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

# FORM 10-K

**(Mark One)**

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

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

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
**For transition period from _____ to _____.**
**Commission File Number: 001-37841**

# Kadmon Holdings, Inc.

(Exact name of registrant as specified in its charter)

| **Delaware** | | **27-3576929** |
|---|---|---|
| (State or other jurisdiction of incorporation or organization) | | (I.R.S. Employer Identification No.) |
| **450 East 29th Street, New York, NY** | | **10016** |
| (Address of principal executive offices) | | (Zip Code) |

**(833) 900-5366**
(Registrant's telephone number, including area code)
**Securities registered pursuant to Section 12(b) of the Act:**

| Title of each class | Trading Symbol(s) | Name of each exchange on which registered |
|---|---|---|
| Common stock, par value $0.001 per share | KDMN | Nasdaq Global Select 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 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 and posted 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 and post 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 has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

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

As of June 30, 2020, the last business day of the registrant's most recently completed second fiscal quarter, the aggregate market value of its voting and non-voting common equity held by non-affiliates was approximately $495,163,071 based upon the closing price of the registrant's common stock on June 30, 2020.

The number of shares of the registrant's common stock outstanding as of March 1, 2021 was 171,816,945.

**DOCUMENTS INCORPORATED BY REFERENCE**

Portions of Kadmon Holdings, Inc.'s definitive proxy statement for the 2021 Annual Meeting of Shareholders are incorporated by reference into Part III of this Annual Report on Form 10-K to the extent stated herein.

**Kadmon Holdings, Inc.**

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## FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements. All statements other than statements of historical facts contained in this Annual Report on Form 10-K may be forward-looking statements. Statements regarding our future results of operations and financial position, business strategy and plans and objectives of management for future operations, including, among others, statements regarding future expenditures, are forward-looking statements. In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "expects," "plans," "anticipates," "could," "intends," "targets," "projects," "contemplates," "believes," "estimates," "predicts," "potential" or "continue" or the negative of these terms or other similar expressions.

Forward-looking statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. We believe that these factors include, but are not limited to, the following:

- the initiation, timing, progress and results of our preclinical studies and clinical trials, and our research and development programs;
- our ability to advance product candidates into, and successfully complete, clinical trials;
- the impact of the COVID-19 pandemic on our business, workforce, patients, collaborators and suppliers, including delays in anticipated timelines and milestones of our clinical trials and on various government agencies who we interact with and/or are governed by;
- our reliance on the success of our product candidates;
- the timing or likelihood of regulatory filings and approvals;
- the benefits of U.S. Food and Drug Administration designations such as Breakthrough Therapy, and review of our New Drug Application under the FDA's Oncology Center of Excellence (OCE) pilot program, Real-Time Oncology Review (RTOR), and the FDA's Project Orbis initiative (Project Orbis);
- the commercialization, pricing and reimbursement of our product candidates, if approved, and our ability to expand our sales and marketing capabilities;
- the implementation of our business model, strategic plans for our business, product candidates and technology;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our product candidates and technology and our ability to operate our business without infringing, misappropriating or otherwise violating the intellectual property rights and proprietary technology of third parties;
- cost associated with defending or enforcing, if any, intellectual property infringement, misappropriation or other intellectual property violation, product liability and other claims;
- regulatory and governmental policy developments in the United States, Europe and other jurisdictions;
- our ability to maintain and establish strategic agreements and collaborations and the potential benefits of those arrangements;
- the rate and degree of market acceptance, if any, of our product candidates, if approved;
- developments relating to our competitors and our industry, including competing therapies;
- our ability to effectively manage our anticipated growth;
- our ability to attract and retain qualified employees and key personnel;
- our ability to achieve cost savings and benefits from our efforts to streamline our operations and to not harm our business with such efforts;
- statements and estimates regarding future revenue, hiring plans, expenses, capital expenditures, capital requirements, needs for additional financing and share performance;
- litigation, including costs associated with prosecuting or defending pending or threatened claims and any adverse outcomes or settlements not covered by insurance;
- our expected use of cash, cash equivalents and marketable debt securities and other sources of liquidity;
- our expected uses for the proceeds from the offering of our convertible senior notes;
- the future trading price of the shares of our common stock and the impact of analysts' reports on these prices;
- our ability to apply unused federal and state net operating loss carryforwards against future taxable income; and
- other risks and uncertainties, including those listed under the caption "Risk Factors."

The forward-looking statements in this Annual Report on Form 10-K are only predictions, and we may not actually achieve the plans, intentions or expectations included in our forward-looking statements. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified, you should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements.

# PART I

## Item 1. Business

### Overview

We are a clinical-stage biopharmaceutical company that discovers, develops and delivers transformative therapies for unmet medical needs. Our team has a proven track record of successful drug development and commercialization. Our clinical pipeline includes treatments for immune and fibrotic diseases as well as immuno-oncology therapies. We expect to continue to progress our clinical candidates and have further clinical trial events throughout 2021. Below is a brief description of our clinical product candidates:

- ***Immune and Fibrotic Diseases.*** We are developing oral small molecule inhibitors of Rho-associated coiled-coil kinase ("ROCK") to treat immune and fibrotic diseases. Research by Kadmon and several academic institutions has demonstrated that inhibition of ROCK can regulate aberrant immune responses and fibrotic processes.

  - ***Belumosudil***. Belumosudil (KD025), our most advanced product candidate, is an orally administered, selective small molecule inhibitor of Rho-associated coiled-coil kinase 2 ("ROCK2"). A pivotal study of belumosudil is ongoing in patients with chronic graft-versus-host disease ("cGVHD"), a complication following hematopoietic cell transplantation ("HCT") that can result in multi-organ inflammation and fibrosis.

    In November 2020, the U.S. Food and Drug Administration ("FDA") accepted the New Drug Application ("NDA") for belumosudil for the treatment of patients with cGVHD. The FDA granted Priority Review for the NDA for belumosudil and assigned a Prescription Drug User Fee Act ("PDUFA") target action date of May 30, 2021. The NDA is being reviewed under the FDA's Real-Time Oncology Review ("RTOR") and Project Orbis pilot programs.

    According to the FDA, the RTOR pilot program aims to explore a more efficient review process to ensure that safe and effective treatments are available to patients as early as possible, while maintaining and improving review quality. In addition, the FDA has granted Breakthrough Therapy Designation (BTD) for belumosudil for the treatment of patients with cGVHD after failure of two or more lines of systemic therapy as well as Orphan Drug Designation to belumosudil for the treatment of cGVHD. BTD is designed to expedite the development and review of drugs that are intended to treat a serious condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over available therapy on a clinically significant endpoint(s).

    According to the FDA, Project Orbis provides a framework for concurrent submission and review of oncology products among international partners. In October 2020 we filed a New Drug Submission (NDS) with Health Canada; a Marketing Authorization Application (MAA) with Swissmedic; and an MAA with the Therapeutic Goods Administration (TGA) in Australia, for belumosudil in certain patients with cGVHD, under Project Orbis. In addition, in November 2020, we filed an MAA with the UK Medicines and Healthcare products Regulatory Agency (MHRA) for belumosudil in cGVHD under Project Orbis. Both the NDS and the Australian MAA have received priority review from the respective applicable agency. Participation in the RTOR and Project Orbis pilot programs does not guarantee or influence approvability of our NDA, NDS, SwissMedic MAA, Australian MAA or UK MAA for belumosudil in certain patients with cGVHD, which are subject to the standard benefit-risk evaluation by the FDA, and the applicable review standards of Health Canada, Swissmedic, MHRA and TGA, respectively, and we may not derive any benefit from inclusion in these programs, including, but not limited to, a more efficient review process. These programs are not formal regulatory pathways and may be changed, suspended or halted at any time.

    In addition to cGVHD, we are developing belumosudil in for the treatment of systemic sclerosis ("SSc"), an autoimmune disease characterized by chronic inflammation, fibrosis and vascular damage. The FDA has granted Orphan Drug Designation to belumosudil for the treatment of SSc. A double-blind, placebo-controlled, 60-patient Phase 2 clinical trial (KD025-209) of belumosudil in diffuse cutaneous SSc, a subtype of SSc, is ongoing. In addition, we plan to initiate KD025-215, an open-label Phase 2 clinical trial of belumosudil in up to 15 patients with diffuse cutaneous SSc, in 2021. KD025-215 is designed to quickly demonstrate the potential of belumosudil in SSc while the placebo-controlled trial is ongoing.

- ***Immuno-oncology.*** We have a biologics research platform focused on the development of immuno-oncology therapeutics, specifically, IL-15-containing fusion proteins for the treatment of cancer.
  - ***KD033.*** KD033 is an anti-PD-L1/IL-15 fusion protein and is the most advanced product candidate from our IL-15 platform. KD033 significantly inhibited tumor growth in many mouse syngeneic models, including PD-L1-expressing models that are resistant to approved immunotherapies. In these models, KD033 has demonstrated long-lasting responses through the induction of immune system memory. A Phase 1 clinical trial of KD033 in adults with metastatic or locally advanced solid tumors is ongoing.

**Our Strategy**

Our goal is to develop innovative therapies for significant unmet medical needs. Our key strategies to achieve this goal are listed below:

- ***Advance belumosudil for the treatment of immune diseases.*** Our NDA has been accepted by the FDA for belumosudil for the treatment of cGVHD. As further discussed below, we recently announced positive results from the 12-month follow-up analysis of the trial. We are also conducting a placebo-controlled Phase 2 clinical trial of belumosudil in systemic sclerosis and plan to initiate an open-label Phase 2 clinical trial of belumosudil in systemic sclerosis in 2021.
- ***Develop KD033 for the treatment of cancer.*** We are conducting a Phase 1 clinical trial of KD033 in adults with metastatic or locally advanced solid tumors.
- ***Leverage our research platforms to develop new product candidates.*** In addition to belumosudil and KD033, we intend to use our small molecule and biologics research capabilities to develop new therapies in the areas of immune and fibrotic diseases and immuno-oncology.

Kadmon Pharmaceuticals is our wholly owned, fully integrated commercial operation. We do not currently depend on commercial revenues from Kadmon Pharmaceuticals to support our non-commercial operations. Our commercial infrastructure, including the regulatory, compliance, quality and chemistry, manufacturing and controls ("CMC") teams, currently supports the development of our clinical-stage product candidates. We plan to leverage our commercial infrastructure to commercialize our product candidates, if approved.

**Our Clinical-Stage Pipeline**

The following chart includes our clinical-stage product candidates. In addition, we continue to leverage our small molecule and biologics research capabilities to develop new therapies in the areas of immune and fibrotic diseases as well as immuno-oncology.

| CANDIDATE | INDICATION | STATUS |
|---|---|---|
| **Belumosudil (KD025)** (Selective ROCK2 inhibitor) | Chronic Graft-Versus-Host Disease (cGVHD) | • Primary endpoint met in pivotal clinical trial<br>• NDA accepted: PDUFA date: May 30, 2021<br>• NDA being reviewed under FDA's Real-Time Oncology Review (RTOR) and Project Orbis pilot programs |
| | Systemic Sclerosis | • Placebo-controlled Phase 2 clinical trial ongoing<br>• Small open-label Phase 2 clinical trial planned 2021 |
| **KD033** (anti-PD-L1/IL-15 fusion protein) | Immuno-oncology | • Phase 1 clinical trial ongoing |

**ROCK Inhibition for Immune and Fibrotic Diseases**

ROCK is an "on" switch in cells that regulates cell movement, shape, differentiation and function. Two isoforms exist: ROCK1 and ROCK2, and dysregulation of ROCK is implicated in many chronic diseases. Kadmon's research has demonstrated that inhibition of ROCK can regulate aberrant immune responses and fibrotic processes. Kadmon is developing a ROCK2-selective inhibitor, belumosudil, for the treatment of immune diseases.

Kadmon's research has helped define the role of ROCK in the pathogenesis of many diseases, including immune and fibrotic diseases. Specifically, our research has demonstrated that belumosudil helps to resolve immune dysregulation by down-regulating pro-inflammatory Th17 cells and increasing regulatory T ("Treg") cells.

ROCK is downstream of major pro-fibrotic mediators and regulates multiple fibrotic processes, including stress fiber formation, myofibroblast activation and pro-fibrotic gene transcription. Belumosudil has down-regulated key fibrotic processes in preclinical models, including with profibrotic gene transcription, stress fiber formation, myofibroblast activation and collagen deposition. In addition to belumosudil, Kadmon is developing KD045, a pan-ROCK inhibitor, for the treatment of fibrotic diseases. KD045 inhibited key fibrotic processes in multiple in vivo pharmacology models. IND-enabling activities are ongoing for KD045.

**Belumosudil Clinical Program**

To date, more than 550 subjects have been dosed with belumosudil for immune or fibrotic diseases or as healthy volunteers. Belumosudil has been well tolerated and demonstrated clinical activity.

***Belumosudil for the Treatment of Chronic Graft-Versus-Host Disease***

*Medical Need: Chronic Graft-Versus-Host Disease*

cGVHD is a common complication that can occur following HCT. In cGVHD, transplanted immune cells (graft) attack the patient's cells (host), leading to inflammation and fibrosis in multiple tissues, including skin, mouth, eye, joints, liver, lung, esophagus and gastrointestinal tract. Approximately 14,000 patients in the United States are living with cGVHD.

*Belumosudil in Chronic Graft-Versus-Host Disease*

Belumosudil has demonstrated clinical activity and tolerability in an ongoing pivotal trial in patients with cGVHD who have received two or more prior lines of systemic therapy (ROCKstar; KD025-213) as well as in an ongoing Phase 2 clinical trial in patients with steroid-dependent or steroid-refractory cGVHD with one to three prior lines of treatment for the disease (KD025-208).

*Ongoing Pivotal Trial of Belumosudil in Chronic Graft-Versus-Host Disease (ROCKstar)*

ROCKstar (KD025-213) is an ongoing, open-label pivotal trial evaluating belumosudil in adults and adolescents with cGVHD who have received at least two prior lines of systemic therapy. Patients were randomized to receive belumosudil 200 mg QD or 200 mg BID (63 patients per arm). Either belumosudil dose may be considered by the FDA for registration. The primary endpoint is the ORR, defined as the percentage of patients who meet the 2014 National Institutes of Health ("NIH") Consensus Conference overall response criteria of Complete Response (CR) or Partial Response (PR).

In December 2020, we announced positive results from the planned 12-month follow-up analysis of ROCKstar (KD025-213). The trial met the primary endpoint of Overall Response Rate ("ORR") at the interim analysis, which was conducted, as scheduled, two months after completion of enrollment. At the 12-month follow-up analysis, belumosudil achieved statistically significant and clinically meaningful ORRs of 73% with 200 mg once daily (95% Confidence Interval ("CI"): 60%, 83%; $p<0.0001$) and 77% with belumosudil 200 mg twice daily (95% CI: 65%, 87%; $p<0.0001$). ORRs were consistent across key patient subgroups and complete responses were observed in all affected organ systems, including in organs with fibrotic disease. Responses were durable, with a median duration of response of 50 weeks; 60% of responders have maintained their responses for 20 weeks or longer. Clinically meaningful improvement from baseline in the Lee Symptom Scale (LSS) score, a quality-of-life measurement, was observed in 60% of patients. In addition, 64% of patients were able to reduce their corticosteroid dose, with 21% of patients completely discontinuing corticosteroid therapy. Belumosudil has been well tolerated and adverse events have been consistent with those expected in the cGVHD patient population.

In November 2020, the FDA accepted the NDA for belumosudil for the treatment of patients with cGVHD. The FDA granted Priority Review for the NDA for belumosudil and assigned a PDUFA target action date of May 30, 2021. The NDA is being reviewed under the FDA's RTOR and Project Orbis pilot programs. The FDA has granted Breakthrough Therapy Designation to belumosudil for the treatment of patients with cGVHD after failure of two or more lines of systemic therapy as well as Orphan Drug Designation to belumosudil for the treatment of cGVHD.

*Ongoing Phase 2a Clinical Trial of Belumosudil in cGVHD (KD025-208)*

KD025-208 is an ongoing Phase 2 clinical trial in patients with steroid-dependent or steroid-refractory cGVHD with one to three prior lines of treatment for the disease. Three cohorts of patients, (belumosudil 200 mg QD (n=17), belumosudil 200 mg BID (n=16) and belumosudil 400 mg QD (n=21)), were enrolled sequentially following a safety assessment of the previous cohort. Belumosudil achieved an ORR of approximately 65% across all three cohorts. Responses were observed across all affected organ systems, including in organs with fibrotic disease. Responses were durable, with a median duration of response of 35 weeks. Patients reported improvements in quality of life and were also able to reduce and/or completely discontinue doses of corticosteroids and other immunosuppressants. Pharmacodynamics data showed a decrease in Th17 cells and an increase in Treg cells during belumosudil treatment, consistent with belumosudil mechanism of action. Belumosudil was well tolerated, with no treatment-related serious adverse events and no apparent increased risk of infection. Forty-three percent (43%) of patients in the trial have remained on belumosudil for more than one year and 28% of patients have remained on belumosudil for more than one-and-a-half years as of February 19, 2020.

***Belumosudil for the Treatment of Systemic Sclerosis***

*Medical Need: Systemic Sclerosis*

Systemic sclerosis (“SSc”) is a chronic autoimmune disease that causes widespread microvascular damage and excessive deposition of collagen in the skin and internal organs. Limited cutaneous systemic sclerosis is primarily cutaneous, affecting the hands, arms, and face. Diffuse cutaneous systemic sclerosis (dcSSc) is a more serious manifestation of the disease and is often rapidly progressive, not only involving the skin, but also involving internal organs. SSc affects 75,000 to 100,000 people in the United States, approximately 35% of whom have dcSSc. Currently, there are no FDA approved drugs for the treatment of dcSSc.

*Ongoing Placebo-Controlled Phase 2 Clinical Trial of Belumosudil in dcSSc (KD025-209)*

We are conducting a double-blind, placebo-controlled Phase 2 clinical trial of belumosudil in dcSSc, a disease in which belumosudil has demonstrated potential in preclinical models. Sixty patients are being randomized to receive belumosudil 200 mg QD, belumosudil 200 mg BID or placebo (20 patients per arm). The primary endpoint is the change in Combined Response Index for Systemic Sclerosis (“CRISS”) score, a measure of improvement in systemic sclerosis, at 24 weeks. The FDA has granted Orphan Drug Designation to belumosudil for the treatment of SSc.

*Planned Open-Label Phase 2 Clinical Trial of Belumosudil in dcSSc (KD025-215)*

In 2021, we expect to enroll the first patient in an open-label Phase 2 clinical trial of belumosudil in dcSSc. Up to fifteen patients are being randomized to receive belumosudil 200 mg BID. The primary endpoint is the change in CRISS score, a measure of improvement in systemic sclerosis, at 24 weeks.

**KD033**

We have an in-house novel phage display library able to generate fully human monoclonal antibodies against many protein targets. This platform is run by an experienced group of scientists with an outstanding antibody development track record. Prior to joining Kadmon, this team was involved in the development of multiple commercially successful antibodies including Erbitux (cetuximab) and Cyramza (ramucirumab). Our scientists are developing monoclonal antibodies as well as fusion proteins and bispecific antibodies that we believe represent the next generation of cancer immunotherapies.

Our most advanced candidate from the biologics platform, KD033, is a novel anti-PD-L1/IL-15 fusion protein designed to stimulate an immune response directed to the tumor microenvironment. IL-15 is a cytokine that expands key tumor-fighting immune cell types, including natural killer (NK), NKT cells and memory T cells without expanding immunosuppressive Treg cells. We believe targeting this activity will allow for robust and durable anti-tumor responses. KD033 is designed to direct IL-15 activity to the tumor microenvironment of PD-L1-expressing tumors to achieve a greater therapeutic window.

Preclinical data demonstrated that a single dose of KD033 inhibited tumor growth across multiple *in vivo* syngeneic tumor models. KD033 induced a strong immune response with a single treatment, resulting in mice that remained tumor-free following several tumor re-challenges. Furthermore, KD033 in combination with anti-PD-1 therapy demonstrated synergistic activity, providing clinical rationale for administering KD033 in combination with other immune checkpoint inhibitors. KD033 has demonstrated significant tumor inhibition in murine models that are resistant to approved immunotherapies (PD-L1, PD-1 or CTLA-4 antibodies), suggesting that KD033 may deliver promising clinical outcomes in cancer patients resistant or refractory to immuno-oncology monotherapy. A Phase 1 clinical trial of KD033 in adults with metastatic or locally advanced solid tumors is ongoing.

**Other Clinical Programs**

*Tesevatinib for the Treatment of Autosomal Dominant Polycystic Kidney Disease (KD019-211)*

Tesevatinib is an oral tyrosine kinase inhibitor in development for the treatment of autosomal dominant polycystic kidney disease ("ADPKD"), a genetic kidney disorder. To date, more than 300 individuals have received tesevatinib for the treatment of PKD or cancer, or as healthy volunteers.

Our randomized, placebo-controlled Phase 2 clinical trial of tesevatinib in ADPKD (KD019-211) is ongoing and has completed enrollment. The primary endpoint is change from baseline of the height-adjusted total kidney volume in patients with ADPKD treated with tesevatinib 50 mg QD compared to placebo at 24 months.

**Our Drug Discovery Platforms**

We have two drug discovery platforms that support our pipeline of clinical-stage product candidates: small molecules and biologics. We are developing novel therapies in the areas of immune and fibrotic diseases as well as immuno-oncology.

**Research and Development**

Research and development expenses consist primarily of costs incurred for the development of our product candidates. For the years ended December 31, 2020 and 2019, we recognized $65.4 million and $56.5 million, respectively, in research and development expenses. For further detail about our research and development activities, refer to the research and development sections in "Management's Discussion and Analysis of Financial Condition and Results of Operations" in this Annual Report on Form 10-K.

**Sales and Marketing**

Kadmon Pharmaceuticals is our wholly owned, fully integrated commercial operation. Although our commercial business generates revenue, we do not currently place significant value on our commercial operations from a revenue-generation standpoint. Until belumosudil is approved for marketing, if at all, revenues from such operations will not support our research and development efforts. We leverage our commercial infrastructure to support the development of our clinical-stage product candidates by providing quality assurance, compliance, regulatory and pharmacovigilance among other capabilities. We believe our commercial infrastructure will be most advantageous to us in the future, in connection with the anticipated commercialization of belumosudil and our pipeline product candidates, if approved. We are further developing our marketing, distribution, market access, patient support services and reimbursement capabilities in anticipation of potential FDA approval for belumosudil. Our intent is to commercialize belumosudil ourselves in the United States with a targeted customer-facing organization to call on treating specialists and payors. To that end, we have established a fully integrated healthcare-provider facing field force who will be responsible for generating awareness of belumosudil, if approved, as well as a team of account directors responsible for generating market access and establishing formulary positions post-approval.

Our commercial organization encompasses managed care and specialty pharmacy account directors, experienced regulatory, quality, compliance and CMC teams, strategic marketing experts and immune hematology managers, with long-standing relationships with key centers of excellence and leading physicians. The specialty pharmacies and specialty distributors through which we distribute our products are fully independent of Kadmon. We do not have any ownership interest in or affiliations with any specialty pharmacy or specialty distributor, nor do we consolidate the financial results of any specialty pharmacies or specialty distributors with our own.

**Strategic Collaborations and License Agreements**

***Nano Terra, Inc.***

In April 2011, in connection with the acquisition of Surface Logix, Inc. ("SLx") by Nano Terra, Inc. ("Nano Terra"), our subsidiary Kadmon Corporation entered into a joint venture with SLx through the formation of NT Life Sciences, LLC ("NT Life"), whereby Kadmon Corporation contributed $0.9 million at the date of formation in exchange for a 50.0% interest in NT Life. Contemporaneously with our entry into the joint venture, we entered into an exclusive sub-license agreement with NT Life and SLx, under which NT Life granted us rights to certain patents and know-how it licensed from SLx relating to belumosudil (KD025) (formerly SLx-2119). Under this agreement, NT Life granted to us an exclusive, worldwide, royalty-bearing, sublicensable license (under the patents and know how it licensed from SLx) to make, have made, use, sell, offer for sale, import and export certain products, including belumosudil. NT Life also granted to us a worldwide, non-exclusive, non-transferable, sublicensable license under certain SLx platform technology to make, have made, use, sell, offer for sale, import and export the products. The initial purpose of the joint venture with SLx was to develop assets licensed to us from SLx and to define the royalty obligations with respect to certain products not exclusively licensed to us. The joint venture is, however, currently inactive. We expect that the joint venture will become active in the future upon the commercialization of belumosudil, if approved.

We are the sublicensee of granted patents in the United States for belumosudil, as well as applications in Australia, Canada, Europe, Japan and the United States, which claim belumosudil as a composition-of-matter, and use of belumosudil to treat certain diseases. The last-to-expire U.S. patent in this family has a term that ends in October 2029 based on a calculated PTA and without regard to any potential PTE, which could further extend the term by an additional five years.

In consideration for the rights granted to us by NT Life, we agreed to assume certain of Nano Terra's payment obligations, which are limited to the royalty percentages discussed in this paragraph, under the Agreement and Plan of Merger dated April 8, 2011, by and among Nano Terra, NT Acquisition, Inc., SLx, and Dion Madsen, as the Stockholder Representative of SLx (the "Nano Terra Merger Agreement"). Pursuant to these obligations, we are required to pay to the Stockholder Representative and NT Life royalties on net sales in the amount of 5% and 10% respectively. As we own 50% of NT Life, the cumulative result of these obligations is that we will owe aggregate royalty payments totaling 9.75% on net sales of licensed products. Pursuant to the assumption of Nano Terra's payment obligations, if we further assign or sublicense our rights to any licensed product to certain third parties, we are also required to pay to the Stockholder Representative a portion of any sublicensing revenue relating to such licensed product ranging from the low twenty percents to the low forty percents, subject to specified deductions and adjustments. We are also required to pay to NT Life any remaining sublicensing revenue after giving effect to the foregoing sublicense revenue payment to the Stockholder Representative.

Unless earlier terminated, our agreement with NT Life will, with respect to a licensed product, end on a country-by-country and licensed product-by-licensed product basis upon the latest of (a) the expiration or invalidation of the last valid claim of a licensed patent right covering such licensed product in such country and (b) the expiration or termination of payment obligations with respect to such licensed product in such country under the Nano Terra Merger Agreement. The agreement will, with respect to the licensed SLx platform technology, end on a country-by-country basis upon the expiration or invalidation of the last valid claim of a licensed patent right covering such SLx platform technology. We may terminate the agreement at any time upon six months' written notice to NT Life and if we provide such notice, NT Life may accelerate such termination upon thirty days' prior written notice. Either party may terminate the agreement for any material breach by the other party that is not cured within a specified time period. NT Life may terminate the agreement if we challenge the licensed patents. Either party may terminate the agreement upon the bankruptcy or insolvency of the other party. The agreement shall terminate in the event we are dissolved.

In addition, the agreement shall terminate on a licensed product-by-licensed product basis in the event such licensed product reverts to the Stockholder Representative because of a failure to satisfy the diligence requirements as set forth in the Nano Terra Merger Agreement. More specifically, pursuant to our sub-license agreement with NT Life and SLx, we agreed to assume certain of Nano Terra's diligence obligations under the Nano Terra Merger Agreement such that we are obligated to use commercially reasonable efforts to develop the licensed products, including belumosudil. With respect to belumosudil, our diligence obligations do not expire until the completion of a certain specified Phase 2 clinical trial of belumosudil in oncology. If, prior to the expiration of our diligence obligations, we fail to comply with such diligence obligations for any licensed product, including belumosudil, the Stockholder Representative may require Nano Terra to assign all assets of SLx, including intellectual property, relating to such licensed product to an entity designated by such Stockholder Representative, subject to Nano Terra's and our rights to contest such assignment. If such an assignment takes place, our sublicense rights to such intellectual property for such licensed product will terminate.

If the agreement is terminated, among other things, we will be required to cease all development and commercialization of the licensed products, including belumosudil, all licenses granted to us will terminate and we are obligated to grant NT Life a perpetual, irrevocable, worldwide, exclusive license under certain intellectual property owned or controlled by us that relate to the licensed products to develop and commercialize such licensed products.

***Dyax Corp. (acquired by Shire Plc in January 2016 and acquired by Takeda Pharmaceutical Co. Ltd in 2018)***

In July 2011, we entered into a license agreement with Dyax Corp. ("Dyax") for the rights to use the Dyax Antibody Libraries, Dyax Materials and Dyax Know-How (collectively "Dyax Property"). The agreement terminated on September 22, 2015, but we had a right to a commercial license of any research target within two years of expiration of the agreement. We exercised this right to a commercial license of two targets in September 2017, one of which is KD033, resulting in a license fee payable to Shire Plc of $1.5 million, which was recorded as research and development expense in the third quarter of 2017. Under the terms of the agreement, we also recorded $1.5 million and as research and development expense during each of the fourth quarter of 2019 and second quarter of 2020, related to development milestones we met during those quarters.

***BioNova Pharmaceuticals Ltd.***

In November 2019, the Company entered into a strategic partnership with BioNova Pharmaceuticals Ltd. ("BioNova") to form a joint venture to exclusively develop and commercialize belumosudil (KD025), the Company's lead product candidate, for the treatment of graft-versus-host-disease ("GVHD") in the People's Republic of China. The joint venture was entered into through the creation of BK Pharmaceuticals Limited ("BK Pharma"), whereby the Company entered into a royalty-bearing exclusive license agreement with BK Pharma and BioNova in exchange for a 20% interest in BK Pharma. BK Pharma is domiciled in Hong Kong with shared oversight between the Company and BioNova.

Under the terms of the license agreement, the Company received an upfront payment of $4.0 million in December 2019 and is eligible to receive an additional $41.0 million in development, regulatory and commercial milestone payments upon the occurrence of specified events over the term of the agreement. In addition, the Company is eligible to receive double-digit percentage royalty payments on sales of belumosudil for GVHD in China.

The Company recognized $4.0 million in license revenue for the year ended December 31, 2019. No other milestone or royalty revenues have been earned as of December 31, 2020.

***Meiji Seika Pharma Co., Ltd***

In December 2019, the Company entered into a collaboration agreement with Meiji Seika Pharma Co., Ltd ("Meiji"), a Tokyo-based wholly owned subsidiary of Meiji Holdings Co., Ltd., to form a joint venture to exclusively develop and commercialize belumosudil in Japan and certain other Asian countries. The joint venture was entered into through the creation of Romeck Pharma, LLC ("Romeck"), whereby the Company entered into a royalty-bearing exclusive license agreement with Romeck and Meiji in exchange for a 50% interest in Romeck. Romeck is domiciled in Japan with shared oversight between the Company and Meiji.

Under the terms of the license agreement, the Company received an upfront payment of $6.0 million in January 2020 and is eligible to receive an additional $23.0 million in development, regulatory and commercial milestone payments upon the occurrence of specified events over the term of the agreement. In addition, the Company is eligible to receive double-digit percentage royalty payments on sales of belumosudil for GVHD in Japan.

The Company recognized $6.0 million in license revenue in the first quarter of 2020 upon completion of the single combined performance obligation. No other milestone or royalty revenues have been earned as of December 31, 2020

**Our Intellectual Property**

The proprietary nature of, and protection for, our product candidates, their methods of use, and our technologies are an important part of our strategy to discover and develop small molecules and biologics that address areas of significant unmet medical needs in inflammatory and fibrotic diseases, and in the area of immuno-oncology. We are the owner or exclusive licensee of patents and applications relating to certain of our product candidates, and are pursuing additional patent protection for them and for our other product candidates and technologies. We also rely on trade secrets to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection. Additionally, we maintain copyrights and trademarks, both registered and unregistered.

Our success will depend significantly on our ability to obtain and maintain patent and other proprietary protection for commercially important products, product candidates, technologies, inventions and know-how related to our business and our ability to defend and enforce our patents, preserve the confidentiality of our trade secrets and operate without infringing the valid and enforceable patents and proprietary rights of third parties. We also rely on know-how, continuing technological innovation and in-licensing opportunities to develop, strengthen and maintain the proprietary position of our development programs. We actively seek to protect our proprietary information, including our trade secrets and proprietary know-how, by requiring our employees, consultants, advisors and partners to enter into confidentiality agreements and other arrangements upon the commencement of their employment or engagement. The chart below identifies which of our clinical product candidates are covered by patents and patent applications that we own or license, the relevant expiration periods and the major jurisdictions. We own additional IP for pre-clinical and commercial stage assets which are not deemed material individually or in the aggregate as of December 31, 2020. Additional patent applications have been filed to extend the patent life on some of these products, but there can be no assurance that these will issue as filed.

| Product Candidate | Description/ Indications | US Patent Numbers | Patent Expiration | Patent Type | Major Jurisdictions | Claim Type |
|---|---|---|---|---|---|---|
| Belumosudil (KD025) | ROCK2 Inhibitor/cGVHD | 15/303,420 (pending) | 2035* | Utility | US | Method of Use |
| Belumosudil (KD025) | ROCK2 Inhibitor/autoimmune diseases (incl. GVHD) | 9,815,820<br>10,183,931<br>10,696,660<br>16/913,267 (pending) | 2033+<br>2033+<br>2033+<br>2033* | Utility | Granted: US, JP<br>Pending: CA, CN, EA, EP | Method of Use |
| Belumosudil (KD025) | ROCK2 Inhibitor/Fibrosis | 8,357,693<br>8,916,576<br>9,440,961<br>10,570,123<br>16/799,076 (pending) | 2029+<br>2026+<br>2026+<br>2026+<br>2026* | Utility | Granted: US, CA, CN, EA, EP, JP | Composition of Matter/ Method of Use/ Method of Making |
| Tesevatinib (KD019) | Multi-kinase Inhibitor/Oncology | 7,576,074<br>8,658,654<br>9,359,332<br>9,796,704<br>10,266,518 | 2026+<br>2025+<br>2023+<br>2023+<br>2023+ | Utility | AU, CA, EP, JP, US | Composition of Matter/ Method of Use/ Formulations/ Method of Making |
| Tesevatinib (KD019) | Multi-kinase Inhibitor/Polycystic Kidney Disease | 9,364,479<br>9,956,221 | 2031+<br>2031+ | Utility | Granted: US, CA, CN, EA, EP, JP, TW | Method of Use |
| KD033 | Monoclonal Antibody (anti-PD-L1), Immunoconjugate/Oncology (anti-PD-L1/IL-15) | 10,407,502<br>16/812,867 | 2035+<br>2035* | Utility | Granted: US<br>Pending: CA, CN, JP, EP | Composition of Matter/ Method of Use |

+ Indicates the expiration date of a granted patent for which a Patent Term Adjustment (PTA) has been fixed by the United States Patent and Trademark Office. The date may be lengthened by a Patent Term Extension (PTE) upon regulatory approval.

* Indicates the calculated expiration date of a pending patent application based solely on a twenty-year term from the international filing date, without regard to the outcome of patent prosecution or obtaining a PTA and/or PTE.

**Manufacturing and Supply**

We currently do not own or operate manufacturing facilities for the production of our product candidates. We currently outsource to a limited number of external service providers the production of all active pharmaceutical ingredients ("API"), drug substances and drug products, and we expect to continue to do so to meet the preclinical and clinical requirements of our product candidates. We do not have long-term agreements with these third parties. We have framework agreements with most of our external service providers, under which they generally provide services to us on a short-term, project-by-project basis. We typically have long-term relationships with our manufacturing and supply chain partners for our commercial products.

Currently, our drug substance or API raw materials for our product candidates can be supplied by multiple source suppliers. Manufacturing is subject to extensive regulations that impose various procedural and documentation requirements, which govern record keeping, manufacturing processes and controls, personnel, quality control and quality assurance, among others. The contract manufacturing organizations that we use to manufacture our product are obligated to operate under current Good Manufacturing Practice regulations (cGMP) conditions.

**Competition**

We compete directly with companies that focus on cGVHD, systemic sclerosis and IL-15 based therapies for cancer, and companies dedicating their resources to novel forms of therapies for these indications. We also face competition from academic research institutions, governmental agencies and other various public and private research institutions. With the proliferation of new drugs and therapies in these areas, we expect to face increasingly intense competition as new technologies become available. Any product candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future.

Many of our competitors have significantly greater financial, manufacturing, marketing, drug development, technical and human resources than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining top qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

The key competitive factors affecting the success of all of our product candidates, if approved, are likely to be their efficacy, safety, dosing convenience, price, the effectiveness of companion diagnostics in guiding the use of related therapeutics, the level of generic competition and the availability of reimbursement from government and other third-party payors.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, less expensive, more convenient or easier to administer, or have fewer or less severe effects than any products that we may develop. Our competitors also may obtain FDA, European Medicines Agency ("EMA") or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. Even if our product candidates achieve marketing approval, they may be priced at a significant premium over competitive products if any have been approved by then.

There are a number of currently marketed therapies and products in late-stage clinical development to treat cGVHD and systemic sclerosis, including:

| cGVHD | Systemic Sclerosis |
|---|---|
| Imbruvica (ibrutinib) | Ofev (nintedanib) |
| Jakafi (ruxolitinib) | Mycophenolate mofetil |
| Corticosteroids | Cyclosporine |
| Calcineurin inhibitors | |

Certain products in development may provide efficacy, safety, dosing convenience and other benefits that are not provided by currently marketed therapies. As a result, they may provide significant competition for any of our product candidates for which we obtain marketing approval.

**Government Regulation**

***Government Regulation and Product Approval***

Government authorities in the United States and in other countries extensively regulate, among other things, the research, development, testing, manufacture (including manufacturing changes), quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, marketing, export and import of products such as those we are developing. The processes for obtaining regulatory approvals in the United States and in foreign countries, along with subsequent compliance with applicable statutes and regulations, require the expenditure of substantial resources.

***U.S. Drug Development Process***

In the United States, the FDA regulates drugs under the Federal Food, Drug and Cosmetic Act ("FDCA"), and in the case of biologics, also the Public Health Service Act, and various implementing regulations. Most biological products meet the FDCA's definition of "drug" and are subject to FDA drug requirements, supplemented by biologics requirements.

Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process, or after approval, may subject an applicant to administrative or judicial sanctions. These sanctions could include the FDA's refusal to approve pending applications, withdrawal of an approval, a clinical hold, untitled or warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties. The process required by the FDA before a drug or biologic may be marketed in the United States generally involves the following:

- completion of preclinical laboratory tests, animal studies and formulation studies according to Good Laboratory Practices regulations;
- submission to the FDA of an IND, which must become effective before human clinical studies may begin;
- approval by an independent institutional review board ("IRB"), at each clinical site before each trial may be initiated;

- performance of adequate and well-controlled human clinical studies according to "good clinical practices" ("GCP") regulations, to establish the safety and efficacy of the proposed drug or biologic for its intended use;
- preparation and submission to the FDA of a NDA or Biologics License Application ("BLA");
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the product, or components thereof, are produced to assess compliance with cGMP to assure that the facilities, methods, and controls are adequate to preserve the drug's identity, strength, quality, and purity; and
- FDA review and approval of the NDA or BLA.

The testing and approval process requires substantial time, effort and financial resources, and we cannot be certain that any approvals for our product candidates will be granted on a timely basis, if at all.

Once a pharmaceutical or biological product candidate is identified for development, it enters the preclinical testing stage. Preclinical tests include laboratory evaluations of product chemistry, toxicity, formulation and stability, as well as animal studies. When a sponsor wants to proceed to test the product candidate in humans, it must submit an IND in order to conduct clinical trials.

An IND sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data and any available clinical data or literature, to the FDA as part of the IND. The sponsor must also include a protocol detailing, among other things, the objectives of the initial clinical study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated if the initial clinical study lends itself to an efficacy evaluation. Some preclinical testing may continue even after the IND is submitted. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA raises concerns or questions related to a proposed clinical study and places the study on a clinical hold within that 30-day time period. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical study can begin. Clinical holds also may be imposed by the FDA at any time before or during clinical studies due to safety concerns or non-compliance, and may be imposed on all product candidates within a certain pharmaceutical class. The FDA also can impose partial clinical holds, for example, prohibiting the initiation of clinical studies of a certain duration or for a certain dose.

All clinical studies must be conducted under the supervision of one or more qualified investigators in accordance with GCP regulations. These regulations include the requirement that all research subjects provide informed consent in writing before their participation in any clinical study. Further, an IRB must review and approve the plan for any clinical study before it commences at any institution, and the IRB must conduct continuing review and reapprove the study at least annually. An IRB considers, among other things, whether the risks to individuals participating in the clinical study are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the information regarding the clinical study and the consent form that must be provided to each clinical study subject or his or her legal representative and must monitor the clinical study until completed.

Each new clinical protocol and any amendments to the protocol must be submitted for FDA review, and to the IRBs for approval. Protocols detail, among other things, the objectives of the clinical study, dosing procedures, subject selection and exclusion criteria, and the parameters to be used to monitor subject safety.

Information about certain clinical trials must be submitted within specific timeframes to the NIH, for public dissemination on their ClinicalTrials.gov website.

Human clinical studies are typically conducted in three sequential phases that may overlap or be combined:

- *Phase 1.* The product is initially introduced into a small number of healthy human subjects or patients and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion and, if possible, to gain early evidence on effectiveness. In the case of some products for severe or life-threatening diseases, especially when the product is suspected or known to be unavoidably toxic, the initial human testing may be conducted in patients.
- *Phase 2.* Involves clinical studies in 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 and schedule.
- *Phase 3.* Clinical studies are undertaken to further evaluate dosage, clinical efficacy and safety in an expanded patient population at geographically dispersed clinical study sites. These clinical studies are intended to establish the overall risk/benefit relationship of the product and provide an adequate basis for product labeling.

Progress reports detailing the results of the clinical studies must be submitted at least annually to the FDA and safety reports must be submitted to the FDA and the investigators for serious and unexpected suspected adverse events. Phase 1, Phase 2 and Phase 3 testing may not be completed successfully within any specified period, if at all. The FDA or the sponsor may suspend or terminate a clinical study at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical study at its institution if the clinical study is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients.

Concurrent with clinical studies, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the product and finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, the manufacturer must develop methods for testing the identity, strength, quality and purity of the final product. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

***United States Review and Approval Processes***

Assuming successful completion of the required clinical testing, the results of product development, preclinical studies and clinical studies, along with descriptions of the manufacturing process, analytical tests conducted on the drug, proposed labeling and other relevant information, are submitted to the FDA as part of an NDA for a new drug, or a BLA for a biological drug product, requesting approval to market the product.

The submission of an NDA or BLA is subject to the payment of a substantial application user fee although a waiver of such fee may be obtained under certain limited circumstances. For example, the agency will waive the application fee for the first human drug application that a small business or its affiliate submits for review. The sponsor of an approved NDA or BLA is also subject to annual product and establishment user fees. For FDA fiscal year 2020 the application fee for an application with clinical data was $2,942,965. Sponsors are also subject to a prescription drug program fee. For fiscal 2020, the prescription drug program fee was $325,424.

In addition, under the Pediatric Research Equity Act of 2003, an NDA or BLA applications (or supplements to applications) for a new active ingredient, new indication, new dosage form, new dosing regimen, or new route of administration must contain data that are adequate to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective, unless the applicant has obtained a waiver or deferral.

In 2012, the Food and Drug Administration Safety and Innovation Act ("FDASIA") amended the FDCA to require that a sponsor who is planning to submit a marketing application for a drug or biological product that includes a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration submit an initial Pediatric Study Plan ("PSP"), within sixty days of an End-of-Phase 2 meeting or as may be agreed between the sponsor and the FDA. The initial PSP must include an outline of the pediatric study or studies that the sponsor plans to conduct, including study objectives and design, age groups, relevant endpoints and statistical approach, or a justification for not including such detailed information, and any request for a deferral of pediatric assessments or a full or partial waiver of the requirement to provide data from pediatric studies along with supporting information. The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of data or full or partial waivers. The FDA and the sponsor must reach agreement on the PSP. A sponsor can submit amendments to an agreed-upon initial PSP at any time if changes to the pediatric plan need to be considered based on data collected from preclinical studies, early phase clinical studies, and/or other clinical development programs.

The FDA also may require submission of a Risk Evaluation and Mitigation Strategy ("REMS") to mitigate any identified or suspected serious risks. The REMS could include medication guides, physician communication plans, assessment plans, and elements to assure safe use, such as restricted distribution methods, patient registries, or other risk minimization tools.

The FDA reviews all NDAs and BLAs submitted to ensure that they are sufficiently complete for substantive review before it accepts them for filing. The FDA may request additional information rather than accept an application for filing. In this event, the application must be re-submitted with the additional information. The re-submitted application also is 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 reviews an NDA to determine, among other things, whether a product is safe and effective for its intended use and whether its manufacturing is cGMP-compliant. For biologics, the applicant must demonstrate that the product is safe, pure, and potent (interpreted to include effectiveness), and that the facilities designed for its production meet standards to ensure the product will consistently be safe, pure, and potent.

The FDA may approve an NDA or BLA only if the methods used in, and the facilities and controls used for, the manufacture processing, packing, and testing of the product are adequate to ensure and preserve its identity, strength, quality, and purity. Drug cGMPs are established in 21 C.F.R. Parts 210 and 211, and biologic drug products must meet the drug standards as well as the supplemental requirements in 21 C.F.R. Part 600 et seq.

Before approving an NDA or BLA, the FDA often will inspect the facility or facilities where the product is or will be manufactured.

The FDA may refer the NDA or BLA to an advisory committee for review, evaluation and recommendation as to whether the application should be approved and under what conditions. An advisory committee is a panel of experts, including clinicians and other scientific experts, who provide advice and recommendations when requested by the FDA. The FDA is not bound by the recommendation of an advisory committee, but it considers such recommendations when making decisions.

Additionally, before approving an NDA or BLA, the FDA will typically inspect one or more clinical sites to ensure that clinical data supporting the submission were developed in compliance with GCP.

The approval process is lengthy and difficult and the FDA may refuse to approve an NDA or BLA if the applicable regulatory criteria are not satisfied, or may require additional clinical data or other data and information. Even if such data and information are submitted, the FDA may ultimately decide that the NDA or BLA does not satisfy the criteria for approval. Data obtained from clinical studies are not always conclusive and the FDA may interpret data differently than an applicant interprets the same data.

After the FDA's evaluation of an application, the FDA may issue an approval letter, or, in some cases, a complete response letter to indicate that the review cycle is complete and that the application is not ready for approval. A complete response letter generally contains a statement of specific conditions that must be met to secure final approval of the application and may require additional clinical or preclinical testing for the FDA to reconsider the application. The deficiencies identified may be minor, for example, requiring labeling changes, or major, for example, requiring additional clinical studies. Additionally, the complete response letter may include recommended actions that the applicant might take to place the application in a condition for approval. If a complete response letter is issued, the applicant may either resubmit the application, addressing all of the deficiencies identified in the letter, or withdraw the application or request an opportunity for a hearing.

Even with submission of additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval. If and when those conditions have been met to the FDA's satisfaction, the FDA will typically issue an approval letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications.

If a product receives regulatory approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling. In addition, the FDA may require post-approval studies, including Phase 4 clinical studies, to further assess safety and effectiveness after approval and may require testing and surveillance programs to monitor the safety of approved products that have been commercialized. After approval, some 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.

***Special FDA Expedited Review and Approval Programs***

The FDA has various programs, including Fast Track Designation, Priority Review, accelerated approval, and BTD, that are intended to expedite or simplify the process for the development and FDA review of drugs that are intended for the treatment of serious or life-threatening diseases or conditions and demonstrate the potential to address unmet medical needs. The purpose of these programs is to provide important new drugs to patients earlier than under standard FDA review procedures. To be eligible for a Fast Track Designation, the FDA must determine, based on the request of a sponsor, that a drug is intended to treat a serious or life-threatening disease or condition and demonstrates the potential to address an unmet medical need. The FDA will determine that a product will fill an unmet medical need if it will provide a therapy where none exists or provide a therapy that may be potentially superior to existing therapy based on efficacy or safety factors.

The FDA may give a Priority Review designation to drugs intended to treat serious conditions that offer major advances in treatment or provide a treatment where no adequate therapy exists. A Priority Review means that the goal for the FDA to review an application is six months, rather than the standard review of ten months under current PDUFA guidelines. These six and ten-month review periods are measured from the "filing" date rather than the receipt date for NDAs for NME, which typically adds approximately two months to the timeline for review and decision from the date of submission. Most products that are eligible for Fast Track Designation are also likely to be considered appropriate to receive a Priority Review.

In addition, drugs studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may receive accelerated approval and may be approved on the basis of adequate and well-controlled clinical trials establishing that the drug has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, 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. As a condition of approval, the FDA may require a sponsor of a drug receiving accelerated approval to perform post-marketing studies to verify and describe the predicted effect on irreversible morbidity or mortality, or other clinical endpoint and to submit promotional materials for preapproval and pre-use review. In addition, the drug may be subject to accelerated withdrawal procedures.

Moreover, a sponsor can request designation of a drug candidate as a "breakthrough therapy." 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. Drugs designated as breakthrough therapies may also be eligible for accelerated approval. The FDA must take certain actions, such as holding timely meetings and providing advice, intended to expedite the development and review of an application for approval of a breakthrough therapy.

In addition, the FDA may review applications under RTOR, which, according to the FDA, aims to explore a more efficient review process to ensure that safe and effective treatments are available to patients as early as possible, while maintaining and improving review quality. Drugs considered for review under RTOR must be likely to demonstrate substantial improvements over available therapy, which may include drugs previously granted BTD for the same or other indications, and must have straight-forward study designs and endpoints that can be easily interpreted. RTOR allows the FDA to review much of the data earlier, before the applicant formally submits the complete application. This analysis of the pre-submission package gives the FDA and applicants an early opportunity to address data quality and potential review issues and allows the FDA to provide early feedback regarding the most effective way to analyze data to properly address key regulatory questions.

Project Orbis is an initiative of the FDA's OCE and, according to the FDA, provides a framework for concurrent submission and review of oncology products among international partners.

Even if a product qualifies for one or more of the expedited review programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened. Furthermore, Fast Track Designation, Priority Review, accelerated approval, BTD, RTOR, and Project Orbis do not change the standards for approval and may not ultimately expedite the development or approval process.

***Post-Approval Requirements***

Drugs and biologics manufactured or distributed pursuant to FDA approvals are subject to extensive and continuing regulation by the FDA, including, among other things, requirements relating to recordkeeping (including certain electronic record and signature requirements), periodic reporting, product sampling and distribution, advertising and promotion and reporting of certain adverse experiences, deviations, and other problems 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.

The FDA strictly regulates labeling, advertising, promotion and other types of information on products that are placed on the market. Products may be promoted only for the approved indications and in accordance with the provisions of the approved label. Further, manufacturers must continue to comply with cGMP requirements, which are extensive and require considerable time, resources and ongoing investment to ensure compliance. In addition, changes to the manufacturing process generally require prior FDA approval before being implemented and other types of changes to the approved product, such as adding new indications and additional labeling claims, are also subject to further FDA review and approval.

Manufacturers and certain other entities involved in the manufacturing and distribution of approved products are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP and other laws. The cGMP requirements apply to all stages of the manufacturing process, including the production, processing, sterilization, packaging, labeling, storage and shipment of the product. Manufacturers must establish validated systems to ensure that products meet specifications and regulatory standards, and test each product batch or lot prior to its release.

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.

The FDA may impose a number of post-approval requirements as a condition of approval of an application. For example, the FDA may require post-marketing testing, including Phase 4 clinical trials, and surveillance to further assess and monitor the product's safety and effectiveness after commercialization.

The FDA may withdraw a product approval if compliance with regulatory requirements 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, problems with manufacturing processes, or failure to comply with regulatory requirements, may result in restrictions on the product or even complete withdrawal of the product from the market.

Potential implications include required 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, complete withdrawal of the product from the market or product recalls;
- warning letters or holds on post-approval clinical trials;
- refusal of the FDA to approve pending NDAs/BLAs or supplements to approved NDAs/BLAs, 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 marketing, labeling, advertising and promotion of products that are placed on the market. Drugs and biologics may be promoted only for the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability.

In addition, the distribution of prescription drugs and biologics is subject to the Prescription Drug Marketing Act (PDMA), which regulates the distribution of the products and product samples at the federal level, and sets minimum standards for the registration and regulation of distributors by the states. Both the PDMA and state laws limit the distribution of prescription pharmaceutical product samples and impose requirements to ensure accountability in distribution.

From time to time, legislation is drafted, introduced and passed in Congress that could significantly change the statutory provisions governing the approval, manufacturing and marketing of products regulated by the FDA. In addition to new legislation, FDA regulations, guidances and policies are often revised or reinterpreted by the agency in ways that may significantly affect our business and our product candidates. It is impossible to predict whether further legislative or FDA regulation or policy changes will be enacted or implemented and what the impact of such changes, if any, may be.

***Patent Term Restoration***

Depending upon the timing, duration and specifics of FDA approval of the use of our product candidates, some of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Act. The Hatch-Waxman Act permits a patent restoration term of up to five years as compensation for patent term effectively lost during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent term restoration period is generally 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/BLA and the approval of that application, except that the review period is reduced by any time during which the applicant failed to exercise due diligence. Only one patent applicable to an approved drug is eligible for the extension. Extensions are not granted as a matter of right and the extension must be applied for prior to expiration of the patent and within a 60-day period from the date the product is first approved for commercial marketing. The U.S. Patent and Trademark Office, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, we may apply for Patent Term Extensions, defined as the length of the regulatory review of products covered by our granted patents, for some of our currently owned or licensed applications and patents to add patent life beyond their current expiration dates. Such extensions will depend on the length of the regulatory review; however, there can be no assurance that any such extension will be granted to us.

***Marketing Exclusivity***

Market exclusivity provisions under the FDCA can also delay the submission or the approval of certain applications. The specific scope varies, but fundamentally the FDCA provides a five-year period of non-patent marketing exclusivity within the United States to the first applicant to gain approval of an NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not accept for review an ANDA or a 505(b)(2) NDA submitted by another company for another version of such drug where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement. The FDCA also provides three years of marketing exclusivity for an NDA, 505(b)(2) NDA or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example, for new indications, dosages or strengths of an existing drug. This three-year exclusivity covers only the conditions of use associated with the new clinical investigations and does not prohibit the FDA from approving applications for drugs containing the original active agent. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA. However, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical studies necessary to demonstrate safety and effectiveness.

Pediatric exclusivity is another type of exclusivity in the United States. Pediatric exclusivity, if granted, provides an additional six months to the term of any existing regulatory exclusivity, including the non-patent exclusivity periods described above. This six-month exclusivity may be granted based on the voluntary completion of a pediatric clinical study in accordance with an FDA-issued "Written Request" for such a clinical study.

With respect to biologics, the Patient Protection and Affordable Care Act, as amended by the Healthcare and Education Reconciliation Act (collectively, the PPACA) signed into law on March 23, 2010, includes a subtitle called the Biologics Price Competition and Innovation Act of 2009 (BPCIA), which created an abbreviated licensure pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. The FDA has issued several guidance documents outlining an approach to review and approval of biosimilars, although there has been significant litigation and questions over interpretation of such guidelines.

Biosimilarity, which requires that the product be "highly similar" and there be no clinically significant differences between the biological product and the reference product in terms of safety, purity, and potency, can be shown through analytical studies, animal studies, and a clinical study or studies. Interchangeability requires that a product is biosimilar to the reference product and the product must demonstrate that it can be expected to produce the same clinical results as the reference product in any given patient and, for products that are administered multiple times to an individual, the biologic and the reference biologic may be alternated or switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic. However, complexities associated with the larger, and often more complex, structures of biological products, as well as the processes by which such products are manufactured, pose significant hurdles to implementation of the abbreviated approval pathway that are still being worked out by the FDA.

Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of their product. The BPCIA also created certain exclusivity periods for biosimilars approved as interchangeable products. At this juncture, it is unclear whether products deemed "interchangeable" by the FDA will, in fact, be readily substituted by pharmacies, which are governed by state pharmacy law.

The BPCIA is complex and only beginning to be interpreted and implemented by the FDA. In addition, recent government proposals have sought to reduce the 12-year reference product exclusivity period. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. As a result, the ultimate impact, implementation, and meaning of the BPCIA is subject to significant uncertainty.

***Orphan Designation and Exclusivity***

Under the Orphan Drug Act, the FDA may grant orphan drug designation to drugs (including biological drug products) intended to treat a rare disease or condition—generally a disease or condition that affects fewer than 200,000 individuals in the United States or that affects more than 200,000 individuals in the United States and for which there is no reasonable expectation that costs of research and development of the drug for the indication can be recovered by sales of the drug in the United States. Orphan drug designation must be requested before submitting an NDA or BLA.

After the FDA grants orphan drug designation, the generic identity of the drug and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. The first applicant to receive FDA approval for a particular active ingredient to treat a particular disease or condition with FDA orphan drug designation is entitled to a seven-year exclusive marketing period in the United States for that product, for that indication. Among the other benefits of orphan drug designation are tax credits for certain research and a waiver of the NDA/BLA application user fee.

During the exclusivity period, the FDA may not approve any other applications to market the same drug for the same disease or condition, except in limited circumstances, such as if the second applicant demonstrates the clinical superiority of its product to the product with orphan drug exclusivity through a demonstration of superior safety, superior efficacy, or a major contribution to patient care, or if the manufacturer of the product with orphan exclusivity is not able to assure sufficient quantities of the product. "Same drug" means a drug that contains the same identity of the active moiety if it is a drug composed of small molecules, or of the principal molecular structural features if it is composed of macromolecules and is intended for the same use as a previously approved drug, except that if the subsequent drug can be shown to be clinically superior to the first drug, it will not be considered to be the same drug. Drug exclusivity does not prevent the FDA from approving a different drug for the same disease or condition, or the same drug for a different disease or condition.

***Pharmaceutical Coverage, Pricing and Reimbursement***

In the United States, sales of any products for which we may receive regulatory approval for commercial sale will depend in part on the availability of coverage and reimbursement from third-party payors. Third-party payors include government authorities, managed care providers, private health insurers and other organizations.

Significant uncertainty exists as to the coverage and reimbursement status of any products for which we may obtain regulatory approval. The process for determining whether a payor will provide coverage for a biologic or drug may be separate from the process for setting the reimbursement rate that the payor will pay for the product. Some of the additional requirements and restrictions on coverage and reimbursement levels imposed by third-party payors influence the purchase of healthcare services and products. Third-party payors may limit coverage to specific biologics and drugs on an approved list, or formulary, which might not include all of the FDA-approved biologics or drugs for a particular indication, or place biologics and drugs at certain formulary levels that result in lower reimbursement levels and higher cost-sharing obligation imposed on patients. Moreover, a payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development. Further, one payor's determination to provide coverage does not assure that other payors will also provide coverage and reimbursement for the product, and the level of coverage and reimbursement may differ significantly from payor to payor.

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

The U.S. government and state legislatures have shown significant interest in implementing cost containment programs to limit the growth of government-paid healthcare costs, including price controls, restrictions on reimbursement and coverage and requirements for substitution of generic products for branded prescription drugs. Adoption of government controls and measures, and tightening of restrictive policies in jurisdictions with existing controls and measures, could exclude or limit our drugs and product candidates from coverage and limit payments for pharmaceuticals.

In addition, we expect that the increased emphasis on managed care and cost containment measures in the United States by third-party payors and government authorities to continue and will place pressure on pharmaceutical pricing and coverage. 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 we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

***Other Healthcare Laws and Compliance Requirements***

Healthcare providers, physicians, and third-party payors often play a primary role in the recommendation and prescription of any currently marketed products and product candidates for which we may obtain marketing approval. Our current and future arrangements with healthcare providers, physicians, third-party payors and customers, and our sales, marketing and educational activities, may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations (at the federal and state level) that may constrain our business or financial arrangements and relationships through which we market, sell and distribute our products for which we obtain marketing approval.

In addition, we may be subject to patient privacy regulation by both the federal government and the states in which we conduct our business. The laws that govern certain of our operations include the following, but are not limited to:

a) federal and state laws relating to the Medicare and Medicaid programs and any other federal healthcare program;
b) federal and state laws relating to healthcare fraud and abuse, including, without limitation, the federal Anti-Kickback Statute (42 U.S.C. § 1320a-7b(b)), the federal False Claims Act (31 U.S.C. §§ 3729 et seq.), the False Statements Statute, (42 U.S.C. § 1320a-7b(a)), the Exclusion Laws (42 U.S.C. § 1320a-7), the federal Physician Payment Sunshine Act (42 U.S.C. § 1320a-7h), the Drug Supply Chain Security Act (21 U.S.C. § 351 et seq.), the Anti-Inducement Statute (42 U.S.C. § 1320a-7a(a)(5)), the Civil Monetary Penalties Law (42 U.S.C. § 1320a-7a) and criminal laws relating to healthcare fraud and abuse, including but not limited to 18 U.S.C. §§ 286, 287 and 1001, and the Health Insurance Portability and Accountability Act of 1996, or HIPAA, (Pub.L. 104-191);
c) state laws relating to Medicaid or any other state healthcare or health insurance programs;
d) federal or state laws relating to billing or claims for reimbursement submitted to any third party payor, employer or similar entity, or patient;
e) any other federal or state laws relating to fraudulent, abusive or unlawful practices connected in any way with the provision or marketing of healthcare items or services, including laws relating to the billing or submitting of claims for reimbursement for any items or services reimbursable under any state, federal or other governmental healthcare or health insurance program or any private payor; and
f) federal and state laws relating to health information privacy and security, including HIPAA, and any rules or regulations promulgated thereunder, and the Health Information Technology for Economic and Clinical Health Act, enacted as part of the American Recovery and Reinvestment Act of 2009 and any regulations promulgated thereunder.

If our operations are found to be in violation of any of the health regulatory laws described above or any other laws that apply to us, we may be subject to penalties, including criminal and significant civil monetary penalties, damages, fines, imprisonment, exclusion from participation in government healthcare programs, injunctions, recall or seizure of products, total or partial suspension of production, denial or withdrawal of pre-marketing product approvals, private qui tam actions brought by individual whistleblowers in the name of the government or refusal to allow us to enter into supply contracts, including government contracts and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

***Foreign Regulation of Drugs and Biologics***

In order to market any product outside of the United States, we will need to comply with numerous and varying regulatory requirements of other countries and jurisdictions regarding development, approval, commercial sales and distribution of our products, and governing, among other things, clinical trials, marketing authorization, commercial sales and distribution of our products, if approved. Whether or not we obtain FDA approval for a product, we must obtain the necessary approvals by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the product in those countries. The approval process 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.

**Human Capital**

As of December 31, 2020, we employed 127 people, including 70 in research and development, 27 in commercial operations and 30 in a general and administrative capacity, including executive officers. We anticipate that the number of employees will grow as we continue to develop our product candidates. In addition, we utilize and will continue to utilize temporary employees and consultants, clinical research organizations and third parties to perform certain activities, such as our pre-clinical studies, clinical studies, manufacturing and regulatory functions. None of our employees is represented by a labor union with respect to his or her employment with us. We have not experienced any work stoppages, and we consider our relations with our employees to be good.

We aspire to create healthier futures for patients and accelerate business results by inspiring the best and brightest talent across all dimensions of diversity to perform at their full potential. We challenge our people to make a difference by doing work that positively impacts our business, empowering them to lead, and letting them know that the Company is behind each of them as they contribute to our success. We enable our people, creating a culture where employees can learn, grow, experiment, and freely express ideas as we collectively seek to enhance long-term shareholder value. We strive to ensure our people are valued and included, treating them with respect, recognizing their unique knowledge and skills, supporting their work/life balance with flexibility, and providing competitive compensation and benefits, all in keeping with the strong performance we expect even in a challenging environment.

As a small, innovative company with developing commercialization plans and strategies, specifically with respect to our most advanced product candidate Belumosudil (KD025), we expect to expand our employee base for primarily managerial, operational, sales and marketing positions. We are committed to rewarding and supporting our employees in order to continue to attract and retain top talent. We believe this commitment supports our core strategy of creating and advancing a high-quality product pipeline. Employee engagement, commitment, and achievements are key drivers of pipeline success and therefore our long-term performance in order to increase stockholder value and the success of our company by motivating such individuals to perform to the best of their abilities and achieve our objectives. The primary underpinning of our pay philosophy is to award equity-based pay to all eligible employees to ensure that when we deliver for patients and for shareholders, everyone shares in the upside growth. Our practice, therefore, has been to award initial equity grants to all new hires, in addition to our comprehensive annual equity program. Total employee compensation packages include market-competitive pay (with the opportunity to receive above-market rewards), broad-based grants of equity-based awards, healthcare benefits, retirement savings options, and matching contributions.

The health and safety of our employees, customers and communities are of primary concern. In response to the COVID-19 pandemic, we implemented significant changes that we determined were in the best interest of our employees. For example, we have taken significant steps to protect our workforce including but not limited to, working remotely, and implementing social distancing protocols consistent with guidelines issued by federal, state, and local law.

**Emerging Growth Company**

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. We will remain an emerging growth company until the earlier of (1) December 31, 2021, (2) the last day of the first fiscal year in which our annual gross revenues exceed $1.07 billion, (3) the date on which we become a "large accelerated filer" as defined in Rule 12b-2 under the Securities Exchange Act of 1934, as amended, which would occur if the market value of our common stock that is held by non-affiliates exceeds $700 million as of the last business day of our most recently completed second fiscal quarter or (4) the date on which we have issued more than $1.0 billion in non-convertible debt during the preceding three-year period. In addition, a company may qualify as a non-accelerated filer if it has (1) annual revenues of less than $100 million in the most recent fiscal year for which audited financial statements are available and (2) a public float of less than $700 million as of the last business day of its second fiscal quarter.

For as long as we remain an "emerging growth company," we may take advantage of certain exemptions from various reporting requirements that are applicable to public companies that are not "emerging growth companies" including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation and financial statements in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote to approve executive compensation and shareholder approval of any golden parachute payments not previously approved. We are choosing to "opt out" of the extended transition periods available under the JOBS Act for complying with new or revised accounting standards, and intend to take advantage of the other reporting exemptions until we are no longer an "emerging growth company."

**Facilities**

Our corporate headquarters are located in New York, New York, and consist of approximately 35,771 square feet of space under a lease that expires in October 2025. In addition, we also have locations in Warrendale, Pennsylvania; Cambridge, Massachusetts and Monmouth Junction, New Jersey. We believe that our facilities are adequate for our current needs and for the foreseeable future.

**Corporate Information**

Our common stock is currently listed on the Nasdaq Select Global Market, or the Nasdaq, under the symbol "KDMN." Our principal executive offices are located at 450 East 29th Street, New York, New York 10016, and our telephone number is (833)-900-5366. Our website address is www.kadmon.com.

**Available Information**

We make available on or through our website certain reports and amendments to those reports that we file with, or furnish to, the SEC in accordance with the Securities Exchange Act of 1934, as amended, or the Exchange Act. These include our Annual Reports on Form 10-K, our Quarterly Reports on Form 10-Q and our Current Reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act. We make this information available on or through our website free of charge as soon as reasonably practicable after we electronically file the information with, or furnish it to, the SEC. Our website address is www.kadmon.com. The SEC maintains a website that contains reports, proxy and information statements, and other information regarding our filings, at www.sec.gov. The information on, or that can be accessed through, our website is not incorporated by reference into this Annual Report on Form 10-K or any other filings we make with the SEC.

## Item 1A. Risk Factors

*The discussion below addresses material factors, of which we are currently aware, that could have a material and adverse effect on our businesses, results of operations and financial condition. Many of the following risks and uncertainties are, and will be, exacerbated by the COVID-19 pandemic and any worsening of the global business and economic environment as a result. These risk factors and other forward-looking statements that relate to future events, expectations, trends and operating periods involve certain factors that are subject to change, and important risks and uncertainties that could cause actual results to differ materially. These risks and uncertainties should not be considered a complete discussion of all the risks and uncertainties we may face and although the risks are organized by headings and each risk is discussed separately, many are interrelated.*

### Summary of Risk Factors Affecting Our Business

Our business is subject to numerous risks. The following summary highlights some of the risks you should consider with respect to our business and prospects. This summary is not complete and the risks summarized below are not the only risks we face. You should review and consider carefully the risks and uncertainties described in the "Risk Factors" section of this Annual Report on Form 10-K, which includes a more complete discussion of the risks summarized below as well as a discussion of other risks related to our business and an investment in our common stock, as well as our other public filings with the SEC.

- We have incurred substantial losses since our inception, anticipate that we will continue to incur losses for the foreseeable future and may not achieve or sustain profitability.
- We will need additional funding in the future, which may not be available to us, and this may force us to delay, reduce or eliminate our product development programs or commercialization efforts.
- We depend heavily on the success of belumosudil. If we are unable to obtain regulatory approval for belumosudil, our ability to create stockholder value will be limited.
- Our ongoing clinical trials may be subject to delays or setbacks for a variety of common and unpredictable reasons.
- The impact of the COVID-19 pandemic on our business, workforce, patients, collaborators and suppliers, including delays in anticipated timelines and milestones of our clinical trials and on various government agencies who we interact with and/or are governed by;
- The regulatory approval processes of the FDA and similar foreign authorities are lengthy, time consuming, expensive and inherently unpredictable. If we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed.
- Priority review of our NDA for belumosudil under the FDA's RTOR pilot program and our marketing applications to Australia, Switzerland, UK and Canada pursuant to the FDA's Project Orbis initiative, may not lead to a faster regulatory review or approval, and do not increase the likelihood that ripretinib will obtain marketing approval.
- Our product candidates may have undesirable side effects that may delay or prevent marketing approval or, if approval is obtained, require them to be taken off the market, require them to include safety warnings or otherwise limit their sales.
- The results of previous clinical trials may not be predictive of future results, and the results of our current and planned clinical trials may not satisfy the requirements of the FDA or non U.S. regulatory authorities.
- We face substantial competition, which may result in others discovering, developing and commercializing products before or more successfully than our products and product candidates.
- We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.
- Even if we receive regulatory approval for our drug candidates, we cannot be certain how profitable, if at all, the commercialization of our marketed products will be.
- If physicians, nurses, pharmacists, patients, the medical community and/or third party payors do not accept our drugs or product candidates, we may be unable to generate significant revenue in future periods.
- Healthcare reform measures could hinder or prevent our product candidates' commercial success, if approved, and could increase our costs.
- If we are unable to obtain and maintain patent protection for our products and product candidates, or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize products and product candidates similar or identical to ours, and our ability to successfully commercialize our products and product candidates may be adversely affected.

- Third party claims of intellectual property infringement, misappropriation or other violation may prevent or delay our development and commercialization efforts.
- If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.
- We expect to continue to contract with third party suppliers for the production of our commercial product portfolio as well as our developmental product candidates for clinical trial use and, if approved, for commercialization.
- We depend on intellectual property licensed from third parties and termination of any of these licenses could result in the loss of significant rights, which would harm our business.
- We rely in part on third parties to conduct our clinical trials and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials.
- Our employees, independent contractors, principal investigators, agents, consultants, commercial partners and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could have a material adverse effect on our business.
- Our operating results are subject to significant fluctuations.
- Our business may become subject to economic, political, regulatory and other risks associated with international operations.
- A disruption in our computer networks, including those related to cybersecurity, could adversely affect our financial performance.
- We may be subject to security breaches or other cybersecurity incidents that could compromise our information and expose us to liability.
- We expect that our stock price will fluctuate significantly.
- Future sales of our common stock or securities convertible into our common stock in the public market could cause our stock price to fall.
- If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, stockholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our common stock.
- Holders of the convertible preferred stock may exert substantial influence over us and may exercise their control in a manner adverse to your interests.
- We will require additional capital in the future, which may not be available to us. Issuances of our equity securities to provide this capital may dilute your ownership in us.
- We are an “emerging growth company,” as defined in the JOBS Act, and as a result of the reduced disclosure and governance requirements applicable to emerging growth companies, our common stock may be less attractive to investors.
- We may not have the ability to raise the funds necessary to settle cash conversions of our convertible senior notes or to repurchase the convertible senior notes upon a fundamental change.

**Risks Related to Our Financial Position and Need for Capital**

***We are a clinical stage biopharmaceutical company with a history of operating losses.***

We are a clinical stage pharmaceutical company with a history of operating losses. We must complete clinical studies and receive regulatory approval before commercial sales of a product can commence. The likelihood of success of our business plan must be considered in light of the problems, substantial expenses, difficulties, complications and delays frequently encountered in connection with developing and expanding early-stage businesses and the regulatory and competitive environment in which we operate. Pharmaceutical product development is a highly speculative undertaking, involves a substantial degree of risk and is a capital-intensive business.

Accordingly, you should consider our prospects in light of the costs, uncertainties, delays and difficulties frequently encountered by companies in the early stages of development, especially clinical pharmaceutical companies such as ours. Potential investors should carefully consider the risks and uncertainties that a company with a limited operating history will face. In particular, potential investors should consider that we cannot assure you that we will be able to:

- successfully implement or execute our current business plan, and we cannot assure you that our business plan is sound;
- successfully manufacture our clinical products and establish commercial drug supply;
- successfully complete the clinical trials necessary to obtain regulatory approval for the marketing of our product candidates;
- secure market exclusivity and/or adequate intellectual property protection for our product candidates;
- attract and retain an experienced management and advisory team;
- secure acceptance of our product candidates in the medical community and with third party payors and consumers;
- launch commercial sales of our product candidates, whether alone or in collaboration with others; and
- raise sufficient funds in the capital markets to effectuate our business plan.

If we cannot successfully execute any one of the foregoing, our business may not succeed and your investment will be adversely affected.

***We have incurred substantial losses since our inception. We may not achieve or sustain profitability.***

Since inception, we have incurred substantial operating losses. Our consolidated net losses were $108.9 million and $61.4 million for the years ended December 31, 2020 and 2019, respectively. Our accumulated deficits were $444.1 million and $333.1 million at December 31, 2020 and 2019, respectively. To date, we have financed our clinical development operations primarily through issuance of common stock and other equity securities in public and private offerings and debt financings. We expect to continue to incur significant expenses related to the development of our clinical product candidates and commercialization of product candidates, if approved, for at least the next several years. We anticipate that our expenses will increase substantially as we:

- initiate or continue our clinical trials related to our most advanced product candidates;
- continue the research and development of our other product candidates;
- seek to discover additional product candidates;
- seek regulatory approvals for our product candidates;
- scale up our sales, marketing and distribution infrastructure and product sourcing capabilities to commercialize additional products we may acquire or license from others or for which we may develop and obtain regulatory approval; and/or
- scale up our operational, financial and management information systems and personnel, including personnel to support our product development and planned additional commercialization efforts.

In the absence of substantial revenue from the sale of our products and products that we distribute, or from other sources (the amount, timing, nature or source of which cannot be predicted), we expect our substantial losses to continue as we develop our business and we may need to discontinue operations. Our ability to generate sufficient revenues from our existing products or from any of our product candidates in development, and to transition to profitability and generate consistent positive cash flow is uncertain. We may continue to incur losses and negative cash flow and may never transition to profitability or positive cash flow.

***We may need additional funding in the future, which may not be available to us, and this may force us to delay, reduce or eliminate our product development programs or commercialization efforts.***

We will need to expend substantial resources for research and development and commercialization of our marketed products, including costs associated with:

- clinical trials for our product candidates;
- discovery of additional product candidates;
- life-cycle management of our marketed products;
- the continued commercialization of our commercial products; and/or
- preparing for potential commercialization of our late-stage product candidates and, if one or more of those product candidates receive(s) regulatory approval, to fund the launch of that (those) product(s).

For example, on February 16, 2021, we issued $240.0 million aggregate principal amount of 3.625% convertible senior notes due 2027 (the "Notes"). We received net proceeds from the issuance of the Notes of approximately $232.8 million, after deducting offering discounts. Any further debt financing obtained by us in the future could involve restrictive covenants relating to our capital raising activities and other financial and operational matters, which may make it more difficult for us to obtain additional capital and to pursue business opportunities. If we raise additional funds through further issuances of equity, convertible debt securities or other securities convertible into equity, our existing stockholders could suffer significant dilution in their percentage ownership of our company, and any new equity securities we issue could have rights, preferences and privileges senior to those of holders of our common stock. If we are unable to obtain adequate financing or financing on terms satisfactory to us, when we require it, our ability to continue to grow or support our business and to respond to business challenges could be limited.

**Risks Related to Our Clinical Development Pipeline**

***We depend heavily on the success of belumosudil. If we are unable to obtain regulatory approval for belumosudil, our ability to create near-term stockholder value will be limited.***

Our most advanced product candidate is belumosudil (KD025), for which we have submitted applications for regulatory approval in the US, UK, Canada, Switzerland and Australia. We do not generate meaningful revenues from any FDA-approved drug products. Three of our product candidates, belumosudil, KD033, and tesevatinib are in clinical trials and we have additional internally developed product candidates, which are in the early stages of development. There is no guarantee that our clinical trials will be successful or that we will continue with clinical studies to support an approval from the FDA of any of our product candidates for any indication. We note that most drug candidates never reach the clinical development stage and even those that do have only a small chance of successfully completing clinical development and gaining regulatory approval. Therefore, our business currently depends heavily on the successful development, regulatory approval and commercialization of belumosudil, which may never occur.

***Clinical development is a lengthy and expensive process with a potentially uncertain outcome. Our long-term success depends upon the successful development and commercialization of our product candidates, which is highly uncertain.***

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. The results of pre-clinical studies and early clinical trials may not be predictive of the results of later-stage clinical trials. We cannot assure you that the FDA will view the results as we do or that any future trials of our drug candidates will achieve positive results. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through pre-clinical studies and initial clinical trials. A number of companies in the pharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. Any future clinical trial results for our drug candidates may not be successful.

In addition, a number of factors could contribute to a lack of favorable safety and efficacy results for our drug candidates. For example, such trials could result in increased variability due to varying site characteristics, such as local standards of care, differences in evaluation period and surgical technique, and due to varying patient characteristics, including demographic factors and health status.

To date, we have invested a significant portion of our efforts and financial resources in the acquisition and development of our product candidates. Our long-term success depends upon the successful development, regulatory approval and commercialization of these product candidates. If we fail to obtain regulatory approval to market and sell our product candidates, or if approval is delayed, we will be unable to generate revenue from the sale of these products, our potential for generating positive cash flow will be diminished and the capital necessary to fund our operations will be increased. Our business depends significantly on the successful development, regulatory approval and commercialization of our product candidates, which may never occur.

We cannot be certain as to what type and how many clinical trials the FDA will require us to conduct before we may successfully gain approval to market any of our product candidates. Prior to approving a new drug or biologic, the FDA generally requires that the effectiveness of the product candidate (which is not typically fully investigated until Phase 3) be demonstrated in two adequate and well-controlled clinical trials. In some situations, the FDA approves drugs or biologics on the basis of a single well-controlled clinical trial establishing effectiveness. However, if the FDA determines that our Phase 3 clinical trial results do not demonstrate a statistically significant, clinically significant benefit with an acceptable safety profile, or if the FDA requires us to conduct additional Phase 3 clinical trials in order to gain approval, we will incur significant additional development costs and commercialization of these products would be prevented or delayed and our business would be adversely affected.

***Our ongoing clinical trials may be subject to delays or setbacks for a variety of common and unpredictable reasons.***

We may experience unforeseen delays or setbacks in our ongoing clinical trials, such as trial initiation timing, trial redesign or amendments, timing and availability of patient enrollment or successful trial completion. Such delays and setbacks are common and unpredictable in pharmaceutical drug development. Clinical trials can be delayed for a variety of reasons, including delays related to:

- regulatory objections to commencing a clinical trial, continuing a clinical trial that is underway, or proceeding to the next phase of investigation, including inability to reach agreement with the FDA or non-U.S. regulators regarding the scope or design of our clinical trials or for other reasons such as safety concerns that might be identified through preclinical testing and animal studies or clinical trials, at any stage;
- reaching agreement on acceptable terms with prospective contract research organizations (CROs), and clinical trial sites (the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites);
- failure of CROs or other third-party contractors to comply with contractual and regulatory requirements or to perform their services in a timely or acceptable manner;
- difficulty identifying and engaging qualified clinical investigators;
- obtaining institutional review board (IRB) approval at each site;
- difficulty recruiting and enrolling patients to participate in clinical trials for a variety of reasons, including meeting the enrollment criteria for our study and competition from other clinical trial programs for the same indication as product candidates we seek to commercialize;
- having patients complete a trial or return for post-treatment follow-up;
- clinical sites deviating from trial protocol or dropping out of a trial;
- inability to retain patients in clinical trials due to the treatment protocol, personal issues, side effects from the therapy or lack of efficacy, particularly for those patients receiving a placebo;
- withdrawal of clinical trial sites from our clinical trials as a result of changing standards of care or the ineligibility of a site to participate in our clinical trials;
- adding new clinical trial sites;
- inability to identify and maintain a sufficient number of trial sites, many of which may already be engaged in other clinical trial programs, including some that may be for the same indication as our product candidates;
- changes in applicable regulatory policies and regulations;
- insufficient data to support regulatory approval;
- difficulty in maintaining contact with subjects during or after treatment, which may result in incomplete data; or
- manufacturing sufficient quantities of the product candidate for use in clinical trials.

In late 2019, a novel strain of COVID-19, also known as coronavirus, was reported in Wuhan, China and began spreading to various parts of the world. Epidemics have adversely impacted, and may adversely impact in the future, our business as they can cause disruptions, such as interruptions to supply chain and reduction in access to personnel and services, which could result in delays and complications with respect to our research and development programs and clinical trials. In addition, certain of our business partners and vendors are based in areas currently affected by coronavirus, which could cause additional adverse impact on our business.

Patient enrollment, a significant factor in the timing of clinical trials, is affected by many factors including the size and nature of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the trial, the design of the clinical trial, competing clinical trials and clinicians' and patients' perceptions as to the potential advantages of the drug being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating. Furthermore, we rely on clinical trial sites to ensure the proper and timely conduct of our clinical trials and while we have agreements governing their committed activities, we have limited influence over their actual performance.

We could encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such trials are being conducted, by the Data Safety Monitoring Board for such trial or by the FDA or other regulatory authorities. Such authorities may impose such a suspension or termination due to a number of factors, including:

- failure by us, CROs or clinical investigators to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols;
- failed inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold;
- unforeseen safety or efficacy issues or any determination that a clinical trial presents unacceptable health risks;
- failure to demonstrate a benefit from using a drug; or
- lack of adequate funding to continue the clinical trial due to unforeseen costs resulting from enrollment delays, requirements to conduct additional trials and studies, increased expenses associated with the services of our CROs and other third parties, changes in governmental regulations or administrative actions, or other reasons.

If we experience delays in the completion or termination of any clinical trial of our product candidates, the commercial prospects of our product candidates will be harmed and our ability to generate product revenues from any of these product candidates will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may harm our business, financial condition and prospects significantly. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

***The regulatory approval processes of the FDA and similar foreign authorities are lengthy, time consuming, expensive and inherently unpredictable. If we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed.***

The time required to obtain approval by the FDA and comparable foreign authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. 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 product candidate's safety and efficacy. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the regulatory authorities. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. It is possible that none of our existing product candidates or any product candidates we may seek to develop in the future will ever obtain regulatory approval.

Our product candidates could fail to receive regulatory approval for many reasons, including:

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective for its proposed indication;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to support a submission for regulatory approval in the United States or elsewhere;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and/or
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

This lengthy approval process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval to market our product candidates, which would significantly harm our business, results of operations and prospects.

In addition, even if we were to obtain approval, regulatory authorities may:

- approve any of our product candidates for fewer or more limited indications than we request;
- may not approve the price we intend to charge for our products;
- may grant approval contingent on the performance of costly post-marketing clinical trials; or
- may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate.

If we do not achieve our projected development goals in the timeframes we announce and expect, or we face significant competition from other biotechnology and pharmaceutical companies, the commercialization of our products may be delayed, our operating results may be lower that we expect, the credibility of our management may be adversely affected and, as a result, the value of our common stock may decline.

***Breakthrough Therapy Designation, priority review of our NDA for belumosudil under the FDA's RTOR pilot program and our marketing applications to Australia, Switzerland, UK and Canada pursuant to the FDA's Project Orbis initiative, may not lead to a faster regulatory review or approval, and do not increase the likelihood that belumosudil will obtain marketing approval.***

Belumosudil has received "breakthrough therapy" designation by the FDA. 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. Drugs designated as breakthrough therapies may also be eligible for accelerated approval. The FDA must take certain actions, such as holding timely meetings and providing advice, intended to expedite the development and review of an application for approval of a breakthrough therapy. In addition, the FDA or other regulatory bodies periodically introduce pilot programs with the goal of a more efficient review of applications, including the RTOR pilot program, which is currently being tested by the FDA. The RTOR pilot program allows the FDA to review data before the applicant formally submits its completed application, aiming to explore a more efficient review process. The FDA's Project Orbis is an initiative of the FDA Oncology Center of Excellence (OCE) and, according to the FDA, is designed to provide a framework for concurrent submission and review of oncology products among international partners.

In October 2020, we filed an NDS with Health Canada, an MAA with Swissmedic, and an MAA with the TGA in Australia, for belumosudil in certain patients with cGVHD, under Project Orbis. In addition, in November 2020, we filed an MAA with MHRA for belumosudil in cGVHD under Project Orbis. According to the FDA, Project Orbis provides a framework for concurrent submission and review of oncology products among international partners. Both the NDS and the AUS MAA have received priority review, from the respective applicable agency. Participation in the RTOR and Project Orbis pilot programs does not guarantee or influence approvability of our NDA, NDS, SwissMedic MAA and/or MAA for belumosudil in certain patients with cGVHD, which are subject to the applicable review standards of Health Canada, Swissmedic, UK MHRA and TGA, respectively, and we may not derive any benefit from inclusion in these programs, including, but not limited to, a more efficient review process. These programs are not formal regulatory pathways and may be changed, suspended, or halted at any time. Priority review is an FDA designation under which the FDA sets the target date for FDA action on a NDA at six months after the FDA accepts the application for filing, rather than the standard 10-month FDA review period. Priority review is granted when there is evidence that the proposed product would be a significant improvement in the safety or effectiveness of the treatment, diagnosis, or prevention of a serious condition.

Although Breakthrough Therapy Designation, priority review designation, the RTOR pilot program and Project Orbis initiative, and other designations we may receive or programs we may participate in, are intended to expedite the review and approval of drug candidates, they do not ensure that marketing approval will be granted in a particular timeframe, or at all. The FDA and other regulatory authorities have broad discretion whether or not to grant designations for expedited review or include product candidates within various programs, and, even if we or our partners believe a particular product candidate is eligible for these designations or programs, we cannot assure you that such authority would agree. Even though the FDA has granted priority review designation for our NDA for belumosudil, and even if we or our partners receive such designations or our product candidates are eligible for inclusion in expedited review programs in the future, we may not experience a faster development, review, or approval process compared to conventional procedures. Furthermore, these designations and programs do not change the scientific and medical standard for approval or the quality of evidence necessary to support approval. As a result, applications for product candidates granted priority review or other expedited review designations or subject to these various programs may be denied based on study data, study design, or other factors.

***Even if we obtain regulatory approval for our product candidates, they may never be successfully launched or become profitable, in which case our business, prospects, operating results and financial condition may be materially harmed.***

In order to successfully launch our product candidates and have them become profitable, we anticipate that we will have to dedicate substantial time and resources and hire additional personnel to expand and enhance our commercial infrastructure, which will at a minimum include the following:

- ensure the quality of the product candidate manufactured by our suppliers and by us;
- expand our sales and marketing force;
- expand and enhance programs and other procedures to educate physicians and drive physician adoption of our product candidates;
- create additional policies and procedures, and hire additional personnel to carry out those policies and procedures, to ensure customer satisfaction with our products;
- obtain reimbursement for hospitals and physicians; and/or
- expand and enhance our general and administrative operations to manage our anticipated growth in operations and to support public company activities.

Because of the numerous risks and uncertainties associated with launch and profitability of our product candidates, we are unable to predict the extent of any future losses, or when we will become profitable, if ever.

***If serious adverse events or other undesirable side effects are identified during the use of product candidates in investigator-sponsored trials, it may adversely affect our development of such product candidates.***

Undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt non-clinical studies and clinical trials, or could make it more difficult for us to enroll patients in our clinical trials. If serious adverse events or other undesirable side effects, or unexpected characteristics of our product candidates are observed in investigator-sponsored trials, further clinical development of such product candidate may be delayed or we may not be able to continue development of such product candidate at all, and the occurrence of these events could have a material adverse effect on our business. Undesirable side effects caused by our product candidates could also result in the delay or denial of regulatory approval by the FDA or other regulatory authorities or in a more restrictive label than we expect.

***Our product candidates may have undesirable side effects that may delay or prevent marketing approval or, if approval is obtained, require them to be taken off the market, require them to include safety warnings or otherwise limit their sales.***

Undesirable or unexpected side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign authorities. Results of our trials could reveal a high and unacceptable severity and prevalence of these or other side effects. In such an event, our trials could be suspended or terminated and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of our product candidates for any or all targeted indications. The drug-related side effects could affect patient recruitment, the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly.

Additionally, if one or more of our product candidates receives marketing approval and we or others later identify undesirable or unexpected side effects caused by such products, a number of potentially significant negative consequences could result, including:

- we could be sued and held liable for harm caused to patients;
- sales of the product may decrease significantly; and/or
- our reputation may suffer.

In addition, a regulatory agency may:

- suspend or withdraw approvals of such product;
- suspend any ongoing clinical trials;
- refuse to approve pending applications or supplements to approved applications filed by us, our collaborators or our potential future collaborators;
- require additional warnings on the label;
- require that we create a medication guide outlining the risks of such side effects for distribution to patients;
- issue warning letters;
- mandate modifications to promotional materials or require us to provide corrective information to healthcare practitioners;
- require us or our collaborators to enter into a consent decree, which can include imposition of various fines, reimbursements for inspection costs, required due dates for specific actions and penalties for noncompliance;
- impose other civil or criminal penalties;
- impose restrictions on operations, including costly new manufacturing requirements; and/or
- seize or detain products or require a product recall.

Non-compliance may also result in potential whistleblower lawsuits and the potential for liability under the False Claims Act or other laws and regulations, as discussed above. Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and could significantly harm our business, results of operations and prospects.

***The results of previous clinical trials may not be predictive of future results, and the results of our current and planned clinical trials may not satisfy the requirements of the FDA or non-U.S. regulatory authorities.***

Clinical failure can occur at any stage of clinical development. Clinical trials may produce negative or inconclusive results, and we or any of our current and future collaborators may decide, or regulators may require us, to conduct additional clinical or preclinical testing. In addition, data obtained from tests are susceptible to varying interpretations, and regulators may not interpret data as favorably as we do, which may delay, limit or prevent regulatory approval.

We will be required to demonstrate with substantial evidence through well-controlled clinical trials that our product candidates are safe and effective for use in a diverse population before we can seek regulatory approvals for their commercial sale. Success in early clinical trials does not mean that future larger registration clinical trials will be successful because product candidates in later-stage clinical trials may fail to demonstrate sufficient safety and efficacy to the satisfaction of the FDA and non-U.S. regulatory authorities despite having progressed through initial clinical trials. Product candidates that have shown promising results in early clinical trials may still suffer significant setbacks in subsequent registration clinical trials. Similarly, the outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and preliminary and interim results of a clinical trial do not necessarily predict final results. A number of companies in the pharmaceutical industry, including those with greater resources and experience than us, have suffered significant setbacks in advanced clinical trials, even after obtaining promising results in earlier clinical trials.

Further, at various points during the course of the preclinical and clinical trial process, companies must assess both the statistical and clinical significance of trial results. In this context, “statistical significance” refers to the likelihood that a result or relationship is caused by something other than random chance or error. Statistical significance is measured by a “p-value,” which indicates the probability value that the results observed in a study were due to chance alone. A p-value of $< 0.05$ is generally considered statistically significant, meaning that the probability of the results occurring by chance alone is less than five percent. The lower the p-value, the less likely that the results observed were random. “Clinical significance,” on the other hand, is a qualitative assessment of the results observed. Where we use the term “clinically significant,” we have not necessarily made a formal statistical assessment of the probability that the change in patient status was attributable to the study drug as opposed to chance alone, nor does such a statement necessarily mean that study endpoints have been met or the protocol has been completed. A clinically significant effect is one that is determined to have practical importance for patients and physicians, and includes benefits that are often defined by peer-reviewed literature as having a meaningful impact on a patient’s condition. An effect that is statistically significant may or may not also be clinically significant. When a study fails to result in statistical significance, the FDA may not consider such study to serve as substantial evidence of safety and effectiveness required for approval. Even if a study results in statistical significance, the FDA may also consider clinical significance in evaluating a marketing application. For example, the FDA typically requires more than one pivotal clinical study to support approval of a new drug. However, the FDA has indicated that approval may be based on a single study in limited situations in which a trial has demonstrated a clinically significant effect. In either case, the clinical or statistical significance of a particular study result in no way guarantees that FDA or other regulators will ultimately determine that the drug being investigated is safe and effective.

In addition, the design of a clinical trial can determine whether its results will support approval of a product and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced. We may be unable to design and execute a clinical trial to support regulatory approval.

In some instances, there can be significant variability in safety and/or efficacy results between different trials of the same product candidate due to numerous factors, including changes in trial protocols, differences in size and type of the patient populations, adherence to the dosing regimen and other trial protocols and the rate of dropout among clinical trial participants. We do not know whether any Phase 1, Phase 2, Phase 3 or other clinical trials we or any of our collaborators may conduct will demonstrate consistent or adequate efficacy and safety to obtain regulatory approval to market our product candidates.

Further, our product candidates may not be approved even if they achieve their primary endpoints in Phase 3 clinical trials or registration trials. The FDA or other non-U.S. regulatory authorities may disagree with our trial design and our interpretation of data from preclinical studies and clinical trials. In addition, any of these regulatory authorities may change requirements for the approval of a product candidate even after reviewing and providing comments or advice on a protocol for a pivotal Phase 3 clinical trial that has the potential to result in the FDA or other agencies’ approval. In addition, any of these regulatory authorities may also approve a product candidate for fewer or more limited indications than we request or may grant approval contingent on the performance of costly post-marketing clinical trials. The FDA or other non-U.S. regulatory authorities may not approve the labeling claims that we believe would be necessary or desirable for the successful commercialization of our product candidates.

***We face substantial competition, which may result in others discovering, developing and commercializing products before or more successfully than our products and product candidates.***

The development and commercialization of new therapeutics is highly competitive. We face competition (from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide) with respect to our current product candidates and will face competition with respect to any product candidates that we may seek to develop or products we commercialize in the future. We also face competition from academic research institutions, governmental agencies and other various public and private research institutions. Many of these competitors are attempting to develop therapeutics for our target indications. With the proliferation of new drugs and therapies in these areas, we expect to face increasingly intense competition as new technologies become available. Any product candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future.

There are products already approved for many of the diseases we are targeting. Many of these approved products are well established therapies and are widely accepted by physicians, patients and third-party payors. This may make it difficult for us to achieve our business strategy of replacing existing therapies with our product candidates. Our commercial operations face significant direct competition and our competitors may develop products that are safer, more effective, more convenient or less costly than any that we are developing or that would render our product candidates obsolete or non-competitive. Our competitors may also obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours.

Many of our competitors have significantly greater financial, manufacturing, marketing, drug development, technical and human resources than we do. Mergers and acquisitions in the pharmaceutical, biotechnology and diagnostic industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

***We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.***

Because we have limited financial and managerial resources, we focus on our most promising research programs and product candidates. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights.

**Risks Related to Our Marketed Products**

***Even if we receive regulatory approval for our drug candidates, we cannot be certain how profitable, if at all, the commercialization of our marketed products will be.***

We must compete effectively against other therapies with our products or any of our product candidates for which we obtain marketing approval. We may never succeed in these activities and may never generate revenues that are significant or large enough to achieve profitability.

In addition to the risks discussed elsewhere in this section, our ability to continue to generate revenues from our commercialized products will depend on a number of factors, including, but not limited to:

- achievement of broad market acceptance and coverage by third-party payors for our products;
- the effectiveness of our collaborators' efforts in marketing and selling our products;
- our ability to successfully manufacture, or have manufactured, commercial quantities of our products at acceptable cost levels and in compliance with regulatory requirements;
- our ability to maintain a cost-efficient organization and, to the extent we seek to do so, to collaborate successfully with additional third parties;
- our ability to expand and maintain intellectual property protection for our products successfully;
- the efficacy and safety of our products; and/or
- our ability to comply with regulatory requirements, which are subject to change.

Because of the numerous risks and uncertainties associated with our commercialization efforts, we may not be able to achieve profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. A failure to become and remain profitable would depress the value of our company and could impair our ability to raise capital, expand our business, diversify our product offerings or continue our operations. A decline in the value of our company could also cause you to lose all or part of your investment.

***Our inability to accurately estimate demand for our products, the uptake of new products or the timing of fluctuations in the inventories maintained by customers makes it difficult for us to accurately forecast sales and may cause our financial results to fluctuate.***

We may be unable to accurately estimate demand for our products, including uptake from new products, as demand is dependent on a number of factors. We sell products primarily to wholesalers and specialty pharmacies. These customers maintain and control their own inventory levels by making estimates to determine end user demand. Our customers may not be effective in matching their inventory levels to actual end user demand. As a result, changes in inventory levels held by our customers can cause our operating results to fluctuate unexpectedly. Adverse changes in economic conditions or other factors may cause our customers to reduce their inventories of our products, which would reduce their orders from us, even if end user demand has not changed. If our inventory exceeds demand from our customers and exceeds its shelf life, we will be required to destroy unsold inventory and write off its value. As our inventory and distribution channels fluctuate from quarter to quarter, we may continue to see fluctuations in our earnings and a mismatch between prescription demand for our products and our revenues.

***If we discover safety issues with any of our products or if we fail to comply with continuing U.S. and applicable foreign regulations, commercialization efforts for the product could be negatively affected, the approved product could be subject to withdrawal of approval or sales could be suspended, and our business could be materially harmed.***

Our products are subject to continuing regulatory oversight, including the review of additional safety information. Drugs are more widely used by patients once approval has been obtained and therefore side effects and other problems may be observed after approval that were not seen or anticipated, or were not as prevalent or severe, during pre-approval clinical trials or nonclinical studies. The subsequent discovery of previously unknown problems with a product, or public speculation about adverse safety events, could negatively affect commercial sales of the product, result in restrictions on the product or lead to the withdrawal of the product from the market.

If we or our collaborators fail to comply with applicable continuing regulatory requirements, we or our collaborators may be subject to fines, suspension or withdrawal of regulatory approvals for specific products, product recalls and seizures, injunctions, consent decrees or other operating restrictions and/or criminal prosecutions. In addition, the manufacturers we engage to make our products and the manufacturing facilities in which our products are made are subject to periodic review and inspection by the FDA and foreign regulatory authorities. If problems are identified during the review or inspection of these manufacturers or manufacturing facilities, it could result in our inability to use the facility to make our product or a determination that inventories are not safe for commercial sale.

***Failure to comply with FDA promotional rules may subject us to withdrawal, and correction, of related product promotion, seizure of product and other administrative or enforcement actions as well as the potential for ancillary liability under the False Claims Act and/or product liability litigation.***

The FDA regulates the promotion of our products, which may only be promoted within their approved indication for use. Promotional materials and activity must be presented with fair balance of the risks and benefits of any product in a manner which is not otherwise inaccurate or misleading. The FDCA and the FDA's implementing regulations require that manufacturers label, advertise and promote their products with appropriate safety warnings and adequate directions for their FDA-approved use. However, the FDA does not have the legal authority to regulate the practice of medicine. Although physicians are permitted, based on their medical judgment, to prescribe products for indications other than those approved by the FDA, manufacturers are prohibited from promoting their products for such off-label uses.

If the FDA determines that our promotional materials, training or other activities constitute off-label promotion, it could request that we modify our training or promotional materials or other activities or subject us to regulatory enforcement actions, including the issuance of a warning letter, injunction, seizure, civil fine and criminal penalties. Violation of the FDCA and other statutes, including the False Claims Act, relating to the promotion and advertising of prescription drugs may also lead to investigations or allegations of violations of federal and state healthcare fraud and abuse laws and state consumer protection laws. The FDA or other regulatory authorities could also request that we enter into a consent decree or a corporate integrity agreement, or seek a permanent injunction against us under which specified promotional conduct is monitored, changed or curtailed.

Although recent decisions of the United States Supreme Court, the U.S. Court of Appeals for the Second Circuit and the U.S. District Court for the Southern District of New York have clarified that the United States may not, consistent with the First Amendment, restrict or punish a pharmaceutical manufacturer's truthful and non-misleading speech promoting the lawful use of an approved drug, there are still significant risks in this area. It is unclear how these court decisions will impact the FDA's enforcement practices, and there is likely to be substantial disagreement and difference of opinion regarding whether any particular statement is truthful and not misleading. In the past we have been subject to enforcement action relating to allegations of improper promotion of our products, and we may be subject to such action in the future.

If we cannot successfully manage the promotion of our currently marketed products, and product candidates, if approved, we could become subject to significant liability which would materially adversely affect our business and financial condition. It is also possible that other federal, state or foreign enforcement authorities, or private parties, might take action if they believe that an alleged improper promotion led to inappropriate use of one of our products and/or the submission and payment of claims for an off-label use, which could result in significant fines or penalties under other statutory provisions, such as the False Claims Act and similar laws. Even if it is later determined that we were not in violation of these laws, we may face negative publicity, incur significant expenses defending our actions and have to divert significant management resources from other matters. In addition, there are a number of specific FDA requirements related to drug labeling and advertising, and failure to adhere to these requirements could result in our products being deemed "misbranded."

***The manufacture of pharmaceutical products is a highly complex process, and if our suppliers encounter problems manufacturing our products, our business could suffer.***

The manufacture of pharmaceutical products is a highly complex process, due in part to strict regulatory requirements. Problems may arise during manufacturing for a variety of reasons, including equipment malfunction, failure to follow specific protocols and procedures, problems with raw materials, delays related to the construction of new facilities or the expansion of existing facilities, including those intended to support future demand for our products, changes in manufacturing production sites and limits to manufacturing capacity due to regulatory requirements, changes in the types of products produced, physical limitations that could inhibit continuous supply, man-made or natural disasters and environmental factors. If problems arise during the production of a batch of product, that batch of product may have to be discarded and we may experience product shortages or incur added expenses. This could, among other things, lead to increased costs, lost revenue, damage to customer relationships, time and expense spent investigating the cause and, depending on the cause, similar losses with respect to other batches or products. If problems are not discovered before the product is released to the market, recall and product liability costs may also be incurred.

**Risks Related to Government Regulation**

***If we engage in research or commercial activities involving any of our products or pipeline assets in a manner that violates federal or state healthcare laws, including fraud and abuse laws, false claims laws, disclosure laws, government price reporting and healthcare information privacy and security laws or other similar laws, we may be subject to corporate or individual civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations.***

Our business operations and activities are subject to extensive federal, state and local fraud and abuse and other healthcare laws and regulations, such as the False Claims Act and the federal Anti-Kickback Statute, the Foreign Corrupt Practices Act ("FCPA"), federal Physician Payment Sunshine Act, the federal Drug Supply Chain Security Act, federal Civil Monetary Penalty statute, the PPACA program integrity requirements, patient privacy laws and regulation, criminal laws relating to healthcare fraud and abuse, including but not limited to the Health Insurance Portability and Accountability Act, federal consumer protection and unfair competition laws, federal government price reporting laws and state law equivalents of each of these. These laws and regulations constrain, among other things, the business or financial arrangements and relationships through which we may research and develop any product candidate, as well as market, sell and distribute any approved products. In addition, any sales of our products or product candidates, if approved, commercialized outside the United States will also likely subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws.

We have entered into consulting agreements, scientific advisory board and other financial arrangements with physicians, including some who prescribe our products and may prescribe our product candidates, if approved. Compensation for some of these arrangements includes the provision of stock options. While these arrangements were structured to comply with all applicable laws, including state and federal anti-kickback laws, to the extent applicable, regulatory agencies may view these arrangements as prohibited arrangements that must be restructured, or discontinued, or for which we could be subject to other significant penalties. Moreover, while we do not submit claims and our customers make the ultimate decision on how to submit claims, we may provide reimbursement guidance and support to our customers and patients. If a government authority were to conclude that we provided improper advice to our customers and/or encouraged the submission of false claims for reimbursement, we could face action against by government authorities.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. The sales and marketing practices of our industry are the subject of immense scrutiny from federal and state government agencies. Despite sequestration measures, governmental enforcement funding continues at robust levels and enforcement officials are interpreting fraud and abuse laws broadly. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. The risk of our being found in violation of these laws is increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are subject to a variety of interpretations. Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources, divert our management's attention from the operation of the business, and generate negative publicity, which could harm our business. If our past or present operations are found to be in violation of any such laws or any other governmental regulations that may apply to us, we may be subject to, without limitation, civil, criminal and administrative penalties, damages, monetary fines, disgorgement, exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings and/or the curtailment or restructuring of our operations.

***Our commercial success depends on adequate reimbursement and coverage from third-party commercial and government payors for our products, and changes to coverage or reimbursement policies, as well as healthcare reform measures, may materially harm our sales and potential revenue.***

Most patients rely on reimbursement from third-party payors, including government programs (such as Medicare and Medicaid) and private payor healthcare and insurance programs to pay for their medical needs, including any drugs we may market. Coverage and reimbursement for our products can differ significantly from payor to payor. Even when we obtain coverage and reimbursement for our products, we may not be able to maintain adequate coverage and reimbursement in the future.

There is significant uncertainty related to the third-party coverage and reimbursement of newly approved products. We intend to seek approval to market our product candidates in the United States, Europe and other selected foreign jurisdictions. Market acceptance and commercial success of our product candidates in both domestic and international markets will depend significantly on the availability of adequate coverage and reimbursement from third-party payors for any of our product candidates.

Obtaining coverage and reimbursement approval for a product from a government or other third-party payor is a time consuming and costly process that could require us to provide to the payor supporting scientific, clinical and cost-effectiveness data for the use of our products to each third-party payor separately, with no assurance that coverage and adequate reimbursement will be obtained or applied consistently. We may not be able to provide data sufficient to gain acceptance with respect to coverage and reimbursement. Additionally, coverage may be more limited than the purposes for which the product is approved by the FDA or similar regulatory authorities outside of the United States. Assuming that coverage is obtained for a given product, the resulting reimbursement rates might not be adequate or may require co-payments that patients find unacceptably high. Patients, physicians, and other healthcare providers may be less likely to prescribe, dispense or use, as applicable, our products unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products.

Government payors and other third-party payors, such as private health insurers and health maintenance organizations, decide which drugs they will cover and the amount of reimbursement. Coverage decisions may depend upon clinical and economic standards that disfavor new drug or biologic products when more established or lower-cost therapeutic alternatives are already available or subsequently become available. Based upon a number of factors, including clinical and economic standards, our products may not qualify for coverage and reimbursement. Coverage and reimbursement by a third-party payor may depend upon a number of factors, including, but not limited to, the third-party payor's determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective;
- neither experimental nor investigational;
- prescribed by a practitioner acting within the scope of license and health plan participation agreements;
- documented adequately in the patient's medical record;
- dispensed by a participating pharmacy; and/or
- logged and documented appropriately by the dispensing pharmacy.

The market for our products will depend significantly on access to third-party payors' drug formularies for which third-party payors provide coverage and reimbursement. The industry competition to be included in such formularies often leads to downward pricing pressures on pharmaceutical companies. Also, third-party payors may refuse to include a particular branded drug in their formularies or otherwise restrict patient access to a branded drug when a less costly generic equivalent or other alternative is available. If coverage and reimbursement of our future products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, we may be unable to achieve or sustain profitability.

In the United States, our products may be subject to discounts from list price and rebate obligations. Third-party payors have from time to time refused to include our products in their formularies, limit the type of patients for whom coverage will be provided, or restrict patient access to our products through formulary control or otherwise, in favor of less-costly generic versions of ribavirin or other treatment alternatives. Any change in formulary coverage, treatment paradigm, reimbursement levels, discounts or rebates offered on our products may impact our anticipated revenues.

In the United States, governmental and commercial third-party payors are developing increasingly sophisticated methods of controlling healthcare costs. We believe that pricing pressure for our products will continue, and future coverage and reimbursement will likely be subject to increased restrictions. For example, the PPACA, which has already imposed significant healthcare cost containment measures, also encourages the development of comparative effectiveness research and any adverse findings for our products from such research may reduce the extent of coverage and reimbursement for our products. The PPACA created the Patient-Centered Outcomes Research Institute to review the effectiveness of treatments and medications in federally-funded healthcare programs. The PCORI publishes the results of its studies. An adverse finding result may result in a treatment or product being removed from Medicare or Medicare coverage.

Managed care organizations continue to seek price discounts and in some cases, to impose restrictions on the coverage of particular drugs. Government efforts to reduce Medicaid expenses may lead to increased use of managed care organizations by Medicaid programs, which may result in managed care organizations influencing prescription decisions for a larger segment of the population, which could constrain pricing, formulary position or reimbursement for our products. Economic pressure on state budgets may also have a similar impact on Medicaid coverage and reimbursement.

In certain countries in the European Union and some other international markets, governments provide healthcare at low-cost to consumers and regulate pharmaceutical pricing, patient eligibility or reimbursement levels to control costs for the government-sponsored healthcare system. We expect to see strong efforts to reduce healthcare costs in our international markets, including: patient access restrictions; suspensions on price increases; prospective and possibly retroactive price reductions, mandatory discounts and rebates, and other recoupments; recoveries of past price increases; and greater importation of drugs from lower-cost countries to higher-cost countries. In addition, certain countries set prices by reference to the prices in other countries where our products are marketed. Thus, our inability to secure adequate prices in a particular country may not only limit the marketing of our products within that country, but may also adversely affect our ability to obtain acceptable prices in other markets.

***Healthcare reform measures could hinder or prevent our product candidates' commercial success, if approved, and could increase our costs.***

In both the United States and certain foreign jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system that could impact our ability to sell our products profitably. Among policy makers and payors in the United States and elsewhere, there is a significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and expanding individual access to healthcare. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. For example, in 2010, the PPACA was enacted, which was intended to expand healthcare coverage within the United States, primarily through the imposition of health insurance mandates on employers and individuals, strengthening of program integrity measures and enforcement authority, and expansion of the Medicaid program. The PPACA substantially changes the way healthcare is financed by both governmental and private insurers and significantly affects the pharmaceutical industry. Several provisions of the new law, which have varying effective dates, may affect us and will likely increase certain of our costs. In this regard, the PPACA includes the following provisions:

- an annual, non-deductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs that began in 2011;
- an increase in the rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13% of the average manufacturer price for branded and generic drugs, respectively;
- an extension of manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- new methodologies by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, and for drugs that are line extensions;

- changes to the Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts to negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for certain individuals with income at or below 133% of the Federal Poverty Level, thereby potentially increasing manufacturers' Medicaid rebate liability;
- a new requirement to annually report drug samples that manufacturers and distributors provide to licensed practitioners or to pharmacies of hospitals or other healthcare entities;
- a licensure framework for follow-on biologic products;
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and
- creation of the Independent Payment Advisory Board which has the authority to recommend certain changes to the Medicare program that could result in reduced payments for prescription drugs.

The reforms imposed by the new law will significantly impact the pharmaceutical industry; however, the full effects of the PPACA cannot be known until these provisions are implemented and the CMS and other federal and state agencies issue and finalize all applicable regulations or guidance. We will continue to evaluate the PPACA, the implementation of regulations or guidance related to various provisions of the PPACA by federal agencies, as well as trends and changes that may be encouraged by the legislation and that may potentially have an impact on our business over time. The cost of implementing more detailed record keeping systems and otherwise complying with these regulations could substantially increase our costs. The changes to the way our products are reimbursed by the CMS could reduce our revenues. Both of these situations could adversely affect our results of operations.

***Government price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our current and future products.***

International operations are also generally subject to extensive price and market regulations and there are many proposals for additional cost-containment measures, including proposals that would directly or indirectly impose additional price controls or reduce the value of our intellectual property portfolio or may make it economically unsound to launch our products in certain countries. We cannot predict the extent to which our business may be affected by these or other potential future legislative or regulatory developments. Future price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our current and future products, which would adversely affect our revenue and results of operations.

Additionally, in some countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product candidate. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after coverage and reimbursement have been obtained. Reference pricing used by various European Union member states and parallel distribution or arbitrage between low-priced and high-priced member states, can further reduce prices. To obtain reimbursement or pricing approval in some countries, we may be required to conduct additional clinical trials that compare the cost-effectiveness of our product candidates to other available therapies, which is time-consuming and costly. If reimbursement of our product candidates is unavailable or limited in scope or amount in a particular country, or if pricing is set at unsatisfactory levels, we may be unable to achieve or sustain profitability of our products in such country.

***If our processes and systems are not compliant with regulatory requirements, we could be subject to restrictions on marketing our products or could be delayed in submitting regulatory filings seeking approvals for our product candidates.***

We have a number of regulated processes and systems that are required to obtain and maintain regulatory approval for our drugs and product candidates. These processes and systems are subject to continual review and periodic inspection by the FDA and other regulatory bodies. If compliance issues are identified at any point in the development and approval process, we may experience delays in filing for regulatory approval for our product candidates, or delays in obtaining regulatory approval after filing. Any later discovery of previously unknown problems or safety issues with approved drugs or manufacturing processes, or failure to comply with regulatory requirements, may result in restrictions on such drugs or manufacturing processes, withdrawal of drugs from the market, the imposition of civil or criminal penalties or a refusal by the FDA and/or other regulatory bodies to approve pending applications for marketing approval of new drugs or supplements to approved applications, any of which could have a material adverse effect on our business. Given the number of high profile adverse safety events associated with certain drug products, regulatory authorities may require, as a condition of approval, costly risk evaluation and mitigation strategies, which may include safety surveillance, restricted distribution and use, patient education, enhanced labeling, expedited reporting of certain adverse events, pre-approval of promotional materials and restrictions on direct-to-consumer advertising. For example, any labeling approved for any of our product candidates may include a restriction on the term of its use, or it may not include one or more intended indications. Furthermore, any new legislation addressing drug safety issues could result in delays or increased costs during the period of product development, clinical trials and regulatory review and approval, as well as increased costs to assure compliance with any new post-approval regulatory requirements. Any of these restrictions or requirements could force us or our collaborators to conduct costly studies.

In addition, we are a party to agreements that transfer responsibility for complying with specified regulatory requirements, such as packaging, storage, advertising, promotion, record-keeping and submission of safety and other post-market information on the product or compliance with manufacturing requirements, to our collaborators and third-party manufacturers. Approved products, manufacturers and manufacturers' facilities are required to comply with extensive FDA requirements, including ensuring that quality control and manufacturing procedures conform to current good manufacturing practices ("cGMP"). As such, we and our contract manufacturers, which we are responsible for overseeing and monitoring for compliance, are subject to continual review and periodic inspections to assess compliance with cGMP. Accordingly, we and others with whom we work must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control. The FDA may hold us responsible for any deficiencies or noncompliance of our contract manufacturers in relation to our product candidates and commercial products. If our collaborators or third-party manufacturers do not fulfill these regulatory obligations, any drugs we market or for which we or they obtain approval may be deemed adulterated, which carries significant legal implications, and may be subject to later restrictions on manufacturing or sale, which could have a material adverse effect on our business.

**Risks Related to Our Intellectual Property Rights**

***If we are unable to obtain and maintain patent protection for our products and product candidates, or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize products and product candidates similar or identical to ours, and our ability to successfully commercialize our products and product candidates may be adversely affected.***

Our commercial success will depend, in part, on our ability to obtain and maintain patent protection in the United States and other countries with respect to our products and product candidates. We seek to protect our proprietary position by filing patent applications in the United States and abroad related to our products and product candidates that are important to our business. We cannot be certain that patents will be issued or granted with respect to applications that are currently pending or that we apply for in the future with respect to one or more of our products and product candidates, or that issued or granted patents will not later be found to be invalid and/or unenforceable.

The patent prosecution process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Although we enter into non-disclosure and confidentiality agreements with parties who have access to patentable aspects of our research and development output, such as our employees, collaboration partners, consultants, advisors and other third parties, any of these parties may breach the agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection.

We may license patent rights that are valuable to our business from third parties, in which event we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology or medicines underlying such licenses. We cannot be certain that these patents and applications will be prosecuted and enforced in a manner consistent with the best interests of our business. If any such licensors fail to maintain such patents, or lose rights to those patents, the rights we have licensed may be reduced or eliminated and our right to develop and commercialize any of our products that are the subject of such licensed rights could be adversely affected. In addition to the foregoing, the risks associated with patent rights that we license from third parties also apply to patent rights we own.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued, and even if issued, the patents may not meaningfully protect our products or product candidates, effectively prevent competitors and third parties from commercializing competitive products or otherwise provide us with any competitive advantage. Our competitors or other third parties may be able to circumvent our patents by developing similar or alternative products in a non-infringing manner. Changes in the patent laws, implementing regulations or interpretation of the patent laws in the United States and other countries may also diminish the value of our patents or narrow the scope of our patent protection.

The laws of foreign countries may not protect our rights to the same extent as the laws of the United States, and many companies have encountered significant difficulties in protecting and defending such rights in foreign jurisdictions. For those countries where we do not have granted patents, we may not have any ability to prevent the unauthorized use or sale of our proprietary medicines and technology or to prevent third parties from selling or importing products made using our inventions in and into the United States and other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products, and further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our products and our intellectual property rights may not be effective or sufficient to prevent them from competing.

We may not be aware of all third-party intellectual property rights potentially relating to our product candidates. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we were the first to make the inventions claimed in our owned or any licensed patents or pending patent applications, or that we were the first to file for patent protection of such inventions.

Assuming the other requirements for patentability are met, prior to March 2013, in the United States, the first to make the claimed invention was entitled to the patent, while outside the United States, the first to file a patent application was entitled to the patent. Beginning in March 2013, the United States transitioned to a first-inventor-to-file system in which, assuming the other requirements for patentability are met, the first-inventor-to-file a patent application will be entitled to the patent. We may be subject to a third-party preissuance submission of prior art to the U.S. Patent and Trademark Office (U.S. PTO) or become involved in opposition, derivation, revocation, reexamination, post-grant and *inter partes* review or interference proceedings challenging our patent rights or the patent rights of others. Participation in these proceedings can be very complex, expensive and may divert our management's attention from our core business. Furthermore, an adverse determination in any such submission, proceeding or 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 medicines without infringing third-party patent rights.

Even if our patent applications do issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us or otherwise provide us with any competitive advantage. Our competitors or other third parties may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical products, or limit the duration of the patent protection of our products and product candidates. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our intellectual property may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. Patent protection may not be available for some of our products or the processes under which they are used or manufactured.

***Issued patents covering one or more of our products could be found invalid or unenforceable if challenged in court.***

If we or one of our licensing partners initiated legal proceedings against a third party to enforce a patent covering one of our product candidates, the defendant could counterclaim that the patent covering our product candidate is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Although we have conducted due diligence on patents we have exclusively in-licensed, the outcome following legal assertions of invalidity and unenforceability during patent litigation is unpredictable. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the U.S. PTO, or made a misleading statement, during prosecution. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post-grant review, inter partes review, interference proceedings, derivation proceedings, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). Such proceedings could result in revocation or amendment to our patents in such a way that they no longer cover our products and product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art of which we and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our product candidates. Such a loss of patent protection would have a material adverse impact on our business.

***Third-party claims of intellectual property infringement, misappropriation or other violation may prevent or delay our development and commercialization efforts.***

Our commercial success depends in part on our avoiding infringement of the patents and proprietary rights of third parties. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the pharmaceutical industries, including patent infringement lawsuits, interferences, oppositions and *inter partes* reexamination proceedings before the U.S. PTO, and corresponding foreign patent offices. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are pursuing development candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the patent rights of third parties.

Third parties may assert that we are employing their proprietary technology without authorization and may assert infringement claims against us based on existing patents or patents that may be granted in the future, regardless of their merit. There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that our product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of any of our product candidates, any molecules formed during the manufacturing process or any final product itself, the holders of any such patents may be able to block our ability to commercialize such product unless we obtained a license under the applicable patents, or until such patents expire.

Similarly, if any third-party patents were held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or methods of use, the holders of any such patents may be able to block our ability to develop and commercialize the applicable product unless we obtained a license or until such patent expires. In either case, such a license may not be available on commercially reasonable terms or at all. Even if we or our future strategic collaborators were able to obtain a license, the rights may be nonexclusive, which could result in our competitors gaining access to the same intellectual property and it could require us to make substantial licensing and royalty payments.

Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, pay royalties, redesign our infringing products or obtain one or more licenses from third parties, which may be impossible or require substantial time and monetary expenditure. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business, financial condition, results of operations and prospects.

Most of our competitors are larger than we are and have substantially greater resources and may be able to sustain the costs of complex patent litigation longer than we could. The uncertainties associated with litigation could have a material adverse effect on our ability to raise the funds necessary to continue our clinical trials, continue our internal research programs, in-license needed technology or enter into strategic collaborations that would help us bring our product candidates to market.

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

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business, or permit us to maintain our competitive advantage. For example:

- others may be able to make compounds that are similar to our product candidates but that are not covered by the claims of the patents that we own or have exclusively licensed;
- we or our licensors or collaboration partners might not have been the first to make the inventions covered by the issued patent or pending patent application that we own or have exclusively licensed;
- we or our licensors or collaboration partners might not have been the first to file patent applications covering certain of our or their inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our pending patent applications will not lead to issued patents;
- issued patents that we own or have exclusively licensed may not provide us with any competitive advantages or may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable; and/or
- the patents of others may have an adverse effect on our business.

Should any of these events occur, they could significantly harm our business, results of operations and prospects.

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

***We expect to continue to contract with third-party suppliers for the production of our commercial product portfolio as well as our developmental product candidates for clinical trial use and, if approved, for commercialization.***

We currently employ third parties for the manufacturing of our commercial products and product candidates. This increases the risk that we will not have sufficient quantities of our products or product candidates within the timeframe and at an acceptable cost which could delay, prevent or impair our development or commercialization efforts. Additionally, we may not be able to quickly respond to changes in customer demand which could harm our business as a result of the inability to supply the market or an excess of inventory that we are unable to sell.

The facilities used by our contract manufacturers to manufacture our product candidates must adhere to FDA requirements, and are subject to inspections that may be conducted after we submit our marketing applications to the FDA in connection with review of our application, and on an ongoing basis relevant to postmarketing compliance. Although we are subject to regulatory responsibility for the quality of products manufactured by our contract manufacturers and oversight of their activities, we do not control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with the regulatory requirements, known as cGMPs, for manufacture of both active drug substances and finished drug products. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, they will be subject to enforcement action, and if substantial noncompliance is identified and not corrected, they may be precluded from manufacturing product for the United States or other markets. In addition, although the FDA will hold us responsible for due diligence in the selection of, and oversight in the operations of, our contract manufacturers, we do not have direct control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority identified significant compliance concerns with our contract manufacturers, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our products or product candidates, if approved.

We have agreements with third-party manufacturers for the provision of active pharmaceutical ingredient (API), drug product manufacturing and packaging of our commercial products. Reliance on third-party manufacturers carries additional risks, such as not being able to comply with cGMP or similar regulatory requirements outside the United States. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our products.

Due to FDA requirements and other factors, we are generally unable to make changes to our supplier arrangements without delay. Manufacturing services related to each of our pharmaceutical products are primarily provided by a single source. Each of our raw materials are also provided by a single source. We attempt to mitigate this risk through long-term contracts and inventory safety stock. In the event that any of these third-party manufacturers fail regulatory compliance, fail to meet quality assurance specifications or experience an unavoidable extraordinary event, our business could be adversely affected.

Any products that we may develop may compete with other product candidates and commercialized products for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us. Any performance failure or refusal to supply on the part of our existing or future suppliers could delay clinical development, marketing approval or commercialization of our products. If our current suppliers cannot perform as agreed, we may be required to replace one or more of these suppliers. Although we believe that there are a number of potential long-term replacements to each supplier, we may incur added costs and delays in identifying and qualifying any such replacements.

We rely on third parties to store and distribute supplies for our clinical trials and for the manufacture of our product candidates. Any performance failure on the part of our existing or future distributors could delay clinical development or regulatory approval or our product candidates or commercialization of our products, producing additional losses and depriving us of potential product revenue.

***We depend on intellectual property licensed from third parties and termination of any of these licenses could result in the loss of significant rights, which would harm our business.***

We are dependent on patents, know-how and proprietary technology, both our own and licensed from others. We are party to intellectual property license agreements with third parties and expect to enter into additional license agreements in the future. Our current license agreements impose, and we expect that future license agreements will impose, various diligence, development, commercialization, payment and other obligations. If we fail to comply with our obligations under these agreements, the licensor may have the right to terminate the license agreement or may exercise a right to have the intellectual property that we license returned. For example, under our exclusive sub-license agreement for belumosudil with NT Life Sciences, LLC and Surface Logix, Inc., if we fail to comply with our diligence obligations, the former owners of the intellectual property licensed under such agreement may require us and our licensors to return such intellectual property, in which case our license to such intellectual property would terminate. Any termination of these licenses could result in the loss of significant rights and could have a material adverse effect on our ability to commercialize our product candidates, including belumosudil.

Disputes may also arise between us and our licensors regarding intellectual property subject to a license agreement, including those relating to:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the license agreement;
- our right to sublicense patent and other rights to third parties under collaborative development relationships;
- whether we are complying with our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our product candidates; and/or
- the allocation of ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and by us and our collaboration partners.

If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates. We are generally also subject to all of the same risks with respect to protection of intellectual property that we license as we are for intellectual property that we own. If we or our licensors fail to adequately protect this intellectual property, our ability to commercialize our products could suffer.

***We face risks in connection with existing and future collaborations with respect to the development, manufacture and commercialization of our products and product candidates.***

The risks that we face in connection with our current and any future collaborations include the following:

- Our collaborators may change the focus of their development and commercialization efforts or may have insufficient resources to effectively develop our product candidates. The ability of some of our products and product candidates to reach their potential could be limited if collaborators decrease or fail to increase development or commercialization efforts related to those products or product candidates.
- Any future collaboration agreements may have the effect of limiting the areas of research and development that we may pursue, either alone or in collaboration with third parties.
- Collaborators may develop and commercialize, either alone or with others, drugs that are similar to or competitive with the drugs or product candidates that are the subject of their collaborations with us.

Our collaboration agreements are subject to termination under various circumstances.

**Risks Related to Our Operations**

***Our business has been, and will likely continue to be adversely affected by the effects of health epidemics and pandemics, including the COVID-19 pandemic, in regions where we or third parties on which we rely have significant concentrations of clinical trial sites or other business operations. The COVID-19 pandemic has impacted our operations, including at our corporate headquarters in New York, commercial operations in Pennsylvania, clinical operations in Massachusetts, research facility in New Jersey and at our clinical trial sites, as well as the business or operations of our CROs or other third parties with whom we conduct business. If these impacts continue for an extended period of time, our business could be materially and adversely affected.***

Our business has been be adversely affected by health epidemics in regions where we have clinical trial sites or other business operations and could cause significant disruption in the operations of CROs upon whom we rely. For example, in response to the COVID-19 pandemic we implemented work-from-home policies and other measures directed at employee safety. These policies have impacted productivity in certain business units, impacted management attention, depleted resources, disrupted our business and delayed our clinical programs and timelines, the magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations on our ability to conduct our business in the ordinary course. These and similar disruptions in our operations could materially and adversely impact our business, operating results and financial condition. In addition, our clinical trials may be affected by the COVID-19 pandemic. Clinical site initiation and patient enrollment may be delayed due to prioritization of hospital resources toward the COVID-19 pandemic. For instance, due to interruptions at clinical sites, enrollment has been delayed in our ongoing Phase 2 clinical trial of belumosudil (KD025) in systemic sclerosis and enrollment was also delayed in our ongoing Phase 1 clinical trial of KD033 in patients with metastatic or locally advanced solid tumors. Also, some patients may not be able to comply with clinical trial protocols if quarantine impedes patient movement or interrupt healthcare services. Similarly, our ability to recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19 and adversely impact our clinical trial operations. The COVID-19 pandemic may materially affect us economically. While the economic impact brought by, and the duration of, COVID-19 may be difficult to assess or predict, the widespread pandemic has resulted in significant disruption of global financial markets, potentially reducing our ability to access capital, which could in the future negatively affect our liquidity. In addition, a recession or market correction resulting from the spread of COVID-19 could materially affect our business and the value of our common stock.

***Our business could be adversely affected by the cyber, privacy and productivity effects of remote working and disruption at management and board levels due to COVID-19.***

We have transitioned all of our employee population to a remote work environment in an effort to mitigate the spread of COVID-19, which may exacerbate certain risks to our business, including an increased demand for information technology resources, increased risk of phishing and other cybersecurity attacks, and increased risk of unauthorized dissemination of sensitive personal information or proprietary or confidential information about us or our members or other third-parties. We may experience disruptions to our business operations resulting from quarantines, self-isolations, or other movement and restrictions on the ability of our employees to perform their jobs that may impact our ability to progress our clinical candidates in a timely manner or meet development milestones. The COVID-19 pandemic could also disrupt our operations due to absenteeism by infected or ill members of management or other employees, or absenteeism by members of management and other employees who elect not to come to work due to the illness affecting others in our office or laboratory facilities, or due to quarantines. COVID-19 illness could also impact members of our Board of Directors resulting in absenteeism from meetings of the directors or committees of directors, and making it more difficult to convene the quorums of the full Board of Directors or its committees needed to conduct meetings for the management of our affairs.

***We may not be entitled to forgiveness of our recently received loan under the Paycheck Protection Program of the Coronavirus Aid, Relief, and Economic Security Act, and our application for the Paycheck Protection Program Loan could in the future be determined to have been impermissible or could damage our reputation.***

On April 14, 2020 we received proceeds of $3.1 million from a loan under the Paycheck Protection Program (“PPP Loan”) of the Coronavirus Aid, Relief, and Economic Security Act (“CARES Act”), which we intend to use to retain current employees, maintain payroll and make lease and utility payments. While we have applied for forgiveness, we cannot provide any assurance that we will be eligible for loan forgiveness, or that any amount of the PPP Loan will ultimately be forgiven by the U.S. Small Business Administration (“SBA”). Furthermore, on April 28, 2020, the Secretary of the U.S. Department of the Treasury stated that the SBA will perform a full review of any PPP loan over $2.0 million before forgiving the loan.

In order to apply for the PPP Loan, we were required to certify, among other things, that the current economic uncertainty made the PPP Loan request necessary to support our ongoing operations. We made this certification in good faith after analyzing, among other things, the maintenance of our entire workforce, notwithstanding certain obvious "work-from-home" limitations associated with the nature of our business and managing risks to our development programs. In considering our position, we, an emerging growth clinical-stage biopharmaceutical research and development company with approximately 120 employees at the time of application (including 27 research staff ordinarily located within our laboratories), currently conducting 6 clinical trials to develop at least 3 medicines for currently unmet and under-served medical needs, took into account our classification as a smaller reporting company under SEC rules, our ability to currently access alternative forms of capital in the current market environment, and that management expressed substantial doubt as described in Note 1 of the financial statements in our Annual Report on Form 10-K filed with the SEC on March 5, 2020 about our ability to continue as a going concern based upon our recurring and continuing losses from operations and our need for additional funding to continue operations. The report of our independent registered public accounting firm BDO USA, LLP also included an explanatory paragraph expressing substantial doubt about our ability to continue as a going concern. Following this analysis, we believe that we satisfied all eligibility criteria for the PPP Loan, and that our receipt of the PPP Loan is consistent with the broad objectives of the PPP of the CARES Act, and following receipt of the loan, we have made no COVID-19 layoffs. The certification described above did not contain any objective criteria and is subject to interpretation. We will continue to assess our continued qualification if and when updated guidance is released by the Treasury Department. If, despite our good-faith belief that given our circumstances we satisfied all eligible requirements for the PPP Loan, we are later determined to have violated any applicable laws or regulations or it is otherwise determined that we were ineligible to receive the PPP Loan, we may be required to repay the PPP Loan in its entirety and/or be subject to additional penalties, which could also result in adverse publicity and damage to reputation. In addition, our receipt of the PPP Loan may result in adverse publicity and damage to our reputation, and a review or audit by the SBA or other government entity or claims under the False Claims Act could consume significant financial and management resources. If these events were to transpire, they could have a material adverse effect on our business, results of operations and financial condition.

***Our future success depends on our ability to retain our key executives and to attract, retain and motivate qualified personnel.***

The biopharmaceutical industry has experienced a high rate of turnover of management personnel in recent years. Our ability to compete in the highly competitive biotechnology and pharmaceuticals industries depends upon our ability to attract and retain highly qualified managerial, scientific and medical personnel.

Recruiting and retaining qualified scientific, clinical, manufacturing and sales and marketing personnel will also be critical to our success. We may not be able to attract and retain these personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities. This may limit their availability to us.

In order to induce valuable employees to continue their employment with us, we have provided equity incentives that vest over time. The value to employees of equity incentives that vest over time is significantly affected by the success of our operations and clinical trials for our product candidates, much of which is beyond our control, and may at any time be insufficient to counteract more lucrative offers from other companies.

Despite our efforts to retain valuable employees, members of our management, scientific and development teams may terminate their employment with us on short notice. Our employment arrangements generally provide for at-will employment, which means that any of our employees could leave our employment at any time, with or without notice. The loss of the services of any of our executive officers or other key employees and our inability to find suitable replacements could potentially harm our business, financial condition and prospects. Our success also depends on our ability to continue to attract, retain and motivate highly skilled junior, mid-level and senior managers as well as junior, mid-level and senior scientific and medical personnel.

We may not be able to attract or retain qualified management and scientific personnel in the future due to the intense competition for a limited number of qualified personnel among biopharmaceutical, biotechnology, pharmaceutical and other businesses and institutions. Many of the other companies and institutions that we compete with for qualified personnel have greater financial and other resources, different risk profiles and a longer history in the industry than we do. They also may provide more diverse opportunities and better chances for career advancement. Some of these characteristics may be more appealing to high quality candidates than what we have to offer. If we are unable to continue to attract and retain high quality personnel, the rate and success at which we can develop and commercialize product candidates will be limited.

***If we are unable to successfully implement our strategic plan, our business may be materially harmed.***

We plan to continue to develop and commercialize novel drugs for significant unmet medical needs while we continue to market our commercial products to eligible patients to generate revenue. Absent a successful launch of one or more of our product candidates, we expect our total revenue to decline significantly. In order to maintain a strong financial position, we are focusing our investment on development programs for our most advanced product candidates. In an effort to mitigate our drug development risk and improve our chance of ultimate commercial success, we are developing multiple product candidates in a variety of disease indications. There can be no assurance that our development programs will be successful or that our research programs will result in drugs that we can successfully develop and commercialize.

***If we engage in future acquisitions or strategic collaborations, this may increase our capital requirements, dilute our equity holders, cause us to incur debt or assume contingent liabilities, and subject us to other risks.***

We may evaluate various acquisitions and strategic collaborations, including licensing or acquiring complementary products, intellectual property rights, technologies or businesses. Any potential acquisition or strategic collaboration may entail numerous risks, including:

- increased operating expenses and cash requirements;
- the assumption of additional indebtedness or contingent liabilities;
- assimilation of operations, intellectual property and products of an acquired company, including difficulties associated with integrating new personnel;
- the diversion of our management's attention from our existing product programs and initiatives in pursuing such a strategic merger or acquisition;
- retention of key employees, the loss of key personnel, and uncertainties in our ability to maintain key business relationships;
- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing products or product candidates and regulatory approvals; and/or
- our inability to generate revenue from acquired technology and/or products sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs.

In addition, if we undertake acquisitions, we may issue dilutive securities, assume or incur debt obligations, incur large one-time expenses and acquire intangible assets that could result in significant future amortization expense. Moreover, we may not be able to locate suitable acquisition opportunities and this inability could impair our ability to grow or obtain access to technology or products that may be important to the development of our business.

***If we acquire or license technologies, products or product candidates, we will incur a variety of costs and may never realize benefits from the transaction.***

If appropriate opportunities become available, we might license or acquire technologies, resources, drugs or product candidates. We might never realize the anticipated benefits of such a transaction, and we may later incur impairment charges related to assets acquired in any such transaction. In particular, due to the risks inherent in drug development, we may not successfully develop or obtain marketing approval for the product candidates we acquire. Future licenses or acquisitions could result in potentially dilutive issuances of equity securities, the incurrence of debt, the creation of contingent liabilities, impairment expenses related to goodwill, and impairment or amortization expenses related to other intangible assets, which could harm our financial condition.

***We will need to grow our organization, and we may experience difficulties in managing this growth, which could disrupt our operations.***

At December 31, 2020, we had 127 full-time employees. As our development and commercialization plans and strategies develop, we expect to expand our employee base for managerial, operational, sales, marketing, financial and other resources. Future growth would impose significant added responsibilities on members of management, including the need to identify, recruit, maintain, motivate and integrate additional employees. Also, our management may need to divert a disproportionate amount of their attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. We may not be able to effectively manage the expansion of our operations which may result in weaknesses in our infrastructure, give rise to operational errors, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Our expected growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of existing and additional product candidates. If our management is unable to effectively manage our expected growth, our expenses may increase more than expected, our ability to generate and/or grow revenue could be reduced and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize our product candidates and compete effectively with others in our industry will depend, in part, on our ability to effectively manage any future growth.

***A disruption in our computer networks, including those related to cybersecurity, could adversely affect our financial performance.***

We rely on sophisticated information technology systems to operate our business. These systems are potentially vulnerable to malicious intrusion, random attack, loss of data privacy, or breakdown. Although we have invested in the protection of our data and information technology and also monitor our systems on an ongoing basis, there can be no assurance that these efforts will prevent breakdowns or breaches in our information technology systems that could adversely affect our business.

We rely on our computer networks and systems, some of which are managed by third parties, to manage and store electronic information (including sensitive data such as confidential business information and personally identifiable data relating to employees, customers and other business partners), and to manage or support a variety of critical business processes and activities. We may face threats to our networks from unauthorized access, security breaches and other system disruptions. Despite our security measures, our infrastructure may be vulnerable to external or internal attacks. Any such security breach may compromise information stored on our networks and may result in significant data losses or theft of sensitive or proprietary information. In addition, a cybersecurity attack could result in other negative consequences, including disruption of our internal operations, increased cybersecurity protection costs, lost revenue, regulatory actions or litigation. Any disruption could also have a material adverse impact on our operations. We have not experienced any known attacks on our information technology systems that have resulted in any material system failure, accident or security breach to date.

***Our ability to use our net operating losses to offset future taxable income may be subject to certain limitations.***

Our net operating loss ("NOL") carryforwards could expire unused and be unavailable to offset future income tax liabilities because of their limited duration or because of restrictions under U.S. tax law. NOLs generated in taxable years beginning before January 1, 2018 are permitted to be carried forward for only 20 taxable years under applicable U.S. federal income tax law. In accordance with the Tax Cuts and Jobs Act of 2017, losses generated beginning with the 2018 tax year may be carried forward indefinitely for U.S. federal tax purposes, however losses were initially limited to offset 80% of taxable income in future years. Thus, 80% of the U.S. federal deferred tax liability related to goodwill was able to be used to offset the valuation allowance as of December 31, 2019. In accordance with the Coronavirus Aid, Relief, and Economic Security Act of 2020, however, losses generated in 2018 through 2020 may now offset 100% of taxable income in future years. Since the Company's losses generated in 2018 through 2020 are greater than the book vs. tax basis difference related to goodwill, all of the U.S. federal deferred tax liability related to goodwill may be used to offset the valuation allowance as of December 31, 2020. The extent to which state income tax law will conform to the Tax Act and CARES Act is uncertain. As of December 31, 2020, we had net operating loss ("NOL") carryforwards for U.S. federal and state income tax purposes of approximately $408.4 million and $349.6 million, respectively. These carryforwards expire at various dates through December 31, 2037, with the exception of approximately $117.3 million of U.S. federal NOL carryforwards, which will not expire.

In general, under Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, a corporation that undergoes an "ownership change" (as defined under Section 382 of the Code and applicable Treasury Regulations) is subject to limitations on its ability to utilize its pre-change NOLs to offset future taxable income. We have undergone ownership changes in the past and, accordingly, our NOLs are subject to limitation. It is possible that we have in the past undergone and may in the future undergo, additional ownership changes that we have not identified, including in connection with conversion of the notes, which could result in additional limitations on our NOLs. Furthermore, our ability to utilize NOLs of companies that we acquire may be subject to limitations. There is also a risk that due to regulatory changes, such as suspensions on the use of NOLs or other unforeseen reasons, our existing NOLs could expire or otherwise be unavailable to reduce future income tax liabilities, including for state tax purposes. For these reasons, we may not be able to utilize a material portion of the NOLs reflected on our balance sheet, even if we attain profitability, which could result in increased future tax liabilities to us and could adversely affect our operating results and financial condition.

**Risks Related to Our Common Stock**

***We expect that our stock price will fluctuate significantly.***

The trading prices of the securities of pharmaceutical and biotechnology companies have been highly volatile. The trading price of our common stock also may be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. In addition to the factors discussed in this "Risk Factors" section, these factors include:

- adverse results or delays in the planned clinical trials of our product candidates or any future clinical trials we may conduct, or changes in the development status of our product candidates;
- any delay in our regulatory filings for our product candidates and any adverse development or perceived adverse development with respect to the applicable regulatory authority's review of such filings, including without limitation the FDA's issuance of a "refusal to file" letter or a request for additional information;
- regulatory or legal developments in the United States and other countries, especially changes in laws or regulations applicable to our products and product candidates, including clinical trial requirements for approvals;
- our inability to obtain or delays in obtaining adequate product supply for any approved product or inability to do so at acceptable prices;
- failure to commercialize our product candidates or if the size and growth of the markets we intend to target fail to meet expectations;
- additions or departures of key scientific or management personnel;
- unanticipated serious safety concerns related to the use of our product candidates;
- introductions or announcements of new products offered by us or significant acquisitions, strategic collaborations, joint ventures or capital commitments by us, our collaborators or our competitors and the timing of such introductions or announcements;
- our ability or inability to effectively manage our growth;
- changes in the structure of healthcare payment systems;
- our failure to meet the estimates and projections of the investment community or that we may otherwise provide to the public;
- publication of research reports about us or our industry, or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- market conditions in the pharmaceutical and biotechnology sectors or the economy generally;
- our ability or inability to raise additional capital through the issuance of equity or debt or collaboration arrangements and the terms on which we raise it;
- trading volume of our common stock;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies; and/or
- significant lawsuits, including patent or stockholder litigation.

The stock market in general, and market prices for the securities of biopharmaceutical companies like ours in particular, have from time to time experienced volatility that often has been unrelated to the operating performance of the underlying companies. These broad market and industry fluctuations may adversely affect the market price of our common stock, regardless of our operating performance. Stock prices of many pharmaceutical companies have fluctuated in a manner unrelated or disproportionate to the operating performance of those companies. In several recent situations when the market price of a stock has been volatile, holders of that stock have instituted securities class action litigation against the company that issued the stock. If any of our stockholders were to bring a lawsuit against us, the defense and disposition of the lawsuit could be costly and divert the time and attention of our management and harm our operating results.

***Future sales of our common stock or securities convertible into our common stock in the public market could cause our stock price to fall.***

Our stock price could decline as a result of sales of a large number of shares of our common stock or securities convertible into our common stock or the perception that these sales could occur. These sales, or the possibility that these sales may occur, also might make it more difficult for us to sell equity securities in the future at a time and at a price that we deem appropriate.

Certain holders of our shares have rights requiring us to file registration statements covering the sale of their shares or to include their shares in registration statements that we may file for ourselves or other stockholders, subject to certain conditions. Shares issued upon the exercise of stock options outstanding under our equity incentive plans or pursuant to future awards granted under those plans will become available for sale in the public market to the extent permitted by the provisions of applicable vesting schedules, any applicable market stand-off and lock-up agreements, Rule 144 and Rule 701 under the Securities Act of 1933 (the "Securities Act"), as well as, to the extent applicable, under the registration statement on Form S-8 that we have filed.

Once we register the offer and sale of shares for the holders of registration rights and shares to be issued under our equity incentive plans, they can be freely sold in the public market upon issuance or resale (as applicable).

In addition, in the future, we may issue additional shares of common stock or other equity or debt securities convertible into common stock in connection with a financing, acquisition, litigation settlement, employee arrangements or otherwise. Any such issuance could result in substantial dilution to our existing stockholders and could cause our stock price to decline.

***If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, stockholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our common stock.***

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our common stock. In addition, any future testing by us conducted in connection with Section 404 of the Sarbanes-Oxley Act, or the subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement.

We are required, pursuant to Section 404 of the Sarbanes-Oxley Act, to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting. However, for as long as we are an "emerging growth company" under the JOBS Act, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal controls over financial reporting pursuant to Section 404. We could be an emerging growth company for up to five years following the date of our IPO. In any event, we will no longer qualify as an emerging growth company as of December 31, 2021. An independent assessment of the effectiveness of our internal controls could detect problems that our management's assessment might not. Undetected material weaknesses in our internal controls could lead to financial statement restatements and require us to incur the expense of remediation.

***Holders of our convertible preferred stock may exert substantial influence over us and may exercise their control in a manner adverse to your interests.***

So long as shares of our convertible preferred stock remain outstanding, without the consent of at least a majority of the then outstanding shares of the convertible preferred stock, we may not (i) authorize or approve the issuance of any convertible preferred stock, senior securities or parity securities (or, in each case, any security convertible into, or convertible or exchangeable therefor or linked thereto) or authorize or create or increase the authorized amount of any convertible preferred stock, senior securities or parity securities (or, in each case, any security convertible into, or convertible or exchangeable therefor or linked thereto); (ii) authorize or approve the purchase or redemption of any parity securities or junior securities; (iii) amend, alter or repeal any of the provisions of the certificate of designations, our certificate of incorporation or our by-laws in a manner that would adversely affect the powers, designations, preferences and rights of the convertible preferred stock; (iv) contract, create, incur, assume or suffer to exist any indebtedness or guarantee any such indebtedness with an aggregate value of more than $5,000,000 (subject to certain exceptions); or (v) agree to take any of the above actions. The holders of convertible preferred stock will have one vote for each share of common stock into which such holders' shares could then be converted at the time, and with respect to such vote, will have voting rights and powers equal to the voting rights and powers of the holders of our common stock.

The certificate of designations governing the convertible preferred stock also provides that no amendment or waiver of any provision of the certificate of designations or our charter or bylaws shall, without the prior written consent of all holders of the convertible preferred stock who are known to us to hold, together with their affiliates, more than 5% of the convertible preferred stock then outstanding (i) reduce any amounts payable or that may become payable to holders of the convertible preferred stock; (ii) postpone the payment date of any amount payable to holders of the convertible preferred stock or waive or excuse any payment; (iii) modify or waive the conversion rights of the convertible preferred stock in a manner that would adversely affect any holder of the convertible preferred stock; or (iv) change any of the voting-related provisions or any other provision of the certificate of designations specifying the number or percentage of holders of the convertible preferred stock which are required to waive, amend or modify any rights under the certificate of designations or make any determination or grant any consent under that document.

***Anti-takeover provisions in our charter documents and under Delaware law could make an acquisition of us difficult, limit attempts by our stockholders to replace or remove our current management and adversely affect our stock price.***

Provisions of our certificate of incorporation and bylaws may delay or discourage transactions involving an actual or potential change in our control or change in our management, including transactions in which stockholders might otherwise receive a premium for their shares, or transactions that our stockholders might otherwise deem to be in their best interests. Therefore, these provisions could adversely affect the price of our stock. Among other things, our certificate of incorporation and bylaws:

- permit the board of directors to issue up to 10,000,000 shares of preferred stock, with any rights, preferences and privileges as they may designate;
- provide that the authorized number of directors may be changed only by resolution of the board of directors;
- provide that all vacancies, including newly-created directorships, may, except as otherwise required by law, be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum; and
- require that any action to be taken by our stockholders must be effected at a duly called annual or special meeting of stockholders and may not be taken by written consent.

In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which generally prohibits a Delaware corporation from engaging in any of a broad range of business combinations with any stockholder owning in excess of 15.0% of our outstanding stock for a period of three years following the date on which the stockholder obtained such 15.0% equity interest in us.

***Our management has broad discretion in using cash, cash equivalents and marketable debt securities and our other capital resources.***

We expect to continue to use our cash, cash equivalents and marketable debt securities and our other capital resources to fund the clinical development of our pipeline and for general corporate purposes. Our management has broad discretion in the application of our cash, cash equivalents and marketable debt securities and our other capital resources and could spend the funds in ways that do not improve our results of operations or enhance the value of our equity. The failure by our management to apply these funds effectively could result in financial losses that could have a material adverse effect on our business, diminish available cash flows available to service our debt, cause the value of our equity to decline and delay the development of our product candidates. Pending their use, we may invest cash, cash equivalents and marketable debt securities and our other capital resources in a manner that does not produce income or that loses value.

***Because we do not anticipate paying any cash dividends on our common stock in the foreseeable future, capital appreciation, if any, will be your sole source of gain.***

We have never declared or paid cash dividends on our common stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. In addition, the terms of existing or any future debt agreements may preclude us from paying dividends. As a result, capital appreciation, if any, of our equity securities will likely be your sole source of gain for the foreseeable future.

**Risks Related to our Outstanding Convertible Senior Notes**

***We may not have the ability to raise the funds necessary to settle cash conversions of the Notes or to repurchase the Notes upon a fundamental change, and our future debt may contain limitations on our ability to pay cash upon conversion or repurchase of the Notes.***

On February 16, 2021, we issued the Notes. The terms of the Notes are governed by an Indenture dated February 16, 2021 (the "Trustee"), by and between Kadmon and U.S. Bank National Association, as trustee (the "Trustee"). The Notes are senior, unsecured obligations of Kadmon and will accrue interest payable semiannually in arrears on February 15 and August 15 of each year, beginning on August 15, 2021, at a rate of 3.625% per year, plus any additional interest or special interest that may accrue pursuant to the terms of the Indenture. The Notes will mature on February 15, 2027, unless earlier converted or repurchased. Upon maturity, the Notes are convertible into cash, shares of our common stock or a combination of cash and shares of our common stock, at our election. We received net proceeds from the offering of approximately $232.8 million, after deducting the Initial Purchasers' discount. Holders of the Notes will have the right, subject to certain conditions and limited exceptions, to require us to repurchase all or a portion of their notes upon the occurrence of a fundamental change at a fundamental change repurchase price equal to 100% of the principal amount of the Notes to be repurchased, plus accrued and unpaid special interest, if any, as defined in the Indenture. In addition, upon conversion of the Notes, unless we elect to deliver solely shares of our common stock to settle such conversion (other than paying cash in lieu of delivering any fractional share), we will be required to make cash payments in respect of the Notes being converted as defined in the Indenture. However, we may not have enough available cash or be able to obtain financing at the time we are required to make repurchases of Notes surrendered therefor or pay cash with respect to Notes being converted. In addition, our ability to repurchase the Notes or to pay cash upon conversions of the Notes may be limited by law, by regulatory authority or by agreements governing our future indebtedness. Our failure to repurchase the Notes at a time when the repurchase is required by the Indenture or to pay any cash payable on future conversions of the Notes as required by the Indenture would constitute a default under the Indenture. A default under the Indenture governing the Notes or the fundamental change itself could also lead to a default under agreements governing our future indebtedness. If the repayment of the related indebtedness were to be accelerated after any applicable notice or grace periods, we may not have sufficient funds to repay the indebtedness and repurchase the Notes or make cash payments upon conversions thereof.

***The conditional conversion feature of the Notes, if triggered, may adversely affect our financial condition and operating results.***

In the event the conditional conversion feature of the Notes is triggered, holders of Notes will be entitled to convert the Notes at any time during specified periods at their option. If one or more holders elect to convert their Notes, unless we elect to satisfy our conversion obligation by delivering solely shares of our common stock (other than paying cash in lieu of delivering any fractional share), we would be required to settle a portion or all of our conversion obligation through the payment of cash, which could adversely affect our liquidity. In addition, even if holders do not elect to convert their notes, we could be required under applicable accounting rules to reclassify all or a portion of the outstanding principal of the notes as a current rather than long-term liability, which would result in a material reduction of our net working capital.

***Transactions relating to our Notes may affect the value of our common stock.***

In connection with the pricing of the Notes, we entered into privately negotiated capped call transactions (the "Capped Call Transactions") with certain financial institutions (the "Capped Call Counterparties"). The Capped Calls cover, subject to customary adjustments, the number of shares of common stock initially underlying the Notes and are expected generally to reduce the potential dilution of our common stock upon any conversion of the Notes or at our election (subject to certain conditions) offset any cash payments we are required to make in excess of the aggregate principal amount of converted Notes, as the case may be, with such reduction or offset subject to a cap.

In addition, the Capped Call Counterparties or their respective affiliates may modify their hedge positions by entering into or unwinding various derivatives with respect to our common stock and/or purchasing or selling our common stock or other securities of ours in secondary market transactions following the pricing of the Notes and from time to time prior to the maturity of the Notes. This activity could also cause or avoid an increase or a decrease in the market price of our common stock.

***We are subject to counterparty risk with respect to the Capped Calls.***

The Capped Call Counterparties are financial institutions, and we will be subject to the risk that any or all of them might default under the Capped Calls. Our exposure to the credit risk of the Capped Call Counterparties will not be secured by any collateral. Past global economic conditions have resulted in the actual or perceived failure or financial difficulties of many financial institutions. If a Capped Call Counterparty becomes subject to insolvency proceedings, we will become an unsecured creditor in those proceedings with a claim equal to our exposure at that time under the Capped Calls with such Capped Call Counterparty. Our exposure will depend on many factors but, generally, an increase in our exposure will be correlated to an increase in the market price subject to the cap and in the volatility of our common stock. In addition, upon a default by a Capped Call Counterparty, we may suffer more dilution than we currently anticipate with respect to our common stock. We can provide no assurances as to the financial stability or viability of the Capped Call Counterparties.

**Item 1B. Unresolved Staff Comments.**

None.

**Item 2. Properties.**

We have three primary operating locations which are occupied under long-term leasing arrangements. In October 2010, Kadmon Corporation, LLC entered into a corporate headquarters and laboratory lease in New York, New York, expiring in February 2021 and opened a secured letter of credit with a third party financial institution in lieu of a security deposit for $2.0 million. Since inception, there have been six amendments to this lease agreement, which have altered office and laboratory capacity and extended the lease term through October 2025. We have the ability to extend portions of the lease on the same terms and conditions as the current lease, except that the base rent will be adjusted to the fair market rental rate for the building based on the rental rate for comparable space in the building at the time of extension.

We are party to an operating lease in Warrendale, Pennsylvania (our specialty-focused commercial operation), which expires on September 30, 2022, with two five-year renewal options, which would extend the term to September 30, 2032, if exercised. Rental payments under the renewal period will be at market rates determined from the average rentals of similar tenants in the same industrial park.

In August 2015, we entered into an office lease agreement in Cambridge, Massachusetts (our clinical office) effective January 2016 and expiring in April 2023. We opened a secured letter of credit with a third party financial institution in lieu of a security deposit for $91,000.

For additional information, see Contractual Obligations and Commitments in Part II, Item 7 of this Annual Report on Form 10-K.

**Item 3. Legal Proceedings**

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

**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 on the Nasdaq Global Select Market under the symbol "KDMN". On October 13, 2020, we provided written notice to the New York Stock Exchange that we intended to voluntarily delist our common stock from the New York Stock Exchange, effective as of the close of trading on October 23, 2020, and transfer the listing of its Common Stock to the Nasdaq Global Select Market. Trading on the Nasdaq Global Select Market commenced on October 26, 2020.

**Holders of Record**

On March 1, 2021, there were approximately 187 stockholders of record of our common stock and the closing price of our common stock was $4.95 per share as reported by the Nasdaq Global Select Market.

**Dividend Policy**

We currently expect to retain all future earnings, if any, for use in the operation and expansion of our business and paying any debts. We have never declared nor paid any dividends on our common stock and do not anticipate paying cash dividends to holders of our common stock in the foreseeable future. See "Risk Factors—Because we do not anticipate paying any cash dividends on our common stock in the foreseeable future, capital appreciation, if any, will be your sole source of gain." Any determination to pay dividends on our common stock in the future will be at the discretion of our board of directors and will depend upon, among other factors, our results of operations, financial condition, capital requirements and covenants in our existing financing arrangements and any future financing arrangements. Holders of the convertible preferred stock are entitled to receive a cumulative dividend at an annual rate of 5% of the original purchase price per share of convertible preferred stock, when and as declared by our board of directors and to the extent of funds legally available for the payment of dividends. Holders of the convertible preferred stock are also entitled to participate in all dividends declared and paid to holders of our common stock on an "as if" converted basis.

**Recent Sales of Unregistered Securities**

On February 16, 2021, we issued $240.0 million aggregate principal amount of 3.625% convertible senior notes due 2027 (the "Notes"), in a private offering pursuant to Rule 144A under the Securities Act. The offer and sale of the Notes to the initial purchasers for the Notes was made in reliance on the exemption from registration provided by Section 4(a)(2) of the Securities Act. We relied on this exemption from registration based in part on representations made by the initial purchasers, including that such initial purchasers would only offer, sell or deliver the Notes to persons whom they reasonably believe to be qualified institutional buyers within the meaning of Rule 144A under the Securities Act.

See Note 17, "Subsequent Events – Convertible Senior Notes" of the notes to our consolidated financial statements in Part IV, Item 15 of this Annual Report on Form 10-K, for additional details regarding the Notes.

**Purchases of Equity Securities by the Issuer of Affiliated Purchasers**

None.

**Securities Authorized for issuance under our Equity Compensation Plans**

The information called for by this item will be included in our definitive proxy statement with respect to our 2021 Annual Meeting of Shareholders to be filed with the SEC, and is incorporated herein by reference.

### Item 6. Selected Financial Data.

As a "smaller reporting company", we are not required to provide the information required by this item.

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

*In this Annual Report on Form 10-K, unless otherwise stated or the context otherwise requires, references to the "Company," "Kadmon," "we," "us" and "our" refer to Kadmon Holdings, Inc. and its consolidated subsidiaries. You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and related notes appearing in this Annual Report on Form 10-K. Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the "Risk Factors" section of this Annual Report on Form 10-K, our actual results could differ materially from the results described in, or implied by, the forward-looking statements contained in the following discussion and analysis.*

**Overview**

We are a clinical-stage biopharmaceutical company engaged in the discovery, development and commercialization of small molecules and biologics to address significant unmet medical needs. Our pipeline includes developmental treatments for immune and fibrotic diseases as well as immuno-oncology therapies. We leverage our multi-disciplinary research and development team members to identify and pursue a diverse portfolio of novel product candidates, both through in-licensing products and employing our small molecule and biologics platforms. Our team has a proven track record of successful drug development and commercialization. We believe that we have the ability to progress these candidates ourselves while maintaining flexibility for commercial and licensing arrangements. We expect to continue to progress our clinical candidates and have further clinical trial and regulatory events to report in 2021.

Our most advanced product candidate, belumosudil (KD025) is an orally administered, selective small molecule inhibitor of Rho-associated coiled-coil kinase 2 ("ROCK2"), a signaling pathway that modulates inflammatory response. A pivotal study of belumosudil is ongoing in patients with chronic graft-versus-host disease ("cGVHD"), a complication that can occur following hematopoietic cell transplantation ("HCT") and results in multi-organ inflammation and fibrosis. In November 2020, the U.S. Food and Drug Administration ("FDA") accepted the New Drug Application (NDA) for belumosudil for the treatment of patients with cGVHD. The FDA granted Priority Review for the NDA for belumosudil and assigned a Prescription Drug User Fee Act ("PDUFA") target action date of May 30, 2021. The NDA is being reviewed under the FDA's Real-Time Oncology Review ("RTOR") and Project Orbis pilot programs. The RTOR program aims to explore a more efficient review process to ensure that safe and effective treatments are available to patients as early as possible. The FDA's Project Orbis is an initiative of the OCE and, according to the FDA, is designed to provide a framework for concurrent submission and review of oncology products among international partners.

The FDA has granted Breakthrough Therapy Designation to belumosudil for the treatment of patients with cGVHD after failure of two or more lines of systemic therapy as well as Orphan Drug Designation to belumosudil for the treatment of cGVHD.

In addition to cGVHD, we are developing belumosudil for the treatment of systemic sclerosis ("SSc"), an autoimmune disease characterized by chronic inflammation, fibrosis and vascular damage. The FDA has granted Orphan Drug Designation to belumosudil for the treatment of SSc. A double-blind, placebo-controlled, 60-patient Phase 2 clinical trial of belumosudil in diffuse cutaneous SSc (KD025-209) is ongoing, and we anticipate initiating an open-label Phase 2 clinical trial of belumosudil in SSc in 2021 designed to quickly demonstrate the potential of belumosudil in SSc while the placebo-controlled trial is ongoing.

Further, we have a biologics research platform focused on the development of immuno-oncology therapeutics, specifically, IL-15-containing fusion proteins for the treatment of cancer. KD033 is an anti-PD-L1/IL-15 fusion protein and is the most advanced product candidate from our IL-15 platform. We initiated a Phase 1 clinical trial of KD033 in adults with metastatic or locally advanced solid tumors in 2020.

The global COVID-19 pandemic, may materially affect us economically. While the economic impact of the COVID-19 pandemic may be difficult to assess or predict, this widespread pandemic has resulted in a significant disruption of global financial markets, which may reduce our ability to access capital. If the disruption to the financial markets is protracted, our liquidity could be negatively affected in the future. In addition, a recession or market correction resulting from the COVID-19 pandemic could materially affect our business and the value of our common stock. During these uncertain times, the Company's top priorities are to ensure the health and welfare of its employees, maintain product safety and continue to advance its clinical studies. However, our clinical trials have been impacted, and we may experience delays in anticipated timelines and milestones. For instance, due to interruptions at clinical sites, enrollment has been delayed in our ongoing Phase 2 clinical trial of belumosudil in systemic sclerosis and enrollment was also delayed in our ongoing Phase 1 clinical trial of KD033 in patients with metastatic or locally advanced solid tumors. In addition, we may experience disruptions in our supply chain, including our supply of our product candidates, which may adversely affect the conduct of our clinical trials. Our CROs may be unable to conduct clinical trials for product candidates as a result of the COVID-19 pandemic. The COVID-19 pandemic could impact our healthcare systems and our clinical trial sites' ability to conduct trials to varied degrees and times. COVID-19 creates risk of interruption availability of necessary clinical supplies as well as local regulatory reviews, hospital ethics committee reviews and site monitors.

Our operations to date have been focused on developing first-in-class innovative therapies for indications with significant unmet medical needs while leveraging our commercial infrastructure. We have never been profitable and had an accumulated deficit of $444.1 million at December 31, 2020. Our net losses were $108.9 million and $61.4 million for the years ended December 31, 2020 and 2019, respectively. Although our commercial business generates revenue, we expect to incur significant losses for the foreseeable future as we continue our development of, and seek regulatory approvals for, our product candidates, hire additional personnel and initiate commercialization of any products that receive regulatory approval. We anticipate that our expenses will increase substantially if, or as, we:

- invest significantly to further develop our most advanced product candidates;
- initiate clinical trials and preclinical studies for our other product candidates;
- seek regulatory approval for our product candidates that successfully complete clinical trials;
- continue to invest in our research discovery platforms;
- seek to identify additional product candidates;
- scale up our sales, marketing and distribution infrastructure and product sourcing capabilities;
- acquire or in-license other product candidates and technologies;
- scale up our operational, financial and management information systems and personnel, including personnel to support our product development;
- make milestone or other payments under any in-license agreements; or
- maintain, expand and protect our intellectual property portfolio.

**Components of Statement of Operations**

***Revenue***

Our revenue is derived from sales of CLOVIQUE™ (Trientine Hydrocholride), licensing revenue related to our strategic partnerships, and service revenue from our sublease agreements with MeiraGTx. No meaningful revenue has been generated from sales of our other products. Revenue in 2020 primarily includes the recognition of $6.0 million licensing fees related to our strategic partnership with Meiji Seika Pharma Co., Ltd ("Meiji"), pursuant to which we and Meiji formed a joint venture to develop belumosudil in Japan. In February 2021, we entered into an agreement to divest the CLOVIQUE™ ANDA's and associated US-based patents and trademarks. We do not expect this to have a significant impact as the revenues derived from CLOVIQUE in 2020 and 2019 were $1.7 million and $0.4 million, respectively.

***Cost of Sales***

Cost of sales consists of product costs, including ingredient costs and costs of contract manufacturers for production, and shipping and handling of the products. Also included are costs related to quality release testing and stability testing of the products. Other costs included in cost of sales are packaging costs, warehousing costs and certain allocated costs related to management, facilities and other expenses associated with supply chain logistics.

***Research and development expenses***

Research and development expenses consist primarily of costs incurred for the development of our product candidates, which include:

- license fees related to our license and collaboration agreements;
- research and development-based employee-related expenses, including salaries, benefits, travel and other compensation expenses;
- expenses incurred under our agreements with contract research organizations that conduct nonclinical and preclinical studies, and clinical sites and consultants that conduct our clinical trials;
- costs associated with regulatory filings;
- costs of laboratory supplies and the acquisition, development and manufacture of preclinical and clinical study materials and study drugs; and
- allocated facility-related expenses.

Our research and development expenses may vary substantially from period to period based on the timing of our research and development activities, including timing of initiation of clinical trials and enrollment of patients in clinical trials. We do not allocate personnel-related costs, including share-based compensation, costs associated with broad technology platform improvements and other indirect costs to specific product candidates. We do not allocate these costs to specific product candidates because they are deployed across multiple overlapping projects under development, making it difficult to specifically and accurately allocate such costs to a particular product candidate.

The successful development of our product candidates is highly uncertain and subject to numerous risks including, but not limited to:

- the scope, rate of progress and expense of our research and development activities;
- clinical trial results;
- the scope, terms and timing of regulatory approvals;
- the expense of filing, prosecuting, defending and enforcing patent claims and other intellectual property rights;
- the cost, timing and our ability to acquire sufficient clinical and commercial supplies for any product candidates and products that we may develop; and
- the risks disclosed in the section entitled “Risk Factors” in this Annual Report on Form 10-K.

A change in the outcome of any of these variables could mean a significant change in the expenses and timing associated with the development of any product candidate.

***Selling, general and administrative expenses***

Selling, general and administrative expenses consist primarily of salaries and related costs for non-research personnel, including stock-based compensation and travel expenses for our employees in executive, operational, finance, legal, commercial, regulatory, and human resource functions. Other selling, general and administrative expenses include facility-related costs, lease expense, business insurance, director compensation, accounting and legal services, consulting costs and programs and marketing costs to support the commercial business.

***Other (expense) income***

Other (expense) income is comprised primarily of interest income we earn on interest-bearing accounts, realized and unrealized gains on equity securities. Other (expense) income also includes gains and losses arising from changes in fair value of our warrant liabilities. The change in fair value is based upon the fair value of the underlying security at the end of each reporting period, as calculated using the Black-Scholes option pricing model.

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

Management's discussion and analysis of our 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 of America ("GAAP"). The preparation of these consolidated financial statements requires us to make estimates and judgments that affect the reporting amounts of assets, liabilities and expenses and the disclosure of contingent assets and liabilities in our financial statements. On an ongoing basis, we evaluate our estimates and judgments, including those related to investments, goodwill, fair value of warrant liabilities, share-based compensation and accrued expenses. We base our estimates on historical experience, known trends and events and various other factors that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. If actual results for the critical accounting estimates listed below varied from our estimates, it could significantly impact our financial results. We believe that full consideration has been given to all relevant circumstances that we may be subject to, and the consolidated financial statements accurately reflect our best estimate of the results of operations, financial position and cash flows for the periods presented. While our significant accounting policies are more fully described in Note 2, "Summary of Significant Accounting Policies" of the notes to our consolidated financial statements in Part IV, Item 15 of this Annual Report on Form 10-K, we believe the following accounting policies to be most critical to the judgements and estimates used in the preparation of our financial statements.

***Revenue Recognition***

We recognize revenue in accordance with the Financial Accounting Standards Board's, or FASB, Accounting Standards Codification, or ASC, Topic 606, *Revenue from Contracts with Customers*. Accordingly, revenue is recognized when the customer obtains control of promised goods or services, in an amount that reflects the consideration which we expect to receive in exchange for those goods or services. To determine revenue recognition for arrangements that we determine are within the scope of ASC Topic 606, we perform 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; and
v. recognize revenue when (or as) performance obligations are satisfied.

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

Any amounts received prior to satisfying the revenue recognition criteria are recognized as deferred revenue in our balance sheet. Any amounts which are deferred and are 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.

Our revenues have primarily been generated through product sales, collaborative research, development and commercialization license agreements and other service agreements. The terms of these license agreements typically 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. Each of these types of revenue are recorded as license revenues in our statement of operations.

In determining the appropriate amount of revenue to be recognized as we fulfill our obligations under each arrangement, we perform the following steps:

i. identify the promised goods and services in the contract;
ii. determine whether the promised goods or services are performance obligations, including whether they are distinct within the context of the contract;
iii. measure the transaction price, including the constraint on variable consideration;
iv. allocate the transaction price to the performance obligations; and
v. recognize revenue when (or as) performance obligations are satisfied.

See Note 11, "License Agreements" of the notes to our consolidated financial statements in Part IV, Item 15 of this Annual Report on Form 10-K, for additional details regarding our license arrangements.

As part of the accounting for these arrangements, we allocate 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, we maximize the use of observable inputs. When the stand-alone selling price of a good or service is not directly observable, we estimate 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, we 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 we consider 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, we recognize revenue when those future goods or services are transferred or when the options expire.

Our 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, we recognize 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, we utilize 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. We evaluate 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, we evaluate whether each milestone is considered probable of being achieved and estimate 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 our control 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 we recognize revenue as or when the performance obligations under the contract are satisfied. At the end of each subsequent reporting period, we re-evaluate the probability of achievement of such milestones and any related constraint, and if necessary, adjust our estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect license revenues and earnings in the period of adjustment.

Research and Development Activities: If we are entitled to reimbursement from our collaborators for specified research and development activities or the reimbursement of costs associated with patent maintenance, we determine whether such funding would result in license revenues or an offset to research and development expenses.

Royalties: If we are entitled to receive sales-based royalties from our 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, we recognize 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, we have not recognized any royalty revenue resulting from any of our 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. We assess if these options provide a material right to the licensee and if so, they are accounted for as separate performance obligations. If we are entitled to additional payments when the licensee exercises these options, any additional payments are recorded in license revenues when the licensee obtains control of the goods, which is upon delivery, or as the services are performed.

We receive payments from our 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 we perform our obligations under these arrangements. Amounts are recorded as accounts receivable when our right to consideration is unconditional. We do 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.

***Share-based compensation expense***

We are required to estimate the grant-date fair value of stock options and stock appreciation rights issued to employees and recognize this cost over the period these awards vest. We estimate the fair value of each stock option granted using the Black-Scholes option pricing model. The Black-Scholes model requires the input of assumptions, including the expected stock price volatility, the calculation of expected term and the fair value of the underlying common stock on the date of grant, among other inputs. Generally, we have issued stock options that vest over time. For these awards, we record compensation cost on a straight-line basis over the vesting period. We calculate the fair value of the award on the grant date, which is the date the award is authorized by the board of directors and the employee has an understanding of the terms of the award.

The assumptions relating to the valuation of our options granted for the years ended December 31, 2020 and 2019 are shown below. The table does not include Performance Options.

| | Years Ended | |
|---|---|---|
| | December 31, 2020 | December 31, 2019 |
| Weighted average fair value of grants | $2.86 | $2.07 |
| Expected volatility | 75.46% - 87.48% | 75.96% - 77.73% |
| Risk-free interest rate | 0.29% - 1.64% | 1.41% - 2.61% |
| Expected life | 2.0 - 6.0 years | 5.5 - 6.0 years |
| Expected dividend yield | 0% | 0% |

The following table summarizes by grant date the number of shares subject to options granted since January 1, 2019, the per share exercise price of the options, the fair value of common stock underlying the options on date of grant and the per share estimated fair value of the options:

| Grant Date | Number of Shares Subject to Options Granted | Per Share Exercise Price of Options | Fair Value of Common Stock per Share on Date of Option Grant | Per Share Estimated Fair Value of Options |
|---|---|---|---|---|
| January 22, 2019 | 64,935 | $ 2.27 | $ 2.27 | $ 1.54 |
| February 6, 2019 | 64,935 | $ 2.27 | $ 2.27 | $ 1.54 |
| February 8, 2019 | 400,000 | $ 2.17 | $ 2.17 | $ 1.48 |
| May 15, 2019 | 664,103 | $ 2.29 | $ 2.29 | $ 1.51 |
| May 22, 2019 | 100,000 | $ 2.25 | $ 2.25 | $ 1.48 |
| August 30, 2019 | 300,000 | $ 2.14 | $ 2.14 | $ 1.42 |
| November 19, 2019 | 1,350,000 | $ 4.15 | $ 4.15 | $ 2.76 |
| January 15, 2020 | 15,000 | $ 4.25 | $ 4.25 | $ 2.81 |
| January 27, 2020 | 4,224,500 | $ 4.34 | $ 4.34 | $ 2.87 |
| March 3, 2020 | 7,500 | $ 4.79 | $ 4.79 | $ 3.15 |
| April 8, 2020 | 20,000 | $ 3.94 | $ 3.94 | $ 2.61 |
| May 5, 2020 | 20,000 | $ 4.40 | $ 4.40 | $ 2.91 |
| May 13, 2020 | 442,176 | $ 4.44 | $ 4.44 | $ 2.94 |
| May 14, 2020 | 100,000 | $ 4.39 | $ 4.39 | $ 2.91 |
| June 1, 2020 | 25,000 | $ 4.56 | $ 4.56 | $ 3.12 |
| June 10, 2020 | 3,500 | $ 4.71 | $ 4.71 | $ 3.23 |
| July 9, 2020 | 4,000 | $ 4.29 | $ 4.29 | $ 2.92 |
| July 22, 2020 | 1,500 | $ 3.95 | $ 3.95 | $ 2.69 |
| July 29, 2020 | 3,000 | $ 3.57 | $ 3.57 | $ 2.43 |
| August 5, 2020 | 7,500 | $ 3.70 | $ 3.70 | $ 2.52 |
| August 12, 2020 | 50,000 | $ 4.15 | $ 4.15 | $ 2.83 |
| August 13, 2020 | 36,364 | $ 4.17 | $ 4.17 | $ 2.75 |
| September 17, 2020 | 2,500 | $ 4.50 | $ 4.50 | $ 3.17 |
| September 30, 2020 | 3,500 | $ 3.92 | $ 3.92 | $ 2.76 |
| October 22, 2020 | 6,500 | $ 3.50 | $ 3.50 | $ 2.48 |
| December 9, 2020 | 40,000 | $ 4.49 | $ 4.49 | $ 3.24 |
| December 10, 2020 | 10,000 | $ 4.47 | $ 4.47 | $ 3.22 |
| December 16, 2020 | 5,000 | $ 4.35 | $ 4.35 | $ 3.13 |

***Accrued Research and Development Expenses Under Contractual Arrangements with Third Parties***

As part of the process of preparing our financial statements, we are required to estimate our accrued expenses. This process involves reviewing open contracts and purchase orders, communicating with our applicable personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of actual cost. The majority of our service providers invoice us monthly in arrears for services performed. We make estimates of our accrued expenses as of each balance sheet date in our financial statements based on facts and circumstances known to us at that time. We periodically confirm the accuracy of our estimates with the service providers and make adjustments if necessary.

Examples of estimated research and development expenses that we accrue include:

- fees paid to CROs in connection with nonclinical studies;
- fees paid to contract manufacturers in connection with the production of drug product for clinical trials;
- fees paid to CRO and research institutions in connection with conducting clinical studies; and
- professional service fees for consulting and related services.

We base our expenses related to clinical trials on our estimates of the services received and efforts expended pursuant to contracts with multiple research institutions and contract research organizations that conduct and manage clinical trials on our behalf. These estimates are reconciled and confirmed with third parties on a regular basis. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. Payments under some of these contracts depend on factors such as the successful enrollment of patients and the completion of clinical trial milestones. In accruing expenses, we estimate the time period over which services will be performed and the level of effort to be expended in each period, which is based on an established protocol specific to each clinical trial. If the actual timing of the performance of services or the level of effort varies from our estimate, we adjust the accrual accordingly. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in us reporting amounts that are too high or too low in any particular period.

To date, we have not experienced significant changes in our estimates of accrued research and development expenses following each applicable reporting period. However, due to the nature of estimates, we cannot assure you that we will not make changes to our estimates in the future as we become aware of additional information regarding the status or conduct of our clinical studies and other research activities.

***Recent Accounting Pronouncements***

See Note 2 “Summary of Significant Accounting Policies,” of the notes to our audited consolidated financial statements included elsewhere in this Annual Report on Form 10-K for a summary of recently issued and adopted accounting pronouncements.

**Results of Operations**

| | Years Ended December 31, | |
|---|---|---|
| | 2020 | 2019 |
| | (in thousands) | |
| Revenues | | |
| Net sales | $ 1,665 | $ 420 |
| License and other revenue | 6,623 | 4,675 |
| Total revenue | 8,288 | 5,095 |
| Cost of sales | 1,150 | 377 |
| Write-down of inventory | 851 | 912 |
| Gross profit | 6,287 | 3,806 |
| Operating expenses: | | |
| Research and development | 65,392 | 56,461 |
| Selling, general and administrative | 43,176 | 36,425 |
| Total operating expenses | 108,568 | 92,886 |
| Loss from operations | (102,281) | (89,080) |
| Other (expense) income | (6,814) | 27,758 |
| Income tax (benefit) expense | (182) | 46 |
| Net loss | $ (108,913) | $ (61,368) |
| Deemed dividend on convertible preferred stock | 2,122 | 2,058 |
| Net loss attributable to common stockholders | $ (111,035) | $ (63,426) |

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

*Revenues*

Total revenue for 2020 increased by 62.7% as compared to 2019 primarily due to a $6.0 million milestone payment earned pursuant to a joint venture and license agreement entered into with Meiji to develop belumosudil in Japan. In 2019, we recognized a $4.0 million milestone payment earned pursuant to a joint venture and license agreement entered into with BioNova to develop belumosudil in China.

*Cost of sales and write-down of inventory*

The increase in cost of sales was primarily attributable to the increase in CLOVIQUE net sales revenue for the year ended December 31, 2020 as compared to the year ended December 31, 2019.

*Research and development expenses*

Research and development expenses increased by 15.8% for the year ended December 31, 2020 as compared the year ended December 31, 2019. The increase of approximately $8.9 million in research and development expense for 2020 was primarily related to direct external costs of developing our lead product candidate, belumosudil. For the years ended December 31, 2020 and 2019, we recognized expense of $26.0 million and $18.3 million, respectively, for belumosudil. There was no significant change in our expense related to developing our other product candidates across multiple projects in 2020 as compared to 2019.

*Selling, general and administrative expenses*

The increase in selling, general and administrative expenses for the year ended December 31, 2020 as compared the year ended December 31, 2019 was primarily attributable to increased expenses related to the preparation for the potential launch of belumosudil.

*Other (expense) income*

The following table provides components of other income (expense):

| | Years Ended December 31, | |
|---|---|---|
| | 2020 | 2019 |
| | (in thousands) | |
| Interest expense | $ (21) | $ (2,816) |
| Amortization of deferred financing costs, debt discount and debt premium | — | (565) |
| Change in fair value of warrant liabilities | 403 | (961) |
| Unrealized (loss) gain on equity securities | (31,433) | 7,922 |
| Realized gain on equity securities | 19,784 | 22,000 |
| Interest income | 1,191 | 2,067 |
| Gain on extinguishment of obligations | 3,684 | — |
| Other (expense) income | (422) | 111 |
| **Other (expense) income** | **$ (6,814)** | **$ 27,758** |

For the years ended December 31, 2020 and 2019, other (expense) income consisted primarily of unrealized and realized gains related to our investment in MeiraGTx ordinary shares, as well as interest income. See Note 10 “Investment in MeiraGTx,” of the notes to our audited consolidated financial statements included elsewhere in this Annual Report on Form 10-K for details related to the Company’s investment in equity securities. Interest expense and other costs related to our debt decreased in 2020 as the Company repaid its debt in full in November 2019.

*Deemed Dividend*

We have 28,708 shares of 5% convertible preferred stock outstanding, which accrue dividends at a rate of 5% and convert into shares of our common stock at $9.60 per share. In May 2019, the holders of 1,292 shares of 5% convertible preferred stock exercised their right to convert their convertible preferred shares into 154,645 shares of the Company’s common stock. We accrued dividends, inclusive of a beneficial conversion feature on the accrued dividends, on the 5% convertible preferred stock during each of the years ended December 31, 2020 and 2019. The stated liquidation preference amount on the 5% convertible preferred stock totaled $34.8 million at December 31, 2020.

**Liquidity and Capital Resources**

***Overview***

We had an accumulated deficit of $444.1 million, working capital of $107.8 million, and cash, cash equivalents and marketable debt securities of $123.9 million at December 31, 2020. Net cash used in operating activities was $87.5 million and $80.1 million for the years ended December 31, 2020 and 2019, respectively.

On February 16, 2021, we issued $240.0 million aggregate principal amount of 3.625% convertible senior notes due 2027 (the "Notes"), pursuant to an Indenture dated February 16, 2021 (the “Indenture”), between us and U.S. Bank National Association, as trustee, in a private offering to qualified institutional buyers pursuant to Rule 144A under the Securities Act. The Notes issued the offering include $40.0 million in aggregate principal amount of Notes sold to the initial purchasers (the “Initial Purchasers”) resulting from the exercise in full of their option to purchase additional Notes. We received net proceeds from the offering of approximately $232.8 million, after deducting the Initial Purchasers’ discount.

We entered into a Sales Agreement with Cantor Fitzgerald & Co. (“Cantor”) in August 2017 under which we could sell up to $50.0 million in shares of its common stock in one or more placements at prevailing market prices for our common stock (the “ATM Program”). Any such sales would be effected pursuant to our registration statement on Form S-3 (File No. 333-233766), which was declared effective by the Securities Exchange Commission (“SEC”) on September 24, 2019. In May 2020, we sold 11,060,786 shares of common stock at a weighted average price of $4.52 per share through the ATM Program and received total net proceeds of $48.4 million (net of $1.6 million of commissions payable by us to Cantor). Under this registration statement, we registered to sell, in one or more transactions, up to $200.0 million of common stock, preferred stock, debt securities, warrants, purchase contracts and units. We had sold securities totaling an aggregate of $151.5 million pursuant to this registration statement as of December 31, 2020. In May 2020, we entered into a single transaction pursuant to which we sold approximately 1.1 million ordinary shares of MeiraGTx Holdings plc (“MeiraGTx”) for gross proceeds of $15.5 million. In July 2020, we entered into an additional single transaction pursuant to which we sold approximately 0.3 million ordinary shares of MeiraGTx for gross proceeds of $4.2 million.

We also filed a shelf registration statement on Form S-3 (File No. 333-238969) on June 5, 2020, which was declared effective by the SEC on June 16, 2020. Under this registration statement, we may sell, in one or more transactions, up to $300.0 million of common stock, preferred stock, debt securities, warrants, purchase contracts and units, an amount which includes $50.0 million of shares of its common stock that may be issued in the ATM Program under the Sales Agreement with Cantor. We had not sold any securities pursuant to this registration statement as of December 31, 2020.

Our plans include continuing to finance operations through the issuance of debt and sale of additional equity securities, monetization of assets, including our ownership of MeiraGTx ordinary shares, and expanding our commercial portfolio through the development of our current pipeline or through strategic collaborations. Any transactions that occur may contain covenants that restrict our ability to operate the business or may have rights, preferences or privileges senior to our common stock and may dilute our current stockholders.

We have not established a source of revenues sufficient to cover our operating costs, and as such, have been dependent on funding operations through the issuance of debt and sale of equity securities. We expect to incur further losses over the next several years as we develop our business. We have spent, and expect to continue to spend, a substantial amount of funds in connection with implementing our business strategy, including our preparation for commercial launch of belumosudil, if approved, planned product development efforts, preparation for our planned clinical trials, performance of clinical trials and our research and discovery efforts.

Our cash, cash equivalents and marketable debt securities available at December 31, 2020 was $123.9 million and in February 2021, we raised $232.8 million of net proceeds through the issuance of the Notes. Although our cash, cash equivalents and marketable debt securities, inclusive of net proceeds from the issuance of the Notes, is expected to enable us to advance our planned commercial launch efforts for belumosudil, if approved, advance certain of our other pipeline product candidates, including KD033, and provide for other working capital purposes, it may not be sufficient to enable us to meet our long-term expected plans, including commercialization of clinical pipeline products, if approved, or initiation or completion of future registrational studies. We have no commitments for any additional financing and may not be successful in our efforts to raise additional funds or achieve profitable operations. Any amounts raised will be used for further development of our product candidates, to provide financing for marketing and promotion, to secure additional property and equipment, and for other working capital purposes.

***Sources of Liquidity***

Since our inception through December 31, 2020, we have raised net proceeds from the issuance of equity and debt.

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

| | Year Ended December 31, | |
|---|---|---|
| | 2020 | 2019 |
| | (in thousands) | |
| Net cash (used in) provided by: | | |
| Operating activities | $ (87,529) | $ (80,067) |
| Investing activities | (30,567) | 21,485 |
| Financing activities | 52,923 | 103,439 |
| Net (decrease) increase in cash, cash equivalents and restricted cash | $ (65,173) | $ 44,857 |

***Operating Activities***

The net cash used in operating activities was $87.5 million for the year ended December 31, 2020, and consisted primarily of a net loss of $108.9 million adjusted for $24.0 million in non-cash items and a net decrease in operating assets and liabilities of $2.0 million. The net loss, adjusted for non-cash items, was primarily driven by selling, general and administrative expenses of $31.6 million and research and development expense related to the advancement of our clinical product candidates of $62.5 million.

The net cash used in operating activities was $80.1 million for the year ended December 31, 2019, and consisted primarily of a net loss of $61.4 million adjusted for $15.1 million in non-cash items and a net decrease in operating assets and liabilities of $3.7 million. The net loss, adjusted for non-cash items, was primarily driven by selling, general and administrative expenses of $26.3 million, research and development expense related to the advancement of our clinical product candidates of $54.2 million and interest paid on our debt of $2.7 million.

***Investing Activities***

Net cash used in investing activities was $30.6 million for the year ended December 31, 2020 consisting primarily of purchases on investment debt securities of $52.5 million offset by the sale of a portion of our investment in MeiraGTx of $19.8 million.

Net cash provided by investing activities was $21.5 million for the year ended December 31, 2019, consisting of proceeds from the sale of a portion of our investment in MeiraGTx of $22.0 million.

***Financing Activities***

Net cash provided by financing activities for the year ended December 31, 2020 was $52.9 million, consisting primarily of net proceeds from the issuance of common stock of $48.4 million.

Net cash provided by financing activities for the year ended December 31, 2019 was $103.4 million, consisting primarily of net proceeds from the issuance of common stock in our 2019 Public Offering and the 2019 placements under our Sales Agreement, together totaling $130.8 million, partially offset by principal payments on our secured term debt of $28.0 million.

**Future Funding Requirements**

We expect our expenses to increase compared to prior periods in connection with our ongoing activities, particularly as we continue research and development, continue and initiate clinical trials and seek regulatory approvals for our product candidates. In anticipation of regulatory approval for belumosudil and any of our other product candidates, we expect to incur pre-commercialization expenses related to product sales, marketing, distribution and manufacturing.

The expected use of our cash, cash equivalents and marketable debt securities at December 31, 2020 represents our intentions based upon our current plans and business conditions, which could change in the future as our plans and business conditions evolve. The amounts and timing of our actual expenditures may vary significantly depending on numerous factors, including the progress of our development, the status of, and results from, clinical trials, the potential need to conduct additional clinical trials to obtain approval of our product candidates for all intended indications, as well as any additional collaborations that we may enter into with third parties for our product candidates and any unforeseen cash needs. As a result, our management will retain broad discretion over the allocation of our existing cash, cash equivalents and marketable debt securities. In addition, we anticipate the need to raise additional funds from the issuance of additional equity, and our management will retain broad discretion over the allocation of those funds as well.

**Contractual Obligations and Commitments**

Our contractual obligations and commitment consist primarily of operating lease obligations in connection with leases for our corporate and clinical headquarters and commercial headquarters. See Note 8 “Leases” of the notes to our audited consolidated financial statements included elsewhere in this Annual Report on Form 10-K for information on our contractual obligations and commitments related to leases.

*Contingent License Agreement Milestones*

We have entered into several license agreements for products currently under development. We may be obligated in future periods to make additional payments, which would become due and payable only upon the achievement of certain research and development, regulatory and approval milestones. The specific timing of such milestones cannot be predicted and depends upon future discretionary clinical developments as well as regulatory agency actions which cannot be predicted with certainty (including action which may never occur). These additional contingent milestone payments aggregate to $229.1 million at December 31, 2020.

Under the terms of certain licensing agreements, we may be obligated to pay commercial milestones contingent upon the realization of sales revenue and sublicense revenues. Due to the long-range nature of such commercial milestones, they are neither probable at this time nor predictable, and consequently are not included in the additional contingent milestone payment amount.

**Off-balance Sheet Arrangements**

During the periods presented we did not have, and we do not currently have, any off-balance sheet arrangements, as defined under the SEC rules other than future contingent payments under license agreements as discussed in Note 15 “Commitments and Contingencies” of the notes to our audited consolidated financial statements included elsewhere in this Annual Report on Form 10-K.

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

As a “smaller reporting company,” we are not required to provide the information required by this item.

**Item 8. Financial Statements and Supplementary Data**

Our financial statements, together with the report of our independent registered public accounting firm, appear in Part IV, Item 15 of this Annual Report on Form 10-K.

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

None.

## Item 9A. Controls and Procedures

### *Management's Evaluation of our Disclosure Controls and Procedures*

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in the reports that we file or submit under the Securities Exchange Act of 1934, as amended, is (1) recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and (2) accumulated and communicated to our management, including our principal executive officer and principal financial officer, to allow timely decisions regarding required disclosure.

At December 31, 2020, 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 Securities Exchange Act of 1934, as amended). Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Our principal executive officer and principal financial officer have concluded based upon the evaluation described above that, at December 31, 2020, our disclosure controls and procedures were effective at the reasonable assurance level.

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

Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rule 13a-15(f) and 15d-15(f) of the Exchange Act). Internal control over financial reporting is a process designed by, or under the supervision of, our Chief Executive Officer and Chief Financial Officer, and effected by our 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 accurately and fairly reflect in reasonable detail the transactions and dispositions of the assets of our 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 our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and
- Provide reasonable assurances regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material adverse effect on our financial statements.

Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2020 based on the criteria established in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission, or COSO 2013. Based on our evaluation under the criteria set forth in Internal Control - Integrated Framework issued by the COSO, our management concluded our internal control over financial reporting was effective as of December 31, 2020.

### *Attestation Report of the Registered Public Accounting Firm*

This Annual Report on Form 10-K does not include an attestation report of our independent registered public accounting firm due to an exemption established by the JOBS Act for "emerging growth companies."

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

No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the fiscal quarter ended December 31, 2020 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 (other than the information set forth in the next paragraph in this Item 10) will be included in our definitive proxy statement with respect to our 2021 Annual Meeting of Shareholders to be filed with the SEC, and is incorporated herein by reference.

We have adopted a written code of business conduct and ethics that applies to our directors, officers and employees, including our principal executive officer, principal financial officer, principal accounting officer, or persons performing similar functions, and third-party consultants. We have posted a current copy of the code on our website, *www.kadmon.com*. In addition, we intend to post on our website all disclosures that are required by law or the Nasdaq Global Select Market listing standards concerning any amendments to, or waivers from, any provision of the code. The reference to our website does not constitute incorporation by reference of the information contained at or available through our website.

### Item 11. Executive Compensation

The information called for by this item will be included in our definitive proxy statement with respect to our 2021 Annual Meeting of Shareholders to be filed with the SEC, and is incorporated herein by reference.

### Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

The information called for by this item will be included in our definitive proxy statement with respect to our 2021 Annual Meeting of Shareholders to be filed with the SEC, and is incorporated herein by reference.

### Item 13. Certain Relationships and Related Transactions, and Director Independence

The information required by this item will be included in our definitive proxy statement with respect to our 2021 Annual Meeting of Shareholders to be filed with the SEC, and is incorporated herein by reference.

### Item 14. Principal Accounting Fees and Services.

The information required by this item will be included in our definitive proxy statement with respect to our 2021 Annual Meeting of Shareholders to be filed with the SEC, and is incorporated herein by reference.

## PART IV

### Item 15. Exhibits, Financial Statement Schedules.

The financial statements listed in the Index to Financial Statements are filed as part of this Annual Report on Form 10-K.

No financial statement schedules have been filed as part of this Annual Report on Form 10-K because they are not applicable, not required or because the information is otherwise included in our financial statements or notes thereto.

The exhibits filed as part of this Annual Report on Form 10-K are set forth on the Exhibit Index immediately following our financial statements. The Exhibit Index is incorporated herein by reference.

### Item 16. Form 10-K Summary

None.

**Kadmon Holdings, Inc.**

**Index to Financial Statements**

## Report of Independent Registered Public Accounting Firm

The Stockholders and Board of Directors
Kadmon Holdings, Inc.
New York, New York

**Opinion on the Consolidated Financial Statements**

We have audited the accompanying consolidated balance sheets of Kadmon Holdings, Inc. and subsidiaries (the "Company") as of December 31, 2020 and 2019, the related consolidated statements of operations and comprehensive loss, stockholders' equity, and cash flows for the years then ended, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2020 and 2019, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

**Basis for Opinion**

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

We conducted our audits 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 consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

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

/s/ BDO USA, LLP

We have served as the Company's auditor since 2010.

New York, New York
March 4, 2021

**Kadmon Holdings, Inc.**
**Consolidated Balance Sheets**
**(in thousands, except share and per share amounts)**

| | December 31, 2020 | December 31, 2019 |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 74,423 | $ 139,597 |
| Marketable debt securities, available-for-sale | 49,435 | — |
| Accounts receivable, net | 695 | 954 |
| Inventories, net | 102 | 640 |
| Prepaid expenses and other current assets | 2,082 | 1,416 |
| Investment, equity securities | 10,564 | 41,997 |
| Total current assets | 137,301 | 184,604 |
| Fixed assets, net | 1,287 | 2,444 |
| Right of use lease asset | 16,112 | 19,651 |
| Goodwill | 3,580 | 3,580 |
| Restricted cash | 2,117 | 2,116 |
| Investment, at cost | 2,300 | 2,300 |
| Other noncurrent assets | 13 | 103 |
| Total assets | $ 162,710 | $ 214,798 |
| **Liabilities and Stockholders' Equity** | | |
| Current liabilities: | | |
| Accounts payable | $ 10,933 | $ 9,043 |
| Accrued expenses | 11,534 | 14,248 |
| Term debt - current | 1,699 | — |
| Lease liability - current | 4,223 | 3,966 |
| Warrant liabilities | 1,082 | 1,485 |
| Total current liabilities | 29,471 | 28,742 |
| Lease liability - noncurrent | 15,579 | 19,759 |
| Deferred tax liability | 278 | 461 |
| Term debt - noncurrent | 1,359 | — |
| Other long term liabilities | — | 101 |
| Total liabilities | 46,687 | 49,063 |
| Commitments and contingencies (Note 15) | | |
| Stockholders' equity: | | |
| Convertible preferred stock, $0.001 par value; 10,000,000 shares authorized at December 31, 2020 and December 31, 2019; 28,708 shares issued and outstanding at December 31, 2020 and December 31, 2019. | 44,555 | 42,433 |
| Common stock, $0.001 par value; 400,000,000 shares authorized at December 31, 2020 and December 31, 2019; 171,530,045 and 159,759,996 shares issued and outstanding at December 31, 2020 and December 31, 2019, respectively | 171 | 160 |
| Additional paid-in capital | 515,429 | 456,211 |
| Accumulated deficit | (444,104) | (333,069) |
| Accumulated other comprehensive loss | (28) | — |
| Total stockholders' equity | 116,023 | 165,735 |
| Total liabilities and stockholders' equity | $ 162,710 | $ 214,798 |

See accompanying notes to consolidated financial statements

**Kadmon Holdings, Inc.**
**Consolidated Statements of Operations and Comprehensive Loss**
**(in thousands, except share and per share amounts)**

| | Years Ended December 31, | |
|---|---|---|
| | 2020 | 2019 |
| Revenues | | |
| Net sales | $ 1,665 | $ 420 |
| License and other revenue | 6,623 | 4,675 |
| Total revenue | 8,288 | 5,095 |
| Cost of sales | 1,150 | 377 |
| Write-down of inventory | 851 | 912 |
| Gross profit | 6,287 | 3,806 |
| Operating expenses: | | |
| Research and development | 65,392 | 56,461 |
| Selling, general and administrative | 43,176 | 36,425 |
| Total operating expenses | 108,568 | 92,886 |
| Loss from operations | (102,281) | (89,080) |
| Other (expense) income: | | |
| Interest income | 1,191 | 2,067 |
| Interest expense | (21) | (3,381) |
| Change in fair value of warrant liabilities | 403 | (961) |
| Realized gain on equity securities | 19,784 | 22,000 |
| Unrealized (loss) gain on equity securities | (31,433) | 7,922 |
| Gain on extinguishment of obligations | 3,684 | — |
| Other (expense) income | (422) | 111 |
| Total other (expense) income | (6,814) | 27,758 |
| Loss before income tax (benefit) expense | (109,095) | (61,322) |
| Income tax (benefit) expense | (182) | 46 |
| Net loss | $ (108,913) | $ (61,368) |
| Deemed dividend on convertible preferred stock | 2,122 | 2,058 |
| Net loss attributable to common stockholders | $ (111,035) | $ (63,426) |
| | | |
| Basic and diluted net loss per share of common stock | $ (0.67) | $ (0.48) |
| Weighted average basic and diluted shares of common stock outstanding | 166,240,356 | 132,308,548 |
| | | |
| Other comprehensive loss: | | |
| Net unrealized loss on available-for-sale securities | 28 | — |
| Other comprehensive loss | 28 | — |
| Comprehensive loss attributable to common shareholders | $ (111,063) | $ (63,426) |

See accompanying notes to consolidated financial statements

**Kadmon Holdings, Inc.**
**Consolidated Statements of Stockholders' Equity**
**(in thousands, except share amounts)**

| | Preferred stock | | Common stock | | Additional paid-in | Accumulated Other Comprehensive | Accumulated | |
|---|---|---|---|---|---|---|---|---|
| | Shares | Amount | Shares | Amount | capital | Loss | Deficit | Total |
| Balance, January 1, 2019 | 30,000 | $ 42,231 | 113,130,817 | $ 113 | $ 315,710 | $ — | $ (269,643) | $ 88,411 |
| Share-based compensation expense | — | — | — | — | 7,208 | — | — | 7,208 |
| Common stock issued in public offering, net | — | — | 46,216,805 | 46 | 130,722 | — | — | 130,768 |
| Common stock issued under ESPP plan | — | — | 88,619 | 1 | 194 | — | — | 195 |
| Common stock issued for warrant exercises | — | — | 76,776 | — | 256 | — | — | 256 |
| Common stock issued for stock option exercises | — | — | 92,334 | — | 265 | — | — | 265 |
| Beneficial conversion feature on convertible preferred stock | — | 412 | — | — | — | — | (412) | — |
| Accretion of dividends on convertible preferred stock | — | 1,646 | — | — | — | — | (1,646) | — |
| Common stock issued upon conversion of convertible preferred stock | (1,292) | (1,856) | 154,645 | — | 1,856 | — | — | — |
| Net loss | — | — | — | — | — | — | (61,368) | (61,368) |
| Balance, December 31, 2019 | 28,708 | $ 42,433 | 159,759,996 | $ 160 | $ 456,211 | $ — | $ (333,069) | $ 165,735 |
| Share-based compensation expense | — | — | — | — | 9,363 | — | — | 9,363 |
| Common stock issued in public offering, net | — | — | 11,060,786 | 11 | 48,430 | — | — | 48,441 |
| Common stock issued under ESPP plan | — | — | 164,614 | — | 436 | — | — | 436 |
| Common stock issued for warrant exercises | — | — | 229,356 | — | 12 | — | — | 12 |
| Common stock issued for option exercises | — | — | 315,293 | — | 977 | — | — | 977 |
| Beneficial conversion feature on convertible preferred stock | — | 424 | — | — | — | — | (424) | — |
| Accretion of dividends on convertible preferred stock | — | 1,698 | — | — | — | — | (1,698) | — |
| Other comprehensive loss | — | — | — | — | — | (28) | — | (28) |
| Net loss | — | — | — | — | — | — | (108,913) | (108,913) |
| Balance, December 31, 2020 | 28,708 | $ 44,555 | 171,530,045 | $ 171 | $ 515,429 | $ (28) | $ (444,104) | $ 116,023 |

See accompanying notes to consolidated financial statements

**Kadmon Holdings, Inc.**
**Consolidated Statements of Cash Flows**
**(in thousands)**

| | Years Ended December 31, | |
|---|---|---|
| | **2020** | **2019** |
| Cash flows from operating activities: | | |
| Net loss | $ (108,913) | $ (61,368) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Amortization of premiums and discounts on available-for-sale securities | 445 | — |
| Depreciation and amortization of fixed assets | 1,643 | 1,784 |
| Non-cash operating lease cost | 3,539 | 3,354 |
| Write-down of inventory | 851 | 912 |
| Amortization of debt discount | — | 565 |
| Share-based compensation | 9,363 | 7,208 |
| Change in fair value of warrant liabilities | (403) | 961 |
| Net unrealized loss (gain) on equity securities | 11,649 | (29,922) |
| Gain on extinguishment of obligations | (3,522) | — |
| Deferred taxes | (182) | 46 |
| Changes in operating assets and liabilities: | | |
| Accounts receivable, net | 259 | 736 |
| Inventories, net | (313) | (627) |
| Prepaid expenses and other assets | (576) | 62 |
| Accounts payable | 1,890 | (902) |
| Lease liability | (3,966) | (3,717) |
| Accrued expenses and other liabilities | 707 | 841 |
| Net cash used in operating activities | (87,529) | (80,067) |
| | | |
| Cash flows from investing activities: | | |
| Purchases of investment debt securities | (52,530) | — |
| Sales and maturities of investment debt securities | 2,622 | — |
| Purchases of fixed assets | (443) | (515) |
| Sales of equity securities | 19,784 | 22,000 |
| Net cash (used in) provided by investing activities | (30,567) | 21,485 |
| | | |
| Cash flows from financing activities: | | |
| Proceeds from issuance of common stock, net | 48,441 | 130,768 |
| Proceeds from issuance of term debt | 3,057 | — |
| Principal payments on secured term debt | — | (28,045) |
| Proceeds from exercise of options | 977 | 265 |
| Proceeds from issuance of ESPP shares | 436 | 195 |
| Proceeds from exercise of warrants | 12 | 256 |
| Net cash provided by financing activities | 52,923 | 103,439 |
| Net (decrease) increase in cash, cash equivalents and restricted cash | (65,173) | 44,857 |
| Cash, cash equivalents and restricted cash, beginning of period | 141,713 | 96,856 |
| Cash, cash equivalents and restricted cash, end of period | $ 76,540 | $ 141,713 |
| | | |
| **Components of cash, cash equivalents, and restricted cash** | | |
| Cash and cash equivalents | 74,423 | 139,597 |
| Restricted cash | 2,117 | 2,116 |
| Total cash, cash equivalents, and restricted cash | 76,540 | 141,713 |
| | | |
| **Supplemental cash flow disclosures:** | | |
| Cash paid for interest | $ — | $ 2,841 |
| **Non-cash investing and financing activities:** | | |
| Beneficial conversion feature on convertible preferred stock | 424 | 412 |
| Accretion of dividends on convertible preferred stock | 1,698 | 1,646 |
| Operating cash flows paid for amounts included in the measurement of lease liabilities | 4,833 | 4,679 |
| Capitalized Lease Obligations | 43 | — |
| Operating lease liabilities arising from obtaining right-of-use assets | — | 212 |
| Unpaid fixed asset additions | — | 59 |
| Common stock issued upon conversion of convertible preferred stock | — | 1,856 |
| Cumulative effect of change in accounting principle - ASC 842 adoption | — | 27,083 |

See accompanying notes to consolidated financial statements

**Kadmon Holdings, Inc.**

**Notes to Consolidated Financial Statements**

## 1. Organization

### *Nature of Business*

Kadmon Holdings, Inc. (together with its subsidiaries, "Kadmon" or "Company") is a clinical-stage biopharmaceutical company engaged in the discovery, development and delivery of transformative therapies to address significant unmet medical needs, with a near-term clinical focus on immune and fibrotic diseases as well as immuno-oncology. The Company leverages its multi-disciplinary research and clinical development team members to identify and pursue a diverse portfolio of novel product candidates, both through in-licensing products and employing its small molecule and biologics platforms.

The Company's most advanced product candidate, belumosudil (KD025) is an orally administered, selective small molecule inhibitor of Rho-associated coiled-coil kinase 2 ("ROCK2"), a signaling pathway that modulates inflammatory response. A pivotal study of belumosudil is ongoing in patients with chronic graft-versus-host disease ("cGVHD"), a complication that can occur following hematopoietic cell transplantation ("HCT") and results in multi-organ inflammation and fibrosis. In November 2020, the U.S. Food and Drug Administration ("FDA") accepted the New Drug Application (NDA) for belumosudil for the treatment of patients with cGVHD. The FDA granted Priority Review for the NDA for belumosudil and assigned a Prescription Drug User Fee Act ("PDUFA") target action date of May 30, 2021. The NDA is being reviewed under the FDA's Real-Time Oncology Review ("RTOR") and Project Orbis pilot programs. The FDA has granted Breakthrough Therapy Designation to belumosudil for the treatment of patients with cGVHD after failure of two or more lines of systemic therapy as well as Orphan Drug Designation to belumosudil for the treatment of cGVHD.

In addition to cGVHD, the Company is developing belumosudil in for the treatment of systemic sclerosis ("SSc"), an autoimmune disease characterized by chronic inflammation, fibrosis and vascular damage. The FDA has granted Orphan Drug Designation to belumosudil for the treatment of SSc. A double-blind, placebo-controlled, 60-patient Phase 2 clinical trial of belumosudil in diffuse cutaneous SSc (KD025-209) is ongoing.

Further, the Company has a biologics research platform focused on the development of immuno-oncology therapeutics, specifically, IL-15-containing fusion proteins for the treatment of cancer. KD033 is an anti-PD-L1/IL-15 fusion protein and is the most advanced product candidate from the Company's IL-15 platform. The Company initiated a Phase 1 clinical trial of KD033 in adults with metastatic or locally advanced solid tumors in 2020.

### *Liquidity*

The Company had an accumulated deficit of $444.1 million, working capital of $107.8 million, and cash, cash equivalents and marketable debt securities of $123.9 million at December 31, 2020. Net cash used in operating activities was $87.5 million and $80.1 million for the years ended December 31, 2020 and 2019, respectively.

On February 16, 2021, we issued $240.0 million aggregate principal amount of 3.625% convertible senior notes due 2027 (the "Notes"), pursuant to an Indenture dated February 16, 2021 (the "Indenture"), between us and U.S. Bank National Association, as trustee, in a private offering to qualified institutional buyers pursuant to Rule 144A under the Securities Act. The Notes issued in the offering include $40.0 million in aggregate principal amount of Notes sold to the initial purchasers (the "Initial Purchasers") resulting from the exercise in full of their option to purchase additional Notes. We received net proceeds from the offering of approximately $232.8 million, after deducting the Initial Purchasers' discount. On February 10, 2021, concurrently with the pricing of the Notes, the Company entered into privately negotiated capped call transactions (the "Capped Call Transactions") with certain financial institutions. The Company used approximately $33.0 million of the net proceeds from the Note Offering to pay for the cost of the Capped Call Transactions (Note 17).

The Company entered into a Sales Agreement with Cantor Fitzgerald & Co. ("Cantor") in August 2017 under which the Company could sell up to $50.0 million in shares of its common stock in one or more placements at prevailing market prices for its common stock (the "ATM Program"). Any such sales would be effected pursuant to the Company's registration statement on Form S-3 (File No. 333-233766), which was declared effective by the Securities Exchange Commission ("SEC") on September 24, 2019. In May 2020, the Company sold 11,060,786 shares of common stock at a weighted average price of $4.52 per share through the ATM Program and received total net proceeds of $48.4 million (net of $1.6 million of commission payable by the Company to Cantor). Under this registration statement, the Company registered to sell, in one or more transactions, up to $200.0 million of common stock, preferred stock, debt securities, warrants, purchase contracts and units. The Company had sold securities totaling an aggregate of $151.5 million pursuant to this registration statement as of December 31, 2020.

In May 2020, the Company entered into a single transaction pursuant to which it sold approximately 1.1 million ordinary shares of MeiraGTx Holdings plc ("MeiraGTx") for gross proceeds of $15.5 million. In July 2020, the Company entered into an additional single transaction pursuant to which it sold approximately 0.3 million ordinary shares of MeiraGTx for gross proceeds of $4.2 million. The Company expects that its cash, cash equivalents and marketable debt securities will enable it to advance its planned commercial launch efforts for belumosudil, if approved, advance certain of its other pipeline product candidates, including KD033, and provide for other working capital purposes.

The Company also filed a shelf registration statement on Form S-3 (File No. 333-238969) on June 5, 2020, which was declared effective by the SEC on June 16, 2020. Under this registration statement, the Company may sell, in one or more transactions, up to $300.0 million of common stock, preferred stock, debt securities, warrants, purchase contracts and units, an amount which includes $50.0 million of shares of its common stock that may be issued in the ATM Program under the Sales Agreement with Cantor. The Company had not sold any securities pursuant to this registration statement as of December 31, 2020.

Management's plans include continuing to finance operations through the issuance of additional equity and debt securities, monetization of assets and expanding the Company's commercial portfolio through the development of its current pipeline or through strategic collaborations. Any transactions that occur may contain covenants that restrict the ability of management to operate the business or may have rights, preferences or privileges senior to the Company's common stock and may dilute current stockholders of the Company.

The Company has not established a source of revenues sufficient to cover operating costs, and as such, has been dependent on funding operations through the issuance of debt and sale of equity securities. The Company's cash, cash equivalents and marketable debt securities available at December 31, 2020 was $123.9 million and in February 2021, we raised $232.8 million of net proceeds through the issuance of the Notes. Although cash, cash equivalents and marketable debt securities, inclusive of net proceeds received from the issuance of the Notes, is expected to enable the Company to advance planned commercial launch efforts for belumosudil, if approved, advance certain of the Company's other pipeline product candidates, including KD033, and provide for other working capital purposes, it may not be sufficient to enable the Company to meet its long-term expected plans, including commercialization of clinical pipeline products, if approved, or initiation or completion of future registrational studies. The Company has no commitments for any additional financing and may not be successful in efforts to raise additional funds or achieve profitable operations. Any amounts raised will be used for further development of product candidates, to provide financing for marketing and promotion, to secure additional property and equipment, and for other working capital purposes.

The Company expressed substantial doubt about its ability to continue as a going concern in the Company's 2019 Annual Report on Form 10-K filed with the SEC on March 5, 2020, based upon our recurring and continuing losses from operations and our need for additional funding to continue operations. The substantial doubt about the Company's ability to continue as a going concern remained in the Company's Quarterly Report on Form 10-Q filed with the SEC on November 5, 2020. Based on the Company's cash, cash equivalents and marketable debt securities after the closing of the February 2021 issuance of the Notes, the Company believes the substantial doubt about its ability to continue as a going concern is alleviated as of the date of the issuance of this report.

**COVID-19**

The global COVID-19 pandemic may materially affect the Company's results of operations and financial position. While the economic impact of the COVID-19 pandemic may be difficult to assess or predict, this widespread pandemic has resulted in a significant disruption of global financial markets, which may reduce the Company's ability to access capital. If the disruption to the financial markets is protracted, the Company's liquidity could be negatively affected in the future. In addition, a recession or market correction resulting from the COVID-19 pandemic could materially affect the Company's business and the value of its common stock. During these uncertain times, the Company's top priorities are to ensure the health and welfare of its employees, maintain product safety and continue to advance its clinical studies. However, the Company's clinical trials have been impacted, and the Company may experience delays in anticipated timelines and milestones. For instance, due to interruptions at clinical sites, enrollment has been delayed in the Company's ongoing Phase 2 clinical trial of belumosudil in systemic sclerosis and enrollment was also delayed in the Company's ongoing Phase 1 clinical trial of KD033 in patients with metastatic or locally advanced solid tumors. In addition, the Company may experience disruptions in its supply chain, including its supply of product candidates, which may adversely affect the conduct of its clinical trials. The Company relies on contract research organizations ("CROs") to conduct its clinical trials. CROs may be unable to conduct clinical trials for product candidates as a result of the COVID-19 pandemic. The COVID-19 pandemic could impact healthcare systems and clinical trial sites' ability to conduct trials to varied degrees and times. COVID-19 creates risk of interrupting availability of necessary clinical supplies as well as local regulatory reviews, hospital ethics committee reviews and site monitors.

**2. Summary of Significant Accounting Policies**

***Basis of Presentation***

The Company operates in one segment considering the nature of the Company's products and services, class of customers, methods used to distribute the products and the regulatory environment in which the Company operates. The accompanying consolidated financial statements, which include the accounts of Kadmon Holdings, Inc. and its domestic and international subsidiaries, all of which are wholly owned by Kadmon Holdings, Inc., have been prepared in conformity with accounting principles generally accepted in the United States of America ("GAAP"), and pursuant to the rules and regulations of the SEC. In the Company's opinion, the financial statements include all adjustments (consisting of normal recurring adjustments) and disclosures considered necessary in order to make the financial statements not misleading.

***Use of Estimates***

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

***Revenue Recognition***

The Company recognizes revenue in accordance with FASB ASC 606, *Revenue from Contracts with Customers* ("ASC 606"), the core principle of which is that an entity should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled to receive in exchange for those goods or services. To achieve this core principle, five basic criteria must be met before revenue can be recognized: (1) identify the contract with a customer; (2) identify the performance obligations in the contract; (3) determine the transaction price; (4) allocate the transaction price to performance obligations in the contract; and (5) recognize revenue when or as the Company 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.

*Disaggregation of Revenue*

The Company's revenues have primarily been generated through product sales, collaborative research, development and commercialization license agreements, and other service agreements. The following table summarizes revenue from contracts with customers for the year ended December 31, 2020 (in thousands):

| | Years Ended December 31, | |
|---|---|---|
| | 2020 | 2019 |
| Product sales | $ 1,665 | 420 |
| License revenue | 6,000 | 4,000 |
| Other revenue | 623 | 675 |
| Total revenue | $ 8,288 | 5,095 |

*Product Sales*

These contracts typically include a single promise to deliver a fixed amount of product to the customer with payment due within 30 days of shipment. Revenues are recognized when control of the promised goods is transferred to the customer, in an amount that reflects the consideration the Company expects to be entitled to in exchange for those goods. The timing of revenue recognition may differ from the timing of invoicing to customers. The Company has not recognized any assets for costs to obtain or fulfill a contract with a customer as of December 31, 2020.

*Sales Returns Reserve, Reserve for Wholesaler Chargebacks and Rebates, and Rebates Payable*

As is typical in the pharmaceutical industry, gross product sales are subject to a variety of deductions, primarily representing rebates, chargebacks, returns, and discounts to government agencies, wholesalers, and managed care organizations. These deductions represent management's best estimates of the related reserves and, as such, judgment is required when estimating the impact of these sales deductions on gross sales for a reporting period. If estimates are not representative of the actual future settlement, results could be materially affected. The Company did not have any significant expense related to these sales deductions during 2020 or 2019.

*License Revenue*

The terms of these license agreements typically 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 license revenues in the Company's statement of operations.

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

i. identify the promised goods and services in the contract;
ii. determine whether the promised goods or services are performance obligations, including whether they are distinct within the context of the contract;
iii. measure the transaction price, including the constraint on variable consideration;
iv. allocate the transaction price to the performance obligations; and
v. recognize revenue when (or as) performance obligations are satisfied.

See Note 11, "License Agreements" for additional details regarding the Company's license 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 estimate 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 Company's control 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, adjust the Company's estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect license 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 license revenues or an offset to research and development expenses.

Royalties: If the Company is entitled to receive sales-based royalties from its collaborators, 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.

Supply Services: Arrangements that include a promise for future supply of drug substance or 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 license 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.

*Transaction Price Allocated to Future Performance Obligations*

ASC 606 requires that the Company disclose the aggregate amount of transaction price that is allocated to performance obligations that have not yet been satisfied as of December 31, 2020. The guidance provides certain practical expedients that limit this requirement. The Company has various contracts that meet the following practical expedients provided by ASC 606:

1. The performance obligation is part of a contract that has an original expected duration of one year or less.

2. Revenue is recognized from the satisfaction of the performance obligations in the amount billable to the customer.

3. The variable consideration is allocated entirely to a wholly unsatisfied performance obligation or to a wholly unsatisfied promise to transfer a distinct good or service that forms part of a single performance obligation.

As of December 31, 2020, the Company had no performance obligations that had not yet been satisfied and therefore there is no transaction price allocated to future performance obligations under ASC 606.

*Other Revenue*

The other revenue generated by the Company is primarily related to a sublease agreement with MeiraGTx (Note 10). The Company recognizes revenue related to sublease agreements as they are performed.

***Share-based Compensation Expense***

The Company's accounting policy for share-based compensation is disclosed in Note 12 "Share-based Compensation".

***Research and Development Expenses***

Costs incurred for research and development are expensed as incurred. Included in research and development expense are personnel related costs including stock-based compensation, expenditures for laboratory equipment and consumables, payments made pursuant to licensing and acquisition agreements, and the cost of conducting clinical trials. Expenses incurred associated with conducting clinical trials include, but are not limited to, drug development trials and studies, drug manufacturing, laboratory supplies, external research and overhead.

The Company has entered into agreements with third parties to acquire technologies and pharmaceutical product candidates for development (Note 11). Such agreements generally require an initial payment by the Company when the contract is executed, and additional payments upon the achievement of certain milestones. Additionally, the Company may be obligated to make future royalty payments in the event the Company commercializes the pharmaceutical product candidate and achieves a certain sales volume. In accordance with FASB ASC Topic 730-10-55, *Research and Development,* expenditures for research and development, including upfront licensing fees and milestone payments associated with products that have not yet been approved by the FDA, are charged to research and development expense as incurred. Future contract milestone payments will be recognized as expense when achievement of the milestone is determined to be probable. Once a product candidate receives regulatory approval, subsequent license payments are recorded as an intangible asset.

Research and development expense was $65.4 million and $56.5 million during the years ended December 31, 2020 and 2019, respectively.

***Accruals for Research and Development Expenses and Clinical Trials***

As part of the process of preparing its financial statements, the Company is required to recognize its expenses resulting from its obligations under contracts with vendors, clinical research organizations and consultants and under clinical site agreements in connection with conducting clinical trials. This process involves reviewing open contracts and purchase orders, communicating with the applicable personnel to identify services that have been performed on behalf of the Company and estimating the level of service performed and the associated cost incurred for the service when the Company has not yet been invoiced or otherwise notified of actual cost. These estimates are periodically confirmed and reconciled with the third parties providing the service. The majority of service providers invoice the Company monthly in arrears for services performed. The Company makes estimates of accrued expenses as of each balance sheet date in the financial statements based on facts and circumstances known to the Company at that time. The Company's clinical trial accruals are dependent upon the timely and accurate reporting of contract research organizations and other third-party vendors. Although the Company does not expect its estimates to be materially different from amounts actually incurred, its understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in it reporting amounts that are too high or too low for any particular period. For the years ended December 31, 2020 and 2019, there were no material adjustments to the Company's prior period estimates of accrued expenses for clinical trials. The Company periodically confirms the accuracy of its estimates with the service providers and makes adjustments if necessary.

***Income Taxes***

The Company's accounting policy for income taxes is disclosed in Note 16 "Income Taxes".

***Cash, Cash Equivalents and Marketable Debt Securities***

The Company considers all highly liquid securities with an original or remaining maturity of three months or less at the time of acquisition to be cash equivalents.

Marketable debt securities are considered to be available-for-sale and are carried at fair market value. The estimated fair value of the available-for-sale marketable debt securities is determined based on quoted market prices or rates for similar instruments. Unrealized gains and losses, if any, are reported in accumulated other comprehensive income (loss). The cost of marketable debt securities is adjusted for amortization of premiums and accretion of discounts to maturity. Such amortization and accretion is included in other (expense) income. Realized gains and losses, and declines in value judged to be other-than-temporary, if any, are also included in other (expense) income. Interest and dividends on available-for-sale securities are included in other income.

The Company determines the appropriate classification of its investments in debt securities at the time of purchase. All of the Company's debt securities are classified as available-for-sale and are reported as short-term or long-term based on maturity dates and whether such assets are reasonably expected to be realized in cash or sold or consumed during the normal cycle of business.

The Company reviews investments for other-than-temporary impairment whenever the fair value of an investment is less than the amortized cost and evidence indicates that an investment's carrying amount is not recoverable within a reasonable period of time. Other-than-temporary impairments of investments are recognized in the consolidated statements of operations if the Company experienced a credit loss and have the intent to sell the investment or if it is more likely than not that the Company will be required to sell the investment before recovery of the amortized cost basis. Evidence considered in this assessment includes reasons for the impairment, compliance with the Company's investment policy, the severity and the duration of the impairment and changes in value subsequent to the end of the period.

The following tables summarize the Company's cash, cash equivalents and marketable debt securities as of December 31, 2020 and 2019:

| | December 31, 2020 | | | |
|---|---|---|---|---|
| | Amortized Cost | Gross Unrealized Gains | Gross Unrealized Losses | Fair Value |
| **Cash and cash equivalents:** | | | | |
| Cash and money market funds | $ 71,382 | $ — | $ — | 71,382 |
| Corporate debt securities | 3,041 | — | — | 3,041 |
| Total cash and cash equivalents | 74,423 | — | — | 74,423 |
| **Marketable debt securities:** | | | | |
| Corporate debt securities | 49,463 | 4 | (32) | 49,435 |
| Total marketable debt securities | 49,463 | 4 | (32) | 49,435 |
| **Total cash, cash equivalents and marketable debt securities** | **$ 123,886** | **$ 4** | **$ (32)** | **$ 123,858** |

| | December 31, 2019 | | | |
|---|---|---|---|---|
| | Amortized Cost | Gross Unrealized Gains | Gross Unrealized Losses | Fair Value |
| **Cash and cash equivalents:** | | | | |
| Cash and money market funds | $ 139,597 | $ — | $ — | 139,597 |
| Total cash and cash equivalents | 139,597 | — | — | 139,597 |
| **Marketable debt securities:** | | | | |
| Corporate debt securities | — | — | — | — |
| Total marketable debt securities | — | — | — | — |
| **Total cash, cash equivalents and marketable debt securities** | **$ 139,597** | **$ —** | **$ —** | **$ 139,597** |

At December 31, 2020, the Company had invested in 18 available-for-sale marketable debt securities that were in an unrealized loss position for less than one year and no securities were in an unrealized loss position for more than 12 months. The aggregate fair value of debt securities in an unrealized loss position at December 31, 2020 was $35.7 million. The unrealized losses of less than $0.1 million related to these corporate debt securities were included in accumulated other comprehensive loss as of December 31, 2020. Unrealized losses on corporate debt securities have not been recognized into income because the issuers' bonds are of high credit quality (rated A3/A- or higher), it is likely that management will not be required to sell the securities prior to their anticipated recovery, and the decline in fair value is largely due to market conditions and/or changes in interest rates. The issuers continue to make timely interest payments on the bonds. The fair value is expected to recover as the bonds approach maturity and the Company does not believe any unrealized losses represent other-than-temporary impairments.

Accrued interest receivable on available-for-sale marketable debt securities totaled $0.4 million at December 31, 2020 and is included in prepaid expenses and other current assets.

***Restricted Cash***

The Company has a lease agreement for the premises it occupies in New York. A secured letter of credit in lieu of a lease deposit totaling $2.0 million is secured by restricted cash in the same amount at December 31, 2020 and 2019. The secured letter of credit will remain in place for the life of the related lease, expiring in October 2025 (Note 8). The Company also has a lease agreement for the premises it occupies in Massachusetts. A secured letter of credit in lieu of a lease deposit totaling approximately $0.1 million is secured by restricted cash in the same amount at December 31, 2020 and 2019. The secured letter of credit will remain in place for the life of the related lease, expiring in April 2023 (Note 8).

***Concentration of Credit Risk***

The Company may from time to time have cash in banks in excess of Federal Deposit Insurance Corporation insurance limits. However, the Company regularly monitors the financial condition of the institutions in which it has depository accounts and believes the risk of loss is minimal as these banks are large financial institutions.

The Company has no off-balance-sheet concentration of credit risk such as foreign exchange contracts, option contracts or other hedging arrangements.

***Accounts Receivable and Allowance for Doubtful Accounts***

Accounts receivable are recorded at the invoiced amount, net of an allowance for doubtful accounts. A receivable is recognized in the period the Company deliver goods or provide services or when the Company's right to consideration is unconditional. The Company reviews the collectability of accounts receivable based on an assessment of historical experience, current economic conditions, and other collection indicators. The Company had no significant allowance for doubtful accounts at December 31, 2020 or December 31, 2019. When accounts are determined to be uncollectible they are written off against the reserve balance and the reserve is reassessed. When payments are received on reserved accounts they are applied to the customer's account and the reserve is reassessed.

***Inventories***

The Company's accounting policy for inventories is disclosed in Note 7 "Inventories".

***Investment in Equity Securities***

Equity securities consist of investments in common stock of companies traded on public markets (Note 10). These shares are carried on the Company's balance sheet at fair value based on the closing price of the shares owned on the last trading day before the balance sheet of this report. Fluctuations in the underlying bid price of the shares result in unrealized gains or losses. In accordance with FASB ASC 321, Investments – Equity Securities ("ASC 321"), the Company recognizes these fluctuations in value as other expense (income). For investments sold, the Company recognizes the gains and losses attributable to these investments as realized gains or losses in other expense (income).

The Company's total investment balance in equity securities totaled $10.6 million and $42.0 million at December 31, 2020 and 2019, respectively.

***Investments***

The Company follows FASB ASC Topic 323, "Investments—Equity Method and Joint Ventures" ("ASC 323"), in accounting for its investments in a joint venture. In the event the Company's share of the joint venture's net losses reduces the Company's investment to zero, the Company will discontinue applying the equity method and will not provide for additional losses unless the Company has guaranteed obligations of the joint venture or is otherwise committed to provide further financial support for the joint venture. If the joint venture subsequently reports net income, the Company will resume applying the equity method only after its share of that net income equals the share of net losses not recognized during the period the equity method was suspended.

The Company follows FASB ASC Topic 325, "Investments—Other" ("ASC 325"), in accounting for its investment in the stock of another company accounted for as cost method investments. The Company currently only has one such investment, which is measured in accordance with the "practicability election" allowable for investments without a readily determinable fair value that do not qualify for the NAV practical expedient under ASC 820, "Fair Value Measurement". This requires investments to be measured at cost minus impairment, plus or minus changes resulting from observable price changes in orderly transactions for an identical or similar investment of the same issuer. In the event further contributions or additional shares are purchased, the Company will increase the basis in the investment. In the event distributions are made or indications exist that the fair value of the investment has decreased below the carrying amount, the Company will decrease the value of the investment as considered appropriate. The Company's cost method investment balance totaled $2.3 million at both December 31, 2020 and 2019, respectively.

For all non-consolidated investments, the Company will continually assess the applicability of FASB ASC Topic 810, "Consolidation" ("ASC 810"), to determine if the investments qualify for consolidation. At December 31, 2020 and 2019, no such investments qualified for consolidation.

***Fixed Assets***

The Company's accounting policy for fixed assets is disclosed in Note 9 "Fixed Assets".

***Goodwill***

The Company's goodwill relates to the 2010 acquisition of Kadmon Pharmaceuticals, a Pennsylvania limited liability company that was formed in April 2000. Goodwill is not amortized, but rather is assessed for impairment annually or upon the occurrence of an event that indicates impairment may have occurred, in accordance with FASB ASC Topic 350 "Intangibles—Goodwill and Other". The Company maintains a goodwill balance of $3.6 million at both December 31, 2020 and 2019. There were no changes in the carrying amount of goodwill and no impairment to goodwill was recorded for the years ended December 31, 2020 and 2019.

***Impairment of Long-Lived Assets***

Long-lived assets, including fixed assets and definite-lived intangible assets, are evaluated for impairment periodically, or when events or changes in circumstances indicate that the carrying amount of the assets may not be recoverable. When any such impairment exists, a charge is recorded in the statement of operations to adjust the carrying value of the related assets.

The Company performed a trigger analysis over all other long-lived assets at the lowest identifiable level of cash flows and determined that no impairment triggers existed during the years ended December 31, 2020 and 2019.

***Accounting for Leases***

The Company's accounting policy for leases is disclosed in Note 8 "Leases".

***Accounting for Contingencies***

The Company follows the guidance of FASB ASC Topic 450, "Contingencies" ("ASC 450"), in accounting for contingencies. If some amount within a range of loss is probable and appears at the time to be a better estimate than any other amount within the range, that amount shall be recognized. If a loss is probable, and no amount within the range is a better estimate than any other amount, the estimated minimum amount in the range shall be recognized.

***Fair Value of Financial Instruments***

The Company follows the provisions of FASB ASC Topic 820, "Fair Value Measurements and Disclosures" ("ASC 820"). This pronouncement defines fair value, establishes a framework for measuring fair value under GAAP and requires expanded disclosures about fair value measurements. ASC 820 emphasizes that fair value is a market-based measurement, not an entity-specific measurement, and defines fair value as the price to sell an asset or transfer a liability in an orderly transaction between market participants at the measurement date. ASC 820 discusses valuation techniques, such as the market approach (comparable market prices), the income approach (present value of future income or cash flow) and the cost approach (cost to replace the service capacity of an asset or replacement cost). These valuation techniques are based upon observable and unobservable inputs. Observable inputs reflect market data obtained from independent sources, while unobservable inputs reflect the Company's market assumptions. ASC 820 utilizes a fair value hierarchy that prioritizes inputs to fair value measurement techniques into three broad levels. The following is a brief description of those three levels:

- Level 1: Observable inputs such as quoted prices for identical assets or liabilities in active markets.
- Level 2: Observable inputs other than quoted prices that are directly or indirectly observable for the asset or liability, including quoted prices for similar assets or liabilities in active markets; quoted prices for similar or identical assets or liabilities in markets that are not active; and model-derived valuations whose inputs are observable or whose significant value drivers are observable.
- Level 3: Unobservable inputs that reflect the reporting entity's own assumptions.

The carrying amounts reported in the consolidated balance sheet for cash and cash equivalents, receivables, accounts payable and accrued expenses approximate their fair value based on the short-term nature of these instruments. The carrying amount reported in the consolidated balance sheet for investment in equity securities approximates fair value as the asset has a readily determinable market value (Note 10).

***Warrants and Derivative Liabilities***

The Company accounts for its derivative financial instruments in accordance with FASB ASC Topic 815, *Derivatives and Hedging* ("ASC 815"). The Company does not have derivative financial instruments that are hedges. ASC 815 establishes accounting and reporting standards requiring that derivative instruments, both freestanding and embedded in other contracts, be recorded on the balance sheet as either an asset or liability measured at its fair value each reporting period. ASC 815 also requires that changes in the fair value of derivative instruments be recognized currently in the results of operations unless specific criteria are met. For embedded features that are not clearly and closely related to the host instrument, are not carried at fair value, and are derivatives, the feature will be bifurcated and recorded as an asset or liability as noted above, unless the exceptions below are met. Freestanding instruments that do not meet these exceptions will be accounted for in the same manner.

ASC 815 provides an exception—if an embedded derivative or freestanding instrument is both indexed to the company's own stock and classified in stockholders' equity, it can be accounted for in stockholders' equity. If at least one of the criteria is not met, the embedded derivative or warrant is classified as an asset or liability and recorded to fair value each reporting period through the income statement.

The Company has historically issued warrants in connection with debt and equity issuances. The Company assesses classification of its warrants and embedded features at each reporting date to determine whether a change in classification is required. The Company's accounting for its embedded warrants are explained further in Note 6.

***Related Party Transactions***

Certain of the Company's existing institutional investors purchased an aggregate of 10,444,117 shares of the Company's common stock in the public offering that closed in November 2019. Consonance Capital Management LP purchased 4,900,000 shares of the Company's common stock for $16.7 million, Perceptive Advisors LLC purchased 1,470,588 shares of the Company's common stock for $5.0 million, Vivo Capital VIII LLC purchased 1,323,529 shares of the Company's common stock for $4.5 million, Acuta Capital Partners LLC purchased 1,250,000 shares of the Company's common stock for $4.3 million and Millenium Management LLC purchased 1,500,000 shares of the Company's common stock for $5.1 million.

***Recent Accounting Pronouncements***

In August 2020, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2020-06, "*Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity"* ("ASU 2020-06"),which simplifies the guidance on an issuer's accounting for convertible instruments and contracts in its own equity. The provisions of ASU 2020-06 are applicable for fiscal years beginning after December 15, 2021, with early adoption permitted no earlier than fiscal years beginning after December 15, 2020. The Company is currently evaluating the impact of ASU 2020-06 on its financial statements.

In December 2019, the FASB issued ASU No. 2019-12, *"Income Taxes: Simplifying the Accounting for Income Taxes"*, which removes certain exceptions for recognizing deferred taxes for investments, performing intraperiod allocation and calculating income taxes in interim periods. The ASU also adds guidance to reduce complexity in certain areas, including recognizing deferred taxes for tax goodwill and allocating taxes to members of a consolidated group. The ASU is effective for annual or interim periods beginning after December 15, 2020, with early adoption permitted. The Company does not expect the standard to have a significant impact on its consolidated financial statements.

In November 2018, the FASB issued ASU No. 2018-18, *"Collaborative Arrangements (Topic 808): Clarifying the Interaction Between Topic 808 and Topic 606",* which requires transactions in collaborative arrangements to be accounted for under ASC 606 if the counterparty is a customer for a good or service (or bundle of goods and services) that is a distinct unit of account. The amendments also preclude entities from presenting consideration from transactions with a collaborator that is not a customer together with revenue recognized from contracts with customers. The Company adopted this standard on January 1, 2020, and the standard did not have a significant impact on its consolidated financial statements as the Company does not have any material agreements that are within the scope of this ASU.

In August 2018, the FASB issued ASU No. 2018-15, "*Intangibles—Goodwill and Other—Internal-Use Software (Subtopic 350-40): Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract (a consensus of the FASB Emerging Issues Task Force)",* which requires customers in a cloud computing arrangement that is a service contract to follow the internal-use software guidance in Accounting Standards Codification 350-40 to determine which implementation costs to capitalize. The Company adopted this standard on January 1, 2020, and the standard did not have a significant impact on its consolidated financial statements as the Company's cloud computing contracts are not material.

In January 2017, the FASB issued ASU No. 2017-04, "*Intangibles – Goodwill and Other"*, which simplifies the subsequent measurement of goodwill by eliminating "Step 2" from the goodwill impairment test. Instead of performing Step 2 to determine the amount of an impairment charge, the fair value of a reporting unit will be compared with its carrying amount and an impairment charge will be recognized for the value by which the carrying amount exceeds the reporting unit's fair value. For smaller reporting companies, ASU 2017-04 is effective for annual or any interim goodwill impairment tests in fiscal years beginning after December 15, 2022. Early adoption is permitted for interim or annual goodwill impairment tests performed on testing dates after January 1, 2017. The Company does not expect the standard to have a significant impact on its consolidated financial statements.

In June 2016, the FASB issued ASU No. 2016-13, "*Measurement of Credit Losses on Financial Instruments"*, to require financial assets carried at amortized cost to be presented at the net amount expected to be collected based on historical experience, current conditions and forecasts. For smaller reporting companies, the ASU is effective for interim and annual periods beginning after December 15, 2022, with early adoption permitted. Adoption of the ASU is on a modified retrospective basis. The Company does not expect this guidance to have a material impact on its financial statements.

**3. Stockholders' Equity**

**5% Convertible Preferred Stock**

The Company's certificate of incorporation permitted the Company's board of directors to issue up to 10,000,000 shares of preferred stock from time to time in one or more classes or series. Concurrently with the closing of the Company's initial public offering (the "IPO") in 2016 and pursuant to the terms of the exchange agreement entered into with the holders of the Company's Senior Convertible Term Loan, the Company issued to such holders 30,000 shares of 5% convertible preferred stock, designated as the convertible preferred stock. Each share of convertible preferred stock was issued for an amount equal to $1,000 per share, which is referred to as the original purchase price. Shares of convertible preferred stock with an aggregate original purchase price and initial liquidation preference of $30.0 million were issued to the holders of the Senior Convertible Term Loan in exchange for an equivalent principal amount of the Senior Convertible Term Loan pursuant to the terms of an exchange agreement dated as of June 8, 2016, between the Company and those holders, which is referred to as the exchange agreement.

The shares of 5% convertible preferred stock are entitled to receive dividends, when and as declared by the board of directors and to the extent of funds legally available for the payment of dividends, at an annual rate of 5% of the sum of the original purchase price per share of 5% convertible preferred stock plus any dividend arrearages. Dividends on the 5% convertible preferred stock shall, at the Company's option, either be paid in cash or added to the stated liquidation preference amount for purposes of calculating dividends at the 5% annual rate (until such time as the Company declares and pays the missed dividend in full and in cash, at which time that dividend will no longer be part of the stated liquidation preference amount). Dividends shall be payable annually on June 30 of each year and shall be cumulative from the most recent dividend payment date on which the dividend has been paid or, if no dividend has ever been paid, from the original date of issuance of the 5% convertible preferred stock and shall accumulate from day to day whether or not declared until paid.

The Company had 28,708 shares of 5% convertible preferred stock outstanding at December 31, 2020, which shares convert into shares of the Company's common stock at a 20% discount to the initial public offering price per share of common stock in the Company's IPO of $12.00 per share, or $9.60 per share. In May 2019, a holder of 1,292 shares of 5% convertible preferred stock exercised its right to convert such shares into 154,645 shares of the Company's common stock. The 5% convertible preferred stock, inclusive of accrued and unpaid dividends, is convertible into 3,712,931 and 3,536,125 shares of common stock at December 31, 2020 and 2019, respectively.

Approximately $1.7 million and $1.6 million of accrued dividends that were payable on both June 30, 2020 and June 30, 2019, respectively, were added to the stated liquidation preference amount of the 5% convertible preferred stock on those respective dates. The stated liquidation preference amount on the 5% convertible preferred stock totaled $34.8 million and $33.1 million at December 31, 2020 and December 31, 2019, respectively.

***Common Stock***

The Company's restated certificate of incorporation authorizes the issuance of up to 400,000,000 shares of the Company's common stock, par value $0.001 per share.

For the year ended December 31, 2020, the Company raised an aggregate of $50.0 million, $48.4 million net of $1.6 million of commissions payable by the Company, from the issuance of 11,060,786 shares of common stock at a weighted average issuance price of $4.52 per share.

For the year ended December 31, 2019, the Company raised an aggregate of $138.5 million, $130.8 million net of $7.7 million of underwriting discounts and other offering costs and expenses, from the issuance of 46,216,805 shares of common stock at a weighted average issuance price of $3.00 per share.

**4. Net Loss per Share Attributable to Common Stockholders**

Basic net loss per share attributable to common stockholders is computed by dividing the net loss attributable to common stockholders by the weighted-average number of common stock outstanding for the period. Because the Company has reported a net loss for all periods presented, diluted net loss per common share is the same as basic net loss per common share for those periods. The following table summarizes the computation of basic and diluted net loss per share attributable to common stockholders of the Company (in thousands, except share and per share amounts):

| | Years Ended December 31, | |
|---|---|---|
| | 2020 | 2019 |
| **Numerator – basic and diluted:** | | |
| Net loss attributable to common stockholders | $ (111,035) | $ (63,426) |
| **Denominator – basic and diluted:** | | |
| Weighted average common stock outstanding used to compute basic and diluted net loss per share | 166,240,356 | 132,308,548 |
| **Net loss per share, basic and diluted** | **$ (0.67)** | **$ (0.48)** |

The amounts in the table below were excluded from the calculation of diluted net loss per share, due to their anti-dilutive effect:

| | Years Ended December 31, | |
|---|---|---|
| | 2020 | 2019 |
| Options to purchase common stock | 17,290,685 | 13,092,601 |
| Warrants to purchase common stock | 10,582,119 | 11,921,452 |
| Convertible preferred stock | 3,712,931 | 3,536,125 |
| **Total shares of common stock equivalents** | **31,585,735** | **28,550,178** |

**5. Debt**

*August 2015 Secured Term Debt*

In August 2015, the Company entered into a secured term loan in the amount of $35.0 million with two lenders ("2015 Credit Agreement"). The interest rate on the loan was LIBOR plus 9.375% with a 1% floor. At December 31, 2018, the Company maintained an outstanding principal balance of $28.0 million under the 2015 Credit Agreement.

In October 2019, the Company entered into a transaction pursuant to which it sold approximately 1.4 million ordinary shares of MeiraGTx for gross proceeds of $22.0 million (Note 10). Pursuant to the 2015 Credit Agreement, half of the proceeds received from the sale, or $11.0 million, were used to pay down part of the outstanding amounts owed under the 2015 Credit Agreement. After this repayment, approximately $17.0 million of principal remained outstanding under the 2015 Credit Agreement. In November 2019, the Company repaid the remaining $17.0 million of principal outstanding under the credit agreement with Perceptive Credit Opportunities Fund, L.P., as amended. As such, the Company has no further payment obligations under the 2015 Credit Agreement at December 31, 2019. The Company recognized $3.4 million of interest expense in 2019 related to the 2015 Credit Agreement.

*Paycheck Protection Program of the Coronavirus Aid, Relief, and Economic Security Act*

On April 15, 2020, the Company received the proceeds from a loan in the amount of approximately $3.1 million (the "Loan") from PNC Bank, National Association, as lender, pursuant to the Paycheck Protection Program ("PPP") of the Coronavirus Aid, Relief, and Economic Security Act ("CARES Act"). The Loan matures on April 15, 2022 and bears interest at a rate of 1% per annum. On August 20, 2020, the loan was amended so that, commencing August 15, 2021, the Company is required to pay the lender equal monthly payments of principal and interest as required to fully amortize by April 15, 2022 the principal amount outstanding on the Loan as of October 15, 2020. The Loan is evidenced by a promissory note dated April 15, 2020 (the "Note"), which contains customary events of default relating to, among other things, payment defaults and breaches of representations and warranties. The Loan may be prepaid by the Company at any time prior to maturity with no prepayment penalties.

The application for these funds required the Company to certify in good faith that the then current economic uncertainty made the loan request necessary to support the ongoing operations of the Company. This certification further required the Company to take into account its current business activity and its ability to access other sources of liquidity sufficient to support ongoing operations in a manner that is not significantly detrimental to the business. The Company made this good faith assertion based upon various factors, including the degree of uncertainty introduced to the capital markets as a result of the COVID-19 pandemic and the Company's dependency on its ability to raise capital to fund ongoing operations.

All or a portion of the Loan may be forgiven by the U.S. Small Business Administration ("SBA") upon application by the Company upon documentation of expenditures in accordance with the SBA requirements. Under the CARES Act, loan forgiveness is available for the sum of eligible and documented payroll costs, covered rent payments, covered mortgage interest and covered utilities during the eight-week period beginning on the date of loan approval. If, despite the Company's good-faith belief that given the circumstances the Company satisfied all eligibility requirements for the Loan, the Company is later determined to have violated any applicable laws or regulations or it is otherwise determined that the Company was ineligible to receive the Loan, the Company may be required to repay the Loan in its entirety and/or be subject to additional penalties. In the event the Loan, or any portion thereof, is forgiven pursuant to the PPP, the amount forgiven is applied to outstanding principal.

The Company used all proceeds from the Loan to retain employees, maintain payroll and make lease, rent and utility payments. Under the terms of the loan, the Company may be eligible for full or partial loan forgiveness. The Company has applied for forgiveness, however, no assurance is provided that the Company will obtain forgiveness for any portion of the Loan.

The Company has accounted for the Loan as a debt instrument in accordance with Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") 470, Debt. At December 31, 2020, $1.7 million of principal payments due in 2021 have been recorded as short-term debt and the remaining balance of $1.4 million is recorded as long-term debt. The Company does not expect to incur any material interest expense under the Loan.

**6. Financial Instruments**

The Company is required to disclose information on all assets and liabilities reported at fair value that enables an assessment of the inputs used in determining the reported fair values. The fair value hierarchy defines three levels and prioritizes valuation inputs based on the observable nature of those inputs. The fair value hierarchy applies only to the valuation inputs used in determining the reported fair value of the investments and is not a measure of the investment credit quality.

Items classified as Level 1 within the valuation hierarchy consist of the Company's cash equivalents held in money market funds and its ownership of MeiraGTx (Note 10). The Company measures these investments at fair value determined based on Level 1 observable quoted price market inputs.

Items classified as Level 2 within the valuation hierarchy consist of the Company's marketable debt securities and warrant liabilities. The Company estimates the fair values of the marketable debt securities by taking into consideration valuations obtained from third-party pricing sources. These pricing sources utilize industry standard valuation models, including both income and market-based approaches, for which all significant inputs are observable, either directly or indirectly, to estimate fair value. These inputs include market pricing based on real-time trade data for the same or similar securities, issuer credit spreads, benchmark yields, and other observable inputs. The Level 2 inputs used to value the Company's warrant liabilities were determined using prices that can be directly observed or corroborated in active markets. Although the fair value of this obligation is calculated using the observable market price of the Company's common stock, an active market for this financial instrument does not exist.

The following tables present information about the Company's financial assets and liabilities that have been measured at fair value at December 31, 2020 and indicates the fair value hierarchy of the valuation inputs utilized to determine such fair value (in thousands):

| | | Fair Value Measurements Using | | |
|---|---|---|---|---|
| Description | Total | Quoted Prices in Active Markets (Level 1) | Significant Other Observable Inputs (Level 2) | Significant Unobservable Inputs (Level 3) |
| **Financial assets** | | | | |
| Cash equivalents: | | | | |
| Money market funds | $ 67,467 | $ 67,467 | $ — | $ — |
| Corporate debt securities | 3,041 | — | 3,041 | — |
| Short-term investments: | | | | |
| Corporate debt securities | 49,435 | — | 49,435 | — |
| Ownership of MeiraGTx | 10,564 | 10,564 | — | — |
| | $ 130,507 | $ 78,031 | $ 52,476 | $ — |
| | | | | |
| **Financial liabilities** | | | | |
| Warrant liabilities | $ 1,082 | $ — | $ 1,082 | $ — |

The following table presents information about the Company's financial assets and liabilities that have been measured at fair value at December 31, 2019 and indicates the fair value hierarchy of the valuation inputs utilized to determine such fair value (in thousands):

| | | Fair Value Measurements Using | | |
|---|---|---|---|---|
| | Amortized Cost | Gross Unrealized Gains | Gross Unrealized Losses | Fair Value |
| Description | Total | Quoted Prices in Active Markets (Level 1) | Significant Other Observable Inputs (Level 2) | Significant Unobservable Inputs (Level 3) |
| **Financial assets** | | | | |
| Cash equivalents: | | | | |
| Money market funds | $ 136,058 | $ 136,058 | $ — | $ — |
| Short-term investments: | | | | |
| Ownership of MeiraGTx | 41,997 | 41,997 | — | — |
| | $ 178,055 | $ 136,058 | $ — | $ — |
| | | | | |
| **Financial liabilities** | | | | |
| Warrant liabilities | $ 1,485 | $ — | $ 1,485 | $ — |

The Company has not recognized any material gross realized gains or losses on sales of available-for-sale marketable debt securities.

***Warrant Liabilities***

In connection with the 2015 Credit Agreement (Note 5), as fees to the lenders thereunder, the Company issued warrants to purchase an aggregate of $6.3 million of the Company's Class A units with an expiration date of August 2022, which were exchanged for 617,651 warrants with a strike price of $10.20 per share to purchase the same number of shares of the Company's common stock upon consummation of the Company's IPO in August 2016 (the "2015 Warrants").

As of December 31, 2020, the exercise price of a portion of the 2015 Warrants to purchase an aggregate of 529,413 shares of the Company's common stock was $3.30 per warrant share and the exercise price of the remaining 2015 Warrants to purchase an aggregate of 88,238 shares of the Company's common stock was $4.50 per warrant share. Since these warrants are exercisable and are redeemable at the option of the holder upon the occurrence of, and during the continuance of, an event of default under the warrant agreement, the fair value of the 2015 Warrants was recorded as a short-term liability of approximately $1.1 million at December 31, 2020 and approximately $1.5 million at December 31, 2019.

The Company used the Black-Scholes pricing model to value the liability related to the 2015 Warrants at December 31, 2020 and 2019 with the following assumptions:

| | December 31, 2020 | December 31, 2019 |
|---|---|---|
| Stock Price | $4.15 | $4.53 |
| Strike price | $3.30 - $4.50 | $3.30 - $4.50 |
| Expected Volatility | 72.92% | 72.20% |
| Risk-free interest rate | 0.12% | 1.62% |
| Expected term | 1.7 years | 2.7 years |
| Expected dividend yield | 0% | 0% |

The change in fair value of the 2015 Warrants was $(0.4) million and $1.0 million for the years ended December 31, 2020 and 2019, respectively. None of these instruments have been exercised at December 31, 2020 or December 31, 2019.

The table below represents a rollforward of the Level 2 financial instruments from January 1, 2018 to December 31, 2020 (in thousands):

| | Significant Other Observable Inputs (Level 2) |
|---|---|
| **Balance as of January 1, 2019** | **$ 524** |
| Change in fair value of warrant liabilities | 961 |
| **Balance as of December 31, 2019** | **$ 1,485** |
| Change in fair value of warrant liabilities | (403) |
| **Balance as of December 31, 2020** | **$ 1,082** |

***Other Warrants***

In connection with the incurrence of the Senior Convertible Term Loan in 2015, the Company issued three tranches of warrants as fees to the lenders that were redeemable for Class A units. Upon consummation of the Company's IPO in 2016, the warrants to purchase Class A units issued to lenders in the Senior Convertible Term Loan were exchanged for 351,992 warrants with a strike price of $10.20 per share to purchase the same number of shares of the Company's common stock. Since the strike price was determined at IPO, the aggregate fair value of these warrants was reclassified from liability to equity upon consummation of the Company's IPO in August 2016. None of these warrants have been exercised at December 31, 2020.

On April 16, 2013, the Company issued warrants with an estimated fair value of $1.4 million for the purchase of 30,000 Class A units at a strike price of $21.24 as consideration for fundraising efforts performed. Upon consummation of the Company's IPO in 2016, these warrants to purchase Class A units were exchanged for 46,163 warrants to purchase the same number of shares of the Company's common stock at a strike price of $138.06. None of these warrants have been exercised at December 31, 2020.

In connection with the 2017 Public Offering, the Company issued warrants to purchase 10,710,000 shares of common stock at an initial exercise price of $3.35 per share for a term of 5 years from the date of issuance. The Company assessed the warrants under FASB ASC 480 and ASC 815. The Company determined that the warrants were indexed to the Company's stock and met all of the criteria for classification as equity under ASC 815. Based on this analysis, the Company recorded the fair value of the warrants to equity at issuance date. As of December 31, 2020, warrants to purchase 9,253,667 shares of common stock were outstanding. During 2020, the Company received proceeds of less than $0.1 million related to exercises of these warrants.

***Warrants Outstanding***

The following table summarizes information about warrants outstanding at December 31, 2020 and 2019:

| | Warrants | Weighted Average Exercise Price |
|---|---|---|
| Balance, January 1, 2019 | 11,999,852 | $ 5.95 |
| Exercised | (78,400) | 3.35 |
| Balance, December 31, 2019 | 11,921,452 | $ 5.97 |
| Exercised | (1,339,333) | 3.35 |
| Balance, December 31, 2020 | 10,582,119 | $ 6.30 |

**7. Inventories**

Inventories are stated at the lower of cost or net realizable value (on a first-in, first-out basis) using standard costs. Standard costs include an allocation of overhead rates, which include those costs attributable to managing the supply chain and are evaluated regularly. Variances are expensed as incurred. The Company capitalizes inventory costs associated with the Company's products after regulatory approval, if ever, when, based on management's judgment, future commercialization is considered probable and the future economic benefit is expected to be realized; otherwise, such costs are expensed as research and development.

The Company regularly reviews the expiration date of its inventories and maintains a reserve for inventories that are probable to expire before shipment. Inventories recorded on the Company's consolidated balance sheets are net of a reserve for expirable inventory of $2.1 million and $3.0 million at December 31, 2020 and 2019, respectively. The Company expensed inventory that it believes will not be sold prior to reaching its product expiration date totaling $0.9 million and $0.9 million during the years ended December 31, 2020 and 2019, respectively. If the amount and timing of future sales differ from management's assumptions, adjustments to the estimated inventory reserves may be required.

Inventories are comprised of the following (in thousands):

| | December 31, | |
|---|---|---|
| | 2020 | 2019 |
| Raw materials | $ — | $ 371 |
| Finished goods, net | 102 | 269 |
| **Total inventories** | **$ 102** | **$ 640** |

During the year ended December 31, 2020, the Company recorded a loss to cost of goods sold for $0.3 million related to minimum batch commitments to purchase CLOVIQUE inventory in 2020. Additionally, in December 2020 the company terminated a supply agreement which included certain minimum batch purchase commitments related to CLOVIQUE through 2023. In connection with the termination, the Company recorded $0.4 million of contract termination cost expense to selling, general and administrative expense in December 2020.

**8. Leases**

The Company has adopted FASB ASU No. 2016 02, Leases ("ASC 842") effective January 1, 2019 using the modified retrospective transition approach allowed under ASU 2018-11, Leases (Topic 842: Targeted Improvements). The Company has also elected to apply (i) the practical expedient, which allows it to not separate lease and non-lease components, for new leases entered into after adoption and (ii) the short-term lease exemption for all leases with an original term of 12 months or less, for purposes of applying the recognition and measurements requirements in ASC 842. As of December 31, 2020, the short-term lease exemption applied to two operating leases for office space which are for a term of one year.

At the inception of an arrangement, the Company determines whether the arrangement is or contains a lease based on specific facts and circumstances, the existence of an identified asset(s), if any, and the Company's control over the use of the identified asset(s), if applicable. Operating lease liabilities and their corresponding ROU assets are recorded based on the present value of future lease payments over the expected lease term. The interest rate implicit in lease contracts is typically not readily determinable. As such, the Company will utilize the incremental borrowing rate, which is the rate incurred to borrow on a collateralized basis over a similar term an amount equal to the lease payments in a similar economic environment. As of the ASC 842 effective date, the Company's incremental borrowing rate ranged from approximately 4.0%-5.6% based on the remaining lease term of the applicable leases.

Operating leases are recognized on the balance sheet as ROU lease assets, lease liabilities current and lease liabilities non-current. Fixed rents are included in the calculation of the lease balances while variable costs paid for certain operating and pass-through costs are excluded. Lease expense is recognized over the expected term on a straight-line basis.

The Company is party to six operating leases for office or laboratory space and two finance leases for office IT equipment. The Company's finance leases are immaterial both individually and in the aggregate. In the consolidated balance sheets at December 31, 2020, the Company has a ROU lease asset balance of $16.1 million and a current and non-current lease liability of $4.2 million and $15.6 million, respectively. The balance of both the ROU lease asset and the lease liabilities primarily consists of future payments under the Company's office lease in New York, New York.

The Company is party to an operating lease in New York, New York for office and laboratory space for its headquarters. The lease commenced in October 2010, its initial term is set to expire in February 2021, and the Company opened a secured letter of credit with a third party financial institution in lieu of providing a security deposit of $2.0 million, which letter of credit is included in restricted cash at December 31, 2020. As of December 31, 2020, there were six amendments to this lease agreement, which altered office and laboratory capacity and extended the lease term through October 2025, with total lease cost of $4.8 million for the year ended December 31, 2020. This office lease contains the ability to extend portions of the lease at fair market value but does not have any renewal options.

The Company is party to an operating lease in Warrendale, Pennsylvania for the Company's specialty-focused commercial operation. In March 2019, the Company entered into an amendment to this lease, which extended the lease term to September 30, 2022 with two five year renewal options, which would extend the term to September 30, 2032, if exercised. Rental payments under the renewal period would be at market rates determined from the average rentals of similar tenants in the same industrial park. The option to renew this office lease was not considered when assessing the value of the ROU asset because the Company was not reasonably certain that it would assert its option to renew the lease. Total lease cost for this lease was $0.7 million for the year ended December 31, 2020.

In August 2015, the Company entered into an operating office lease agreement in Cambridge, Massachusetts for the Company's clinical office effective January 2016 and expiring in April 2023. The Company opened a secured letter of credit with a third party financial institution in lieu of providing a security deposit of $0.1 million, which letter of credit is included in restricted cash at 2019. The Company is also party to an operating lease for laboratory space in Monmouth Junction, New Jersey, which expires in February 2022. Neither of these office leases contain any renewal options. Total lease cost for these leases was $0.4 million for the year ended December 31, 2020.

Quantitative information regarding the Company's leases for the year ended December 31, 2020 and 2019 is as follows (in thousands):

| Lease Cost | Classification | Year Ended December 31, 2020 | Year Ended December 31, 2019 |
|---|---|---|---|
| Operating lease cost [(a)] | SG&A expenses | $ 4,592 | $ 4,632 |
| Variable lease cost | SG&A expenses | 1,487 | 1,346 |
| Sublease income [(b)] | Other revenue | (623) | (674) |
| **Net Lease Cost** | | $ 5,456 | $ 5,304 |
| | | | |
| **Other Information** | | | |
| Weighted average remaining lease term (years) | | 4.5 | 5.5 |
| Weighted average discount rate | | 4.1% | 4.1% |

(a) Includes short-term lease costs and finance leases costs, which are immaterial.
(b) Includes sublease income related to MeiraGTx (Note 10).

Future lease payments under noncancellable leases are as follows (in thousands) at December 31, 2020:

| Year ending December 31, | Operating Leases | Finance Leases |
|---|---|---|
| 2021 | $ 4,937 | $ 25 |
| 2022 | 4,868 | 19 |
| 2023 | 4,174 | 14 |
| 2024 | 4,158 | — |
| 2025 | 3,573 | — |
| Thereafter | — | — |
| **Total Lease Payments** | **$ 21,710** | **$ 58** |
| | | |
| Less: Imputed Interest | (1,956) | (10) |
| **Total Lease Liabilities** | **$ 19,754** | **$ 48** |

Note: As most of the Company's leases do not provide an implicit rate, the Company uses its incremental borrowing rate based on the information available at commencement date in determining the present value of lease payments.

**9. Fixed Assets**

Fixed assets are carried at cost less accumulated depreciation and amortization. Depreciation and amortization of fixed assets is calculated using the straight-line method over their estimated useful lives. Leasehold improvements are amortized over the shorter of their estimated useful lives or the lease term, using the straight-line method. Construction-in-progress and software under development are stated at cost and not depreciated. These items are transferred to fixed assets when the assets are placed into service.

When assets are retired or otherwise disposed of, the cost and accumulated depreciation are removed from the balance sheet and any resulting gain or loss is reflected in operations in the period realized. Expenditures for repairs and maintenance, which do not improve or extend the life of the assets, are expensed as incurred.

Fixed assets consisted of the following (in thousands):

| | Useful Lives (Years) | December 31, 2020 | December 31, 2019 |
|---|---|---|---|
| Leasehold improvements | 4-8 | $ 10,398 | $ 10,397 |
| Office equipment and furniture | 3-15 | 1,363 | 1,234 |
| Machinery and laboratory equipment | 3-15 | 3,835 | 3,599 |
| Software | 1-5 | 4,136 | 3,971 |
| Construction-in-progress | – | — | 45 |
| | | 19,732 | 19,246 |
| Less accumulated depreciation and amortization | | (18,445) | (16,802) |
| Fixed assets, net | | $ 1,287 | $ 2,444 |

Depreciation and amortization of fixed assets totaled $1.6 million and $1.8 million in the years ended December 31, 2020 and 2019, respectively.

**10. Ownership of MeiraGTx Ordinary Shares**

In April 2015, the Company executed several agreements which transferred its ownership of Kadmon Gene Therapy, LLC to MeiraGTx. As part of these agreements, the Company also transferred various property rights, employees and management tied to the intellectual property and contracts identified in the agreements to MeiraGTx. At a later date, MeiraGTx ratified its shareholder agreement and accepted the pending equity subscription agreements, which provided equity ownership to various parties. The execution of these agreements resulted in a 48% ownership in MeiraGTx by the Company. On June 12, 2018, MeiraGTx completed its initial public offering (the "MeiraGTx IPO") whereby it sold 5,000,000 ordinary shares at $15.00 per share. The shares began trading on the Nasdaq Global Select Market on June 7, 2018 under the symbol "MGTX."

In October 2019, the Company entered into a transaction pursuant to which it sold approximately 1.4 million ordinary shares of MeiraGTx for gross proceeds of $22.0 million, which was recorded as a realized gain on equity securities. The Company entered into transactions in May 2020 and July 2020 pursuant to which it sold an aggregate of approximately 1.4 million ordinary shares of MeiraGTx for gross proceeds of $19.8 million, which was recorded as a realized gain on equity securities. The realized gain represents the total gain on the sale of ordinary shares since the MeiraGTx IPO in June 2018. The Company has recorded a net unrealized (loss) gain on its MeiraGTx ordinary share investment of $(31.4) million and $7.9 million for the years ended December 31, 2020 and 2019, respectively. The unrealized gains on equity securities consists of two components: (i) the reversal of the gain or loss recognized in previous periods on equity securities sold and (ii) the change in unrealized gain or loss resulting from mark-to-market adjustments on equity securities still held. The table below represents a rollforward of the MeiraGTx investment from January 1, 2019 to December 31, 2020 (in thousands).

| | Significant Observable Inputs (Level 1) |
|---|---|
| **Balance as of January 1, 2019** | **$ 34,075** |
| Unrealized gain on ordinary shares sold during year | 8,148 |
| Realized gain on sale of ordinary shares | (22,000) |
| Unrealized gain on remaining ownership of ordinary shares | 21,774 |
| **Balance as of December 31, 2019** | **$ 41,997** |
| Unrealized loss on ordinary shares sold during the year | (8,244) |
| Realized gain on sale of ordinary shares | (19,784) |
| Unrealized loss on remaining ownership of ordinary shares | (3,405) |
| **Balance as of December 31, 2020** | **$ 10,564** |

As of December 31, 2020 and 2019, the Company maintained a 1.6% and 5.7% ownership in the ordinary shares of MeiraGTx with a fair value of $10.6 million and $42.0 million, respectively. During the third quarter of 2019 the affiliate restrictions on the resale of these securities were removed and, accordingly, the Company's investment in MeiraGTx has been recorded as a current investment in equity securities at both December 31, 2020 and 2019. The investment in MeiraGTx is valued using Level 1 inputs which includes quoted prices in active markets for identical assets in accordance with the fair value hierarchy (Note 2).

As part of the agreements executed with MeiraGTx in April 2015, the Company entered into a transition services agreement ("TSA") with MeiraGTx which expired in April 2018. Upon expiration of the TSA, the Company continued to provide office space to MeiraGTx. On October 1, 2018, the Company and MeiraGTx entered into a sublease agreement which is effective from October 1, 2018 for a period of two months and will automatically be renewed on a monthly basis unless MeiraGTx provides 30 days prior written notice. The monthly sublease amount is approximately $50 thousand. As part of the TSA and sublease agreement with MeiraGTx, the Company recognized $0.6 million and $0.6 million to license and other revenue during the years ended December 31, 2020 and 2019, respectively. The Company received cash payments of $0.6 million from MeiraGTx during both 2020 and 2019 and the Company has no amounts receivable from MeiraGTx at either December 31, 2020 or 2019.

**11. License Agreements**

***Nano Terra, Inc.***

On April 8, 2011, the Company entered into a series of transactions with Nano Terra, Inc. ("Nano Terra"), pursuant to which the Company (i) paid $2.3 million for Nano Terra's Series B Preferred Stock, (ii) entered into a joint venture with Surface Logix, Inc. ("Surface Logix") (Nano Terra's wholly-owned subsidiary) through the formation of NT Life Sciences, LLC ("NT Life"), whereby the Company contributed $0.9 million at the date of formation in exchange for a 50% interest in NT Life and (iii) entered into a sub-licensing arrangement with NT Life and Surface Logix. Pursuant to the sub-licensing arrangement, the Company was granted a worldwide, exclusive license under certain intellectual property owned by Surface Logix to three clinical-stage product candidates, including belumosudil, each of which were licensed by Surface Logix to NT Life. In December 2014, the Company received one share of Nano Terra's Common Stock for every 100 shares of Series B Preferred Stock held by the Company, resulting in approximately a 1% holding in Nano Terra as of December 31, 2020 and 2019. In accordance with ASC 325, "Investments—Other", the Company continues to account for the investment under the cost method (Note 2).

Nano Terra and NT Life are research and development companies, each of which independently maintains intellectual property for the purpose of pursuing medical discoveries. The Company is a minority shareholder of Nano Terra and thereby is unable to exercise significant influence with regard to the entity's daily operations. The Company is represented on the board of managers of NT Life and is a party to decisions which influence the direction of the organization.

Since inception, the Company has continuously assessed the applicability of ASC 810, based on the corporate structure, voting rights and contributions of the various parties in connection with these agreements, and determined that Nano Terra and NT Life are not variable interest entities ("VIE") and not subject to consolidation. On April 8, 2011 the Company recorded its $2.3 million investment in Nano Terra in accordance with ASC 325 and the Company has assessed the recoverability of the investment in Nano Terra as of December 31, 2020 and 2019 and identified no events or changes in circumstances that may have a significant adverse impact on the fair value of this investment. No impairment or changes resulting from observable price changes occurred during the year ended December 31, 2020. There was no activity of the joint venture during the years ended December 31, 2020 and 2019 which resulted in income or loss to the Company. The Company's maximum exposure associated with Nano Terra and NT Life is limited to cash contributions made.

Additionally, subject to certain exceptions, the Company must pay a percentage that ranges between a low twenty percent and a low forty percent of all sublicensing revenue the Company receives in the event the Company further assigns or sublicenses its rights under the sub-licensing arrangement to certain third parties. In addition, the Company must pay to the previous shareholders of Surface Logix from which Nano Terra acquired Surface Logix and NT Life royalties on net sales in the amount of 5% and 10%, respectively. As the Company owns 50% of NT Life, the cumulative results of these obligations is that the Company will owe an aggregate royalty a 9.75% on net sales of licensed products. No sublicensing revenue or sales were achieved as of December 31, 2020 and 2019.

***Dyax Corp. (acquired by Shire Plc in January 2016, acquired by Takeda Pharmaceuticals Co., Ltd. in 2018)***

On July 22, 2011 the Company entered into a license agreement with Dyax Corp. ("Dyax") for the rights to use the Dyax Antibody Libraries, Dyax Materials and Dyax Know-How (collectively "Dyax Property"). The agreement terminated on September 22, 2015, but the Company had a right to a commercial license of any research target within two years of expiration of the agreement. The Company exercised its right to a commercial license of two targets in September 2017, one of which is KD033. Under the terms of the agreement, the Company recorded $1.5 million in development milestone expense during each of the fourth quarter of 2019 and second quarter of 2020 related to development milestones reached by the Company.

***BioNova Pharmaceuticals Ltd.***

In November 2019, the Company entered into a strategic partnership with BioNova Pharmaceuticals Ltd. ("BioNova") to form a joint venture to exclusively develop and commercialize belumosudil (KD025), the Company's lead product candidate, for the treatment of graft-versus-host-disease ("GVHD") in the People's Republic of China. The joint venture was entered into through the creation of BK Pharmaceuticals Limited ("BK Pharma"), whereby the Company entered into a royalty-bearing exclusive license agreement with BK Pharma and BioNova in exchange for a 20% interest in BK Pharma. BK Pharma is domiciled in Hong Kong with shared oversight between the Company and BioNova.

Under the terms of the license agreement, the Company received an upfront payment of $4.0 million in December 2019 and is eligible to receive an additional $41.0 million in development, regulatory and commercial milestone payments upon the occurrence of specified events over the term of the agreement. In addition, the Company is eligible to receive double-digit percentage royalty payments on sales of belumosudil for GVHD in China.

The Company assessed the applicability of ASC 810 to the aforementioned agreements and based on the corporate structure, voting rights and contributions of the various parties in connection with these agreements, determined that BK Pharma was a VIE, however consolidation was not required as the Company was not the primary beneficiary based upon the voting and managerial structure of the entity. The purpose of the VIE is to develop and commercialize belumosudil in China and the operations of BK Pharma will be financed and guaranteed entirely by BioNova. The Company has not and is not required to provide financial support under the agreements and has no exposure to loss as a result of its involvement in the VIE. The Company's investment in BK Pharma was accounted for under the equity method as the Company has the ability to exercise significant influence over BK Pharma. The equity method investment was recorded at immaterial cost representing the Company's initial capital contribution for its ownership. This value was determined based upon the corporate structure which does not allocate profits or losses to the Company. An adjustment to this recorded investment will only occur upon a sales transaction or liquidation event, as defined in the agreement.

The Company evaluated the arrangement under ASC 808, *Collaborative Arrangements* ("ASC 808"), and determined that the license agreement and related joint venture with BioNova is not within the scope of ASC 808, and that the license agreement represents a contract with a customer under ASC 606. The Company has determined that the license agreement contains a single performance obligation that consists of the exclusive license to Kadmon's intellectual property and related initial technology transfer. All other promises included in the license agreement were deemed to be immaterial in the context of the contract including clinical supply, participation in a joint steering committee ("JSC"), and limited technical assistance as requested by BK Pharma and BioNova.

The Company determined that the $4.0 million non-refundable, upfront payment under the license agreement constituted the entire consideration to be included in the transaction price at the inception of the arrangement. As such, this amount was allocated to the single performance obligation. The potential development, regulatory and commercial milestone payments and sales-based royalties that the Company is eligible to receive represent variable consideration under the license agreement. The development and regulatory milestone amounts were excluded from the transaction price and were fully constrained based on their probability of achievement and the fact that Company cannot reasonably conclude that a significant reversal of revenue related to these milestones would not occur. Any future sales-based royalties, including commercial milestone payments based on the level of sales, will be included in the transaction price and recognized as revenue when the related sales occur and the milestones are achieved. The Company will reevaluate the transaction price at the end of each reporting period as uncertain events are resolved or other changes in circumstances occur, and, if necessary, adjust its estimate of the transaction price.

The single performance obligation represents a license of functional intellectual property and the associated revenue was recognized upon completion of the initial technology transfer in December 2019. The Company recognized $4.0 million in license revenue for the year ended December 31, 2019. No other milestone or royalty revenues have been earned as of December 31, 2020.

***Meiji Seika Pharma Co., Ltd***

In December 2019, the Company entered into a collaboration agreement with Meiji Seika Pharma Co., Ltd ("Meiji"), a Tokyo-based wholly owned subsidiary of Meiji Holdings Co., Ltd., to form a joint venture to exclusively develop and commercialize belumosudil in Japan and certain other Asian countries. The joint venture was entered into through the creation of Romeck Pharma, LLC ("Romeck"), whereby the Company entered into a royalty-bearing exclusive license agreement with Romeck and Meiji in exchange for a 50% interest in Romeck. Romeck is domiciled in Japan with shared oversight between the Company and Meiji.

Under the terms of the license agreement, the Company received an upfront payment of $6.0 million in January 2020 and is eligible to receive an additional $23.0 million in development, regulatory and commercial milestone payments upon the occurrence of specified events over the term of the agreement. In addition, the Company is eligible to receive double-digit percentage royalty payments on sales of belumosudil for GVHD in Japan.

The Company assessed the applicability of ASC 810 to the aforementioned agreements and based on the corporate structure, voting rights and contributions of the various parties in connection with these agreements, determined that Romeck was a VIE, however consolidation was not required as the Company was not the primary beneficiary based upon the voting and managerial structure of the entity. The purpose of the VIE is to develop and commercialize belumosudil in Japan and the operations of Romeck will be financed entirely by Meiji. The Company has not and is not required to provide financial support under the agreements and has no exposure to loss as a result of its involvement in the VIE. The Company's investment in Romeck was accounted for under the equity method as the Company has the ability to exercise significant influence over Romeck. The equity method investment was recorded at immaterial cost representing the Company's initial capital contribution for its ownership. This value was determined based upon the corporate structure which does not allocate profits or losses to the Company. An adjustment to this recorded investment will only occur upon a sales transaction or liquidation event, as defined in the agreement.

The Company evaluated the arrangement under ASC 808 and determined that the license agreement and related joint venture with Romeck is not within the scope of ASC 808, and that the license agreement represents a contract with a customer under ASC 606. The Company has determined that the license agreement contains a single performance obligation that consists of the exclusive license to Kadmon's intellectual property and related initial technology transfer. All other promises included in the license agreement were deemed to be immaterial in the context of the contract including clinical supply, participation in a JSC, and limited technical assistance as requested by Romeck and Meiji.

The Company determined that the $6.0 million non-refundable, upfront payment under the license agreement constituted the entire consideration to be included in the transaction price at the inception of the arrangement. As such, this amount was allocated to the single performance obligation. The potential development, regulatory and commercial milestone payments and sales-based royalties that the Company is eligible to receive represent variable consideration under the license agreement. The development and regulatory milestone amounts were excluded from the transaction price and were fully constrained based on their probability of achievement and the fact that Company cannot reasonably conclude that a significant reversal of revenue related to these milestones would not occur. Any future sales-based royalties, including commercial milestone payments based on the level of sales, will be included in the transaction price and recognized as revenue when the related sales occur and the milestones are achieved. The Company will reevaluate the transaction price at the end of each reporting period as uncertain events are resolved or other changes in circumstances occur, and, if necessary, adjust its estimate of the transaction price.

The single performance obligation represents a license of functional intellectual property and the associated revenue was recognized upon completion of the initial technology transfer in the first quarter of 2020. The Company had not received the upfront payment or completed the single combined performance obligation as of December 31, 2019. As such, the Company recognized $6.0 million in license revenue in the first quarter of 2020 upon completion of the single combined performance obligation. No other milestone or royalty revenues have been earned as of December 31, 2020.

**12. Share-based Compensation**

***Accounting for Share-based Compensation***

The Company recognizes share-based compensation expense in accordance with FASB ASC Topic 718, "Stock Compensation" ("ASC 718"), for all share-based awards made to employees, non-employees and board members based on estimated fair values. ASC 718 requires companies to measure the cost of employee services incurred in exchange for the award of equity instruments based on the estimated fair value of the share-based award on the grant date. The expense is recognized over the requisite service period. The Company recognizes share-based award forfeitures as they occur.

The Company uses a Black-Scholes option-pricing model to value the Company's option awards. Using this option-pricing model, the fair value of each employee and board member award is estimated on the grant date. The fair value is expensed on a straight-line basis over the vesting period. The option awards generally vest pro-rata annually. The expected volatility assumption is based on the volatility of the share price of comparable public companies. The expected life is determined using the "simplified method" permitted by Staff Accounting Bulletin Numbers 107 and 110 (the midpoint between the term of the agreement and the weighted average vesting term). The risk-free interest rate is based on the implied yield on a U.S. Treasury security at a constant maturity with a remaining term equal to the expected term of the option granted. The dividend yield is zero, as the Company has never declared a cash dividend.

As of December 31, 2020, the only equity compensation plans from which the Company may currently issue new awards are the Company's 2016 Equity Incentive Plan (as amended and restated to date, the "2016 Equity Plan") and 2016 Employee Stock Purchase Plan (as amended and restated to date, the "2016 ESPP"), each as more fully described below.

***2016 Equity Incentive Plan***

Pursuant to the 2016 Equity Plan, the Company's Board of Directors may grant incentive and nonqualified stock options, stock appreciation rights, restricted stock, restricted stock units, performance shares and units and other cash-based or stock-based awards.

A total of 21,785,738 shares of the Company's common stock were authorized and reserved for issuance under the 2016 Equity Plan at December 31, 2020 and there were 3,973,996 shares available for future grants. The 2016 Equity Plan provides for annual increases in the number of shares available for issuance under the 2016 Equity Plan on January 1 of each year by an amount equal to the smaller of (a) 4% of the number of shares of common stock issued and outstanding on the immediately preceding December 31, or (b) an amount determined by the board of directors. In accordance with the terms of the 2016 Equity Plan, effective as of January 1, 2020, the number of shares of common stock available for issuance under the 2016 Equity Plan increased by 5,591,600 shares, which was less than four percent (4%) of the outstanding shares of common stock on December 31, 2019. On January 1, 2021, the number of shares of common stock available for issuance under the 2016 Equity Plan increased by 6,861,201 shares, which was four percent (4%) of the outstanding shares of common stock on December 31, 2020.

Options issued under the 2016 Equity Plan generally vest over 3 years from the date of grant in equal annual tranches and are exercisable for up to 10 years from the date of issuance. Upon exercise of stock options granted under the 2016 Equity Plan, the Company issues new shares from the shares reserved for issuance. Shares subject to awards which expire or are cancelled or forfeited will again become available for issuance under the 2016 Equity Plan. The shares available will not be reduced by awards settled in cash or by shares withheld to satisfy tax withholding obligations. Only the net number of shares issued upon the exercise of stock appreciation rights or options exercised by means of a net exercise or by tender of previously owned shares will be deducted from the shares available under the 2016 Equity Plan.

The Company recorded share-based option compensation expense under the 2016 Equity Plan for all outstanding stock options, performance stock options and stock appreciation rights of $9.4 million and $7.2 million for the years ended December 31, 2020 and 2019, respectively. Total unrecognized compensation expense related to unvested stock options granted under the Company's share-based compensation plan was $11.9 million and $6.5 million at December 31, 2020 and 2019, respectively. That expense is expected to be recognized over a weighted average period of 1.9 years and 2.2 years as of December 31, 2020 and 2019, respectively.

The following table summarizes information about stock options outstanding, not including performance stock options, at December 31, 2020 and 2019:

| | Options Outstanding | | | |
|---|---|---|---|---|
| | Number of Options | Weighted Average Exercise Price | Weighted Average Remaining Contractual Term (years) | Aggregate Intrinsic Value (in thousands) |
| Balance, January 1, 2019 | 9,764,539 | $ 6.24 | 7.84 | $ — |
| Granted | 2,943,973 | 3.11 | | |
| Exercised | (92,334) | 2.87 | | 166 |
| Forfeited | (813,577) | 4.63 | | |
| Balance, December 31, 2019 | 11,802,601 | $ 5.59 | 7.52 | $ 9,520 |
| Granted | 5,027,540 | 4.35 | | |
| Exercised | (321,769) | 3.11 | | 438 |
| Forfeited | (507,687) | 4.51 | | |
| Balance, December 31, 2020 | 16,000,685 | $ 5.29 | 7.11 | $ 7,365 |
| Options vested and exercisable, December 31, 2020 | 9,749,998 | $ 6.04 | 5.97 | $ 5,951 |

The aggregate intrinsic value in the table above represents the total pre-tax intrinsic value calculated as the difference between the fair value of the Company's common stock at December 31, 2020 ($4.15 per share) and December 31, 2019 ($4.53 per share) and the exercise price, multiplied by the related in-the-money options that would have been received by the option holders had they exercised their options at the end of the fiscal year. This amount changes based on the fair value of the Company's common stock. There were 321,769 options exercised during the year ended December 31, 2020 with an aggregate intrinsic value of $0.4 million. There were 92,334 options exercised during the year ended December 31, 2019 with an aggregate intrinsic value of $0.2 million.

The weighted-average fair value of the stock option awards, not including performance stock options, granted to employees, officers, directors and advisors was $2.86 and $2.07 during the years ended December 31, 2020 and 2019, respectively, and was estimated at the date of grant using the Black-Scholes option-pricing model and the assumptions noted in the following table:

| | Years Ended | |
|---|---|---|
| | December 31, 2020 | December 31, 2019 |
| Weighted average fair value of grants | $2.86 | $2.07 |
| Expected volatility | 75.46% - 87.48% | 75.96% - 77.73% |
| Risk-free interest rate | 0.29% - 1.64% | 1.41% - 2.61% |
| Expected life | 2.0 - 6.0 years | 5.5 - 6.0 years |
| Expected dividend yield | 0% | 0% |

*Performance Options*

The Company granted 1,597,000 nonqualified performance-based stock options under the 2016 Equity Plan to three executive employees during the year ended December 31, 2018. No other performance-based stock options have been granted under the 2016 Equity Plan. Compensation expense for the Performance Options is recognized on a straight-line basis over the awards' requisite service period. The Performance Options vest upon the satisfaction of both a service condition and the satisfaction of one or more performance conditions. The Company initially determined which outcomes are probable of achievement. The requisite service period would be three years as that is the longest period of both the explicit service period and the implicit service periods. The first two performance conditions were satisfied during 2018 and the third performance condition was satisfied in 2019.

A total of 1,290,000 Performance Options with an exercise price of $4.06 were outstanding at both December 31, 2020 and 2019 with an intrinsic value of $0.3 million and $0.6 million, respectively. The weighted average remaining contractual life of outstanding Performance Options at December 31, 2020 was 5.7 years. At December 31, 2020, there was $0.1 million of total unrecognized compensation expense related to unvested Performance Options, which is expected to be recognized over a weighted-average period of 0.3 years. At December 31, 2020 and December 31, 2019, 962,502 and 853,335 Performance Options had vested, respectively, and no Performance Options had been exercised.

*Stock Appreciation Rights*

The Company granted 1,040,000 stock appreciation rights ("SARs") under the 2016 Equity Plan to three executive employees during the year ended December 31, 2017. No other SARs have been granted under the 2016 Equity Plan. A total of 835,000 SARs with an exercise price of $3.64 were outstanding at both December 31, 2020 and 2019 with an intrinsic value of $0.5 million and $0.7 million, respectively. The weighted average remaining contractual life of outstanding SARs at December 31, 2020 was 5.6 years. Compensation expense for SARs is recognized on a straight-line basis over the awards' requisite service period. At December 31, 2020, there was no unrecognized compensation cost related to SARs. At December 31, 2020 and December 31, 2019, 835,000 and 616,667 SARs had vested and no SARs had been exercised.

***2014 Long-term Incentive Plan ("LTIP")***

The LTIP was adopted in May 2014 and amended in December 2014. Under the LTIP, the Company's board of directors may grant up to 10% of the equity value of the Company in Equity Appreciation Rights Units ("EAR units") or Performance Awards. In 2015 and 2014, certain employees were granted a total of 9,750 EAR units with a base price of $6.00 per unit, expiring 10 years from the grant date. No other awards have been granted under the LTIP and no future awards are available to be granted under the LTIP.

The EAR units vested in 2016 and are payable upon the fair market value of the Company's common stock exceeding 333% of the $6.00 grant price ($20.00) per share prior to December 7, 2024. The EAR units are also payable upon a change in control where the acquisition price of the Company's common stock exceeds $6.00 per share. The payment amount with respect to the holder's EAR units will be determined using the fair market value of the common stock on the trading date immediately preceding the settlement date. Each payment under the Award will be made in a lump sum and is considered a separate payment. The holders of the LTIP have no right to demand a particular form of payment, and the Company reserves the right to make payment in the form of cash or common stock. Any settlement in the form of common stock will be limited to a maximum share allocation, which is 3,478,057 shares of the Company's common stock.

A total of 9,750 units were outstanding under the LTIP at December 31, 2020 and 2019. The compensation expense for this award was recognized upon consummation of the Company's IPO in 2016 and was recorded as additional paid in capital.

***2016 Employee Stock Purchase Plan***

In July 2016, the Company adopted the 2016 ESPP. The 2016 ESPP provides for annual increases in the number of shares available for sale under the 2016 ESPP on January 1 of each year by an amount equal to the smaller of (a) 750,000 shares, (b) one-and-a-half percent (1.5%) of the number of shares of common stock issued and outstanding on the immediately preceding December 31, or (c) an amount determined by the board of directors. On January 1, 2020 and January 1, 2021, the number of shares reserved for sale was not increased by the Company's board of directors. As of December 31, 2020, there was a total of 2,551,180 shares reserved for sale under the 2016 ESPP and there were 2,235,354 shares available for future sales.

The Company issued 164,614 shares and 88,619 shares of common stock under the 2016 ESPP during the years ended December 31, 2020 and 2019, respectively. No significant compensation expense was recognized for the ESPP during the years ended December 31, 2020 and 2019.

**13. Accrued Expenses**

Short-term accrued expenses at December 31, 2020 and 2019 include the following (in thousands):

| | December 31, 2020 | December 31, 2019 |
|---|---|---|
| Commission payable | $ — | $ 2,395 |
| Compensation, benefits and severance | 5,585 | 4,668 |
| Research and development | 4,183 | 4,962 |
| Other | 1,766 | 2,223 |
| Total Accrued Expenses | $ 11,534 | $ 14,248 |

*Commission payable*

Commission payable represents commissions to third parties for Class E redeemable convertible unit raises during 2014 and 2015. During the year ended December 31, 2020, the Company recorded $2.4 million as a non-cash gain on extinguishment of obligation due to the expiration of the Company's obligation related to this portion of the commission.

*Compensation, benefits and severance*

Compensation, benefits and severance represent earned and unpaid employee wages and bonuses, as well as contractual severance to be paid to former employees.

*Research and development*

The Company has contracts with third parties for the development of the Company's product candidates. The timing of the expenses varies depending upon the timing of initiation of clinical trials and enrollment of patients in clinical trials. Accrued research and development expenses represent incurred expenses for which the Company has not yet been invoiced.

*Other*

During the year ended December 31, 2020, the Company recorded $1.0 million as a non-cash gain on extinguishment of obligation due to the expiration of the Company's obligation relating to a terminated license agreement.

**14. Employee Benefit Plan**

In October 2011, the Company began sponsoring a qualified Tax Deferred Savings Plan (401(k)) for all eligible employees of the Company. Participation in the plan is voluntary. Participating employees may defer up to 75% of their compensation up to the maximum prescribed by the Internal Revenue Code. The Company has an obligation to match non-highly compensated employee contributions of up to 6% of deferrals and also has the option to make discretionary matching contributions and profit sharing contributions to the plan annually, as determined by the Company's board of directors.

The Company expensed employer matching contributions of $0.2 million and $0.3 million for the years ended December 31, 2020 and 2019, respectively. The Company made disbursements of $0.3 million and $0.2 million for the years ended December 31, 2020 and 2019, respectively. The Company typically disburses employer matching contributions during the first quarter following the plan year.

**15. Commitments and Contingencies**

***Lease Commitments***

The Company's commitments related to lease agreements are disclosed in Note 8.

***Contingent License Agreement Milestones***

The Company has entered into several license agreements for products currently under development (Note 11). The Company may be obligated in future periods to make additional payments, which would become due and payable only upon the achievement of certain research and development, regulatory, and approval milestones. The specific timing of such milestones cannot be predicted and depends upon future discretionary clinical developments as well as regulatory agency actions which cannot be predicted with certainty (including action which may never occur). These additional contingent milestone payments aggregate to $229.1 million at December 31, 2020. Any payments made prior to FDA approval will be expensed as research and development. Payments made after FDA approval will be capitalized.

Further, under the terms of certain licensing agreements, the Company may be obligated to pay commercial milestones contingent upon the realization of sales revenues and sublicense revenues. Due to the long-range nature of such commercial milestones, they are neither probable at this time nor predictable, and consequently are not included in the additional contingent milestone payment amount.

***Legal Contingencies***

The Company has been subject to various legal proceedings that arise from time to time in the ordinary course of its business. Although the Company believes that the various proceedings brought against it have been without merit, and that it has adequate product liability and other insurance to cover any claims, litigation is subject to many factors which are difficult to predict and there can be no assurance that the Company will not incur material costs in the resolution of legal matters. Should the Company determine that any future obligations exist, the Company will record an expense equal to the amount which is deemed probable and estimable. The Company has no significant contingencies related to legal proceedings at December 31, 2020.

**16. Income Taxes**

The Company accounts for income taxes in accordance with the asset and liability method of accounting for income taxes prescribed by FASB ASC Topic 740, "Accounting for Income Taxes" ("ASC 740"). Under the asset and liability method of ASC 740, deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax basis and operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to the taxable income in the years in which those temporary differences are expected to be recovered or settled. Under ASC 740, the effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment dates.

The Company follows FASB ASC Topic 740-10, "Accounting for Uncertainty in Income Taxes", which prescribes a recognition threshold and measurement attribute for financial statement recognition and measurement of a tax position taken, or expected to be taken, in a tax return. For those benefits to be recognized, a tax position must be more likely than not to be sustained upon examination by taxing authorities. At December 31, 2020 and 2019, the Company had no material uncertain tax positions to be accounted for in the financial statements. The Company recognizes interest and penalties, if any, related to unrecognized tax benefits in interest expense. The Company is obligated to file income tax returns in the U.S. federal jurisdiction and several U.S. states. Since the Company had losses in the past, all prior years that generated net operating loss carryforwards are open and subject to audit examination in relation to the net operating loss generated from those years.

The Company recorded an income tax (benefit) expense of approximately $(0.2) million and less than $0.1 million for the years ended December 31, 2020 and 2019, respectively, related to adjustments to the deferred tax liability. The deferred tax liability was initially recorded to account for the book vs. tax basis difference related to the goodwill intangible asset, also known as a "naked credit". The deferred tax liability was excluded from sources of future taxable income, as the timing of its reversal cannot be predicted due to the indefinite life of the goodwill. In accordance with the Tax Cuts and Jobs Act of 2017, losses generated beginning with the 2018 tax year may be carried forward indefinitely for U.S. federal tax purposes, however losses were initially limited to offset 80% of taxable income in future years. Thus, 80% of the U.S. federal deferred tax liability related to goodwill was able to be used to offset the valuation allowance as of December 31, 2019. In accordance with the Coronavirus Aid, Relief, and Economic Security Act of 2020, however, losses generated in 2018 through 2020 may now offset 100% of taxable income in future years. Since the Company's losses generated in 2018 through 2020 are greater than the book vs. tax basis difference related to goodwill, all of the U.S. federal deferred tax liability related to goodwill may be used to offset the valuation allowance as of December 31, 2020. This resulted in a reduction of the deferred tax liability of approximately $0.2 million during the year ended December 31, 2020. The Company files income tax returns in various states including New York, Massachusetts, and Pennsylvania, which provide for a 20-year loss carryforward before expiration. Thus, none of the U.S. state deferred tax liability related to goodwill may be used to offset the valuation allowance. As such, approximately $0.3 million of the deferred tax liability cannot be used to offset the valuation allowance for U.S. state income tax purposes.

Other than the $0.2 million deferred tax benefit mentioned above, no provision or benefit for federal or state income taxes has been recorded during the year ended December 31, 2020, as the Company has incurred a net loss for all of the periods presented, and the Company has provided a full valuation allowance against its deferred tax assets.

The income tax (benefit) expense differs from the (benefit) expense that would result from applying federal statutory rates to loss before income taxes as follows (in thousands):

| | For the Years Ended December 31, | | | |
|---|---|---|---|---|
| | 2020 | | 2019 | |
| | Amount | Rate | Amount | Rate |
| Expected federal statutory income tax | $ (22,862) | 21.0% | $ (12,897) | 21.0% |
| State income taxes, net of federal benefits | (9,733) | 8.9% | 1,700 | -2.8% |
| Adjustment to deferred tax assets related to ownership change | — | 0.0% | 26,287 | -42.8% |
| Adjustment to deferred tax assets | 1,013 | -0.9% | 469 | -0.8% |
| Change in valuation allowance | 31,400 | -28.8% | (15,513) | 25.3% |
| **Income tax (benefit) expense** | **$ (182)** | **0.2%** | **$ 46** | **-0.1%** |

Deferred income tax (benefit) expense results primarily from the timing of temporary differences between the tax and financial statement carrying amounts of goodwill. The net deferred tax asset and liability in the accompanying consolidated balance sheets consists of the following components (in thousands):

| | For the Years Ended December 31, | |
|---|---|---|
| | 2020 | 2019 |
| Deferred tax assets | | |
| Net operating loss carryforward | $ 106,848 | $ 96,924 |
| Foreign tax credit carryforward | 631 | 631 |
| Capitalized research and development | 104,876 | 92,265 |
| Share-based compensation | 24,908 | 22,846 |
| Depreciation | 1,198 | 1,039 |
| Intangibles | 22,073 | 24,647 |
| Right of use lease liability | 5,684 | 6,677 |
| Other | 788 | 250 |
| Total deferred tax assets | 267,006 | 245,279 |
| Deferred tax liabilities | | |
| Goodwill | (972) | (461) |
| Right of use lease asset | (4,636) | (5,531) |
| Unrealized gain on MeiraGTx equity securities investment | (1,677) | (7,604) |
| Change in fair value of warrant liabilities | — | (3,536) |
| Total deferred tax liabilities | (7,285) | (17,132) |
| Total deferred tax assets, net | 259,721 | 228,147 |
| Valuation allowance | (259,999) | (228,608) |
| Deferred tax liability | $ (278) | $ (461) |

At December 31, 2020, the Company has unused federal and state net operating loss ("NOL") carryforwards of $408.4 million and $349.6 million, respectively, that may be applied against future taxable income. Approximately $291.1 million of the federal NOL carryforwards expire at various dates through December 31, 2037, and approximately $117.3 million of federal net operating loss carryforwards will not expire. Approximately all of the $349.6 million state NOL carryforwards expire at various dates through December 31, 2040. The 20-year limitation was eliminated for federal losses generated after January 1, 2018, giving the taxpayer the ability to carry forward federal losses indefinitely. However, federal NOL carryforwards arising after January 1, 2021, are limited to 80 percent of taxable income.

The use of the Company's NOL carryforwards may, however, be subject to limitations as a result of an ownership change. A corporation undergoes an "ownership change," in general, if a greater than 50% change (by value) in its equity ownership by one or more five-percent stockholders (or certain groups of non-five-percent stockholders) over a three-year period occurs. After such an ownership change, the corporation's use of its pre-change NOL carryforwards and other pre-change tax attributes to offset its post-change income is subject to an annual limitation determined by the equity value of the corporation on the date the ownership change occurs multiplied by a rate determined monthly by the Internal Revenue Service. The Company experienced ownership changes under Section 382 of the Code in 2010, 2011 and 2016, but the Company did not reduce the gross deferred tax assets related to the NOL carryforwards because the limitations do not hinder the Company's ability to potentially utilize all of the NOL carryforwards. The Company also experienced an ownership change under Section 382 of the Code in 2019, as a result of equity offerings. This ownership change reduced the Company's ability to potentially utilize all of the NOL carryforwards and, consequently, resulted in a reduction to the Company's gross deferred tax assets and related valuation allowance of $125.2 million during November 2019.

If an additional ownership change occurred in the future and if the Company earned net taxable income, the Company's ability to use its pre-change NOLs to offset U.S. federal taxable income would be subject to these limitations, which could potentially result in increased future tax liability compared to the tax liability the Company would incur if its use of NOL carryforwards were not so limited. In addition, for state income, franchise and similar tax purposes, there may be periods during which the use of NOL carryforwards is suspended or otherwise limited, which could accelerate or permanently increase the Company's state income, franchise or similar taxes.

In accordance with ASC 740, "Income Taxes," the Company recorded a valuation allowance to fully offset the gross deferred tax asset, because it is more likely than not that the Company will not realize future benefits associated with these deferred tax assets at December 31, 2020 and 2019. The change in deferred tax liability has been recognized as an income tax expense and benefit in the consolidated statements of operations for the years ended December 31, 2020 and 2019, respectively.

**17. Subsequent Events**

**CLOVIQUE ANDA Sale**

The Company currently markets CLOVIQUE™ (Trientine Hydrochloride Capsules, USP), a room-temperature stable innovative product developed in-house at Kadmon and generic Trientine Hydrochloride Capsules USP, 250 mg (collectively, "CLOVIQUE"). Trientine hydrochloride is used for the treatment of Wilson's disease in patients who are intolerant of penicillamine. In February 2021, the Company entered into an agreement to divest the CLOVIQUE ANDA's and associated US-based patents and trademarks for $0.1 million, with the opportunity to earn up to $1.0 million more per year, for 3 years post-relaunch, in the form of backend sales-related payment. The Company does not expect this to have a significant impact on the consolidated financial statements as the revenues derived from CLOVIQUE in 2020 and 2019 were $1.6 million and $0.4 million, respectively, and Kadmon will have the right to reference, and to continue to market and sell, under the CLOVIQUE ANDAs until such time as it has exhausted its existing inventory.

**Convertible Senior Notes**

On February 16, 2021, the Company issued $240.0 million aggregate principal amount of 3.625% convertible senior notes due 2027 (the "Notes"), pursuant to an Indenture dated February 16, 2021 (the "Indenture"), between Kadmon and U.S. Bank National Association, as trustee (the "Trustee"), in a private offering to qualified institutional buyers pursuant to Rule 144A under the Securities Act of 1933, as amended. The Notes issued in the Note Offering include $40.0 million in aggregate principal amount of Notes sold to the initial purchasers (the "Initial Purchasers") resulting from the exercise in full of their option to purchase additional Notes. Kadmon received net proceeds from the Note Offering of approximately $232.8 million, after deducting the Initial Purchasers' discount. This transaction will be recorded in the first quarter of 2021 and the accounting for the transaction is not yet finalized.

The Notes are senior, unsecured obligations of Kadmon and will accrue interest payable semiannually in arrears on February 15 and August 15 of each year, beginning on August 15, 2021, at a rate of 3.625% per year. The Notes will mature on February 15, 2027, unless earlier converted or repurchased. Upon maturity, the Notes are convertible into cash, shares of Kadmon's common stock or a combination of cash and shares of Kadmon's common stock, at Kadmon's election.

The conversion rate will initially be 143.7815 shares of Kadmon's common stock per $1,000 principal amount of Notes (equivalent to an initial conversion price of approximately $6.96 per share of Kadmon's common stock, for a total of approximately 34,507,560 shares).

*Capped Call Transactions with Respect to the Notes*

On February 10, 2021, concurrently with the pricing of the Notes, the Company entered into privately negotiated capped call transactions (the "Capped Call Transactions") with certain financial institutions (the "Capped Call Counterparties"). The Company used approximately $33.0 million of the net proceeds from the Note Offering to pay for the cost of the Capped Call Transactions. The Capped Call Transactions are expected generally to reduce the potential dilution to Kadmon's common stock upon any conversion of Notes and/or offset any cash payments the Company is required to make in excess of the principal amount of converted Notes, as the case may be, with such reduction and/or offset subject to a cap initially equal to $10.70 (which represents a premium of 100% over the last reported sale price of Kadmon's common stock on February 10, 2021) and is subject to certain adjustments under the terms of the Capped Call Transactions. The Capped Calls cover 34,507,560 shares of our common stock (subject to anti-dilution and certain other adjustments), which is the same number of shares of common stock that initially underlie the Notes. The Capped Calls have an initial strike price of approximately $6.96 per share, which corresponds to the initial conversion price of the Notes. The Capped Call Transactions are separate transactions, entered into by us with the Capped Call Counterparties, and are not part of the terms of the Notes. The accounting for these Capped Call instruments is not finalized.

## EXHIBIT INDEX

| Exhibit Number | Description of Exhibit |
|---|---|
| 3.1 | Restated Certificate of Incorporation of Kadmon Holdings, Inc. (incorporated herein by reference to Exhibit 3.1 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-37841), filed with the SEC on August 5, 2019). |
| 3.2 | Certificate of Designations of Kadmon Holdings, Inc. creating the 5% Convertible Preferred Stock (incorporated herein by reference to Exhibit 3.3 to the Registrant's Current Report on Form 8-K (File No. 001-37841), filed with the SEC on August 1, 2016). |
| 3.3 | Bylaws of Kadmon Holdings, Inc. (incorporated herein by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K (File No. 001-37841), filed with the SEC on August 1, 2016). |
| 4.1 | Form of Kadmon Holdings, Inc.'s Common Stock Certificate (incorporated herein by reference to Exhibit 4.1 to the Registrant's Registration Statement on Form S-1/A (File No. 333-211949), filed with the SEC on July 14, 2016). |
| 4.2* | Description of the Company's Common Stock |
| 4.3 | Form of Warrant Agreement dated September 28, 2017 (incorporated herein by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K (File No. 001-37841), filed with the SEC on September 28, 2017). |
| 4.4 | Form of 2013 Warrant (incorporated by reference to Exhibit 10.46 to the Registrant's Registration Statement on Form S-1 (File No. 333-211949), filed with the SEC on June 10, 2016). |
| 4.5 | Form of 2013/2014 Warrant (incorporated by reference to Exhibit 10.47 to the Registrant's Registration Statement on Form S-1 (File No. 333-211949), filed with the SEC on June 10, 2016). |
| 4.6 | Form of 2015 Warrant (incorporated by reference to Exhibit 10.48 to the Registrant's Registration Statement on Form S-1 (File No. 333-211949), filed with the SEC on June 10, 2016). |
| 10.1 | Sub-license Agreement, dated April 8, 2011, by and among NT Life Sciences, LLC, Kadmon Pharmaceuticals, LLC and Surface Logix, Inc. (incorporated by reference to Exhibit 10.17 to the Registrant's Registration Statement on Form S-1 (File No. 333-211949), filed with the SEC on June 10, 2016). |
| 10.2*+ | Antibody License Agreement, dated July 22, 2011, between Dyax Corp. and Kadmon Pharmaceuticals, LLC. |
| 10.3* | 1st Amendment to the Antibody Library License Agreement dated July 22, 2015, between Dyax Corp. and Kadmon Pharmaceuticals, LLC. |
| 10.4 | Lease Agreement, dated October 28, 2010, by and between ARE-East River Science Park, LLC and Kadmon Pharmaceuticals, LLC (incorporated by reference to Exhibit 10.37 to the Registrant's Registration Statement on Form S-1 (File No. 333-211949), filed with the SEC on June 10, 2016). |
| 10.5 | First Amendment to Lease Agreement, dated July 1, 2011, by and between ARE-East River Science Park, LLC and Kadmon Pharmaceuticals, LLC (incorporated by reference to Exhibit 10.38 to the Registrant's Registration Statement on Form S-1 (File No. 333-211949), filed with the SEC on June 10, 2016). |
| 10.6 | Second Amendment to Lease Agreement, dated November 16, 2011, by and between ARE-East River Science Park, LLC and Kadmon Pharmaceuticals, LLC (incorporated by reference to Exhibit 10.39 to the Registrant's Registration Statement on Form S-1 (File No. 333-211949), filed with the SEC on June 10, 2016). |
| 10.7 | Third Amendment to Lease Agreement, dated January 4, 2013, by and between ARE-East River Science Park, LLC and Kadmon Pharmaceuticals, LLC (incorporated by reference to Exhibit 10.40 to the Registrant's Registration Statement on Form S-1 (File No. 333-211949), filed with the SEC on June 10, 2016). |
| 10.8 | Fourth Amendment to Lease Agreement, dated July 25, 2013, by and between ARE-East River Science Park, LLC and Kadmon Pharmaceuticals, LLC (incorporated by reference to Exhibit 10.41 to the Registrant's Registration Statement on Form S-1 (File No. 333-211949), filed with the SEC on June 10, 2016). |
| 10.9 | Fifth Amendment to Lease Agreement, dated August 11, 2017, by and between ARE-East River Science Park, LLC and Kadmon Corporation, LLC (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-37841), filed with the SEC on August 14, 2017). |
| 10.10 | Sixth Amendment to Lease Agreement, dated August 11, 2017, by and between ARE-East River Science Park, LLC and Kadmon Corporation, LLC (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K (File No. 001-37841), filed with the SEC on August 14, 2017). |
| 10.11 | Kadmon Holdings, LLC 2014 Long-Term Incentive Plan, as amended (incorporated by reference to Exhibit 10.43 to the Registrant's Registration Statement on Form S-1 (File No. 333-211949), filed with the SEC on June 10, 2016). |

| | |
|---|---|
| 10.12 | Form of Indemnification to be entered into by Kadmon Holdings, Inc. and each of its directors, executive officers and certain key employees (incorporated by reference to Exhibit 10.55 to the Registrant's Registration Statement on Form S-1/A (File No. 333-211949), filed with the SEC on July 14, 2016). |
| 10.13 | Amended and Restated Kadmon Holdings, Inc. 2016 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.57 to the Registrant's Annual Report on Form 10-K (File No. 001-37841), filed with the SEC on March 6, 2018). |
| 10.14 | Form of Stock Appreciation Right Agreement under Amended and Restated Kadmon Holdings, Inc. 2016 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.58 to the Registrant's Annual Report on Form 10-K (File No. 001-37841), filed with the SEC on March 6, 2018). |
| 10.15 | Amended and Restated Kadmon Holdings, Inc. 2016 Employee Stock Purchase Plan (incorporated herein by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-37841), filed with the SEC on May 8, 2018). |
| 10.16 | Form of Subscription Agreement dated June 11, 2018 (incorporated herein by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-37841), filed with the SEC on June 14, 2018). |
| 10.17 | Controlled Equity Offering Sales Agreement, dated August 4, 2017, between the Registrant and Cantor Fitzgerald & Co. (incorporated herein by reference to Exhibit 1.2 to the Registrant's Registration Statement on Form S-3 (File No. 333-219712), filed with the SEC on August 4, 2017). |
| 10.18 | Form of Performance Stock Option Agreement under Amended and Restated Kadmon Holdings, Inc. 2016 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.39 to the Registrant's Annual Report on Form 10-K (File No. 001-37841), filed with the SEC on March 7, 2019). |
| 10.19 | Employment Agreement between Kadmon Corporation, LLC and Steven Meehan, dated effective as of February 8, 2019 (incorporated herein by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-37841), filed with the SEC on May 9, 2019). |
| 10.20 | Employment Agreement between Kadmon Corporation, LLC and Gregory S. Moss, effective as of August 30, 2019 (incorporated herein by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-37841), filed with the SEC on November 7, 2019). |
| 10.21 | Employment Agreement between Kadmon Corporation, LLC and Harlan W. Waksal, M.D., dated effective as of January 1, 2020 (incorporated herein by reference to Exhibit 10.29 to the Registrant's Quarterly Report on Form 10-K (File No. 001-37841), filed with the SEC on March 5, 2020). |
| 10.22* | Amendment to Employment Agreement between Kadmon Corporation, LLC and Gregory S. Moss, effective January 1, 2021. |
| 10.23* | Amendment to Employment Agreement between Kadmon Corporation, LLC and Steven Meehan, effective January 1, 2021. |
| 10.24* | Amendment to Employment Agreement between Kadmon Corporation, LLC and Harlan W. Waksal, effective January 1, 2021. |
| 21.1* | List of subsidiaries. |
| 23.1* | Consent of independent registered public accounting firm. |
| 31.1* | Certification of Principal Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended, as adopted pursuant to Section 302 of The Sarbanes-Oxley Act of 2002. |
| 31.2* | Certification of Principal Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended, as adopted pursuant to Section 302 of The 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* | Inline XBRL Instance Document – The instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document. |
| 101.SCH* | Inline XBRL Taxonomy Extension Schema |
| 101.CAL* | Inline XBRL Taxonomy Extension Calculation Linkbase Document |
| 101.DEF* | Inline XBRL Taxonomy Extension Definition Linkbase Document |
| 101.LAB* | Inline XBRL Taxonomy Extension Labels Linkbase Document |

| | |
|---|---|
| 101.PRE | *Inline XBRL Taxonomy Extension Presentation Linkbase Document |
| 104 | *Cover Page Interactive Data (formatted as Inline XBRL and contained in Exhibit 101) |

*Filed herewith.

**Furnished herewith. In accordance with Item 601(b)(32)(ii) of Regulation S-K and SEC Release No. 34-47986, the certifications furnished in Exhibits 32.1 and 32.2 hereto are deemed to accompany this Form 10-K and will not be deemed "filed" for purposes of Section 18 of the Exchange Act. Such certifications will not be deemed to be incorporated by reference into any filing under the Securities Act or the Exchange Act.

+Portions of this document (indicated by "[***]" have been omitted because they are not material and would likely cause competitive harm to Kadmon Holdings, Inc. if disclosed.

## SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this Annual Report on Form 10-K to be signed on its behalf by the undersigned, thereunto duly authorized.

Kadmon Holdings, Inc.

Date: March 4, 2021

By: /s/ Harlan W. Waksal
Harlan W. Waksal
*President and Chief Executive Officer*
*(Principal Executive Officer)*

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

| Signature | Title | Date |
|---|---|---|
| /s/ Harlan W. Waksal<br>Harlan W. Waksal | President and Chief Executive Officer<br>(Principal Executive Officer) | March 4, 2021 |
| /s/ Steven Meehan<br>Steven Meehan | Executive Vice President, Chief Financial Officer<br>(Principal Financial Officer) | March 4, 2021 |
| /s/ Kyle Carver<br>Kyle Carver | Senior Vice President, Chief Accounting Officer, Controller<br>(Principal Accounting Officer) | March 4, 2021 |
| /s/ Tasos G. Konidaris<br>Tasos G. Konidaris | Director | March 4, 2021 |
| /s/ Eugene Bauer<br>Eugene Bauer | Director | March 4, 2021 |
| /s/ David E. Cohen<br>David E. Cohen | Director | March 4, 2021 |
| /s/ Arthur Kirsch<br>Arthur Kirsch | Director | March 4, 2021 |
| /s/ Nancy Miller-Rich<br>Nancy Miller-Rich | Director | March 4, 2021 |
| /s/ Cynthia Schwalm<br>Cynthia Schwalm | Director | March 4, 2021 |

# DESCRIPTION OF CAPITAL STOCK

*The following summary describes our capital stock and certain provisions of our restated certificate of incorporation, our bylaws, the registration rights agreements to which we and certain of our stockholders are parties and the General Corporation Law of the State of Delaware. Because the following is only a summary, it does not contain all of the information that may be important to you. For a complete description, you should refer to our restated certificate of incorporation, bylaws, and registration rights agreements, copies of which are filed with this Annual Report on Form 10-K.*

## General

We are a Delaware corporation. We completed transactions on July 26, 2016 pursuant to which we converted into a Delaware corporation and changed our name from Kadmon Holdings, LLC to Kadmon Holdings, Inc. Our authorized share capital consists of 400,000,000 shares of common stock, par value $0.001 per share, and 10,000,000 preferred shares, par value $0.001 per share.

The following descriptions are summaries of important terms contained in our restated certificate of incorporation and our bylaws (our "Certificate of Incorporation" and "Bylaws," respectively). Reference is made to the more detailed provisions of, and the descriptions are qualified in their entirety by reference to, our Certificate of Incorporation and Bylaws, copies of which are filed with the United States Securities and Exchange Commission ("SEC") as exhibits to this Annual Report on Form 10-K, and to relevant portions of the General Corporation Law of the State of Delaware ("DGCL").

## Common Stock

*General*. As of December 31, 2020, there were 171,530,045 shares of common stock issued and outstanding. All outstanding shares of common stock are validly issued, fully paid and nonassessable.

*Voting Rights*. The holders of our common stock are entitled to one vote for each share held of record on all matters submitted to a vote of the stockholders, including the election of directors, and do not have cumulative voting rights. Unless otherwise required by law, matters submitted to a vote of our stockholders require the approval of a majority of votes cast by stockholders represented in person or by proxy and entitled to vote on such matter, except that directors will be elected by a plurality of votes cast. Accordingly, the holders of a majority of the shares of common stock entitled to vote in any election of directors are able to elect all of the directors standing for election, if they so choose.

*Dividend Rights*. Holders of shares of common stock are entitled to receive ratably dividends if, as and when dividends are declared from time to time by our board of directors out of funds legally available for that purpose, subject to any preferential dividend rights of any then outstanding preferred stock.

*Liquidation*. Upon our liquidation, dissolution or winding up, the holders of shares of common stock are entitled to share ratably in the net assets legally available for distribution to stockholders after the payment of all of our debts and other liabilities, subject to any liquidation preference granted to holders of any outstanding preferred stock.

*Rights and Preferences.* Holders of shares of common stock have no preemptive or conversion rights or other subscription rights, and no redemption or sinking fund provisions are applicable to our common stock. The rights, preferences and privileges of the holders of our common stock are subject to and may be adversely affected by the rights of the holders of shares of any series of our preferred stock that we may designate in the future.

*Fully Paid and Nonassessable.* All outstanding shares of common stock are, and the shares of common stock to be issued in this offering will be, fully paid and nonassessable.

*Registration Rights.* In connection with a private placement of our securities in March 2017, we entered into a Registration Rights Agreement dated March 8, 2017 with certain investors. Pursuant to the terms of the registration rights agreement, we were obligated to prepare, file and maintain with the SEC a registration statement to register

for resale certain shares purchased by investors in the private placement following the closing of the private placement, among other customary obligations for agreements of this type.

*Listing.* Our common stock is listed under the symbol "KDMN" on the Nasdaq Global Select Market.

*Transfer Agent and Registrar.* The transfer agent and registrar for our common stock is American Stock Transfer & Trust Company, LLC.

**Preferred Stock**

As of December 31, 2020, no shares of our preferred stock were outstanding other than shares of our 5% convertible preferred stock, as described below under "—5% Convertible Preferred Stock." Our Certificate of Incorporation authorizes our board of directors, without further action by our stockholders, to issue up to 10,000,000 shares of preferred stock in one or more series and to fix the rights, preferences, privileges and restrictions thereof. These rights, preferences and privileges could include dividend rights, conversion rights, voting rights, redemption rights, terms of sinking funds, liquidation preferences, the number of shares constituting any class or series and the designation of the class or series. Terms selected by our board of directors in the future could decrease the amount of earnings and assets available for distribution to holders of shares of common stock or adversely affect the rights and powers, including voting rights, of the holders of shares of common stock without any further vote or action by the stockholders. As a result, the rights of holders of our common stock will be subject to, and may be adversely affected by, the rights of the holders of the 5% convertible preferred stock and any other preferred stock that may be issued by us in the future, which could have the effect of decreasing the market price of our common stock. The issuance of preferred stock could, among other things, have the effect of delaying, deferring or preventing a change in control of our company, which could depress the market price of our common stock.

The terms of any particular series of preferred stock will be described in the prospectus supplement relating to the offering of shares of such series of preferred stock. If we issue shares of preferred stock under this prospectus and any related prospectus supplement, the shares will be fully paid and nonassessable and will not have, or be subject to, any preemptive or similar rights.

***5% Convertible Preferred Stock***

As of December 31, 2020, we had 28,708 shares of convertible preferred stock issued and outstanding, designated as the 5% convertible preferred stock pursuant to the certificate of designations filed by us with the Secretary of State of the State of Delaware, with an aggregate original purchase price and initial liquidation preference of $30.0 million. As of December 31, 2020, the stated liquidation preference of the 5% convertible preferred stock was $34.8 million. Each share of convertible preferred stock was issued for an amount equal to $1,000 per share, which we refer to as the original purchase price.

The following description is a summary of the material provisions of the 5% convertible preferred stock and the certificate of designations and does not purport to be complete. This summary is subject to and is qualified by reference to all the provisions of the convertible preferred stock and certificate of designations, including the definitions of certain terms used in the certificate of designations. We urge you to read this document because it, and not this description, defines the rights of a holder of the 5% convertible preferred stock. A copy of the form of certificate of designations that we filed with the Secretary of State of the State of Delaware on July 26, 2016 has been incorporated by reference as an exhibit to this Annual Report on Form 10-K.

*No Mandatory Redemption Date or Sinking Fund*

The shares of 5% convertible preferred stock do not have a mandatory redemption date and are not subject to any sinking fund. The shares of convertible preferred stock will remain outstanding indefinitely unless we are required to redeem them under the circumstances described below in "—Redemption" or we otherwise repurchase them or they are converted into shares of our common stock as described below under "—Conversion Rights."

*Dividends*

The shares of 5% convertible preferred stock are entitled to receive dividends, when and as declared by our board of directors and to the extent of funds legally available for the payment of dividends, at an annual rate of 5% of the sum of the original purchase price per share of 5% convertible preferred stock plus any dividend arrearages. Dividends on the convertible preferred stock shall, at our option, either be paid in cash or added to the stated liquidation preference amount for purposes of calculating dividends at the 5% annual rate (until such time as we declare and pay the missed dividend in full and in cash, at which time that dividend will no longer be part of the stated liquidation preference amount). Dividends shall be payable annually on June 30 of each year and shall be cumulative from the most recent dividend payment date on which dividend has been paid or, if no dividend has ever been paid, from the original date of issuance of the 5% convertible preferred stock and shall accumulate from day to day whether or not declared until paid.

The shares of 5% convertible preferred stock are also entitled to participate in all dividends declared and paid on shares of company common stock on an "as if" converted basis.

Liquidation Preference

In the event of:

(A) a liquidation, dissolution or winding up of our company, whether voluntary or involuntary;

(B) certain changes of control;

(C) a sale or transfer of all, or substantially all, of our consolidated assets other than to a wholly-owned subsidiary of ours;

(D) any other event of discharge, retirement or cancellation of the 5% convertible preferred stock, in each case in this clause (D), that is not described in the foregoing clauses (A), (B) or (C) or a redemption pursuant to the certificate of designations;

(E) our company or one of our significant subsidiaries becoming the subject of certain bankruptcy events;

(F) a material breach of our obligations under the exchange agreement that is not cured within 15 days after we receive notice from a holder of the 5% convertible preferred stock; or

(G) upon our failure to make any payment of principal, interest, or other amount due and payable of any of our or our subsidiaries' indebtedness after giving effect to any applicable cure period,

the holders of the 5% convertible preferred stock shall be entitled to receive for each share of 5% convertible preferred stock an amount equal to the greater of (i) (A) (I) the original purchase price per share of 5% convertible preferred stock plus dividend arrearages thereon in cash *plus* (II) any dividends accrued and unpaid thereon from the last dividend payment date to the date of the final distribution to such holder *plus* (B) solely in connection with an event specified in clauses (A), (D), (E), (F) or (G) above, a premium equal to 20.2% of the amount described in clause (i)(A) of this sentence at such time or (ii) an amount per share of 5% convertible preferred stock equal to the amount which would have been payable or distributable had each share of 5% convertible preferred stock been converted into shares of our common stock immediately before the event occurred under clause (A), (B), (C) or (D) above.

Subject to the rights of the holders of any parity shares, upon any of the events specified in clauses (A) through (D) above, after payment shall have been made in full to the holders of the convertible preferred stock and any parity securities, any other series or class or classes of junior securities shall be entitled to receive any and all assets remaining to be paid or distributed, and the holders of the convertible preferred stock and any parity securities as such shall not be entitled to share in that payment or distribution.

In the event that the event giving rise to the determination of the amount that holders of 5% convertible preferred stock shall be entitled to receive as their liquidation preference is a failure by us to make any payment of principal, interest, or other amount due and payable of any of our or our subsidiaries' indebtedness after giving effect to any applicable cure period, that event shall be deemed never to have occurred if, subsequent to the expiration of the cure period, (i) that failure to make payment is cured in full, (ii) all other obligations to pay

principal, interest or other amounts due and payable of any of our or our subsidiaries' indebtedness have been paid at that time, and (iii) no bankruptcy event has occurred.

*Ranking*

The 5% convertible preferred stock ranks, with respect to rights to the payment of dividends and the distribution of assets in the event of any of the events specified in clauses (A) through (D) under "—Liquidation Preference" above,

(1) senior to all common stock and to all other equity securities of our company other than equity securities referred to in clauses (2) and (3) of this sentence ("junior securities");

(2) to the extent authorized under the certificate of designations, on a parity with all equity securities of our company the terms of which specifically provide that such equity securities rank on a parity with the 5% convertible preferred stock ("parity securities"); and

(3) to the extent authorized under the certificate of designations, junior to all equity securities of our company the terms of which specifically provide that such equity securities rank senior to the 5% convertible preferred stock ("senior securities").

See "Voting Rights—Matters Requiring Approval of Holders of 5% Convertible Preferred Stock" for a description of the types of issuances of equity securities and other securities of our company requiring approval of holders of a majority of shares of 5% convertible preferred stock then outstanding, voting together as a class.

*Redemption*

If:

(A) we or one of our significant subsidiaries becomes the subject of certain bankruptcy events;

(B) a material breach of our obligations under the exchange agreement occurs that is not cured within 15 days after we receive notice from a holder of the 5% convertible preferred stock; or

(C) we fail to make any payment of principal, interest, or other amount due and payable of any of our or our subsidiaries' indebtedness after giving effect to any applicable cure period,

each holder of 5% convertible preferred stock shall have the right to cause us to redeem all or part of the shares of 5% convertible preferred stock held by such holder for a redemption price per share equal to (i) the original purchase price *plus* any dividend arrearages *plus* any dividends accrued and unpaid thereon from the last dividend payment date to, but excluding, the redemption date *plus* (ii) a premium equal to 20.2% of the amount described in clause (i) of this sentence at such time.

We are required to mail notice of any redemption event to the holders of 5% convertible preferred stock not later than one business day after we acquire knowledge of that event. That notice must state, among other things, (1) the redemption price and the date of redemption, which shall be no sooner than 30 days and no later than 90 days from the date the notice is mailed and (2) any holder of 5% convertible preferred stock electing to have its shares redeemed shall be required to surrender its shares, with a properly completed redemption request, to us before the close of business on the fifth business day before the redemption date. If we fail to give notice of the redemption event within the time period specified above, then any holder of 5% convertible preferred stock may deliver that notice to us and the other holders, in which case the redemption date shall occur on the 45th day after the date of the notice and any holder electing to have any of its shares of 5% convertible preferred stock redeemed shall be required to surrender its shares, with a properly completed redemption request, to us before the close of business on the fifth business day preceding that redemption date.

Until the holders of the 5% convertible preferred stock who have delivered a notice to us requesting redemption have been paid the redemption price specified in the previous paragraph in full, no payment will be made to any holder of parity securities or junior securities.

Notwithstanding anything to the contrary, in the event that the event giving rise to the above redemption right is a failure by us to make any payment of principal, interest or other amount due and payable of any of our

indebtedness after giving effect to any applicable cure period, that event shall be deemed never to have occurred and any request for redemption delivered by a holder of 5% convertible preferred stock in respect of that event shall be deemed automatically rescinded if, subsequent to the expiration of the cure period, (i) our failure to make payment is cured in full, (ii) all other obligations to pay principal, interest or other amounts due and payable of any of our or our subsidiaries' indebtedness have been paid at such time and (iii) no bankruptcy event has occurred.

*Conversion Rights*

*Conversion at the Option of the Holder.* The holders of shares of 5% convertible preferred stock will, at any time, be entitled to convert some or all of their 5% convertible preferred stock into the number of shares of our common stock obtained by dividing the aggregate original purchase price of the shares to be converted *plus* any dividend arrearages *plus* any dividends accrued and unpaid from the last dividend payment date to but excluding the conversion date by an amount equal to 80% of the initial public offering price per share in our initial public offering, which amount we refer to as the conversion price. The conversion price will be adjustable upon the occurrence of certain events and transactions to prevent dilution as described under "—Adjustments to Conversion Price to Prevent Dilution." Any shares of our common stock issued upon conversion of the shares of 5% convertible preferred stock shall be validly issued, fully paid and nonassessable. Cash shall be paid in lieu of fractional shares.

*Conversion at our Option.* At any time following the first anniversary of the issuance of the 5% convertible preferred stock, provided that (A) the volume-weighted average price of our common stock for the 30 consecutive trading days immediately preceding the date we elect for conversion is in excess of 150% of the initial public offering price per share in this offering (as adjusted for the events described below under "—Adjustments to Conversion Price to Prevent Dilution" and dividends paid in shares of our common stock) and (B) we have in place an effective resale shelf registration statement permitting the resale of all of the shares of common stock issuable upon conversion of the 5% convertible preferred stock, we have the right to require the conversion of any number of shares of 5% convertible preferred stock then outstanding into the number of shares of our common stock obtained by dividing the aggregate original purchase price of the shares to be converted *plus* any dividend arrearages *plus* any dividends accrued and unpaid from the last dividend payment date to but excluding the conversion date by the then applicable conversion price.

*Adjustments to Conversion Price to Prevent Dilution*

The 5% convertible preferred stock is subject to provisions that protect the holders against dilution by adjustment of the conversion price and/or number of shares of common stock issuable upon conversion in certain events such as a subdivision, combination or reclassification of our outstanding common stock.

*Voting Rights—Matters Requiring Approval of Holders of 5% Convertible Preferred Stock*

Holders of the 5% convertible preferred stock shall be entitled to vote on any and all matters on which holders of the company common stock are entitled to vote on an "as if" converted basis. Additionally, so long as any 5% convertible preferred stock remains outstanding, without the affirmative approval of the holders of at least a majority of the shares of 5% convertible preferred stock then outstanding, we shall not, directly or indirectly (including through merger or consolidation with any other corporation), and shall not permit any of our subsidiaries to:

(1) authorize or approve the issuance of any senior securities, 5% convertible preferred stock, or parity securities (or, in each case, any security convertible into, or convertible or exchangeable therefor or linked thereto) or authorize or create or increase the authorized amount of any senior securities, 5% convertible preferred stock or parity securities (or, in each case, any security convertible into, or convertible or exchangeable therefor or linked thereto);

(2) authorize or approve the purchase or redemption of any parity securities or junior securities;

(3) amend, alter or repeal any of the provisions of the certificate of designations, our Certificate of Incorporation or our Bylaws in a manner that would adversely affect the powers, designations, preferences and rights of the 5% convertible preferred stock;

(4) contract, create, incur, assume or suffer to exist any indebtedness or guarantee any such indebtedness with an aggregate value of more than $5,000,000 (subject to certain exceptions); or

(5) agree to take any of the foregoing actions.

The certificate of designations governing the 5% convertible preferred stock also provides that no amendment or waiver of any provision of the certificate of designations or our Certificate of Incorporation or Bylaws shall, without the prior written consent of all holders of the 5% convertible preferred stock who are known to us to hold, together with their affiliates, more than 5% of the 5% convertible preferred stock then outstanding, (i) reduce any amounts payable or that may become payable to holders of the 5% convertible preferred stock, (ii) postpone the payment date of any amount payable to holders of the 5% convertible preferred stock or waive or excuse any payment, (iii) modify or waive the conversion rights of the 5% convertible preferred stock in a manner that would adversely affect any holder of the 5% convertible preferred stock, or (iv) change any of the voting-related provisions or any other provision of the certificate of designations specifying the number or percentage of holders of the 5% convertible preferred stock which are required to waive, amend or modify any rights under the certificate of designations or make any determination or grant any consent under that document.

*Registration Rights*

The holders of the 5% convertible preferred stock were granted registration rights, subject to customary cutbacks, blackout periods and other exceptions, for all shares of our common stock issued or issuable upon conversion of the 5% convertible preferred stock, including (a) two demand registrations at any time after the expiration of 180 days from the closing of our initial public offering, (b) unlimited piggyback rights and (c) the right to require filing of a resale S-3 registration statement (once we became eligible to file on such form) and maintenance of its effectiveness on an "evergreen" basis until such time as there are no longer any registrable securities.

**Anti-Takeover Effects of Provisions of Our Certificate of Incorporation and Bylaws and Delaware Law**

The provisions of the DGCL and our Certificate of Incorporation and Bylaws could have the effect of discouraging others from attempting an unsolicited offer to acquire our company. Such provisions may also have the effect of preventing changes in our management. It is possible that these provisions could make it more difficult to accomplish transactions that stockholders may otherwise deem to be in their best interests.

*Election and Removal of Directors.* Our directors are elected until the expiration of the term for which they are elected and until their respective successors are elected. Our directors may be removed only by the affirmative vote of at least a majority of the holders of our then outstanding common stock. This system of electing and removing directors generally makes it more difficult for stockholders to replace a majority of our directors. For more information on our board of directors, see the section entitled "Corporate Governance" in our Definitive Proxy Statement dated as of April 2, 2019.

*Authorized but Unissued Shares.* The authorized but unissued shares of our common stock and our preferred stock are available for future issuance without any further vote or action by our stockholders. These additional shares may be utilized for a variety of corporate purposes, including future public offerings to raise additional capital, corporate acquisitions and employee benefit plans. The existence of authorized but unissued shares of our common stock and our preferred stock could render more difficult or discourage an attempt to obtain control over us by means of a proxy contest, changes in our management, tender offer, merger or otherwise.

*Stockholder Action; Advance Notification of Stockholder Nominations and Proposals.* Our Certificate of Incorporation and Bylaws require that any action required or permitted to be taken by our stockholders must be effected at a duly called annual or special meeting of stockholders and may not be effected by a consent in writing. Our Certificate of Incorporation and Bylaws also require that special meetings of stockholders be called only by our board of directors, the Chairman of our board of directors or our Chief Executive Officer. In addition, our Bylaws provide that candidates for director may be nominated and other business brought before an annual meeting only by the board of directors or by a stockholder who gives written notice to us no later than 90 days prior to nor earlier than 120 days prior to the first anniversary of the last annual meeting of stockholders. These provisions may have the effect of deterring unsolicited offers to acquire our company or delaying changes in our management, which could depress the market price of our common stock.

*Delaware Anti-Takeover Law.* Our Certificate of Incorporation provides that Section 203 of the DGCL, an anti-takeover law, applies to us. In general, Section 203 prohibits a publicly held Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a period of three years following the date the person became an interested stockholder, unless the "business combination" or the transaction in which the person became

an interested stockholder is approved in a prescribed manner. Generally, a "business combination" includes a merger, asset or stock sale, or other transaction resulting in a financial benefit to the interested stockholder. Generally, an "interested stockholder" is a person who, together with affiliates and associates, owns or, within three years prior to the determination of interested stockholder status, did own, 15% or more of a corporation's voting stock.

**Limitation of Liability and Indemnification**

Our Certificate of Incorporation provides that no director will be personally liable for monetary damages for breach of any fiduciary duty as a director, except with respect to liability:

- for any breach of the director's duty of loyalty to us or our stockholders;
- for acts or omissions not in good faith or that involve intentional misconduct or a knowing violation of law;
- under Section 174 of the DGCL (governing distributions to stockholders); or
- for any transaction from which the director derived any improper personal benefit.

If the DGCL is amended to authorize corporate action further eliminating or limiting the personal liability of directors, then the liability of our directors will be eliminated or limited to the fullest extent permitted by the DGCL, as so amended. The modification or repeal of this provision of our Certificate of Incorporation will not adversely affect any right or protection of a director existing at the time of such modification or repeal.

Our Bylaws also provide that we will, to the fullest extent permitted by law, indemnify our directors and officers against all liabilities and expenses in any suit or proceeding or arising out of their status as an officer or director or their activities in these capacities. We also indemnify any person who, at our request, is or was serving as a director, officer, employee, agent or trustee of another corporation or of a partnership, limited liability company, joint venture, trust or other enterprise. We may, by action of our board of directors, provide indemnification to our employees and agents within the same scope and effect as the foregoing indemnification of directors and officers.

**Exclusive Forum**

Our Certificate of Incorporation provides that the Court of Chancery of the State of Delaware shall, to the fullest extent permitted by law, be the sole and exclusive forum for any (i) derivative action or proceeding brought on behalf of our company, (ii) action asserting a claim of breach of a fiduciary duty owed by any director or officer of our company to our company or our company's stockholders, (iii) action asserting a claim against our company arising pursuant to any provision of the DGCL or our Certificate of Incorporation or our Bylaws or (iv) action asserting a claim against our company governed by the internal affairs doctrine. This exclusive forum provision would not apply to suits brought to enforce any liability or duty created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction. Section 27 of the Exchange Act creates exclusive federal jurisdiction over all suits brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder. In addition, Section 22 of the Securities Act 1933, as amended (the "Securities Act"), creates concurrent jurisdiction for federal and state courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder. As a result, there is uncertainty as to whether a court would enforce our forum selection clause in connection with claims arising under the Securities Act or the rules and regulations thereunder.

Any person or entity purchasing or otherwise acquiring any interest in shares of capital stock of our company shall be deemed to have notice of and consented to the forum provisions in our Certificate of Incorporation. However, the enforceability of similar forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that a court could find these types of provisions to be unenforceable.

**EXHIBIT 10.2**

CERTAIN IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THE EXHIBIT BECAUSE IT BOTH (I) IS NOT MATERIAL AND (II) WOULD LIKELY CAUSE COMPETITIVE HARM TO THE COMPANY IF PUBLICLY DISCLOSED. SUCH EXCLUDED INFORMATION HAS BEEN MARKED WITH "[***]".

# ANTIBODY LIBRARY LICENSE AGREEMENT

This ANTIBODY LIBRARY LICENSE AGREEM ENT ("Agreement"), effective as of July 22, 2011 (the "Effective Date"), is between **DYAX CORP**., a Delaware corporation, with offices at 300 Technology Square, Cambridge, Massachusetts 02139, U.S.A. ("Dyax"), and **KADMON PHARMACEUTICALS LLC**, a Delaware limited liability company with its principal place of business at Alexandria Center for Life Sciences, 450 East 29th Street, 5th Floor, New York, New York 10016 ("Licensee").

WHEREAS, Dyax possesses intellectual property and know-how related to, among other things, the use of phage display to discover antibodies having novel binding properties;

WHEREAS, Licensee is engaged in the development and commercialization of products for human diseases and disorders; and

WHEREAS, Licensee desires to obtain, and Dyax agrees to provide, the Dyax Antibody Libraries (as defined herein) and a license to certain intellectual property owned or controlled by Dyax for use with the Dyax Antibody Libraries under the terms and conditions hereof.

NOW, THEREFORE, in consideration of the mutual covenants set forth in this Agreement, the Parties hereto agree as follows:

## 1. DEFINITIONS.

1.1. "Affiliate" means, with respect to either Party, a corporation or other legal entity that controls, is controlled by, or is under common control with such Party. For purposes of this definition, "control" means the ownership, directly or indirectly, of more than fifty percent (50%) of the outstanding equity securities of a corporation which are entitled to vote in the election of directors or a more than fifty percent (50%) interest in the net assets or profits of an entity which is not a corporation.

1.2. "Affimed Agreement" means that certain Patent Cross-License Agreement dated August 4, 2003 by and between Affimed Therapeutics AG ("Affimed") and Dyax.

1.3. "Affimed Patent Rights" means United States Patent Nos. 5,840,479 and 6,319,690 and all Patent Rights which claim priority or otherwise derive therefrom including, without limitation the patents and patent applications listed on **Appendix A** hereto and any other patent applications or patents licensed to Dyax under the Affimed Agreement.

1.4. "Affimed Sublicense" has the meaning set forth in **Section 3.2** hereof.

1.5. "Antibody" means a molecule comprising or containing one or more immunoglobulin variable domains or parts of such domains or any existing or future fragments, variants, modifications or derivatives thereof or a gene encoding such a molecule.

1.6. "Biosite Agreement" means that certain License Agreement dated March 28, 2002 by and between Biosite Incorporated ("Biosite") and Dyax.

1.7. "Biosite Patent Rights" means (a) all patents and patent applications described herein in the attached **Appendix B**, (b) all patents that have issued or in the future issue therefrom, including without limitation utility, model and design patents and certificates of invention, and (c) all divisionals, continuations, continuations-inpart, reexaminations, reissues, renewals, extensions or additions to any such patent applications and patents, as well as all foreign counterparts thereof and any other patent applications or patents licensed to Dyax under the Biosite Agreement.

1.8. "Biosite Sublicense" has the meaning set forth in **Section 3.3** hereof.

1.9. "CAT" means MedImmune Limited, formerly known as Cambridge Antibody Technology Limited.

1.10. "CAT Agreement" means that certain Amended and Restated License Agreement dated as of June 21, 2006 by and between CAT and Dyax.

1.11. [***]

1.12. "CAT Patent Rights" means the patents and patent applications listed in **Appendix D** hereto and any patents issuing from such patent applications, together with any divisionals, registrations, confirmations, reissues, extensions, renewals, continuations, continuations-in-part, revalidations, additions, substitutions, renewals or supplementary protection certificates thereof throughout the world and any other patent applications or patents licensed to Dyax under the CAT Agreement or the CAT Product License.

1.13. "CAT Product License" means a license from CAT which is required, under the terms of the CAT Agreement, to be granted (prior to the commencement of the first Phase I Clinical Trial of a Therapeutic Antibody Product) in order to commercialize Licensed Antibodies to any Target, as described in more detail in **Section 3.4**. The form of CAT Product License is attached hereto as **Appendix E**.

1.14. "CAT Sublicense" has the meaning set forth in **Section 3.4(c)** hereof.

1.15. "CAT Valid Claim" means a claim of an issued and unexpired patent included within the CAT Patent Rights which has been licensed to CAT by the Medical Research Council which has not been held permanently revoked, unenforceable or invalid by a decision of a court or other governmental agency of competent jurisdiction unappealed within the time allowed for appeal, and which has not been admitted to be invalid or unenforceable through reissue or disclaimer or otherwise.

1.16. "Commercial Field" means all human therapeutic uses, excluding Research Products.

1.17. "Commercial License" has the meaning set forth in **Section 3.1(b)(ii)** hereof.

1.18. "Commercially Reasonable and Diligent Efforts" shall mean the level of effort and resources normally used by a Party for a product or compound owned or controlled by it, which is of similar market potential and at a similar stage in its development or product life, taking into account, without limitation, with respect to a product issues of safety and efficacy, product profile, the proprietary position of the product, the then current competitive environment for the product and the likely timing of the product's entry into the market, the regulatory environment of the product, and other relevant scientific, technical and commercial factors.

1.19. "Confidential Information" has the meaning set forth in **Section 6.1** hereof.

1.20. "Display Library" means a collection of at least 1,000 genetically different organisms that each contains genetic information encoding a different fusion protein, wherein such collection was created for the purpose of displaying such fusion protein on the outer surface of such organisms.

1.21. "Domantis Agreement" means that certain Cross License Agreement dated April 6, 2006 by and between Domantis Limited ("Domantis") and Dyax.

1.22. "Domantis Patent Rights" means (a) all patents and patent applications described herein in the attached **Appendix F**, (b) all patents that have issued or in the future issue therefrom, including without limitation utility, model and design patents and certificates of invention and (c) all divisionals, continuations, continuations-inpart, reexaminations, reissues, renewals, extensions or additions to any such patent applications and patents, as well as all foreign counterparts thereof and any other patent applications or patents licensed to Dyax under the Domantis Agreement.

1.23. "Domantis Sublicense" has the meaning set forth in **Section 3.5** hereof.

1.24. "Dyax Antibody Libraries" means (i) Dyax's proprietary phagemid-based Fab libraries and phage-based Fab libraries of human antibody sequences described on **Appendix G** hereto and all materials, Updates provided pursuant to **Section 2.2**, and (ii) any second-generation phage or phagemid-based Fab based Display Library developed by Licensee in connection with the affinity maturation of a Licensed Antibody.

1.25. "Dyax Antibody Library Improvements" means any and all improvements to the Dyax Antibody Libraries and/or Dyax Materials discovered or made by Licensee by use of the Dyax Antibody Libraries and/or Dyax Materials, such as an increase in library diversity, efficiency of display, infectivity of the phage, and the like, and any library that is derived by Licensee from the Dyax Antibody Libraries.

1.26. "Dyax Know-How" means any know-how, data, technical or other information related to the Dyax Patent Rights Dyax Antibody Libraries and/or Dyax Materials in the possession of Dyax as of the Effective Date. The Dyax Know-How includes those items identified as Dyax Know-How in **Appendix G** hereto.

1.27. "Dyax Materials" means any materials, including but not limited to antibody coding expression vectors and antibody expressing transfected cell lines (but excluding Antibodies) provided by Dyax related to the practice of the Dyax Antibody Libraries, including those materials set forth in **Appendix G** hereto and including all materials, Updates and improvements provided by Dyax pursuant to **Section 2.2**.

1.28. "Dyax Patent Rights" means the patents and patent applications set forth in **Appendix H** and any other patent application or patent owned by Dyax as of the Effective Date or acquired (by assignment, license, or otherwise) during the Library License Term related to antibody phage display and any patents issuing from such applications, together with any reissues, reexaminations, renewals, and extensions thereof, and all continuations, continuations-in-part and divisionals of the patents and patent applications throughout the world.

1.29. "Dyax Technology" means Dyax Patent Rights and/or Dyax Know-How and/or Dyax Antibody Libraries and/or Dyax Materials and/or Dyax Antibody Library improvements and/or Updates.

1.30. "First Commercial Sale" means, with respect to any Product, the first commercial sale of any Product by Licensee, its Affiliates or Sublicensees in any country after grant of a Marketing Authorization in such country.

1.31. "Genentech Agreement" means that certain Patent Cross-License Agreement dated September 19, 2002 by and between Genentech Inc. ("Genentech") and Dyax.

1.32. "Genentech Patent Rights" means United States Patent Nos. 5,750,373, 5,780,279, 5,821,047, 5,846,765, 6,040,136 and any reissues, reexaminations, renewals, and extensions thereof, and all continuations, continuations-in-part and divisionals of the foregoing, and patents that issue on such applications; and all counterparts thereto in countries outside the United States, including without limitation, the patents and patent applications listed on **Appendix I** hereto and any other patent applications or patents licensed to Dyax under the Genentech Agreement.

1.33. "Genentech Sublicense" has the meaning set forth in **Section 3.6** hereof.

1.34. "IND" means an Investigational New Drug Application filed with FDA or a similar application to conduct clinical studies in humans filed with an applicable Regulatory Authority outside of the United States.

1.35. "Indication" means a new and distinct disease category (for example, cancer versus inflammation) and does not mean a different type or subpopulation within the same primary disease {for example, colon cancer versus breast cancer).

1.36. "Licensee" means Kadmon Pharmaceuticals LLC, as identified above.

1.37. "Library License" has the meaning set forth in **Section 3.1(a)** hereof.

1.38. "Library License Term" means the period during which Licensee may continue to use the Dyax Technology to identify, isolate and generate Licensed Antibodies, as set forth in **Section 9.1(a)** hereof.

1.39. "Licensed Antibody" means any Antibody identified, generated, developed, produced or obtained by Licensee from the Dyax Antibody Libraries and/or Dyax Materials. For the avoidance of doubt, the Parties acknowledge and agree that any Antibody identified from a source other than Dyax Antibody Libraries shall not become a Licensed Antibody solely as a result of Licensee's use of one or more Licensed Antibodies to validate the Target to which such Antibody binds.

1.40. "Licensed Antibody Information" means any data, know-how or other information relating, concerning or pertaining to a Licensed Antibody, including, without limitation, data, know-how or other information characterizing

or constituting such Licensed Antibody's polynucleotide or amino acid sequence, purported function or utility, antigen binding affinity, or physical or biochemical property.

1.41. "Major Market" means any one of the following: (i) the United States of America, (ii) any country in Europe which is subject to the Marketing Authorization procedure of the European Medicines Evaluation Agency, or (iii) Japan.

1.42. "Marketing Authorization" means any approval (including all applicable pricing and governmental reimbursement approvals) required from the relevant Regulatory Authority to market and sell a Product in a particular country.

1.43. "NDA" means New Drug Application as defined in 21 CFR 314 or other comparable regulation imposed by the U.S. Food and Drug Administration, or its foreign counterpart.

1.44. "Net Sales" means, with respect to any Product sold by Licensee, its Affiliates or Sublicensees, the price invoiced by that party to the relevant Third Party purchaser (or in the case of a sale or other disposal otherwise than at arm's length, the price which would have been invoiced in a bona fide arm's length contract or sale) but deducting the costs of packing, transport and insurance, customs duties, any credits actually given for returned or defective Products, normal trade discounts actually given, and sales taxes, VAT or other similar tax charged on and included in the invoice price to the purchaser. In the case of any sale of Product between or among Licensee, it's Affiliates and/or Sublicensees for later resale to a Third Party purchaser, Net Sales shall be calculated on the gross sales price invoiced to such Third Party purchaser.

In the event the Product is sold in the form of a Combination Product, Net Sales will be determined by multiplying actual Net Sales of such Combination Product by the fraction A/(A+B), where A is the invoice price of the Product, if sold separately, and B is the invoice price of any other active component or components in the combination, if sold separately, in each case in the same country and similar class, purity and dosage as in the Combination Product. If, on a country-by-country basis, the Product or the other active component or components in the Combination Product is / are not sold separately in such country, Net Sales shall be determined by multiplying actual Net Sales of such Combination Product by the fraction C/(C+D}, where C is the fair market value of the Product portion of such combination and D is the fair market value of the other a active component or components (such fair market values to be determined by mutual agreement of the parties or, in the absence of such mutual agreement, by a neutral Third Party mutually designated by the parties and whose decision shall be binding on the parties).

1.45. "Nominated Target" has the meaning set forth in **Section 3.4(a)(iv)** hereof.

1.46. "Party" means Dyax or Licensee, and "Parties" means Dyax and Licensee.

1.47. "Phase I Clinical Trial" means a human clinical trial in any country that is intended to initially evaluate the safety of an investigational Product in volunteer subjects or patients that would satisfy the requirements of 21 CFR 312.21(a}, or other comparable regulation imposed by the U.S. Food and Drug Administration, or its foreign counterpart.

1.48. "Phase III Clinical Trial" means a pivotal human clinical trial in any country the results of which could be used to establish safety and efficacy of a Product as a basis for a marketing application that would satisfy the requirements of 21 CFR 312.21(c) or other comparable regulation imposed by the U.S. Food and Drug Administration, or its foreign counterpart.

1.49. "Product" means any Therapeutic Antibody Product.

1.50. "Product Inventions" has the meaning set forth in **Section 5.2** hereof.

1.51. "Quarter" means each period of three (3) months ending on March 31, June 30, September 30, or December 31 and "Quarterly" shall be construed accordingly.

1.52. "Regulatory Authority" means the United States Food and Drug Administration, or any national or local agency, authority, department, inspectorate, minister, ministry official, parliament or public or statutory person (whether autonomous or not) of any government of any country having jurisdiction over any of the activities contemplated by this Agreement or the Parties, or any successor bodies thereto.

1.53. "Research and Development" means, solely for the purposes of the XOMA Covenant (as described in

**Section 3.7**), the identification, selection, isolation, purification, characterization, study and/or testing of an Antibody for any purpose, including, without limitation, the discovery and development of human therapeutics. Included within the definition of "Research and Development" shall be all in vitro screening or assays customarily performed in pre-clinical and clinical research and uses associated with obtaining FDA or equivalent agency regulatory approval.

1.54. "Research Field" means use in in vitro and in vivo studies (including IND-enabling studies) in connection with Licensee's internal discovery and development programs, and not for any other purpose. For the avoidance of doubt, the Research Field specifically excludes any studies in humans.

1.55. "Research License" has the meaning set forth in **Section 3.1(b)(i)** hereof.

1.56. "Research Products" means (i) any kit, vial or array (protein chip) containing one or more Antibodies intended for sale to an end user solely for research (and not diagnostic, prophylactic or therapeutic) purposes and (ii) any Antibodies sold to a Third Party for incorporation into any kit, vial or array (protein chip) that are intended for sale to an end user for research (and not diagnostic, prophylactic or therapeutic) purposes. Research Products shall exclude Therapeutic Antibody Products.

1.57. "Selected Target" has the meaning set forth in **Section 3.4(c)** hereof.

1.58. "Sublicensee" means any person or entity to whom Licensee: (i) grants a license or sublicense or (ii) otherwise authorizes or allows (with or without the grant of a license or sublicense); to develop, make, have made, use, have used, distribute, have distributed, offer for sale, sell or have sold any Product.

1.59. "Target" means:

(a) a polynucleotide sequence corresponding to a sequence identified in a publicly available curated database such as Genbank® by means of an accession number or similar sequence information that uniquely identifies that sequence; together with

(i) all variants of the identified sequence in man and other species known and demonstrated to CAT or Dyax (as the case may be) at the time of submission [***] to Dyax (as the case may be) to have functional equivalence to (a); and

(ii) all post-transcriptional material encoded by (a) and (i) (including splice variants); and

(iii) all post-translational material encoded by such post-transcriptional material; and

(iv) all multimeric forms of (iii) irrespective of whether homomeric or heteromeric; and

(v) where any of (iii) or (iv) is known to form a heteromeric complex with one or more non-identical subunits, that heteromeric complex must be identified in its entirety at the time of submission to [***] Dyax (as the case may be) using such accession numbers of a publicly available curated database entry as correspond to each of the component subunits.

(b) a non-proteinaceous antigen that is uniquely identifiable in a routine manner using publicly available curated databases and/or such other suitable written material as is available.

1.60. "Target Acceptance Notification" has the meaning set forth in **Section 3.4(b)(iii)** hereof.

1.61. "Therapeutic Antibody Product" means any preparation which is intended for use in the Commercial Field as a treatment or prevention of disease, infection or other condition in humans, which contains, comprises, or the process of development or manufacture of which utilizes one or more Licensed Antibodies.

1.62. "Third Party" means any entity other than (i) Dyax and its Affiliates, or (ii) Licensee and its Affiliates and Sublicensees.

1.63. "Third Party Phage Display Agreements" means (a) the Affimed Agreement, (b) the Biosite Agreement, (c) the CAT Agreement, (d) the Genentech Agreement, (e) the XOMA Agreement and (f) the Domantis Agreement.

1.64. "Updates" has the meaning set forth in **Section 2.2** hereof.

1.65. "Valid Claim" means (a) a claim of an issued and unexpired patent included in the Dyax Patent Rights, Affimed Patent Rights, Biosite Patent Rights, CAT Patent Rights, Genentech Patent Rights, XOMA Patent Rights or Domantis Patent Rights, as the case may be, which has not been held invalid in a final decision of a court or administrative authority of competent jurisdiction from which no appeal may be taken, and which has not been disclaimed or admitted to be invalid or unenforceable through reissue or otherwise, or (b) a claim of a pending patent application within the Biosite Patent Rights, Domantis Patent Rights or XOMA Patent Rights, as the case may be.

1.66. "XOMA Agreement" means that certain Amended and Restated License Agreement dated October 27,2006 by and between XOMA Ireland Limited ("XOMA") and Dyax, a redacted copy of which has been provided by Dyax to Licensee on or prior to the Effective Date.

1.67. "XOMA Covenant" has the meaning set forth in **Section 3.1(c)** hereof.

1.68. "XOMA Know-How" means unpatented or unpatentable technical information, including ideas, concepts, inventions, discoveries, data, designs, formulas, specifications, procedures for experiments and tests and other protocols, results of experimentation and testing, fermentation and purification techniques, and assay protocols, whether now existing or obtained in the future, owned by XOMA which XOMA has the right to license or sublicense and which may be necessary for the practice of the XOMA Patent Rights or which would be misappropriated by the activities of Licensee contemplated hereunder but for this Agreement. All XOMA Know-How shall be confidential information of XOMA.

1.69. "XOMA Patent Rights" means the patent applications and patents set forth in **Appendix J** attached hereto and incorporated herein, and, solely to the extent any Valid Claim would cover or be included in the license grants provided for herein, all divisionals, continuations, continuations-in-part, applications claiming priority thereto, and substitutions thereof; all foreign patent applications corresponding to the preceding applications; all U.S. and foreign patents issuing on any of the preceding applications, including extensions, reissues and re-examinations; and any other patent rights owned by XOMA which XOMA has the right to license or sublicense and which would be infringed by the activities contemplated hereunder but for this Agreement. XOMA Patent Rights shall also include (i) any improvements of the foregoing that are owned or controlled by XOMA and (ii) any patents or patent applications, whether now existing or obtained in the future, owned or controlled by XOMA containing a claim that is dominating over the foregoing patent rights (i.e., is necessarily infringed by the practicing of a claim in one of the foregoing applications).

## 2. TRANSFER OF DYAX TECHNOLOGY.

2.1. Transfer to Licensee. Within five (5) days after its receipt of the Technology Access Fee under **Section 4.1,** Dyax shall transfer to Licensee the Dyax Antibody Libraries (in quantities sufficient for at least 100 selections), Dyax Materials and Dyax Know-How, all for use by Licensee in accordance with the terms and conditions of this Agreement. During each twelve (12) month period of the Library License Term, Dyax agrees to provide Licensee with additional quantities of the Dyax Antibody Libraries sufficient for 100 selections at no additional cost or expense to Licensee. Furthermore, as needed and upon Licensee's request during the Library License Term (including any extensions exercised by Licensee under **Section 9.1(a)**), Dyax agrees to provide Licensee with additional quantities of the Dyax Antibody Libraries at a price no greater than Dyax's actual cost.

2.2. Updates. On the first anniversary of the Effective Date and each such anniversary thereafter during the Library License Term, Dyax shall provide Licensee with all material updates and improvements made by Dyax to the Dyax Antibody Libraries, Dyax Materials and all related Dyax Know-How ("Updates") at no additional cost to Licensee and such Updates shall thereafter be deemed to be included in the Dyax Technology licensed to Licensee under **Sections 3.1(a)** and **3.1(b)**.

2.3. [***]

## 3. GRANT OF RIGHTS.

3.1. Dyax Grants.

(a) Library License. Subject to the terms and conditions of this Agreement (including without

limitation, the restrictions set forth in **Sections 3.2, 3.3, 3.4, 3.5, 3.6** and **3.7** and the payment obligations set forth in **Article 4**), Dyax hereby grants to Licensee a world-wide, non-exclusive, royalty-free, non-transferable license, without the right to sublicense, under the Dyax Technology, Affimed Patent Rights, Biosite Patent Rights, CAT Patent Rights, Domantis Patent Rights and Genentech Patent Rights solely to make and use the Dyax Antibody Libraries and Dyax Materials to identify and isolate Licensed Antibodies during the Library License Term (the "Library License").

(b) Licensed Antibodies. With respect to each Licensed Antibody isolated by Licensee under the Library License granted to Licensee under **Section 3.1(a)** above, and subject to the terms and conditions of this Agreement (including without limitation, the restrictions set forth in **Sections 3.2, 3.3, 3.4, 3.5, 3.6** and **3.7** and the payment obligations set forth in **Article 4**), Dyax hereby grants to Licensee and its Affiliates:

(i) a world-wide, non-exclusive, royalty-free license, under the Dyax Technology, Affimed Patent Rights, Biosite Patent Rights, CAT Patent Rights, Domantis Patent Rights and Genentech Patent Rights to use, have used, develop, make, have made, and import Licensed Antibodies, solely in the Research Field (the "Research License"); and

(ii) an option to obtain a worldwide, non-exclusive license, under the Dyax Technology, Affimed Patent Rights, Biosite Patent Rights, CAT Patent Rights, Domantis Patent Rights and Genentech Patent Rights to develop, make, have made, use, have used, sell, offer for sale, have sold, import and export Therapeutic Antibody Products to the applicable Target in the Commercial Field (the "Commercial License") on the following terms:

(A) Licensee shall have no rights to obtain a Commercial License unless Licensee also obtains a sublicense to a CAT Product License with respect to the applicable Target as contemplated in **Section 3.4(b)(iv)** hereof;

(B) once Licensee has obtained a sublicense to a CAT Product License to the applicable Licensee Target (which must be obtained prior to the commencement of the first Phase I Clinical Trial of a Therapeutic Antibody Product or two (2) years following the expiration of the Library license Term), Dyax shall and hereby does grant to Licensee a Commercial License to the applicable Target (which Commercial License shall not be evidenced by a separate agreement but shall be automatically granted upon execution of a CAT Sublicense with respect to the applicable licensee Target);

(C) the Commercial License granted to Licensee under **Section 3.1(b)(ii)** shall be subject to the terms and conditions of this Agreement, including without limitation, the restrictions set forth in **Sections 3.2, 3.3, 3.4, 3.5, 3.6** and **3.7** and the payment obligations set forth in **Article 4**;

(D) subject to the restrictions imposed by the CAT and XOMA Agreements (as set forth in **Sections 3.4** and **3.7**), licensee may sublicense the rights granted to Licensee under the Commercial License to allow Third Parties to use Licensed Antibodies and Licensed Antibody Information to develop, make, have made, use, have used, sell, offer for sale, have sold, import and export Therapeutic Antibody Products to the applicable Target in the Commercial Field; provided that Licensee shall have no right to sublicense the Affimed Patent Rights, Biosite Patent Rights or Genentech Patent Rights (which restriction shall not be construed to prevent Licensee from making, having made, using, selling, offering for sale, and importing or exporting Therapeutic Antibody in the Commercial Field, which activities are agreed and understood by the Parties are not covered by Valid Claims of the Affimed Patent Rights, Biosite Patent Rights or Genentech Patent Rights).

(c) XOMA Covenant. Subject to the terms and conditions of this Agreement, including the provisions of **Section 3.7** below, Dyax represents to Licensee that, pursuant to a covenant

running from XOMA to Dyax contained in the XOMA Agreement (the "XOMA Covenant"), XOMA has agreed that it shall not initiate or permit any Third Party over whom it has control to initiate or assist in any way in the initiation or prosecution of any action asserting a claim of infringement under the XOMA Patent Rights or misappropriation of the XOMA Know-How to the extent reasonably necessary to allow parties such as Licensee to use the Dyax Antibody Libraries and Dyax Materials to conduct the Research and Development activities that are contemplated under the terms of this Agreement.

3.2. Restrictions on the Affimed Sublicense. As required by the Affimed Agreement, Licensee hereby acknowledges and agrees that any sublicense granted to Licensee under the Affimed Patent Rights pursuant to the provisions of **Sections 3.1(a)** and **3.1(b)** above (the "Affimed Sublicense") is subject to the following provisions:

(a) Nothing in this Agreement shall be deemed to grant Licensee rights under the Affimed Patent Rights broader than the field and scope of the license granted to Dyax under the Affimed Agreement; and nothing in this Agreement shall be deemed to grant Licensee the right to (i) make, sell, offer for sale or import any composition of matter other than Products which would, but for the licenses granted herein, infringe a Valid Claim of the Affimed Patent Rights, or (ii) use any phage or phagemid library other than a Dyax Library;

(b) The Affimed Sublicense shall be subject to the applicable terms and conditions of the Affimed Agreement;

(c) Licensee agrees that, promptly after execution of this Agreement, Dyax shall deliver to Affimed only those relevant portions of this Agreement evidencing the sublicense granted hereunder is in compliance with the terms and conditions set forth in the Affimed Agreement;

(d) In the event that the Affimed Agreement is terminated prior to its expiration for any reason, the Affimed Sublicense shall terminate; and

(e) If Licensee fails to comply with any terms and conditions set forth in this **Section 3.2**, the Affimed Sublicense shall automatically terminate.

3.3. Restrictions on the Biosite Sublicense. As required by the Biosite Agreement, Licensee hereby acknowledges and agrees that the sublicense granted to Licensee under the Biosite Patent Rights pursuant to Sections **3.1(a)** and **3.1(b)** above (the "Biosite Sublicense") is subject to the following provisions:

(a) Nothing in this Agreement shall be deemed to grant Licensee rights under the Biosite Patent Rights broader than the field and scope of the license granted to Dyax under the Biosite Agreement; and nothing in this Agreement shall be deemed to grant Licensee the right to (i) make, sell, offer for sale or import any composition of matter other than Products which would, but for the licenses granted herein, infringe a Valid Claim of the Biosite Patent Rights, (ii) use any phage or phagemid library other than a Dyax Antibody Library, or (iii) research, develop, make, have made, use, offer for sale, sell, have sold or import any in vitro diagnostic product for any disease, state, or condition in humans;

(b) The Biosite Sublicense shall be subject to the applicable terms and conditions of the Biosite Agreement;

(c) Licensee hereby covenants and agrees not to enforce (or attempt or purport to enforce) against Biosite or its Affiliates, and to cause its Affiliates not to enforce (or attempt or purport to enforce) against Biosite or its Affiliates, any patent that claims (or purports to claim) any process of, any composition for or any use of (i) creating, constructing or producing immune libraries from immunized rodents for the purpose of phage display therefrom of antibodies or binding fragments thereof, or (ii) phage display of antibodies or binding fragments thereof, or (iii) selecting or producing antibodies or binding fragments thereof derived from such libraries. The obligations under this **Section 3.3(c)** shall survive any termination of this Agreement or the Biosite Sublicense. Furthermore, Licensee agrees that the obligations under this **Section 3.3(c)** shall transfer with any sale, disposition or other grant of rights by Licensee or its Affiliates of the applicable patent right(s). In the event of any material breach of this **Section 3.3(c)** by

Licensee, or any action by an Affiliate of Licensee in contradiction to this **Section 3.3(c)**, the Biosite Sublicense shall immediately terminate;

(d) Licensee agrees that, promptly after execution of this Agreement, Dyax shall have the right to deliver to Biosite relevant portions of this Agreement evidencing the sublicense granted hereunder by Dyax and compliance with the terms and conditions set forth in the Biosite Agreement;

(e) If the Biosite Agreement is terminated prior to its expiration for any reason, the Biosite Sublicense shall terminate; and

(f) The Biosite Sublicense shall not be effective unless and until Dyax delivers to Biosite relevant portions of a signed copy of this Agreement evidencing the Biosite Sublicense and compliance with the terms and conditions set forth in the Biosite Agreement and Dyax hereby agrees and covenants to comply with this requirement promptly after execution of this Agreement. In addition, if Licensee fails to comply with any of the terms and conditions set forth in this **Section 3.3**, the Biosite Sublicense shall automatically terminate.

3.4. Restrictions on the CAT Patent Rights. As required by the CAT Agreement, the Parties acknowledge and agree that the license granted to Licensee under the CAT Patent Rights pursuant to **Sections 3.1(a)** and **3.1(b)** above is subject to the following provisions:

(a) CAT Product License.

(i) As required by the CAT Agreement, in the event that Licensee wishes to develop and commercialize any Product with respect to a Target, then Licensee must first obtain a sublicense under a CAT Product License with respect to such Target. Furthermore, each such sublicense must be obtained prior to the earlier of (i) the commencement of the first Phase I Clinical Trial in relation to any Therapeutic Antibody Product related to such CAT Product License, or (ii) two (2) years following the expiration of the Library License Term.

(ii) Dyax hereby warrants and represents that, under the CAT Agreement, CAT has granted Dyax a certain number of options to obtain CAT Product Licenses. Upon execution of this Agreement, Dyax will guarantee Licensee the right to obtain a CAT Sublicense under three (3) CAT Product licenses in accordance with the terms of this **Section 3.4**. In addition, after Licensee has executed a CAT Sublicense with respect to these three (3) guaranteed CAT Product Licenses, then, provided that Dyax determines that it has sufficient availability to allow for an additional guarantee, Dyax will immediately guarantee licensee the right to obtain a CAT Sublicense under one (1) additional CAT Product License and shall also notify Licensee of this guarantee (or its denial if Dyax determines that it does not have sufficient availability to allow for such guarantee). This process will continue during the Term of this Agreement, with Dyax guaranteeing Licensee the right to obtain a CAT Sublicense under one (1) additional CAT Product License, subject to availability, each time licensee has executed a CAT Sublicense with respect to the CAT Product License previously guaranteed to Licensee. For purposes of clarification and other than as set forth in **Section 3.4(a)(ii)**(B) below, the availability for each additional guaranteed CAT Product License (beyond the initial three) shall be determined by Dyax, in view of other ongoing collaborations and internal research projects, and will be made by Dyax in its sole discretion.

(iii) As required by the CAT Agreement, in the event that Licensee wishes to develop and commercialize any Product with respect to a Target, then prior to the commencement of the first Phase I Clinical Trial in relation to any Therapeutic Antibody Product, Licensee must first obtain a sublicense under a CAT Product License with respect to such Target.

(iv) In order to determine whether a CAT Product License can be obtained with respect to a Target, Licensee must first request that Dyax submit such Target (the "Nominated Target") [***].

(b) [***]

(i) [***]

(ii) [***]

(iii) [***]

(iv) [***]

(c) Reservation of Nominated Targets. Pursuant to the terms of the CAT Agreement, Dyax may place a limited number of Targets that have passed the CAT Gatekeeping Procedure on a reservation list. Licensee shall have the right to place up to three (3) Nominated Targets on this reservation list at any one time, whereby each such licensee Target will be reserved for a period of twelve (12) months from the date of that Dyax received the Target Acceptance Notice for such Nominated Target. Licensee may extend the reservation period by an additional six (6) months notification and payment of a non-refundable reservation fee of fifty thousand dollars ($50,000) at least five (5) business days before the expiration of the twelve (12) month reservation period, which amount will be fully creditable towards the CAT Product License fee due under **Section 4.3**. For the purposes of this **Section 3.4(c)** "reserved for" means that a CAT Product License will continue to be available to Dyax (and Licensee, as Dyax's sublicensee) during that reservation period; *provided that*, if, at any time during which a Nominated Target is reserved on Licensee's behalf in accordance with this **Section 3.4(c)**, Dyax receives notice from CAT that a Third Party has requested from CAT an exclusive license in respect of the relevant Nominated Target, pursuant to an agreement entered into between CAT and that Third Party prior to January 3, 2003, Dyax will then so notify Licensee. Licensee will then have twenty (20) days from the date of such notice to decide whether or not it wishes to take a CAT Product License for that Nominated Target. If Licensee notifies Dyax within that period that it does not wish to take such a CAT Product License or fails to notify Dyax at all then such Nominated Target shall no longer be reserved and CAT may grant an exclusive license in respect of such Nominated Target.

(d) Sublicense of CAT Product License. Upon receipt of a Target Acceptance Notification, or at any point during the reservation period described in **Section 3.4(c)**, Licensee may, by written notice and by payment of the Product License Fee referred to in **Section 4.3**, request that Dyax secure a CAT Product license for the Nominated Target. In such event, Dyax shall have ten (10) business days in which to obtain secure a CAT Product License with respect to such Nominated Target, and to deliver to licensee a fully executed redacted copy thereof. Within ten (10) business days following delivery of such redacted copy, Dyax and Licensee shall enter into a written sublicense agreement, the form of which is attached hereto as **Appendix K** (a "CAT Sublicense"), under which Dyax shall grant to Licensee a worldwide, non-exclusive sublicense (and thereby concurrently the Commercial license) to the rights granted to Dyax under the CAT Product License to develop, make, have made, use, sell, offer for sale, import and export Products against such licensee Target in the Commercial Field.

(e) Effect of Termination of CAT Agreement. Pursuant to the terms of the CAT Agreement, upon termination of the CAT Agreement, Dyax represents and warrants that (i) any CAT Product License granted to Dyax before the date of termination shall continue and the Parties will continue to be bound by the terms of the CAT Agreement in relation to any such CAT Product license, and (ii) any CAT Sublicense granted by Dyax to licensee under a CAT Product license pursuant to this Agreement will continue in force provided that Licensee is not in breach of the relevant any CAT Sublicense and licensee agrees to enter into a direct

agreement with CAT upon the terms of the CAT Product License Agreement. The Parties acknowledge that Licensee derives independent and significant value from the agreements set forth in the CAT Agreement and may rely thereon and to that extent only shall have the right to enforce the provisions of **Section 3.4(e)(ii)** above and be a third party beneficiary for that purpose only.

(f) Licensee Acknowledgement. As required by the CAT Agreement, Licensee hereby acknowledges and agrees that Dyax must request, and be granted a CAT Product License, in relation to a Therapeutic Antibody Product prior to Dyax or Licensee's commencement of the first Phase I Clinical Trial in relation to such Therapeutic Antibody Product.

(g) Third Party Beneficiary Right. As required by the CAT Agreement, Licensee agrees that CAT shall be a third party beneficiary of the CAT Sublicense and CAT shall have the right to enforce (including claim damages as a result of any breach) of such CAT Sublicense. If at any time CAT does have to enforce its rights under such CAT Sublicense Dyax will, if requested by CAT, supply to CAT a copy of the relevant CAT Sublicense as soon as possible.

3.5. Restrictions on the Domantis Sublicense. Licensee hereby acknowledges and agrees that the sublicense granted to Licensee under the Domantis Patent Rights pursuant to **Sections 3.1(a)** and **3.1(b)** above (the "Domantis Sublicense") is subject to the following provisions:

(a) Nothing in this Agreement shall be deemed to grant Licensee rights under the Domantis Patent Rights broader than the field and scope of the license granted to Dyax under the Domantis Agreement; and nothing in this Agreement shall be deemed to grant Licensee the right to (i) make, sell, offer for sale or import any composition of matter other than Products which would, but for the licenses granted herein, infringe a Valid Claim of the Domantis Patent Rights, or (ii) use any phage or phagemid library other than a Dyax Antibody Library; and

(b) Licensee agrees that, promptly after execution of this Agreement, Dyax shall have the right to notify Domantis of this Agreement in compliance with the terms and conditions set forth in the Domantis Agreement.

3.6. Restrictions on the Genentech Sublicense. As required by the Genentech Agreement, Licensee hereby acknowledges and agrees that the sublicense granted to Licensee under the Genentech Patent Rights pursuant to the provisions of **Sections 3.1(a)** and **3.1(b)** above (the "Genentech Sublicense") is subject to the following provisions:

(a) Nothing in this Agreement shall be deemed to grant Licensee rights under the Genentech Patent Rights broader than the field and scope of the license granted to Dyax under the Genentech Agreement and; and nothing in this Agreement shall be deemed to grant Licensee the right to (i) make, sell, offer for sale or import any composition of matter other than Products which would, but for the licenses granted herein, infringe a Valid Claim of the Genentech Patent Rights, or (ii) use any phage or phagemid library other than a Dyax Antibody Library; and such rights shall be subject to the applicable terms and conditions of the Genentech Agreement.

(b) The Genentech Sublicense shall be subject to the applicable terms and conditions of the Genentech Agreement;

(c) Licensee agrees that, promptly after execution of this Agreement, Dyax shall have the right

to deliver to Genentech relevant portions of this Agreement evidencing the sublicense granted hereunder is in compliance with the terms and conditions set forth in the Genentech Agreement;

(d) In the event that the Genentech Agreement is terminated prior to its expiration for any reason, the Genentech Sublicense shall terminate; and

(e) If Licensee fails to comply with any terms and conditions set forth in this **Section 3.6**, the Genentech Sublicense shall automatically terminate.

3.7. Restrictions Applicable to the XOMA Covenant. Licensee acknowledges and agrees that:

(a) Licensee has received from Dyax a copy of the XOMA Agreement;

(b) Licensee's rights under the XOMA Covenant are subject to all of the limitations, restrictions and other obligations contained in the XOMA Agreement that are applicable to Dyax Collaborators who have received licensed Antibody Phage Display Materials (as such terms are defined in the XOMA Agreement), including those provisions set forth in Section 2.5(a)(i)-(viii) thereof;

(c) the XOMA Covenant, as extended to Licensee, shall not apply to use of the XOMA Expression Technology (as such term is defined in the XOMA Agreement) and that Dyax has not provided to Licensee any know-how or materials relating to the XOMA Expression Technology;

(d) Dyax shall have the right to deliver to XOMA a written report which shall specify the name, address and contact person for Licensee as required by Section 2.6(a) of the XOMA Agreement.

3.8. Limitation of Rights. Licensee acknowledges that its rights with respect to the Dyax Technology, Affimed Patent Rights, Biosite Patent Rights, CAT Patent Rights, Genentech Patent Rights, and XOMA Patent Rights are limited to those expressly granted in this **Article 3**. licensee acknowledges and agrees that, except as expressly set forth in this Agreement, no other rights or licenses, express or implied, are granted to any patents, patent applications, inventions, trademarks, trade secrets or other intellectual property, or to any materials, information, data or know-how, of the other Party. Without in any way limiting the scope of the foregoing, Licensee also acknowledges and agrees that:

(a) no rights are granted to Licensee by Dyax outside of the Research Field and, upon exercise of its option to obtain a Commercial License, the Commercial Field;

(b) Licensee shall not transfer the Dyax Antibody Libraries, Dyax Materials, or Dyax Know How to any Third Party and shall not perform services using the Dyax Antibody Libraries, Dyax Materials or Dyax Know-How for any Third Party; provided that Licensee may transfer Dyax Materials and Licensed Antibodies to Third Parties to the extent required to perform research and development activities hereunder;

(c) Dyax has previously licensed and will continue to license use of the Dyax Antibody Libraries to Third Parties and as such it may be possible that Third Parties may generate the same Antibodies as Licensee and therefore have access and rights to same, and nothing contained in this Agreement shall be deemed to prohibit or restrict Dyax from continuing to supply Dyax

Antibody Libraries to Third Parties, or serve as the basis for any claim of liability against Dyax as a result of such activities; and

(d) Dyax has used and will continue to use the Dyax Antibody Libraries and Dyax Patent Rights in connection with Dyax's own internal research and development activities to discover Antibodies and as such it may be possible for Dyax to generate Antibodies or products that are the same or similar to Licensed Antibodies or Products developed by Licensee; and

(e) any Dyax Materials that are provided by Dyax to Licensee are to be used for research purposes only.

3.9. Diligence Requirement. Licensee agrees to use Commercially Reasonable and Diligent Efforts to research, develop and commercialize Licensed Antibodies into commercial products. Specifically, Licensee agrees that its rights to obtain a Commercial License with respect to each Licensed Antibody directed towards a Target or Bi Specific Target shall terminate unless Licensee has obtained a Commercial License with respect to such Target or Bi Specific Target within four (4) years following the expiration of the Library License Term. Furthermore, upon obtaining a Commercial License, Licensee agrees that it shall obtain approval of an IND (or non-US equivalent) within 5 years. Upon approval of the ND, Licensee agrees to use Commercially Reasonable and Diligent Efforts to develop and clinically test, market and sell such Product in the Commercial Field, which will be deemed satisfied if, during any given calendar year, Licensee: (i) has expended at least one million dollars ($1,000,000.00) in development of the Product; (ii) is manufacturing the Product for a clinical trial under an approved IND Application; (iii) is actively conducting a Phase I, II or III clinical trial with respect to the Product; (iv) filed a Biologics License Application ("BLA") for the Product; (v) pursuing a filed BLA for the Product; (vi) received approval of a BLA for the Product; or (vii) has launched or is selling the Product in a Major Market country. Until the first filing for Marketing Authorization for any Product, Licensee shall provide Dyax with annual written reports summarizing its development and commercialization efforts for all Products during the period since the previous such report; provided that such reports shall not be required to include any non-public technical or scientific information. Dyax agrees that the efforts of Licensee's Affiliates, Collaborators or Sublicensees may satisfy Licensee's obligations under this **Section 3.9**.

3.10. Additional Licensee Covenant. In partial consideration for the grant of rights hereunder, Licensee agrees that neither it nor any of its Affiliates, Sublicensees or collaborators (to the extent they claim rights or receive rights under this Agreement) shall seek a judgment of invalidity or unenforceability of, enter into any opposition to, and/or appeal from any decision with respect to validity or enforceability of the Dyax Patent Rights and shall not assist or otherwise cooperate with another party, unless compelled by a court of competent jurisdiction, in any such attempt to obtain judgment, opposition or appeal without first giving Dyax written notice forty-five (45) days prior to such action. Dyax and Licensee agree that this covenant is a material term of this Agreement, and breach of this covenant will constitute a material breach of this Agreement.

## 4. PAYMENTS AND REPORTS.

4.1. Technology Access Fee. Licensee shall pay to Dyax a technology access fee of [***] within five (5) business days of the Effective Date of this Agreement.

4.2. Annual license Maintenance Fee.

(a) Licensee shall pay to Dyax an annual fee on or before the first (1st) anniversary of the Effective Date and each anniversary of the Effective Date thereafter during the library License Term. The license fee for the term of the license shall be [***].

(b) Licensee acknowledges and agrees that the annual fees for the second and third years of the license shall be committed fees, and shall be due and payable even if the term of the Library License and/or this Agreement is otherwise terminated by the Licensee.

(c) The failure by Licensee to provide payment of the annual fee on or before the due date shall permit Dyax to terminate this Agreement pursuant to **Section 9.2(c)** hereof.

4.3. Product License Fee. Licensee shall pay to Dyax a product license fee of [***] (less any reservation fee previously paid by Licensee under **Section 3.4(c)**) prior to the execution of a CAT Product License with respect to any Selected Target. If for any reason a signed copy of such CAT Product License is not provided to Licensee within ten (10) business days after the receipt of such fee, Licensee may request its immediate return, and Dyax shall promptly do so.

4.4. Therapeutic Development Milestones. Within thirty (30) days of the occurrence of each of the following events by Licensee, its Affiliates or Sublicensees with respect to a Therapeutic Antibody Product against a particular Selected Target in the first Indication, Licensee shall make the following payments to Dyax:

[***]

For subsequent
Indications, Therapeutic Development Milestones in the above chart shall be reduced by fifty percent (50%).

4.5. Therapeutic Antibody Product Royalties. Licensee shall pay to Dyax royalties of [***] on Net Sales for Therapeutic Antibody Products commercialized by Licensee, its Affiliates or Sublicensees, calculated separately for each Therapeutic Antibody Product.

4.6. Duration of Royalty Payments. The royalties payable by Licensee to Dyax pursuant to **Sections 4.5** hereof shall be payable on a country-by-country and Product-by-Product basis for a period commencing with the First Commercial Sale in the relevant country [***].

4.7. No Offset. Licensee shall not be entitled to offset any royalties that may be due to any Third Party in connection with the development, manufacture, use or sale of any Product against any royalties due to Dyax under this Agreement. Licensee shall be responsible for any and all fees, royalties and other payments that may be due to any Third Party for any Product, provided that Dyax shall be responsible for the payment of all fees, royalties and other payments under the Third Party Phage Display Agreements (except where Licensee elects to enter into a direct Agreement with CAT pursuant to **Section 3.4(e)** in which event the amount of royalties payable to CAT by Licensee may be offset against those payable hereunder). All fees payable by Licensee under this **Article 4** shall are nonrefundable and, unless otherwise expressly provided, may not be credited against any other sums which may be payable by Licensee under this Agreement

4.8. Reports. Payments. Records and Audits.

(a) Licensee shall make the payments due to Dyax under this **Article 4** in United States Dollars. Where the payments due to Dyax under this **Article 4** are being converted from a currency other than United States Dollars, Licensee will use the conversion rate reported in *The Wall Street Journal* two (2) Business Days before the day on which Licensee pays Dyax. Such payment will be made without deduction of exchange, collection or other charges.

(b) All royalty payments will be made at Quarterly intervals. Within forty-five (45) days of the end of each Quarter after the First Commercial Sale of each Product in any country, Licensee

shall prepare a statement which shall show on a country-by-country basis for the previous Quarter Net Sales of each Product by Licensee or its Affiliates or Sublicensees and all monies due to Dyax based on such Net Sales. That statement shall include details of Net Sales broken down to show the country of the sales and the total Net Sales by Licensee or its Affiliates or Sublicensees in such country and shall be submitted to Dyax within such forty-five (45) day period together with remittance of the monies due.

(c) All payments shall be made free and clear of and without deduction or deferment in respect of any disputes or claims whatsoever and/or as far as is legally possible in respect of any taxes imposed by or under the authority of any government or public authority. Any tax (other than VAT) which Licensee is required to pay or withhold with respect of the payments to be made to Dyax hereunder shall be deducted from the amount otherwise due provided that, in regard to any such deduction, Licensee shall give Dyax such assistance, which shall include the provision of such documentation as may be required by any revenue authority and other revenue services, as may reasonably be necessary to enable Dyax to claim exemption therefrom or obtain a repayment thereof or a reduction thereof and shall upon request provide such additional documentation from time to time as is needed to confirm the payment of tax. If by law, regulation or fiscal policy of a particular country, a remittance of royalties in the currency stipulated in **Section 4.8(a)** above is restricted or forbidden, notice thereof will be promptly given to Dyax, and payment of the royalty shall be made by the deposit thereof in local currency to the credit of Dyax in a recognized banking institution designated by Dyax or its Affiliates. When in any country a law or regulation that prohibits both the transmittal and deposit of such payments ceases to be in effect, all royalties or other sums that Licensee would have been under obligation to transmit or deposit but for the prohibition, shall forthwith be deposited or transmitted promptly to the extent allowable.

(d) Licensee shall keep and shall procure that its Affiliates and Sublicensees keep true and accurate records and books of account containing all data necessary for the calculation of the amounts payable by it to Dyax pursuant to this Agreement. Those records and books of account shall be kept for seven (7) years following the end of the calendar year to which they relate. Upon Dyax's written request, a firm of accountants appointed by agreement between the Parties or, failing such agreement within ten (10) business days of the initiation of discussions between them on this point Dyax shall have the right to cause an international firm of independent certified public accountants that has not performed auditing or other services for either Party or their Affiliates and is acceptable to Licensee, such acceptance not to be unreasonably withheld, to inspect such records and books of account. In particular such firm:

(i) shall be given access to and shall be permitted to examine and copy such books and records of Licensee and its Affiliates and Sublicensees upon twenty (20) business days notice having been given by Dyax and at all reasonable times on business days for the purpose of certifying that the Net Sales or other relevant sums calculated by licensee and its Affiliates and Sublicensees during any calendar year were reasonably calculated, true and accurate or, if this is not their opinion, certify the Net Sales figure or other relevant sums for such period which in their judgment is true and correct;

(ii) prior to any such examination taking place, such firm of accountants shall undertake to Licensee that they shall keep all information and data contained in such books and records, strictly confidential and shall not disclose such information or copies of such books and records to any third person including Dyax, but shall only use the same for

the purpose of calculations which they need to perform in order to issue the certificate to which this Section envisages;

(iii) any such access examination and certification shall occur no more than once per calendar year and will not go back over records more than two (2) years old;

(iv) Licensee and its Affiliates and Sublicensees shall make available personnel to answer queries on all books and records required for the purpose of that certification; and

(v) the cost of the accountant shall be the responsibility of Licensee if the certification shows it to have underpaid monies to Dyax by more than five percent (5%) and the responsibility of Dyax otherwise.

(e) All payments due to Dyax under the terms of this Agreement are expressed to be exclusive of value added tax (VAT) howsoever arising. If Dyax is required to charge VAT on any such payment, Dyax will notify Licensee. Licensee will then use all commercially reasonable endeavors to obtain a VAT registration as soon as reasonably possible in order to allow it to reclaim any VAT so chargeable. If Licensee does obtain a VAT registration then VAT will be added to any relevant payment at the applicable rate. If having used all commercially reasonable endeavors Licensee is not able to reclaim the VAT (in whole or in part) the Parties agree that the amount of any VAT payable will be shared between them equally.

4.9. Payments Made by Wire Transfer. All payments made to Dyax under this Agreement shall be made by wire transfer to the following bank account of Dyax, or such other bank account as notified by Dyax to Licensee from time to time:

[***]

4.10. Late Payments. If Licensee fails to make any payment to Dyax hereunder on the due date for payment, without prejudice to any other right or remedy available to Dyax it shall be entitled to charge Licensee interest (both before and after judgment) of the amount unpaid at the annual rate of LIBOR (London Interbank Offering Rate) plus four percent (4%) calculated on a daily basis until payment in full is made without prejudice to Dyax's right to receive payment on the due date.

4.11. Licensee Acknowledgement. Licensee acknowledges and agrees that the amount of milestones and royalties due under this **Article 4** and the duration of the royalty payments (set forth in **Section 4.8**) have been chosen for the convenience of the Parties as payment for use of the Dyax Technology during the library License Term to identify, generate, develop, produce or obtain the Licensed Antibodies and licensed Antibody Information.

## 5. INTELLECTUAL PROPERTY.

5.1. [***]

5.2. Ownership by Licensee. As between the Parties, licensee shall own any Licensed Antibodies and Licensed Antibody Information, as well as any methods of manufacture and/or use of licensed Antibodies and Licensed Antibody Information (collectively, "Product Inventions"), and any intellectual property rights thereto. Dyax hereby grants and shall execute and deliver to Licensee, without charge, irrevocable assignments of all of its right, title and interest in and to such Product Inventions and any intellectual property rights thereto and shall take all other

actions as may reasonably be requested by licensee to vest in Licensee all right, title and interest in such Product Inventions and any intellectual property rights thereto. Licensee shall have the sole right to prepare, file, prosecute, maintain, defend, and enforce patent applications and patents arising therefrom claiming Product Inventions.

5.3. Further Assurances. The Parties agree to execute, acknowledge and deliver any documents, papers, instruments, applications and certificates, and make all payments, that may be necessary or appropriate in order to vest rights among the Parties as set forth in this **Article 5**. Each Party has and will have appropriate agreements with its employees and contractors necessary to fully effect the provisions of this **Article 5**. Each Party agrees to execute such assignments and other documents, to cause its employees and agents to execute such assignments and other documents, and to take such other actions, as may reasonably be requested by the other Party from time to time to give effect to the provisions of this **Article 5**.

## 6. CONFIDENTIALI TY AND PUBLICITY.

6.1. Definition of Confidential Information. Except as otherwise expressly provided in this Agreement, the term "Confidential Information" shall mean (i) any information, correspondence, drawings, manuals and other documents transmitted or communicated directly or indirectly on behalf of one Party (the "Disclosing Party") to the other Party (the "Receiving Party) that is marked [or orally described) as "confidential" or "proprietary," (ii) any other data or information of the Disclosing Party, in any form, that relates to the products or services provided by the Disclosing Party, or to the activities of the Disclosing Party, its licensees or Affiliates, that is held in confidence by the Disclosing Party or (iii) any conversations statements, discussion of issues, or draft documents relating to the scope or licensing of the Disclosing Party's intellectual property (collectively, "IP Discussions"). Confidential Information shall include, without limitation, patent and patent applications, ideas, techniques, sketches, drawings, works of authorship, models, inventions and know-how, processes, equipment, gene sequences, cell lines, samples, vectors, clones, media, chemical compounds, biological materials, algorithms, software programs, software source documents and client lists, and other information relating to the Disclosing Party's product research and development activities, marketing plans or other business activities (whether or not patentable).

6.2. Confidentiality. With respect to any confidential information received by one Party from the other Party ("Confidential Information"), the receiving Party undertakes and agrees to during the term of this Agreement and for an additional period of five (5) years thereafter:

(a) only use the Confidential information for the purposes envisioned under this Agreement and not to use the same for any other purpose whatsoever;

(b) ensure that only those of its Affiliates and sublicensees and their respective officers, directors, employees, consultants or other advisors who are directly concerned with the carrying out of this Agreement have access to the Confidential information on a strictly "need to know" basis and are informed of the secret and confidential nature of it;

(c) keep the Confidential information secret, confidential, safe and secure and shall not directly or indirectly disclose or permit to be disclosed the same to any Third Party other than those Affiliates, sublicensees and their respective officers, directors, employees, consultants or other advisors described in **Section 6.2(b)**, or, with respect to financial information, to sources of finance, without the prior written consent of the disclosing Party, except to the extent disclosure is in connection with its use as envisioned under this Agreement;

(d) ensure that the Confidential Information will not be covered by any lien or other encumbrance in any way; and

(e) not copy, reproduce or otherwise replicate for any purpose or in any manner whatsoever any documents containing the Confidential information except in connection with its use as envisioned under this Agreement.

6.3. Exclusions. Confidential Information shall not include any Confidential Information which:

(a) was in the public domain prior to this Agreement or becomes part of the public domain through no fault of the receiving Party, or

(b) is known or becomes known to the receiving Party (having been generated independently by the receiving Party or by a Third Party in circumstances where it has not been derived directly or indirectly from any improper use of Confidential Information of the disclosing Party), or

(c) is or was disclosed to the receiving Party at any time by a Third Party having no obligation of confidentiality with respect to such Confidential Information, or

(d) is information concerning Product which Licensee is reasonably required to disclose to consultants (such as advertising agencies, reimbursement experts and marketing research companies), customers, healthcare professionals, consumers or regulatory agencies, or which is disclosed by Licensee to Affiliates and Sublicensees in order to allow them to make, market or sell Products; or

(e) is disclosed by Licensee to a Third Party in exercising the rights and licenses granted under this Agreement, provided that such Third Party has confidentiality obligations similar to those of this Agreement.

6.4. Permitted Disclosure. If receiving Party, its Affiliates or Sublicensees are required by law, regulation or court order to disclose any Confidential Information, receiving Party shall: (a) promptly notify disclosing Party; (b) reasonably assist it in obtaining a protective order or other remedy of disclosing Party's election; and (c) only provide that portion of the Confidential Information that is legally required.

6.5. Publicity. No public announcement or other disclosures concerning the terms of this Agreement shall be made to a Third Party, whether directly or indirectly, by either Party (except confidential disclosures to those parties described in **Section 6.2(b)**) without first obtaining the approval of the other Party and agreement upon the nature and text of such announcement or disclosure except that: (i) a Party may disclose those terms which it is required by regulation or law to disclose, provided that it takes advantage of all provisions to keep confidential as many terms as possible; and (ii) a Party desiring to make such public announcement or other public disclosure shall obtain the consent of the other Party to the proposed announcement or public disclosure prior to public release. Each Party agrees that it shall cooperate fully with the other with respect to all disclosures regarding this Agreement as required under the regulations of the U.S. Securities and Exchange Commission, applicable stock exchanges, NASDAQ and any other comparable foreign body including requests for confidential information or proprietary information of either Party included in any such disclosure. Licensee agrees that Dyax may include Licensee on a list of Dyax licensees. Dyax agrees Licensee, its Affiliates and Sublicensees may state that they are licensed under the rights hereunder. In addition, a Party may disclose the terms and conditions of this Agreement to a Third Party in connection with an equity investment in such Party, a loan or other financing, a merger, consolidation, change in control or similar transaction

by such Party, the transfer or sale of the assets of such Party relating to this Agreement, or in connection with the granting of a sublicense under this Agreement. Licensee acknowledges and agrees that Dyax shall also be permitted to disclose this Agreement in confidence to Affimed, Biosite, CAT, Genentech and XOMA to the extent reasonably necessary to comply with Dyax's obligations pursuant to the Affimed Agreement, Biosite Agreement, CAT Agreement, Genentech Agreement and XOMA Agreement. The Parties agree to release a mutually agreeable press release within seven (7) days of executing this Agreement.

## 7. REPRESENTATIONS, WARRANTIES AND COVENANTS.

7.1. Authorization. Each Party represents and warrants to the other Party that it has the legal right and power to enter into this Agreement, to extend the rights and licenses granted to the other in this Agreement, and to fully perform its obligations hereunder, and that the performance of such obligations will not conflict with its charter documents or any agreements, contracts, or other arrangements to which it is a party.

7.2. Additional Dyax Representations. Warranties and Covenants. Dyax hereby represents, warrants, covenants and agrees that with respect to each Third Party Phage Display Agreement for the duration that the activities of Licensee may require a license thereunder (i) it shall not consent to any amendment or modification or termination of the Third Party Phage Display Agreements that would materially and adversely affect the licenses granted hereunder without the written permission of Licensee, such permission not to be unreasonably withheld (except in the case of CAT, to the extent that a license may be available directly under **Section 3.4(e)**; (ii) it shall not assign any of the Third Party Phage Display Agreements without the written consent of Licensee (which consent shall not be unreasonably withheld), except that such consent shall not be required for assignment in connection with the transfer or sale of all or substantially all of its antibody phage display business, or in the event of its merger, consolidation, change in control or similar transaction, provided that such assignment does not adversely affect the Third Party Phage Display Agreements or Licensee's rights thereunder; and (iii) it shall promptly advise Licensee of any notice of a breach or intent to terminate any Third Party Phage Display Agreement that is received, and to the extent permitted under the Third Party Phage Display Agreement, Licensee shall have the right but not the obligation to cure any such breach.

7.3. Disclaimer. Nothing in this Agreement is or shall be construed as (a) obligating Dyax to bring or prosecute actions or suits against Third Parties for infringement of any of the patent rights licensed or sublicensed by Dyax to Licensee hereunder, (b) obligating Dyax to maintain any patent or to continue to prosecute any patent application licensed or sublicensed by Dyax to Licensee hereunder, or (c) granting by implication, estoppel, or otherwise any licenses or rights under patents or other rights of Dyax or Third Parties, other than the licenses and rights expressly granted herein, regardless of whether such patents or other rights are dominant or subordinate to any patent rights licensed or sublicensed by one Party to the other Party hereunder.

7.4. No Other Warranties. Nothing in this Agreement shall be construed as a warranty or representation by Dyax that the use of the Dyax Antibody Libraries or Dyax Materials and the practice of the patent rights and know-how licensed or sublicensed to Licensee hereunder will result in any Licensed Antibodies or Products, or as a warranty or representation by Dyax that the exploitation of any of the foregoing will be free from infringement of patents of Third Parties. NEITHER PARTY HERETO MAKES ANY REPRESENTATIONS OR WARRANTIES INCLUDING WITH RESPECT TO ANY OF THE PATENT RIGHTS, MATERIALS (INCLUDING WITHOUT LIMITATION THE DYAX ANTIBODY LIBRARIES, DYAX ANTIBODY LIBRARY IMPROVEMENTS AND DYAX MATERIALS) OR KNOW-HOW LICENSED HEREUNDER, EXPRESS OR IMPLIED, EITHER IN FACT OR BY OPERATION OF LAW, BY STATUTE OR OTHERWISE, OR THAT ANY PRODUCT OR SERVICE MADE, USED, SOLD, OR OTHERWISE DISPOSED OF UNDER ANY LICENSE OR SUBLICENSE GRANTED IN THIS AGREEMENT IS OR WILL BE FREE FROM INFRINGEMENT OF ANY PATENT RIGHTS OR OTHER INTELLECTUAL PROPERTY RIGHT OF ANY THIRD PARTY. EXCEPT AS PROVIDED HEREIN, EACH

PARTY SPECFICALLY DISCLAIMS ANY EXPRESS OR IMPLIED REPRESENTATIONS AND WARRANTIES INCLUDING OF MERCHANT ABILITY, OF FITNESS FOR A PARTICULAR PURPOSE, OF VALIDITY OR SCOPE OF SUCH PATENT RIGHTS, MATERIALS OR KNOW-HOW, ARISING FROM COURSE OF DEALING OR OF NON-INFRINGEMENT OF THE INTELLECTUAL PROPERTY RIGHTS OF ANY THIRD PARTY

7.5. Limitation of Liability. Except for indemnification as provided in **Article 8**, neither Party shall be liable to the other for consequential, incidental (including lost or anticipated revenues or profits), indirect or punitive damages arising from the performance or nonperformance of such Party under this Agreement whether such claim is based on contract, tort (including negligence) or otherwise, even if an authorized representative of such Party is advised of the possibility or likelihood of same.

## 8. INDEMNIFICATION.

8.1. Indemnification by Licensee. Licensee shall indemnify, defend, and hold harmless Dyax and its Affiliates, directors, officers, employees, representatives and agents and their respective successors, heirs and assigns (the "Dyax Indemnitees") against any liability, damage, loss, or expense (including reasonable attorneys fees and expenses of litigation) incurred by or imposed upon the Dyax Indemnitees or any one of them in connection with any claims, suits, actions, demands, or judgments in each case initiated by a Third Party which arise out of: (a) any Product developed or commercialized by or on behalf of Licensee; or (b) the negligence or willful misconduct of Licensee in connection with this Agreement; or (c) the failure of Licensee to comply with the provisions of this Agreement, including without limitation, **Sections 3.2** through **3.7** and **4.1** through Error! Reference source not found of this Agreement. Notwithstanding the foregoing, Licensee shall have no obligation under this **Section 8.1** with respect to any liability, damage, loss or expense arising out of the negligence or willful misconduct of any Dyax Indemnitee or the failure of Dyax or any Dyax Indemnitees to comply with the provisions of this Agreement.

8.2. Procedure. A party that intends to claim indemnification under this **Article 8** ("Indemnitee") shall: (i) promptly notify the indemnifying party (the "Indemnitor") in writing of any claim, action, suit, or other proceeding brought by Third Parties in respect of which the Indemnitee or any of its Affiliates, directors, officers, employees, representatives, agents and their respective successors, heirs or assigns intend to claim such indemnification hereunder; (ii) provide the Indemnitor sole control of the defense and/or settlement thereof, provided, however, such defense and/or settlement does not admit fault or create an obligation on Indemnitee for which Indemnitee has consented; and (iii) provide the lndemnitor, at the Indemnitor's request and expense, with reasonable assistance and full information with respect thereto. Notwithstanding the foregoing, the indemnity obligation in this **Article 8** shall not apply to amounts paid in settlement of any loss, claim, damage, liability or action if such settlement is effected without the consent of the Indemnitor, to the extent such consent is not withheld unreasonably or delayed and it shall not be deemed unreasonable to withhold consent for an admission of fault by or material obligation created on Indemnitor. Without limiting the foregoing provisions of this **Section 8.2**, the Indemnitor shall keep the Indemnitee reasonably informed of the progress of any claim, suit or action under this **Section 8.2** and the Indemnitee shall have the right to participate in any such claim, suit or proceeding with counsel of its choosing at its own expense, but the Indemnitor shall have the sole right to control the defense or settlement thereof in accordance with the terms of this **Section 8.2**.

## 9. TERM AND TERMINATION.

9.1. Term of Library License.

(a) Unless earlier terminated in accordance with this **Section 9.1**, the term of the Library License (the "Library License Term") shall commence on the Effective Date and remain in effect unless extended until the first to occur of (i) the fourth (4th) anniversary of the Effective Date, or (ii) the termination of this Agreement under Section **9.2(b)**, **(c)** or **(d)**.

(b) Licensee shall have the right to terminate the Library License Term at any time by providing six (6) months prior written notice to Dyax.

(c) Upon expiration or termination of the Library License Term, the Library License will terminate and Licensee shall immediately cease all use of the Dyax Technology licensed under this Agreement and shall, as directed by Dyax, return to Dyax or destroy all Dyax Libraries and Dyax Library Materials in Licensee's possession; otherwise this Agreement shall remain in full force and effect. Notwithstanding the foregoing, if Licensee has taken one or more Commercial License(s), Licensee may continue use of the Dyax Antibody Libraries and Dyax Materials in respect of the relevant Target(s) being the subject of such Commercial License(s) and may retain quantities the Dyax Antibody Libraries and Dyax Materials for such purpose; but only if (i) Licensee is not in breach of its obligations under this Agreement, (ii) Licensee provides written notice to Dyax of its intent to continue to use the Dyax Antibodies Libraries for such purpose, and (iii) pays Dyax an annual license fee of $50,000 for such use, which license fee shall be due and payable on each anniversary of the termination of the Library License Term.

9.2. Term of Agreement.

(a) Expiration. Unless earlier terminated as provided in **Sections 9.2(b)**, **9.2(c)** and **9.2(d)** below, this Agreement shall commence on the Effective Date and shall remain in effect with respect to each Licensed Antibody until the expiration date of the last to expire of Valid Claims licensed to Licensee hereunder.

(b) Termination by Licensee. Licensee shall have the right to terminate this Agreement at any time by providing six (6) months prior written notice to Dyax.

(c) Termination by Dyax. In the event that Licensee fails to make timely payment of any amounts due to Dyax under **Article 4** of this Agreement, Dyax may terminate this Agreement upon thirty (30) days prior written notice to Licensee, unless Licensee pays all past-due amounts prior to the expiration of such thirty (30) day notice period. In the event that (i) Licensee breaches its covenant under **Section 3.10**, or (ii) Licensee or any of its Affiliates, Sublicensees (to the extent they claim rights or receive rights under this Agreement) seeks a judgment of invalidity or unenforceability of, enters into any opposition to, and/or appeal from any decision with respect to validity or enforceability of the Patent Rights or assists or otherwise cooperates with another party, unless compelled by a court of competent jurisdiction, in any such attempt to obtain judgment, opposition or appeal, Dyax may terminate this Agreement immediately by written notice to Licensee.

(d) Termination for Other Material Breach. Without limitation to any other legal or equitable remedies to either Party, in the event that either Party commits a material breach of any of its obligations under this Agreement other than those described in **Section 9.2(c)**, and such Party fails to remedy that breach within sixty (60) days after receiving written notice thereof from the other Party, then the other Party may immediately terminate this Agreement upon written notice to the breaching Party.

9.3. Effect of Expiration or Termination of Agreement.

(a) Upon the expiration or earlier termination of this Agreement and except as expressly provided for herein, all Confidential Information received hereunder shall be returned or destroyed at the disclosing Party's election (provided that the receiving Party may retain one copy to the extent necessary to comply with any contractual or other legal obligations applicable thereto),

all rights and licenses granted to Licensee hereunder shall terminate and Licensee shall immediately cease all use of the Dyax Technology licensed under this Agreement and shall, as directed by Dyax, return to Dyax or destroy all Dyax Libraries and Dyax Library Materials in Licensee's possession. Subject to the payment provisions of **Article 4**, Licensee may continue to use Licensed Antibodies and Licensed Antibody Information in existence as of the date of expiration or termination, in accordance with the license rights set forth in **Section 3.1(b)**, which shall survive the expiration or earlier termination of this Agreement with respect to such Licensed Antibodies, as shall the rights of Licensee under any sublicense of any Product License granted to Dyax by CAT in accordance with **Section 3.4(c)** before the end of the Term, subject to the terms of such CAT Sublicense.

(b) In addition to the survival described in the last sentence of **Section 9.3(a)** above, the following provisions shall survive the expiration or termination of this Agreement: **Articles 1, 4, 5, 6, 8** and **0** and **Sections 3.9, 7.3, 7.4** and this **Section 9.3**.

(c) Upon expiration or termination of this Agreement for any reason, nothing herein shall be construed to release either Party from any obligation that matured prior to the effective date of such expiration or termination.

(d) In the event that Licensee disputes a payment obligation and Licensee notifies Dyax of such dispute and makes the payment under protest, then notwithstanding such payment, Licensee shall have the right to bring an action as to whether or not Licensee is obligated to make such payment and to the extent Licensee prevails in such action, Dyax shall return such disputed payment to Licensee.

(e) This Agreement may be terminated only as expressly provided in this **Article 9**.

## 10. DISPUTE RESOLUTION

10.1. Resolution by Executives. Any dispute, controversy or claim initiated by either Party arising out of, or resulting from the breach or alleged breach by either Party of its obligations under this Agreement (other than bona fide Third Party actions or proceedings filed or instituted in an action or proceeding by a Third Party against a Party to this Agreement), whether before or after termination of this Agreement, shall be in the first instance referred to the respective chief executive officers of the Parties.

10.2. Arbitration. If chief executive officers (or their representatives, it being agreed that the chief executive officer of either Party may designate a representative, provided such representative is empowered with decision making in the dispute) of the Parties fail to resolve any dispute as provided in **Section 11.1** within thirty days, then such dispute shall be finally resolved by binding arbitration as follows:

(a) A Party may submit such dispute to arbitration by notifying the other Party, in writing, of such dispute. Within thirty (30) days after receipt of such notice, the Parties shall designate in writing a single arbitrator to resolve the dispute; *provided, however,* that if the Parties cannot agree on an arbitrator within such thirty (30)-day period, the arbitrator shall be selected by the Boston, Massachusetts office of the American Arbitration Association (the "AAA"). The arbitrator shall be a lawyer knowledgeable and experienced in the law concerning the subject matter of the dispute, and shall not be an Affiliate, employee, consultant, officer, director or stockholder of either Party or of an Affiliate of either Party.

(b) Within thirty (30) days after the designation of the arbitrator, the arbitrator and the Parties shall meet, at which time the Parties shall be required to set forth in writing all disputed issues and a proposed ruling on the merits of each such issue.

(c) The arbitrator shall set a date for a hearing, which shall be no later than forty-five (45) days after the submission of written proposals pursuant to **Section 10.2(b)**, to discuss each of the issues identified by the Parties. The Parties shall have the right to be represented by counsel. Except as provided herein, the arbitration shall be governed by the Commercial Arbitration Rules of the AAA; provided, however, that the Federal Rules of Evidence shall apply with regard to the admissibility of evidence and the arbitration shall be conducted by a single arbitrator.

(d) The arbitrator shall use his or her best efforts to rule on each disputed issue within thirty (30) days after the completion of the hearings described in this **Section 10.2**. The determination of the arbitrator as to the resolution of any dispute shall be binding and conclusive upon all Parties. All rulings of the arbitrator shall be in writing and shall be delivered to the Parties.

(e) The (i) attorneys' fees of the Parties in any arbitration, (ii) fees of the arbitrator and (iii) costs and expenses of the arbitration shall be borne by the Parties as determined by the arbitrator.

(f) Any arbitration pursuant to this **Section 10.2** shall be conducted in Boston, Massachusetts. Any arbitration award may be entered in and enforced by a court in accordance with **Section 11.4**.

(g) Nothing in this **Section 10.2** shall be construed as limiting in any way the right of a Party to seek injunctive relief with respect to any actual or threatened breach of this Agreement from, or to bring an action in aid of arbitration in, a court in accordance with **Section 11.4**. Should any Party seek injunctive relief, then for purposes of determining whether to grant such injunctive relief, the dispute underlying the request for such injunctive relief may be heard by a court in accordance with **Section 11.4**.

(h) The arbitrator shall not award damages excluded pursuant to **Section 7.5**.

## 11. **MISCELLANEOUS.**

11.1. Relationship of Parties. Nothing in this Agreement or in the course of business between Dyax and Licensee shall make or constitute either Party a partner, employee, joint venturer or agent of the other. Neither Party shall have any right or authority to commit or legally obligate or bind the other in any way whatsoever including, without limitation, the making of any agreement, representation or warranty.

11.2. Notices. All notices, requests, demands and other communications required or permitted to be given pursuant to this Agreement shall be in writing and shall be deemed to have been duly given upon the date of receipt if delivered by hand, recognized international overnight courier, confirmed facsimile transmission, or registered or certified mail, return receipt requested, postage prepaid to the following addresses or facsimile numbers:

If to Dyax: Dyax Corp.

300 Technology Square

Cambridge, MA 02139, USA

Attention: Vice President, Business Development

Attention: Corporate Counsel, Legal Department

Fascimile: (617) 225-2501

If to Licensee: Kadmon Pharmaceuticals LLC

Alexandria Center for Life Sciences

450 East 29th Street, 5th Floor

New York, New York, 10016

Attention: Senior Vice President, Business Development

Fascimile: (212) 683-2105

Either Party may change its designated address, contact person and facsimile number by notice to the other Party in the manner provided in this Section.

11.3. Assignment. This Agreement may be assigned by Dyax without the prior written consent of Licensee. The performance of the Licensee hereunder is of a personal nature and, therefore, neither this Agreement nor the license granted to licensee under **Article 3** may be assigned, sublicensed (except as expressly provided under **Article 3**), or otherwise transferred by the Licensee without the prior written consent of Dyax, and any such attempted assignment, sublicense or transfer, directly or indirectly, shall be void and of no force or effect; provided that Licensee may assign this Agreement by operation of law pursuant to a merger or sale of all or substantially all of Licensee's assets without the consent of Dyax. The direct or indirect transfer or issuance of any shares of the Licensee or the voting rights of such shares shall be deemed a violative assignment hereof if such transfer or issuance in any way shall limit or reduce the rights or ability of the current owners of the Licensee to control the business and affairs of the Licensee.

11.4. Governing Law. This Agreement shall be governed by and construed in accordance with the laws of the Commonwealth of Massachusetts, without regard to any choice of law principles that would dictate the application of the laws of another jurisdiction. Each Party (a) submits to the exclusive jurisdiction of the state and federal courts sitting in Boston, Massachusetts, with respect to actions or proceedings arising out of or relating to this Agreement in which a Party brings an action in aid of arbitration, (b) agrees that all claims in respect of such action or proceeding may be heard and determined only in any such court, and (c) agrees not to bring any action or proceeding arising out of or relating to this Agreement in any other court, other than an action or proceeding seeking injunctive relief or brought to enforce an arbitration ruling issued pursuant to **Section 10.2** or an action related to intellectual property. Each Party waives any defense of inconvenient forum to the maintenance of any action or proceeding so brought. Each Party may make service on the other Party by sending or delivering a copy of the process to the Party to be served at the address and in the manner provided for the giving of notices in **Section 11.2**. Nothing in this **Section 11.4**, however, shall affect the right of any Party to serve legal process in any other manner permitted by law.

11.5. Compliance With Law. Nothing in this Agreement shall be construed so as to require the commission of any act contrary to law, and wherever there is any conflict between any provision of this Agreement and any statute, law, ordinance or treaty, the latter shall prevail, but in such event the affected provisions of the Agreement shall be conformed and limited only to the extent necessary to bring it within the applicable legal requirements.

11.6. Force Majeure. Neither Party shall be liable for failure or delay in performance of any obligation under this Agreement, other than payment of any amount due and payable, if such failure or delay is caused by circumstances beyond the control of the Party concerned, including, without limitation, failures resulting from fires, earthquakes, power surges or failures, accidents, labor stoppages, war, revolution, civil commotion, acts of public enemies, blockade, embargo, inability to secure materials or labor, any law, order, proclamation, regulation, ordinance, demand, or requirement having a legal effect of any government or any judicial authority or representative of any such government, acts of God, or acts or omissions of communications carriers, or other causes beyond the reasonable control of the Party affected, whether or not similar to the forgoing. Any such cause shall delay the performance of the affected obligation until such cause is removed.

11.7. Amendment and Waiver. This Agreement may be amended, supplemented, or otherwise modified only by means of a written instrument signed by both Parties. Any waiver of any rights or failure to act in a specific instance shall relate only to such instance and shall not be construed as an agreement to waive any rights or fail to act in any other instance, whether or not similar. A valid waiver must be signed by the Party so waiving.

11.8. Headings. All headings used in this Agreement are inserted for convenience only and are not intended to affect the meaning or interpretation of this Agreement or any Article or Section hereof.

11.9. Severability. In the event any provision of this Agreement should be held invalid, illegal or unenforceable, the remaining provisions shall not be affected or impaired and the Parties will use all reasonable efforts to replace the applicable provision with a valid, legal and enforceable provision which insofar as practical implements the purposes hereof.

11.10. Entire Agreement. This Agreement with its appendices, constitutes the entire agreement between the Parties with respect to the subject matter hereof and supersedes any term sheets and all prior agreements or understandings between the Parties relating to the subject matter hereof.

11.11. Bankruptcy. All rights and licenses granted under or pursuant to this Agreement by Dyax to Licensee are, and shall irrevocably be deemed to be, "intellectual property" as defined in Section 101(56) of the Bankruptcy Code. In the event of the commencement of a case by or against either Party under any Chapter of the Bankruptcy Code, this Agreement shall be deemed an executory contract and all rights and obligations hereunder shall be determined in accordance with Section 365(n) thereof. Unless a Party rejects this Agreement and the other Party decides not to retain its rights hereunder, the other Party shall be entitled to a complete duplicate of (or complete access to, as appropriate) all intellectual property and all embodiments of such intellectual property held by the Party and the Party shall not interfere with the rights of the other Party, which are expressly granted hereunder, to such intellectual property and all embodiments of such intellectual property from another entity.

11.12. Counterparts. This Agreement may be executed in two or more counterparts, each of which shall be deemed an original agreement.

**[SIGNATURES SET FORTH ON FOLLOWING PAGE]**

IN WITNESS WHEREOF, the undersigned have duly executed and delivered this Agreement as a sealed instrument effective as of the date first above written.

| | |
|---|---|
| **DYAX CORP.** | **LICENSEE:** |
| | **KADMON PHARMACEUTICALS LLC** |
| By: /s/Ivana Magovcevic-Liebisch | By:/s/ Steven N. Gordon |
| Title: Executive Vice President, CBO and General Counsel | Title: Executive Vice President and General Counsel |
| Date: July 21, 2011 | Date: July 22, 2011 |

**Appendix A**

[***]

**Appendix B**

[***]

**Appendix C**

[***]

**Appendix D**

[***]

**Appendix E**

[***]

**Appendix F**

[***]

**Appendix G**

[***]

**Appendix H**

[***]

**Appendix I**

[***]

**EXHIBIT 10.22**

**Amendment to Employment Agreement**

This Amendment to the Employment Agreement (the "Amendment") is made and entered into as of January 8, 2021 and is effective as of January 1, 2021 (the "Effective Date") by and between Kadmon Corporation, LLC, a Delaware limited liability company having a principal place of business at 450 East 29th Street, New York, NY 10016 ("Kadmon") and Gregory S. Moss, with a place of domicile at [ADDRESS REDACTED] ("Employee"). Capitalized terms used but not defined herein shall have the meaning provided in the Employment Agreement (defined below).

**WHEREAS**, Kadmon and Employee (together, the "Parties") are parties to an Employment Agreement with an effective date of August 30, 2019 (the "Employment Agreement");

**WHEREAS**, Kadmon and Employee have agreed to changes to certain terms of the Employment Agreement; and

**NOW, THEREFORE**, for good and valuable consideration contained herein, the exchange, receipt and sufficiency of which are acknowledged, the Parties agree as follows:

1. Section 3(a) of the Employment Agreement shall be deleted in its entirety and replaced with the following:

   **Base Salary**. Beginning as of the Effective Date, Kadmon shall pay to Employee an annual base salary for all services to be rendered by Employee under this Employment Agreement of $468,000 (the "Base Salary"), which Base Salary shall be paid in accordance with Kadmon's normal payroll schedule, procedures and policies (which schedule, procedures and policies may be modified from time to time) and subject to applicable deductions as required by law and elected by Employee. Kadmon shall review Employee's salary on an annual basis and may, in its discretion, consider and declare from time to time increases in the Base Salary that it pays Employee. The level of Base Salary as provided in this section shall become the level of Base Salary for the remainder of the term of this Agreement unless there is a further increase in Base Salary as provided herein.

2. Section 3(c) of the Employment Agreement shall be deleted in its entirety and replaced with the following:

   **Discretionary Bonus**. Employee will be eligible for an annual (calendar year) target bonus of 40% of the Base Salary ("Target Bonus"), based on Company performance and Employee performance. The evaluation of both Company performance and Employee performance, and the amount of any bonus awarded hereunder (the "Discretionary Bonus"), will be at the discretion of the Board's Compensation Committee, and no bonus or amount of bonus is guaranteed. Kadmon shall review Employee's Target Bonus percentage on an annual basis and may, in its discretion, consider and declare from time to time increases in the Target Bonus percentage, including with potential individual performance modifiers, that it pays Employee. Employee must be employed on the date the bonus is paid in order to receive any Discretionary Bonus described hereunder.

3. Section 5(d) of the Employment Agreement shall be deleted in its entirety and replaced with the following:

   **Resignation by Employee for Good Reason.** Employee may resign from his employment hereunder at any time if Employee has Good Reason. For purposes of this Agreement, the term "Good Reason" shall mean: (i) any diminution in Employee's duties or responsibilities hereunder (other than in connection with a termination of Employee's employment), which remains uncured by the Company for 5 days following receipt by the Company of written notice of same, which notice shall include reasonable detail as to the nature of the potential resulting Good Reason; (ii) a diminution in Employee's Base Salary; (iii) a relocation of the Company's principal place of business outside New York City; or (iv) the

Company's consummation of a Change in Control (which for the purposes of this Agreement shall be defined as such term is defined in in the Kadmon Holdings, Inc. 2016 Equity Incentive Plan, as amended, the "Plan").

4. A new Section 5(h) shall read as follows:

**Acceleration of Equity Awards Upon or Following a Change in Control**. In the event that Employee's employment hereunder is terminated without Cause, or Employee resigns with Good Reason, in either case during the three (3) months prior to, as of, or within twelve (12) months following the effective date of a Change in Control, then, in addition to Employee's eligibility to receive the payments under Section 5(f) above (including Severance), each current or future Award (as defined in the Plan) granted to Employee that is then outstanding, or any other then outstanding equity award granted to Employee under any successor plan or otherwise (collectively the "Awards"), including Awards that would otherwise vest only upon satisfaction of performance criteria, shall accelerate and vest in full as of the date of such termination or, if later, on the closing date of the Change in Control and, if applicable, become exercisable. In the case of the consummation of the Change in Control in which an outstanding Award is not continued, assumed or substituted for by the Company or the acquiror or any of its affiliates as part of such Change in Control transaction, then such Award will become fully vested and exercisable on or immediately prior to the closing date of the Change in Control, whether Employee terminates employment or not. For purposes of this Section 5(h), the unvested portion of Awards will remain in effect for no less than three months in the case of a termination occurring before a Change in Control, but in any case no longer than the original term or expiration date of the Award. The provision of accelerated vesting hereunder is subject to a valid and fully effective comprehensive release of claims that can no longer be revoked as set forth in Section 5(f) above. This Section 5(h) is in addition to, and is not intended to supersede or replace, any other provision for accelerated vesting of equity under the Plan or otherwise.

5. A new Section 5(i) shall read as follows:

**Excise Tax Adjustment**.

i. Notwithstanding any other Section 280G agreement applicable to Employee, if any payment or benefit Employee will or may receive from the Company or otherwise (a "280G Payment") would (i) constitute a "parachute payment" within the meaning of Section 280G of the Code, and (ii) but for this Section, be subject to the excise tax imposed by Section 4999 of the Code (the "Excise Tax"), then any such 280G Payments (the "Payments") will be equal to the "Reduced Amount" where the Reduced Amount is (1) the largest portion of the Payments that will result in no portion of such Payments being subject to the Excise Tax, or (2) the entire amount of the Payments otherwise scheduled to be paid (without reduction), whichever of the forgoing amounts, after taking into account all applicable federal, state and local employment taxes, income taxes and the Excise Tax (all computed at the highest applicable merged rate, net of the maximum reduction in federal income taxes which could be obtained from a deduction of all state and local taxes), results in Employee's receipt, on an after-tax basis, of the greatest dollar value of the Payments. If subsection (1) above applies and a reduced amount of the Payments is payable, then any reduction of Payments required by such provision will occur in a manner necessary to provide Employee with the greatest post-reduction economic benefit as determined by the Company. If more than one manner of reduction of Payments necessary to arrive at the Reduced Amount yields the greatest economic benefit to Employee, the Payments shall be reduced pro rata. The method used to reduce Payments is the "Reduction Method."

ii. In connection with a Change in Control transaction, the Company shall engage its accounting firm or law firm ("Firm") to perform the calculations to determine if the Payments to Employee would reasonably be subject to Section 280G of the Code, and the Company shall use reasonable efforts to cause the Firm to finalize such calculations, and the Company shall deliver such calculations and any supporting documentation to

Employee, by no later than ten (10) days before the closing of the Change in Control. The Company shall bear all expenses with respect to the determinations by such Firm required to be made hereunder.

iii. Notwithstanding any provision of this Section 5(i) to the contrary, if the Reduction Method would result in any portion of the Payments being subject to taxes pursuant to Section 409A that would not otherwise be subject to taxes pursuant to Section 409A, then the Reduction Method will be modified so as to avoid the imposition of taxes pursuant to Section 409A as follows: (A) as a first priority, the modification shall preserve to the greatest extent possible, the greatest economic benefit for Employee as determined on an after-tax basis; (B) as a second priority, Payments that are contingent on future events (*e.g.*, being terminated without Cause), shall be reduced (or eliminated) before Payments that are not contingent on future events; and (C) as a third priority, Payments that are "deferred compensation" within the meaning of Section 409A shall be reduced (or eliminated) before Payments that are not deferred compensation within the meaning of Section 409A.

6. Section 6(k) of the Employment Agreement shall be deleted in its entirety and replaced with the following:

**Section 409A and Taxes**. All forms of compensation paid to Employee by the Company, including any payments made pursuant to this Agreement, are subject to reduction (or payment by Employee, to the extent that additional amounts are required) to reflect applicable withholding and payroll taxes and other applicable deductions. Employee agrees that the Company does not have a duty to design its compensation policies in a manner that minimizes his tax liabilities, and Employee will not make any claim against the Company related to tax liabilities arising from his compensation. The payments and benefits under this Agreement are intended, and will be construed, to be exempt from or comply with Section 409A of the Internal Revenue Code of 1986, as amended ("Section 409A"); provided, however, that nothing in this Agreement shall be construed or interpreted to transfer any liability for any tax (including a tax or penalty due as a result of a failure to comply with Section 409A) from Employee to the Company or to any other entity or person. Any payment to Employee under this Agreement that is subject to Section 409A and that is contingent on a termination of employment is contingent on a "separation from service" within the meaning of Section 409A. If, upon separation from service, Employee is a "specified employee" within the meaning of Section 409A, any payment under this Agreement that is subject to Section 409A and triggered by a separation from service and would otherwise be paid within six months after Employee's separation from service will instead be paid in the seventh month following such separation from service or, if earlier, upon Employee's death (to the extent required by Section 409A(a)(2)(B)(i)). Each installment of severance pay or compensation hereunder is considered a separate payment for purposes of Section 409A. Any taxable reimbursement due under the terms of this Agreement shall be paid no later than December 31 of the year after the year in which the expense is incurred, and all taxable reimbursements and in-kind benefits shall be provided in accordance with Treas. Reg. § 1.409A-3(i)(1)(iv). The parties agree that if necessary to avoid non-compliance with Section 409A, they will cooperate in good faith to modify the terms of this Agreement or any applicable equity award, provided, that such modification shall endeavor to maintain the economic intent of this Agreement or any such equity award.

7. Except as herein modified or amended, no other term or provision of the Employment Agreement is amended or modified in any respect. The Employment Agreement, as modified by this Amendment, sets forth the entire understanding between the parties with regard to the subject matter hereof and supersedes any prior oral discussions or written communications and agreements. This Amendment cannot be modified or amended except in writing signed by Employee and a duly authorized member of the Board.

**IN WITNESS WHEREOF**, the Parties hereto, by and through their duly authorized representatives, have executed this Amendment effective as of the Effective Date.

**KADMON CORPORATION, LLC**

By: /s/ Harlan W. Waksal
Harlan W. Waksal, M.D.
President and Chief Executive Officer

Date: January 8, 2021

/s/ Gregory S. Moss
Gregory S. Moss
Executive Vice President, General Counsel
and Corporate Secretary, Chief Compliance Officer
Date: January 8, 2021

**EXHIBIT 10.23**

**Amendment to Employment Agreement**

This Amendment to the Employment Agreement (the "Amendment") is made and entered into as of January 8, 2021 and is effective as of January 1, 2021 (the "Effective Date") by and between Kadmon Corporation, LLC, a Delaware limited liability company having a principal place of business at 450 East 29th Street, New York, NY 10016 ("Kadmon") and Steven Meehan, with a mailing address of [ADDRESS REDACTED] ("Employee"). Capitalized terms used but not defined herein shall have the meaning provided in the Employment Agreement (defined below).

**WHEREAS**, Kadmon and Employee (together, the "Parties") are parties to an Employment Agreement with an effective date of February 8, 2019 (the "Employment Agreement");

**WHEREAS**, Kadmon and Employee have agreed to changes to certain terms of the Employment Agreement; and

**NOW, THEREFORE**, for good and valuable consideration contained herein, the exchange, receipt and sufficiency of which are acknowledged, the Parties agree as follows:

1. Section 3(a) of the Employment Agreement shall be deleted in its entirety and replaced with the following:

> **Base Salary**. Beginning as of the Effective Date, Kadmon shall pay to Employee an annual base salary for all services to be rendered by Employee under this Employment Agreement of $520,000 (the "Base Salary"), which Base Salary shall be paid in accordance with Kadmon's normal payroll schedule, procedures and policies (which schedule, procedures and policies may be modified from time to time) and subject to applicable deductions as required by law and elected by Employee. Kadmon shall review Employee's salary on an annual basis and may, in its discretion, consider and declare from time to time increases in the Base Salary that it pays Employee. The level of Base Salary as provided in this section shall become the level of Base Salary for the remainder of the term of this Agreement unless there is a further increase in Base Salary as provided herein.

2. Section 3(c) of the Employment Agreement shall be deleted in its entirety and replaced with the following:

> **Discretionary Bonus**. Employee will be eligible for an annual (calendar year) target bonus of 45% of the Base Salary ("Target Bonus"), based on Company performance and Employee performance. The evaluation of both Company performance and Employee performance, and the amount of any bonus awarded hereunder (the "Discretionary Bonus"), will be at the discretion of the Board's Compensation Committee, and no bonus or amount of bonus is guaranteed. Kadmon shall review Employee's Target Bonus percentage on an annual basis and may, in its discretion, consider and declare from time to time increases in the Target Bonus percentage, including with potential individual performance modifiers, that it pays Employee. Employee must be employed on the date the bonus is paid in order to receive any Discretionary Bonus described hereunder.

3. Section 5(d) of the Employment Agreement shall be deleted in its entirety and replaced with the following:

> **Resignation by Employee for Good Reason.** Employee may resign from his employment hereunder at any time if Employee has Good Reason. For purposes of this Agreement, the term "Good Reason" shall mean: (i) any diminution in Employee's duties or responsibilities hereunder (other than in connection with a termination of Employee's employment), which remains uncured by the Company for 5 days following receipt by the Company of written notice of same, which notice shall include reasonable detail as to the nature of the potential resulting Good Reason; (ii) a

diminution in Employee's Base Salary; (iii) a relocation of the Company's principal place of business outside New York City; or (iv) the Company's consummation of a Change in Control (which for the purposes of this Agreement shall be defined as such term is defined in in the Kadmon Holdings, Inc. 2016 Equity Incentive Plan, the "Plan").

4. The second sentence of Section 5(f) shall be replaced with the following:

In the event that the Employee's employment hereunder is terminated without Cause, or Employee resigns with Good Reason, and provided that Employee first signs and does not revoke any portion of a comprehensive release of claims against the Company, and its current and former affiliated entities and individuals, in a form drafted by the Company, the Company shall pay the Employee severance in an amount equal to his Base Salary and an amount equal to the greater of his Target Bonus or the previous year's Discretionary Bonus (collectively, the "Severance").

The remaining provisions of Section 5(f) will be unchanged.

5. A new Section 5(h) shall read as follows:

**Acceleration of Equity Awards Upon or Following a Change in Control**. In the event that Employee's employment hereunder is terminated without Cause, or Employee resigns with Good Reason, in either case during the three (3) months prior to, as of, or within twelve (12) months following the effective date of a Change in Control, then, in addition to Employee's eligibility to receive the payments under Section 5(f) above (including Severance), each current or future Award (as defined in the Plan) granted to Employee that is then outstanding, or any other then outstanding equity award granted to Employee under any successor plan or otherwise (collectively the "Awards"), including Awards that would otherwise vest only upon satisfaction of performance criteria, shall accelerate and vest in full as of the date of such termination or, if later, on the closing date of the Change in Control and, if applicable, become exercisable. In the case of the consummation of the Change in Control in which an outstanding Award is not continued, assumed or substituted for by the Company or the acquiror or any of its affiliates as part of such Change in Control transaction, then such Award will become fully vested and exercisable on or immediately prior to the closing date of the Change in Control, whether Employee terminates employment or not. For purposes of this Section 5(h), the unvested portion of Awards will remain in effect for no less than three months in the case of a termination occurring before a Change in Control, but in any case no longer than the original term or expiration date of the Award. The provision of accelerated vesting hereunder is subject to a valid and fully effective comprehensive release of claims that can no longer be revoked as set forth in Section 5(f) above. This Section 5(h) is in addition to, and is not intended to supersede or replace, any other provision for accelerated vesting of equity under the Plan or otherwise.

6. A new Section 5(i) shall read as follows:

**Excise Tax Adjustment**.

i. Notwithstanding any other Section 280G agreement applicable to Employee, if any payment or benefit Employee will or may receive from the Company or otherwise (a "280G Payment") would (i) constitute a "parachute payment" within the meaning of Section 280G of the Code, and (ii) but for this Section, be subject to the excise tax imposed by Section 4999 of the Code (the "Excise Tax"), then any such 280G Payments (the "Payments") will be equal to the "Reduced Amount" where the Reduced Amount is (1) the largest portion of the Payments that will result in no portion of such Payments being subject to the Excise Tax, or (2) the entire amount of the Payments otherwise scheduled to be paid (without reduction), whichever of the forgoing amounts, after taking into account all applicable federal, state and local employment taxes, income taxes and the Excise Tax (all computed at the highest applicable merged rate, net of the maximum reduction in federal income taxes which could be obtained from a deduction

of all state and local taxes), results in Employee's receipt, on an after-tax basis, of the greatest dollar value of the Payments. If subsection (1) above applies and a reduced amount of the Payments is payable, then any reduction of Payments required by such provision will occur in a manner necessary to provide Employee with the greatest post-reduction economic benefit as determined by the Company. If more than one manner of reduction of Payments necessary to arrive at the Reduced Amount yields the greatest economic benefit to Employee, the Payments shall be reduced pro rata. The method used to reduce Payments is the "Reduction Method."

ii. In connection with a Change in Control transaction, the Company shall engage its accounting firm or law firm ("Firm") to perform the calculations to determine if the Payments to Employee would reasonably be subject to Section 280G of the Code, and the Company shall use reasonable efforts to cause the Firm to finalize such calculations, and the Company shall deliver such calculations and any supporting documentation to Employee, by no later than ten (10) days before the closing of the Change in Control. The Company shall bear all expenses with respect to the determinations by such Firm required to be made hereunder.

iii. Notwithstanding any provision of this Section 5(i) to the contrary, if the Reduction Method would result in any portion of the Payments being subject to taxes pursuant to Section 409A that would not otherwise be subject to taxes pursuant to Section 409A, then the Reduction Method will be modified so as to avoid the imposition of taxes pursuant to Section 409A as follows: (A) as a first priority, the modification shall preserve to the greatest extent possible, the greatest economic benefit for Employee as determined on an after-tax basis; (B) as a second priority, Payments that are contingent on future events (e.g., being terminated without Cause), shall be reduced (or eliminated) before Payments that are not contingent on future events; and (C) as a third priority, Payments that are "deferred compensation" within the meaning of Section 409A shall be reduced (or eliminated) before Payments that are not deferred compensation within the meaning of Section 409A.

7. Section 6(k) of the Employment Agreement shall be deleted in its entirety and replaced with the following:

> **Section 409A and Taxes**. All forms of compensation paid to Employee by the Company, including any payments made pursuant to this Agreement, are subject to reduction (or payment by Employee, to the extent that additional amounts are required) to reflect applicable withholding and payroll taxes and other applicable deductions. Employee agrees that the Company does not have a duty to design its compensation policies in a manner that minimizes his tax liabilities, and Employee will not make any claim against the Company related to tax liabilities arising from his compensation. The payments and benefits under this Agreement are intended, and will be construed, to be exempt from or comply with Section 409A of the Internal Revenue Code of 1986, as amended ("Section 409A"); provided, however, that nothing in this Agreement shall be construed or interpreted to transfer any liability for any tax (including a tax or penalty due as a result of a failure to comply with Section 409A) from Employee to the Company or to any other entity or person. Any payment to Employee under this Agreement that is subject to Section 409A and that is contingent on a termination of employment is contingent on a "separation from service" within the meaning of Section 409A. If, upon separation from service, Employee is a "specified employee" within the meaning of Section 409A, any payment under this Agreement that is subject to Section 409A and triggered by a separation from service and would otherwise be paid within six months after Employee's separation from service will instead be paid in the seventh month following such separation from service or, if earlier, upon Employee's death (to the extent required by Section 409A(a)(2)(B)(i)). Each installment of severance pay or compensation hereunder is considered a separate payment for purposes of Section 409A. Any taxable reimbursement due under the terms of this Agreement shall be paid no later than December 31 of the year after the year in which the expense is incurred, and all taxable reimbursements and in-kind benefits shall be provided in accordance with Treas. Reg. § 1.409A-3(i)(1)(iv). The parties agree that if necessary to avoid non-compliance with Section 409A, they will cooperate in good faith to modify the terms of this Agreement or any applicable equity award, provided, that such modification shall endeavor to maintain the economic intent of this Agreement or any such equity award.

8. Except as herein modified or amended, no other term or provision of the Employment Agreement is amended or modified in any respect. The Employment Agreement, as modified by this Amendment, sets forth the entire understanding between the parties with regard to the subject matter hereof and supersedes any prior oral discussions or written communications and agreements. This Amendment cannot be modified or amended except in writing signed by Employee and a duly authorized member of the Board.

**IN WITNESS WHEREOF**, the Parties hereto, by and through their duly authorized representatives, have executed this Amendment effective as of the Effective Date.

[Signature Page to Follow]

**KADMON CORPORATION, LLC**

By: /s/ Harlan W. Waksal
Harlan W. Waksal, M.D.
President and Chief Executive Officer
Date: January 8, 2021

/s/ Steven Meehan
Steven Meehan
Executive Vice President, Chief Financial Officer
Date: January 8, 2021

**EXHIBIT 10.24**

**Amendment to Employment Agreement**

This Amendment to the Employment Agreement (the "Amendment") is made and entered into as of January 8, 2021 and is effective as of January 1, 2021 (the "Effective Date") by and between Kadmon Corporation, LLC, a Delaware limited liability company having a principal place of business at 450 East 29th Street, New York, NY 10016 ("Kadmon") and Harlan W. Waksal, M.D, with a place of domicile at [ADDRESS REDACTED] ("Employee"). Capitalized terms used but not defined herein shall have the meaning provided in the Employment Agreement (defined below).

**WHEREAS**, Kadmon and Employee (together, the "Parties") are parties to an Employment Agreement with an effective date of January 1, 2020 (the "Employment Agreement");

**WHEREAS**, Kadmon and Employee have agreed to changes to certain terms of the Employment Agreement; and

**NOW, THEREFORE**, for good and valuable consideration contained herein, the exchange, receipt and sufficiency of which are acknowledged, the Parties agree as follows:

1. Section 3(a) of the Employment Agreement shall be deleted in its entirety and replaced with the following:

> **Base Salary**. Beginning as of the Effective Date, Kadmon shall pay to Employee an annual base salary for all services to be rendered by Employee under this Employment Agreement of $650,000 (the "Base Salary"), which Base Salary shall be paid in accordance with Kadmon's normal payroll schedule, procedures and policies (which schedule, procedures and policies may be modified from time to time) and subject to applicable deductions as required by law and elected by Employee. Kadmon shall review Employee's salary on an annual basis and may, in its discretion, consider and declare from time to time increases in the Base Salary that it pays Employee. The level of Base Salary as provided in this section shall become the level of Base Salary for the remainder of the term of this Agreement unless there is a further increase in Base Salary as provided herein.

2. Section 3(b) of the Employment Agreement shall be deleted in its entirety and replaced with the following:

> **Discretionary Bonus**. Employee will be eligible for an annual (calendar year) target bonus of 70% of the Base Salary ("Target Bonus"), based on Company performance and Employee performance. The evaluation of both Company performance and Employee performance, and the amount of any bonus awarded hereunder (the "Discretionary Bonus"), will be at the discretion of the Board's Compensation Committee, and no bonus or amount of bonus is guaranteed. Kadmon shall review Employee's Target Bonus percentage on an annual basis and may, in its discretion, consider and declare from time to time increases in the Target Bonus percentage, including with potential individual performance modifiers, that it pays Employee. Employee must be employed on the date the bonus is paid in order to receive any Discretionary Bonus described hereunder.

3. A new Section 3(f) of the Employment Agreement shall read as follows:

> **Guaranteed Incentives**. The terms of any stock option awards granted to you during your employment will provide, or shall be modified to provide, that if you are involuntarily terminated without Cause (as defined in this Agreement), or if you terminate your employment with Good Reason (as defined in the Agreement), then you will be eligible to exercise any then outstanding options that have vested as of your termination date until the earlier of: (i) the second anniversary of your termination date, and (ii) the date the options would otherwise expire pursuant to their terms.

4. Section 5(d) of the Employment Agreement shall be deleted in its entirety and replaced with the following:

**Resignation by Employee for Good Reason.** Employee may resign from his employment hereunder at any time if Employee has Good Reason. For purposes of this Agreement, the term "Good Reason" shall mean: (i) any diminution in Employee's duties or responsibilities hereunder (other than in connection with a termination of Employee's employment), which remains uncured by the Company for 5 days following receipt by the Company of written notice of same, which notice shall include reasonable detail as to the nature of the potential resulting Good Reason; (ii) a diminution in Employee's Base Salary; (iii) a relocation of the Company's principal place of business outside New York City; or (iv) the Company's consummation of a Change in Control (which for the purposes of this Agreement shall be defined as such term is defined in in the Kadmon Holdings, Inc. 2016 Equity Incentive Plan, the "Plan").

5. A new Section 5(h) shall read as follows:

**Acceleration of Equity Awards Upon or Following a Change in Control**. In the event that Employee's employment hereunder is terminated without Cause, or Employee resigns with Good Reason, in either case during the three (3) months prior to, as of, or within twelve (12) months following the effective date of a Change in Control, then, in addition to Employee's eligibility to receive the payments under Section 5(f) above (including Severance), each current or future Award (as defined in the Plan) granted to Employee that is then outstanding, or any other then outstanding equity award granted to Employee under any successor plan or otherwise (collectively the "Awards"), including Awards that would otherwise vest only upon satisfaction of performance criteria, shall accelerate and vest in full as of the date of such termination or, if later, on the closing date of the Change in Control and, if applicable, become exercisable. In the case of the consummation of the Change in Control in which an outstanding Award is not continued, assumed or substituted for by the Company or the acquiror or any of its affiliates as part of such Change in Control transaction, then such Award will become fully vested and exercisable on or immediately prior to the closing date of the Change in Control, whether Employee terminates employment or not. For purposes of this Section 5(h), the unvested portion of Awards will remain in effect for no less than three months in the case of a termination occurring before a Change in Control, but in any case no longer than the original term or expiration date of the Award. The provision of accelerated vesting hereunder is subject to a valid and fully effective comprehensive release of claims that can no longer be revoked as set forth in Section 5(f) above. This Section 5(h) is in addition to, and is not intended to supersede or replace, any other provision for accelerated vesting of equity under the Plan, an Award or otherwise.

6. A new Section 5(i) shall read as follows:

**Excise Tax Adjustment**.

i. Notwithstanding any other Section 280G agreement applicable to Employee, if any payment or benefit Employee will or may receive from the Company or otherwise (a "280G Payment") would (i) constitute a "parachute payment" within the meaning of Section 280G of the Code, and (ii) but for this Section, be subject to the excise tax imposed by Section 4999 of the Code (the "Excise Tax"), then any such 280G Payments (the "Payments") will be equal to the "Reduced Amount" where the Reduced Amount is (1) the largest portion of the Payments that will result in no portion of such Payments being subject to the Excise Tax, or (2) the entire amount of the Payments otherwise scheduled to be paid (without reduction), whichever of the forgoing amounts, after taking into account all applicable federal, state and local employment taxes, income taxes and the Excise Tax (all computed at the highest applicable merged rate, net of the maximum reduction in federal income taxes which could be obtained from a deduction of all state and local taxes), results in Employee's receipt, on an after-tax basis, of the greatest dollar value of the Payments. If subsection (1) above applies and a reduced amount of the Payments is payable, then any reduction of Payments required by such provision will occur in a manner necessary to provide Employee with the greatest post-reduction economic benefit as determined by the Company. If more than one manner of reduction of Payments necessary to arrive at the Reduced Amount yields the greatest economic benefit to Employee, the Payments shall be reduced pro rata. The method used to reduce Payments is the "Reduction Method."

ii. In connection with a Change in Control transaction, the Company shall engage its accounting firm or law firm ("Firm") to perform the calculations to determine if the Payments to Employee would reasonably be subject to Section 280G of the Code, and the Company shall use reasonable efforts to cause the Firm to finalize such calculations, and the Company shall deliver such calculations and any supporting documentation to Employee, by no later than ten (10) days before the closing of the Change in Control. The Company shall bear all expenses with respect to the determinations by such Firm required to be made hereunder.

iii. Notwithstanding any provision of this Section 5(h) to the contrary, if the Reduction Method would result in any portion of the Payments being subject to taxes pursuant to Section 409A that would not otherwise be subject to taxes pursuant to Section 409A, then the Reduction Method will be modified so as to avoid the imposition of taxes pursuant to Section 409A as follows: (A) as a first priority, the modification shall preserve to the greatest extent possible, the greatest economic benefit for Employee as determined on an after-tax basis; (B) as a second priority, Payments that are contingent on future events (*e.g.*, being terminated without Cause), shall be reduced (or eliminated) before Payments that are not contingent on future events; and (C) as a third priority, Payments that are "deferred compensation" within the meaning of Section 409A shall be reduced (or eliminated) before Payments that are not deferred compensation within the meaning of Section 409A.

7. Section 6(k) of the Employment Agreement shall be deleted in its entirety and replaced with the following:

**Section 409A and Taxes**. All forms of compensation paid to Employee by the Company, including any payments made pursuant to this Agreement, are subject to reduction (or payment by Employee, to the extent that additional amounts are required) to reflect applicable withholding and payroll taxes and other applicable deductions. Employee agrees that the Company does not have a duty to design its compensation policies in a manner that minimizes his tax liabilities, and Employee will not make any claim against the Company related to tax liabilities arising from his compensation. The payments and benefits under this Agreement are intended, and will be construed, to be exempt from or comply with Section 409A of the Internal Revenue Code of 1986, as amended ("Section 409A"); provided, however, that nothing in this Agreement shall be construed or interpreted to transfer any liability for any tax (including a tax or penalty due as a result of a failure to comply with Section 409A) from Employee to the Company or to any other entity or person. Any payment to Employee under this Agreement that is subject to Section 409A and that is contingent on a termination of employment is contingent on a "separation from service" within the meaning of Section 409A. If, upon separation from service, Employee is a "specified employee" within the meaning of Section 409A, any payment under this Agreement that is subject to Section 409A and triggered by a separation from service and would otherwise be paid within six months after Employee's separation from service will instead be paid in the seventh month following such separation from service or, if earlier, upon Employee's death (to the extent required by Section 409A(a)(2)(B)(i)). Each installment of severance pay or compensation hereunder is considered a separate payment for purposes of Section 409A. Any taxable reimbursement due under the terms of this Agreement shall be paid no later than December 31 of the year after the year in which the expense is incurred, and all taxable reimbursements and in-kind benefits shall be provided in accordance with Treas. Reg. § 1.409A-3(i)(1)(iv). The parties agree that if necessary to avoid non-compliance with Section 409A, they will cooperate in good faith to modify the terms of this Agreement or any applicable equity award, provided, that such modification shall endeavor to maintain the economic intent of this Agreement or any such equity award.

8. Except as herein modified or amended, no other term or provision of the Employment Agreement is amended or modified in any respect. The Employment Agreement, as modified by this Amendment, sets forth the entire understanding between the parties with regard to the subject matter hereof and supersedes any prior oral discussions or written communications and agreements. This Amendment cannot be modified or amended except in writing signed by Employee and a duly authorized member of the Board.

**IN WITNESS WHEREOF**, the Parties hereto, by and through their duly authorized representatives, have executed this Amendment effective as of the Effective Date.

[Signature Page to Follow]

**KADMON CORPORATION, LLC**

By: /s/ Steven Meehan
Steven Meehan
Executive Vice President, Chief Financial Officer
Date: January 8, 2021

/s/ Harlan W. Waksal
Harlan W. Waksal, M.D.
President and Chief Executive Officer
Date: January 8, 2021

**EXHIBIT 10.3**

**FIRST AMENDMENT TO THE**
**ANTIBODY LIBRARY LICENSE AGREEMENT**

This FIRST AMENDMENT TO UCENSE AGREEMENT (this "First Amendment"), dated effective as of July 22, 2015 (the "Amendment Date"), is entered into between DYAX CORP., a Delaware, United States corporation, with offices at 55 Network Drive, Burlington Massachusetts 01803, U.S.A. ("Dyax"), and KADMON PHARMACEUTICALS LLC1 a Delaware limited liability company with its principal place of business at Alexandria Center for Life Sciences, 450 East 29th Street, 5th Floor, New York, New York 10016 (""). This First Amendment amends that certain Antibody Library License Agreement (the "Original Agreement"), dated effective as July 22, 2011, by and between Dyax and Kadmon. All capitalized terms not otherwise defined in this First Amendment shall be as defined in the Original Agreement.

NOW, THEREFORE, in consideration of the promises and agreements set forth herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Dyax and Kadmon hereby agree as follows:

1. Section 9.1 of the Original Agreement is hereby deleted in its entirety and replaced by the following, in lieu thereof:

   9.1 Term of Library License.

   (a) Unless earlier terminated in accordance with this **Section 0**, the term of the Library License (the "Library License Term") shall commence on the Effective Date and remain in effect unless extended until the first to occur of (i) the September 22, 2015, or (ii) the termination of this Agreement under Section **9.2(b)**, **(c)** or **(d)**.

2. Except as expressly provided otherwise in this First Amendment, all provisions of the Original Agreement remain in full force and effect without modification and all such terms are hereby ratified and confirmed.

3. From and after the Amendment Date, the term "Agreement" as used in the Original Agreement shall mean the Original Agreement, as amended by this First Amendment.

4. This First Amendment may be executed in one or more counterparts, each of which shall be deemed an original and all of which shall constitute one and the same instrument.

IN WITNESS WHEREOF, Dyax and Kadmon have caused this First Amendment to be duly executed by their authorized representatives under seal, effective as of the Amendment Date.

**DYAX CORP.**
By: /s/ Shelby J. Walker
Name: Shelby J. Walker, Esq.
Title: Vice President, Legal and Associate General Counsel

**KADMON PHARMACEUTICALS LLC**
By: /s/ Harlan W. Waksal
Name: Harlan W. Waksal, M.D.
Title: Chief Executive Officer

**EXHIBIT 21.1**

**List of Subsidiaries of the Registrant**

| Name of Subsidiary | Jurisdiction of Organization |
|---|---|
| Kadmon Corporation, LLC | Delaware |
| Kadmon Pharmaceuticals, LLC | Pennsylvania |

**EXHIBIT 23.1**

**Consent of Independent Registered Public Accounting Firm**

Kadmon Holdings, Inc.
New York, New York

We hereby consent to the incorporation by reference in the Registration Statements on Form S3 (No. 333-233766 and No. 333-238969) and Form S8 (No. 333-233770 and No. 333-238972) of Kadmon Holdings, Inc. of our report dated March 4, 2021, relating to the consolidated financial statements which appear in this Form 10-K.

/s/ BDO USA, LLP
New York, New York

March 4, 2021

**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, Harlan W. Waksal, certify that:

1. I have reviewed this Annual Report on Form 10-K of Kadmon Holdings, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: March 4, 2021

/s/ Harlan W. Waksal
Harlan W. Waksal
President and Chief Executive Officer

**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, Steven Meehan, certify that:

1. I have reviewed this Annual Report on Form 10-K of Kadmon Holdings, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: March 4, 2021

/s/ Steven Meehan
Steven Meehan
Executive Vice President, Chief Financial Officer

**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 Kadmon Holdings, Inc. (the "Company") for the period ended December 31, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Harlan W. Waksal, President and Chief Executive Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to 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 Kadmon Holdings, Inc. and will be retained by Kadmon Holdings, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.

Dated: March 4, 2021

/s/ Harlan W. Waksal
Harlan W. Waksal
President and Chief Executive Officer

**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 Kadmon Holdings, Inc. (the "Company") for the period ended December 31, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Steven Meehan, Executive Vice President, Chief Financial Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to 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 Kadmon Holdings, Inc. and will be retained by Kadmon Holdings, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.

Dated: March 4, 2021

/s/ Steven Meehan
Steven Meehan
Executive Vice President, Chief Financial Officer