) In any annual, special or adjourned meeting of the stockholders of the Company at which the matter covered by the Required Shareholder Approval are presented to the Company's stockholders for approval, each Investor agrees that it will vote, by proxy or otherwise, its Shares (i) in favor of such matter and any matter that would reasonably be expected to facilitate such Required Shareholder Approval, and (ii) against approval of any proposal made in opposition to such matters. Each Investor shall retain at all times the right to vote its Shares in its sole discretion and without any other limitation on those matters other than those set forth in clauses (i) and (ii) of this Section 2(a) that are at any time or from time to time presented for consideration to the Company's stockholders generally.

(b) In the event that a meeting of the stockholders of the Company is held, each Investor shall, or shall cause the holder of record on any applicable record date to, appear at such meeting or otherwise cause such Investor's Shares to be counted as present thereat for purposes of establishing a quorum.

3. Representations, Warranties and Other Covenants of Investor. Each Investor, as to itself and not with respect to any other Investor, hereby represents, warrants and covenants to the Company as follows:

(a) Such Investor has all requisite power, legal capacity and authority to enter into this Agreement. This Agreement has been duly executed and delivered by Investor and, assuming the due authorization, execution and delivery of this Agreement by the Company, constitutes a valid and binding obligation of Investor, enforceable against Investor in accordance with its terms, except as limited by (a) applicable bankruptcy, insolvency, reorganization, moratorium, and other laws of general application affecting enforcement of creditors' rights generally, and (b) laws relating to the availability of specific performance, injunctive relief or other equitable remedies.

(b) The execution, delivery and performance of this Agreement by such Investor will not (i) conflict with, require a consent, waiver or approval under, or result in a breach of or default under, any of the terms of any agreement to which Investor is a party or by which any of such Investor's assets are bound or (ii) violate any order, writ, injunction, decree, judgment or any applicable law applicable to such Investor or any of its assets, except for any such conflict, violation or any failure to obtain such consent, waiver or approval that would not result in such Investor being able to perform its obligations under this Agreement.

(c) Such Investor shall not, directly or indirectly, take any action that would make any representation or warranty contained herein untrue or incorrect in any material respects or in any way have the effect of restricting, limiting, interfering with, preventing or disabling such Investor from performing his, her or its obligations in any material respects under this Agreement.

4. No Ownership Interest. Nothing contained in this Agreement shall be deemed to vest in the Company any direct or indirect ownership or incidence of ownership of or with respect to any Shares.

5. Miscellaneous.

(a) *Notices*. All notices, requests, and other communications hereunder shall be in writing and will be deemed to have been duly given and received (a) when personally delivered, (b) when sent by facsimile or email upon confirmation of receipt, (c) one business day after the day on which the same has been delivered prepaid to a nationally recognized courier service, or (d) five business days after the deposit in the United States mail, registered or certified, return receipt requested, postage prepaid, in each case addressed, as to the Company, to:

Idera Pharmaceuticals, Inc.
505 Eagleview Blvd., Suite 212
Exton, Pennsylvania 19341
Attn: General Couunsel

with copy to:
Morgan, Lewis & Bockius LLP
1701 Market Street
Philadelphia, Pennsylvania 19103-2921
Attn: Joanne R. Soslow, Esq.
Morgan, Lewis & Bockius LLP

and as to any Investor, at the address set forth below such Investor's signature on the signature pages of this Agreement. Any party hereto from time to time may change its address, facsimile number, or other information for the purpose of notices to that party by giving notice specifying such change to the other parties hereto. Each Investor and the Company may each agree in writing to accept notices and other communications to it hereunder by electronic communications pursuant to procedures reasonably approved by it; provided that approval of such procedures may be limited to particular notices or communications.

(b) *Amendments; Waiver*. This Agreement may be amended by the parties hereto, and the terms and conditions hereof may be waived, only by an instrument in writing and signed by the Company and the Investors. The failure of any party hereto to exercise any right, power or remedy provided under this Agreement or otherwise available in respect of this Agreement at law or in equity, or to insist upon compliance by any other party with its obligation under this Agreement, and any custom or practice of the parties at variance with the terms of this Agreement, shall not constitute a waiver by such party of such party's right to exercise any such or other right, power or remedy or to demand such compliance.

(c) *Rules of Construction*. The parties hereto hereby waive the application of any law, regulation, holding or rule of construction providing that ambiguities in an agreement or other document will be construed against the party drafting such agreement or document.

(d) *Counterparts*. This Agreement may be executed in one or more counterparts, all of which shall be considered one and the same instrument and shall become effective when one or more counterparts have been signed by each of the parties and delivered to the other parties hereto; it being understood that all parties need not sign the same counterpart.

(e) *Specific Performance; Injunctive Relief*. The parties hereto agree that the Company will be irreparably harmed and that there will be no adequate remedy at law for a violation of any of the covenants or agreements of any Investor set forth herein. Therefore, it is agreed that, in addition to any other remedies that may be available to the Company upon any such violation of this Agreement, the Company and the Investors shall have the right to enforce such covenants and agreements by specific performance, injunctive relief or by any other means available to the Company or the Investors at law or in equity and each Investor hereby waives any and all defenses which could exist in its favor in connection with such enforcement and waives any requirement for the security or posting of any bond in connection with such enforcement.

(f) *Additional Documents*. Investor shall execute and deliver any additional documents necessary or desirable in the reasonable opinion of the Company to carry out the purpose and intent of this Agreement.

(g) *Severability*. In the event that any provision of this Agreement, or the application thereof, becomes or is declared by a court of competent jurisdiction to be illegal, void or unenforceable, the remainder of this Agreement shall continue in full force and effect and the application of such provision to other persons or circumstances shall be interpreted so as reasonably to effect the intent of the parties hereto. The parties hereto further agree to use their commercially reasonable efforts to replace such void or unenforceable provision of this

Agreement with a valid and enforceable provision that shall achieve, to the extent possible, the economic, business and other purposes of such void or unenforceable provision.

(h) *Governing Law; Consent to Jurisdiction*. This Agreement, and the provisions, rights, obligations, and conditions set forth herein, and the legal relations between the parties hereto, including all disputes and claims, whether arising in contract, tort, or under statute, shall be governed by and construed in accordance with the laws of the State of New York without giving effect to its conflict of law provisions.

(i) *Expenses*. All costs and expenses incurred in connection with this Agreement and the transactions contemplated hereby shall be paid by the party incurring the expenses.

(j) *Termination*. This Agreement shall terminate and shall have no further force or effect from and after the earlier to occur of (i) date upon which the Company receives the Required Shareholder Approval, (ii) the termination of the Purchase Agreement in accordance with its terms and (iii) December 31, 2020, and thereafter there shall be no liability or obligation on the part of the Investors, provided, that no such termination shall relieve any party from liability for any willful or intentional breach of this Agreement prior to such termination.

(k) WAIVER OF JURY TRIAL. EACH OF THE PARTIES HERETO HEREBY IRREVOCABLY WAIVES ALL RIGHT TO TRIAL BY JURY IN ANY ACTION, PROCEEDING OR COUNTERCLAIM (WHETHER BASED ON CONTRACT, TORT, OR OTHERWISE) ARISING OUT OF OR RELATING TO THIS AGREEMENT OR THE ACTIONS OF ANY PARTY HERETO IN NEGOTIATION, ADMINISTRATION, PERFORMANCE OR ENFORCEMENT HEREOF.

IN WITNESS WHEREOF, the parties hereto have caused this **VOTING AGREEMENT** to be executed as of the date first written above.

IDERA PHARMACEUTICALS, INC.

By: /s/ Vincent J. Milano
Name: Vincent J. Milano
Title: Chief Executive Officer

IN WITNESS WHEREOF, the parties hereto have caused this **VOTING AGREEMENT** to be executed as of the date first written above.

667, L.P.

By: BAKER BROS. ADVISORS LP, management company and investment adviser to **667, L.P.**, pursuant to authority granted to it by Baker Biotech Capital, L.P., general partner to 667, L.P., and not as the general partner.

By: /s/ Scott L. Lessing
Scott L. Lessing
President

BAKER BROTHERS LIFE SCIENCES, L.P.

By: BAKER BROS. ADVISORS LP, management company and investment adviser to **Baker Brothers Life Sciences, L.P**., pursuant to authority granted to it by Baker Brothers Life Sciences Capital, L.P., general partner to Baker Brothers Life Sciences, L.P., and not as the general partner.

By: /s/ Scott L. Lessing
Scott L. Lessing
President

Exhibit 4.13

Execution Copy

WARRANT AMENDMENT AGREEMENT

This Warrant Amendment Agreement (this "Agreement"), dated as of December 23, 2019 (the "Effective Date"), by and between Idera Pharmaceuticals, Inc., a Delaware corporation (the "Company"), and each of the entities list on Schedule I hereto, as the Requisite Holders (as defined below). All capitalized terms used in this Agreement but not otherwise defined herein shall have the respective meanings ascribed to such terms in the Warrants (as defined below).

WHEREAS, on May 7, 2013, the Company issued to the Requisite Holders those certain Warrants to Purchase Common Stock to purchase shares of the Company's common stock, par value $0.001 per share (the "Common Stock"), at an exercise price equal to $0.08 per share (the "First Warrants");

WHEREAS, on September 30, 2013, the Company issued to the Requisite Holders those certain Warrants to Purchase Common Stock to purchase shares of Common Stock at an exercise price equal to $0.08 per share (the "Second Warrants");

WHEREAS, on February 10, 2014, the Company issued to the Requisite Holders those certain Warrants to Purchase Common Stock to purchase shares of Common Stock at an exercise price equal to $0.08 per share (the "Third Warrants", and together with the First Warrants and Second Warrants, the "Warrants");

WHEREAS, the Warrants were initially issued in the name of Piper Jaffray & Co.;

WHEREAS, the Warrants were transferred to be held as Global Warrant Agreements with a CUSIP in DTC;

WHEREAS, Section 16(d) of the First Warrants and Section 15(d) of the Second Warrants and the Third Warrants requires the written consent of the holders representing no less than a majority of the interest (based upon the number of Warrant Shares issuable upon exercise) of the outstanding Warrants, to amend or waive any terms of each of the Warrants (the "Requisite Holders");

WHEREAS, the undersigned constitute the Requisite Holders to amend each of the Warrants as the owner of a majority of the interest in the Warrants; and

WHEREAS, the Company and the Requisite Holder have agreed to amend and restate the Warrants to provide that such Warrants will be exercisable indefinitely.

NOW, THEREFORE, in consideration of the foregoing and the promises and covenants contained herein, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, and intending to be legally bound hereby, the undersigned hereby agree as follows:

1. Amendment and Restatement of the First Warrants. Effective upon the Effective Date, each of the First Warrants shall be amended and restated in the form attached hereto as Exhibit A.

2. Amendment and Restatement of the Second Warrants. Effective upon the Effective Date, each of the Second Warrants shall be amended and restated in the form attached hereto as Exhibit B.

3. Amendment and Restatement of the Third Warrants. Effective upon the Effective Date, each of the Third Warrants shall be amended and restated in the form attached hereto as Exhibit C.

4. Governing Law. In all respects, including all matters of construction, validity and performance, this Agreement and the obligations arising hereunder shall be governed by, and construed and enforced in accordance with, the laws of the State of New York (without regard to its conflicts of law principals) applicable to contracts made and performed in such state.

5. Counterparts; Facsimile. This Agreement may be executed in any number of counterparts, each of which shall be an original, but all of which together shall be deemed to constitute one instrument. Delivery of an executed signature page to this Agreement by facsimile or any other electronic transmission shall be as effective as delivery of a manually signed counterpart hereof.

6. Titles and Subtitles Headings. The titles of the sections and subsections of this Agreement are for convenience of reference only and are not to be considered in construing this Agreement.

7. Severability of this Agreement. If any provision of this Agreement shall be judicially determined to be invalid, illegal or unenforceable, the validity, legality and enforceability of the remaining provisions shall not in any way be affected or impaired thereby.

8. Further Assurances. At any time or from time to time after the date hereof, the parties agree to cooperate with each other, and at the request of any other party, to execute and deliver any further instruments or documents and to take all such further action as the other party may reasonably request in order to evidence or effectuate the consummation of the transactions contemplated hereby and to otherwise carry out the intent of the parties hereunder.

9. Entire Agreement. This Agreement embodies the entire agreement and understanding among the parties hereto and supersedes all prior or contemporaneous agreements and understandings of such parties, verbal or written, relating to the subject matter hereof.

[Remainder of Page Intentionally Left Blank]

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be duly executed by their respective authorized officers as of the date first above written.

COMPANY:

IDERA PHARMACEUTICALS, INC.

By: /s/ Bryant D. Lim
Name: Bryant D. Lim
Title: Senior Vice President, General Counsel

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be duly executed by their respective authorized officers as of the date first above written.

REQUISITE HOLDERS:

667, L.P.

By: BAKER BROS. ADVISORS LP, management company and investment adviser to **667, L.P.**, pursuant to authority granted to it by Baker Biotech Capital, L.P., general partner to 667, L.P., and not as the general partner.

By: /s/ Scott L. Lessing
Scott L. Lessing
President

BAKER BROTHERS LIFE SCIENCES, L.P.

By: BAKER BROS. ADVISORS LP, management company and investment adviser to **Baker Brothers Life Sciences, L.P**., pursuant to authority granted to it by Baker Brothers Life Sciences Capital, L.P., general partner to Baker Brothers Life Sciences, L.P., and not as the general partner.

By: /s/ Scott L. Lessing
Scott L. Lessing
President

SCHEDULE I

Requisite Holder	Issue Date
667, L.P.	May 7, 2013
667, L.P.	September 30, 2013
667, L.P.	February 10, 2014
Baker Brothers Life Sciences, L.P.	May 7, 2013
Baker Brothers Life Sciences, L.P.	September 30, 2013
Baker Brothers Life Sciences, L.P.	February 10, 2014

Exhibit A

Amendment and Restatement of the First Warrant

THE WARRANTS INITIALLY WILL BE REPRESENTED BY ONE OR MORE PERMANENT GLOBAL CERTIFICATES IN FULLY REGISTERED FORM AND WILL BE DEPOSITED WITH A CUSTODIAN FOR, AND REGISTERED IN THE NAME OF, A NOMINEE OF THE DEPOSITORY TRUST COMPANY, NEW YORK, NEW YORK ("DTC"), AS DEPOSITARY.

IDERA PHARMACEUTICALS, INC.

FORM OF AMENDED AND RESTATED WARRANT TO PURCHASE COMMON STOCK

Number of Shares: [●]
(subject to adjustment)
Original Issue Date: May 7, 2013
Re-issue Date: July 27, 2018
Warrant No. [●] Amendment Date: December [●], 2019

Idera Pharmaceuticals, Inc., a Delaware corporation (the "*Company*"), hereby certifies that, for good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, [●] or its permitted registered assigns (the "*Holder*"), is entitled, subject to the terms set forth below, to purchase from the Company up to a total of [●] shares of common stock, $0.001 par value per share (the "*Common Stock*"), of the Company (each such share, a "*Warrant Share*" and all such shares, the "*Warrant Shares*") at an exercise price per share equal to $0.08 per share (as adjusted from time to time as provided in Section 9 herein, the "*Exercise Price*"), upon surrender of this Warrant to Purchase Common Stock (including any Warrants to Purchase Common Stock issued in exchange, transfer or replacement hereof, the "*Warrant*") at any time and from time to time on or after the date hereof (the "*Original Issue Date*"), and subject to the following terms and conditions:

1. Definitions. For purposes of this Warrant, the following terms shall have the following meanings:

(a) "*Commission*" means the United States Securities and Exchange Commission.

(b) "*Closing Sale Price*" means, for any security as of any date, the last trade price for such security on the Principal Trading Market for such security, as reported by Bloomberg Financial Markets, or, if such Principal Trading Market begins to operate on an extended hours basis and does not designate the last trade price, then the last trade price of such security prior to 4:00 P.M., New York City time, as reported by Bloomberg Financial Markets, or if the foregoing do not apply, the last trade price of such security in the over-the-counter market on the electronic bulletin board for such security as reported by Bloomberg Financial Markets, or, if no last trade price is reported for such security by Bloomberg Financial Markets, the average of the bid and ask prices, of any market makers for such security as reported in the "pink sheets" by Pink Sheets LLC. If the Closing Sale Price cannot be calculated for a security on a particular date on any of the foregoing bases, the Closing Sale Price of such security on such date shall be the fair market value as mutually determined by the Company and the Holder. If the Company and the Holder are unable to agree upon the fair market value of such security, then the Board of Directors of the Company shall use its good faith judgment to determine the fair market value. The Board of Directors' determination shall be binding upon all parties absent demonstrable error. All such determinations shall be appropriately adjusted for any stock dividend, stock split, stock combination or other similar transaction during the applicable calculation period.

(c) "*Principal Trading Market*" means the Trading Market on which the Common Stock is primarily listed on and quoted for trading, which, as of the Original Issue Date shall be the Nasdaq Capital Market.

(d) "*Registration Statement*" means the Company's Registration Statement on Form S-1, as amended (File No. 333- 187155), initially filed on March 11, 2013.

(e) "*Securities Act*" means the Securities Act of 1933, as amended.

(f) "*Transfer Agent*" means Computershare Shareowner Services LLC, the Company's transfer agent for the Common Stock and Warrants.

2. Registration of Warrants. The Company shall register this Warrant, upon records to be maintained by the Company for that purpose (the "Warrant Register"), in the name of the record Holder (which shall include the initial Holder or, as the case may be, any registered assignee to which this Warrant is permissibly assigned hereunder) from time to time. The Company may deem and treat the registered Holder of this Warrant as the absolute owner hereof for the purpose of any exercise hereof or any distribution to the Holder, and for all other purposes, absent actual notice to the contrary.

3. Registration of Transfers. Subject to compliance with all applicable securities laws, the Company shall, or will cause its Transfer Agent to, register the transfer of all or any portion of this Warrant in the Warrant Register, upon surrender of this Warrant, and payment for all applicable transfer taxes. Upon any such registration or transfer, a new warrant to purchase Common Stock in substantially the form of this Warrant (any such new warrant, a "New Warrant") evidencing the portion of this Warrant so transferred shall be issued to the transferee, and a New Warrant evidencing the remaining portion of this Warrant not so transferred, if any, shall be issued to the transferring Holder. The acceptance of the New Warrant by the transferee thereof shall be deemed the

acceptance by such transferee of all of the rights and obligations in respect of the New Warrant that the Holder has in respect of this Warrant. The Company shall, or will cause its Transfer Agent to, prepare, issue and deliver at the Company's own expense any New Warrant under this Section 3. Until due presentment for registration of transfer, the Company may treat the registered Holder hereof as the owner and holder for all purposes, and the Company shall not be affected by any notice to the contrary.

4. Exercise and Duration of Warrants.

(a) All or any part of this Warrant shall be exercisable by the registered Holder in any manner permitted by Section 10 of this Warrant at any time and from time to time on or after the Original Issue Date. The rights represented by this Warrant shall have no termination date.

(b) The Holder may exercise this Warrant by delivering to the Company (i) an exercise notice, in the form attached as Schedule 1 hereto (the "Exercise Notice"), completed and duly signed, and (ii) payment of the Exercise Price for the number of Warrant Shares as to which this Warrant is being exercised (which may take the form of a "cashless exercise" if so indicated in the Exercise Notice and if a "cashless exercise" may occur at such time pursuant to Section 10 below), and the date on which the last of such items is delivered to the Company (as determined in accordance with the notice provisions hereof) is an "Exercise Date." The Holder shall not be required to deliver the original Warrant in order to effect an exercise hereunder. Execution and delivery of the Exercise Notice shall have the same effect as cancellation of the original Warrant and issuance of a New Warrant evidencing the right to purchase the remaining number of Warrant Shares.

5. Delivery of Warrant Shares.

(a) Upon exercise of this Warrant, the Company shall promptly (but in no event later than three (3) Trading Days after the Exercise Date), upon the request of the Holder, credit such aggregate number of shares of Common Stock to which the Holder is entitled pursuant to such exercise to the Holder's or its designee's balance account with The Depository Trust Company ("DTC") through its Deposit Withdrawal Agent Commission system, or if the Transfer Agent is not participating in the Fast Automated Securities Transfer Program (the "FAST Program") or if the certificates are required to bear a legend regarding restriction on transferability, issue and dispatch by overnight courier to the address as specified in the Exercise Notice, a certificate, registered in the Company's share register in the name of the Holder or its designee, for the number of shares of Common Stock to which the Holder is entitled pursuant to such exercise. The Holder, or any Person permissibly so designated by the Holder to receive Warrant Shares, shall be deemed to have become the holder of record of such Warrant Shares as of the Exercise Date, irrespective of the date such Warrant Shares are credited to the Holder's DTC account or the date of delivery of the certificates evidencing such Warrant Shares, as the case may be.

(b) If by the close of the third (3rd) Trading Day after the Exercise Date, the Company fails to deliver to the Holder a certificate representing the required number of Warrant Shares in the manner required pursuant to Section 5(a) or fails to credit the Holder's balance account with DTC for such number of Warrant Shares to which the Holder is entitled, and if after such third (3rd) Trading Day and prior to the receipt of such Warrant Shares, the Holder purchases (in an open market transaction or otherwise) shares of Common Stock to deliver in satisfaction of a sale by the Holder of the Warrant Shares which the Holder anticipated receiving upon such exercise (a "Buy-In"), then the Company shall, within three (3) Trading Days after the Holder's request and in the Holder's sole discretion, either (1) pay in cash to the Holder an amount equal to the Holder's total purchase price (including brokerage commissions, if any) for the shares of Common Stock so purchased (the "Buy-In Price"), at which point the Company's obligation to deliver such certificate (and to issue such Warrant Shares) shall terminate or (2) promptly honor its obligation to deliver to the Holder a certificate or certificates representing such Warrant Shares and pay cash to the Holder in an amount equal to the excess (if any) of Holder's total purchase price (including brokerage commissions, if any) for the shares of Common Stock so purchased in the Buy-In over the product of (A) the number of shares of Common Stock purchased in the Buy-In, times (B) the closing bid price of a share of Common Stock on the Exercise Date.

(c) To the extent permitted by law, the Company's obligations to issue and deliver Warrant Shares in accordance with and subject to the terms hereof (including the limitations set forth in Section 11 below) are absolute and unconditional, irrespective of any action or inaction by the Holder to enforce the same, any waiver or consent with respect to any provision hereof, the recovery of any judgment against any Person or any action to enforce the same, or any setoff, counterclaim, recoupment, limitation or termination, or any breach or alleged breach by the Holder or any other Person of any obligation to the Company or any violation or alleged violation of law by the Holder or any other Person, and irrespective of any other circumstance that might otherwise limit such obligation of the Company to the Holder in connection with the issuance of Warrant Shares. Nothing herein shall limit the Holder's right to pursue any other remedies available to it hereunder, at law or in equity including, without limitation, a decree of specific performance and/or injunctive relief with respect to the Company's failure to timely deliver certificates representing shares of Common Stock upon exercise of the Warrant as required pursuant to the terms hereof.

6. Charges, Taxes and Expenses. Issuance and delivery of certificates for shares of Common Stock upon exercise of this Warrant shall be made without charge to the Holder for any issue or transfer tax, transfer agent fee or other incidental tax or expense in respect of the issuance of such certificates, all of which taxes and expenses shall be paid by the Company; *provided, however,* that the Company shall not be required to pay any tax that may be payable in respect of any transfer involved in the registration of any

certificates for Warrant Shares or the Warrants in a name other than that of the Holder or an Affiliate thereof. The Holder shall be responsible for all other tax liability that may arise as a result of holding or transferring this Warrant or receiving Warrant Shares upon exercise hereof.

7. Replacement of Warrant. If this Warrant is mutilated, lost, stolen or destroyed, the Company shall issue or cause to be issued in exchange and substitution for and upon cancellation hereof, or in lieu of and substitution for this Warrant, a New Warrant, but only upon receipt of evidence reasonably satisfactory to the Company of such loss, theft or destruction (in such case) and, in each case, a customary and reasonable indemnity and surety bond, if requested by the Company. Applicants for a New Warrant under such circumstances shall also comply with such other reasonable regulations and procedures and pay such other reasonable third-party costs as the Company may prescribe. If a New Warrant is requested as a result of a mutilation of this Warrant, then the Holder shall deliver such mutilated Warrant to the Company as a condition precedent to the Company's obligation to issue the New Warrant.

8. Reservation of Warrant Shares. The Company covenants that it will at all times while this Warrant is outstanding reserve and keep available out of the aggregate of its authorized but unissued and otherwise unreserved Common Stock, solely for the purpose of enabling it to issue Warrant Shares upon exercise of this Warrant as herein provided, the number of Warrant Shares that are initially issuable and deliverable upon the exercise of this entire Warrant, free from preemptive rights or any other contingent purchase rights of persons other than the Holder (taking into account the adjustments and restrictions of Section 9). The Company covenants that all Warrant Shares so issuable and deliverable shall, upon issuance and the payment of the applicable Exercise Price in accordance with the terms hereof, be duly and validly authorized, issued and fully paid and nonassessable. The Company will take all such action as may be reasonably necessary to assure that such shares of Common Stock may be issued as provided herein without violation of any applicable law or regulation, or of any requirements of any securities exchange or automated quotation system upon which the Common Stock may be listed.

9. Certain Adjustments. The Exercise Price and number of Warrant Shares issuable upon exercise of this Warrant are subject to adjustment from time to time as set forth in this Section 9.

(a) Stock Dividends and Splits. If the Company, at any time while this Warrant is outstanding, (i) pays a stock dividend on its Common Stock or otherwise makes a distribution on any class of capital stock, other than Series E Preferred Stock or Series D Preferred Stock issued and outstanding on the Original Issue Date and in accordance with the terms of such stock on the Original Issue Date or as amended, as described in the Registration Statement, that is payable in shares of Common Stock, (ii) subdivides its outstanding shares of Common Stock into a larger number of shares of Common Stock, (iii) combines its outstanding shares of Common Stock into a smaller number of shares of Common Stock or (iv) issues by reclassification of shares of capital stock any additional shares of Common Stock of the Company, then in each such case the Exercise Price shall be multiplied by a fraction, the numerator of which shall be the number of shares of Common Stock outstanding immediately before such event and the denominator of which shall be the number of shares of Common Stock outstanding immediately after such event. Any adjustment made pursuant to clause (i) of this paragraph shall become effective immediately after the record date for the determination of stockholders entitled to receive such dividend or distribution, provided, however, that if such record date shall have been fixed and such dividend is not fully paid on the date fixed therefor, the Exercise Price shall be recomputed accordingly as of the close of business on such record date and thereafter the Exercise Price shall be adjusted pursuant to this paragraph as of the time of actual payment of such dividends. Any adjustment pursuant to clause (ii) or (iii) of this paragraph shall become effective immediately after the effective date of such subdivision or combination.

(b) Pro Rata Distributions. If the Company, at any time while this Warrant is outstanding, distributes to all holders of Common Stock for no consideration (i) evidences of its indebtedness, (ii) any security (other than a distribution of Common Stock covered by the preceding paragraph) or (iii) rights or warrants to subscribe for or purchase any security, or (iv) any other asset (in each case, *"Distributed Property"*), then, upon any exercise of this Warrant that occurs after the record date fixed for determination of stockholders entitled to receive such distribution, the Holder shall be entitled to receive, in addition to the Warrant Shares otherwise issuable upon such exercise (if applicable), the Distributed Property that such Holder would have been entitled to receive in respect of such number of Warrant Shares had the Holder been the record holder of such Warrant Shares immediately prior to such record date without regard to any limitation on exercise contained therein.

(c) Fundamental Transactions. If, at any time while this Warrant is outstanding (i) the Company effects any merger or consolidation of the Company with or into another Person, in which the Company is not the surviving entity or the stockholders of the Company immediately prior to such merger or consolidation do not own, directly or indirectly, at least 50% of the voting power of the surviving entity immediately after such merger or consolidation, (ii) the Company effects any sale to another Person of all or substantially all of its assets in one or a series of related transactions, (iii) pursuant to any tender offer or exchange offer (whether by the Company or another Person), holders of capital stock who tender shares representing more than 50% of the voting power of the capital stock of the Company and the Company or such other Person, as applicable, accepts such tender for payment, (iv) the Company consummates a stock purchase agreement or other business combination (including, without limitation, a reorganization, recapitalization, spin-off or scheme of arrangement) with another Person whereby such other Person acquires more than the 50% of the voting power of the capital stock of the Company or (v) the Company effects any reclassification of the Common Stock or any compulsory share exchange pursuant to which the Common Stock is effectively converted into or exchanged for other securities,

cash or property (other than as a result of a subdivision or combination of shares of Common Stock covered by Section 9(a) above) (in any such case, a "*Fundamental Transaction*"), then following such Fundamental Transaction the Holder shall have the right to receive, upon exercise of this Warrant, the same amount and kind of securities, cash or property as it would have been entitled to receive upon the occurrence of such Fundamental Transaction if it had been, immediately prior to such Fundamental Transaction, the holder of the number of Warrant Shares then issuable upon exercise in full of this Warrant without regard to any limitations on exercise contained herein (the "*Alternate Consideration*"). The Company shall not effect any Fundamental Transaction in which the Company is not the surviving entity or the Alternate Consideration includes securities of another Person unless prior to or simultaneously with the consummation thereof, any successor to the Company, surviving entity or other Person (including any purchaser of assets of the Company) shall assume the obligation to deliver to the Holder, such Alternate Consideration as, in accordance with the foregoing provisions, the Holder may be entitled to receive, and the other obligations under this Warrant. The provisions of this paragraph (c) shall similarly apply to subsequent transactions analogous of a Fundamental Transaction type.

(d) Number of Warrant Shares. Simultaneously with any adjustment to the Exercise Price pursuant to paragraphs (a) of this Section 9, the number of Warrant Shares that may be purchased upon exercise of this Warrant shall be increased or decreased proportionately, so that after such adjustment the aggregate Exercise Price payable hereunder for the increased or decreased number of Warrant Shares shall be the same as the aggregate Exercise Price in effect immediately prior to such adjustment.

(e) Calculations. All calculations under this Section 9 shall be made to the nearest cent or the nearest share, as applicable.

(f) Notice of Adjustments. Upon the occurrence of each adjustment pursuant to this Section 9, the Company at its expense will, at the written request of the Holder, promptly compute such adjustment, in good faith, in accordance with the terms of this Warrant and prepare a certificate setting forth such adjustment, including a statement of the adjusted Exercise Price and adjusted number or type of Warrant Shares or other securities issuable upon exercise of this Warrant (as applicable), describing the transactions giving rise to such adjustments and showing in detail the facts upon which such adjustment is based. Upon written request, the Company will promptly deliver a copy of each such certificate to the Holder and to the Company's transfer agent.

(g) Notice of Corporate Events. If, while this Warrant is outstanding, the Company (i) declares a dividend or any other distribution of cash, securities or other property in respect of its Common Stock, including, without limitation, any granting of rights or warrants to subscribe for or purchase any capital stock of the Company or any subsidiary, (ii) authorizes or approves, enters into any agreement contemplating or solicits stockholder approval for any Fundamental Transaction or (iii) authorizes the voluntary dissolution, liquidation or winding up of the affairs of the Company, then, except if such notice and the contents thereof shall be deemed to constitute material non-public information, the Company shall deliver to the Holder a notice of such transaction at least ten (10) days prior to the applicable record or effective date on which a Person would need to hold Common Stock in order to participate in or vote with respect to such transaction; *provided, however,* that the failure to deliver such notice or any defect therein shall not affect the validity of the corporate action required to be described in such notice. In addition, if while this Warrant is outstanding, the Company authorizes or approves, enters into any agreement contemplating or solicits stockholder approval for any Fundamental Transaction contemplated by Section 9(c), other than a Fundamental Transaction under clause (iii) of Section 9(c), the Company shall deliver to the Holder a notice of such Fundamental Transaction at least seventy five (75) days prior to the date such Fundamental Transaction is consummated. To the extent that any notice provided hereunder constitutes, or contains, material, non-public information regarding the Company or any of its subsidiaries, the Company shall simultaneously file such notice with the Commission pursuant to a Current Report on Form 8-K.

10. Payment of Exercise Price. Notwithstanding anything contained herein to the contrary, if a registration statement registering the issuance of the Warrant Shares under the Securities Act is not effective or available for the issuance of the Warrant Shares and an exemption from registration under the Securities Act is not available for the issuance of the Warrant Shares, the Holder may, in its sole discretion, satisfy its obligation to pay the Exercise Price through a "cashless exercise", in which event the Company shall issue to the Holder the number of Warrant Shares determined as follows:

$$X = Y [(A-B)/A]$$

where:

"X" equals the number of Warrant Shares to be issued to the Holder;

"Y" equals the total number of Warrant Shares with respect to which this Warrant is then being exercised;

"A" equals the average of the Closing Sale Prices of the shares of Common Stock (as reported by Bloomberg Financial Markets) for the five (5) consecutive Trading Days ending on the date immediately preceding the Exercise Date; and

"B" equals the Exercise Price then in effect for the applicable Warrant Shares at the time of such exercise.

For purposes of Rule 144 promulgated under the Securities Act, it is intended, understood and acknowledged that the Warrant Shares issued in a "cashless exercise" transaction shall be deemed to have been acquired by the Holder, and the holding period for the Warrant Shares shall be deemed to have commenced, on the date this Warrant was originally issued (provided that the Commission continues to take the position that such treatment is proper at the time of such exercise).

11. Limitations on Exercise.

(a) Notwithstanding anything to the contrary contained herein, the number of Warrant Shares that may be acquired by the Holder upon any exercise of this Warrant (or otherwise in respect hereof) shall be limited to the extent necessary to ensure that, following such exercise (or other issuance), the total number of shares of Common Stock then beneficially owned by the Holder and its Affiliates and any other Persons whose beneficial ownership of Common Stock would be aggregated with the Holder's for purposes of Section 13(d) of the Exchange Act, does not exceed 4.999% of the total number of then issued and outstanding shares of Common Stock (including for such purpose the shares of Common Stock issuable upon such exercise), it being acknowledged by the Holder that the Company is not representing to such Holder that such calculation is in compliance with Section 13(d) of the Exchange Act and such Holder is solely responsible for any schedules required to be filed in accordance therewith. To the extent that the limitation contained in this Section 11(a) applies, the determination of whether this Warrant is exercisable (in relation to other securities owned by such Holder) and of which a portion of this Warrant is exercisable shall be in the sole discretion of a Holder, and the submission of a Notice of Exercise shall be deemed to be the Holder's determination of whether this Warrant is exercisable (in relation to other securities owned by such Holder) and of which portion of this Warrant is exercisable, in each case subject to such aggregate percentage limitation, and the Company shall have no obligation to verify or confirm the accuracy of such determination. In addition, a determination under this Section 11(a) as to any group status shall be determined in accordance with Section 13(d) of the Exchange Act and the rules and regulations promulgated thereunder. For purposes of this Section 11(a), in determining the number of outstanding shares of Common Stock, the Holder may rely on the number of outstanding shares of Common Stock as reflected in (x) the Company's most recent Form 10-Q or Form 10-K, as the case may be, (y) a more recent public announcement by the Company or (z) any other notice by the Company or the Transfer Agent setting forth the number of shares of Common Stock outstanding. Upon the written request of the Holder, the Company shall within three (3) Trading Days confirm orally and in writing to such Holder the number of shares of Common Stock then outstanding. By written notice to the Company, which will not be effective until the sixty-first (61st) day after such notice is delivered to the Company, the Holder may waive the provisions of this Section 11(a) (but such waiver will not affect any other holder) to change the beneficial ownership limitation to such percentage of the number of shares of the Common Stock outstanding immediately after giving effect to the issuance of shares of Common Stock upon exercise of this Warrant as the Holder shall determine, in its sole discretion, subject to Section 11(b), and the provisions of this Section 11(a) shall continue to apply. Upon such a change by a Holder of the beneficial ownership limitation from such 4.999% limitation to such other percentage limitation, the beneficial ownership limitation may not be further waived by such Holder without first providing the minimum notice required by this Section 11(a). Notwithstanding the foregoing, at any time following notice of a Fundamental Transaction under Section 9(g)(ii) with respect to a Section 9(c)(iii) Fundamental Transaction, the Holder may waive and/or change the beneficial ownership limitation effective immediately upon written notice to the Company and may reinstitute a beneficial ownership limitation at any time thereafter effective immediately upon written notice to the Company.

(b) Notwithstanding anything to the contrary contained herein, including Section 11(a), the Company shall not effect any exercise of this Warrant, and the Holder shall not be entitled to exercise this Warrant for a number of Warrant Shares in excess of that number of Warrant Shares which, upon giving effect to such exercise, would cause (i) the aggregate number of shares of Common Stock beneficially owned by the Holder and its Affiliates and any other Persons whose beneficial ownership of Common Stock would be aggregated with the Holder's for purposes of Section 13(d) of the Exchange Act, to exceed 19.99% of the total number of issued and outstanding shares of Common Stock of the Company following such exercise, or (ii) the combined voting power of the securities of the Company beneficially owned by the Holder and its Affiliates and any other Persons whose beneficial ownership of Common Stock would be aggregated with the Holder's for purposes of Section 13(d) of the Exchange Act to exceed 19.99% of the combined voting power of all of the securities of the Company then outstanding following such exercise. For purposes of this Section 11(b), the aggregate number of shares of Common Stock or voting securities beneficially owned by the Holder and its Affiliates and any other Persons whose beneficial ownership of Common Stock would be aggregated with the Holder's for purposes of Section 13(d) of the Exchange Act shall include the shares of Common Stock issuable upon the exercise of this Warrant with respect to which such determination is being made, but shall exclude the number of shares of Common Stock which would be issuable upon (x) exercise of the remaining unexercised and non-cancelled portion of this Warrant by the Holder and (y) exercise or conversion of the unexercised, non-converted or non-cancelled portion of any other securities of the Company that do not have voting power (including without limitation any securities of the Company which would entitle the holder thereof to acquire at any time Common Stock, including without limitation any debt, preferred stock, right, option, warrant or other instrument that is at any time convertible into or exercisable or exchangeable for, or otherwise entitles the holder thereof to receive, Common Stock), is subject to a limitation on conversion or exercise analogous to the limitation contained herein and is beneficially owned by the Holder or any of its Affiliates and other Persons whose beneficial ownership of Common Stock would be aggregated with the Holder's for purposes of Section 13(d) of the Exchange Act.

(c) This Section 11 shall not restrict the number of shares of Common Stock that a Holder may receive or beneficially own in order to determine the amount of securities or other consideration that such Holder may receive in the event of a Fundamental Transaction as contemplated in Section 9 of this Warrant.

12. No Fractional Shares. No fractional Warrant Shares will be issued in connection with any exercise of this Warrant. In lieu of any fractional shares that would otherwise be issuable, the number of Warrant Shares to be issued shall be rounded down to the next whole number and the Company shall pay the Holder in cash the fair market value (based on the Closing Sale Price) for any such fractional shares.

13. Redemption of Warrants.

(a) At any time on or after the date that is two years following the Original Issue Date, subject to the terms of this Section 13, the Company shall have the right to redeem all or a portion of this Warrant for a redemption price (the "*Redemption Price*") equal to the result obtained by multiplying (i) $0.01 by (ii) the number of Warrant Shares that the Holder is entitled to purchase upon exercise of all or the portion of this Warrant that is being redeemed (such Redemption Price being subject to adjustment for stock splits, stock dividends, combinations, recapitalizations, reclassifications, and similar transactions affecting the Common Stock) following notice to the holder thereof if the closing price of our common stock for 20 or more trading days in a period of 30 consecutive trading days is greater than or equal to $2.80 (subject to adjustment).

(b) The Company shall exercise this redemption right by providing at least thirty (30) days' prior written notice to the Holder of such redemption (the "*Redemption Notice*"). Such Redemption Notice shall be provided to the Holder in accordance with Section 14 of this Warrant. The Redemption Notice shall specify the time, manner and place of redemption, including without limitation the date on which this Warrant shall be redeemed (the "*Redemption Date*") and the Redemption Price payable to the Holder (assuming that this Warrant is not exercised on or prior to the Redemption Date).

(c) Notwithstanding the foregoing, the Company may not redeem any part of this Warrant, which may not be exercised by the redeeming Holder as of the date of the Redemption Notice under Section 11 of this Warrant.

14. Notices. Any and all notices or other communications or deliveries hereunder (including, without limitation, any Exercise Notice) shall be in writing and shall be deemed given and effective on the earliest of (i) the date of transmission, if such notice or communication is delivered via facsimile or confirmed e-mail at the facsimile number or e-mail address specified in the books and records of the Transfer Agent prior to 5:30 P.M., New York City time, on a Trading Day, (ii) the next Trading Day after the date of transmission, if such notice or communication is delivered via facsimile or confirmed e-mail at the facsimile number or e-mail address specified in the books and records of the Transfer Agent on a day that is not a Trading Day or later than 5:30 P.M., New York City time, on any Trading Day, (iii) the Trading Day following the date of mailing, if sent by nationally recognized overnight courier service specifying next business day delivery, or (iv) upon actual receipt by the Person to whom such notice is required to be given, if by hand delivery.

15. Warrant Agent. The Transfer Agent shall serve as warrant agent under this Warrant. Upon thirty (30) days' notice to the Holder, the Company may appoint a new warrant agent. Any corporation into which the Company or any new warrant agent may be merged or any corporation resulting from any consolidation to which the Company or any new warrant agent shall be a party or any corporation to which the Company or any new warrant agent transfers substantially all of its corporate trust or shareholders services business shall be a successor warrant agent under this Warrant without any further act. Any such successor warrant agent shall promptly cause notice of its succession as warrant agent to be mailed (by first class mail, postage prepaid) to the Holder at the Holder's last address as shown on the Warrant Register.

16. Miscellaneous.

(a) No Rights as a Stockholder. The Holder, solely in such Person's capacity as a holder of this Warrant, shall not be entitled to vote or receive dividends or be deemed the holder of share capital of the Company for any purpose, nor shall anything contained in this Warrant be construed to confer upon the Holder, solely in such Person's capacity as the Holder of this Warrant, any of the rights of a stockholder of the Company or any right to vote, give or withhold consent to any corporate action (whether any reorganization, issue of stock, reclassification of stock, consolidation, merger, amalgamation, conveyance or otherwise), receive notice of meetings, receive dividends or subscription rights, or otherwise, prior to the issuance to the Holder of the Warrant Shares which such Person is then entitled to receive upon the due exercise of this Warrant. In addition, nothing contained in this Warrant shall be construed as imposing any liabilities on the Holder to purchase any securities (upon exercise of this Warrant or otherwise) or as a stockholder of the Company, whether such liabilities are asserted by the Company or by creditors of the Company.

(b) Authorized Shares. (i) Except and to the extent as waived or consented to by the Holder, the Company shall not by any action, including, without limitation, amending its certificate or articles of incorporation or through any reorganization, transfer of assets, consolidation, merger, dissolution, issue or sale of securities or any other voluntary action, avoid or seek to avoid the observance or performance of any of the terms of this Warrant, but will at all times in good faith assist in the carrying out of all such terms and in the taking of all such actions as may be necessary or appropriate to protect the rights of Holder as set forth in this Warrant against impairment. Without limiting the generality of the foregoing, the Company will (a) not increase the par value of any Warrant Shares above the amount payable therefor upon such exercise immediately prior to such increase in par value, (b) take all such action as may be necessary or appropriate in order that the Company may validly and legally issue fully paid and nonassessable Warrant Shares upon the exercise of this Warrant, and (c) use commercially reasonable efforts to obtain all such authorizations, exemptions or consents from any public regulatory body having jurisdiction thereof as may be necessary to enable

the Company to perform its obligations under this Warrant.

(ii) Before taking any action which would result in an adjustment in the number of Warrant Shares for which this Warrant is exercisable or in the Exercise Price, the Company shall obtain all such authorizations or exemptions thereof, or consents thereto, as may be necessary from any public regulatory body or bodies having jurisdiction thereof.

(c) Successors and Assigns. Subject to the restrictions on transfer set forth in this Warrant and compliance with applicable securities laws, this Warrant may be assigned by the Holder. This Warrant may not be assigned by the Company without the written consent of the Holder except to a successor in the event of a Fundamental Transaction. This Warrant shall be binding on and inure to the benefit of the Company and the Holder and their respective successors and assigns. Subject to the preceding sentence, nothing in this Warrant shall be construed to give to any Person other than the Company and the Holder any legal or equitable right, remedy or cause of action under this Warrant. This Warrant may be amended only in writing signed by the Company and the Holder, or their successors and assigns.

(d) Amendment and Waiver. Except as otherwise provided herein, the provisions of the Warrants may be amended and the Company may take any action herein prohibited, or omit to perform any act herein required to be performed by it, only if the Company has obtained the written consent of the Holders of Warrants representing no less than a majority of the Warrant Shares obtainable upon exercise of the Warrants then outstanding.

(e) Acceptance. Receipt of this Warrant by the Holder shall constitute acceptance of and agreement to all of the terms and conditions contained herein.

(f) Governing Law; Jurisdiction. ALL QUESTIONS CONCERNING THE CONSTRUCTION, VALIDITY, ENFORCEMENT AND INTERPRETATION OF THIS WARRANT SHALL BE GOVERNED BY AND CONSTRUED AND ENFORCED IN ACCORDANCE WITH THE LAWS OF THE STATE OF NEW YORK WITHOUT REGARD TO THE PRINCIPLES OF CONFLICTS OF LAW THEREOF. EACH OF THE COMPANY AND THE HOLDER HEREBY IRREVOCABLY SUBMITS TO THE EXCLUSIVE JURISDICTION OF THE STATE AND FEDERAL COURTS SITTING IN THE CITY OF NEW YORK, BOROUGH OF MANHATTAN, FOR THE ADJUDICATION OF ANY DISPUTE HEREUNDER OR IN CONNECTION HEREWITH OR WITH ANY TRANSACTION CONTEMPLATED HEREBY OR DISCUSSED HEREIN (INCLUDING WITH RESPECT TO THE ENFORCEMENT OF ANY OF THE TRANSACTION DOCUMENTS), AND HEREBY IRREVOCABLY WAIVES, AND AGREES NOT TO ASSERT IN ANY SUIT, ACTION OR PROCEEDING, ANY CLAIM THAT IT IS NOT PERSONALLY SUBJECT TO THE JURISDICTION OF ANY SUCH COURT. EACH OF THE COMPANY AND THE HOLDER HEREBY IRREVOCABLY WAIVES PERSONAL SERVICE OF PROCESS AND CONSENTS TO PROCESS BEING SERVED IN ANY SUCH SUIT, ACTION OR PROCEEDING BY MAILING A COPY THEREOF VIA REGISTERED OR CERTIFIED MAIL OR OVERNIGHT DELIVERY (WITH EVIDENCE OF DELIVERY) TO SUCH PERSON AT THE ADDRESS IN EFFECT FOR NOTICES TO IT AND AGREES THAT SUCH SERVICE SHALL CONSTITUTE GOOD AND SUFFICIENT SERVICE OF PROCESS AND NOTICE THEREOF. NOTHING CONTAINED HEREIN SHALL BE DEEMED TO LIMIT IN ANY WAY ANY RIGHT TO SERVE PROCESS IN ANY MANNER PERMITTED BY LAW. EACH OF THE COMPANY AND THE HOLDER HEREBY WAIVES ALL RIGHTS TO A TRIAL BY JURY.

(g) Headings. The headings herein are for convenience only, do not constitute a part of this Warrant and shall not be deemed to limit or affect any of the provisions hereof.

(h) Severability. In case any one or more of the provisions of this Warrant shall be invalid or unenforceable in any respect, the validity and enforceability of the remaining terms and provisions of this Warrant shall not in any way be affected or impaired thereby, and the Company and the Holder will attempt in good faith to agree upon a valid and enforceable provision which shall be a commercially reasonable substitute therefor, and upon so agreeing, shall incorporate such substitute provision in this Warrant.

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IN WITNESS WHEREOF, the Company has caused this Amended and Restated Warrant to be duly executed by its authorized officer as of the date first indicated above.

IDERA PHARMACEUTICALS, INC.

By: _____

Name:

Title:

SCHEDULE 1

FORM OF EXERCISE NOTICE

[To be executed by the Holder to purchase shares of Common Stock under the Warrant]

Ladies and Gentlemen:

(1) The undersigned is the Holder of Warrant No. (the " *Warrant*") issued by Idera Pharmaceuticals, Inc., a Delaware corporation (the "*Company*"). Capitalized terms used herein and not otherwise defined herein have the respective meanings set forth in the Warrant.

(2) The undersigned hereby exercises its right to purchase Warrant Shares pursuant to the Warrant.

(3) The Holder intends that payment of the Exercise Price shall be made as (check one):

¨ Cash Exercise

¨ "Cashless Exercise" under Section 10 of the Warrant

(4) If the Holder has elected a Cash Exercise, the Holder shall pay the sum of $ in immediately available funds to the Company in accordance with the terms of the Warrant.

(5) Pursuant to this Exercise Notice, the Company shall deliver to the Holder Warrant Shares determined in accordance with the terms of the Warrant.

(6) By its delivery of this Exercise Notice, the undersigned represents and warrants to the Company that in giving effect to the exercise evidenced hereby the Holder will not beneficially own in excess of the number of shares of Common Stock (as determined in accordance with Section 13(d) of the Securities Exchange Act of 1934) permitted to be owned under Section 11(a) or Section 11(b), as applicable, of the Warrant to which this notice relates.

Dated: _____

Name of Holder: _____

By: _____

Name: _____

Title: _____

(Signature must conform in all respects to name of Holder as specified on the face of the Warrant)

Exhibit B

Amendment and Restatement of the Second Warrant

THE WARRANTS INITIALLY WILL BE REPRESENTED BY ONE OR MORE PERMANENT GLOBAL CERTIFICATES IN FULLY REGISTERED FORM AND WILL BE DEPOSITED WITH A CUSTODIAN FOR, AND REGISTERED IN THE NAME OF, A NOMINEE OF THE DEPOSITORY TRUST COMPANY, NEW YORK, NEW YORK ("DTC"), AS DEPOSITARY.

IDERA PHARMACEUTICALS, INC.

FORM OF AMENDED AND RESTATED WARRANT TO PURCHASE COMMON STOCK

Number of Shares: [●]
(subject to adjustment)
Original Issue Date: September 30, 2013
Re-issue Date: July 27, 2018
Warrant No. [●] Amendment Date: December [●], 2019

Idera Pharmaceuticals, Inc., a Delaware corporation (the "*Company*"), hereby certifies that, for good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, [●] or its permitted registered assigns (the "*Holder*"), is entitled, subject to the terms set forth below, to purchase from the Company up to a total of [●] shares of common stock, $0.001 par value per share (the "*Common Stock*"), of the Company (each such share, a "*Warrant Share*" and all such shares, the "*Warrant Shares*") at an exercise price per share equal to $0.08 per share (as adjusted from time to time as provided in Section 9 herein, the "*Exercise Price*"), upon surrender of this Warrant to Purchase Common Stock (including any Warrants to Purchase Common Stock issued in exchange, transfer or replacement hereof, the "*Warrant*") at any time and from time to time on or after the date hereof (the "*Original Issue Date*"), and subject to the following terms and conditions:

1. Definitions. For purposes of this Warrant, the following terms shall have the following meanings:

(a) "*Commission*" means the United States Securities and Exchange Commission.

(b) "*Closing Sale Price*" means, for any security as of any date, the last trade price for such security on the Principal Trading Market for such security, as reported by Bloomberg Financial Markets, or, if such Principal Trading Market begins to operate on an extended hours basis and does not designate the last trade price, then the last trade price of such security prior to 4:00 P.M., New York City time, as reported by Bloomberg Financial Markets, or if the foregoing do not apply, the last trade price of such security in the over-the-counter market on the electronic bulletin board for such security as reported by Bloomberg Financial Markets, or, if no last trade price is reported for such security by Bloomberg Financial Markets, the average of the bid and ask prices, of any market makers for such security as reported in the "pink sheets" by Pink Sheets LLC. If the Closing Sale Price cannot be calculated for a security on a particular date on any of the foregoing bases, the Closing Sale Price of such security on such date shall be the fair market value as mutually determined by the Company and the Holder. If the Company and the Holder are unable to agree upon the fair market value of such security, then the Board of Directors of the Company shall use its good faith judgment to determine the fair market value. The Board of Directors' determination shall be binding upon all parties absent demonstrable error. All such determinations shall be appropriately adjusted for any stock dividend, stock split, stock combination or other similar transaction during the applicable calculation period.

(c) "*Principal Trading Market*" means the Trading Market on which the Common Stock is primarily listed on and quoted for trading, which, as of the Original Issue Date shall be the Nasdaq Capital Market.

(d) "*Registration Statement*" means the Company's Registration Statement on Form S-3, as amended (File No. 333- 191073), initially filed on September 10, 2013.

(e) "*Securities Act*" means the Securities Act of 1933, as amended.

(f) "*Transfer Agent*" means Computershare Shareowner Services LLC, the Company's transfer agent for the Common Stock and Warrants.

2. Registration of Warrants. The Company shall register this Warrant, upon records to be maintained by the Company for that purpose (the "Warrant Register"), in the name of the record Holder (which shall include the initial Holder or, as the case may be, any registered assignee to which this Warrant is permissibly assigned hereunder) from time to time. The Company may deem and treat the registered Holder of this Warrant as the absolute owner hereof for the purpose of any exercise hereof or any distribution to the Holder, and for all other purposes, absent actual notice to the contrary.

3. Registration of Transfers. Subject to compliance with all applicable securities laws, the Company shall, or will cause its Transfer Agent to, register the transfer of all or any portion of this Warrant in the Warrant Register, upon surrender of this Warrant, and payment for all applicable transfer taxes. Upon any such registration or transfer, a new warrant to purchase Common Stock in substantially the form of this Warrant (any such new warrant, a "New Warrant") evidencing the portion of this Warrant so transferred shall be issued to the transferee, and a New Warrant evidencing the remaining portion of this Warrant not so transferred, if any, shall be issued to the transferring Holder. The acceptance of the New Warrant by the transferee thereof shall be deemed the

acceptance by such transferee of all of the rights and obligations in respect of the New Warrant that the Holder has in respect of this Warrant. The Company shall, or will cause its Transfer Agent to, prepare, issue and deliver at the Company's own expense any New Warrant under this Section 3. Until due presentment for registration of transfer, the Company may treat the registered Holder hereof as the owner and holder for all purposes, and the Company shall not be affected by any notice to the contrary.

4. Exercise and Duration of Warrants.

(a) All or any part of this Warrant shall be exercisable by the registered Holder in any manner permitted by Section 10 of this Warrant at any time and from time to time on or after the Original Issue Date. The rights represented by this Warrant shall have no termination date.

(b) The Holder may exercise this Warrant by delivering to the Company (i) an exercise notice, in the form attached as Schedule 1 hereto (the "Exercise Notice"), completed and duly signed, and (ii) payment of the Exercise Price for the number of Warrant Shares as to which this Warrant is being exercised (which may take the form of a "cashless exercise" if so indicated in the Exercise Notice pursuant to Section 10 below), and the date on which the last of such items is delivered to the Company (as determined in accordance with the notice provisions hereof) is an "Exercise Date." The Holder shall not be required to deliver the original Warrant in order to effect an exercise hereunder. Execution and delivery of the Exercise Notice shall have the same effect as cancellation of the original Warrant and issuance of a New Warrant evidencing the right to purchase the remaining number of Warrant Shares.

5. Delivery of Warrant Shares.

(a) Upon exercise of this Warrant, the Company shall promptly (but in no event later than three (3) Trading Days after the Exercise Date), upon the request of the Holder, credit such aggregate number of shares of Common Stock to which the Holder is entitled pursuant to such exercise to the Holder's or its designee's balance account with The Depository Trust Company ("DTC") through its Deposit Withdrawal Agent Commission system, or if the Transfer Agent is not participating in the Fast Automated Securities Transfer Program (the "FAST Program") or if the certificates are required to bear a legend regarding restriction on transferability, issue and dispatch by overnight courier to the address as specified in the Exercise Notice, a certificate, registered in the Company's share register in the name of the Holder or its designee, for the number of shares of Common Stock to which the Holder is entitled pursuant to such exercise. The Holder, or any Person permissibly so designated by the Holder to receive Warrant Shares, shall be deemed to have become the holder of record of such Warrant Shares as of the Exercise Date, irrespective of the date such Warrant Shares are credited to the Holder's DTC account or the date of delivery of the certificates evidencing such Warrant Shares, as the case may be.

(b) If by the close of the third (3rd) Trading Day after the Exercise Date, the Company fails to deliver to the Holder a certificate representing the required number of Warrant Shares in the manner required pursuant to Section 5(a) or fails to credit the Holder's balance account with DTC for such number of Warrant Shares to which the Holder is entitled, and if after such third (3rd) Trading Day and prior to the receipt of such Warrant Shares, the Holder purchases (in an open market transaction or otherwise) shares of Common Stock to deliver in satisfaction of a sale by the Holder of the Warrant Shares which the Holder anticipated receiving upon such exercise (a "Buy-In"), then the Company shall, within three (3) Trading Days after the Holder's request and in the Holder's sole discretion, either (1) pay in cash to the Holder an amount equal to the Holder's total purchase price (including brokerage commissions, if any) for the shares of Common Stock so purchased (the "Buy-In Price"), at which point the Company's obligation to deliver such certificate (and to issue such Warrant Shares) shall terminate or (2) promptly honor its obligation to deliver to the Holder a certificate or certificates representing such Warrant Shares and pay cash to the Holder in an amount equal to the excess (if any) of Holder's total purchase price (including brokerage commissions, if any) for the shares of Common Stock so purchased in the Buy-In over the product of (A) the number of shares of Common Stock purchased in the Buy-In, times (B) the closing bid price of a share of Common Stock on the Exercise Date.

(c) To the extent permitted by law, the Company's obligations to issue and deliver Warrant Shares in accordance with and subject to the terms hereof (including the limitations set forth in Section 11 below) are absolute and unconditional, irrespective of any action or inaction by the Holder to enforce the same, any waiver or consent with respect to any provision hereof, the recovery of any judgment against any Person or any action to enforce the same, or any setoff, counterclaim, recoupment, limitation or termination, or any breach or alleged breach by the Holder or any other Person of any obligation to the Company or any violation or alleged violation of law by the Holder or any other Person, and irrespective of any other circumstance that might otherwise limit such obligation of the Company to the Holder in connection with the issuance of Warrant Shares. Nothing herein shall limit the Holder's right to pursue any other remedies available to it hereunder, at law or in equity including, without limitation, a decree of specific performance and/or injunctive relief with respect to the Company's failure to timely deliver certificates representing shares of Common Stock upon exercise of the Warrant as required pursuant to the terms hereof.

6. Charges, Taxes and Expenses. Issuance and delivery of certificates for shares of Common Stock upon exercise of this Warrant shall be made without charge to the Holder for any issue or transfer tax, transfer agent fee or other incidental tax or expense in respect of the issuance of such certificates, all of which taxes and expenses shall be paid by the Company; *provided, however,* that the Company shall not be required to pay any tax that may be payable in respect of any transfer involved in the registration of any

certificates for Warrant Shares or the Warrants in a name other than that of the Holder or an Affiliate thereof. The Holder shall be responsible for all other tax liability that may arise as a result of holding or transferring this Warrant or receiving Warrant Shares upon exercise hereof.

7. Replacement of Warrant. If this Warrant is mutilated, lost, stolen or destroyed, the Company shall issue or cause to be issued in exchange and substitution for and upon cancellation hereof, or in lieu of and substitution for this Warrant, a New Warrant, but only upon receipt of evidence reasonably satisfactory to the Company of such loss, theft or destruction (in such case) and, in each case, a customary and reasonable indemnity and surety bond, if requested by the Company. Applicants for a New Warrant under such circumstances shall also comply with such other reasonable regulations and procedures and pay such other reasonable third-party costs as the Company may prescribe. If a New Warrant is requested as a result of a mutilation of this Warrant, then the Holder shall deliver such mutilated Warrant to the Company as a condition precedent to the Company's obligation to issue the New Warrant.

8. Reservation of Warrant Shares. The Company covenants that it will at all times while this Warrant is outstanding reserve and keep available out of the aggregate of its authorized but unissued and otherwise unreserved Common Stock, solely for the purpose of enabling it to issue Warrant Shares upon exercise of this Warrant as herein provided, the number of Warrant Shares that are initially issuable and deliverable upon the exercise of this entire Warrant, free from preemptive rights or any other contingent purchase rights of persons other than the Holder (taking into account the adjustments and restrictions of Section 9). The Company covenants that all Warrant Shares so issuable and deliverable shall, upon issuance and the payment of the applicable Exercise Price in accordance with the terms hereof, be duly and validly authorized, issued and fully paid and nonassessable. The Company will take all such action as may be reasonably necessary to assure that such shares of Common Stock may be issued as provided herein without violation of any applicable law or regulation, or of any requirements of any securities exchange or automated quotation system upon which the Common Stock may be listed.

9. Certain Adjustments. The Exercise Price and number of Warrant Shares issuable upon exercise of this Warrant are subject to adjustment from time to time as set forth in this Section 9.

(a) Stock Dividends and Splits. If the Company, at any time while this Warrant is outstanding, (i) pays a stock dividend on its Common Stock or otherwise makes a distribution on any class of capital stock, other than Series E Preferred Stock or Series D Preferred Stock issued and outstanding on the Original Issue Date and in accordance with the terms of such stock on the Original Issue Date or as amended, as described in the Registration Statement, that is payable in shares of Common Stock, (ii) subdivides its outstanding shares of Common Stock into a larger number of shares of Common Stock, (iii) combines its outstanding shares of Common Stock into a smaller number of shares of Common Stock or (iv) issues by reclassification of shares of capital stock any additional shares of Common Stock of the Company, then in each such case the Exercise Price shall be multiplied by a fraction, the numerator of which shall be the number of shares of Common Stock outstanding immediately before such event and the denominator of which shall be the number of shares of Common Stock outstanding immediately after such event. Any adjustment made pursuant to clause (i) of this paragraph shall become effective immediately after the record date for the determination of stockholders entitled to receive such dividend or distribution, provided, however, that if such record date shall have been fixed and such dividend is not fully paid on the date fixed therefor, the Exercise Price shall be recomputed accordingly as of the close of business on such record date and thereafter the Exercise Price shall be adjusted pursuant to this paragraph as of the time of actual payment of such dividends. Any adjustment pursuant to clause (ii) or (iii) of this paragraph shall become effective immediately after the effective date of such subdivision or combination.

(b) Pro Rata Distributions. If the Company, at any time while this Warrant is outstanding, distributes to all holders of Common Stock for no consideration (i) evidences of its indebtedness, (ii) any security (other than a distribution of Common Stock covered by the preceding paragraph) or (iii) rights or warrants to subscribe for or purchase any security, or (iv) any other asset (in each case, *"Distributed Property"*), then, upon any exercise of this Warrant that occurs after the record date fixed for determination of stockholders entitled to receive such distribution, the Holder shall be entitled to receive, in addition to the Warrant Shares otherwise issuable upon such exercise (if applicable), the Distributed Property that such Holder would have been entitled to receive in respect of such number of Warrant Shares had the Holder been the record holder of such Warrant Shares immediately prior to such record date without regard to any limitation on exercise contained therein.

(c) Fundamental Transactions. If, at any time while this Warrant is outstanding (i) the Company effects any merger or consolidation of the Company with or into another Person, in which the Company is not the surviving entity or the stockholders of the Company immediately prior to such merger or consolidation do not own, directly or indirectly, at least 50% of the voting power of the surviving entity immediately after such merger or consolidation, (ii) the Company effects any sale to another Person of all or substantially all of its assets in one or a series of related transactions, (iii) pursuant to any tender offer or exchange offer (whether by the Company or another Person), holders of capital stock who tender shares representing more than 50% of the voting power of the capital stock of the Company and the Company or such other Person, as applicable, accepts such tender for payment, (iv) the Company consummates a stock purchase agreement or other business combination (including, without limitation, a reorganization, recapitalization, spin-off or scheme of arrangement) with another Person whereby such other Person acquires more than the 50% of the voting power of the capital stock of the Company or (v) the Company effects any reclassification of the Common Stock or any compulsory share exchange pursuant to which the Common Stock is effectively converted into or exchanged for other securities,

cash or property (other than as a result of a subdivision or combination of shares of Common Stock covered by Section 9(a) above) (in any such case, a "*Fundamental Transaction*"), then following such Fundamental Transaction the Holder shall have the right to receive, upon exercise of this Warrant, the same amount and kind of securities, cash or property as it would have been entitled to receive upon the occurrence of such Fundamental Transaction if it had been, immediately prior to such Fundamental Transaction, the holder of the number of Warrant Shares then issuable upon exercise in full of this Warrant without regard to any limitations on exercise contained herein (the "*Alternate Consideration*"). The Company shall not effect any Fundamental Transaction in which the Company is not the surviving entity or the Alternate Consideration includes securities of another Person unless prior to or simultaneously with the consummation thereof, any successor to the Company, surviving entity or other Person (including any purchaser of assets of the Company) shall assume the obligation to deliver to the Holder, such Alternate Consideration as, in accordance with the foregoing provisions, the Holder may be entitled to receive, and the other obligations under this Warrant. The provisions of this paragraph (c) shall similarly apply to subsequent transactions analogous of a Fundamental Transaction type.

(d) Number of Warrant Shares. Simultaneously with any adjustment to the Exercise Price pursuant to paragraphs (a) of this Section 9, the number of Warrant Shares that may be purchased upon exercise of this Warrant shall be increased or decreased proportionately, so that after such adjustment the aggregate Exercise Price payable hereunder for the increased or decreased number of Warrant Shares shall be the same as the aggregate Exercise Price in effect immediately prior to such adjustment.

(e) Calculations. All calculations under this Section 9 shall be made to the nearest cent or the nearest share, as applicable.

(f) Notice of Adjustments. Upon the occurrence of each adjustment pursuant to this Section 9, the Company at its expense will, at the written request of the Holder, promptly compute such adjustment, in good faith, in accordance with the terms of this Warrant and prepare a certificate setting forth such adjustment, including a statement of the adjusted Exercise Price and adjusted number or type of Warrant Shares or other securities issuable upon exercise of this Warrant (as applicable), describing the transactions giving rise to such adjustments and showing in detail the facts upon which such adjustment is based. Upon written request, the Company will promptly deliver a copy of each such certificate to the Holder and to the Company's transfer agent.

(g) Notice of Corporate Events. If, while this Warrant is outstanding, the Company (i) declares a dividend or any other distribution of cash, securities or other property in respect of its Common Stock, including, without limitation, any granting of rights or warrants to subscribe for or purchase any capital stock of the Company or any subsidiary, (ii) authorizes or approves, enters into any agreement contemplating or solicits stockholder approval for any Fundamental Transaction or (iii) authorizes the voluntary dissolution, liquidation or winding up of the affairs of the Company, then, except if such notice and the contents thereof shall be deemed to constitute material non-public information, the Company shall deliver to the Holder a notice of such transaction at least ten (10) days prior to the applicable record or effective date on which a Person would need to hold Common Stock in order to participate in or vote with respect to such transaction; *provided, however,* that the failure to deliver such notice or any defect therein shall not affect the validity of the corporate action required to be described in such notice. In addition, if while this Warrant is outstanding, the Company authorizes or approves, enters into any agreement contemplating or solicits stockholder approval for any Fundamental Transaction contemplated by Section 9(c), other than a Fundamental Transaction under clause (iii) of Section 9(c), the Company shall deliver to the Holder a notice of such Fundamental Transaction at least seventy five (75) days prior to the date such Fundamental Transaction is consummated. To the extent that any notice provided hereunder constitutes, or contains, material, non-public information regarding the Company or any of its subsidiaries, the Company shall simultaneously file such notice with the Commission pursuant to a Current Report on Form 8-K.

10. Payment of Exercise Price. Notwithstanding anything contained herein to the contrary, the Holder may, in its sole discretion, satisfy its obligation to pay the Exercise Price through a "cashless exercise", in which event the Company shall issue to the Holder the number of Warrant Shares determined as follows:

$$X = Y [(A-B)/A]$$

where:

"X" equals the number of Warrant Shares to be issued to the Holder;

"Y" equals the total number of Warrant Shares with respect to which this Warrant is then being exercised;

"A" equals the average of the Closing Sale Prices of the shares of Common Stock (as reported by Bloomberg Financial Markets) for the five (5) consecutive Trading Days ending on the date immediately preceding the Exercise Date; and

"B" equals the Exercise Price then in effect for the applicable Warrant Shares at the time of such exercise.

For purposes of Rule 144 promulgated under the Securities Act, it is intended, understood and acknowledged that the Warrant Shares issued in a "cashless exercise" transaction shall be deemed to have been acquired by the Holder, and the holding period for the Warrant Shares shall be deemed to have commenced, on the date this Warrant was originally issued (provided that the Commission continues to take the position that such treatment is proper at the time of such exercise).

11. Limitations on Exercise.

(a) Notwithstanding anything to the contrary contained herein, the number of Warrant Shares that may be acquired by the Holder upon any exercise of this Warrant (or otherwise in respect hereof) shall be limited to the extent necessary to ensure that, following such exercise (or other issuance), the total number of shares of Common Stock then beneficially owned by the Holder and its Affiliates and any other Persons whose beneficial ownership of Common Stock would be aggregated with the Holder's for purposes of Section 13(d) of the Exchange Act, does not exceed 4.999% of the total number of then issued and outstanding shares of Common Stock (including for such purpose the shares of Common Stock issuable upon such exercise), it being acknowledged by the Holder that the Company is not representing to such Holder that such calculation is in compliance with Section 13(d) of the Exchange Act and such Holder is solely responsible for any schedules required to be filed in accordance therewith. To the extent that the limitation contained in this Section 11(a) applies, the determination of whether this Warrant is exercisable (in relation to other securities owned by such Holder) and of which a portion of this Warrant is exercisable shall be in the sole discretion of a Holder, and the submission of a Notice of Exercise shall be deemed to be the Holder's determination of whether this Warrant is exercisable (in relation to other securities owned by such Holder) and of which portion of this Warrant is exercisable, in each case subject to such aggregate percentage limitation, and the Company shall have no obligation to verify or confirm the accuracy of such determination. In addition, a determination under this Section 11(a) as to any group status shall be determined in accordance with Section 13(d) of the Exchange Act and the rules and regulations promulgated thereunder. For purposes of this Section 11(a), in determining the number of outstanding shares of Common Stock, the Holder may rely on the number of outstanding shares of Common Stock as reflected in (x) the Company's most recent Form 10-Q or Form 10-K, as the case may be, (y) a more recent public announcement by the Company or (z) any other notice by the Company or the Transfer Agent setting forth the number of shares of Common Stock outstanding. Upon the written request of the Holder, the Company shall within three (3) Trading Days confirm orally and in writing to such Holder the number of shares of Common Stock then outstanding. By written notice to the Company, which will not be effective until the sixty-first (61st) day after such notice is delivered to the Company, the Holder may waive the provisions of this Section 11(a) (but such waiver will not affect any other holder) to change the beneficial ownership limitation to such percentage of the number of shares of the Common Stock outstanding immediately after giving effect to the issuance of shares of Common Stock upon exercise of this Warrant as the Holder shall determine, in its sole discretion, subject to Section 11(b), and the provisions of this Section 11(a) shall continue to apply. Upon such a change by a Holder of the beneficial ownership limitation from such 4.999% limitation to such other percentage limitation, the beneficial ownership limitation may not be further waived by such Holder without first providing the minimum notice required by this Section 11(a). Notwithstanding the foregoing, at any time following notice of a Fundamental Transaction under Section 9(g)(ii) with respect to a Section 9(c)(iii) Fundamental Transaction, the Holder may waive and/or change the beneficial ownership limitation effective immediately upon written notice to the Company and may reinstitute a beneficial ownership limitation at any time thereafter effective immediately upon written notice to the Company.

(b) Notwithstanding anything to the contrary contained herein, including Section 11(a), the Company shall not effect any exercise of this Warrant, and the Holder shall not be entitled to exercise this Warrant for a number of Warrant Shares in excess of that number of Warrant Shares which, upon giving effect to such exercise, would cause (i) the aggregate number of shares of Common Stock beneficially owned by the Holder and its Affiliates and any other Persons whose beneficial ownership of Common Stock would be aggregated with the Holder's for purposes of Section 13(d) of the Exchange Act, to exceed 19.99% of the total number of issued and outstanding shares of Common Stock of the Company following such exercise, or (ii) the combined voting power of the securities of the Company beneficially owned by the Holder and its Affiliates and any other Persons whose beneficial ownership of Common Stock would be aggregated with the Holder's for purposes of Section 13(d) of the Exchange Act to exceed 19.99% of the combined voting power of all of the securities of the Company then outstanding following such exercise. For purposes of this Section 11(b), the aggregate number of shares of Common Stock or voting securities beneficially owned by the Holder and its Affiliates and any other Persons whose beneficial ownership of Common Stock would be aggregated with the Holder's for purposes of Section 13(d) of the Exchange Act shall include the shares of Common Stock issuable upon the exercise of this Warrant with respect to which such determination is being made, but shall exclude the number of shares of Common Stock which would be issuable upon (x) exercise of the remaining unexercised and non-cancelled portion of this Warrant by the Holder and (y) exercise or conversion of the unexercised, non-converted or non-cancelled portion of any other securities of the Company that do not have voting power (including without limitation any securities of the Company which would entitle the holder thereof to acquire at any time Common Stock, including without limitation any debt, preferred stock, right, option, warrant or other instrument that is at any time convertible into or exercisable or exchangeable for, or otherwise entitles the holder thereof to receive, Common Stock), is subject to a limitation on conversion or exercise analogous to the limitation contained herein and is beneficially owned by the Holder or any of its Affiliates and other Persons whose beneficial ownership of Common Stock would be aggregated with the Holder's for purposes of Section 13(d) of the Exchange Act.

(c) This Section 11 shall not restrict the number of shares of Common Stock that a Holder may receive or beneficially own in order to determine the amount of securities or other consideration that such Holder may receive in the event of a Fundamental Transaction as contemplated in Section 9 of this Warrant.

12. No Fractional Shares. No fractional Warrant Shares will be issued in connection with any exercise of this Warrant. In lieu of any fractional shares that would otherwise be issuable, the number of Warrant Shares to be issued shall be rounded down to the next whole number and the Company shall pay the Holder in cash the fair market value (based on the Closing Sale Price) for any such fractional shares.

13. Notices. Any and all notices or other communications or deliveries hereunder (including, without limitation, any Exercise Notice) shall be in writing and shall be deemed given and effective on the earliest of (i) the date of transmission, if such notice or communication is delivered via facsimile or confirmed e-mail at the facsimile number or e-mail address specified in the books and records of the Transfer Agent prior to 5:30 P.M., New York City time, on a Trading Day, (ii) the next Trading Day after the date of transmission, if such notice or communication is delivered via facsimile or confirmed e-mail at the facsimile number or e-mail address specified in the books and records of the Transfer Agent on a day that is not a Trading Day or later than 5:30 P.M., New York City time, on any Trading Day, (iii) the Trading Day following the date of mailing, if sent by nationally recognized overnight courier service specifying next business day delivery, or (iv) upon actual receipt by the Person to whom such notice is required to be given, if by hand delivery.

14. Warrant Agent. The Transfer Agent shall serve as warrant agent under this Warrant. Upon thirty (30) days' notice to the Holder, the Company may appoint a new warrant agent. Any corporation into which the Company or any new warrant agent may be merged or any corporation resulting from any consolidation to which the Company or any new warrant agent shall be a party or any corporation to which the Company or any new warrant agent transfers substantially all of its corporate trust or shareholders services business shall be a successor warrant agent under this Warrant without any further act. Any such successor warrant agent shall promptly cause notice of its succession as warrant agent to be mailed (by first class mail, postage prepaid) to the Holder at the Holder's last address as shown on the Warrant Register.

15. Miscellaneous.

(a) No Rights as a Stockholder. The Holder, solely in such Person's capacity as a holder of this Warrant, shall not be entitled to vote or receive dividends or be deemed the holder of share capital of the Company for any purpose, nor shall anything contained in this Warrant be construed to confer upon the Holder, solely in such Person's capacity as the Holder of this Warrant, any of the rights of a stockholder of the Company or any right to vote, give or withhold consent to any corporate action (whether any reorganization, issue of stock, reclassification of stock, consolidation, merger, amalgamation, conveyance or otherwise), receive notice of meetings, receive dividends or subscription rights, or otherwise, prior to the issuance to the Holder of the Warrant Shares which such Person is then entitled to receive upon the due exercise of this Warrant. In addition, nothing contained in this Warrant shall be construed as imposing any liabilities on the Holder to purchase any securities (upon exercise of this Warrant or otherwise) or as a stockholder of the Company, whether such liabilities are asserted by the Company or by creditors of the Company.

(b) Authorized Shares. (i) Except and to the extent as waived or consented to by the Holder, the Company shall not by any action, including, without limitation, amending its certificate or articles of incorporation or through any reorganization, transfer of assets, consolidation, merger, dissolution, issue or sale of securities or any other voluntary action, avoid or seek to avoid the observance or performance of any of the terms of this Warrant, but will at all times in good faith assist in the carrying out of all such terms and in the taking of all such actions as may be necessary or appropriate to protect the rights of Holder as set forth in this Warrant against impairment. Without limiting the generality of the foregoing, the Company will (a) not increase the par value of any Warrant Shares above the amount payable therefor upon such exercise immediately prior to such increase in par value, (b) take all such action as may be necessary or appropriate in order that the Company may validly and legally issue fully paid and nonassessable Warrant Shares upon the exercise of this Warrant, and (c) use commercially reasonable efforts to obtain all such authorizations, exemptions or consents from any public regulatory body having jurisdiction thereof as may be necessary to enable the Company to perform its obligations under this Warrant.

(ii) Before taking any action which would result in an adjustment in the number of Warrant Shares for which this Warrant is exercisable or in the Exercise Price, the Company shall obtain all such authorizations or exemptions thereof, or consents thereto, as may be necessary from any public regulatory body or bodies having jurisdiction thereof.

(c) Successors and Assigns. Subject to the restrictions on transfer set forth in this Warrant and compliance with applicable securities laws, this Warrant may be assigned by the Holder. This Warrant may not be assigned by the Company without the written consent of the Holder except to a successor in the event of a Fundamental Transaction. This Warrant shall be binding on and inure to the benefit of the Company and the Holder and their respective successors and assigns. Subject to the preceding sentence, nothing in this Warrant shall be construed to give to any Person other than the Company and the Holder any legal or equitable right, remedy or cause of action under this Warrant. This Warrant may be amended only in writing signed by the Company and the Holder, or their successors and assigns.

(d) Amendment and Waiver. Except as otherwise provided herein, the provisions of the Warrants may be amended and the Company may take any action herein prohibited, or omit to perform any act herein required to be performed by it, only if the Company has obtained the written consent of the Holders of Warrants representing no less than a majority of the Warrant Shares obtainable upon exercise of the Warrants then outstanding.

(e) Acceptance. Receipt of this Warrant by the Holder shall constitute acceptance of and agreement to all of the terms and conditions contained herein.

(f) Governing Law; Jurisdiction. ALL QUESTIONS CONCERNING THE CONSTRUCTION, VALIDITY, ENFORCEMENT AND INTERPRETATION OF THIS WARRANT SHALL BE GOVERNED BY AND CONSTRUED AND ENFORCED IN ACCORDANCE WITH THE LAWS OF THE STATE OF NEW YORK WITHOUT REGARD TO THE PRINCIPLES OF CONFLICTS OF LAW THEREOF. EACH OF THE COMPANY AND THE HOLDER HEREBY IRREVOCABLY SUBMITS TO THE EXCLUSIVE JURISDICTION OF THE STATE AND FEDERAL COURTS SITTING IN THE CITY OF NEW YORK, BOROUGH OF MANHATTAN, FOR THE ADJUDICATION OF ANY DISPUTE HEREUNDER OR IN CONNECTION HEREWITH OR WITH ANY TRANSACTION CONTEMPLATED HEREBY OR DISCUSSED HEREIN (INCLUDING WITH RESPECT TO THE ENFORCEMENT OF ANY OF THE TRANSACTION DOCUMENTS), AND HEREBY IRREVOCABLY WAIVES, AND AGREES NOT TO ASSERT IN ANY SUIT, ACTION OR PROCEEDING, ANY CLAIM THAT IT IS NOT PERSONALLY SUBJECT TO THE JURISDICTION OF ANY SUCH COURT. EACH OF THE COMPANY AND THE HOLDER HEREBY IRREVOCABLY WAIVES PERSONAL SERVICE OF PROCESS AND CONSENTS TO PROCESS BEING SERVED IN ANY SUCH SUIT, ACTION OR PROCEEDING BY MAILING A COPY THEREOF VIA REGISTERED OR CERTIFIED MAIL OR OVERNIGHT DELIVERY (WITH EVIDENCE OF DELIVERY) TO SUCH PERSON AT THE ADDRESS IN EFFECT FOR NOTICES TO IT AND AGREES THAT SUCH SERVICE SHALL CONSTITUTE GOOD AND SUFFICIENT SERVICE OF PROCESS AND NOTICE THEREOF. NOTHING CONTAINED HEREIN SHALL BE DEEMED TO LIMIT IN ANY WAY ANY RIGHT TO SERVE PROCESS IN ANY MANNER PERMITTED BY LAW. EACH OF THE COMPANY AND THE HOLDER HEREBY WAIVES ALL RIGHTS TO A TRIAL BY JURY.

(g) Headings. The headings herein are for convenience only, do not constitute a part of this Warrant and shall not be deemed to limit or affect any of the provisions hereof.

(h) Severability. In case any one or more of the provisions of this Warrant shall be invalid or unenforceable in any respect, the validity and enforceability of the remaining terms and provisions of this Warrant shall not in any way be affected or impaired thereby, and the Company and the Holder will attempt in good faith to agree upon a valid and enforceable provision which shall be a commercially reasonable substitute therefor, and upon so agreeing, shall incorporate such substitute provision in this Warrant.

[REMAINDER OF PAGE INTENTIONALLY LEFT BLANK]

IN WITNESS WHEREOF, the Company has caused this Amended and Restated Warrant to be duly executed by its authorized officer as of the date first indicated above.

IDERA PHARMACEUTICALS, INC.

By: _____

Name:

Title:

SCHEDULE 1

FORM OF EXERCISE NOTICE

[To be executed by the Holder to purchase shares of Common Stock under the Warrant]

Ladies and Gentlemen:

(1) The undersigned is the Holder of Warrant No. (the " *Warrant*") issued by Idera Pharmaceuticals, Inc., a Delaware corporation (the "*Company*"). Capitalized terms used herein and not otherwise defined herein have the respective meanings set forth in the Warrant.

(2) The undersigned hereby exercises its right to purchase Warrant Shares pursuant to the Warrant.

(3) The Holder intends that payment of the Exercise Price shall be made as (check one):

¨ Cash Exercise

¨ "Cashless Exercise" under Section 10 of the Warrant

(4) If the Holder has elected a Cash Exercise, the Holder shall pay the sum of $ in immediately available funds to the Company in accordance with the terms of the Warrant.

(5) Pursuant to this Exercise Notice, the Company shall deliver to the Holder Warrant Shares determined in accordance with the terms of the Warrant.

(6) By its delivery of this Exercise Notice, the undersigned represents and warrants to the Company that in giving effect to the exercise evidenced hereby the Holder will not beneficially own in excess of the number of shares of Common Stock (as determined in accordance with Section 13(d) of the Securities Exchange Act of 1934) permitted to be owned under Section 11(a) or Section 11(b), as applicable, of the Warrant to which this notice relates.

Dated: _____

Name of Holder: _____

By: _____

Name: _____

Title: _____

(Signature must conform in all respects to name of Holder as specified on the face of the Warrant)

Exhibit C

Amendment and Restatement of the Third Warrant

THE WARRANTS INITIALLY WILL BE REPRESENTED BY ONE OR MORE PERMANENT GLOBAL CERTIFICATES IN FULLY REGISTERED FORM AND WILL BE DEPOSITED WITH A CUSTODIAN FOR, AND REGISTERED IN THE NAME OF, A NOMINEE OF THE DEPOSITORY TRUST COMPANY, NEW YORK, NEW YORK ("DTC"), AS DEPOSITARY.

IDERA PHARMACEUTICALS, INC.

FORM OF AMENDED AND RESTATED WARRANT TO PURCHASE COMMON STOCK

Number of Shares: [●]
(subject to adjustment)
Original Issue Date: February 10, 2014
Re-issue Date: July 27, 2018
Warrant No. [●] Amendment Date: December [●], 2019

Idera Pharmaceuticals, Inc., a Delaware corporation (the "*Company*"), hereby certifies that, for good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, [●] or its permitted registered assigns (the "*Holder*"), is entitled, subject to the terms set forth below, to purchase from the Company up to a total of [●] shares of common stock, $0.001 par value per share (the "*Common Stock*"), of the Company (each such share, a "*Warrant Share*" and all such shares, the "*Warrant Shares*") at an exercise price per share equal to $0.08 per share (as adjusted from time to time as provided in Section 9 herein, the "*Exercise Price*"), upon surrender of this Warrant to Purchase Common Stock (including any Warrants to Purchase Common Stock issued in exchange, transfer or replacement hereof, the "*Warrant*") at any time and from time to time on or after the date hereof (the "*Original Issue Date*"), and subject to the following terms and conditions:

1. Definitions. For purposes of this Warrant, the following terms shall have the following meanings:

(a) "*Commission*" means the United States Securities and Exchange Commission.

(b) "*Closing Sale Price*" means, for any security as of any date, the last trade price for such security on the Principal Trading Market for such security, as reported by Bloomberg Financial Markets, or, if such Principal Trading Market begins to operate on an extended hours basis and does not designate the last trade price, then the last trade price of such security prior to 4:00 P.M., New York City time, as reported by Bloomberg Financial Markets, or if the foregoing do not apply, the last trade price of such security in the over-the-counter market on the electronic bulletin board for such security as reported by Bloomberg Financial Markets, or, if no last trade price is reported for such security by Bloomberg Financial Markets, the average of the bid and ask prices, of any market makers for such security as reported in the "pink sheets" by Pink Sheets LLC. If the Closing Sale Price cannot be calculated for a security on a particular date on any of the foregoing bases, the Closing Sale Price of such security on such date shall be the fair market value as mutually determined by the Company and the Holder. If the Company and the Holder are unable to agree upon the fair market value of such security, then the Board of Directors of the Company shall use its good faith judgment to determine the fair market value. The Board of Directors' determination shall be binding upon all parties absent demonstrable error. All such determinations shall be appropriately adjusted for any stock dividend, stock split, stock combination or other similar transaction during the applicable calculation period.

(c) "*Principal Trading Market*" means the Trading Market on which the Common Stock is primarily listed on and quoted for trading, which, as of the Original Issue Date shall be the Nasdaq Capital Market.

(d) "*Registration Statement*" means the Company's Registration Statement on Form S-3 (File No. 333- 191073), initially filed on September 10, 2013.

(e) "*Securities Act*" means the Securities Act of 1933, as amended.

(f) "*Transfer Agent*" means Computershare Shareowner Services LLC, the Company's transfer agent for the Common Stock and Warrants.

2. Registration of Warrants. The Company shall register this Warrant, upon records to be maintained by the Company for that purpose (the "Warrant Register"), in the name of the record Holder (which shall include the initial Holder or, as the case may be, any registered assignee to which this Warrant is permissibly assigned hereunder) from time to time. The Company may deem and treat the registered Holder of this Warrant as the absolute owner hereof for the purpose of any exercise hereof or any distribution to the Holder, and for all other purposes, absent actual notice to the contrary.

3. Registration of Transfers. Subject to compliance with all applicable securities laws, the Company shall, or will cause its Transfer Agent to, register the transfer of all or any portion of this Warrant in the Warrant Register, upon surrender of this Warrant, and payment for all applicable transfer taxes. Upon any such registration or transfer, a new warrant to purchase Common Stock in substantially the form of this Warrant (any such new warrant, a "New Warrant") evidencing the portion of this Warrant so transferred shall be issued to the transferee, and a New Warrant evidencing the remaining portion of this Warrant not so transferred, if any, shall be issued to the transferring Holder. The acceptance of the New Warrant by the transferee thereof shall be deemed the

acceptance by such transferee of all of the rights and obligations in respect of the New Warrant that the Holder has in respect of this Warrant. The Company shall, or will cause its Transfer Agent to, prepare, issue and deliver at the Company's own expense any New Warrant under this Section 3. Until due presentment for registration of transfer, the Company may treat the registered Holder hereof as the owner and holder for all purposes, and the Company shall not be affected by any notice to the contrary.

4. Exercise and Duration of Warrants.

(a) All or any part of this Warrant shall be exercisable by the registered Holder in any manner permitted by Section 10 of this Warrant at any time and from time to time on or after the Original Issue Date. The rights represented by this Warrant shall have no termination date.

(b) The Holder may exercise this Warrant by delivering to the Company (i) an exercise notice, in the form attached as Schedule 1 hereto (the "Exercise Notice"), completed and duly signed, and (ii) payment of the Exercise Price for the number of Warrant Shares as to which this Warrant is being exercised (which may take the form of a "cashless exercise" if so indicated in the Exercise Notice pursuant to Section 10 below), and the date on which the last of such items is delivered to the Company (as determined in accordance with the notice provisions hereof) is an "Exercise Date." The Holder shall not be required to deliver the original Warrant in order to effect an exercise hereunder. Execution and delivery of the Exercise Notice shall have the same effect as cancellation of the original Warrant and issuance of a New Warrant evidencing the right to purchase the remaining number of Warrant Shares.

5. Delivery of Warrant Shares.

(a) Upon exercise of this Warrant, the Company shall promptly (but in no event later than three (3) Trading Days after the Exercise Date), upon the request of the Holder, credit such aggregate number of shares of Common Stock to which the Holder is entitled pursuant to such exercise to the Holder's or its designee's balance account with The Depository Trust Company ("DTC") through its Deposit Withdrawal Agent Commission system, or if the Transfer Agent is not participating in the Fast Automated Securities Transfer Program (the "FAST Program") or if the certificates are required to bear a legend regarding restriction on transferability, issue and dispatch by overnight courier to the address as specified in the Exercise Notice, a certificate, registered in the Company's share register in the name of the Holder or its designee, for the number of shares of Common Stock to which the Holder is entitled pursuant to such exercise. The Holder, or any Person permissibly so designated by the Holder to receive Warrant Shares, shall be deemed to have become the holder of record of such Warrant Shares as of the Exercise Date, irrespective of the date such Warrant Shares are credited to the Holder's DTC account or the date of delivery of the certificates evidencing such Warrant Shares, as the case may be.

(b) If by the close of the third (3rd) Trading Day after the Exercise Date, the Company fails to deliver to the Holder a certificate representing the required number of Warrant Shares in the manner required pursuant to Section 5(a) or fails to credit the Holder's balance account with DTC for such number of Warrant Shares to which the Holder is entitled, and if after such third (3rd) Trading Day and prior to the receipt of such Warrant Shares, the Holder purchases (in an open market transaction or otherwise) shares of Common Stock to deliver in satisfaction of a sale by the Holder of the Warrant Shares which the Holder anticipated receiving upon such exercise (a "Buy-In"), then the Company shall, within three (3) Trading Days after the Holder's request and in the Holder's sole discretion, either (1) pay in cash to the Holder an amount equal to the Holder's total purchase price (including brokerage commissions, if any) for the shares of Common Stock so purchased (the "Buy-In Price"), at which point the Company's obligation to deliver such certificate (and to issue such Warrant Shares) shall terminate or (2) promptly honor its obligation to deliver to the Holder a certificate or certificates representing such Warrant Shares and pay cash to the Holder in an amount equal to the excess (if any) of Holder's total purchase price (including brokerage commissions, if any) for the shares of Common Stock so purchased in the Buy-In over the product of (A) the number of shares of Common Stock purchased in the Buy-In, times (B) the closing bid price of a share of Common Stock on the Exercise Date.

(c) To the extent permitted by law, the Company's obligations to issue and deliver Warrant Shares in accordance with and subject to the terms hereof (including the limitations set forth in Section 11 below) are absolute and unconditional, irrespective of any action or inaction by the Holder to enforce the same, any waiver or consent with respect to any provision hereof, the recovery of any judgment against any Person or any action to enforce the same, or any setoff, counterclaim, recoupment, limitation or termination, or any breach or alleged breach by the Holder or any other Person of any obligation to the Company or any violation or alleged violation of law by the Holder or any other Person, and irrespective of any other circumstance that might otherwise limit such obligation of the Company to the Holder in connection with the issuance of Warrant Shares. Nothing herein shall limit the Holder's right to pursue any other remedies available to it hereunder, at law or in equity including, without limitation, a decree of specific performance and/or injunctive relief with respect to the Company's failure to timely deliver certificates representing shares of Common Stock upon exercise of the Warrant as required pursuant to the terms hereof.

6. Charges, Taxes and Expenses. Issuance and delivery of certificates for shares of Common Stock upon exercise of this Warrant shall be made without charge to the Holder for any issue or transfer tax, transfer agent fee or other incidental tax or expense in respect of the issuance of such certificates, all of which taxes and expenses shall be paid by the Company; *provided, however,* that the Company shall not be required to pay any tax that may be payable in respect of any transfer involved in the registration of any

certificates for Warrant Shares or the Warrants in a name other than that of the Holder or an Affiliate thereof. The Holder shall be responsible for all other tax liability that may arise as a result of holding or transferring this Warrant or receiving Warrant Shares upon exercise hereof.

7. Replacement of Warrant. If this Warrant is mutilated, lost, stolen or destroyed, the Company shall issue or cause to be issued in exchange and substitution for and upon cancellation hereof, or in lieu of and substitution for this Warrant, a New Warrant, but only upon receipt of evidence reasonably satisfactory to the Company of such loss, theft or destruction (in such case) and, in each case, a customary and reasonable indemnity and surety bond, if requested by the Company. Applicants for a New Warrant under such circumstances shall also comply with such other reasonable regulations and procedures and pay such other reasonable third-party costs as the Company may prescribe. If a New Warrant is requested as a result of a mutilation of this Warrant, then the Holder shall deliver such mutilated Warrant to the Company as a condition precedent to the Company's obligation to issue the New Warrant.

8. Reservation of Warrant Shares. The Company covenants that it will at all times while this Warrant is outstanding reserve and keep available out of the aggregate of its authorized but unissued and otherwise unreserved Common Stock, solely for the purpose of enabling it to issue Warrant Shares upon exercise of this Warrant as herein provided, the number of Warrant Shares that are initially issuable and deliverable upon the exercise of this entire Warrant, free from preemptive rights or any other contingent purchase rights of persons other than the Holder (taking into account the adjustments and restrictions of Section 9). The Company covenants that all Warrant Shares so issuable and deliverable shall, upon issuance and the payment of the applicable Exercise Price in accordance with the terms hereof, be duly and validly authorized, issued and fully paid and nonassessable. The Company will take all such action as may be reasonably necessary to assure that such shares of Common Stock may be issued as provided herein without violation of any applicable law or regulation, or of any requirements of any securities exchange or automated quotation system upon which the Common Stock may be listed.

9. Certain Adjustments. The Exercise Price and number of Warrant Shares issuable upon exercise of this Warrant are subject to adjustment from time to time as set forth in this Section 9.

(a) Stock Dividends and Splits. If the Company, at any time while this Warrant is outstanding, (i) pays a stock dividend on its Common Stock or otherwise makes a distribution on any class of capital stock, other than Series E Preferred Stock or Series D Preferred Stock issued and outstanding on the Original Issue Date and in accordance with the terms of such stock on the Original Issue Date or as amended, as described in the Registration Statement, that is payable in shares of Common Stock, (ii) subdivides its outstanding shares of Common Stock into a larger number of shares of Common Stock, (iii) combines its outstanding shares of Common Stock into a smaller number of shares of Common Stock or (iv) issues by reclassification of shares of capital stock any additional shares of Common Stock of the Company, then in each such case the Exercise Price shall be multiplied by a fraction, the numerator of which shall be the number of shares of Common Stock outstanding immediately before such event and the denominator of which shall be the number of shares of Common Stock outstanding immediately after such event. Any adjustment made pursuant to clause (i) of this paragraph shall become effective immediately after the record date for the determination of stockholders entitled to receive such dividend or distribution, provided, however, that if such record date shall have been fixed and such dividend is not fully paid on the date fixed therefor, the Exercise Price shall be recomputed accordingly as of the close of business on such record date and thereafter the Exercise Price shall be adjusted pursuant to this paragraph as of the time of actual payment of such dividends. Any adjustment pursuant to clause (ii) or (iii) of this paragraph shall become effective immediately after the effective date of such subdivision or combination.

(b) Pro Rata Distributions. If the Company, at any time while this Warrant is outstanding, distributes to all holders of Common Stock for no consideration (i) evidences of its indebtedness, (ii) any security (other than a distribution of Common Stock covered by the preceding paragraph) or (iii) rights or warrants to subscribe for or purchase any security, or (iv) any other asset (in each case, *"Distributed Property"*), then, upon any exercise of this Warrant that occurs after the record date fixed for determination of stockholders entitled to receive such distribution, the Holder shall be entitled to receive, in addition to the Warrant Shares otherwise issuable upon such exercise (if applicable), the Distributed Property that such Holder would have been entitled to receive in respect of such number of Warrant Shares had the Holder been the record holder of such Warrant Shares immediately prior to such record date without regard to any limitation on exercise contained therein.

(c) Fundamental Transactions. If, at any time while this Warrant is outstanding (i) the Company effects any merger or consolidation of the Company with or into another Person, in which the Company is not the surviving entity or the stockholders of the Company immediately prior to such merger or consolidation do not own, directly or indirectly, at least 50% of the voting power of the surviving entity immediately after such merger or consolidation, (ii) the Company effects any sale to another Person of all or substantially all of its assets in one or a series of related transactions, (iii) pursuant to any tender offer or exchange offer (whether by the Company or another Person), holders of capital stock who tender shares representing more than 50% of the voting power of the capital stock of the Company and the Company or such other Person, as applicable, accepts such tender for payment, (iv) the Company consummates a stock purchase agreement or other business combination (including, without limitation, a reorganization, recapitalization, spin-off or scheme of arrangement) with another Person whereby such other Person acquires more than the 50% of the voting power of the capital stock of the Company or (v) the Company effects any reclassification of the Common Stock or any compulsory share exchange pursuant to which the Common Stock is effectively converted into or exchanged for other securities,

cash or property (other than as a result of a subdivision or combination of shares of Common Stock covered by Section 9(a) above) (in any such case, a "*Fundamental Transaction*"), then following such Fundamental Transaction the Holder shall have the right to receive, upon exercise of this Warrant, the same amount and kind of securities, cash or property as it would have been entitled to receive upon the occurrence of such Fundamental Transaction if it had been, immediately prior to such Fundamental Transaction, the holder of the number of Warrant Shares then issuable upon exercise in full of this Warrant without regard to any limitations on exercise contained herein (the "*Alternate Consideration*"). The Company shall not effect any Fundamental Transaction in which the Company is not the surviving entity or the Alternate Consideration includes securities of another Person unless prior to or simultaneously with the consummation thereof, any successor to the Company, surviving entity or other Person (including any purchaser of assets of the Company) shall assume the obligation to deliver to the Holder, such Alternate Consideration as, in accordance with the foregoing provisions, the Holder may be entitled to receive, and the other obligations under this Warrant. The provisions of this paragraph (c) shall similarly apply to subsequent transactions analogous of a Fundamental Transaction type.

(d) Number of Warrant Shares. Simultaneously with any adjustment to the Exercise Price pursuant to paragraphs (a) of this Section 9, the number of Warrant Shares that may be purchased upon exercise of this Warrant shall be increased or decreased proportionately, so that after such adjustment the aggregate Exercise Price payable hereunder for the increased or decreased number of Warrant Shares shall be the same as the aggregate Exercise Price in effect immediately prior to such adjustment.

(e) Calculations. All calculations under this Section 9 shall be made to the nearest cent or the nearest share, as applicable.

(f) Notice of Adjustments. Upon the occurrence of each adjustment pursuant to this Section 9, the Company at its expense will, at the written request of the Holder, promptly compute such adjustment, in good faith, in accordance with the terms of this Warrant and prepare a certificate setting forth such adjustment, including a statement of the adjusted Exercise Price and adjusted number or type of Warrant Shares or other securities issuable upon exercise of this Warrant (as applicable), describing the transactions giving rise to such adjustments and showing in detail the facts upon which such adjustment is based. Upon written request, the Company will promptly deliver a copy of each such certificate to the Holder and to the Company's transfer agent.

(g) Notice of Corporate Events. If, while this Warrant is outstanding, the Company (i) declares a dividend or any other distribution of cash, securities or other property in respect of its Common Stock, including, without limitation, any granting of rights or warrants to subscribe for or purchase any capital stock of the Company or any subsidiary, (ii) authorizes or approves, enters into any agreement contemplating or solicits stockholder approval for any Fundamental Transaction or (iii) authorizes the voluntary dissolution, liquidation or winding up of the affairs of the Company, then, except if such notice and the contents thereof shall be deemed to constitute material non-public information, the Company shall deliver to the Holder a notice of such transaction at least ten (10) days prior to the applicable record or effective date on which a Person would need to hold Common Stock in order to participate in or vote with respect to such transaction; *provided, however,* that the failure to deliver such notice or any defect therein shall not affect the validity of the corporate action required to be described in such notice. In addition, if while this Warrant is outstanding, the Company authorizes or approves, enters into any agreement contemplating or solicits stockholder approval for any Fundamental Transaction contemplated by Section 9(c), other than a Fundamental Transaction under clause (iii) of Section 9(c), the Company shall deliver to the Holder a notice of such Fundamental Transaction at least seventy five (75) days prior to the date such Fundamental Transaction is consummated. To the extent that any notice provided hereunder constitutes, or contains, material, non-public information regarding the Company or any of its subsidiaries, the Company shall simultaneously file such notice with the Commission pursuant to a Current Report on Form 8-K.

10. Payment of Exercise Price. Notwithstanding anything contained herein to the contrary, the Holder may, in its sole discretion, satisfy its obligation to pay the Exercise Price through a "cashless exercise", in which event the Company shall issue to the Holder the number of Warrant Shares determined as follows:

$$X = Y [(A-B)/A]$$

where:

"X" equals the number of Warrant Shares to be issued to the Holder;

"Y" equals the total number of Warrant Shares with respect to which this Warrant is then being exercised;

"A" equals the average of the Closing Sale Prices of the shares of Common Stock (as reported by Bloomberg Financial Markets) for the five (5) consecutive Trading Days ending on the date immediately preceding the Exercise Date; and

"B" equals the Exercise Price then in effect for the applicable Warrant Shares at the time of such exercise.

For purposes of Rule 144 promulgated under the Securities Act, it is intended, understood and acknowledged that the Warrant Shares issued in a "cashless exercise" transaction shall be deemed to have been acquired by the Holder, and the holding period for the Warrant Shares shall be deemed to have commenced, on the date this Warrant was originally issued (provided that the Commission continues to take the position that such treatment is proper at the time of such exercise).

11. Limitations on Exercise.

(a) Notwithstanding anything to the contrary contained herein, the number of Warrant Shares that may be acquired by the Holder upon any exercise of this Warrant (or otherwise in respect hereof) shall be limited to the extent necessary to ensure that, following such exercise (or other issuance), the total number of shares of Common Stock then beneficially owned by the Holder and its Affiliates and any other Persons whose beneficial ownership of Common Stock would be aggregated with the Holder's for purposes of Section 13(d) of the Exchange Act, does not exceed 4.999% of the total number of then issued and outstanding shares of Common Stock (including for such purpose the shares of Common Stock issuable upon such exercise), it being acknowledged by the Holder that the Company is not representing to such Holder that such calculation is in compliance with Section 13(d) of the Exchange Act and such Holder is solely responsible for any schedules required to be filed in accordance therewith. To the extent that the limitation contained in this Section 11(a) applies, the determination of whether this Warrant is exercisable (in relation to other securities owned by such Holder) and of which a portion of this Warrant is exercisable shall be in the sole discretion of a Holder, and the submission of a Notice of Exercise shall be deemed to be the Holder's determination of whether this Warrant is exercisable (in relation to other securities owned by such Holder) and of which portion of this Warrant is exercisable, in each case subject to such aggregate percentage limitation, and the Company shall have no obligation to verify or confirm the accuracy of such determination. In addition, a determination under this Section 11(a) as to any group status shall be determined in accordance with Section 13(d) of the Exchange Act and the rules and regulations promulgated thereunder. For purposes of this Section 11(a), in determining the number of outstanding shares of Common Stock, the Holder may rely on the number of outstanding shares of Common Stock as reflected in (x) the Company's most recent Form 10-Q or Form 10-K, as the case may be, (y) a more recent public announcement by the Company or (z) any other notice by the Company or the Transfer Agent setting forth the number of shares of Common Stock outstanding. Upon the written request of the Holder, the Company shall within three (3) Trading Days confirm orally and in writing to such Holder the number of shares of Common Stock then outstanding. By written notice to the Company, which will not be effective until the sixty-first (61st) day after such notice is delivered to the Company, the Holder may waive the provisions of this Section 11(a) (but such waiver will not affect any other holder) to change the beneficial ownership limitation to such percentage of the number of shares of the Common Stock outstanding immediately after giving effect to the issuance of shares of Common Stock upon exercise of this Warrant as the Holder shall determine, in its sole discretion, subject to Section 11(b), and the provisions of this Section 11(a) shall continue to apply. Upon such a change by a Holder of the beneficial ownership limitation from such 4.999% limitation to such other percentage limitation, the beneficial ownership limitation may not be further waived by such Holder without first providing the minimum notice required by this Section 11(a). Notwithstanding the foregoing, at any time following notice of a Fundamental Transaction under Section 9(g)(ii) with respect to a Section 9(c)(iii) Fundamental Transaction, the Holder may waive and/or change the beneficial ownership limitation effective immediately upon written notice to the Company and may reinstitute a beneficial ownership limitation at any time thereafter effective immediately upon written notice to the Company.

(b) Notwithstanding anything to the contrary contained herein, including Section 11(a), the Company shall not effect any exercise of this Warrant, and the Holder shall not be entitled to exercise this Warrant for a number of Warrant Shares in excess of that number of Warrant Shares which, upon giving effect to such exercise, would cause (i) the aggregate number of shares of Common Stock beneficially owned by the Holder and its Affiliates and any other Persons whose beneficial ownership of Common Stock would be aggregated with the Holder's for purposes of Section 13(d) of the Exchange Act, to exceed 19.99% of the total number of issued and outstanding shares of Common Stock of the Company following such exercise, or (ii) the combined voting power of the securities of the Company beneficially owned by the Holder and its Affiliates and any other Persons whose beneficial ownership of Common Stock would be aggregated with the Holder's for purposes of Section 13(d) of the Exchange Act to exceed 19.99% of the combined voting power of all of the securities of the Company then outstanding following such exercise. For purposes of this Section 11(b), the aggregate number of shares of Common Stock or voting securities beneficially owned by the Holder and its Affiliates and any other Persons whose beneficial ownership of Common Stock would be aggregated with the Holder's for purposes of Section 13(d) of the Exchange Act shall include the shares of Common Stock issuable upon the exercise of this Warrant with respect to which such determination is being made, but shall exclude the number of shares of Common Stock which would be issuable upon (x) exercise of the remaining unexercised and non-cancelled portion of this Warrant by the Holder and (y) exercise or conversion of the unexercised, non-converted or non-cancelled portion of any other securities of the Company that do not have voting power (including without limitation any securities of the Company which would entitle the holder thereof to acquire at any time Common Stock, including without limitation any debt, preferred stock, right, option, warrant or other instrument that is at any time convertible into or exercisable or exchangeable for, or otherwise entitles the holder thereof to receive, Common Stock), is subject to a limitation on conversion or exercise analogous to the limitation contained herein and is beneficially owned by the Holder or any of its Affiliates and other Persons whose beneficial ownership of Common Stock would be aggregated with the Holder's for purposes of Section 13(d) of the Exchange Act.

(c) This Section 11 shall not restrict the number of shares of Common Stock that a Holder may receive or beneficially own in order to determine the amount of securities or other consideration that such Holder may receive in the event of a Fundamental Transaction as contemplated in Section 9 of this Warrant.

12. No Fractional Shares. No fractional Warrant Shares will be issued in connection with any exercise of this Warrant. In lieu of any fractional shares that would otherwise be issuable, the number of Warrant Shares to be issued shall be rounded down to the next whole number and the Company shall pay the Holder in cash the fair market value (based on the Closing Sale Price) for any such fractional shares.

13. Notices. Any and all notices or other communications or deliveries hereunder (including, without limitation, any Exercise Notice) shall be in writing and shall be deemed given and effective on the earliest of (i) the date of transmission, if such notice or communication is delivered via facsimile or confirmed e-mail at the facsimile number or e-mail address specified in the books and records of the Transfer Agent prior to 5:30 P.M., New York City time, on a Trading Day, (ii) the next Trading Day after the date of transmission, if such notice or communication is delivered via facsimile or confirmed e-mail at the facsimile number or e-mail address specified in the books and records of the Transfer Agent on a day that is not a Trading Day or later than 5:30 P.M., New York City time, on any Trading Day, (iii) the Trading Day following the date of mailing, if sent by nationally recognized overnight courier service specifying next business day delivery, or (iv) upon actual receipt by the Person to whom such notice is required to be given, if by hand delivery.

14. Warrant Agent. The Transfer Agent shall serve as warrant agent under this Warrant. Upon thirty (30) days' notice to the Holder, the Company may appoint a new warrant agent. Any corporation into which the Company or any new warrant agent may be merged or any corporation resulting from any consolidation to which the Company or any new warrant agent shall be a party or any corporation to which the Company or any new warrant agent transfers substantially all of its corporate trust or shareholders services business shall be a successor warrant agent under this Warrant without any further act. Any such successor warrant agent shall promptly cause notice of its succession as warrant agent to be mailed (by first class mail, postage prepaid) to the Holder at the Holder's last address as shown on the Warrant Register.

15. Miscellaneous.

(a) No Rights as a Stockholder. The Holder, solely in such Person's capacity as a holder of this Warrant, shall not be entitled to vote or receive dividends or be deemed the holder of share capital of the Company for any purpose, nor shall anything contained in this Warrant be construed to confer upon the Holder, solely in such Person's capacity as the Holder of this Warrant, any of the rights of a stockholder of the Company or any right to vote, give or withhold consent to any corporate action (whether any reorganization, issue of stock, reclassification of stock, consolidation, merger, amalgamation, conveyance or otherwise), receive notice of meetings, receive dividends or subscription rights, or otherwise, prior to the issuance to the Holder of the Warrant Shares which such Person is then entitled to receive upon the due exercise of this Warrant. In addition, nothing contained in this Warrant shall be construed as imposing any liabilities on the Holder to purchase any securities (upon exercise of this Warrant or otherwise) or as a stockholder of the Company, whether such liabilities are asserted by the Company or by creditors of the Company.

(b) Authorized Shares. (i) Except and to the extent as waived or consented to by the Holder, the Company shall not by any action, including, without limitation, amending its certificate or articles of incorporation or through any reorganization, transfer of assets, consolidation, merger, dissolution, issue or sale of securities or any other voluntary action, avoid or seek to avoid the observance or performance of any of the terms of this Warrant, but will at all times in good faith assist in the carrying out of all such terms and in the taking of all such actions as may be necessary or appropriate to protect the rights of Holder as set forth in this Warrant against impairment. Without limiting the generality of the foregoing, the Company will (a) not increase the par value of any Warrant Shares above the amount payable therefor upon such exercise immediately prior to such increase in par value, (b) take all such action as may be necessary or appropriate in order that the Company may validly and legally issue fully paid and nonassessable Warrant Shares upon the exercise of this Warrant, and (c) use commercially reasonable efforts to obtain all such authorizations, exemptions or consents from any public regulatory body having jurisdiction thereof as may be necessary to enable the Company to perform its obligations under this Warrant.

(ii) Before taking any action which would result in an adjustment in the number of Warrant Shares for which this Warrant is exercisable or in the Exercise Price, the Company shall obtain all such authorizations or exemptions thereof, or consents thereto, as may be necessary from any public regulatory body or bodies having jurisdiction thereof.

(c) Successors and Assigns. Subject to the restrictions on transfer set forth in this Warrant and compliance with applicable securities laws, this Warrant may be assigned by the Holder. This Warrant may not be assigned by the Company without the written consent of the Holder except to a successor in the event of a Fundamental Transaction. This Warrant shall be binding on and inure to the benefit of the Company and the Holder and their respective successors and assigns. Subject to the preceding sentence, nothing in this Warrant shall be construed to give to any Person other than the Company and the Holder any legal or equitable right, remedy or cause of action under this Warrant. This Warrant may be amended only in writing signed by the Company and the Holder, or their successors and assigns.

(d) Amendment and Waiver. Except as otherwise provided herein, the provisions of the Warrants may be amended and the Company may take any action herein prohibited, or omit to perform any act herein required to be performed by it, only if the Company has obtained the written consent of the Holders of Warrants representing no less than a majority of the Warrant Shares obtainable upon exercise of the Warrants then outstanding.

(e) Acceptance. Receipt of this Warrant by the Holder shall constitute acceptance of and agreement to all of the terms and conditions contained herein.

(f) Governing Law; Jurisdiction. ALL QUESTIONS CONCERNING THE CONSTRUCTION, VALIDITY, ENFORCEMENT AND INTERPRETATION OF THIS WARRANT SHALL BE GOVERNED BY AND CONSTRUED AND ENFORCED IN ACCORDANCE WITH THE LAWS OF THE STATE OF NEW YORK WITHOUT REGARD TO THE PRINCIPLES OF CONFLICTS OF LAW THEREOF. EACH OF THE COMPANY AND THE HOLDER HEREBY IRREVOCABLY SUBMITS TO THE EXCLUSIVE JURISDICTION OF THE STATE AND FEDERAL COURTS SITTING IN THE CITY OF NEW YORK, BOROUGH OF MANHATTAN, FOR THE ADJUDICATION OF ANY DISPUTE HEREUNDER OR IN CONNECTION HEREWITH OR WITH ANY TRANSACTION CONTEMPLATED HEREBY OR DISCUSSED HEREIN (INCLUDING WITH RESPECT TO THE ENFORCEMENT OF ANY OF THE TRANSACTION DOCUMENTS), AND HEREBY IRREVOCABLY WAIVES, AND AGREES NOT TO ASSERT IN ANY SUIT, ACTION OR PROCEEDING, ANY CLAIM THAT IT IS NOT PERSONALLY SUBJECT TO THE JURISDICTION OF ANY SUCH COURT. EACH OF THE COMPANY AND THE HOLDER HEREBY IRREVOCABLY WAIVES PERSONAL SERVICE OF PROCESS AND CONSENTS TO PROCESS BEING SERVED IN ANY SUCH SUIT, ACTION OR PROCEEDING BY MAILING A COPY THEREOF VIA REGISTERED OR CERTIFIED MAIL OR OVERNIGHT DELIVERY (WITH EVIDENCE OF DELIVERY) TO SUCH PERSON AT THE ADDRESS IN EFFECT FOR NOTICES TO IT AND AGREES THAT SUCH SERVICE SHALL CONSTITUTE GOOD AND SUFFICIENT SERVICE OF PROCESS AND NOTICE THEREOF. NOTHING CONTAINED HEREIN SHALL BE DEEMED TO LIMIT IN ANY WAY ANY RIGHT TO SERVE PROCESS IN ANY MANNER PERMITTED BY LAW. EACH OF THE COMPANY AND THE HOLDER HEREBY WAIVES ALL RIGHTS TO A TRIAL BY JURY.

(g) Headings. The headings herein are for convenience only, do not constitute a part of this Warrant and shall not be deemed to limit or affect any of the provisions hereof.

(h) Severability. In case any one or more of the provisions of this Warrant shall be invalid or unenforceable in any respect, the validity and enforceability of the remaining terms and provisions of this Warrant shall not in any way be affected or impaired thereby, and the Company and the Holder will attempt in good faith to agree upon a valid and enforceable provision which shall be a commercially reasonable substitute therefor, and upon so agreeing, shall incorporate such substitute provision in this Warrant.

[REMAINDER OF PAGE INTENTIONALLY LEFT BLANK]

IN WITNESS WHEREOF, the Company has caused this Amended and Restated Warrant to be duly executed by its authorized officer as of the date first indicated above.

IDERA PHARMACEUTICALS, INC.

By: _____

Name:

Title:

SCHEDULE 1

FORM OF EXERCISE NOTICE

[To be executed by the Holder to purchase shares of Common Stock under the Warrant]

Ladies and Gentlemen:

(1) The undersigned is the Holder of Warrant No. (the " *Warrant*") issued by Idera Pharmaceuticals, Inc., a Delaware corporation (the "*Company*"). Capitalized terms used herein and not otherwise defined herein have the respective meanings set forth in the Warrant.

(2) The undersigned hereby exercises its right to purchase Warrant Shares pursuant to the Warrant.

(3) The Holder intends that payment of the Exercise Price shall be made as (check one):

¨ Cash Exercise

¨ "Cashless Exercise" under Section 10 of the Warrant

(4) If the Holder has elected a Cash Exercise, the Holder shall pay the sum of $ in immediately available funds to the Company in accordance with the terms of the Warrant.

(5) Pursuant to this Exercise Notice, the Company shall deliver to the Holder Warrant Shares determined in accordance with the terms of the Warrant.

(6) By its delivery of this Exercise Notice, the undersigned represents and warrants to the Company that in giving effect to the exercise evidenced hereby the Holder will not beneficially own in excess of the number of shares of Common Stock (as determined in accordance with Section 13(d) of the Securities Exchange Act of 1934, as amended) permitted to be owned under Section 11(a) or Section 11(b), as applicable, of the Warrant to which this notice relates.

Dated: _____

Name of Holder: _____

By: _____

Name: _____

Title: _____

(Signature must conform in all respects to name of Holder as specified on the face of the Warrant)

Exhibit 4.14

DESCRIPTION OF THE REGISTRANT'S SECURITIES REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934

The following description sets forth certain material terms and provisions of Idera Pharmaceuticals, Inc.'s ("Idera," "we," "us," and "our") securities that are registered under Section 12 of the Securities Exchange Act of 1934, as amended.

The following description is a summary and does not purport to be complete. It is subject to, and qualified in its entirety by reference to, Idera's Restated Certificate of Incorporation, as amended (the "Certificate of Incorporation") and Idera's Amended and Restated Bylaws (the "Bylaws"), each of which are incorporated by reference as an exhibit to the Annual Report on Form 10-K of which this Exhibit 4.14 is a part. The terms of these securities also may be affected by the Delaware General Corporation Law.

Unless otherwise indicated, any share and per share amounts included in the description of our securities, reflect, as applicable, the occurrence of a 1-for-8 reverse split of our common stock that occurred on June 29, 2006 and a 1-for-8 reverse split of our common stock that occurred on July 27, 2018.

Description of Common Stock

Voting

Each outstanding share of common stock, par value $0.001 per share, is entitled to one vote per share on all matters submitted to a vote of our stockholders, except as set forth in the Certificate of Incorporation. Holders of common stock do not have cumulative voting rights.

Dividends; Liquidation and Dissolution

Subject to the preferences that may be applicable to any then outstanding shares of preferred stock, holders of common stock are entitled to receive ratably on a per share basis such dividends and other distributions in cash, stock or property of Idera as may be declared by our Board of Directors (the "Board") from time to time out of the legally available assets or funds of Idera. Upon our voluntary or involuntary liquidation, dissolution or winding up, holders of common stock are entitled to receive ratably all assets of Idera available for distribution to its stockholders after payment of any amounts due to creditors and any amounts due to the holders of our preferred stock.

Other Rights and Restrictions

Holders of our common stock have no preemptive rights and no right to convert their common stock into any other securities. There are no redemption or sinking fund provisions applicable to our common stock. The Certificate of Incorporation and Bylaws do not restrict the ability of holders of common stock to transfer their shares of common stock. Our Board may authorize the issuance of preferred stock with voting, conversion, dividend, liquidation and other rights that may adversely affect the rights of the holder of our common stock.

Put Right

Pursuant to the terms of that certain Unit Purchase Agreement, dated May 5, 1998 (the "UPA") we issued and sold a total of 149,960 shares of common stock (the "Put Shares") at a price of $128.00 per share. Under the UPA, the initial purchasers of the Put Shares (the "Put Holders") have the right to require us to repurchase the put shares (the "Put Right"). In order for the Put Right to be exercised by any Put

Holder all of the following must occur: (1) we liquidate, dissolve or wind up our affairs pursuant to applicable bankruptcy law, whether voluntarily or involuntarily; (2) all of our indebtedness and obligations, including without limitation the indebtedness under our outstanding notes, has been paid in full; and (3) all rights of the holders of any series or class of capital stick raking prior and senior to the common stock with respect to liquidation have been satisfied in full. We may terminate the Put Right upon written notice to the Put Holders if the closing sales price of our common stock exceeds $256.00 per share for the 20 consecutive trading days prior to the date of notice of termination. Because the Put Right is not transferable, in the event that a Put Holder has transferred Put Shares since May 5, 1998, the Put Right with respect to those Put Shares has terminated. As a consequence of the Put Right, in the event we are liquidated, holders of shares of common stock that do not have a Put Right with respect to such shares may receive smaller distributions per share upon our liquidation than if there was no Put Right outstanding. As of the date of the Annual Report on Form 10-K of which this Exhibit 4.14 is a part, we had repurchased or received documentation of the transfer of 49,993 Put Shares and 4,472 of the Put Shares continued to be held in the name of the Put Holders. We cannot determine at this time what portion of the Put Rights of the remaining 95,494 Put Shares have terminated.

Certain Anti-Takeover Provisions of Our Certificate Incorporation and Bylaws

The following is a summary of certain provisions of our Certificate of Incorporation and Bylaws that may have the effect of delaying, deterring or preventing hostile takeovers or changes in control or management of Idera. Such provisions could deprive our stockholders of opportunities to realize a premium on their stock. At the same time, these provisions may have the effect of inducing any persons seeking to acquire or control us to negotiate terms acceptable to our Board.

Undesignated Preferred Stock

Our Certificate of Incorporation authorizes our Board to issue shares of preferred stock and set the voting powers, designations, preferences, and other rights related to that preferred stock without stockholder approval. Any such designation and issuance of shares of preferred stock could delay, defer or prevent any attempt to acquire or control us.

Staggered Board

Our Certificate of Incorporation and Bylaws provide for the division of our Board into three classes as nearly equal in size as possible with staggered three-year terms. The classification of the Board could have the effect of making it more difficult for a third party to acquire, or of discouraging a third party from acquiring, control of us. Our Certificate of Incorporation and Bylaws require the affirmative vote of the holders of at least 75% of the shares of our capital stock issued and outstanding and entitled to vote to amend or repeal this provision.

Vacancies on the Board of Directors; Removal of Directors

Our Certificate of Incorporation and our Bylaws provide that, subject to any rights of holders of our preferred stock, any vacancies in our Board for any reason will be filled only by a majority of our directors remaining in office, and directors so elected will hold office until the next election of directors. The inability of our stockholders to fill vacancies on the Board may make it more difficult to change the composition of our Board. Additionally, our Certificate of Incorporation and Bylaws provide that a director may be removed from office by our stockholders only for cause and by the affirmative vote of at least two-thirds of our outstanding voting stock. Our Certificate of Incorporation and Bylaws require the affirmative

vote of the holders of at least 75% of the shares of our capital stock issued and outstanding and entitled to vote to amend or repeal these provisions.

Cumulative Voting

Our Certificate of Incorporation and Bylaws do not provide for cumulative voting. Accordingly, the holders of a majority of the shares of common stock entitled to vote in any election of directors may elect all of the directors standing for election. As a result, subject to the voting rights, of which there currently are none, of any outstanding preferred stock, persons who hold more than 50% of the outstanding common stock entitled to elect members of our Board can elect all of the directors who are up for election in a particular year.

Business Combinations

We are subject to Section 203 of the Delaware General Corporation Law. Subject to certain exceptions, Section 203 prevents a publicly-held Delaware corporation from engaging in a "business combination" with any "interested stockholder" for three years following the date that such person became an interested stockholder, unless either the interested stockholder attained such status with the approval of our Board, the business combination is approved by our Board and stockholders in a prescribed manner or the interested stockholder acquired at least 85% of our outstanding voting stock in the transaction in which such person became an interested stockholder. A "business combination" includes, among other things, a merger or consolidation involving us and the "interested stockholder" and the sale of more than 10% of our assets. In general, an "interested stockholder" is any entity or person beneficially owning 15% or more of our outstanding voting stock and any entity or person affiliated with or controlling or controlled by such entity or person.

No Stockholder Action by Written Consent; Special Meeting of Stockholders

Our Certificate of Incorporation and our Bylaws provide do not provide for action by written consent, which may require our stockholders to wait for a regularly scheduled annual meeting to change the composition of our Board. Our Certificate of Incorporation and our Bylaws also provide that special meetings of our stockholders may be called only by a majority of the Board or by our chief executive officer or, if the office the chief executive officer is vacant, our president. In no event may our stockholders call a special meeting of stockholders. Our Certificate of Incorporation and Bylaws require the affirmative vote of the holders of at least 75% of the shares of our capital stock issued and outstanding and entitled to vote to amend or repeal these provisions.

Advance Notification of Stockholder Nominations and Proposals

Our Bylaws provide that stockholders seeking to bring business before an annual meeting of stockholders, or to nominate candidates for election as directors at an annual meeting of stockholders, must meet specified procedural requirements. These provisions may preclude stockholders from bringing matters before an annual meeting of stockholders or from making nominations for directors at an annual or special meeting of stockholders.

Exhibit 10.42

SECOND AMENDMENT TO LEASE

THIS SECOND AMENDMENT TO LEASE ("Amendment") is made this 13th day of January, 2020 by and between **505 EAGLEVIEW BOULEVARD ASSOCIATES,** a Pennsylvania limited partnership ("Landlord") and **IDERA PHARMACEUTICALS, INC.,** a corporation ("Tenant").

BACKGROUND

Landlord and Tenant are parties to that certain lease agreement dated March 31, 2015, as amended by Amendment to Lease dated September 23, 2015 (collectively the "Lease") relating to certain premises consisting of approximately 11,015 rentable square feet, more or less ("Leased Space") as shown on Exhibit A to the Lease in the building known as 505 Eagleview Boulevard, Eagleview Corporate Center, Uwchlan Township, Exton, Chester County, Pennsylvania (the "Building").

NOW THEREFORE, the parties hereto, each intending to be legally bound hereby, agree that the Lease is hereby amended and modified as follows:

1. Extension of Term. The Term of the Lease is hereby extended for a period of five (5) years from June 1, 2020 through May 31, 2025 (the "Extension Term"), which shall hereinafter be the Expiration Date of the Term.

2. Landlord's Work. Tenant accepts the Leased Space for the Extension Term, except that Landlord agrees that, at its expense, it shall provide improvements, described on Exhibit A, to be further documented by plans and specifications to be reviewed and approved by Landlord and Tenant prior to the commencement of work, which shall be treated as Landlord' Work to which Section 8 of the Lease shall apply.

3. Rent for Extension Term. Effective as of the June 1, 2010, Minimum Annual Rent payable in accordance with Section 1(h) of the Lease applicable to the Leased Space shall be in the following amounts:

Lease Period	Rate Per Rentable Square Foot	Minimum Annual Rent	Monthly Installment
6/1/2020-5/31/2021	$20.00	$220,300.00	$18,358.33
6/1/2021-5/31/2022	$20.50	$225,807.50	$18,817.29
6/1/2022-5/31/2023	$21.00	$231,315.00	$19,276.25
6/1/2023-5/31/2024	$21.50	$236,822.50	$19,735.21
6/1/2024-5/31/2025	$22.00	$242,330.00	$20,194.17

4. Amendment to Early Termination Option.

Section 17 of the Lease is amended to substitute for "more than 13,769 rentable square feet" the phrase "more than 11,015 rentable square feet".

5. Brokers. Tenant and Landlord represent and warrant to each other neither has had any dealings, negotiations or consultations with Tenant relating to this transaction and that no other

broker or finder called the Expansion Space to Tenant's attention for lease or took any part in any dealings, negotiations or consultations relating to the Expansion Space or this Amendment. Tenant agrees to be responsible for, indemnify, defend and hold harmless Landlord from and against all costs, fees (including, without limitation, attorney's fees), expenses, liabilities and claims incurred or suffered by Landlord arising from any breach by Tenant of Tenant's foregoing representation and warranty. Landlord agrees to be responsible for, indemnify, defend and hold harmless Tenant from and against all costs, fees (including, without limitation, attorney's fees), expenses, liabilities and claims incurred or suffered by Tenant arising from any breach by Landlord of Landlord's foregoing representation and warranty.

6. Miscellaneous.

(a) All capitalized terms not defined herein shall have the same meaning as the Lease. From and after the date hereof, except to the extent that the context otherwise requires, the term "Lease" shall mean the Lease as modified by this Amendment.

(b) Except as expressly modified hereby, the terms and conditions of the Lease remain unmodified and in full force and effect, which the parties hereby ratify and confirm. In the event of a conflict between the terms of the Lease and this Amendment, the latter shall control. The foregoing shall apply to Section 44 of the Lease granting to Tenant an option to renew for an additional five (5) years, which shall apply to a period commencing at the end of the Extension Term. Without limiting the foregoing, the parties hereby expressly ratify and restate the confession of judgment as provided in Section 25 of the Lease as follows:

Confession of Judgment

WHEN THE LEASE SHALL BE TERMINATED BY COVENANT OR CONDITION BROKEN, EITHER DURING THE ORIGINAL TERM OR ANY RENEWALS OR EXTENSIONS THEREOF, AND ALSO WHEN AND AFTER THE TERM CREATED OR, ANY RENEWAL OR EXTENSION THEREOF SHALL HAVE EXPIRED, IT SHALL BE LAWFUL FOR ANY ATTORNEY OF ANY COURT OF RECORD AS ATTORNEY FOR TENANT TO CONFESS JUDGMENT IN EJECTMENT AGAINST TENANT AND ALL PERSONS CLAIMING UNDER TENANT, AND A JUDGMENT FOR THE RECOVERY BY LANDLORD OF POSSESSION MAY ISSUE FORTHWITH WITHOUT ANY PRIOR WRIT OR PROCEEDINGS WHATSOEVER. IF FOR ANY REASON AFTER SUCH ACTION SHALL HAVE BEEN COMMENCED, IT SHALL BE CANCELED OR SUSPENDED AND POSSESSION OF THE LEASED SPACE REMAINS IN OR IS RESTORED TO TENANT, LANDLORD SHALL HAVE THE RIGHT UPON ANY SUBSEQUENT DEFAULT OR TERMINATION OF THE LEASE, OR ANY RENEWAL OR EXTENSION THEREOF, TO BRING ONE OR MORE ACTIONS IN CONFESSION OF JUDGMENT FOR EJECTMENT AS HEREINBEFORE SET FORTH TO RECOVER POSSESSION OF THE LEASED SPACE. IF IN ANY ACTION TO CONFESS JUDGMENT IN EJECTMENT, LANDLORD SHALL CAUSE TO BE FILED IN SUCH ACTION AN AFFIDAVIT SETTING FORTH THE FACTS NECESSARY TO AUTHORIZE THE ENTRY OF JUDGMENT AND IF A TRUE COPY OF THE LEASE OR THIS INSTRUMENT (AND THE TRUTH OF THE COPY STATED IN SUCH AFFIDAVIT SHALL BE SUFFICIENT PROOF) BE FILED IN SUCH ACTION, IT SHALL NOT BE NECESSARY TO FILE THE ORIGINAL AS A WARRANT OF ATTORNEY, ANY LAW, RULE OF COURT, CUSTOM OR PRACTICE TO THE

CONTRARY NOTWITHSTANDING. TENANT EXPRESSLY RELEASES TO LANDLORD, AND TO ANY AND ALL ATTORNEYS WHO MAY APPEAR FOR TENANT, ALL ERRORS IN THE SAID PROCEEDINGS, AND ALL LIABILITY THEREFOR. TENANT EXPRESSLY WAIVES THE BENEFIT OF ALL LAWS, NOW OR HEREAFTER IN FORCE, EXEMPTING ANY GOODS WITHIN THE LEASED SPACE OR ELSEWHERE FROM DISTRAINT, LEVY OR SALE.

TENANT

IDERA PHARMACEUTICALS, INC.

By: /s/ Vincent J. Milano

Vincent J. Milano, Chief Executive Officer

(c) The terms and conditions of the Lease, as amended hereby, constitutes the whole agreement between the parties and any further amendments or modifications to the terms of the Lease must be in writing and duly executed by the parties hereto.

(d) This Amendment shall be binding upon and shall inure to the benefit of the parties hereto and their respective heirs and assigns, except as specifically provided herein or in the Lease, and is not intended to benefit any person or entity not a party hereto.

(e) This Amendment shall be construed under the laws of the Commonwealth of Pennsylvania without regard to conflicts of laws principles.

(f) This Amendment may be executed in any number of counterparts, each of which shall be deemed an original and all of which counterparts together shall constitute one and the same instrument. It shall not be necessary for all parties to execute the same counterpart, so long as each party shall have executed at least one counterpart, but in this latter event, each party shall have delivered to it photocopies of counterparts showing signatures of all of the parties.

(g) This instrument may not be recorded in the Office of the Recorder of Deeds or any other place of public record.

THE REMAINDER OF THIS PAGE INTENTIONALLY LEFT BLANK

IN WITNESS WHEREOF, Landlord and Tenant have executed this Amendment as of the day and year first above written.

LANDLORD:

505 Eagleview Boulevard Associates, a Pennsylvania limited partnership

By: 505 Eagleview Boulevard Associates, Inc., its general partner

By: /s/ Robert S. Hankin
Robert S. Hankin, President

TENANT:

IDERA PHARMACEUTICALS, INC., a corporation

By: /s/ Vincent J. Milano
Vincent J. Milano, Chief Executive Officer

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the following Registration Statements:

(1) Registration Statement (Form S-8 No. 333-152669) pertaining to the 2008 Stock Incentive Plan of Idera Pharmaceuticals, Inc.

(2) Registration Statement (Form S-8 No. 333-176067) pertaining to the 2008 Stock Incentive Plan and 1995 Employee Stock Purchase Plan of Idera Pharmaceuticals, Inc.

(3) Registration Statement (Form S-8 No. 333-191076) pertaining to the 2013 Stock Incentive Plan of Idera Pharmaceuticals, Inc.

(4) Registration Statement (Form S-8 No. 333-197062) pertaining to the 2013 Stock Incentive Plan of Idera Pharmaceuticals, Inc.

(5) Registration Statement (Form S-8 No. 333-202691) pertaining to Inducement Stock Option Awards of Idera Pharmaceuticals, Inc.

(6) Registration Statement (Form S-8 No. 333-206129) pertaining to the 2013 Stock Incentive Plan, as amended, of Idera Pharmaceuticals, Inc.

(7) Registration Statement (Form S-8 No. 333-210090) pertaining to an Inducement Stock Option Award of Idera Pharmaceuticals, Inc.

(8) Registration Statement (Form S-1 as amended by Form S-3/A No. 333-136610) of Idera Pharmaceuticals, Inc.

(9) Registration Statement (Form S-1 as amended by Form S-3/A No. 333-187155) of Idera Pharmaceuticals, Inc.

(10) Registration Statement (Form S-2 as amended by Form S-3/A No. 333-109630) of Idera Pharmaceuticals, Inc.

(11) Registration Statement (Form S-3 No. 333-119943) of Idera Pharmaceuticals, Inc.

(12) Registration Statement (Form S-3 No. 333-126634) of Idera Pharmaceuticals, Inc.

(13) Registration Statement (Form S-3 No. 333-131804) of Idera Pharmaceuticals, Inc.

(14) Registration Statement (Form S-3 No. 333-133455) of Idera Pharmaceuticals, Inc.

(15) Registration Statement (Form S-3 No. 333-133456) of Idera Pharmaceuticals, Inc.

(16) Registration Statement (Form S-3 No. 333-139830) of Idera Pharmaceuticals, Inc.

(17) Registration Statement (Form S-3 as amended by Form S-3/A No. 333-185392) of Idera Pharmaceuticals, Inc.

(18) Registration Statement (Form S-3 No. 333-186312) of Idera Pharmaceuticals, Inc.

(19) Registration Statement (Form S-3 No. 333-189700) of Idera Pharmaceuticals, Inc.

(20) Registration Statement (Form S-3 No. 333-191073) of Idera Pharmaceuticals, Inc.

(21) Registration Statement (Form S-3 No. 333-210140) of Idera Pharmaceuticals, Inc.

(22) Registration Statement (Form S-8 No. 333-217665) pertaining to an Inducement Stock Option Award of Idera Pharmaceuticals, Inc.

(23) Registration Statement (Form S-8 No. 333-219740) pertaining to the 2017 Employee Stock Purchase Plan of Idera Pharmaceuticals, Inc.

(24) Registration Statement (Form S-8 No. 333-219741) pertaining to the 2013 Stock Incentive Plan, as amended, of Idera Pharmaceuticals, Inc.

(25) Registration Statement (Form S-3 No. 333-219851) of Idera Pharmaceuticals, Inc.

(26) Registration Statement (Form S-8 No. 333-232609) pertaining to the 2017 Employee Stock Purchase Plan of Idera Pharmaceuticals, Inc.

(27) Registration Statement (Form S-8 No. 333-232610) pertaining to the 2013 Stock Incentive Plan, as amended, of Idera Pharmaceuticals, Inc.

of our reports dated March 11, 2020, with respect to the financial statements of Idera Pharmaceuticals, Inc., and the effectiveness of internal control over financial reporting of Idera Pharmaceuticals, Inc., included in this Annual Report (Form 10-K) of Idera Pharmaceuticals, Inc. for the year ended December 31, 2019.

/s/ ERSNT & YOUNG LLP

Philadelphia, Pennsylvania
March 11, 2020

Exhibit 31.1

Certification of Chief Executive Officer pursuant to Exchange Act Rules 13a-14 and 15d-14, as adopted pursuant to Section 302 of Sarbanes-Oxley Act of 2002

I, Vincent J. Milano, certify that:

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

/s/ Vincent J. Milano
Vincent J. Milano
Chief Executive Officer

Dated: March 11, 2020

Exhibit 31.2

Certification of Chief Financial Officer pursuant to Exchange Act Rules 13a-14 and 15d-14, as adopted pursuant to Section 302 of Sarbanes-Oxley Act of 2002

I, John J. Kirby, certify that:

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

/s/ John J. Kirby
John J. Kirby
Chief Financial Officer

Dated: March 11, 2020

Exhibit 32.1

**Certification of Chief Executive Officer pursuant to 18 U.S.C.
Section 1350, as adopted pursuant to Section 906 of the
Sarbanes-Oxley Act of 2002**

In connection with the Annual Report on Form 10-K of Idera Pharmaceuticals, Inc. (the "Company") for the period ended December 31, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Vincent J. Milano, Chief Executive Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, that to his knowledge:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

A signed original of this written statement has been provided to Idera Pharmaceuticals, Inc. and will be retained by Idera Pharmaceuticals, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.

/s/ Vincent J. Milano
Vincent J. Milano
Chief Executive Officer

Dated: March 11, 2020

Exhibit 32.2

Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

In connection with the Annual Report on Form 10-K of Idera Pharmaceuticals, Inc. (the "Company") for the period ended December 31, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, John J. Kirby, Chief Financial Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, that to his knowledge:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

A signed original of this written statement has been provided to Idera Pharmaceuticals, Inc. and will be retained by Idera Pharmaceuticals, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.

/s/ John J. Kirby
John J. Kirby
Chief Financial Officer

Dated: March 11, 2020