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

Form 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13, OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 2019
OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the transition period from to

Commission file number: 001-38940

MORPHIC HOLDING, INC.

(Exact name of registrant as specified in its charter)

Delaware	**47-3878772**
(State or other jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)
35 Gatehouse Drive, A2 **Waltham, MA** (Address of Principal Executive Offices)	**02451** (Zip Code)

Registrant's telephone number, including area code: **(781) 996-0955**

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

Title of each class	Trading symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.0001 per share	MORF	The Nasdaq Global Market

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 Section 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 pursuant to Rule 405 of Regulation S-T (Section 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

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

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

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

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

The aggregate market value (approximate) of the registrant's common equity held by non-affiliates based on the closing price of a share of the registrant's common stock for as reported on The Nasdaq Global Market on June 28, 2019 (the last business day of the registrant's most recently completed second fiscal quarter) was $373,528,000.

The number of shares outstanding of the registrant's Common Stock as of February 27, 2020 was 30,483,521.

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PART I

FORWARD LOOKING STATEMENTS.

This Annual Report on Form 10-K, or Annual Report, contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act, and section 27A of the Securities Act of 1933, as amended, or the Securities Act. All statements contained in this Annual Report other than statements of historical fact, including statements regarding our future results of operations and financial position, business strategy, market size, potential growth opportunities, nonclinical and clinical development activities, efficacy and safety profile of our product candidates, our ability to maintain and recognize the benefits of certain designations received by product candidates, the timing and results of nonclinical studies and clinical trials, collaboration with third parties, and the receipt and timing of potential regulatory designations, approvals and commercialization of product candidates, are forward-looking statements. The words “believe,” “may,” “will,” “potentially,” “estimate,” “continue,” “anticipate,” “intend,” “could,” “would,” “project,” “plan,” “expect” and similar expressions that convey uncertainty of future events or outcomes are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

We have based these forward-looking statements largely on our current expectations and projections about future events and trends that we believe may affect our financial condition, results of operations, business strategy, short-term and long-term business operations and objectives and financial needs. These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including those described in “Risk Factors” and elsewhere in this Annual Report. Moreover, we operate in a competitive and rapidly changing environment, and new risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this Annual Report may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements.

You should not rely upon forward-looking statements as predictions of future events. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee that the future results, levels of activity, performance or events and circumstances reflected in the forward-looking statements will be achieved or occur. We undertake no obligation to update publicly any forward-looking statements for any reason after the date of this Annual Report to conform these statements to actual results or to changes in our expectations, except as required by law. You should read this Annual Report with the understanding that our actual future results, levels of activity, performance and events and circumstances may be materially different from what we expect.

Except where the context otherwise requires, as used in this Annual Report, the terms “we,” “us,” “our” and the “Company” refer to Morphic Holding, Inc., a Delaware corporation, and its subsidiaries taken as a whole, unless otherwise noted. “Morphic,” “Morphic Therapeutic,” the Morphic logo, and all product names are our common law trademarks. This Annual Report contains additional trade names, trademarks and service marks of other companies, which are the property of their respective owners. We do not intend our use or display of other companies’ trade names, trademarks or service marks to imply a relationship with, or endorsement or sponsorship of us by, these other companies.

ITEM 1. BUSINESS.

Overview

We are a biopharmaceutical company applying our proprietary insights into integrins to discover and develop a pipeline of potentially first-in-class oral small-molecule integrin therapeutics. Integrins are a target class with multiple approved injectable blockbuster drugs for the treatment of serious chronic diseases, including autoimmune, cardiovascular and metabolic diseases, fibrosis and cancer. To date, no oral small-molecule integrin therapies have been approved by the U.S. Food and Drug Administration, or FDA. Despite significant unsuccessful efforts, we believe tremendous untapped potential remains for us to develop oral integrin therapies. We created the Morphic integrin technology platform, or MInT Platform, by leveraging our unique understanding of integrin structure and biology to develop novel product

candidates designed to achieve the potency, high selectivity, and pharmaceutical properties required for oral administration. We are advancing our preclinical pipeline, including our wholly-owned program MORF-057, a $\alpha_4\beta_7$ specific integrin inhibitor affecting inflammation, into clinical development for the treatment of inflammatory bowel disease, or IBD. We are also developing MORF-720, our selective oral $\alpha_v\beta_6$ specific integrin inhibitor affecting fibrosis, toward Investigational New Drug applications, or INDs, and intend to advance MORF-057 and MORF-720 toward IND submissions by the middle and the end of 2020, respectively. Beyond our current targets, we are using our MInT Platform to create a broad pipeline of programs across a variety of therapeutic areas, all of which aim to harness the potential of inhibition or activation.

Integrins are a family of transmembrane cell adhesion proteins that localize cells in specific tissues and then modulate cellular functions in response to these environments. They are the only receptors that can "integrate" extracellular and intracellular stimuli. Integrins contain two subunits: one protein in the integrin dimer comes from the α family and one from the β family. Combinations of various α and β subunits form 24 integrins that are subdivided across four receptor subgroups: those on leukocytes, and those that recognize RGD-peptide, collagen and laminin ligands. Their activity is modulated by the complexity of their conformational states. Tissues have distinct integrin expressions and these integrins play a role in autoimmune, cardiovascular and metabolic diseases, fibrosis and cancer. We believe the diversity and specificity of integrin involvement in a broad range of diseases make this set of molecules ideal drug targets.

Based on the broad therapeutic potential of integrin inhibition and activation and the productivity of our MInT Platform, we have made the strategic decision to retain full commercial rights to certain compounds and indications in our development pipeline while selectively collaborating on the development of those that do not match our current resources or therapeutic focus. In October 2018, we entered with AbbVie into an agreement designed to advance a number of our oral integrin programs for fibrosis-related indications, which included an upfront payment of $100.0 million to us to provide research and development activities, and we provided AbbVie with exclusive license options on product candidates directed at a number of targets. In February 2019, we entered into an agreement with Janssen Pharmaceuticals, Inc., or Janssen, to develop novel integrin therapeutics. In the aggregate, we are eligible to receive up to $729 million from the collaboration in upfront, option and milestone payments, as well as royalties on net sales. We believe these collaborations further validate the transformational potential of our MInT Platform.

We were founded in 2014 by Dr. Timothy A. Springer of Harvard Medical School and Boston Children's Hospital, a world-renowned immunologist and biophysicist who discovered integrins. He established the importance of integrin conformations in modulating disease activity. Today, pursuant to an exclusive license from the Children's Medical Center Corporation, or the Springer Laboratory, our MInT platform is powered by these initial insights, together with our proprietary knowledge of integrin conformations, affinity regulation and dynamics. Together, this enables us to discover novel product candidates that bind and revert disease-specific integrin conformations to a non-disease physiologic state.

We have assembled an experienced management team, board of directors and scientific advisory board with specialized expertise in integrin therapies. They collectively bring extensive experience in discovering, developing and commercializing therapeutics, having worked at companies such as Biogen Inc., Cubist Pharmaceuticals, Inc., Gilead Sciences, Inc., and Pfizer Inc.

Since our inception, we have raised $351.6 million in gross proceeds through equity financings, including our initial public offering in July 2019, and collaborations.

Our Strategy

Our goal is to utilize our MInT Platform to discover and develop potentially first-in-class oral small-molecule integrin therapeutics. We believe our platform has the potential to transform the treatment paradigm for patients suffering from a broad range of serious chronic diseases. The key tenets of our business strategy to achieve this goal include:

- ***Establishing orally available integrin modulators as a new treatment for serious chronic diseases, including autoimmune, cardiovascular and metabolic diseases, fibrosis and cancer.*** We are leveraging our MInT Platform to create a new class of oral integrin targeted therapeutics to treat diseases where

integrins are dysregulated and a potential benefit for oral therapies exists. We have prioritized our initial development efforts on diseases with established clinical endpoints and biomarkers, which we believe will enable us to more rapidly achieve clinical proof of concept. We are advancing our lead wholly-owned program, MORF-057, a $\alpha_4\beta_7$ specific integrin inhibitor, into clinical development for the treatment of IBD. We are also developing MORF-720 and MR β6 #2, our selective first in class $\alpha_v\beta_6$ specific integrin inhibitors of the growth of fibrotic tissue product candidate, into clinical development for the treatment of IPF or primary sclerosing cholangitis, or PSC. We intend to advance MORF-057 and MORF-720 toward IND submissions by the middle and the end of 2020, respectively.

§ ***Leveraging our proprietary MInT Platform and knowledge base to grow our pipeline of novel integrin therapeutics.*** Our comprehensive MInT Platform, coupled with our development capabilities, have enabled us to build a pipeline of novel product candidates targeting chronic diseases caused by integrin dysregulation. We intend to expand our pipeline by unlocking the therapeutic potential of the four integrin subgroups to treat diseases with high unmet medical need and to potentially expand our current product candidates into new indications.

§ ***Continuing to drive innovation across our MInT Platform.*** We intend to extend our leading position in the field of integrin medicine by continuing to develop and incorporate platform innovations that can further broaden the potential therapeutic reach of our oral integrin programs. Our key focus areas include iteratively expanding the breadth of our structural knowledge in crystallography through technological investments, broadening our library of conformationally-specific integrin chemotypes and deepening our fundamental understanding of integrin disease biology. We believe that as we further expand our knowledge base, we will be able to iteratively grow our platform and deepen our understanding of additional integrin targets.

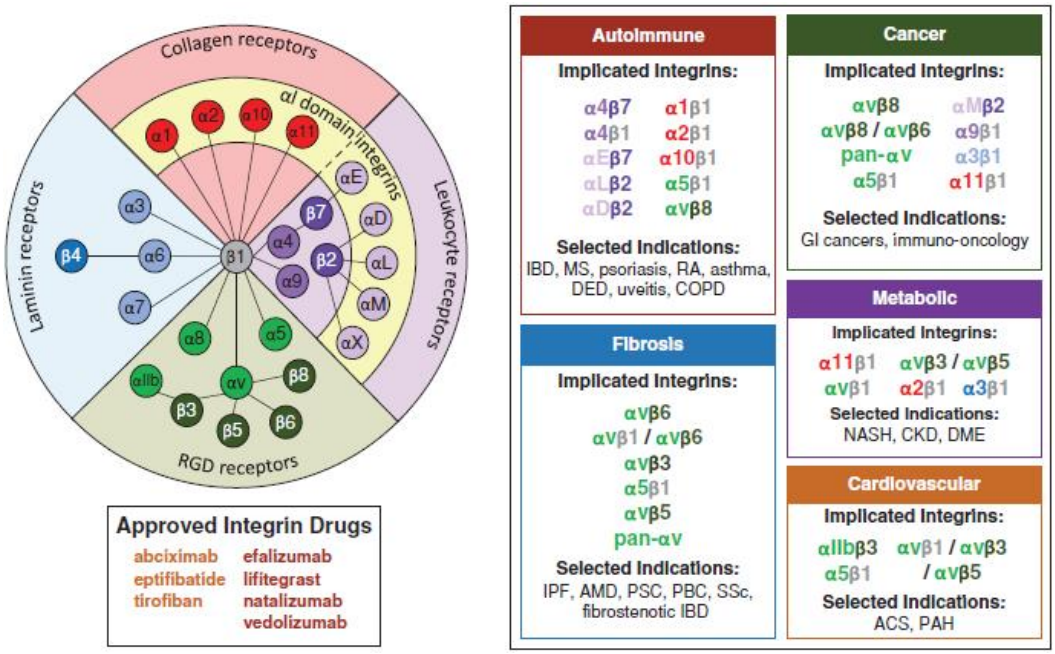
§ ***Independently commercializing our products, if approved, in indications and geographies where we believe we can realize maximum value.*** We plan to independently advance those product candidates that we believe have well-defined clinical and regulatory approval pathways, and that we believe we can commercialize successfully, if approved. We may also seek to form strategic collaborations around certain targets, product candidates or disease areas that we believe could benefit from the resources of either larger biopharmaceutical companies or those specialized in a particular area. Our current collaborations with AbbVie and Janssen exemplify various aspects of this strategy.

Our Focus — Integrin Receptors

Integrins are the only receptors in the human body that use both intracellular and extracellular ligands to transmit signals both from inside of the cell to the outside of the cell and from the outside of the cell to the inside of the cell. Reciprocally, these states are regulated by tensile forces transmitted through integrins when they bind to extracellular ligands and the intracellular cytoskeleton. This bi-directional signaling ability allows integrins to affect virtually every aspect of cell and organ homeostasis. Consequently, the dysregulation of integrin signaling is associated with many human diseases including autoimmune, cardiovascular and metabolic diseases, fibrosis and cancer.

Integrin receptors are evolutionarily conserved. Integrins exist as paired combinations of 18 α and eight β subunits resulting in 24 known heterodimers. These pairings give integrins their unique abilities to recognize their ligands and modulate cellular function in specific ways. Integrins are subdivided into those on leukocytes, and those that recognize RGD-peptide, collagen and laminin ligands. They regulate numerous aspects of cell biology and physiology including leukocyte trafficking, activation of platelets and leukocytes, activation of growth factors such as TGF-β, cell adhesion to the basement membrane and extracellular matrix, and retention or adhesion strengthening of cells within tissues. This diverse set of functions makes them actionable targets across a broad range of human diseases based on preclinical

modeling or clinical establishment. The figure below summarizes the 24-member integrin family and areas of clinical relevance:



Integrins as a Therapeutic Target Family

Integrins have long been recognized as drug targets. In the 1980s, the therapeutic interrogation of integrins focused on the RGD integrin, $\alpha II_b\beta_3$. When $\alpha II_b\beta_3$ on platelets is activated, it binds to fibrin, which bridges it to adjacent platelets and leads to clot formation. As the molecular details establishing the essential role of $\alpha II_b\beta_3$ in platelet aggregation emerged, it became clear that inhibition of its ligand binding function would be antithrombotic. In 1994, abciximab (marketed as ReoPro) became the first approved integrin therapy for patients undergoing percutaneous transluminal coronary angioplasty, followed by the approval of tirofiban (marketed as Aggrastat) and eptifibatide (marketed as Integrilin).

The next stage of development of integrins as drug targets has focused on integrin receptors on leukocytes. These therapies modulate autoimmunity by inhibiting the ability of activated immune cells, including T-cells, to enter chronically inflamed tissues. Four approved integrin medicines belong to this category:

- Efalizumab (marketed as Raptiva), an injectable antibody inhibitor of $\alpha_L\beta_2$, approved by the FDA in 2003 for the treatment of chronic moderate to severe psoriasis;
- Natalizumab (marketed as Tysabri), an infusible antibody inhibitor of $\alpha_4\beta_1$, approved by the FDA in 2004 for the treatment of relapsing forms of multiple sclerosis and in 2008 for the treatment of moderate to severe active Crohn's disease;
- Vedolizumab (marketed as Entyvio), an infusible antibody inhibitor of $\alpha_4\beta_7$, approved by the FDA in 2014 for the treatment of moderate to severe active ulcerative colitis or Crohn's disease; and

- § Lifitegrast (marketed as Xiidra), a topical small-molecule inhibitor of $\alpha_L\beta_2$, approved by the FDA in 2016 for the treatment of keratoconjunctivitis sicca.

According to Global Data, these autoimmune therapies were estimated to have achieved combined annual sales in their respective 2019 fiscal years of approximately $5.1 billion.

Development Challenges of Oral Integrin Modulators

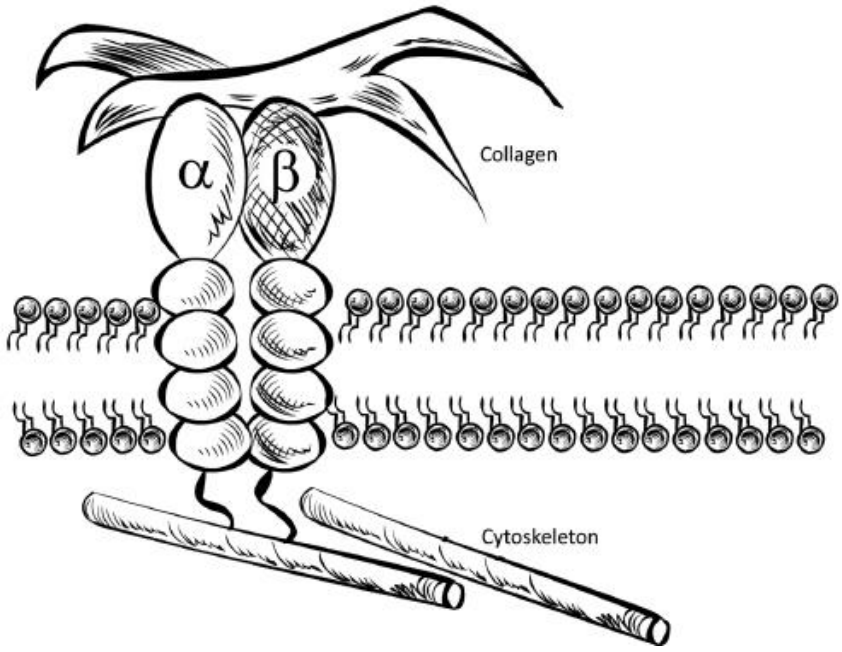
The infusible, injectable or topical nature of these therapies has limited their utility. To address the limitations of these therapies, the pharmaceutical industry has invested significant resources in discovering and developing oral systemic integrin therapies. For $\alpha II_b\beta_3$ alone, six different compounds (roxifiban, sibrafiban, orbofiban, xemilofiban, lefradafiban, lotrafiban) were advanced into registrational Phase 3 clinical trials. Disappointingly, the results of these trials showed these oral systemic inhibitors of $\alpha II_b\beta_3$ increased vascular death in patients with acute coronary syndrome. The reason for these failures took another decade to establish. We now know that all failed oral inhibitors stabilized the active integrin conformation and promoted ligand signaling if they were not potent enough to maintain full active site binding. These drawbacks resulted in greater platelet aggregation and an increased rate of adverse events.

Additionally, the unexpected disease-activating activity of oral leukocyte integrin inhibitors was observed during a Phase 2 development of firategrast, an oral non-selective inhibitor of $\alpha_4\beta_1$ and $\alpha_4\beta_7$, where the symptoms in the patients with multiple sclerosis were exacerbated when firategrast was administered in non-saturating doses. This resulted in an increase in lesions and an increased rate of adverse events. The development of this compound was subsequently halted.

Our Platform and Approach

We believe that our MInT Platform allows us to address and overcome the challenges faced by developers of first-generation oral integrin-targeted therapeutics.

Integrin Model



We believe that our discovery platform enables us to be the only company working across the entire 24-member integrin target family. Our MInT Platform consists of three unique capabilities:

- **Proprietary ability to determine integrin structures.** Using our protein constructs, cell lines and know-how, we have elucidated more than 150 proprietary structures for clinically important targets across nine of the 24 integrins.

- **Tunable product candidate design engine.** We have built a library of optimized compounds using sophisticated medicinal chemistry capabilities and biological assays that allows us to tune highly potent and selective integrin inhibitors and activators into product candidates for preclinical and clinical development. Our ability to generate product candidates from our tunable product engine is accelerated by our exclusive computational design collaboration with Schrödinger.

- **Biology and disease translation capability.** Our sophisticated and comprehensive suite of biologic tools includes a gene and protein expression atlas, a single-cell resolution profiling of human tissues from diseases of interest and development of biomarkers, which allow us to assess target engagement and pharmacodynamic activity in the disease of interest.

We initially focused on developing product candidates with a target class for areas of high unmet medical needs including:

- $\alpha_4\beta_7$ and $\alpha_4\beta_1$, which are established targets for autoimmune diseases; their mechanism of action and the benefits and risks of their inhibition are well understood; and

- certain α_v integrins that have a preclinically well-characterized mechanism of action through the activation of TGF-β, a clinically important anti-inflammatory cytokine dysregulated in many human pathologies.

To date, we have not tested any of our product candidates in any clinical studies, and we currently only have pre-clinical data regarding oral bioavailability of our product candidates.

Our understanding of the mechanism of integrin receptor activity, modulated by complex conformations and signaling, is unique and allows us to discover both inhibitors and activators across the integrin receptor target family. Our capability has been validated by our advancement of $\alpha_v\beta_6$ and $\alpha_4\beta_7$ programs, as well as our collaborations with AbbVie and Janssen. Our MInT Platform consists of three major components:

- Proprietary ability to determine integrin structures;

- Tunable product candidate design engine; and

- Biology and disease translation capability.

Leveraging our deep understanding of integrin conformation and molecular modes of action is a key element of our strategy to identify product candidates. These receptors undergo large conformational changes as shown in Figure 1 resulting in both inactive (bent-closed and extended-closed) and activated states of the receptor (extended-open). In the bent-closed form, the top portion of the integrin, formed by both α and β subunits, folds in half so that the top and lower half associate with each other (Figure 1 left) rendering the integrin inactive. For the integrin to be active, the extended-close state (Figure 1 middle) extends at the α and β mid-leg on the cell surface to render an extended open state (Figure 1 right). As shown with multiple integrins, the bent-closed and extended-closed conformations have low affinities for ligand, while depending on the integrin, the extended-open conformation is 700 to 5,000-fold higher in affinity for ligand. These changes in integrin conformation and affinity function to transmit bi-directional signals,

enabling communication of the cell expressing the integrin on its surface and the extracellular matrix or ligands on other cells.

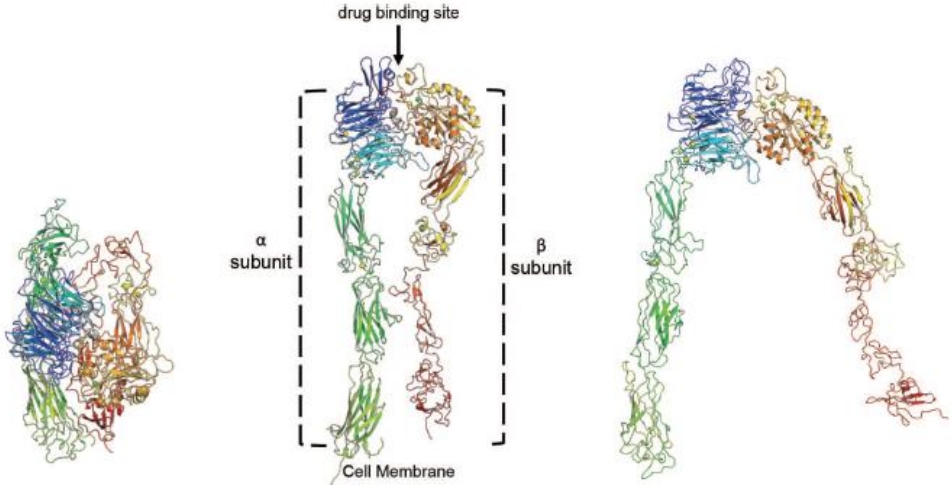


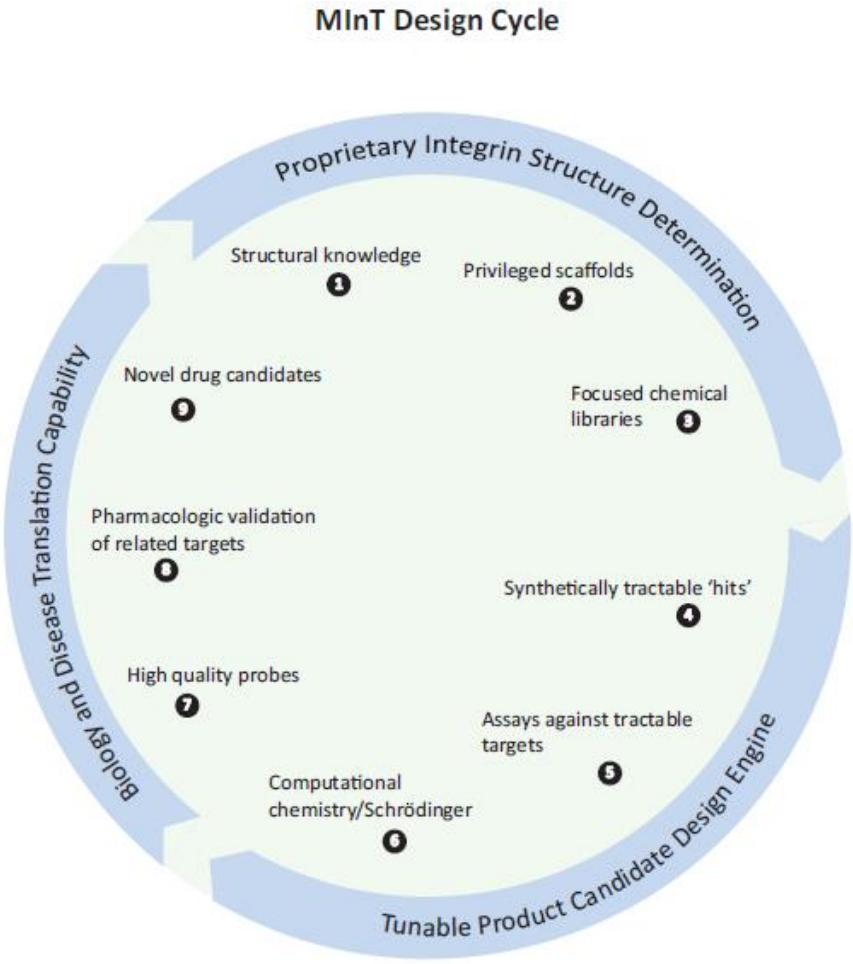
Figure 1: Integrin dynamic conformational states. Left — bent-closed inactive form of the integrin heterodimer pair, Middle — extended-closed inactive, and Right — extended-open active.

Our novel MInT Platform is rooted in our structural biology capability based on deep insights into control of complex integrin conformational states. Dr. Springer characterized an initial set of small molecules to lock specific integrin conformations and we have used and advanced this knowledge to optimize the pharmacology of our oral integrins. We design our compounds to recognize integrin conformational states that are physiologic dysregulated in disease. Binding of our compounds to integrins promotes the integrin to adopt a structure that is characteristic of healthy tissue and stops disease specific integrin signaling. We believe past attempts to develop small molecules targeting integrins have in part failed due to a lack of sufficient understanding of these conformational changes and their impact on disease. We believe our MInT Platform has positioned us to apply our deep understanding of the biologic underpinnings of diseases linked to integrin dysfunction to develop a pipeline of novel integrin therapeutics.

The Morphic Integrin Technology (MInT) Platform

Given that the integrin target family consists of structurally and functionally related proteins, each cycle of the MInT Platform yields chemistry assets and biological data in our programs of interest while in parallel furthering our understanding of the structure and function of new integrin complexes. We believe this results in a rapid strategic compounding of knowledge and assets with each turn of the MInT design cycle. Our $\alpha_4\beta_7$ program produced its first development candidate over three years after program initiation. Our $\alpha_v\beta_6$ program took only two years to achieve the same goal, which we believe was due in part to insights we had gained on chemical features that optimized oral bioavailability, clearance and metabolic stability. The chemotypes and initial medicinal chemistry hits we discover become tools and compounds that can further our knowledge base around each individual integrin, which also extends to related integrins. For example, discovery efforts in $\alpha_v\beta_6$ led to starting points for $\alpha_v\beta_1$, $\alpha_v\beta_8$ and additional targets, directly enabling new programs and supporting collaboration efforts.

As shown in the graphic below, the iterative MInT design cycle consists of nine steps based on the three pillars of our MInT Platform: our proprietary ability to determine integrin structures, our tunable product candidate design engine, and our biology and disease translation capability.



Proprietary ability to determine integrin structures

We believe that an understanding of protein crystal structures enables more effective product candidate design. Integrins are difficult to characterize structurally because they are composed of many flexible domains and interdomain linkers (see Figure 1). Our unique position of integrin structural knowledge and cell lines, and access to proprietary protein reagents and know-how has allowed us to elucidate more than 150 proprietary structures for clinically important targets across nine of the 24 integrins. Our novel approach is based on combining our deep understanding of structural biology and how integrin protein conformation regulates function in disease. An example of this is in our $\alpha_4\beta_7$ program where the crystal structure of the drug binding site enables the design of novel ligands that bind at the interface of the α and β

subunits (Figure 2). This critical information at the molecular level directs our research to unlock the potential of this family of receptors and develop small molecules for targeting specific conformations of the integrin receptors.

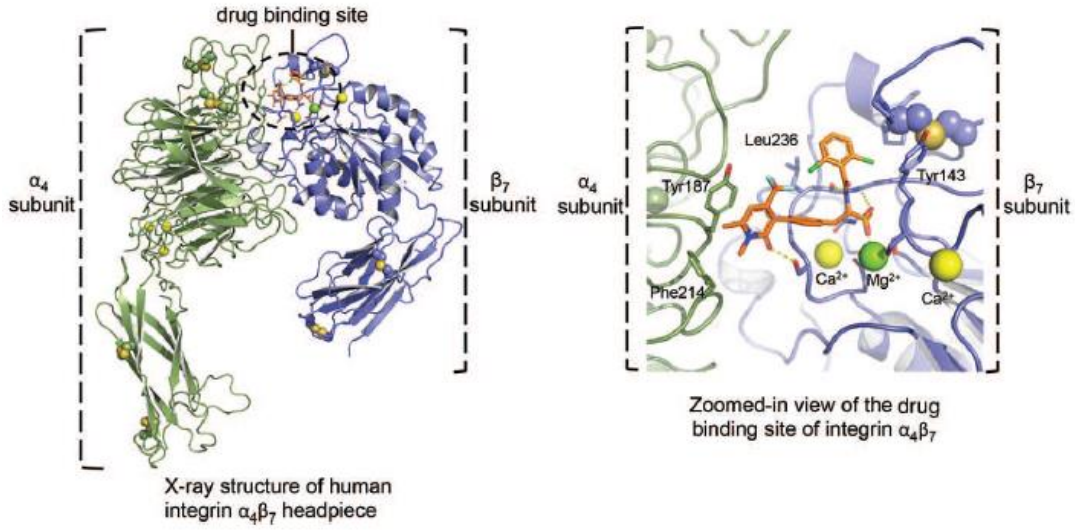


Figure 2: Left — X-ray crystal structural of the top portion of the heterodimer or headpiece of the human α 4β7 integrin receptor with the α-subunit on the left and β-subunit on the right. The drug binding site for this receptor is at the interface of the α and β subunits. Right — Zoomed in view of the drug binding site showing the key interactions responsible for regulation of protein conformation in this integrin. Data for structural rendering from: Yu, Y., Zhu, J., Mi, L.Z., Walz, T., Sun, H., Chen, J.-F., Springer, T.A. (2012). Structural specializations of α4β7 an integrin that mediates rolling adhesion. J. Cell Biol. 196, 131-146.

Tunable product candidate design engine

Proprietary Chemistry: We have significant know-how in the development of molecules that stabilize specific integrin receptor conformations, which supports our novel approach to the identification of oral integrin inhibitors. Today, our small molecule chemical library contains over 6,000 uniquely designed integrin modulators (inhibitors and activators), which continues to grow, and our drug design technology leverages our proprietary understanding of integrin target dynamics. When coupled with our deep understanding of the molecular mode of action of specific integrins, we believe we can design appropriate chemotypes for each integrin function. Further optimization of library compounds, combined with excellence in medicinal chemistry, enables the identification of potent, selective oral small molecule product candidates.

Exclusive Schrödinger Computational Chemistry Collaboration: We have a collaboration with Schrödinger, a leader in chemical simulation and *in silico* drug discovery, that is exclusive as to integrins. We believe this collaboration enables us to undertake accelerated drug discovery through design, iteration and optimization of leads using a variety of next-generation physics-based computational technologies. Our collaboration with Schrödinger enables us to design molecules with atomic precision utilizing advanced structure-guided drug design technology.

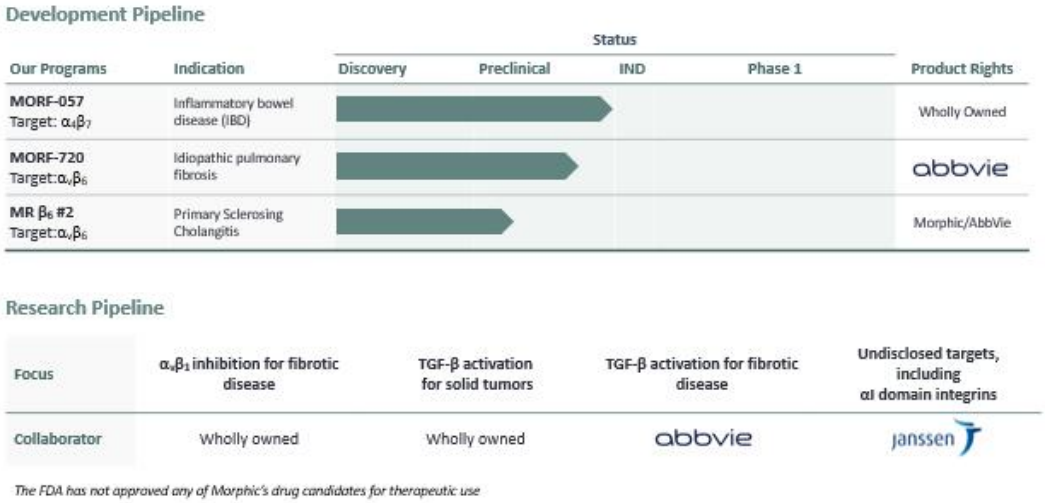
Our In Vitro Integrin Assay Panels: To identify novel inhibitors that stabilize disease-relevant receptor conformations, we have established a suite of robust *in vitro* assays that cover a majority of integrin family members. These proprietary in-house screening assays enable biochemical and functional characterization of potency and selectivity within the integrin family, serving as powerful tools in different stages of the drug design process.

Biology and disease translation capability

The MInT Platform is built upon a deep understanding of integrin biology in human diseases, including integrin tissues and a cell expression atlas. We have built a sophisticated and comprehensive suite of *in vitro*, *ex vivo*, and disease-specific *in vivo* assays designed to evaluate the pharmacological effects of integrin modulation and to gain additional insights into their mechanism of action. For example, in December 2019 we entered into a research collaboration with Engitix Ltd. to identify new MInT amenable targets in fibrostenotic IBD and strengthen our translational capabilities in IBD. The biological learnings from these assays have the potential to accelerate our work across multiple integrin discovery programs. We hope to strategically translate preclinical observations into our clinical development plans. These, along with our growing capabilities in pharmacokinetic and pharmacodynamic modeling, have enabled our discovery of integrin inhibitors that have the potential to impact human diseases of autoimmune, cardiovascular and metabolic diseases, fibrosis and cancer.

Our Pipeline Programs

We have conducted an analysis of opportunities for integrin inhibition in human disease on the basis of validating biology, safety, technology readiness and development feasibility. We have identified a number of actionable integrin targets across all four integrin families, and our initial focus is in high unmet medical need areas of autoimmune, cardiovascular and metabolic diseases, fibrosis and cancer. The following table summarizes key information about our current product candidates:



Our Lead Product Candidates

MORF-057: Our $\alpha_4\beta_7$-specific Integrin Inhibitor for Autoimmune Inflammation

We are advancing our $\alpha_4\beta_7$ integrin program, including lead candidate MORF-057, as a treatment for ulcerative colitis and Crohn's disease. Current medical management strategies focus on treating disease relapses and prolonging remission with immunomodulators and monoclonal antibody therapies. We believe our oral integrins have the potential, if approved, to offer a targeted and more convenient method of treatment for patients suffering from chronic gastrointestinal and gastroesophageal inflammatory diseases.

Background on Inflammatory Bowel Diseases

IBD is a group of chronic autoimmune and inflammatory conditions of the gastrointestinal tract that can have periods of relapse or remittance. Ulcerative colitis and Crohn's disease are the principal sub-types of IBD. In ulcerative colitis, the lining of the colon, or large intestine, becomes inflamed, resulting in the formation of ulcers, which may subsequently lead to bleeding and diarrhea. In Crohn's disease, inflammation may be presented segmentally, affecting some areas of the gastrointestinal tract while leaving other areas unharmed. According to a report by the Crohn's and Colitis Foundation, as of November 2014, there were approximately 907,000 people living with ulcerative colitis and 780,000 with Crohn's disease in the United States. The disease incidence is approximately 38,000 new cases per year of ulcerative colitis and 33,000 of Crohn's disease in the United States. According to Evaluate Pharma, as of December 31, 2018, the IBD market is estimated to be approximately $17.5 billion.

The mainstays of therapy over many years have been oral and topical salicylates and glucocorticoids, and various immunosuppressive agents. Anti-integrin antibody therapy for IBD was first introduced with the approval of the α_4 integrin inhibitor natalizumab for Crohn's disease, an indication approved following its initial approval for multiple sclerosis. Natalizumab therapy is associated with, and carries a black box warning for, progressive multifocal leukoencephalopathy, or PML, related to its $\alpha_4\beta_1$ inhibitory activity, which has limited its use in Crohn's disease. PML is a rare and often fatal viral disease characterized by progressive damage of the white matter of the brain at multiple locations. Vedolizumab, a monoclonal antibody inhibitor of the integrin $\alpha_4\beta_7$, is approved for the induction and maintenance of remission in late-line ulcerative colitis and does not carry a black box warning. Vedolizumab is also approved as a late-line option for Crohn's disease.

Overview of Pathway and Target Biology

Integrin $\alpha_4\beta_7$ binds to mucosal addressing cell adhesion molecule, or MAdCAM, which is expressed at a high level almost exclusively on the endothelial cells of the gut. Blockade of this interaction prevents immune cell entry into inflamed tissue in the gut and has been shown to be effective in treating IBD, as evidenced by the approval of vedolizumab.

Our Solution

We have generated oral small-molecule integrin therapeutics targeting $\alpha_4\beta_7$ intended to treat patients with ulcerative colitis and Crohn's disease. Our strategy is driven by our ability to discover oral therapies and our knowledge of how to minimize off-target risk of inhibiting $\alpha_4\beta_1$, which is implicated in PML. We believe this program represents an example of a target class with opportunities to differentiate from established therapies, utilizing our MInT Platform. We believe that safe and effective oral therapies have the potential to transform the lives of IBD patients in two distinct ways: (i) as an earlier line of therapy, and (ii) in combination with other agents in the IBD landscape.

In preclinical studies, our $\alpha_4\beta_7$ inhibitor molecules have exhibited high potency and selectivity for $\alpha_4\beta_7$, good oral absorption and pharmacokinetic properties suitable for twice daily dosing. We have completed preclinical studies of multiple $\alpha_4\beta_7$ inhibitors in which we established pharmacological proof of concept, including observed effects on T cell trafficking similar to a comparator $\alpha_4\beta_7$ antibody, DATK-32 (a rodent surrogate of vedolizumab). We have selected a development candidate, MORF-057, and expect an IND application to be filed in the middle of 2020.

Preclinical Data, Pharmacology and Biomarker Data

Using our proprietary MInT Platform, we have designed $\alpha_4\beta_7$ small molecule-inhibitors, including MORF-057, that are potent and have high selectivity for $\alpha_4\beta_7$ relative to other integrins, including $\alpha_4\beta_1$, as assessed by a suite of *in vitro* assays. Table 1 below shows measurements of the potency of MORF-057 as assessed in our cell adhesion assays, as compared to reference products vedolizumab and natalizumab, as well as AJM300, a product candidate being developed by a third party. We determined all of these potencies in our laboratories. The cell adhesion assay evaluated the ability of $\alpha_4\beta_7$ to bind to its ligand MAdCAM, and $\alpha_4\beta_1$ to its ligand VCAM *in vitro*. These assays have been shown to be useful in discovering drug candidates for IBD. IC50 values are commonly accepted measurements of drug potency.

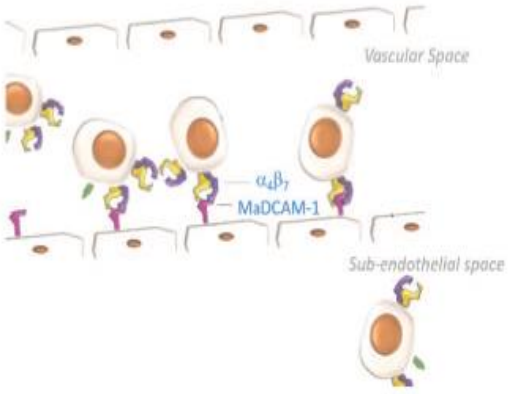
MORF-057 has been observed to be a highly potent $\alpha_4\beta_7$ inhibitor with a 3,303-fold selectivity in our cell adhesion assay as compared to $\alpha_4\beta_1$. MR b7#2 did not meet our development criteria and therefore we have discontinued development of this candidate.

Inhibitor	$\alpha_4\beta_7$ IC_{50}*	$\alpha_4\beta_1$ IC_{50}*	Fold selectivity
MORF-057	1.2 nM	>50 µM	>41,600
Natalizumab	0.15 nM	1.8 nM	12
Vedolizumab	0.059 nM	>180 nM	>3,060
BIO 5192	>50 µM	0.65 nM	$<1.3x10^{-5}$

**RPMI8866 and Jurkat cell lines used for $\alpha_4\beta_7$ and $\alpha_4\beta_1$, respectively.*

The *in vivo* activity of our $\alpha_4\beta_7$ inhibitor was also evaluated in a single dose acute pharmacodynamic model, where the impact of blocking the $\alpha_4\beta_7$ integrin on the trafficking of T lymphocytes to the gut was assessed in mice. The procedure of the T lymphocyte homing uses fluorescently labelled TK1 cells, which expresses high level of $\alpha_4\beta_7$ integrin on the surface and an *n* of 5 animals per group. A number of our compounds, including our development candidate MORF-057, have been evaluated in this assay to assess dose response (Figure 3). We observed a statistically significant response at all doses tested, and at the highest dose tested with both compounds, we observed our compound to be as potent as DATK32, a mouse surrogate of the $\alpha_4\beta_7$ antibody vedolizumab. In Figure 3 below, the right panel shows dose-dependent inhibition of the carboxyfloresce in succinimidyl ester, or CFSE, labeled T cells homing to mesenteric lymph nodes observed with our small molecule $\alpha_4\beta_7$ inhibitor and DATK32, a mouse surrogate of vedolizumab, in the assay with an *n* of 5 animals per group. All treatment groups showed a statistical significance of ***p<0.0001 compared to vehicle, using a one-way analysis of variance (ANOVA), followed by Bonferroni's multiple comparison test. MORF-057 exhibited good cell permeability *in vitro*, resulting in oral exposure in multiple preclinical models (rat = 39%, dog = >100%). We are progressing MORF-057 through IND-enabling studies and, based on its properties, we intend to advance MORF-057 into clinical development in 2020.

Homing into mLN
mean±SEM



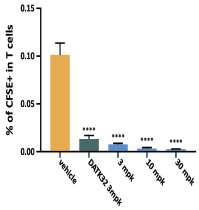


Figure 3: The panel on the left shows the mechanism of the $\alpha_4\beta_7$-expressing lymphocytes in IBD. The $\alpha_4\beta_7$-expressing lymphocytes traffic to the gut and adhere to MAdCAM, followed by extravasation and migration to the inflammation site. The panel on the right shows the results of the in vivo assay to detect activity of our product candidates as compared to a mouse surrogate of vedolizumab.

Translational biomarkers such as receptor occupancy, or RO, have been validated as a pharmacodynamics marker in preclinical studies and early clinical trials of vedolizumab. When a product candidate binds to $\alpha_4\beta_7$, it occupies the integrin ligand binding site and interferes with the ability of MAdCAM to bind and contribute to immune cell accumulation into the inflamed gut tissue. An assay that measures binding of the product candidate to $\alpha_4\beta_7$ in lymphocytes in circulating blood is termed a blood based- $\alpha_4\beta_7$ RO assay. We are planning to assess the relationships of pharmacokinetics, pharmacodynamics and RO of our two $\alpha_4\beta_7$ product candidates in a nonhuman primate study.

Clinical Development Overview

We expect that the early clinical development program will aim to demonstrate therapeutic engagement of $\alpha_4\beta_7$ by our product candidate, MORF-057. We intend to monitor inhibition of $\alpha_4\beta_7$ using a RO assay in blood as a marker of clinical activity.

We expect that a Phase 1a clinical program will be conducted in healthy volunteers, with single and multiple ascending dose trials designed to assess drug safety and pharmacokinetics. Additionally, our Phase 1a program will focus on finding doses of the product candidate that can achieve sustained RO.

We expect that our Phase 1b program will be conducted in patients with IBD to assess safety and pharmacokinetics, as well as RO as a pharmacodynamic marker of $\alpha_4\beta_7$ inhibition. We expect that patients will be treated with multiple ascending doses of the product candidate until a dose is reached at which sustained RO levels consistent with those of vedolizumab are observed. Once this dose is achieved, we expect that patients will be continued on treatment for a minimum of eight additional weeks. Assessments of disease activity will be conducted at baseline and at the completion of the treatment regimen. They may include flexible sigmoidoscopy with biopsy to assess colonic mucosa, fecal calprotectin, serum biomarkers and standardized scores of disease activity.

We anticipate reporting clinical data for MORF-057 in 2021.

MORF-720: Our $\alpha_v\beta_6$-specific Integrin Inhibitor Program for Fibrosis

Fibrosis is an intrinsic response to chronic injury that can progress toward excessive tissue scarring and organ failure, such as liver cirrhosis and renal failure. The lack of antifibrotic treatments that can halt or ameliorate the progression of disease represents an unmet medical need for patients with diseases, such as IPF, PSC, and NASH. The primary clinical indications for the $\alpha_v\beta_6$ program are IPF and late-stage liver fibrosis. AbbVie has an option to acquire worldwide development and commercialization rights for our $\alpha_v\beta_6$ programs in IPF and liver indications prior the commencement of clinical development.

Designed using our MInT Platform, our product candidate, MORF-720, is a highly potent inhibitor of $\alpha_v\beta_6$, with a single digit nM affinity in a cell-free isolated protein-binding assay as well as single digit nM in a cell-based functional assay, and has high selectivity for $\alpha_v\beta_6$ as compared to other integrins (selectivity is ≥50x in the cell free isolated protein-binding assay). MORF-720 seeks to stabilize the inactive bent closed conformation of the $\alpha_v\beta_6$ integrin and has exhibited antifibrotic activity in preclinical fibrosis models. MORF-720 also exhibited good cell permeability *in vitro*, resulting in oral exposure in multiple preclinical models.

MORF-720 has been observed to be very potent in a variety of *in vitro* and *ex vivo* assays. Because $\alpha_v\beta_6$-mediated TGF-β activation is a key driver of fibrogenesis, we believe the TGF-β activation assay is the most biologically relevant measure of a compound's *in vivo* efficacy. In this assay, we observed that MORF-720 was highly potent with an IC_{50} of less than 10 nM. Another assay that we believe is highly relevant is precision-cut liver slice *ex vivo* system using fibrotic livers, in which the expression of fibrogenesis-related genes, such as COL1A1, are measured following treatment with a compound. Precision-cut liver slice represents an *ex vivo* tissue culture technique that replicates the multicellular characteristics of whole liver *in vivo* as they contain all physiologically relevant cells, as well as intact intercellular and cell-matrix interactions. The IC_{50} value of MORF-720 in this *ex vivo* system was observed to have an IC_{50} of less than 10 nM.

The anti-fibrotic activity of MORF-720 was evaluated in a chronic 3,5-diethoxycarboncyl-1,4-dihydrocollidine, or DDC, diet-induced PSC-like liver fibrosis model as described earlier. We have observed that twice daily oral dosing of MORF-720 was associated with a statistically significant dose-dependent inhibition of fibrogenesis as measured by expression of the collagen gene COL1A1, reduction of collagen content as measured by hydroxyproline and improvement of liver function as measured by total plasma bilirubin levels, which was more favorable that the liver collagen content that we observed with an ALK5i, a TGF-βR1 inhibitor in development by a third party. Based on preclinical oral exposure data described above, we believe MORF-720 will, in humans, be suitable to support favorable dosing strategies.

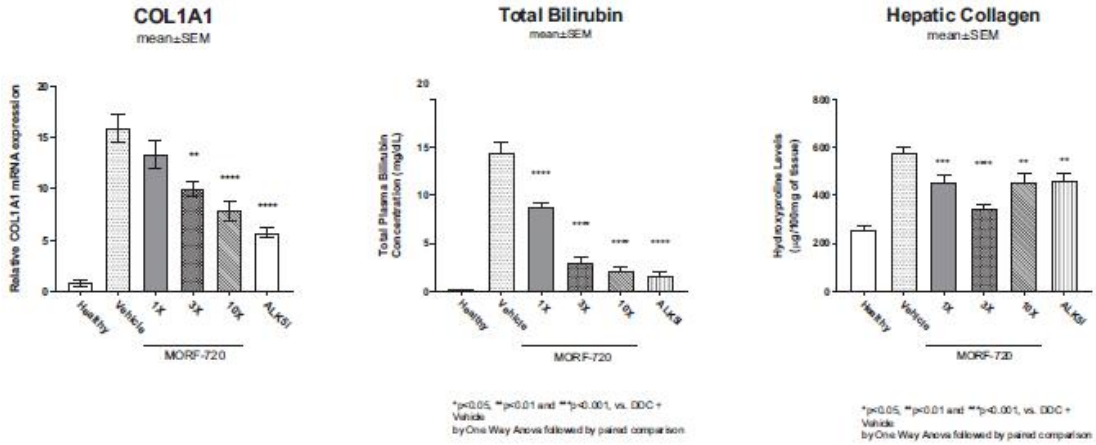


*Figure 4: We observed that MORF-720 was associated with dose-dependent reductions in liver fibrotic gene Col1A1 expression (Panel A), total plasma bilirubin (Panel B) and liver collagen content (Panel C) in chronic DDC mice. Statistical analysis: *p<0.05, **p<0.01, ***p<0.001, and ****p<0.0001 indicate statistical significance compared to DDC vehicle group by one-way ANOVA followed by paired comparison. Animal numbers: n=5 for Healthy Control, n=15 for Vehicle (Disease Control), and n=10 for all treatment groups.*

Background on Idiopathic Pulmonary Fibrosis

IPF is a life-threatening disease characterized by progressive fibrosis of the lungs leading to their deterioration and destruction. The cause of IPF is unknown. IPF primarily occurs in persons over 55 years old, with generally poor prognoses. Median survival time for IPF patients has been estimated to be two to five years from time of diagnosis. Most patients die from progressive loss of lung function. According to studies, conservative estimates of incidence ranges from three to nine cases per 100,000 per year for Europe and North America.

The current medical treatment strategy for IPF aims to slow disease progression and improve quality of life, as no medical therapies have been found to cure IPF. U.S and European regulatory agencies have approved pirfenidone (marketed as Esbriet) and nintedanib (marketed as Ofev) for the treatment of mild to moderate IPF. Both pirfenidone and nintedanib have been shown to slow the rate of functional decline in IPF and are viewed as the standard of care worldwide. While the regulatory approval of these drugs represents a significant advancement for IPF patients, neither drug improves lung function, and the disease continues to progress in most patients. Moreover, the adverse effects associated with these therapies includes diarrhea and liver function test abnormalities with nintedanib and nausea and rash with pirfenidone. The last line of treatment is lung transplantation, but many patients die while awaiting a transplant, as donors are limited.

Background on Primary Sclerosing Cholangitis

PSC is a rare, serious, chronic cholestatic liver disease characterized by a progressive, autoimmune-based destruction of bile ducts with eventual onset of cirrhosis. PSC is often complicated by the development of malignancies, the most common being cholangiocarcinoma, as well as complications involving the biliary tree, including cholangitis, and ductal strictures and gallstones, which may require frequent endoscopic or surgical interventions. The true prevalence of ulcerative colitis in the patients with PSC is estimated to be 90 percent. PSC is usually a progressive disorder that ultimately leads to complications of cholestasis and hepatic failure. Median survival without liver transplantation after diagnosis is 10 to 12 years, depending upon stage of the disease at the time of diagnosis. According to studies, the estimated incidence of PSC is one case per 100,000 people in the U.S.

The current medical treatment strategy for PSC is limited. The FDA has not approved any therapies for the treatment of PSC. Liver transplant is currently the only treatment shown to improve clinical outcomes. However, the post-transplant recurrence rate of PSC has been shown to be as high as 20%. First-line treatment is typically off-label ursodeoxycholic acid, UDCA, although UDCA has not been shown to improve transplant-free survival and, at high doses, has been associated with increased risk for serious complications.

Overview of Pathway and Target Biology

Fibrosis is a major contributing factor in all of these diseases, with TGF-β being a recognized driver. Tissue release of active TGF-β is mediated by α_v integrins, including $\alpha_v\beta_6$. We believe that targeting $\alpha_v\beta_6$ will result in local inhibition of TGF-β to achieve anti-fibrotic effect in tissues, while limiting collateral unwanted effects associated with pan-TGF-β inhibition. An $\alpha_v\beta_6$ inhibitor may prevent the release of activated TGF-β thereby abrogating a main driver of fibrosis in IPF. Pharmacological inhibition of $\alpha_v\beta_6$ has been observed to be associated with anti-fibrotic activity in four lung fibrosis models, including a bleomycin-induced lung fibrosis model.

Our Integrin Approach to Fibrosis

We have developed oral small-molecule integrin therapeutics designed to have high potency and selectivity for $\alpha_v\beta_6$, oral absorption and favorable pharmacokinetic properties. In the case of $\alpha_v\beta_6$, we believe it is critical to stabilize a fully inactive state in order to achieve the desired activity, and all of our $\alpha_v\beta_6$ programs thus seek to stabilize an inactive

bent-closed state of the receptor. This approach is supported by studies that suggest that a significant population of the receptors exists in this inactive closed form in native tissue.

We investigated the impact of differences in conformational state in a preclinical, 3, 5-diethoxycarbonyl-1, 3-dihydrocollidine, or DDC, model of liver fibrosis. The opening compound is expected to shift the $\alpha_v\beta_6$ integrin further towards the extended open conformation while the closing compound shifts the $\alpha_v\beta_6$ integrin to the closed conformation (Figure 5, Panel A). In this model, we observed that a tool compound (closing compound) of the bent closed state of $\alpha_v\beta_6$ not only statistically significantly inhibited TGF-β-mediated downstream genes related to fibrosis, such as the collagen gene Col1a1, as compared to the disease state but that it also statistically significantly normalized other fibrosis-related pathways such as connective tissue growth factor, or CTGF, and matrix metalloproteinase-3, or MMP3 as compared to the disease state. On the other hand, we observed that a tool compound (opening compound) of the extended open activated conformation of the integrin did not have these additional benefits on CTGF or MMP3 (Figure 5). CTGF has important roles in many biological processes, including fibrosis and several forms of cancers, while MMP3 is known to be involved in tissue remodeling and has been implicated in increased susceptibility to diseases where hyperpermeability in endothelium or epithelium would result in the exacerbation of diseases.

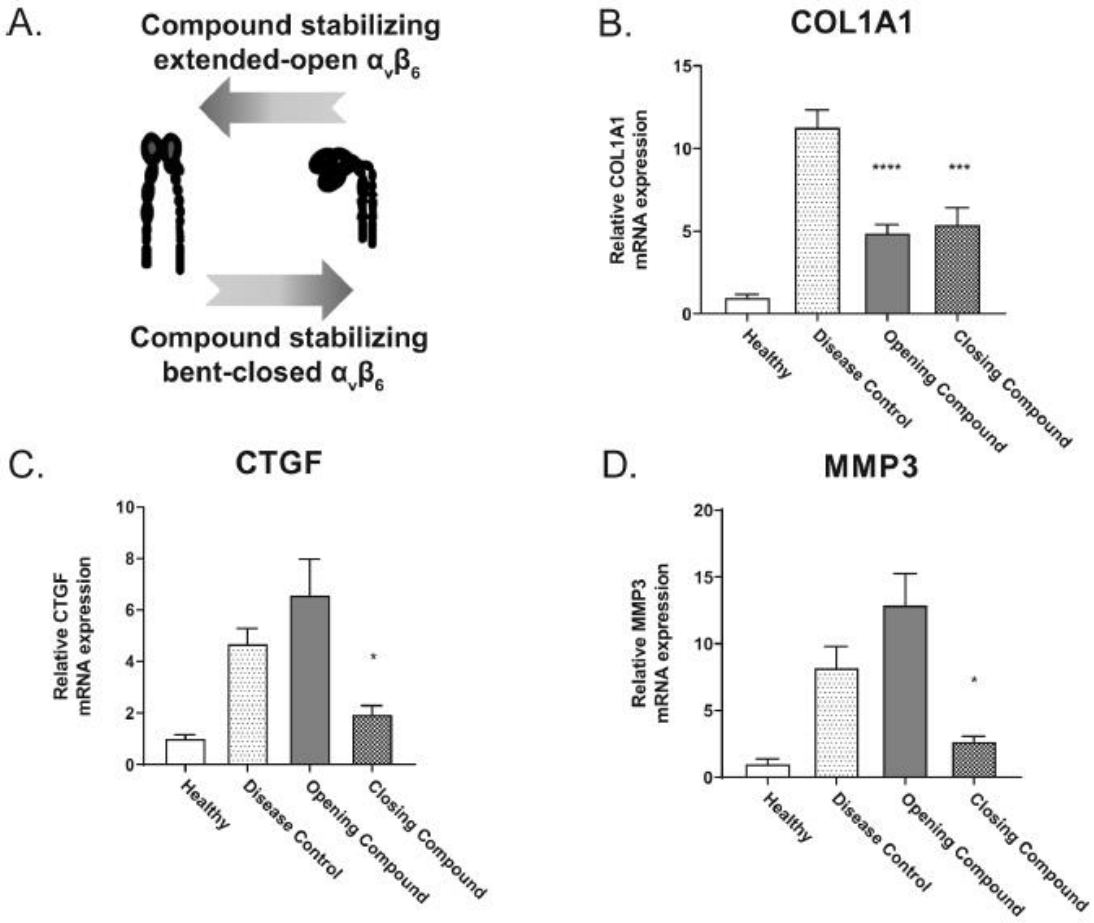


Figure 5: Differential effects of α $_v\beta_6$ inhibitors that stabilize the extended-open and bent-closed conformation in an acute liver fibrosis model on collagen 1, CTGF and MMP3. The opening inhibitor is expected to shift the $\alpha_v\beta_6$ integrin further towards the extended open conformation while the

*closing inhibitor shifts the $\alpha_v\beta_6$ integrin to the closed conformation (Panel A). While we observed that both compounds inhibited TGF-β downstream fibrosis genes such as collagen 1 (Panel B), only the bent closed inhibitor was observed to decrease the expression of CTGF (Panel C) and MMP3 (Panel D), both of which are involved in various diseases. Statistical analysis: *p<0.05, **p<0.01, and ***p<0.001, vs. Disease control by one-way ANOVA followed by paired comparison.*

We have also observed antifibrotic activity of our small-molecule- inhibitors in a variety of rodent fibrosis models, as described in this section on our Morphic tool compounds. Specific data on our development candidate MORF-720 is discussed below. Testing of MORF-720 is still ongoing and Figures 4 through 8 in this section do not incorporate data regarding MORF-720, but we believe that the data from our tool compounds are comparable to our MORF-720 product candidate. We examined the effects of one of our $\alpha_v\beta_6$ tool compounds in an intratracheal-bleomycininduced-IPF mouse model, in which mice develop serious lung fibrosis. Therapeutic dosing of a Morphic $\alpha_v\beta_6$ inhibitor was observed to improve lung fibrosis in intratracheal -bleomycin-induced lung fibrosis model in mice in comparison to pirfenidone. As shown in the left panel of Figure 5 below, we observed that our compound was associated with statistically significantly improved lung fibrosis, as measured by Ashcroft scores, as compared to pirfenidone. We also examined the effects of one of our $\alpha_v\beta_6$ compounds and an ALK5 inhibitor in lung fibrosis in a scleroderma model induced by mini-pump infusion of bleomycin for 28 days. The preliminary results are shown in the right panel of Figure 6. We observed that our compound was associated with a statistically significant reduction of collagen content in the lung to near normal lung collagen content as compared to the disease state, which was equivalent to or more favorable than the lung collagen content that we observed with an ALK5i, a TGF-βR1 inhibitor published by a third party.

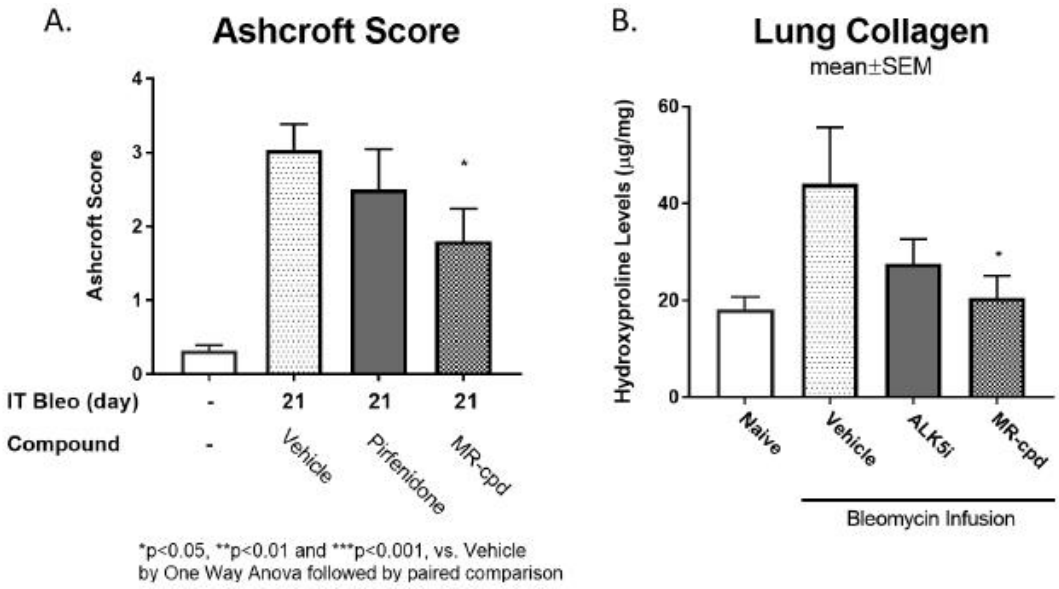


Figure 6: Effects of Morphic α $_v\beta_6$ inhibitors in lung fibrosis models. Panel A: Therapeutic dosing of a Morphic $\alpha_v\beta_6$ inhibitor was observed to improve lung fibrosis in intratracheal-dosed bleomycin-induced lung fibrosis model in mice in comparison to pirfenidone. Formalin-fixed mouse lung lobes were sectioned and stained. Lung sections were scored according to the modified Ashcroft scale. Scores for five representative 200x microscopic fields per sample were averaged to obtain a mean score for each animal. Two-tailed tests were used, and significance was set at p≤0.05 for all tests. Panel B: The effects of prophylactically dosed $\alpha_v\beta_6$ compound and an ALK5i inhibitor in a fibrosis model induced by bleomycin through mini-pump infusion for 28 days. Mouse lung fibrosis was measured through collagen content (hydroxyproline concentration). Two-tailed tests were used, and significance was set at p: 0.05 for all tests. Animal numbers per group: n=10 for Naïve (Healthy Control), n=12 for Vehicle (Disease Control), n=8 for Pirfenidone treatment, n=9 for all other groups.

The therapeutic potential of our $\alpha_v\beta_6$ inhibitors has also been evaluated in a diet-induced PSC-like biliary fibrosis model that cause mice to develop advanced biliary fibrosis. We observed that all of our $\alpha_v\beta_6$ compounds evaluated in this model were associated with improvements in liver function and fibrosis. As shown in Figure 6 (left), we observed that our tool $\alpha_v\beta_6$ inhibitor was associated with statistically significant nearly normal the total plasma bilirubin levels as compared to

the disease state. As shown in Figure 7 (right), we also observed that our $\alpha_v\beta_6$ inhibitor was associated with abrogated liver fibrosis as shown by Sirius Red staining. The activity of our small molecule was observed to be substantially better than a mouse version of BG00011, an anti-$\alpha_v\beta_6$ antibody that was in development by Biogen Inc ("Biogen"). Biogen recently terminated a Phase 2 study of its monoclonal antibody targeting $\alpha_v\beta_6$, citing safety concerns.

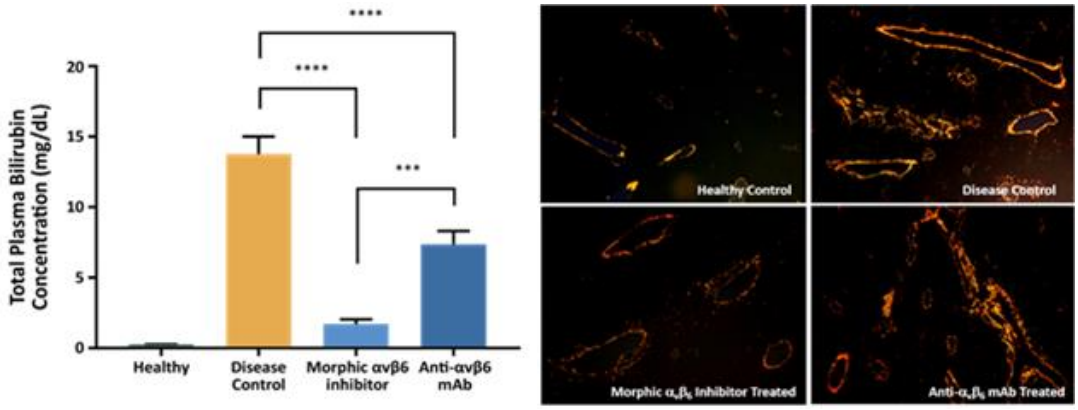


Figure 7: Our $\alpha_v\beta_6$ inhibitor activity in a chronic DDC-induced PSC-like biliary fibrosis model in comparison to an anti-$\alpha_v\beta_6$ antibody (Panel A). Collagen deposition in the mouse liver as detected by Sirius Red staining (Panel B). Animal numbers per group: n=10 for all groups.

The differential effects between our tool $\alpha_v\beta_6$ small-molecule inhibitors and the anti-$\alpha_v\beta_6$ antibody were also observed in a surgically created unilateral ureteral obstruction, or UUO, mouse model, in which the mice developed renal fibrosis. We observed that the blockade of the $\alpha_v\beta_6$ integrin with our compound was associated with reduced kidney fibrosis, as shown in Figure 8, and that our $\alpha_v\beta_6$ inhibitor exhibited greater activity than the anti-$\alpha_v\beta_6$ antibody.

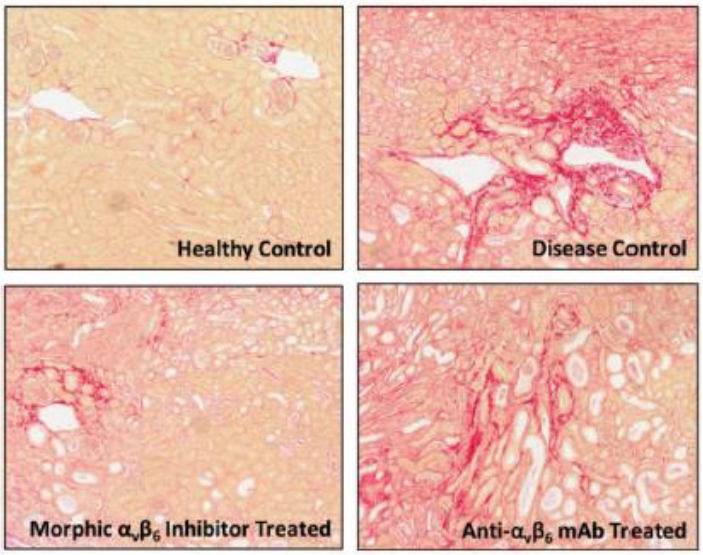


Figure 8: Our tool $\alpha_v\beta_6$ small-molecule inhibitor and anti-$\alpha_v\beta_6$ mAb 3G9 were both observed to reduce kidney fibrosis in UUO model after 14-day treatment. Collagen was stained by Sirius Red. Images were taken under bright-field microscopy.

A critical biochemical change associated with TGF-β pathway activation is an increase in the ratio of cellular phosphorylated SMAD, or pSMAD, to cell protein. The SMAD is a downstream protein of TGF-β signaling pathway, which is phosphorylated upon activation of TGF-β levels of TGF-β pathway inhibition that correspond to active doses in animals (Figure 9).

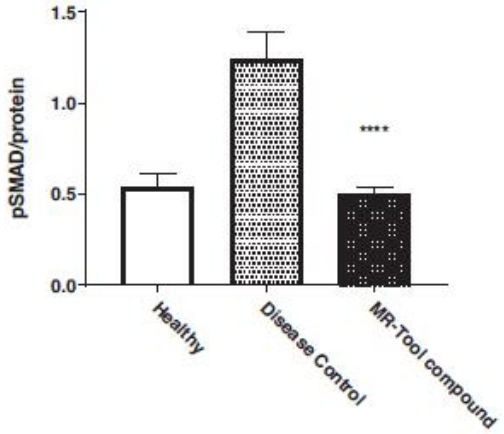


*Figure 9: We observed that our compound was associated inhibition of TGF-β signaling as illustrated by a decrease in the ratio of hepatic phosphorylated SMAD to total protein in chronic DDC mice. ****p<0.0001 indicates statistical significance compared to DDC vehicle group by one-way ANOVA followed by paired comparison.*

Clinical Development Overview

Early clinical development of $\alpha_v\beta_6$ inhibitor

The goal of our Phase 1a study comprising single and multiple dose ascending trials in healthy volunteers will be to demonstrate safety, tolerability and pharmacodynamic activity of MORF-720 and may include imaging of its binding to $\alpha_v\beta_6$ and measurement of downstream markers of its inhibitory activity on TGF-β signaling.

The presence of $\alpha_v\beta_6$ integrin in the lung may be assessed by positron emission tomography, or PET, scanning imaging using a specific probe that binds to the $\alpha_v\beta_6$ integrin. Since MORF-720 is designed to inhibit binding of this probe competitively, we believe the change in the PET signal after MORF-720 administration in human trials will be indicative of its RO of $\alpha_v\beta_6$.

We also plan to use the pSMAD/tSMAD ratio as a pharmacodynamic marker of MORF-720's activity on TGF-β signaling.

$\alpha_v\beta_6$ inhibitor for treatment of Idiopathic Pulmonary Fibrosis (IPF)

As part of our collaboration with AbbVie, they have an option to license this program at IND for future development and commercialization, and if they exercise this option, they will control clinical development of MORF-720, or a backup molecule, and will pursue it in IPF.

In November 2019, we received feedback from the FDA which required us to conduct one additional toxicology study before submitting an IND for MORF-720. Additionally, we are pursuing a backup molecule for idiopathic pulmonary fibrosis, or IPF, in accordance with the terms of our collaboration agreement with AbbVie. Based on the request for an additional preclinical study by the FDA, we expect to file an IND for MORF-720 in the second half of 2020.

We expect the Phase 1b clinical program will assess MORF-720's safety, tolerability and pharmacokinetics, and may include PET RO imaging and pSMAD/tSMAD analysis. We expect that multiple ascending doses of MORF720 will be administered to IPF patients for two-week intervals until a sustained inhibition of $\alpha_v\beta_6$ is achieved. Patients may be continued on treatment with this dose of MORF-720 for additional 12-24 weeks.

Assessments of disease activity in Phase 1b clinical program may include, but are not limited to, quantitative high resolution-computed tomography with computer aided algorithm analysis and assessments of forced vital capacity and diffusion capacity.

$\alpha_v\beta_6$ inhibitor for treatment of Primary Sclerosing Cholangitis (PSC)

As part of our collaboration with AbbVie, they have an option to license this program at IND for future development and commercialization, and if they exercise this option, they will control clinical development of MORF-720 and will pursue it in IPF. The liver collaboration compound MR β6 #2 will be pursued in liver indications, including PSC. If AbbVie does not exercise its option with respect to MORF-720, we will have an opportunity to develop either MORF-720 or MR β6 #2 in PSC.

The Phase 1b clinical development program will aim to demonstrate safety, tolerability, pharmacokinetics and the therapeutic engagement of the $\alpha_v\beta_6$ integrin by the compound. The Phase 1 clinical plan is to perform multiple ascending dose trials in the patients with PSC. The approach of directly starting clinical trials in the target patient populations may be acceptable given that $\alpha_v\beta_6$ inhibitors are expected to have already been tested in Phase 1 trials in healthy volunteers and IPF patients. Pharmacodynamic assessments may include, but are not limited to, serum biomarkers of cholestasis, serum biomarkers of fibrosis, magnetic resonance elastography, and magnetic resonance cholangiography.

Additional Preclinical and Discovery Efforts

Integrin modulator program for immuno-oncology

The involvement of the TGF-β pathways and extracellular matrix in cancer has been publicly reported by the scientific community. We seek to block the TGF-β pathway through antagonizing TGF-β-activating integrins in the tumor microenvironment which we believe would both inhibit tumor growth directly and inhibit down-regulation by TGF-β of immune responses and thereby also enable productive anti-tumor immune responses. This program aims to deliver an oral small-molecule integrin modulator as an immuno-oncology therapy. The target is expressed in solid tumor and tumor stroma cells, including both immune and non-immune cells. The integrin modulator is expected to have several mechanisms of action, which include the blockade of regulatory T cell formation through dendritic cells, the modulation of immune suppressive tumor environment through inhibition of local TGF-β activation and the increase of immune cell infiltration through tumor microenvironment remodeling. For this program, chemical matter has advanced thanks to synergistic structure activity relationship, or SAR, screening with other integrin modulator programs. The crystal structure of the target integrin has been elucidated for the first time in the field using our MInT Platform. Several of our compounds have been co-crystalized to fuel our understanding of the features driving compound selectivity and potency. Target validation and translational biology efforts are underway using small-molecule inhibitors.

New anti-fibrosis programs

We are pursuing additional integrin modulator programs for fibrosis-related indications such as NASH, cirrhosis, and pulmonary arterial fibrosis. Due to the role of integrins in TGF-β activation, mechano-transduction, cell migration and cell proliferation, integrins may trigger different pathways to initiate or exacerbate fibrosis under various pathologic conditions. Our strategy has enabled the identification of small molecules of multiple integrin targets that allow in-depth interrogations of these mechanisms. The $\alpha_v\beta_1$ integrin is an emerging target for fibrosis based on literature and our internal data. The $\alpha_v\beta_1$ heterodimer can be detected in hepatic stellate cells and fibroblasts, especially when they are activated. In human tissues, increase in $\alpha_v\beta_1$ dimerization is observed in IPF, chronic kidney disease, or CKD, and NASH tissues. While our team continues to investigate the mechanisms of action of $\alpha_v\beta_1$ in fibrosis, we have generated crystal structures and advanced chemical matter for this target. These programs are at different discovery stages, with at least one of them expected to transition to lead optimization by the fourth quarter of 2019. AbbVie has an option to

acquire worldwide development and commercialization rights for this program prior the commencement of clinical development.

Integrin modulators targeting additional receptors

Our research collaboration with Janssen has strategically expanded the targets that our MInT Platform addresses, including αI integrins and modulators that are both antagonists and agonists. Several αI integrins play critical roles in immune cell tissue retention, regulation of collagen stiffness or cell attachment in extracellular matrix. Aberrant expression and function of these integrins have been implicated in a variety of diseases.

License Agreements

AbbVie Agreement

In October 2018, we entered into a research and development collaboration with AbbVie designed to advance a number of our oral integrin therapeutics for fibrosis-related indications.

Under the terms of the agreement, AbbVie paid us an upfront payment of $100.0 million for research and development activities, and we provided AbbVie with exclusive license options on product candidates directed at a number of targets. For each compound, we will conduct research and development activities through the completion of IND-enabling studies, at which point AbbVie may pay a license fee of $20.0 million, on a compound-by-compound basis, to exercise its exclusive license option and assume responsibility for global development and commercialization. We are also eligible for clinical and commercial milestone payments and tiered royalties from high single digit to low teens on worldwide net sales on a product-by-product and country-by-country basis for each licensed product until the later of (i) the expiration of the last valid claim within the royalty bearing patents covering such product in such country for so long as a generic product for such licensed product is not available in such country, (ii) ten years after the first commercial sale of such product in such country and (iii) the expiration of any other regulatory commercial exclusivity period in such country. In addition, for certain compounds for which we have completed IND-enabling studies and which meet certain advancement criteria for a liver fibrosis indication, we have the option to commit to share development costs in exchange for an increased fixed royalty rate. We may exercise this option following completion of the first Phase 2b clinical trial for the relevant product.

With respect to certain additional integrin targets, we have also granted AbbVie a fully paid up, irrevocable and one-time (with limited exceptions) right of first negotiation to obtain an exclusive license to develop and commercialize licensed compounds directed to such targets, and corresponding licensed products, in consideration for additional payments to be negotiated by the parties.

We and AbbVie have each agreed to certain exclusivity obligations under the agreement. In particular, we have agreed not to develop, either alone or with any third party, any product directed to a target for which we have granted AbbVie an exclusive option until the expiration of the agreement or, if AbbVie does not exercise an option, the end of the option period for such target.

AbbVie may terminate the agreement in its entirety, on a country-by-country basis, or on a target-by-target basis (for each target for which AbbVie has exercised an option), at any time and without cause, upon 180 days' prior written notice to us. Additionally, AbbVie may terminate the agreement on a target-by-target basis (for each target for which AbbVie has exercised an option) immediately upon for any safety reason. Either party may terminate the agreement for an uncured material breach by the other party or in the case of the other party's insolvency.

Prior to this collaboration, AbbVie Ventures was an investor in our Series A and Series B financings.

Janssen Agreement

In February 2019, we entered into an agreement with Janssen, to discover and develop novel integrin therapeutics for patients with conditions not adequately addressed by current therapies. The Janssen collaboration focuses on three

integrin targets, each target the subject of a research program, with the ability to substitute up to two integrin targets not explored by us.

Under the terms of the Janssen Agreement, on a research program-by-research program basis, the companies will collaborate through preclinical development to identify and advance candidates. Upon completing IND-enabling studies, on a research program-by-research program basis, Janssen may exercise an exclusive option to obtain an exclusive license with respect to the target that is the subject of the research program, including all licensed compounds that are the subject of the applicable research program, and then Janssen will be responsible for global clinical development and commercialization. In consideration of the rights granted, Janssen paid us an upfront fee of $10.0 million for each of the first two research programs, and will pay us an additional $5.0 million fee upon commencement of the third research program and fund research activities. In addition, on a research program-by-research program basis, we may be eligible to receive up to an additional $10.0 million in payments for late lead candidate optimization activities and Janssen's exercise of its exclusive option for such research program. We are eligible to receive up to $729.0 million in the aggregate from the collaboration in upfront, option and milestone payments, as well as royalties on net sales. We will also receive, on a product-by-product and country-by-country basis, mid-single digit royalties (subject to royalty adjustments with aggregate floors) on worldwide net sales for any products resulting from the collaboration until the later of (i) the expiration of the last valid claim within the royalty bearing patents covering such product in such country and (ii) ten years after the first commercial sale of such product in such country.

In the event that Janssen does not exercise an option for a research program, and we have completed a POC clinical trial for a product that was the subject of such research program, then Janssen will have an exclusive right of first negotiation to negotiate the terms of a definitive agreement pursuant to which Janssen would be granted exclusive rights to develop and commercialize such product. In addition, if we have not completed a POC clinical trial for a product that was the subject of such research program and we make or receive a bona fide offer from a third party to license or transfer the rights to develop and commercialize such product, then under certain circumstances Janssen will have an exclusive first right to negotiate the terms of a definitive agreement pursuant to which Janssen would be granted exclusive rights to develop and commercialize such product.

Under the Janssen Agreement, we have agreed to certain exclusivity obligations, including not to exploit, either alone or with a third party, any molecules that are intended to bind to any of the targets that are the subject of a research program, and also not to conduct clinical trials for, manufacture or commercialize compounds synthesized by us during our research activities in patients with chronic kidney disease or acute kidney injury for three years after Janssen's exercise of a first option. The Janssen Agreement will expire, on a research program-by-research program basis, upon (i) the expiration of the option period for such research program, if Janssen does not exercise its option for such research program, or (ii) the expiration all royalty terms for all products that are the subject of the research program, if Janssen does exercise its option for such research program. In addition, Janssen may terminate the agreement in its entirety or on a research program-by-research program basis or country-by-country basis at any time and for any reason, upon 60 days' advance written notice to us. Either party may terminate the agreement on program-by-research program basis for an uncured material breach by the other party or in the case of the other party's insolvency.

Schrödinger Agreement

In June 2015, we entered into a collaboration agreement (as amended) with Schrödinger, or Schrödinger Agreement, to explore drug targets selected by us. Under the collaboration, Schrödinger will use its technology platform to perform virtual screens, and we and Schrödinger will collaborate to facilitate prioritization of targets, perform target validation and analysis, identify leads and perform lead optimization. Under the terms of the agreement, Schrödinger will exclusively work with us on integrin targets during the term of the agreement. In consideration for its performance of activities under the collaboration, Schrödinger received approximately 3.4 million units of Series Seed preferred units. In addition, with respect to compounds identified as part of the collaboration, Schrödinger may be eligible to receive certain payments from us related to development milestones, not to exceed in the aggregate, on a target-by-target basis, a low six-figure payment upon initiation of lead optimization and on a compound-by-compound basis, $3.1 million, as well as royalties in the low single digits on sales of products containing such compounds. In addition, we have agreed to pay Schrödinger a percentage, in the mid-single digits, of certain payments we receive from third parties in connection with the licensing or transfer of the rights to exploit such compounds to such third parties, including a one-time fee of $1.0

million paid in 2019. Schrödinger may terminate the Schrödinger Agreement under certain circumstances, including if a certain number of developmental milestones have not been achieved by us within a certain timeframe.

Children's Medical Center Corporation Agreement

In October 2015, we entered into an exclusive license agreement (as amended) with CMCC, or CMCC Agreement, relating to technology on inhibiting integrins developed by Dr. Springer during the course of his employment at Boston Children's Hospital, an affiliate of CMCC. Under this agreement, we have an exclusive license under certain patent rights, and a non-exclusive license under certain know-how, owned by CMCC to develop and commercialize products worldwide for any therapeutic or diagnostic use in humans and veterinary applications. We also have the option to add new patent rights and know-how generated by the laboratory of Dr. Springer within a specified time period after the effective date of the CMCC Agreement to that agreement for additional payments consistent with fair market value. In consideration of the license grants, upon execution of the CMCC Agreement we issued CMCC a number of shares of common stock representing 6% of the issued and outstanding units on a fully diluted basis. We also paid CMCC an upfront license issue fee of $50,000, and reimbursed CMCC for certain patent prosecution costs. We have also agreed to pay CMCC a license maintenance fee for the first three years after the effective date of the CMCC Agreement, certain development milestones, a percentage of sublicensing income we may receive, and running royalties in the low single digits on net sales of licensed products.

Under the CMCC Agreement, we have agreed to use commercially reasonably efforts to bring one or more licensed products to market, and to implement activities in a development plan within the timeframes set forth therein. In addition, if we fail to meet one or more specific developmental milestones, and do not take appropriate corrective action, then CMCC shall have the right to terminate the agreement.

Intellectual Property

Our success depends, in part, on our ability to protect (i) our intellectual property related to our product candidates and related methods, and (ii) our MInT Platform for generating integrin structures and modulators of those structures. Our success also depends on having the freedom to operate to enable commercialization of our product candidates, if approved, and preventing others from infringing our patent rights. We protect our MInT Platform using trade secrets, proprietary know-how, and, on rare occasion, patents. We protect our small molecule products using patents, and our policy is to seek product patent protection in key jurisdictions, including the United States, major European countries, and other jurisdictions we deem appropriate or as required by our collaboration agreements.

We file patent applications with respect to claims to compositions comprising our small-molecule inhibitors that modulate integrin activity, the compounds themselves, the use of such compounds to treat disease, as well as related manufacturing methods.

Patent Rights

We have exclusively licensed one U.S. patent and related, subsequent pending U.S. patent applications from CMCC with claims relating to modified integrin polypeptides and modified integrin polypeptide dimers. The licensed U.S. patent and any other U.S. patents issuing from the licensed pending U.S. divisional patent application or any other related licensed U.S. patent applications that may be filed in the future are expected to expire August 6, 2035, absent any adjustments or extensions. In addition, we rely extensively on trade secret protection for our MInT Platform, which extends beyond the initial integrin technology licensed from CMCC.

As of December 31, 2019, we solely owned various pending patent applications with respect to compositions-of-matter and methods of use for treating therapeutic indications related to the $\alpha_4\beta_7$ and $\alpha_v\beta_6$ integrins. These are discussed below.

For our $\alpha_4\beta_7$ program compounds, we own one patent family comprising four pending applications (one international patent application and national patent applications in the United States and two other countries) which, if granted, are expected to expire in April 2039, absent any surrendered term, adjustments or extensions. In addition, we also own a second pending U.S. provisional patent application on additional compounds (including MORF-057) which can provide

the priority patent filing for future U.S. and global patent applications that, if granted, are expected to expire in October 2040, absent any surrendered patent term, adjustments or extensions.

For our $\alpha_v\beta_6$ program compounds, we own four patent families (including at least one to MORF-720) comprising a total of thirteen pending patent applications (four international patent applications, and pending patent applications in the United States, Europe and other jurisdictions), each of which, if granted, would expire in August 2039, absent any surrendered term, adjustments or extensions. In addition, we own two other patent families comprising twenty-three pending patent applications (national patent applications in the United States, Europe and other national jurisdictions), which, if granted, are expected to expire in February 2038, absent any surrendered term, adjustments or extensions.

Intellectual Property Protection

We cannot predict whether the patent applications we pursue will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide any proprietary protection from competitors. Further, any issued patents may expire before the expected expiration dates disclosed above due to actions taken during patent prosecution, such as submission of a disclaimer surrendering the term of a patent beyond a certain date. Even if our pending patent applications are granted as issued patents, those patents, as well as any patents we license from third parties, may be challenged, circumvented or invalidated by third parties. While there are currently no contested proceedings or third-party claims relating to any of the patent applications described above, we cannot provide any assurances that we will not have such proceedings or third-party claims at a later date or once any patent is granted.

The term of a patent depends upon the legal term of patents in the particular country in which it is obtained. In most countries in which we file, the patent term is 20 years from the earliest date of filing a non-provisional patent application. In the United States, the term of a patent that covers an FDA-approved drug may be eligible for patent term extension, which permits in some cases restoration of patent term as compensation for patent term lost during the FDA regulatory review process. In certain circumstances, the Hatch-Waxman Act permits a patent term extension of up to five years beyond the unextended expiration date of the U.S. patent. The length of the patent term extension is related to the length of time the approved drug is under regulatory review. Patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, and only one patent applicable to an approved drug may be extended. Provisions are available in Europe and other foreign jurisdictions to extend the term of a patent that covers an approved drug, or provide an additional period of protection for the approved pharmaceutical product following expiry of the patent. In the future, if our products receive FDA approval, we expect to apply for patent term extensions on patents covering those products. We plan to seek patent term extensions to any of our issued patents in any jurisdiction where these are available; however, there is no guarantee that the applicable authorities, including the U.S. Patent and Trademark Office in the United States and the national patent offices in Europe, will agree with our assessment of whether such extensions should be granted, and, if granted, the length of such extensions.

In addition to our reliance on patent protection for our inventions, product candidates, and research programs, we also rely on trade secret protection for our confidential and proprietary information. For example, certain elements of our MInT Platform may be based on unpatented trade secrets that are not publicly disclosed. Although we take steps to protect our proprietary information and trade secrets, including through contractual means with our employees and consultants, third parties may independently develop substantially equivalent proprietary information and techniques, or otherwise gain access to our trade secrets or disclose our technology. Thus, we may not be able to meaningfully protect our trade secrets. It is our policy to require our employees, consultants, outside scientific collaborators, sponsored researchers, and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements provide that all confidential information concerning our business or financial affairs developed or made known to the individual or entity during the course of the party's relationship with us is to be kept confidential, and not disclosed to third parties except in specific circumstances. In the case of employees, the agreements provide that all inventions conceived by the individual, and which are related to our current or planned business or research and development or made during normal working hours, on our premises or using our equipment or proprietary information, are our exclusive property. In addition, we take other appropriate precautions, such as physical and technological security measures, to guard against misappropriation of our proprietary technology by third parties. We have also adopted policies and conduct training that provides guidance on our expectations and practices to protect our trade secrets.

Manufacturing

Currently, all of our clinical manufacturing facilities for clinical drug manufacturing, storage, distribution or quality testing is outsourced to third-party manufacturers. As our development programs progress and we build new process efficiencies, we expect to continually evaluate this strategy with the objective of satisfying demand for registration trials and, if approved, the manufacture, sale and distribution of commercial products. Under our collaboration agreements with AbbVie and Janssen, our partners will assume responsibility for the manufacturing according to the terms of those agreements for licensed products.

Competition

The biotechnology and pharmaceutical industries are characterized by rapid evolution of technologies, fierce competition and strong defense of intellectual property. While we believe that our MInT Platform and our knowledge, experience and scientific resources provide us with competitive advantages, we face competition from major pharmaceutical and biotechnology companies, academic institutions, governmental agencies and public and private research institutions, among others.

Any product candidates that we successfully develop and commercialize will compete with currently approved therapies and new therapies that may become available in the future. Key product features that would affect our ability to effectively compete with other therapeutics include the efficacy, safety and convenience of our products.

Despite significant biopharmaceutical industry investment, no oral integrin therapies have been approved. We are advancing MORF-057, a $\alpha_4\beta_7$-specific integrin inhibitor affecting inflammation into clinical development initially for the treatment of IBD. There are currently approved IBD treatments marketed by AbbVie, Johnson & Johnson, UCB, Biogen and Pfizer, in addition to other major pharmaceutical companies, against which our product candidate may compete, if approved. Further, Takeda Pharmaceutical Company Ltd. currently markets Entyvio, which is an $\alpha_4\beta_7$ monoclonal antibody to treat ulcerative colitis and Crohn's disease. In addition, we are aware of IBD treatments in clinical development by AbbVie, Johnson & Johnson, Pfizer, Gilead, Eli Lilly, Bristol-Myers Squibb, Boehringer Ingelheim, Theravance, and Arena Pharmaceuticals, in addition to other pharmaceutical companies. Further, Roche has an $\alpha_4\beta_7$ / $\alpha_E\beta_7$ monoclonal antibody in Phase 3 development for IBD and Protagonist has a Phase 2 gut-restricted $\alpha_4\beta_7$ program in Phase 2 development for ulcerative colitis.

We are also developing MORF-720, our selective oral $\alpha_v\beta_6$-specific integrin inhibitor product candidate, into clinical development for the treatment of IPF, in collaboration with AbbVie. There are currently approved IPF treatments marketed by Roche Holding AG and Boehringer Ingelheim GmbH against which our product candidate may compete, if approved. In addition, we are aware of IPF treatments in development by Galapagos NV, FibroGen, Galecto, Roche, and Bristol-Myers Squibb, in addition to other pharmaceutical companies. Further, we are aware of programs targeting $\alpha_v\beta_6$ that are currently being investigated in clinical trials by companies including Pliant Therapeutics, Inc. and Indalo Therapeutics, Inc.

Many of our competitors have significantly greater financial resources and expertise than we do in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products. 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. Additionally, our competitors may also include companies that are or will be developing therapies for the same therapeutic areas that we are targeting, including autoimmune, cardiovascular and metabolic diseases, fibrosis and cancer.

Government Regulation

Government authorities in the United States, at the federal, state and local level, and in other countries and jurisdictions extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, marketing, post-approval monitoring and reporting, and import and export of pharmaceutical products. The processes for obtaining regulatory approvals in the

United States and in foreign countries and jurisdictions, along with subsequent compliance with applicable statutes and regulations and other regulatory authorities, require the expenditure of substantial time and financial resources.

FDA Approval Process

In the United States, pharmaceutical products are subject to extensive regulation by FDA. The Federal Food, Drug, and Cosmetic Act, or FD&C Act, and other federal and state statutes and regulations govern, among other things, the research, development, testing, manufacture, storage, recordkeeping, approval, labeling, promotion and marketing, distribution, post-approval monitoring and reporting, sampling and import and export of pharmaceutical products. Failure to comply with applicable U.S. requirements may subject a company to a variety of administrative or judicial sanctions, such as FDA refusal to approve pending NDAs, warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties and criminal prosecution.

Pharmaceutical product development for a new product or certain changes to an approved product in the U.S. typically involves preclinical laboratory and animal tests, the submission to FDA of an investigational new drug application, or IND, which must become effective before clinical testing may commence, and adequate and well-controlled clinical trials to establish the safety and effectiveness of the drug for each indication for which FDA approval is sought. Satisfaction of FDA pre-market approval requirements typically takes many years and the actual time required may vary substantially based upon the type, complexity and novelty of the product or disease.

Preclinical tests include laboratory evaluation of product chemistry, formulation and toxicity, as well as animal trials to assess the characteristics and potential safety and efficacy of the product. The conduct of the preclinical tests must comply with federal regulations and requirements, including good laboratory practices. The results of preclinical testing are submitted to FDA as part of an IND along with other information, including information about product chemistry, manufacturing and controls, and a proposed clinical trial protocol. Long-term preclinical tests, such as animal tests of reproductive toxicity and carcinogenicity, may continue after the IND is submitted. A 30-day waiting period after the submission of each IND is required prior to the commencement of clinical testing in humans. If FDA has neither commented on nor questioned the IND within this 30-day period, the clinical trial proposed in the IND may begin. Clinical trials involve the administration of the investigational new drug to healthy volunteers or patients under the supervision of a qualified investigator. Clinical trials must be conducted: (i) in compliance with federal regulations; (ii) in compliance with good clinical practice, or GCP, an international standard meant to protect the rights and health of patients and to define the roles of clinical trial sponsors, administrators and monitors; as well as (iii) under protocols detailing the objectives of the trial, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. Each protocol involving testing on U.S. patients and subsequent protocol amendments must be submitted to FDA as part of the IND.

FDA may order the temporary, or permanent, discontinuation of a clinical trial at any time, or impose other sanctions, if it believes that the clinical trial either is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial patients. The study protocol and informed consent information for patients in clinical trials must also be submitted to an institutional review board, or IRB, and ethics committee for approval. An IRB may also require the clinical trial at the site to be halted, either temporarily or permanently, for failure to comply with the IRB’s requirements, or may impose other conditions.

Clinical trials to support NDAs for marketing approval are typically conducted in three sequential phases, but the phases may overlap. In Phase 1, the initial introduction of the drug into healthy human subjects or patients, the drug is tested to assess metabolism, pharmacokinetics, pharmacological actions, side effects associated with increasing doses, and, if possible, early evidence of effectiveness. Phase 2 usually involves trials in a limited patient population to determine the effectiveness of the drug for a particular indication, dosage tolerance and optimum dosage, and to identify common adverse effects and safety risks. If a drug demonstrates evidence of effectiveness and an acceptable safety profile in Phase 2 evaluations, Phase 3 trials are undertaken to obtain the additional information about clinical efficacy and safety in a larger number of patients, typically at geographically dispersed clinical trial sites, to permit FDA to evaluate the overall benefit-risk relationship of the drug and to provide adequate information for the labeling of the drug. In most cases FDA requires two adequate and well-controlled Phase 3 clinical trials to demonstrate the efficacy of the drug. A single Phase 3 trial with other confirmatory evidence may be sufficient in rare instances, such as where the study is a

large multicenter trial demonstrating internal consistency and a statistically very persuasive finding of a clinically meaningful effect on mortality, irreversible morbidity or prevention of a disease with a potentially serious outcome and confirmation of the result in a second trial would be practically or ethically impossible.

The manufacturer of an investigational drug in a Phase 2 or 3 clinical trial for a serious or life-threatening disease is required to make available, such as by posting on its website, its policy on evaluating and responding to requests for expanded access.

After completion of the required clinical testing, an NDA is prepared and submitted to FDA. FDA approval of the NDA is required before marketing of the product may begin in the U.S. The NDA must include the results of all preclinical, clinical and other testing and a compilation of data relating to the product's pharmacology, chemistry, manufacture and controls. The cost of preparing and submitting an NDA is substantial. The submission of most NDAs is additionally subject to a substantial application user fee, currently exceeding $2,580,000 for Fiscal Year 2019, and the manufacturer and/or sponsor under an approved drugs license application are also subject to annual program fees, currently exceeding $300,000 for each prescription product. These fees are typically increased annually. Sponsors of applications for drugs granted Orphan Drug Designation are exempt from these user fees.

FDA has 60 days from its receipt of an NDA to determine whether the application will be accepted for filing based on the agency's threshold determination that it is sufficiently complete to permit substantive review. Once the submission is accepted for filing, FDA begins an in-depth review. FDA has agreed to certain performance goals in the review of new drug applications to encourage timeliness. Most applications for standard review drug products are reviewed within ten to twelve months; most applications for priority review drugs are reviewed in six to eight months. Priority review can be applied to drugs that FDA determines offer major advances in treatment or provide a treatment where no adequate therapy exists. The review process for both standard and priority review may be extended by FDA for three additional months to consider certain late-submitted information, or information intended to clarify information already provided in the submission.

FDA may also refer applications for novel drug products, or drug products that present difficult questions of safety or efficacy, to an outside advisory committee — typically a panel that includes clinicians and other experts — for review, evaluation and a recommendation as to whether the application should be approved. FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations.

Before approving an NDA, FDA will typically inspect one or more clinical sites to assure compliance with GCP. Additionally, FDA will inspect the facility or the facilities at which the drug is manufactured. FDA will not approve the product unless compliance with current good manufacturing practices, or cGMPs, is satisfactory and the NDA contains data that provide substantial evidence that the drug is safe and effective in the indication studied.

After FDA evaluates the NDA and the manufacturing facilities, it issues either an approval letter or a complete response letter. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional testing, or information, in order for FDA to reconsider the application. If, or when, those deficiencies have been addressed to FDA's satisfaction in a resubmission of the NDA, FDA will issue an approval letter. FDA has committed to reviewing such resubmissions in two or six months depending on the type of information included. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. As a condition of NDA approval, FDA may require a risk evaluation and mitigation strategy, or REMS, to help ensure that the benefits of the drug outweigh the potential risks. REMS can include medication guides, communication plans for healthcare professionals, and elements to assure safe use, or ETASU. ETASU can include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring and the use of patient registries. The requirement for a REMS can materially affect the potential market and profitability of the drug. Moreover, product approval may require substantial post-approval testing and surveillance to monitor the drug's safety or efficacy. Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained or problems are identified following initial marketing.

Changes to some of the conditions established in an approved application, including changes in indications, labeling, or manufacturing processes or facilities, require submission and FDA approval of a new NDA or NDA supplement before

the change can be implemented. An NDA supplement for a new indication typically requires clinical data similar to that in the original application, and FDA uses the same procedures and actions in reviewing NDA supplements as it does in reviewing NDAs.

Fast Track Designation and Accelerated Approval

FDA is required to facilitate the development, and expedite the review, of drugs that are intended for the treatment of a serious or life-threatening disease or condition for which there is no effective treatment and which demonstrate the potential to address unmet medical needs for the condition. Under the Fast Track program, the sponsor of a new drug candidate may request that FDA designate the drug candidate for a specific indication as a Fast Track drug concurrent with, or after, the filing of the IND for the drug candidate. FDA must determine if the drug candidate qualifies for Fast Track Designation within 60 days of receipt of the sponsor's request. Under the Fast Track program and FDA's accelerated approval regulations, FDA may approve a drug for a serious or life-threatening illness that provides meaningful therapeutic benefit to patients over existing treatments based upon 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.

In clinical trials, a surrogate endpoint is a measurement of laboratory or clinical signs of a disease or condition that substitutes for a direct measurement of how a patient feels, functions or survives. Surrogate endpoints can often be measured more easily or more rapidly than clinical endpoints. A drug candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of Phase 4 or post-approval clinical trials to confirm the effect on the clinical endpoint. Failure to conduct required post-approval studies, or confirm a clinical benefit during post-marketing studies, will allow FDA to withdraw the drug from the market on an expedited basis. All promotional materials for drug candidates approved under accelerated regulations are subject to priority review by FDA.

If a submission is granted Fast Track Designation, the sponsor may engage in more frequent interactions with FDA, and FDA may review sections of the NDA before the application is complete. This rolling review is available if the applicant provides, and FDA approves, a schedule for the submission of the remaining information and the applicant pays applicable user fees. However, FDA's time period goal for reviewing an application does not begin until the last section of the NDA is submitted. Additionally, Fast Track Designation may be withdrawn by FDA if FDA believes that the designation is no longer supported by data emerging in the clinical trial process.

Breakthrough Therapy Designation

FDA is also required to expedite the development and review of the application for approval of drugs that are intended to treat a serious or life-threatening disease or condition where preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints. Under the Breakthrough Therapy program, the sponsor of a new drug candidate may request that FDA designate the drug candidate for a specific indication as a breakthrough therapy concurrent with, or after, the filing of the IND for the drug candidate. FDA must determine if the drug candidate qualifies for Breakthrough Therapy designation within 60 days of receipt of the sponsor's request.

Orphan Drugs

Under the Orphan Drug Act, FDA may grant Orphan Drug Designation to drugs intended to treat a rare disease or condition — generally a disease or condition that affects fewer than 200,000 individuals in the U.S. Orphan Drug designation must be requested before submitting an NDA. After FDA grants Orphan Drug Designation, the generic identity of the drug and its potential orphan use are disclosed publicly by FDA. Orphan Drug Designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. The first NDA applicant to receive FDA approval for a particular active ingredient to treat a particular disease with FDA Orphan Drug Designation is entitled to a seven-year exclusive marketing period in the U.S. for that product, for that indication. During the seven-year exclusivity period, FDA may not approve any other applications to market the same drug for the same

disease, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity. Orphan drug exclusivity does not prevent FDA from approving a different drug for the same disease or condition, or the same drug for a different disease or condition. Among the other benefits of Orphan Drug Designation are tax credits for certain research and an exemption from the NDA application user fee.

Disclosure of Clinical Trial Information

Sponsors of clinical trials of FDA regulated products, including drugs, are required to register and disclose certain clinical trial information. Information related to the product, patient population, phase of investigation, study sites and investigators, and other aspects of the clinical trial is then made public as part of the registration. Sponsors are also obligated to discuss the results of their clinical trials after completion. Disclosure of the results of these trials can be delayed in certain circumstances for up to two years after the date of completion of the trial. Competitors may use this publicly available information to gain knowledge regarding the progress of development programs.

Pediatric Information

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

The Best Pharmaceuticals for Children Act, or BPCA, provides NDA holders a six-month extension of any exclusivity — patent or nonpatent — for a drug if certain conditions are met. Conditions for exclusivity include FDA's determination that information relating to the use of a new drug in the pediatric population may produce health benefits in that population, FDA making a written request for pediatric studies, and the applicant agreeing to perform, and reporting on, the requested studies within the statutory timeframe. Applications under the BPCA are treated as priority applications, with all of the benefits that designation confers.

Post-Approval Requirements

Once an NDA is approved, a product will be subject to certain post-approval requirements. For instance, FDA closely regulates the post-approval marketing and promotion of drugs, including standards and regulations for direct-to-consumer advertising, off-label promotion, industry-sponsored scientific and educational activities and promotional activities involving the internet. Drugs may be marketed only for the approved indications and in accordance with the provisions of the approved labeling.

Adverse event reporting and submission of periodic reports are required following FDA approval of an NDA. FDA also may require post-marketing testing, known as Phase 4 testing, risk evaluation and mitigation strategies, or REMS, and surveillance to monitor the effects of an approved product, or FDA may place conditions on an approval that could restrict the distribution or use of the product. In addition, quality control, drug manufacture, packaging and labeling procedures must continue to conform to cGMPs after approval. Drug manufacturers and certain of their subcontractors are required to register their establishments with FDA and certain state agencies. Registration with FDA subjects entities to periodic unannounced inspections by FDA, during which the Agency inspects manufacturing facilities to assess compliance with cGMPs. Accordingly, manufacturers must continue to expend time, money and effort in the areas of production and quality-control to maintain compliance with cGMPs. Regulatory authorities may withdraw product approvals or request product recalls if a company fails to comply with regulatory standards, if it encounters problems following initial marketing, or if previously unrecognized problems are subsequently discovered.

The Hatch-Waxman Act

Orange Book Listing

In seeking approval for a drug through an NDA, applicants are required to list with the FDA each patent whose claims cover the applicant's product. Upon approval of a drug, each of the patents listed in the application for the drug is then published in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. Drugs listed in the Orange Book can, in turn, be cited by potential generic competitors in support of approval of an abbreviated new drug application, or ANDA. An ANDA provides for marketing of a drug product that has the same active ingredients in the same strengths and dosage form as the listed drug and has been shown through bioequivalence testing to be therapeutically equivalent to the listed drug. Other than the requirement for bioequivalence testing, ANDA applicants are not required to conduct, or submit results of, pre-clinical or clinical tests to prove the safety or effectiveness of their drug product. Drugs approved in this way are commonly referred to as "generic equivalents" to the listed drug and can often be substituted by pharmacists under prescriptions written for the original listed drug.

The ANDA applicant is required to certify to the FDA concerning any patents listed for the approved product in the FDA's Orange Book. Specifically, the applicant must certify that (i) the required patent information has not been filed; (ii) the listed patent has expired; (iii) the listed patent has not expired but will expire on a particular date and approval is sought after patent expiration; or (iv) the listed patent is invalid or will not be infringed by the new product. The ANDA applicant may also elect to submit a section viii statement certifying that its proposed ANDA label does not contain (or carve out) any language regarding the patented method-of-use rather than certify to a listed method-of-use patent. If the applicant does not challenge the listed patents, the ANDA application will not be approved until all the listed patents claiming the referenced product have expired. A certification that the new product will not infringe the already approved product's listed patents, or that such patents are invalid, is called a Paragraph IV certification. If the ANDA applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA and patent holders once the ANDA has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days of the receipt of a Paragraph IV certification automatically prevents the FDA from approving the ANDA until the earlier of 30 months, expiration of the patent, settlement of the lawsuit, or a decision in the infringement case that is favorable to the ANDA applicant.

The ANDA application also will not be approved until any applicable non-patent exclusivity listed in the Orange Book for the referenced product has expired.

Exclusivity

Upon NDA approval of a new chemical entity, or NCE, which is a drug that contains no active moiety that has been approved by FDA in any other NDA, that drug receives five years of marketing exclusivity during which FDA cannot receive any ANDA seeking approval of a generic version of that drug. Certain changes to a drug, such as the addition of a new indication to the package insert, are associated with a three-year period of exclusivity during which FDA cannot approve an ANDA for a generic drug that includes the change. An ANDA may be submitted one year before NCE exclusivity expires if a Paragraph IV certification is filed. If there is no listed patent in the Orange Book, there may not be a Paragraph IV certification, and, thus, no ANDA may be filed before the expiration of the exclusivity period.

Patent Term Extension

After NDA approval, owners of relevant drug patents may apply for up to a five-year patent extension. The allowable patent term extension is calculated as half of the drug's testing phase (the time between IND application and NDA submission) and all of the review phase (the time between NDA submission and approval up to a maximum of five years). The time can be shortened if FDA determines that the applicant did not pursue approval with due diligence. The total patent term after the extension may not exceed 14 years, and only one patent can be extended. For patents that might expire during the application phase, the patent owner may request an interim patent extension. An interim patent extension increases the patent term by one year and may be renewed up to four times. For each interim patent extension

granted, the post-approval patent extension is reduced by one year. The director of the United States Patent and Trademark Office must determine that approval of the drug covered by the patent for which a patent extension is being sought is likely. Interim patent extensions are not available for a drug for which an NDA has not been submitted.

Other Healthcare Laws

In addition to FDA restrictions on marketing of pharmaceutical products, several other types of state and federal laws have been applied to restrict certain general business and marketing practices in the pharmaceutical industry in recent years. These laws include anti-kickback statutes, false claims statutes and other healthcare laws and regulations.

The federal Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce, or in return for, purchasing, leasing, ordering or arranging for the purchase, lease or order of any healthcare item or service reimbursable under Medicare, Medicaid, or other federally financed healthcare programs. The Patient Protection and Affordable Care Act as amended by the Health Care and Education Reconciliation Act, collectively, the ACA, amended the intent element of the federal statute so that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to commit a violation. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers, among others, on the other. Although there are a number of statutory exceptions and regulatory safe harbors protecting certain common activities from prosecution or other regulatory sanctions, the exceptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor.

Federal civil and criminal false claims laws, including the federal civil False Claims Act, prohibit any person or entity from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to have a false claim paid. This includes claims made to programs where the federal government reimburses, such as Medicare and Medicaid, as well as programs where the federal government is a direct purchaser, such as when it purchases off the Federal Supply Schedule. Recently, several pharmaceutical and other healthcare companies have been prosecuted under these laws for allegedly inflating drug prices they report to pricing services, which in turn were used by the government to set Medicare and Medicaid reimbursement rates, and for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. In addition, certain marketing practices, including off-label promotion, may also violate false claims laws. Additionally, the ACA amended the federal Anti-Kickback Statute such that a violation of that statute can serve as a basis for liability under the federal civil False Claims Act. Most states also have statutes or regulations similar to the federal Anti-Kickback Statute and civil False Claims Act, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor.

Other federal statutes pertaining to healthcare fraud and abuse include the civil monetary penalties statute, which prohibits, among other things, the offer or payment of remuneration to a Medicaid or Medicare beneficiary that the offeror or payor knows or should know is likely to influence the beneficiary to order a receive a reimbursable item or service from a particular supplier, and the additional federal criminal statutes created by the Health Insurance Portability and Accountability Act of 1996, or HIPAA, which prohibits, among other things, knowingly and willfully executing or attempting to execute a scheme to defraud any healthcare benefit program or obtain by means of false or fraudulent pretenses, representations or promises any money or property owned by or under the control of any healthcare benefit program in connection with the delivery of or payment for healthcare benefits, items or services.

In addition, HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, including the Final Omnibus Rule published on January 25, 2013, impose obligations on certain healthcare providers, health plans, and healthcare clearinghouses, known as covered entities, as well as their business associates that perform certain services involving the storage, use or disclosure of individually identifiable health information, including mandatory contractual terms, with respect to safeguarding the privacy, security, and transmission of individually identifiable health information, and require notification to affected individuals and regulatory authorities of certain breaches of security of individually identifiable health information. HITECH increased the civil and criminal penalties that may be imposed against covered entities, business associates and possibly other persons, and gave state attorneys general new authority to file civil actions for damages or injunctions in

federal courts to enforce the federal HIPAA laws and seek attorney's fees and costs associated with pursuing federal civil actions. In addition, many state laws govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, and often are not pre-empted by HIPAA.

Further, pursuant to the ACA, the Centers for Medicare & Medicaid Services, or CMS, has issued a final rule that requires manufacturers of prescription drugs to collect and report information on certain payments or transfers of value to physicians and teaching hospitals, as well as investment interests held by physicians and their immediate family members. The first reports were due in 2014 and must be submitted on an annual basis. The reported data is made available in searchable form on a public website on an annual basis. Failure to submit required information may result in civil monetary penalties. Effective January 1, 2022, reporting on transfers of value to physician assistants, nurse practitioners or clinical nurse specialists, certified registered nurse anesthetists, and certified nurse-midwives will also be required.

In addition, several states now require prescription drug companies to report certain expenses relating to the marketing and promotion of drug products and to report gifts and payments to individual healthcare practitioners in these states. Other states prohibit various marketing-related activities, such as the provision of certain kinds of gifts or meals. Still other states require the posting of information relating to clinical studies and their outcomes. Some states require the reporting of certain drug pricing information, including information pertaining to and justifying price increases, or prohibit prescription drug price gouging. In addition, states such as California, Connecticut, Nevada, and Massachusetts require pharmaceutical companies to implement compliance programs and/or marketing codes. Several additional states are considering similar proposals. Certain states and local jurisdictions also require the registration of pharmaceutical sales and medical representatives. Compliance with these laws is difficult and time consuming, and companies that do not comply with these state laws face civil penalties.

Efforts to ensure that business arrangements with third parties comply with applicable healthcare laws and regulations involve substantial costs. If a drug company's operations are found to be in violation of any such requirements, it may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, the curtailment or restructuring of its operations, loss of eligibility to obtain approvals from the FDA, exclusion from participation in government contracting, healthcare reimbursement or other federal or state government healthcare programs, including Medicare and Medicaid, integrity oversight and reporting obligations, imprisonment, and reputational harm. Although effective compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, these risks cannot be entirely eliminated. Any action for an alleged or suspected violation can cause a drug company to incur significant legal expenses and divert management's attention from the operation of the business, even if such action is successfully defended.

U.S. Healthcare Reform

In the United States there have been, and continue to be, proposals by the federal government, state governments, regulators and third-party payors to control or manage the increased costs of health care and, more generally, to reform the U.S. healthcare system. The pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. For example, in March 2010, the ACA was enacted, which intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for the healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms, substantially changed the way healthcare is financed by both governmental and private insurers, and significantly impacts the U.S. pharmaceutical industry. The ACA, among other things, (i) subjected therapeutic biologics to potential competition by lower-cost biosimilars by creating a licensure framework for follow-on biologic products, (ii) proscribed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs and therapeutic biologics that are inhaled, infused, instilled, implanted or injected, (iii) increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extended the rebate program to individuals enrolled in Medicaid managed care organizations, (iv) established annual nondeductible fees and taxes on manufacturers of certain branded prescription drugs and therapeutic biologics, apportioned among these entities according to their market share in certain government healthcare programs (v) established a new Medicare Part D coverage gap discount program, in which

manufacturers must agree to offer 50% (now 70%) point of-sale discounts off negotiated prices of applicable brand drugs and therapeutic biologics to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs and therapeutic biologics to be covered under Medicare Part D, (vi) expanded 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 individuals with income at or below 133% of the federal poverty level, thereby potentially increasing manufacturers' Medicaid rebate liability, (vii) expanded the entities eligible for discounts under the Public Health program (viii) created 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 (ix) established a Center for Medicare Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

The current U.S. presidential administration and Congress have, and we expect they will continue to, seek to modify, repeal, or otherwise invalidate all, or certain provisions of, the ACA. Since January 2017, the current U.S. presidential administration has issued two executive orders and other directives designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. For example, on October 12, 2017, the current U.S. presidential administration issued an executive order that expands the use of association health plans and allows anyone to purchase short-term health plans that provide temporary, limited insurance. This executive order also calls for the halt of federal payments to health insurers for cost-sharing reductions previously available to lower-income Americans to afford coverage. There is still uncertainty with respect to the impact this executive order could have on coverage and reimbursement for healthcare items and services covered by plans that were authorized by the ACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the ACA have been signed into law. The Tax Cuts and Jobs Act of 2017, or the Tax Reform Act, among other things, included a provision that repealed, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." Additionally, on January 22, 2018, the current U.S. presidential administration signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain ACA-mandated fees, including the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices. Further, the Bipartisan Budget Act of 2018, or the BBA, among other things, amended the ACA, effective January 1, 2019, to increase from 50% to 70% the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole". More recently, in July 2018, CMS published a final rule permitting further collections and payments to and from certain ACA qualified health plans and health insurance issuers under the ACA risk adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. On December 14, 2018, a Texas U.S. District Court Judge ruled that the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Reform Act. While the Texas U.S. District Court Judge, as well as the current U.S. presidential administration and CMS, have stated that the ruling will have no immediate effect pending appeal of the decision, it is unclear how this decision, subsequent appeals, and other efforts to repeal and replace the ACA will impact the ACA. There is still uncertainty with respect to the impact the current U.S. presidential administration and the Congress may have, if any, and any changes will likely take time to unfold, and could have an impact on coverage and reimbursement for healthcare items and services covered by plans that were authorized by the ACA. However, we cannot predict the ultimate content, timing or effect of any healthcare reform legislation or the impact of potential legislation on us.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted to reduce healthcare expenditures. United States federal government agencies also currently face potentially significant spending reductions, which may further impact healthcare expenditures. On August 2, 2011, the Budget Control Act of 2011 among other things, created measures for spending reductions by Congress. A joint select committee on deficit reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers of 2% per fiscal year. These reductions went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, including the BBA, will

remain in effect through 2027 unless additional Congressional action is taken. Moreover, on January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. If federal spending is further reduced, anticipated budgetary shortfalls may also impact the ability of relevant agencies, such as the FDA or the National Institutes of Health to continue to function at current levels. Amounts allocated to federal grants and contracts may be reduced or eliminated. These reductions may also impact the ability of relevant agencies to timely review and approve research and development, manufacturing, and marketing activities, which may delay our ability to develop, market and sell any products we may develop.

Moreover, payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives. For example, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or MMA, changed the way Medicare covers and pays for pharmaceutical products. The legislation expanded Medicare coverage for drug purchases by the elderly and introduced a new reimbursement methodology based on average sales prices for physician-administered drugs. In addition, this legislation provided authority for limiting the number of drugs that will be covered in any therapeutic class. While the MMA only applies to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates. Therefore, any reduction in reimbursement that results from the MMA may result in a similar reduction in payments from private payors.

Recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. At the federal level, the current U.S. presidential administration’s budget proposal for fiscal year 2019 contains further drug price control measures that could be enacted during the 2019 budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid, and to eliminate cost sharing for generic drugs for low-income patients. Additionally, on May 11, 2018, the current U.S. presidential administration laid out the administration’s “Blueprint” to reduce the cost of prescription medications while preserving innovation and cures. While the Department of Health and Human Services, or HHS, is soliciting feedback on some of these measures, other actions may be immediately implemented by HHS under existing authority. Further, on January 31, 2019, the HHS Office of Inspector General, proposed modifications to the federal Anti-Kickback Statute discount safe harbor for the purpose of reducing the cost of drug products to consumers which, among other things, if finalized, will affect discounts paid by manufacturers to Medicare Part D plans, Medicaid managed care organizations and pharmacy benefit managers working with these organizations. Although a number of these, and other potential, proposals will require additional authorization to become effective, Congress and the current U.S. presidential administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

Additionally, on May 30, 2018, the Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2017 was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational new drug products that have completed a Phase I clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA authorization under an FDA expanded access program; however, manufacturers are not obligated to provide investigational new drug products under the current federal right to try law.

Employees

As of December 31, 2019, we had 76 full-time employees. Of these employees, 32 have an M.D. or a Ph.D. From time to time, we also retain independent contractors to support our organization. None of our employees are represented by a labor union or covered by collective bargaining agreements, and we believe our relationship with our employees is good.

Corporate Information

We were formed under the laws of the State of Delaware in August 2014 under the name Integrin Rock, LLC. We subsequently changed our name to Morphic Rock Holding, LLC in October 2014 and then to Morphic Holding, LLC in June 2016. On December 5, 2018, we completed a series of transactions, or the Reorganization, pursuant to which Morphic Holding, LLC was converted in a tax-free reorganization into Morphic Holding, Inc. and three wholly-owned subsidiaries, namely Lazuli, Inc., Tourmaline, Inc, and Phyllite, Inc, were merged with and into another wholly-owned subsidiary, Morphic Therapeutic, Inc. Our principal executive offices are located at 35 Gatehouse Drive, A2, Waltham, MA 02451, and our telephone number is (781) 996-0955. Our website address is www.morphictx.com. The information contained on, or that can be accessed through, our website is not part of, and is not incorporated by reference into, this Annual Report.

Available Information

We file annual, quarterly and current reports, proxy statements and other documents with the Securities and Exchange Commission, or SEC, under the Securities Exchange Act of 1934, as amended, or Exchange Act. The SEC maintains an Internet website that contains reports, proxy and information statements, and other information regarding issuers, including us, that file electronically with the SEC. The public can obtain any documents that we file with the SEC at www.sec.gov. Copies of each of our filings with the SEC can also be viewed and downloaded free of charge at our website, www.morphictx.com, after the reports and amendments are electronically filed with or furnished to the SEC.

ITEM 1A. RISK FACTORS

Investing in our common stock involves a high degree of risk. Before making your decision to invest in shares of our common stock, you should carefully consider the risks described below, together with the other information contained in this annual report, including our financial statements and the related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations." The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties that we are unaware of, or that we currently believe are not material, may also become important factors that affect us. We cannot assure you that any of the events discussed below will not occur. These events could have a material and adverse impact on our business, financial condition, results of operations and prospects. If that were to happen, the trading price of our common stock could decline, and you could lose all or part of your investment.

Risks Related to Our Financial Position and Need for Capital

We are a preclinical stage biopharmaceutical company with a limited operating history and no products in clinical development or approved for commercial sale. We have a history of significant losses and expect to continue to incur significant losses for the foreseeable future.

We are a preclinical stage biopharmaceutical company with a limited operating history on which to base your investment decision. Biopharmaceutical product development is a highly speculative undertaking because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate effect or an acceptable safety profile, gain regulatory approval or become commercially viable.

We have identified lead product candidates for our $\alpha_4\beta_7$ (MORF-057) and $\alpha_v\beta_6$ (MORF-720) programs, which are still in the preclinical testing stage. We have no products in clinical development or approved for commercial sale and have not generated any revenue from commercial product sales, and we will continue to incur significant research and development and other expenses related to our clinical development and ongoing operations. For year ended

December 31, 2019, we reported a net loss $43.3 million. As of December 31, 2019, we had an accumulated deficit of approximately $97.5 million. Substantially all of our losses have resulted from expenses incurred in connection with our research and development programs and from general and administrative costs associated with our operations. We expect to incur significant losses for the foreseeable future, and we expect these losses to increase as we continue our research and development of our product candidates.

We anticipate that our expenses will increase substantially if, and as, we:

- § conduct additional preclinical testing for MORF-720 to enable an IND filing, or develop a backup molecule;
- § conduct clinical trials for our lead product candidates, MORF-057 and MORF-720, and any future product candidates;
- § discover and develop new product candidates, and conduct research and development activities, preclinical studies and clinical trials;
- § manufacture, or have manufactured, pre-clinical, clinical and commercial supplies of our product candidates;
- § seek regulatory approvals for our product candidates or any future product candidates;
- § commercialize our current product candidates or any future product candidates, if approved;
- § attempt to transition from a company with a research focus to a company capable of supporting commercial activities, including establishing sales, marketing and distribution infrastructure;
- § hire additional clinical, scientific and management personnel;
- § add operational, financial and management information systems and personnel;
- § identify additional compounds or product candidates and acquire rights from third parties to those compounds or product candidates through licenses; and
- § incur additional costs associated with operating as a public company.

Even if we succeed in commercializing one or more product candidates, we may continue to incur substantial research and development and other expenditures to develop and market additional product candidates. We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue. Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' equity and working capital.

We have never generated revenue from product sales and may never be profitable.

Our ability to become and remain profitable depends on our ability to generate revenue. We do not expect to generate significant revenue, if any, unless and until we, either alone or with a collaborator, are able to obtain regulatory approval for, and successfully commercialize, our lead product candidates, or any other product candidates we may develop. Successful commercialization will require achievement of many key milestones, including demonstrating safety and efficacy in clinical trials, obtaining regulatory, including marketing, approval for these product candidates, manufacturing, marketing and selling those products for which we, or any of our current or future collaborators, may obtain regulatory approval, satisfying any post-marketing requirements and obtaining reimbursement for our products from private insurance or government payors. Because of the uncertainties and risks associated with these activities, we are unable to accurately and precisely predict the timing and amount of revenues, the extent of any further losses or if or

when we might achieve profitability. We and any current or future collaborators may never succeed in these activities and, even if we do, or any collaborators do, we may never generate revenues that are large enough for us 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. Additionally, our expenses could increase if we are required by the U.S. Food and Drug Administration, or the FDA, or any comparable foreign regulatory authority to perform clinical trials in addition to those currently expected, or if there are any delays in completing our clinical trials or the development of any of our product candidates.

Our failure to become and remain profitable may depress the market price of our common stock and could impair our ability to raise capital, expand our business or continue our operations. If we continue to suffer losses as we have in the past, investors may not receive any return on their investment and may lose their entire investment.

We will need substantial additional funds to advance development of our product candidates, which may not be available on acceptable terms, or at all. Failure to obtain this necessary capital when needed may force us to delay, limit or terminate our product development programs, commercialization efforts or other operations.

The development of biopharmaceutical product candidates is capital-intensive. If our product candidates enter and advance through preclinical studies and clinical trials, we will need substantial additional funds to expand or create our development, regulatory, manufacturing, marketing and sales capabilities. We have used substantial funds to develop our technology and product candidates and will require significant funds to conduct further research and development and preclinical testing and clinical trials of our product candidates, to seek regulatory approvals for our product candidates and to manufacture and market products, if any, which are approved for commercial sale. In addition, we expect to incur increased costs associated with operating as a public company.

Since our inception, we have invested a significant portion of our efforts and financial resources in research and development activities for our product candidates from our lead programs, $\alpha_4\beta_7$ and $\alpha_v\beta_6$. Preclinical studies and clinical trials for our product candidates will require substantial funds to complete. As of December 31, 2019, we had $237.0 million in cash, cash equivalents, and marketable securities. We expect to incur substantial expenditures in the foreseeable future as we seek to advance our current product candidates from our lead programs, $\alpha_4\beta_7$ and $\alpha_v\beta_6$, and any future product candidates through preclinical and clinical development, the regulatory approval process and, if approved, commercial launch activities. Based on our current operating plan, we believe that our available cash and cash equivalents will be sufficient to fund our operating expenses and capital expenditure requirements through at least the end of 2022. However, our future capital requirements and the period for which we expect our existing resources to support our operations, fund expansion, develop new or enhanced products, or otherwise respond to competitive pressures, may vary significantly from what we expect and we may need to seek additional funds sooner than planned. Our monthly spending levels vary based on new and ongoing research and development and other corporate activities. Because the length of time and activities associated with successful research and development of our product candidates is highly uncertain, we are unable to estimate the actual funds we will require for development and any marketing and commercialization activities for approved products. Our future funding requirements, both near and long-term, will depend on many factors, including, but not limited to:

- the timing, cost and progress of preclinical and clinical development activities;
- the number and scope of preclinical and clinical programs we decide to pursue;
- the progress of the development efforts of parties with whom we have entered or may in the future enter into collaborations and/or research and development agreements;
- the timing and amount of milestone and other payments we may receive or make under our collaboration agreements;
- our ability to maintain our current licenses and research and development programs and to establish new collaboration arrangements;
- the costs involved in prosecuting and enforcing patent and other intellectual property claims;

- the costs of manufacturing our product candidates by third parties;
- the cost of regulatory submissions and timing of regulatory approvals;
- the cost of commercialization activities if our product candidates or any future product candidates are approved for sale, including marketing, sales and distribution costs;
- our efforts to enhance operational systems and hire additional personnel, including personnel to support development of our product candidates; and
- our need to implement additional internal systems and infrastructure, including financial and reporting systems to satisfy our obligations as a public company.

If we are unable to obtain funding on a timely basis or on acceptable terms, we may have to delay, reduce or terminate our research and development programs and preclinical studies or clinical trials, limit strategic opportunities or undergo reductions in our workforce or other corporate restructuring activities. We do not expect to realize revenue from sales of commercial products or royalties from licensed products in the foreseeable future, if at all, and, in no event, before our product candidates are clinically tested, approved for commercialization and successfully marketed. To date, we have primarily financed our operations through payments received under our collaboration agreements, the sale of equity securities and debt financing.

We will be required to seek additional funding in the future and currently intend to do so through additional collaborations and/or licensing agreements, public or private equity offerings or debt financings, credit or loan facilities, or a combination of one or more of these funding sources. If we raise additional funds by issuing equity securities, our stockholders will suffer dilution and the terms of any financing may adversely affect the rights of our stockholders. In addition, as a condition to providing additional funds to us, future investors may demand, and may be granted, rights superior to those of existing stockholders. Our future debt financings, if available, are likely to involve restrictive covenants limiting our flexibility in conducting future business activities, and, in the event of insolvency, debt holders would be repaid before holders of our equity securities received any distribution of our corporate assets. If we raise additional funds through licensing or collaboration arrangements with third parties, we may have to relinquish valuable rights to our product candidates, or grant licenses on terms that are not favorable to us. We also could be required to seek collaborators for product candidate at an earlier stage than otherwise would be desirable or relinquish our rights to product candidates or technologies that we otherwise would seek to develop or commercialize ourselves. Failure to obtain capital when needed on acceptable terms may force us to delay, limit or terminate our product development and commercialization of our current or future product candidates, which could have a material and adverse effect on our business, financial condition, results of operations and prospects.

Risks Related to Discovery, Development and Commercialization

Our product candidates are in early stages of development and may fail in development or suffer delays that materially adversely affect their commercial viability. If we or our collaborators are unable to complete development of, or commercialize, our product candidates or experience significant delays in doing so, our business will be materially harmed.

We have no products on the market and all of our product candidates are in early stages of development. We expect the Investigational New Drug applications, or INDs, with respect to our development candidates, MORF-057 and MORF-720, to be submitted by the middle of 2020 and the end of 2020, respectively. Additionally, we have a portfolio of targets and programs that are in earlier stages of discovery and preclinical development and may never advance to clinical-stage development. Our ability to achieve and sustain profitability depends on obtaining regulatory approvals for, and successfully commercializing our product candidates, either alone or with third parties, and we cannot guarantee you that we will ever obtain regulatory approval for any of our product candidates. We have limited experience in conducting and managing the clinical trials necessary to obtain regulatory approvals, including approval by the FDA. Before obtaining regulatory approval for the commercial distribution of our product candidates, we or an existing or

future collaborator must conduct extensive preclinical tests and clinical trials to demonstrate the safety and efficacy in humans of our product candidates.

We may not have the financial resources to continue development of, or to modify existing or enter into new collaborations for, a product candidate if we experience any issues that delay or prevent regulatory approval of, or our ability to commercialize, product candidates, including:

- § preclinical study results may show the product candidate to be less effective than desired or to have harmful or problematic side effects;
- § preclinical studies conducted outside of the United States may be affected by tariffs or import/export restrictions imposed by the United States or other governments;
- § negative or inconclusive results from our clinical trials or the clinical trials of others for product candidates similar to ours, leading to a decision or requirement to conduct additional preclinical testing or clinical trials or abandon a program;
- § product-related side effects experienced by patients in our clinical trials or by individuals using drugs or therapeutic biologics similar to our product candidates;
- § our third-party manufacturers' inability to successfully manufacture our products;
- § inability of any third-party contract manufacturer to scale up manufacturing of our product candidates and those of our collaborators to supply the needs of clinical trials or commercial sales;
- § delays in submitting INDs or comparable foreign applications or delays or failures in obtaining the necessary approvals from regulators to commence a clinical trial, or a suspension or termination of a clinical trial once commenced;
- § conditions imposed by the FDA or comparable foreign authorities regarding the scope or design of our clinical trials;
- § delays in enrolling patients in our clinical trials;
- § high drop-out rates of our clinical trial patients;
- § inadequate supply or quality of product candidate components or materials or other supplies necessary for the conduct of our clinical trials;
- § inability to obtain alternative sources of supply for which we have a single source for product candidate components or materials;
- § greater than anticipated costs of our clinical trials;
- § manufacturing costs, formulation issues, pricing or reimbursement issues, or other factors that no longer make a product candidate economically feasible;
- § harmful side effects or inability of our product candidates to meet efficacy endpoints during clinical trials;
- § failure to demonstrate a benefit-risk profile acceptable to the FDA or other regulatory agencies;
- § unfavorable FDA or other regulatory agency inspection and review of one or more clinical trial sites or manufacturing facilities used in the testing and manufacture of any of our product candidates;

- failure of our third-party contractors or investigators to comply with regulatory requirements or otherwise meet their contractual obligations in a timely manner, or at all;

- delays and changes in regulatory requirements, policy and guidelines, including the imposition of additional regulatory oversight around clinical testing generally or with respect to our technology in particular; or

- varying interpretations of our data by the FDA and similar foreign regulatory agencies.

We or our collaborators' inability to complete development of, or commercialize our product candidates, or significant delays in doing so due to one or more of these factors, could have a material and adverse effect on our business, financial condition, results of operations and prospects.

Our business is heavily dependent on the success of our MORF-057 program and of our product candidate, MORF-720. Existing and future preclinical studies and clinical trials of these product candidates may not be successful, and if we are unable to commercialize these product candidates or experience significant delays in doing so, our business will be materially harmed.

We have invested a significant portion of our efforts and financial resources in the development of our MORF-057 and MORF-720 programs. However, our lead product candidates are still in the preclinical stage. Our ability to generate commercial product revenues, which we do not expect will occur for many years, if ever, will depend heavily on the successful development and eventual commercialization of our lead product candidates. We have not previously submitted a new drug application, or NDA, to the FDA, or similar regulatory approval filings to comparable foreign authorities, for any product candidate, and we cannot be certain that our product candidates will be successful in clinical trials or receive regulatory approval. Further, our product candidates may not receive regulatory approval even if they are successful in clinical trials. In addition, regulatory authorities may not complete their review processes in a timely manner, or additional delays may result if an FDA Advisory Committee or other regulatory authority recommends non-approval or restrictions on approval. In addition, we may experience delays or rejections based upon additional government regulation from future legislation or administrative action, or changes in regulatory authority policy during the period of product development, clinical trials and the review process. Regulatory authorities also may approve a product candidate for more limited indications than requested or with labeling that includes warnings, contraindications or precautions with respect to conditions of use. Regulatory authorities may also require Risk Evaluation and Mitigation Strategies, or REMS, or the performance of costly post-marketing clinical trials. If we do not receive regulatory approvals for our product candidates, we may not be able to continue our operations. Even if we successfully obtain regulatory approvals to market our product candidates, our revenues will be dependent, in part, upon the size of the markets in the territories for which we gain regulatory approval and have commercial rights. If the markets for patient subsets that we are targeting are not as significant as we estimate, we may not generate significant revenues from sales of such products, if approved.

We plan to seek regulatory approval to commercialize our product candidates both in the United States and in selected foreign countries. In order to obtain separate regulatory approvals in other countries, we must comply with numerous and varying regulatory requirements of such countries regarding safety and efficacy. Other countries also have their own regulations governing, among other things, clinical trials and commercial sales, as well as pricing and distribution of our product candidates, and we may be required to expend significant resources to obtain regulatory approval, which may not be successful, and to comply with ongoing regulations in these jurisdictions.

The success of our MORF-057 and MORF-720 product candidates, and our other product candidates will depend on many factors, including the following:

- successful completion of necessary preclinical studies to enable the initiation of clinical trials;

- successful enrollment of patients in, and the completion of, our clinical trials;

- receiving required regulatory authorizations for the development and approvals for the commercialization of our product candidates;
- establishing and maintaining arrangements with third-party manufacturers;
- obtaining and maintaining patent and trade secret protection and non-patent exclusivity for our product candidates and their components;
- enforcing and defending our intellectual property rights and claims;
- achieving desirable therapeutic properties for our product candidates' intended indications;
- launching commercial sales of our product candidates, if and when approved, whether alone or in collaboration with third parties;
- acceptance of our product candidates, if and when approved, by patients, the medical community and third-party payors;
- effectively competing with other therapies; and
- maintaining an acceptable safety profile of our product candidates through clinical trials and following regulatory approval.

If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize our product candidates, which would materially harm our business.

If we do not achieve our projected development goals in the time frames we announce and expect, the commercialization of our products may be delayed and, as a result, our stock price may decline.

From time to time, we estimate the timing of the anticipated accomplishment of various scientific, clinical, regulatory and other product development goals, which we sometimes refer to as milestones. These milestones may include the commencement or completion of scientific studies and clinical trials and the submission of regulatory filings. From time to time, we may publicly announce the expected timing of some of these milestones. All of these milestones are and will be based on numerous assumptions. The actual timing of these milestones can vary dramatically compared to our estimates, in some cases for reasons beyond our control. For example, in November 2019 we updated our guidance around the timing of our IND submission for MORF-720 based on the request for an additional preclinical study by the FDA. If we do not meet these milestones as publicly announced, or at all, the commercialization of our products may be delayed or never achieved and, as a result, our stock price may decline.

Our approach to the discovery and development of our therapeutic treatments is based on novel technologies that are unproven and may not result in marketable products.

We are developing a pipeline of product candidates using our Morphic integrin technology platform, or MInT Platform. Historically, dozens of integrin-targeted oral small molecule candidates of other companies that entered late-stage clinical trials have failed to result in FDA or EMA approved medicines. We are aware of certain companies currently exploring oral approaches to integrins. For example, Pliant Therapeutics, Inc. is currently in clinic for an $\alpha_v\beta_6$ /$\alpha_v\beta_1$ oral small-molecule integrin inhibitor. Development efforts and clinical results of these other companies may be unsuccessful, which could result in a negative perception of oral integrins and negatively impact the regulatory approval process of our product candidates, which would have a material and adverse effect on our business. For example, Biogen recently terminated a Phase 2 study of its monoclonal antibody targeting $\alpha_v\beta_6$, citing safety concerns. We believe that product candidates identified with our MInT Platform may offer an optimized therapeutic approach by taking advantage of conformational targeting next-generation physics-based technologies augmented with machine learning and artificial intelligence, which allow us to design, iterate and optimize leads in our discovery process. However, the scientific

research that forms the basis of our efforts to develop product candidates using our MInT Platform is ongoing and may not result in viable product candidates.

To date, we have not tested any of our product candidates in any clinical studies. We may ultimately discover that our MInT Platform and any product candidates resulting therefrom do not possess certain properties required for therapeutic effectiveness, including the ability to lock specific integrin conformations. Our product candidates may also be unable to remain stable in the human body for the period of time required for the drug to reach the target tissue or they may trigger immune responses that inhibit the ability of the product candidate to reach the target tissue or that cause adverse side effects in humans. We currently have only pre-clinical data regarding oral bioavailability of our product candidates. We may spend substantial funds attempting to introduce these properties and may never succeed in doing so. In addition, product candidates based on our MInT Platform may demonstrate different chemical and pharmacological properties in patients than they do in laboratory studies. Our MInT Platform and any product candidates resulting therefrom may not demonstrate the same chemical and pharmacological properties in humans and may interact with human biological systems in unforeseen, ineffective or harmful ways.

The regulatory approval process for novel product candidates such as ours can be more expensive and take longer than for other, better known or extensively studied product candidates. To our knowledge, no regulatory authority has granted approval for an oral small-molecule integrin inhibitor. We believe the FDA has limited experience with integrin-based therapeutics, which may increase the complexity, uncertainty and length of the regulatory approval process for our product candidates. We and our existing or future collaborators may never receive approval to market and commercialize any product candidate. Even if we or an existing or future collaborator obtains regulatory approval, the approval may be for targets, disease indications or patient populations that are not as broad as we intended or desired or may require labeling that includes significant use or distribution restrictions or safety warnings. We or an existing or future collaborator may be required to perform additional or unanticipated clinical trials to obtain approval or be subject to post-marketing testing requirements to maintain regulatory approval. If the products resulting from our MInT Platform and research programs prove to be ineffective, unsafe or commercially unviable, our MInT Platform and pipeline would have little, if any, value, which would have a material and adverse effect on our business, financial condition, results of operations and prospects.

Preclinical and clinical development involve a lengthy and expensive process, with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our current product candidates or any future product candidates.

All of our product candidates are in preclinical development and their risk of failure is high. It is impossible to predict when or if any of our product candidates will receive regulatory approval. To obtain the requisite regulatory approvals to commercialize any product candidates, we must demonstrate through extensive preclinical studies and lengthy, complex and expensive clinical trials that our product candidates are safe and effective in humans. Clinical testing 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 preclinical studies and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. We may be unable to establish clinical endpoints that applicable regulatory authorities would consider clinically meaningful, and a clinical trial can fail at any stage of testing. Differences in trial design between early-stage clinical trials and later-stage clinical trials make it difficult to extrapolate the results of earlier clinical trials to later clinical trials. Moreover, clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in clinical trials have nonetheless failed to obtain marketing approval of their products. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or to unfavorable safety profiles, notwithstanding promising results in earlier trials. There is typically a high rate of failure of product candidates proceeding through clinical trials. Most product candidates that commence clinical trials are never approved as products and there can be no assurance that any of our future clinical trials will ultimately be successful or support clinical development of our current or any of our future product candidates.

Our two lead programs are MORF-057 and MORF-720. We intend to advance our development candidates, MORF-057 and MORF-720, toward IND submissions by the middle of 2020 and the end of 2020, respectively. Commencing our

future clinical trials is subject to finalizing the trial design and submitting an IND or similar submission to the FDA or similar foreign regulatory authority. Even after we submit our IND or comparable submissions in other jurisdictions, the FDA or other regulatory authorities could disagree that we have satisfied their requirements to commence our clinical trials or disagree with our study design, which may require us to complete additional preclinical studies or amend our protocols or impose stricter conditions on the commencement of clinical trials.

We or our collaborators may experience delays in initiating or completing clinical trials. We or our collaborators also may experience numerous unforeseen events during, or as a result of, any future clinical trials that we could conduct that could delay or prevent our ability to receive marketing approval or commercialize our MORF-057 program or MORF-720 or any future product candidates, including:

- § regulators or institutional review boards, or IRBs, the FDA or ethics committees may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- § we may experience delays in reaching, or fail to reach, agreement on acceptable terms with prospective trial sites and prospective contract research organizations, or CROs, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- § clinical trial sites deviating from trial protocol or dropping out of a trial;
- § clinical trials of any product candidates may fail to show safety or efficacy, produce negative or inconclusive results and we may decide, or regulators may require us, to conduct additional preclinical studies or clinical trials or we may decide to abandon product development programs;
- § the number of subjects required for clinical trials of any product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or subjects may drop out of these clinical trials or fail to return for post-treatment follow-up at a higher rate than we anticipate;
- § our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all, or may deviate from the clinical trial protocol or drop out of the trial, which may require that we add new clinical trial sites or investigators;
- § we may elect to, or regulators, IRBs, or ethics committees may require that we or our investigators, suspend or terminate clinical research or trials for various reasons, including noncompliance with regulatory requirements or a finding that the participants in our trials are being exposed to unacceptable health risks;
- § the cost of clinical trials of any of our product candidates may be greater than we anticipate;
- § the quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be inadequate to initiate or complete a given clinical trial;
- § our inability to manufacture sufficient quantities of our product candidates for use in clinical trials;
- § reports from clinical testing of other therapies may raise safety or efficacy concerns about our product candidates;
- § our failure to establish an appropriate safety profile for a product candidate based on clinical or preclinical data for such product candidate as well as data emerging from other molecules in the same class as our product candidate; and
- § the FDA, EMA or other regulatory authorities may require us to submit additional data such as long-term toxicology studies, or impose other requirements before permitting us to initiate a clinical trial.

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 number and location of clinical sites we enroll, the proximity of patients to clinical sites, the eligibility and exclusion criteria for the trial, the design of the clinical trial, the inability to obtain and maintain patient consents, the risk that enrolled participants will drop out before completion, competing clinical trials and clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new drugs or therapeutic biologics that may be approved for the indications being investigated by us. Furthermore, we expect to rely on our collaborators, CROs and clinical trial sites to ensure the proper and timely conduct of our future clinical trials, including the patient enrollment process, and we have limited influence over their performance. Additionally, we could encounter delays if treating physicians encounter unresolved ethical issues associated with enrolling patients in future clinical trials of our product candidates in lieu of prescribing existing treatments that have established safety and efficacy profiles.

We could also encounter delays if a clinical trial is suspended or terminated by us, the IRBs of the institutions in which such trials are being conducted, or the FDA, EMA or other regulatory authorities, or if a clinical trial is recommended for suspension or termination by the Data Safety Monitoring Board, or the DSMB, for such trial. A suspension or termination may be imposed due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA, EMA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a product or treatment, failure to establish or achieve clinically meaningful trial endpoints, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. Clinical studies may also be delayed or terminated as a result of ambiguous or negative interim results. 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. Further, the FDA, EMA or other regulatory authorities may disagree with our clinical trial design and our interpretation of data from clinical trials, or may change the requirements for approval even after they have reviewed and commented on the design for our clinical trials.

Our product development costs will increase if we experience delays in clinical testing or marketing approvals. We do not know whether any of our clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. Significant clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates and may allow our competitors to bring products to market before we do, potentially impairing our ability to successfully commercialize our product candidates and harming our business and results of operations. Any delays in our clinical development programs may harm our business, financial condition and results of operations significantly.

Results of preclinical studies and early clinical trials may not be predictive of results of future clinical trials.

The outcome of preclinical studies and early clinical trials may not be predictive of the success of later clinical trials, and interim results of clinical trials. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials after achieving positive results in earlier development, and we could face similar setbacks. 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 have limited experience in designing clinical trials and may be unable to design and execute a clinical trial to support marketing approval. In addition, preclinical and clinical data are often susceptible to varying interpretations and analyses. Many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval for the product candidates. Even if we, or future collaborators, believe that the results of clinical trials for our product candidates warrant marketing approval, the FDA or comparable foreign regulatory authorities may disagree and may not grant marketing approval of our product candidates.

In some instances, there can be significant variability in safety or efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the dosing regimen and other clinical trial protocols and the rate of dropout among clinical trial patients. If we fail to receive positive results in clinical trials of our product candidates, the development timeline and regulatory approval and commercialization prospects for our product candidates, and, correspondingly, our business and financial prospects would be negatively impacted.

Interim and preliminary or topline data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publish interim topline or preliminary data from our clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Preliminary or topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary or topline data we previously published. As a result, interim and preliminary data should be viewed with caution until the final data are available. Adverse differences between interim or preliminary or topline data and final data could significantly harm our reputation and business prospects.

Our future clinical trials or those of our current and future collaborators may reveal significant adverse events not seen in our preclinical studies and may result in a safety profile that could inhibit regulatory approval or market acceptance of any of our product candidates.

If significant adverse events or other side effects are observed in any of our clinical trials, we may have difficulty recruiting patients to our clinical trials, patients may drop out of our trials, or we may be required to abandon the trials or our development efforts of one or more product candidates altogether. For example, progressive multifocal leukoencephalopathy, or PML, has been observed by others as an adverse effect during late-stage clinical development of infusible antibody inhibitor of $\alpha_4\beta_1$ integrin, natalizumab. This adverse effect was not observed in the preclinical studies or during early clinical development of natalizumab. We, the FDA, EMA or other applicable regulatory authorities, or an IRB may suspend clinical trials of a product candidate at any time for various reasons, including a belief that subjects or patients in such trials are being exposed to unacceptable health risks or adverse side effects. Some potential therapeutics developed in the biotechnology industry that initially showed therapeutic promise in early-stage trials have later been found to cause side effects that prevented their further development. Even if the side effects do not preclude the product candidate from obtaining or maintaining marketing approval, undesirable side effects may inhibit market acceptance of the approved product due to its tolerability versus other therapies. Any of these developments could materially harm our business, financial condition and prospects.

We may not be successful in our efforts to use our MInT Platform to expand our pipeline of product candidates and develop marketable products.

The success of our business depends in part upon our ability to discover, develop and commercialize products based on our MInT Platform. MORF-057 and MORF-720 are our lead product candidates and our research programs may fail to identify other potential product candidates for clinical development for a number of reasons. Our research methodology may be unsuccessful in identifying potential product candidates or our potential product candidates may be shown to have harmful side effects or may have other characteristics that may make the products unmarketable or unlikely to receive marketing approval. If any of these events occur, we may be forced to abandon our development efforts for a program or for multiple programs, which would materially harm our business and could potentially cause us to cease operations. Research programs to identify new product candidates require substantial technical, financial and human resources.

We may expend our limited resources to pursue a particular product candidate and fail to capitalize on product candidates 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 our research and development efforts on certain selected product candidates. For example, we are initially focused on our lead product candidates, MORF-057 and MORF-720. As a result, we may forgo or delay pursuit of opportunities with other product candidates 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 product candidates. 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 to such product candidate.

We face competition from entities that have developed or may develop product candidates for autoimmune, cardiovascular and metabolic diseases, fibrosis and cancer, including companies developing novel treatments and technology platforms. If these companies develop technologies or product candidates more rapidly than we do or their technologies are more effective, our ability to develop and successfully commercialize product candidates may be adversely affected.

The development and commercialization of drugs is highly competitive. Our product candidates, if approved, will face significant competition and our failure to effectively compete may prevent us from achieving significant market penetration. Most of our competitors have significantly greater resources than we do, and we may not be able to successfully compete. We compete with a variety of multinational biopharmaceutical companies, specialized biotechnology companies and emerging biotechnology companies, as well as with technologies and product candidates being developed at universities and other research institutions. Our competitors have developed, are developing or will develop product candidates and processes competitive with our product candidates and processes. Competitive therapeutic treatments include those that have already been approved and accepted by the medical community and any new treatments, including those based on novel technology platforms that enter the market. We believe that a significant number of products are currently under development, and may become commercially available in the future, for the treatment of conditions for which we are trying, or may try, to develop product candidates. There is intense and rapidly evolving competition in the biotechnology, biopharmaceutical and integrin and immunoregulatory therapeutics fields. Competition from many sources exists or may arise in the future. Our competitors include larger and better funded biopharmaceutical, biotechnological and therapeutics companies, including companies focused on therapeutics for autoimmune, cardiovascular and metabolic diseases, fibrosis and cancer, as well as numerous small companies. Moreover, we also compete with current and future therapeutics developed at universities and other research institutions. Some of these companies are well-capitalized and, in contrast to us, have significant clinical experience, and may include our existing or future collaborators. In addition, these companies compete with us in recruiting scientific and managerial talent.

Our success will depend partially on our ability to develop and commercialize therapeutics that are safer and more effective than competing products. Our commercial opportunity and success will be reduced or eliminated if competing products are safer, more effective, or less expensive than the therapeutics we develop.

Our MORF-057 program, initially under development for treatment of IBD, if approved would face competition from approved IBD treatments marketed by AbbVie, Johnson & Johnson, UCB, Biogen and Pfizer, in addition to other major pharmaceutical companies, against which our product candidate may compete, if approved. Further, Takeda Pharmaceutical Company Ltd. currently markets Entyvio, which is an $\alpha_4\beta_7$ monoclonal antibody to treat ulcerative colitis and Crohn's disease. In addition, we are aware of IBD treatments in clinical development by AbbVie, Johnson & Johnson, Pfizer, Gilead, Eli Lilly, Bristol-Myers Squibb, Boehringer Ingelheim, Theravance, and Arena Pharmaceuticals, in addition to other pharmaceutical companies. Further, Roche has an $\alpha_4\beta_7$ / $\alpha_E\beta_7$ monoclonal antibody in Phase 3 development for IBD and Protagonist has a Phase 2 gut-restricted $\alpha_4\beta_7$ program in Phase 2 development for ulcerative colitis.

MORF-720, under development for the treatment of IPF, if approved, would face competition from approved IPF treatments marketed by Roche Holding AG and Boehringer Ingelheim GmbH. In addition, we are aware of IPF treatments in development by Galapagos NV, FibroGen, Galecto, Roche, and Bristol-Myers Squibb, in addition to other pharmaceutical companies. Further, we are aware of programs targeting $\alpha_v\beta_6$ that are currently being investigated in clinical trials by companies including Pliant Therapeutics, Inc., and Indalo Therapeutics, Inc. Biogen recently terminated a Phase 2 study of its monoclonal antibody targeting $\alpha_v\beta_6$, citing safety concerns.

Many of these competitors have significantly greater financial, technical, manufacturing, marketing, sales, and supply resources or experience than we have. If we successfully obtain approval for any product candidate, we will face competition based on many different factors, including the safety and effectiveness of our products, the ease with which our products can be administered and the extent to which patients accept relatively new routes of administration, the

timing and scope of regulatory approvals for these products, the availability and cost of manufacturing, marketing and sales capabilities, price, reimbursement coverage and patent position. Competing products could present superior treatment alternatives, including by being more effective, safer, less expensive or marketed and sold more effectively than any products we may develop. Competitive products may make any products we develop obsolete or noncompetitive before we recover the expense of developing and commercializing our product candidates. Such competitors could also recruit our employees, which could negatively impact our level of expertise and our ability to execute our business plan.

Our current product candidates or any future product candidates may not achieve adequate market acceptance among physicians, patients, healthcare third-party payors and others in the medical community necessary for commercial success, if approved, and we may not generate any future revenue from the sale or licensing of product candidates.

Even if regulatory approval is obtained for a product candidate, we may not generate or sustain revenue from sales of the product due to factors such as whether the product can be sold at a competitive cost and whether it will otherwise be accepted in the market. Historically, several injectable integrin inhibitors have been approved by the FDA for treatment of inflammatory bowel disease, multiple sclerosis, psoriasis, acute coronary syndrome and dry eye disease. However, our product candidates are based on a novel approach to oral integrin therapies, and while integrins are a well-understood receptor family, to date, no oral small molecule integrin therapies have been approved by the FDA. Market participants with significant influence over acceptance of new treatments, such as physicians and third-party payors, may not adopt an orally bioavailable product based on our novel technologies, and we may not be able to convince the medical community and third-party payors to accept and use, or to provide favorable reimbursement for, any product candidates developed by us or our existing or future collaborators. Market acceptance of our product candidates will depend on, among other factors:

- the timing of our receipt of any marketing and commercialization approvals;
- the terms of any approvals and the countries in which approvals are obtained;
- the safety and efficacy of our product candidates as demonstrated in clinical trials;
- the prevalence and severity of any adverse side effects associated with our product candidates;
- limitations or warnings contained in any labeling approved by the FDA or other regulatory authority;
- relative convenience and ease of administration of our product candidates;
- the willingness of patients to accept any new methods of administration;
- unfavorable publicity relating to our current product candidates or any future product candidates;
- the success of our physician education programs;
- the effectiveness of sales and marketing efforts;
- the availability of coverage and adequate reimbursement from government and third-party payors;
- the pricing of our products, particularly as compared to alternative treatments; and
- the availability of alternative effective treatments for the disease indications our product candidates are intended to treat and the relative risks, benefits and costs of those treatments.

Sales of medical products also depend on the willingness of physicians to prescribe the treatment, which is likely to be based on a determination by these physicians that the products are safe, therapeutically effective and cost effective. In

addition, the inclusion or exclusion of products from treatment guidelines established by various physician groups and the viewpoints of influential physicians can affect the willingness of other physicians to prescribe the treatment. We cannot predict whether physicians, physicians' organizations, hospitals, other healthcare providers, government agencies or private insurers will determine that our product is safe, therapeutically effective and cost effective as compared with competing treatments. If any product candidate is approved but does not achieve an adequate level of acceptance by such parties, we may not generate or derive sufficient revenue from that product candidate and may not become or remain profitable.

Because our product candidates are based on new technology, we expect that they will require extensive research and development and have substantial manufacturing and processing costs. In addition, our estimates regarding potential market size for any indication may be materially different from what we discover to exist at the time we commence commercialization, if any, for a product, which could result in significant changes in our business plan and have a material adverse effect on our business, financial condition, results of operations and prospects. Moreover, if any product candidate we commercialize fails to achieve market acceptance, it could have a material and adverse effect on our business, financial condition, results of operations and prospects.

If in the future we are unable to establish U.S. or global sales and marketing capabilities or enter into agreements with third parties to sell and market our product candidates, we may not be successful in commercializing our product candidates if they are approved and we may not be able to generate any revenue.

We currently do not have a marketing or sales team for the marketing, sales and distribution of any of our product candidates that are able to obtain regulatory approval. To commercialize any product candidates after approval, we must build on a territory-by-territory basis marketing, sales, distribution, managerial and other non-technical capabilities or arrange with third parties to perform these services, and we may not be successful in doing so. If our product candidates receive regulatory approval, we may decide to establish an internal sales or marketing team with technical expertise and supporting distribution capabilities to commercialize our product candidates, which will be expensive and time consuming and will require significant attention of our executive officers to manage. For example, some state and local jurisdictions have licensing and continuing education requirements for pharmaceutical sales representatives, which requires time and financial resources. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of any of our product candidates that we obtain approval to market.

With respect to the commercialization of all or certain of our product candidates, we may choose to collaborate, either globally or on a territory-by-territory basis, with third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems. If we are unable to enter into such arrangements when needed on acceptable terms, or at all, we may not be able to successfully commercialize any of our product candidates that receive regulatory approval, or any such commercialization may experience delays or limitations. If we are not successful in commercializing our product candidates, either on our own or through collaborations with one or more third parties, our future product revenue will suffer and we may incur significant additional losses.

If any of our product candidates receives marketing approval and we or others later identify undesirable side effects caused by the product candidate, our ability to market and derive revenue from the product candidates could be compromised.

Undesirable side effects caused by our product candidates could cause regulatory authorities to interrupt, delay or halt clinical trials and could result in more restrictive labeling or the delay or denial of regulatory approval by the FDA or other regulatory authorities. Results of future clinical trials could reveal a high and unacceptable severity and prevalence of side effects. In such an event, our future clinical 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. Such side effects could also affect patient recruitment or the ability of enrolled patients to initiate or complete the clinical trial or result in potential product liability claims. Any of these occurrences may materially and adversely affect our business, financial condition, results of operations and prospects.

Further, clinical trials by their nature utilize a sample of the potential patient population. With a limited number of patients and limited duration of exposure, rare and severe side effects of our product candidates may only be uncovered with a significantly larger number of patients exposed to the product candidate.

If any of our product candidates receive regulatory approval and we or others identify undesirable side effects caused by such product, any of the following adverse events could occur:

- § regulatory authorities may withdraw their approval of the product or seize the product;
- § we may be required to recall the product or change the way the product is administered to patients;
- § additional restrictions may be imposed on the marketing of the particular product or the manufacturing processes for the product or any component thereof;
- § we may be subject to fines, injunctions or the imposition of civil or criminal penalties;
- § regulatory authorities may require the addition of labeling statements, such as a boxed warning or a contraindication;
- § we may be required to create a Medication Guide outlining the risks of such side effects for distribution to patients;
- § we could be sued and held liable for harm caused to patients;
- § the product may become less competitive; and
- § our reputation may suffer.

Any of these occurrences could have a material and adverse effect on our business, financial condition, results of operations and prospects.

We anticipate that some of our product candidates may be studied in combination with third-party drugs, some of which may still be in development, and we have limited or no control over the supply, regulatory status, or regulatory approval of such drugs.

Some of our product candidates may be studied in combination with third-party drugs. For example, we may explore the use of our oral small-molecule integrin therapeutics targeting $\alpha_4\beta_7$ as a combination therapy with other drugs for the treatment of inflammatory bowel disease. The development of product candidates for use in combination with another product or product candidate may present challenges that are not faced for single agent product candidates. The FDA or other regulatory authorities may require us to use more complex clinical trial designs in order to evaluate the contribution of each product and product candidate to any observed effects. It is possible that the results of these trials could show that any positive previous trial results are attributable to the combination therapy and not our product candidates. Moreover, following product approval, the FDA or other regulatory authorities may require that products used in conjunction with each other be cross labeled for combined use. To the extent that we do not have rights to the other product, this may require us to work with a third party to satisfy such a requirement. Moreover, developments related to the other product may impact our clinical trials for the combination as well as our commercial prospects should we receive marketing approval. Such developments may include changes to the other product's safety or efficacy profile, changes to the availability of the approved product, and changes to the standard of care.

If we pursue such combination therapies, we cannot be certain that a steady supply of such drugs will be commercially available. Any failure to enter into such commercial relationships, or the expense of purchasing therapies in the market, may delay our development timelines, increase our costs and jeopardize our ability to develop our product candidates as commercially viable combination therapies. The occurrence of any of these could adversely affect our business, results of operations and financial condition.

In the event that any future collaborator or supplier cannot continue to supply their products on commercially reasonable terms, we would need to identify alternatives for accessing such products. Additionally, should the supply of products of any collaborator or supplier be interrupted, delayed or otherwise be unavailable to us, our clinical trials may be delayed. In the event we are unable to source a supply of any alternative therapy, or are unable to do so on commercially reasonable terms, our business, results of operations and financial condition may be adversely affected.

Risks Related to Our Reliance on Third Parties

We have entered into collaborations with AbbVie and Janssen and may, in the future, seek to enter into collaborations with other third parties for the discovery, development and commercialization of our product candidates. If our collaborators cease development efforts under our collaboration agreements, or if any of those agreements are terminated, these collaborations may fail to lead to commercial products and we may never receive milestone payments or future royalties under these agreements.

Our collaborations with AbbVie and Janssen are important to our business. We have entered into collaborations with AbbVie and Janssen to discover or develop certain integrin-based therapeutics, and such collaborations currently represent a significant portion of our product pipeline. In particular, MORF-720 is developed in collaboration with AbbVie. In both collaborations, we will conduct research and development activities through the completion of IND-enabling studies, upon which AbbVie and Janssen can exercise their options to develop and commercialize a successful product candidate. We have derived substantially all of our revenue to date from these collaboration agreements, and we expect a significant portion of our future revenue and cash resources to be derived from these agreements or other similar agreements into which we may enter in the future. Revenue from research and development collaborations depends upon continuation of the collaborations, payments for research and development services and resulting options to acquire any licenses of successful product candidates, and the achievement of milestones, contingent payments and royalties, if any, derived from future products developed from our research. If we are unable to successfully advance the development of our product candidates or achieve milestones, revenue and cash resources from milestone payments under our collaboration agreements will be substantially less than expected.

In addition, we may in the future seek third-party collaborators for research, development and commercialization of other therapeutic technologies or product candidates. Biopharmaceutical companies are our prior and likely future collaborators for any marketing, distribution, development, licensing or broader collaboration arrangements. If we fail to enter into future collaborations on commercially reasonable terms, or at all, or such collaborations are not successful, we may not be able to execute our strategy to develop certain targets, product candidates or disease areas that we believe could benefit from the resources of either larger biopharmaceutical companies or those specialized in a particular area of relevance.

With respect to our existing collaboration agreements, and what we expect will be the case with any future collaboration agreements, we have and expect to have limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of our product candidates. Moreover, our ability to generate revenues from these arrangements will depend on our collaborators' abilities to successfully perform the functions assigned to them in these arrangements.

Collaborations involving our product candidates currently pose, and will continue to pose, the following risks to us:

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations;

- collaborators may not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization programs based on preclinical studies or clinical trial results, changes in the collaborators' strategic focus or available funding, or external factors such as an acquisition that diverts resources or creates competing priorities;

- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;

- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;

- collaborators with marketing and distribution rights to one or more products may not commit sufficient resources to the marketing and distribution of such product or products;

- collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to litigation or potential liability;

- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability;

- disputes may arise between the collaborators and us that result in the delay or termination of the research, development or commercialization of our product candidates or that result in costly litigation or arbitration that diverts management attention and resources; and

- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates.

As a result of the foregoing, our current and any future collaboration agreements may not lead to development or commercialization of our product candidates in the most efficient manner or at all. If a collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our product development or commercialization program could be delayed, diminished or terminated. Any failure to successfully develop or commercialize our product candidates pursuant to our current or any future collaboration agreements could have a material and adverse effect on our business, financial condition, results of operations and prospects.

Moreover, to the extent that any of our existing or future collaborators were to terminate a collaboration agreement, we may be forced to independently develop these product candidates, including funding preclinical studies or clinical trials, assuming marketing and distribution costs and defending intellectual property rights, or, in certain instances, abandon product candidates altogether, any of which could result in a change to our business plan and have a material adverse effect on our business, financial condition, results of operations and prospects.

Our existing discovery collaboration with Schrödinger is important to our business. If we are unable to maintain this collaboration, or if this collaboration is not successful, our business could be adversely affected.

In June 2015, we entered into a Collaboration Agreement with Schrödinger, which was subsequently amended in March 2018 and in May 2019, or the Schrödinger Agreement. Under the collaboration, Schrödinger will use its technology platform to perform virtual screens of members of the target class of human integrins, and we and Schrödinger will collaborate to facilitate prioritization of targets, perform target validation and analysis, identify leads and perform lead optimization. See “Management’s Discussion and Analysis of Financial Condition and Results of Operation.” Schrödinger has granted us an exclusive license for all intellectual property for our product candidates.

Because we currently rely on Schrödinger for a substantial portion of our discovery capabilities, if Schrödinger delays or fails to perform its obligations under the Schrödinger Agreement, disagrees with our interpretation of the terms of the collaboration or our discovery plan or terminates the Schrödinger Agreement, our pipeline of product candidates would be adversely affected. Schrödinger may also fail to properly maintain or defend the intellectual property we have licensed from them, or even infringe upon, our intellectual property rights, leading to the potential invalidation of our

intellectual property or subjecting us to litigation or arbitration, any of which would be time-consuming and expensive. Additionally, either party has the right to terminate the collaboration pursuant to the terms of the Schrödinger Agreement. If our collaboration with Schrödinger is terminated, especially during our discovery phase, the development of our product candidates would be materially delayed or harmed.

We may have conflicts with our collaborators that could delay or prevent the development or commercialization of our product candidates.

We may have conflicts with our collaborators, such as conflicts concerning the interpretation of preclinical or clinical data, the achievement of milestones, the interpretation of contractual obligations, payments for services, development obligations or the ownership of intellectual property developed during our collaboration. If any conflicts arise with any of our collaborators, such collaborator may act in a manner that is averse to our best interests. Any such disagreement could result in one or more of the following, each of which could delay or prevent the development or commercialization of our product candidates, and in turn prevent us from generating revenues: unwillingness on the part of a collaborator to pay us milestone payments or royalties we believe are due to us under a collaboration, which could require us to raise additional capital; uncertainty regarding ownership of intellectual property rights arising from our collaborative activities, which could prevent us from entering into additional collaborations; unwillingness by the collaborator to cooperate in the development or manufacture of the product, including providing us with product data or materials; unwillingness on the part of a collaborator to keep us informed regarding the progress of its development and commercialization activities or to permit public disclosure of the results of those activities; initiating of litigation or alternative dispute resolution options by either party to resolve the dispute; or attempts by either party to terminate the agreement.

We may not successfully engage in strategic transactions, including any additional collaborations we seek, which could adversely affect our ability to develop and commercialize product candidates, impact our cash position, increase our expenses and present significant distractions to our management.

From time to time, we may consider strategic transactions, such as additional collaborations, acquisitions of companies, asset purchases and out- or in-licensing of product candidates or technologies that we believe will complement or augment our existing business. In particular, we will evaluate and, if strategically attractive, seek to enter into additional collaborations, including with major biotechnology or biopharmaceutical companies. The competition for collaborators is intense, and the negotiation process is time-consuming and complex. Any new collaboration may be on terms that are not optimal for us, and we may not be able to maintain any new collaboration if, for example, development or approval of a product candidate is delayed, sales of an approved product candidate do not meet expectations or the collaborator terminates the collaboration. In addition, a significant number of recent business combinations among large pharmaceutical companies has resulted in a reduced number of potential future strategic partners. Our collaborators may consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate. Our ability to reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the strategic partner’s resources and expertise, the terms and conditions of the proposed collaboration and the proposed strategic partner’s evaluation of a number of factors. These factors may include the design or results of clinical trials, the likelihood of approval by the FDA or similar regulatory authorities outside the United States, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge and industry and market conditions generally. Moreover, if we acquire assets with promising markets or technologies, we may not be able to realize the benefit of acquiring such assets if we are not able to successfully integrate them with our existing technologies. We may encounter numerous difficulties in developing, testing, manufacturing and marketing any new products resulting from a strategic acquisition that delay or prevent us from realizing their expected benefits or enhancing our business.

We cannot assure you that following any such collaboration, or other strategic transaction, we will achieve the expected synergies to justify the transaction. For example, such transactions may require us to incur non-recurring or other charges, increase our near- and long-term expenditures and pose significant integration or implementation challenges or

disrupt our management or business. These transactions would entail numerous operational and financial risks, including exposure to unknown liabilities, disruption of our business and diversion of our management's time and attention in order to manage a collaboration or develop acquired products, product candidates or technologies, incurrence of substantial debt or dilutive issuances of equity securities to pay transaction consideration or costs, higher than expected collaboration, acquisition or integration costs, write-downs of assets or goodwill or impairment charges, increased amortization expenses, difficulty and cost in facilitating the collaboration or combining the operations and personnel of any acquired business, impairment of relationships with key suppliers, manufacturers or customers of any acquired business due to changes in management and ownership and the inability to retain key employees of any acquired business.

Accordingly, although there can be no assurance that we will undertake or successfully complete any transactions of the nature described above, any transactions that we do complete may be subject to the foregoing or other risks and would have a material and adverse effect on our business, financial condition, results of operations and prospects. Conversely, any failure to enter any additional collaboration or other strategic transaction that would be beneficial to us could delay the development and potential commercialization of our product candidates and have a negative impact on the competitiveness of any product candidate that reaches market.

We expect to rely on third parties to conduct certain of our preclinical studies or clinical trials. If those third parties do not perform as contractually required, fail to satisfy legal or regulatory requirements, miss expected deadlines or terminate the relationship, our development program could be delayed with potentially material and adverse effects on our business, financial condition, results of operations and prospects.

We intend to rely in the future on third-party clinical investigators, CROs, clinical data management organizations and consultants to assist or provide the design, conduct, supervision and monitoring of preclinical studies and clinical trials of our product candidates. Because we intend to rely on these third parties and will not have the ability to conduct all preclinical studies or clinical trials independently, we will have less control over the timing, quality and other aspects of preclinical studies and clinical trials than we would have had we conducted them on our own. These investigators, CROs and consultants will not be our employees and we will have limited control over the amount of time and resources that they dedicate to our programs. These third parties may have contractual relationships with other entities, some of which may be our competitors, which may draw time and resources from our programs. The third parties with which we may contract might not be diligent, careful or timely in conducting our preclinical studies or clinical trials, resulting in the preclinical studies or clinical trials being delayed or unsuccessful.

If we cannot contract with acceptable third parties on commercially reasonable terms, or at all, or if these third parties do not carry out their contractual duties, satisfy legal and regulatory requirements for the conduct of preclinical studies or clinical trials or meet expected deadlines, our clinical development programs could be delayed and otherwise adversely affected. In all events, we will be responsible for ensuring that each of our preclinical studies and clinical trials are conducted in accordance with the general investigational plan and protocols for the trial as well as applicable legal and regulatory requirements. The FDA generally requires preclinical studies to be conducted in accordance with good laboratory practices and clinical trials to be conducted in accordance with good clinical practices, including for designing, conducting, recording and reporting the results of preclinical studies and clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of clinical trial participants are protected. Our reliance on third parties that we do not control will not relieve us of these responsibilities and requirements. Any adverse development or delay in our preclinical studies or clinical trials as a result of our reliance on third parties could have a material and adverse effect on our business, financial condition, results of operations and prospects.

If any of our relationships with these third-party CROs or others terminate, we may not be able to enter into arrangements with alternative CROs or other third parties or to do so on commercially reasonable terms. Switching or adding additional CROs involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO begins work. As a result, delays may occur, which can materially impact our ability to meet our desired clinical development timelines.

We rely on third-party manufacturers and suppliers to supply components of our product candidates. The loss of our third-party manufacturers or suppliers, or our or their failure to comply with applicable regulatory requirements or to supply sufficient quantities at acceptable quality levels or prices, or at all, would materially and adversely affect our business.

We do not own or operate facilities for drug manufacturing, storage, distribution or quality testing. We currently rely, and may continue to rely, on third-party contract manufacturers, including in the U.K. and China, to manufacture bulk drug substances, drug products, raw materials, samples, components, or other materials and reports. Reliance on third-party manufacturers may expose us to different risks than if we were to manufacture product candidates ourselves. Under our collaboration agreements with AbbVie and Janssen, our collaborators will assume responsibility for the manufacturing according to the terms of those agreements for licensed products. There can be no assurance that our preclinical and clinical development product supplies will not be limited, interrupted, terminated or of satisfactory quality or continue to be available at acceptable prices. In particular, any replacement of our manufacturer could require significant effort and expertise because there may be a limited number of qualified replacements.

The manufacturing process for a product candidate is subject to FDA and foreign regulatory authority review. We, and our suppliers and manufacturers, must meet applicable manufacturing requirements and undergo rigorous facility and process validation tests required by regulatory authorities in order to comply with regulatory standards, such as current Good Manufacturing Practices, or cGMPs. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the FDA and foreign regulatory authorities. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or comparable foreign regulatory authorities, we may not be able to rely on their manufacturing facilities for the manufacture of elements of our product candidates. Moreover, we do not control the manufacturing process at our contract manufacturers, and are completely dependent on them for compliance with current regulatory requirements. In the event that any of our manufacturers fails to comply with such requirements or to perform its obligations in relation to quality, timing or otherwise, or if our supply of components or other materials becomes limited or interrupted for other reasons, we may be forced to enter into an agreement with another third party, which we may not be able to do on reasonable terms, if at all. In some cases, the technical skills or technology required to manufacture our product candidates may be unique or proprietary to the original manufacturer and we may have difficulty transferring such to another third party. These factors would increase our reliance on such manufacturer or require us to obtain a license from such manufacturer in order to enable us, or to have another third party, manufacture our product candidates. If we are required to change manufacturers for any reason, we will be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations and guidelines; and we may be required to repeat some of the development program. The delays associated with the verification of a new manufacturer could negatively affect our ability to develop product candidates in a timely manner or within budget.

We expect to continue to rely on third-party manufacturers if we receive regulatory approval for any product candidate. To the extent that we have existing, or enter into future, manufacturing arrangements with third parties, we will depend on these third parties to perform their obligations in a timely manner consistent with contractual and regulatory requirements, including those related to quality control and assurance. Any manufacturing facilities used to produce our products will be subject to periodic review and inspection by the FDA and foreign regulatory authorities, including for continued compliance with cGMP requirements, quality control, quality assurance and corresponding maintenance of records and documents. If we are unable to obtain or maintain third-party manufacturing for product candidates, or to do so on commercially reasonable terms, we may not be able to develop and commercialize our product candidates successfully. Our or a third party’s failure to execute on our manufacturing requirements, comply with cGMPs or maintain a compliance status acceptable to the FDA or foreign regulatory authorities could adversely affect our business in a number of ways, including:

- an inability to initiate or continue clinical trials of product candidates under development;
- delay in submitting regulatory applications, or receiving regulatory approvals, for product candidates;
- loss of the cooperation of existing or future collaborators;

- § subjecting third-party manufacturing facilities to additional inspections by regulatory authorities;
- § requirements to cease distribution or to recall batches of our product candidates; and
- § in the event of approval to market and commercialize a product candidate, an inability to meet commercial demands for our products.

Additionally, our contract manufacturers may experience manufacturing difficulties due to resource constraints or as a result of labor disputes, unstable political environments, or medical epidemics such as the coronavirus outbreak. If our contract manufacturers were to encounter any of these difficulties, our ability to provide our product candidates to patients in preclinical and clinical trials, or to provide product for treatment of patients once approved, would be jeopardized.

For example, the United Kingdom formally left the European Union on January 31, 2020, often referred to as Brexit, which has caused uncertainty in the current regulatory framework in Europe. Brexit has resulted in the European Medicines Agency, or the EMA, moving from the United Kingdom to the Netherlands. In the United Kingdom, this transition may cause disruption in the administrative and medical scientific links between the EMA and MHRA. Although the government of the United Kingdom has stated its intent to comply with legislation regarding the authorization of medical products as it leaves the European Union, the EMA and the United Kingdom are drawing up contingency plans should a “no deal” exit occur. A “no deal” exit would lead to disruption in the execution of international multi-center clinical trials, the monitoring of adverse events in through pharmacovigilance programs, the evaluation of the benefit-risk profiles of new medicinal products, and determination of marketing authorization. There would also be disruption to the supply and distribution as well as the import/export both of active pharmaceutical ingredients (API) and finished product. Such a disruption would create supply difficulties for ongoing clinical trials and may damage the integrity of the pharmacovigilance database for the safety of new products. When the United Kingdom leaves the European Union, it will no longer automatically comply with the standards of clinical efficacy, safety and chemistry control, and manufacture as applied by the European Medicines Directive. The current lack of detail and resolution with regard to the Brexit implementation may result in a disruption of the manufacturing and supply of components of our product candidates in the U.K. and we are unable to confidently predict the effects of such disruption to the regulatory framework in Europe.

We, or our third-party contract research organizations, face risks related to health epidemics and other outbreaks, which could significantly disrupt our operations.

Our business could be adversely impacted by the effects of the coronavirus or other epidemics. We currently rely, and may continue to rely, on third-party contract research organizations in China to manufacture raw materials, samples, components, or other materials and reports. Several of our contract research organizations are located throughout China, including in Wuhan. Consequently, supply of research materials and early research activities are susceptible to factors adversely affecting one or more of these locations. We may also experience impacts to certain of our suppliers as a result of coronavirus or other health epidemic or outbreak occurring in one or more of these locations, which may materially and adversely affect our business, financial condition and results of operations. Further, our operation may experience disruptions, such as temporary closure of the offices of our suppliers and suspension of services, which may result in us having to procure the components for our product candidates from alternate suppliers, which may materially and adversely affect our development timelines, and our business, financial condition and results of operations.

The manufacturing of small molecules is complex and our third-party manufacturers may encounter difficulties in production. If we or any of our third-party manufacturers encounter such difficulties, our ability to provide supply of our product candidates for clinical trials, our ability to obtain marketing approval, or our ability to provide supply of our products for patients, if approved, could be delayed or stopped.

Our product candidates are biopharmaceuticals and the process of manufacturing biopharmaceuticals is complex, time-consuming, highly regulated and subject to multiple risks. Our contract manufacturers must comply with legal requirements, cGMPs and guidelines for the manufacturing of biopharmaceuticals used in clinical trials and, if approved, marketed products. Our contract manufacturers may have limited experience in the manufacturing of cGMP batches.

Manufacturing biopharmaceuticals is highly susceptible to product loss due to contamination, equipment failure, improper installation or operation of equipment, vendor or operator error, inconsistency in yields, variability in product characteristics and difficulties in scaling the production process. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects and other supply disruptions. If microbial, viral or other contaminations are discovered at our third-party manufacturers' facilities, such facilities may need to be closed for an extended period of time to investigate and remedy the contamination, which could delay clinical trials and adversely harm our business. Moreover, if the FDA determines that our third-party manufacturers' facilities are not in compliance with FDA laws and regulations, including those governing cGMPs, the FDA may deny NDA approval until the deficiencies are corrected or we replace the manufacturer in our NDA with a manufacturer that is in compliance.

In addition, there are risks associated with large scale manufacturing for clinical trials or commercial scale including, among others, cost overruns, potential problems with process scale-up, process reproducibility, stability issues, compliance with cGMPs, lot consistency and timely availability of raw materials. Even if our collaborators obtain regulatory approval for any of our product candidates, there is no assurance that manufacturers will be able to manufacture the approved product to specifications acceptable to the FDA or other regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential launch of the product or to meet potential future demand. If our manufacturers are unable to produce sufficient quantities for clinical trials or for commercialization, commercialization efforts would be impaired, which would have an adverse effect on our business, financial condition, results of operations and prospects.

Scaling up a biopharmaceutical manufacturing process is a difficult and uncertain task, and our third-party manufacturers may not have the necessary capabilities to complete the implementation, manufacturing and development process. If we are unable to adequately validate or scale-up the manufacturing process at our current manufacturers' facilities, we will need to transfer to another manufacturer and complete the manufacturing validation process, which can be lengthy. If we are able to adequately validate and scale-up the manufacturing process for our product candidates with a contract manufacturer, we will still need to negotiate with such contract manufacturer an agreement for commercial supply and it is not certain we will be able to come to agreement on terms acceptable to us.

We cannot assure you that any stability or other issues relating to the manufacture of any of our product candidates or products will not occur in the future. If our third-party manufacturers were to encounter any of these difficulties, our ability to provide any product candidates to patients in planned clinical trials and products to patients, once approved, would be jeopardized. Any delay or interruption in the supply of clinical trial supplies could delay the completion of planned clinical trials, increase the costs associated with maintaining clinical trial programs and, depending upon the period of delay, require us to commence new clinical trials at additional expense or terminate clinical trials completely. Any adverse developments affecting clinical or commercial manufacturing of our product candidates or products may result in shipment delays, inventory shortages, lot failures, product withdrawals or recalls, or other interruptions in the supply of our product candidates or products. We may also have to take inventory write-offs and incur other charges and expenses for product candidates or products that fail to meet specifications, undertake costly remediation efforts or seek more costly manufacturing alternatives. Accordingly, failures or difficulties faced at any level of our supply chain could adversely affect our business and delay or impede the development and commercialization of any of our product candidates or products, if approved, and could have an adverse effect on our business, prospects, financial condition and results of operations.

As part of our process development efforts, we also may make changes to the manufacturing processes at various points during development, for various reasons, such as controlling costs, achieving scale, decreasing processing time, increasing manufacturing success rate or other reasons. Such changes carry the risk that they will not achieve their intended objectives, and any of these changes could cause our product candidates to perform differently and affect the results of our ongoing clinical trials or future clinical trials. In some circumstances, changes in the manufacturing process may require us to perform *ex vivo* comparability studies and to collect additional data from patients prior to undertaking more advanced clinical trials. For instance, changes in our process during the course of clinical development may require us to show the comparability of the product used in earlier clinical phases or at earlier portions of a trial to the product used in later clinical phases or later portions of the trial.

Risks Related to Our Business and Operations

We will need to grow our organization, and we may experience difficulties in managing our growth and expanding our operations, which could adversely affect our business.

As of December 31, 2019, we had approximately 76 full-time employees. As a newly public company, and as our development and commercialization plans and strategies develop, we expect to expand our employee base for managerial, operational, financial and other resources. In addition, we have limited experience in product development. As our product candidates enter and advance through preclinical studies and clinical trials, we will need to expand our development and regulatory capabilities and contract with other organizations to provide manufacturing and other capabilities for us. In the future, we expect to have to manage additional relationships with collaborators or partners, suppliers and other organizations. Our ability to manage our operations and future growth will require us to continue to improve our operational, financial and management controls, reporting systems and procedures. We may not be able to implement improvements to our management information and control systems in an efficient or timely manner and may discover deficiencies in existing systems and controls. Our inability to successfully manage our growth and expand our operations could have a material and adverse effect on our business, financial condition, results of operations and prospects.

Any inability to attract and retain qualified key management and technical personnel would impair our ability to implement our business plan.

Our success largely depends on the continued service of key management, advisors and other specialized personnel, including Praveen P. Tipirneni, M.D., our chief executive officer, Robert E. Farrell, Jr., CPA, our vice president of finance and operations and treasurer, Bruce N. Rogers, Ph.D., our chief scientific officer, Alexey A. Lugovskoy, Ph.D., our chief development officer, and Timothy A. Springer, Ph.D., our founder and advisor. We currently do not maintain key person insurance on these individuals. The loss of one or more members of our management team or other key employees or advisors could delay our research and development programs and have a material and adverse effect on our business, financial condition, results of operations and prospects. The relationships that our key managers have cultivated within our industry make us particularly dependent upon their continued employment with us. We are dependent on the continued service of our technical personnel, in particular, personnel involved with crystallization of integrins, because of the highly technical nature of our product candidates and technologies related to our MInT Platform, and the specialized nature of the regulatory approval process. Because our management team and key employees are not obligated to provide us with continued service, they could terminate their employment with us at any time without penalty.

We conduct our operations at our facility in Waltham, Massachusetts. This region is headquarters to many other biopharmaceutical companies and many academic and research institutions. Competition for skilled personnel in our market is intense and may limit our ability to hire and retain highly qualified personnel on acceptable terms or at all. We also face competition for personnel from other companies, universities, public and private research institutions, government entities and other organizations. Our future success will depend in large part on our continued ability to attract and retain other highly qualified scientific, technical and management personnel, as well as personnel with expertise in clinical testing, manufacturing, governmental regulation and commercialization. If we are unable to continue to attract and retain high-quality personnel, the rate and success at which we can discover and develop product

candidates will be limited which could have a material and adverse effect on our business, financial condition, results of operations and prospects.

Our future growth may depend, in part, on our ability to operate in foreign markets, where we would be subject to additional regulatory burdens and other risks and uncertainties.

Our future growth may depend, in part, on our ability to develop and commercialize our product candidates in foreign markets for which we may rely on collaboration with third parties. We are not permitted to market or promote any of our product candidates before we receive regulatory approval from the applicable regulatory authority in that foreign market, and may never receive such regulatory approval for any of our product candidates. To obtain separate regulatory approval in many other countries, we must comply with numerous and varying regulatory requirements of such countries regarding safety and efficacy and governing, among other things, clinical trials and commercial sales, pricing and distribution of our product candidates, and we cannot predict success in these jurisdictions. If we fail to comply with the regulatory requirements in international markets and receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed and our business will be adversely affected. We may not obtain foreign regulatory approvals on a timely basis, if at all. Our failure to obtain approval of any of our product candidates by regulatory authorities in another country may significantly diminish the commercial prospects of that product candidate and our business, financial condition, results of operations and prospects could be materially and adversely affected. Moreover, even if we obtain approval of our product candidates and ultimately commercialize our product candidates in foreign markets, we would be subject to the risks and uncertainties, including the burden of complying with complex and changing foreign regulatory, tax, accounting and legal requirements and reduced protection of intellectual property rights in some foreign countries.

Our business entails a significant risk of product liability and our ability to obtain sufficient insurance coverage could have a material and adverse effect on our business, financial condition, results of operations and prospects.

When we conduct clinical trials of our product candidates, we may be exposed to significant product liability risks inherent in the development, testing, manufacturing and marketing of therapeutic treatments. Product liability claims could delay or prevent completion of our development programs. If we succeed in marketing products, such claims could result in an FDA investigation of the safety and effectiveness of our products, our manufacturing processes and facilities or our marketing programs and potentially a recall of our products or more serious enforcement action, limitations on the approved indications for which they may be used or suspension or withdrawal of approvals. Regardless of the merits or eventual outcome, liability claims may also result in decreased demand for our products, termination of clinical trial sites or entire trial programs, withdrawal of clinical trial participants, injury to our reputation and significant negative media attention, significant costs to defend the related litigation, a diversion of management's time and our resources from our business operations, substantial monetary awards to trial participants or patients, loss of revenue, the inability to commercialize and products that we may develop, and a decline in our stock price. We currently maintain general liability insurance with coverage up to $10.0 million. We may, however, need to obtain higher levels of product liability insurance for later stages of clinical development or marketing any of our product candidates. Any insurance we have or may obtain may not provide sufficient coverage against potential liabilities. Furthermore, clinical trial and product liability insurance is becoming increasingly expensive. As a result, we may be unable to obtain sufficient insurance at a reasonable cost to protect us against losses caused by product liability claims that could have a material and adverse effect on our business, financial condition, results of operations and prospects.

Our employees, independent contractors, consultants, commercial partners and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk of employee fraud or other illegal activity by our employees, independent contractors, consultants, commercial partners and vendors. Misconduct by these parties could include intentional, reckless and/or negligent conduct that fails to comply with FDA regulations, provide true, complete and accurate information to the FDA and other similar foreign regulatory bodies, comply with manufacturing standards we may establish, comply with healthcare fraud and abuse laws and regulations, report financial information or data accurately or disclose unauthorized activities to us. If we obtain FDA approval of any of our product candidates and begin commercializing those products in the United States, our potential exposure under these laws will increase significantly, and our costs associated with

compliance with these laws are likely to increase. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. Additionally, we are subject to the risk that a person could allege such fraud or other misconduct, even if none occurred. It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a material and adverse effect on our business, financial condition, results of operations and prospects, including the imposition of significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, the curtailment or restructuring of our operations, loss of eligibility to obtain approvals from the FDA, exclusion from participation in government contracting, healthcare reimbursement or other government programs, including Medicare and Medicaid, integrity oversight and reporting obligations, or reputational harm.

We depend on our information technology systems, and any failure of these systems, or those of our CROs or other contractors or consultants we may utilize, could harm our business. Security breaches, cyber-attacks, loss of data, and other disruptions could compromise sensitive information related to our business or prevent us from accessing critical information and expose us to liability, which could adversely affect our business, results of operations, financial condition and prospects.

We collect and maintain information in digital form that is necessary to conduct our business, and we are increasingly dependent on information technology systems and infrastructure to operate our business. In the ordinary course of our business, we collect, store and transmit large amounts of confidential information, including intellectual property, proprietary business information and personal data. It is critical that we do so in a secure manner to maintain the confidentiality and integrity of such confidential information. We have established physical, electronic and organizational measures to safeguard and secure our systems to prevent a data compromise, and rely on commercially available systems, software, tools, and monitoring to provide security for our information technology systems and the processing, transmission and storage of digital information. We have also outsourced elements of our information technology infrastructure, and as a result a number of third-party vendors may or could have access to our confidential information. Our internal information technology systems and infrastructure, and those of our current and any future collaborators, contractors and consultants and other third parties on which we rely, are vulnerable to damage from cyber incidents such as third parties getting access to employee accounts using stolen or inferred credentials, computer viruses, phishing attacks, spamming, malware, cyber-attacks or cyber-intrusions over the Internet, attachments to emails, persons inside our organization, or persons with access to systems inside our organization, and attempts to gain unauthorized access to computer systems and networks. Our internal information technology systems and infrastructure is also vulnerable to damage from natural disasters, terrorism, war, telecommunication and electrical failures.

The risk of a security breach or disruption or data loss, particularly through cyber-attacks or cyber intrusion, including by computer hackers, foreign governments and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. In addition, the prevalent use of mobile devices that access confidential information increases the risk of data security breaches, which could lead to the loss of confidential information or other intellectual property. The costs to us to mitigate network security problems, bugs, viruses, worms, malicious software programs and security vulnerabilities could be significant, and while we have implemented security measures to protect our data security and information technology systems, our efforts to address these problems may not be successful, and these problems could result in unexpected interruptions, delays, cessation of service and other harm to our business and our competitive position. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our product development programs. For example, the loss of clinical trial data from completed or ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Moreover, if a computer security breach affects our systems or results in the unauthorized release of personally identifiable information, our reputation could be materially damaged. In addition, such a breach may require notification to governmental agencies,

the media or individuals pursuant to various federal and state privacy and security laws, if applicable, including the Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and its implementing rules and regulations, as well as regulations promulgated by the Federal Trade Commission and state breach notification laws. In addition, such cyber-attacks, data breaches or destruction or loss of data could result in violation of applicable international privacy, data protection and other laws, resulting in exposure to material civil and/or criminal liability. Further, our general liability insurance and corporate risk program may not cover all potential claims to which we are exposed and may not be adequate to indemnify us for all liability that maybe imposed; and could materially adversely affect our business, results of operations, financial condition and prospects. For example, the loss of clinical trial data from completed or ongoing clinical trials for any of our product candidates could result in delays in our development and regulatory approval efforts and significantly increase our costs to recover or reproduce the data. In addition, we may suffer reputational harm or face litigation or adverse regulatory action as a result of cyber-attacks or other data security breaches and may incur significant additional expense to implement further data protection measures.

If we do not comply with laws regulating the protection of the environment and health and human safety, our business could be affected adversely.

Our research and development involves the use of hazardous chemicals and materials, including radioactive materials. We maintain quantities of various flammable and toxic chemicals in our facilities in Waltham, Massachusetts that are required for our research and development activities. We are subject to federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of these hazardous chemicals and materials. We believe our procedures for storing, handling and disposing these materials in our facilities comply with the relevant guidelines of Middlesex County, Massachusetts. Although we believe that our safety procedures for handling and disposing of these materials comply with the standards mandated by applicable regulations, the risk of accidental contamination or injury from these materials cannot be eliminated. If an accident occurs, we could be held liable for resulting damages, which could be substantial. We are also subject to numerous environmental, health and workplace safety laws and regulations, including those governing laboratory procedures, exposure to blood-borne pathogens and the handling of animals and biohazardous materials. Although we maintain workers' compensation insurance to cover us for costs and expenses, we may incur due to injuries to our employees resulting from the use of these materials, this insurance may not provide adequate coverage against potential liabilities. We may incur substantial costs to comply with, and substantial fines or penalties if we violate, any of these laws or regulations.

Our current operations concentrated in one location, and we or the third parties upon whom we depend may be adversely affected by a heavy snowstorm or other natural disasters and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Our current operations are located in our facilities in Waltham, Massachusetts. Any unplanned event, such as flood, fire, explosion, earthquake, extreme weather condition, medical epidemic, power shortage, telecommunication failure or other natural or manmade accidents or incidents that result in us being unable to fully utilize our facilities, or the manufacturing facilities of our third-party contract manufacturers, may have a material and adverse effect on our ability to operate our business, particularly on a daily basis, and have significant negative consequences on our financial and operating conditions. For example, our operations are concentrated primarily on the east coast of the United States, and any adverse weather event or natural disaster, such as a hurricane or heavy snowstorm, could have a material adverse effect on a substantial portion of our operations. Loss of access to these facilities may result in increased costs, delays in the development of our product candidates or interruption of our business operations. Extreme weather conditions or other natural disasters could further disrupt our operations, and have a material and adverse effect on our business, financial condition, results of operations and prospects. If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure, such as our research facilities or the manufacturing facilities of our third-party contract manufacturers, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible, for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we have in place may prove inadequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which could have a material adverse effect on our business. As part of our risk management policy, we maintain insurance coverage at levels that we believe are appropriate for our business. However,

in the event of an accident or incident at these facilities, we cannot assure you that the amounts of insurance will be sufficient to satisfy any damages and losses. If our facilities, or the manufacturing facilities of our third-party contract manufacturers, are unable to operate because of an accident or incident or for any other reason, even for a short period of time, any or all of our research and development programs may be harmed. Any business interruption could have a material and adverse effect on our business, financial condition, results of operations and prospects.

We are subject to complex tax rules relating to our business, and any audits, investigations or tax proceedings could have a material adverse effect on our business, results of operations and financial condition.

We are subject to income and non-income taxes in the United States. Income tax accounting often involves complex issues, and judgment is required in determining our provision for income taxes and other tax liabilities. We may operate in other non-United States jurisdictions in the future. We could become subject to income and non-income taxes in non-United States jurisdictions as well. In addition, many jurisdictions have detailed transfer pricing rules, which require that all transactions with non-resident related parties be priced using arm's length pricing principles within the meaning of such rules. The application of withholding tax, goods and services tax, sales taxes and other non-income taxes is not always clear and we may be subject to tax audits relating to such withholding or non-income taxes. We believe that our tax positions are reasonable. We are currently not subject to any tax audits. However, the Internal Revenue Service or other taxing authorities may disagree with our positions. If the Internal Revenue Service or any other tax authorities were successful in challenging our positions, we may be liable for additional tax and penalties and interest related thereto or other taxes, as applicable, in excess of any reserves established therefor, which may have a significant impact on our results and operations and future cash flow.

Our ability to utilize our net operating loss carryforwards and certain other tax attributes may be limited.

As of December 31, 2019 we had net operating loss carryforwards for federal and state income tax purposes of $3.9 million and $5.6 million, respectively, which begin to expire in 2037. As of December 31, 2019, we also had available tax credit carryforwards for federal and state income tax purposes of $1.0 million and $0.1 million, respectively, which begin to expire in 2032. To the extent that our taxable income exceeds any current year operating losses, we plan to use our carryforwards to offset income that would otherwise be taxable. However, utilization of carryforwards generated in tax years beginning after December 31, 2018 is limited to a maximum of 80% of the taxable income for such year determined without regard to such carryforwards. In addition, under Section 382 of the Code, changes in our ownership may limit the amount of our net operating loss carryforwards and tax credit carryforwards that could be utilized annually to offset our future taxable income, if any. This limitation would generally apply in the event of a cumulative change in ownership of our company of more than 50% within a three-year period. We have not performed an analysis to determine whether there has been an ownership change pursuant to Section 382. Any such limitation may significantly reduce our ability to utilize our net operating loss carryforwards and tax credit carryforwards before they expire. Private placements, our IPO and other transactions that have occurred since our inception may trigger such an ownership change pursuant to Section 382. Any such limitation, whether as the result of our IPO, prior private placements, sales of our common stock by our existing stockholders or additional sales of our common stock by us, could have a material adverse effect on our results of operations in future years. Under the Tax Cuts and Jobs Act of 2017, net operating losses generated after December 31, 2018 will not be subject to expiration.

Risks Related to Intellectual Property

If we are not able to obtain, maintain, and enforce patent protection for our technologies or product candidates, development and commercialization of our product candidates may be adversely affected.

Our success depends in part on our ability to obtain and maintain patents and other forms of intellectual property rights, including in-licenses of intellectual property rights of others, for our product candidates, as well as our ability to preserve our trade secrets, to prevent third parties from infringing upon our proprietary rights and to operate without infringing upon the proprietary rights of others. As of December 31, 2019, we solely owned published and unpublished pending global patent applications including U.S. and ex-U.S. international counterpart patent filings protecting our integrin therapeutic compounds across multiple programs (including our product candidates). In addition, we hold an exclusive, worldwide license agreement with the Children's Medical Center Corporation the "CMCC Agreement" to one U.S.

patent and a related pending U.S. patent application relating to the modified integrin polypeptides, crystallizable dimers comprising a modified integrin polypeptide, and related methods. We may not be able to apply for patents on certain aspects of our product candidates in a timely fashion or at all. Further, we may not be able to prosecute all necessary or desirable patent applications, or maintain, enforce and license any patents that may issue from such 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. We may not have the right to control the preparation, filing and prosecution of all patent applications that we license from third parties, or to maintain the rights to patents licensed to third parties. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. Future patents we obtain may not be sufficiently broad to prevent others from using our technology or from developing competing products and technology. There is no guarantee that any of our pending patent applications will result in issued or granted patents, that any of our future issued or granted patents will not later be found to be invalid or unenforceable or that any future issued or granted patents will include claims that are sufficiently broad to cover our product candidates or to provide meaningful protection from our competitors. Moreover, the patent position of biotechnology and biopharmaceutical companies can be highly uncertain because it involves complex legal and factual questions. We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our current and future proprietary technology and product candidates are covered by valid and enforceable patents, or are effectively maintained as trade secrets. If third parties disclose or misappropriate our proprietary rights, it may materially and adversely affect our position in the market.

Our pending patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications. Assuming the other requirements for patentability are met, currently, the first to file a patent application is generally entitled to the patent. However, prior to March 16, 2013, in the United States, the first to invent was entitled to the patent. 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 patents or pending patent applications, or that we were the first to file for patent protection of such inventions.

The U.S. Patent and Trademark Office, or USPTO, and various foreign governmental patent agencies require compliance with a large number of procedural, documentary, fee payment and other provisions during the patent process. There are situations in which noncompliance can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, competitors might be able to enter the market earlier than would otherwise have been the case. The standards applied by the USPTO and foreign patent offices in granting patents are not always applied uniformly or predictably. For example, there is no uniform worldwide policy regarding patentable subject matter or the scope of claims allowable in biotechnology and biopharmaceutical patents. As such, we do not know the degree of future protection that we will have on our proprietary products and technology. The process of obtaining patents is time consuming, expensive and sometimes unpredictable.

Once granted, for a given period after allowance or grant patents may remain open to opposition, interference, re-examination, post-grant review, *inter partes* review, nullification, or derivation action in court or before patent offices or similar proceedings, during which time third parties can raise objections against such initial grant. Such proceedings may continue for a protracted period of time and an adverse determination in any such proceedings could reduce the scope of the allowed or granted claims thus attacked, or could result in our patents being invalidated in whole or in part, or being held unenforceable, which could allow third parties to commercialize our product candidates and compete directly with us without payment to us. In addition, there can be no assurance that:

- § others will not or may not be able to make, use or sell compounds that are the same as or similar to our product candidates but that are not covered by the claims of the patents that we own or license;
- § we or our licensors, or our existing or future collaborators are the first to make the inventions covered by each of our issued patents and pending patent applications that we own or license;
- § we or our licensors, or our existing or future collaborators are the first to file patent applications covering certain aspects of our inventions;

- § others will not independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- § a third party may not challenge our patents and, if challenged, a court would hold that our patents are valid, enforceable and infringed;
- § any issued patents that we own or have licensed or that we may license in the future will provide us with any competitive advantages, or will not be challenged by third parties;
- § we may develop additional proprietary technologies that are patentable;
- § the patents of others will not have a material or adverse effect on our business, financial condition, results of operations and prospects; and
- § our competitors do not conduct research and development activities in countries where we do not have enforceable patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets.

If we or our licensors or collaborators fail to maintain the patents and patent applications covering our product candidates, our competitors might be able to enter the market, which could have a material and adverse effect on our business, financial condition, results of operations and prospects. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, regardless of the outcome, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to seeking patent protection for certain aspects of our product candidates, we also consider trade secrets, including confidential and unpatented know-how, important to the maintenance of our competitive position. Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed. We seek to protect trade secrets and confidential and unpatented know-how, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to such knowledge, such as our employees, corporate collaborators, outside scientific collaborators, CROs, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants that obligate them to maintain confidentiality and assign their inventions to us. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time- consuming, and the outcome is unpredictable. In addition, some courts in the United States and certain foreign jurisdictions are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed which could have a material and adverse effect on our business, financial condition, results of operations and prospects.

Other companies or organizations may challenge our or our licensors' patent rights or may assert patent rights that prevent us from developing and commercializing our products.

Oral integrin therapies in fibrosis and inflammatory bowel disease or other disease areas are a relatively new scientific field. We have applied for, and have obtained a license from, a third party on an exclusive basis to U.S. patent filings related to our MInT Platform. Other pending patent applications in the United States and in key markets around the world that we own or license claim many different methods, compositions and processes relating to the discovery, development, and manufacture of small-molecule integrin inhibitor-based and other therapeutics.

As the field of small-molecule integrin inhibitor-based therapeutics continues to mature, patent applications are being processed by national patent offices around the world. There is uncertainty about which patents will issue and, if they do, as to when, to whom, and with what claims. In addition, third parties may attempt to invalidate our intellectual property rights. Even if our rights are not directly challenged, disputes could lead to the weakening of our intellectual property rights. Our defense against any attempt by third parties to circumvent or invalidate our intellectual property rights could be costly to us, could require significant time and attention of our management and could have a material and adverse effect on our business, financial condition, results of operations and prospects or our ability to successfully compete. If we are found to infringe a third party's intellectual property rights, we could be forced, including by court order, to cease developing, manufacturing or commercializing the infringing product candidate or product.

We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting, defending and enforcing patents covering our technology in the United States and in other jurisdictions worldwide would be extremely costly, and our or our licensors' or collaborators' intellectual property rights may not exist in some countries outside the United States or may be less extensive in some countries than in the United States. In jurisdictions where we or our licensors or collaborators have not obtained patent protection, competitors may seek to use our or our licensors' or collaborators' technology to develop competing products and further, may export otherwise infringing products to territories where we have patent protection, but where it is more difficult to enforce a patent as compared to the United States. Competitor products may compete with our future products in jurisdictions where we do not have issued or granted patents or where our or our licensors' or collaborators' issued or granted patent claims or other intellectual property rights are not sufficient to prevent competitor activities in these jurisdictions. The legal systems of certain countries, particularly certain developing countries, make it difficult to enforce patents and such countries may not recognize other types of intellectual property protection, particularly relating to pharmaceuticals or biopharmaceuticals. This could make it difficult for us or our licensors or collaborators to prevent the infringement of our or their patents or marketing of competing products in violation of our or their proprietary rights generally in certain jurisdictions. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial cost and divert our and our licensors' or collaborators' efforts and attention from other aspects of our business, could put our and our licensors' or collaborators' patents at risk of being invalidated or interpreted narrowly and our and our licensors' or collaborators' patent applications at risk of not issuing and could provoke third parties to assert claims against us or our licensors or collaborators. We or our licensors or collaborators may not prevail in any lawsuits that we or our licensors or collaborators initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful.

When we elect to pursue patent protection on an invention, we generally first file a U.S. provisional patent application (a priority filing) at the USPTO. An international patent application under the Patent Cooperation Treaty, or PCT, and/or a national application in a non-PCT country may then be filed within twelve months after the priority filing. Based on the PCT filing, national and regional patent applications may be filed in one or more PCT member countries. We have thus far not filed for patent protection in all national and regional jurisdictions where such protection may be available. In addition, we may decide to abandon national and regional patent applications before grant. Finally, the grant proceeding of each national or regional patent office is an independent proceeding which may lead to situations in which applications might in some jurisdictions be refused by the relevant registration authorities, while granted by others. It is also quite common that, depending on the country, various scopes of patent protection may be granted on the same product candidate or technology.

The laws of some jurisdictions do not protect intellectual property rights to the same extent as the laws in the United States, and many companies have encountered significant difficulties in protecting and defending such rights in such jurisdictions. If we or our licensors or collaborators encounter difficulties in protecting, or are otherwise precluded from effectively protecting, the intellectual property rights important for our business in such jurisdictions, the value of these rights may be diminished and we may face additional competition from others in those jurisdictions. Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such a patent. If we or any of our licensors or collaborators are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position in the relevant jurisdiction may be impaired and our business, financial condition, results of operations and prospects may be adversely affected.

If we fail to comply with our obligations under any license, collaboration or other agreements, we may be required to pay damages and could lose intellectual property rights that are necessary for developing and protecting our product candidates or we could lose certain rights to grant sublicenses.

We are dependent on patents, know-how and proprietary technology, both our own and licensed from others. Any termination of these licenses could result in the loss of significant rights and could harm our ability to develop our product candidates. Our current licenses impose, and any future licenses we enter into are likely to impose, various development, commercialization, funding, milestone, royalty, diligence, sublicensing, insurance, patent prosecution and enforcement and/or other obligations on us. If we breach any of these obligations, or use the intellectual property licensed to us in an unauthorized manner, we may be required to pay damages and the licensor may have the right to terminate the license, which could result in us being unable to develop, manufacture and sell any future products that are covered by the licensed technology or enable a competitor to gain access to the licensed technology. Moreover, our licensors may own or control intellectual property that has not been licensed to us and, as a result, we may be subject to claims, regardless of their merit, that we are infringing or otherwise violating a licensor's rights. In addition, while we cannot determine currently the amount of the royalty obligations we would be required to pay on sales of future products, if any, the amounts may be significant. The amount of our future royalty obligations will depend on the technology and intellectual property we use in products that we successfully develop and commercialize, if any. Therefore, even if we successfully develop and commercialize products, we may be unable to achieve or maintain profitability.

Moreover, disputes may arise regarding intellectual property subject to a licensing agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which our product candidates, technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patent and other rights under our collaborative development relationships;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and
- the priority of invention of patented technology.

In addition, the agreements under which we currently license intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations, and prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates, which could have a material adverse effect on our business, financial conditions, results of operations, and prospects.

We, our licensors or collaborators, or any future strategic partners may need to resort to litigation to protect or enforce our patents, if and when granted, or other proprietary rights, all of which could be costly, time consuming, delay or prevent the development and commercialization of our product candidates, or put our patents, if and when granted, and other proprietary rights at risk.

Competitors may infringe our patents, if and when granted, or other intellectual property. If we were to initiate legal proceedings against a third party to enforce a patent covering one of our products or our technology, the defendant could

counterclaim that our patent is invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, for example, lack of novelty, lack of adequate written description, obviousness or non-enablement. Grounds for an unenforceability assertion could be an allegation that an individual connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. The outcome following legal assertions of invalidity or unenforceability during patent litigation 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 or unenforceability, we would lose at least part, and perhaps all, of the patent protection on one or more of our products or certain aspects of our platform technology. Such a loss of patent protection could have a material and adverse effect on our business, financial condition, results of operations and prospects. Interference or derivation proceedings provoked by third parties or brought by us or declared by the USPTO may be necessary to determine the inventorship or priority of inventions with respect to our patents or patent applications. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms or at all, or if a non-exclusive license is offered and our competitors gain access to the same technology. In addition, 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 research programs, license necessary technology from third parties, or enter into development partnerships that would help us bring our product candidates to market. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions, or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our common stock. Patents and other intellectual property rights will not protect our technology if competitors design around our protected technology without legally infringing our patents or other intellectual property rights.

Intellectual property rights of third parties could adversely affect our ability to commercialize our product candidates, and we, our licensors or collaborators, or any future strategic partners may become subject to third party claims or litigation alleging infringement of patents or other proprietary rights or seeking to invalidate patents or other proprietary rights. We might be required to litigate or obtain licenses from third parties in order to develop or market our product candidates. Such litigation or licenses could be costly or not available on commercially reasonable terms.

We, our licensors or collaborators, or any future strategic partners, may be subject to third-party claims for infringement or misappropriation of patent or other proprietary rights. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, derivations, oppositions and *inter partes* review proceedings before the USPTO, and corresponding foreign patent offices. There may be issued patents and pending patent applications that claim aspects of our targets, our MInT Platform, or our product candidates and modifications that we may need to apply to our product candidates. There may be issued patents that claim integrin inhibitors which may be relevant to the products we wish to develop. Thus, it is possible that one or more organizations will hold patent rights to which we will need a license. If those organizations refuse to grant us a license to such patent rights on reasonable terms, we may not be able to market products or perform research and development or other activities covered by these patents, which could have a material and adverse effect on our business, financial condition, results of operations and prospects. If we, our licensors or collaborators, or any future strategic partners are found to infringe a third-party patent or other intellectual property rights, we could be required to pay damages, potentially including treble damages and attorneys' fees if we or they are found to have infringed willfully. In addition, we, our licensors or collaborators, or any future strategic partners may choose to seek, or be required to seek, a license from a third party, which may not be available on acceptable terms, if at all. Even if a license can be obtained on acceptable terms, the rights may be non-exclusive, which could give our competitors access to the same technology or intellectual property rights licensed to us. If we fail to obtain a required license, we or our existing or future collaborators may be unable to effectively market product candidates based on our technology, which could limit our ability to generate revenue or achieve profitability and possibly prevent us from generating revenue sufficient to sustain our operations. In addition, we may find it necessary to pursue claims or initiate lawsuits to protect or enforce our patent or other intellectual property rights. The cost to us in

defending or initiating any litigation or other proceeding relating to patent or other proprietary rights, even if resolved in our favor, could be substantial, and litigation could divert our management's attention. Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could delay our research and development efforts and limit our ability to continue our operations.

Because the integrin-based therapeutics landscape is still evolving, it is difficult to conclusively assess our freedom to operate without infringing on third-party rights. There are numerous companies that have pending patent applications and issued patents broadly covering integrins generally, covering integrins directed against the same targets as, or targets similar to, those we are pursuing, or covering compounds similar to our product candidates. Failure to receive a license could delay commercialization of our product candidates. Our competitive position may suffer if patents issued to third parties or other third-party intellectual property rights cover our products or product candidates or elements thereof, or our manufacture or uses relevant to our development plans. In such cases, we may not be in a position to develop or commercialize products or product candidates until such patents expire or unless we successfully pursue litigation to nullify or invalidate the third-party intellectual property right concerned, or enter into a license agreement with the intellectual property right holder, if available on commercially reasonable terms. There may be issued patents of which we are not aware, held by third parties that, if found to be valid and enforceable, could be alleged to be infringed by our MInT Platform and product candidates. There also may be pending patent applications of which we are not aware that may result in issued patents, which could be alleged to be infringed by our MInT Platform and product candidates. If such an infringement claim should be brought and be successful, we may be required to pay substantial damages, including potentially treble damages and attorneys' fees for willful infringement, and we may be forced to abandon our product candidates or seek a license from any patent holders. No assurances can be given that a license will be available on commercially reasonable terms, if at all.

It is also possible that we have failed to identify relevant third-party patents or applications. For example, U.S. applications filed before November 29, 2000, and certain U.S. applications filed after that date that will not be filed outside the United States remain confidential unless and until corresponding patents issue. Patent applications in the United States and elsewhere are published approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Therefore, patent applications covering our products or MInT Platform could have been filed by others without our knowledge. Additionally, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our MInT Platform, our products or the use of our products. Third-party intellectual property right holders may also actively bring infringement claims against us. We cannot guarantee that we will be able to successfully settle or otherwise resolve such infringement claims. If we are unable to successfully settle future claims on terms acceptable to us, we may be required to engage in or continue costly, unpredictable and time-consuming litigation and may be prevented from or experience substantial delays in marketing our products. Parties making claims against us may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or administrative proceedings, there is a risk that some of our confidential information could be compromised by disclosure. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have material adverse effect on our ability to raise additional funds or otherwise have a material adverse effect on our business, results of operations, financial condition and prospects. If we fail in any such dispute, in addition to being forced to pay damages, we may be temporarily or permanently prohibited from commercializing any of our product candidates that are held to be infringing. We might, if possible, also be forced to redesign product candidates so that we no longer infringe the third-party intellectual property rights. Any of these events, even if we were ultimately to prevail, could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business and could have a material and adverse effect on our business, financial condition, results of operations and prospects.

Intellectual property litigation could cause us to spend substantial resources and distract our personnel from their normal responsibilities.

Litigation and other legal proceedings relating to intellectual property claims, with or without merit, are unpredictable and generally expensive and time consuming and are likely to divert significant resources from our core business,

including distracting our technical and management personnel from their normal responsibilities. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Moreover, such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities.

We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon or misappropriating or from successfully challenging our intellectual property rights. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

We may be subject to claims that we or our employees or consultants have wrongfully used or disclosed alleged trade secrets of our employees' or consultants' former employers or their clients. These claims may be costly to defend and if we do not successfully do so, we may be required to pay monetary damages and may lose valuable intellectual property rights or personnel.

Many of our employees, including our management, were previously employed at universities or biotechnology or biopharmaceutical companies, including our competitors or potential competitors. Some of these employees executed proprietary rights, non-disclosure and non-competition agreements in connection with such previous employment. Although no claims against us are currently pending, we may be subject to claims that these employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. If we fail in defending such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. A loss of key research personnel or their work product could hamper our ability to develop and ultimately commercialize, or prevent us from developing and commercializing, our product candidates, which could severely harm our business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

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

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various patent term adjustments or extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired, we may be open to competition from competitive products, including generics or biosimilars. 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 owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

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

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or applications will be due to be paid to the USPTO and various governmental patent agencies outside of the United States in several stages over the lifetime of the patents and/or applications. We have systems in place to remind us to pay these fees, and we employ an outside firm and/or rely on our outside counsel to pay these fees due to the USPTO and non-U.S. patent agencies. The USPTO and various non-U.S. governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. We employ reputable law firms and other professionals to help us comply, and in many cases an inadvertent lapse can be cured by

payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, our competitors might be able to enter the market and this circumstance would have a material adverse effect on our business.

Changes in U.S. patent and ex-U.S. patent laws could diminish the value of patents in general, thereby impairing our ability to protect our products.

Changes in either the patent laws or interpretation of the patent laws in the United States or in other jurisdictions could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. In the United States, numerous recent changes to the patent laws and proposed changes to the rules of the USPTO may have a significant impact on our ability to protect our technology and enforce our intellectual property rights. We cannot assure you that subsequent rulings will not adversely impact our patents or patent applications. In addition to increasing uncertainty regarding to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once granted. Depending on decisions by the U.S. Congress, the federal courts and the USPTO, and similar legislative and regulatory bodies in other countries in which may pursue patent protection, the laws and regulations governing patents could change in unpredictable ways, particularly with respect to pharmaceutical patent protection, that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

Our common law trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names or may be forced to stop using these names, which we need for name recognition by potential partners or customers in our markets of interest. If we are unable to establish name recognition based on our trademarks and trade names, we may not be able to compete effectively which could have a material and adverse effect on our business, financial condition, results of operations and prospects.

Risks Related to Government Regulation

We and/or our collaborators may be unable to obtain, or may be delayed in obtaining, U.S. or foreign regulatory approval and, as a result, unable to commercialize our product candidates.

Our product candidates are subject to extensive governmental regulations relating to, among other things, research, testing, development, manufacturing, approval, recordkeeping, reporting, labeling, storage, packaging, advertising and promotion, pricing, post-approval monitoring, marketing and distribution of drugs. Rigorous preclinical testing and clinical trials and an extensive regulatory approval process are required to be completed successfully in the United States and in many foreign jurisdictions before a new drug can be marketed. Satisfaction of these and other regulatory requirements is costly, time consuming, uncertain and subject to unanticipated delays. It is possible that none of the product candidates we may develop, either alone or with our collaborators, will obtain the regulatory approvals necessary for us or our existing or future collaborators to begin selling them.

We have no prior experience in conducting and managing the clinical trials necessary to obtain regulatory approvals, including approval by the FDA. The time required to obtain FDA and other approvals is unpredictable but typically takes many years following the commencement of clinical trials, depending upon the type, complexity and novelty of the product candidate. The standards that the FDA and its foreign counterparts use when regulating us require judgment and can change, which makes it difficult to predict with certainty their application. Any analysis we perform of data from preclinical and clinical activities is subject to confirmation and interpretation by regulatory authorities, which could delay, limit or prevent regulatory approval. We or our collaborators may also encounter unexpected delays or increased costs due to new government regulations, for example, from future legislation or administrative action, or from changes in FDA policy during the period of product development, clinical trials and FDA regulatory review. It is impossible to

predict whether legislative changes will be enacted, or whether FDA or foreign regulations, guidance or interpretations will be changed, or the impact of such changes, if any.

Given that the product candidates we are developing, either alone or with our collaborators, represent a new therapeutic approach, the FDA and its foreign counterparts may not have established any definitive policies, practices or guidelines in relation to these product candidates. Moreover, the FDA may respond to any NDA that we may submit by defining requirements that we do not anticipate. Such responses could delay clinical development of our product candidates. In addition, because there may be approved treatments for some of the diseases for which we may seek approval, in order to receive regulatory approval, we may need to demonstrate through clinical trials that the product candidates we develop to treat these diseases, if any, are not only safe and effective, but safer or more effective than existing products. Furthermore, in recent years, there has been increased public and political pressure on the FDA with respect to the approval process for new drugs, and FDA standards, especially regarding product safety.

Any delay or failure in obtaining required approvals could have a material and adverse effect on our ability to generate revenues from the particular product candidate for which we are seeking approval. Furthermore, any regulatory approval to market a product may be subject to limitations on the approved uses for which we may market the product or on the labeling or other restrictions.

We are also subject to or may in the future become subject to numerous foreign regulatory requirements governing, among other things, the conduct of clinical trials, manufacturing and marketing authorization, pricing and third-party reimbursement. The foreign regulatory approval process varies among countries and may include all of the risks associated with the FDA approval process described above, as well as risks attributable to the satisfaction of local regulations in foreign jurisdictions. Moreover, the time required to obtain approval may differ from that required to obtain FDA approval. FDA approval does not ensure approval by regulatory authorities outside the United States and vice versa. Any delay or failure to obtain U.S. or foreign regulatory approval for a product candidate could have a material and adverse effect on our business, financial condition, results of operations and prospects.

Even if we receive regulatory approval for any of our product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense. Additionally, our product candidates, if approved, could be subject to labeling and other restrictions and market withdrawal. We may also be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our products.

Any regulatory approvals that we or our existing or future collaborators obtain for our product candidates may also be subject to limitations on the approved indicated uses for which a product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing and surveillance to monitor the safety and efficacy of the product candidate.

In addition, if the FDA or a comparable foreign regulatory authority approves any of our product candidates, the manufacturing processes, labeling, packaging, distribution, post-approval monitoring and adverse event reporting, storage, import, export, advertising, promotion and recordkeeping for the product will be subject to extensive and ongoing regulatory requirements. The FDA has significant post-market authority, including the authority to require labeling changes based on new safety information and to require post-market studies or clinical trials to evaluate safety risks related to the use of a product or to require withdrawal of the product from the market. The FDA also has the authority to require a REMS plan after approval, which may impose further requirements or restrictions on the distribution or use of an approved drug. The manufacturing facilities we use to make a future product, if any, will also be subject to periodic review and inspection by the FDA and other regulatory agencies, including for continued compliance with cGMP requirements. The discovery of any new or previously unknown problems with our third-party manufacturers, manufacturing processes or facilities may result in restrictions on the product, manufacturer or facility, including withdrawal of the product from the market. If we rely on third-party manufacturers, we will not have control over compliance with applicable rules and regulations by such manufacturers. Any product promotion and advertising will also be subject to regulatory requirements and continuing regulatory review. The FDA imposes stringent restrictions on manufacturers' communications regarding use of their products. If we promote our product candidates in a manner inconsistent with FDA-approved labeling or otherwise not in compliance with FDA regulations, we may be subject to

enforcement action. If we or our existing or future collaborators, manufacturers or service providers fail to comply with applicable continuing regulatory requirements in the United States or foreign jurisdictions in which we seek to market our products, we or they may be subject to, among other things, fines, warning letters, holds on clinical trials, delay of approval or refusal by the FDA or similar foreign regulatory bodies to approve pending applications or supplements to approved applications, suspension or withdrawal of regulatory approval, product recalls and seizures, administrative detention of products, refusal to permit the import or export of products, operating restrictions, injunction, civil penalties and criminal prosecution.

Subsequent discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- § restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market or voluntary or mandatory product recalls;
- § fines, warning or untitled letters or holds on clinical trials;
- § refusal by the FDA to approve pending applications or supplements to approved applications filed by us or our strategic partners;
- § suspension or revocation of product license approvals;
- § product seizure or detention or refusal to permit the import or export of products; and
- § injunctions or the imposition of civil or criminal penalties.

The FDA policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. For example, in December 2016, the 21st Century Cures Act, or Cures Act, was signed into law. The Cures Act, among other things, is intended to modernize the regulation of drugs and biologics and to spur innovation. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability, which would adversely affect our business.

We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. For example, certain policies of the current U.S. presidential administration may impact our business and industry. Namely, the current U.S. presidential administration has taken several executive actions, including the issuance of a number of executive orders, that could impose significant burdens on, or otherwise materially delay, the FDA's ability to engage in routine regulatory and oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. Changes in FDA staffing could result in delays in the FDA's responsiveness or in its ability to review submissions or applications, issue regulations or guidance, or implement or enforce regulatory requirements in a timely fashion or at all. Similar consequences would also result in the event of another significant shutdown of the federal government such as the one that occurred from December 22, 2018 through January 25, 2019. It is difficult to predict how these requirements will be implemented, and the extent to which they will impact the FDA's ability to exercise its regulatory authority. If these executive actions impose constraints on the FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted.

We may face difficulties from healthcare legislative reform measures.

Existing regulatory policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are

not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability.

In the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs. For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Healthcare and Education Reconciliation Act, or together, the ACA, was enacted, which substantially changed the way healthcare is financed by both governmental and private insurers, and significantly impacts the U.S. pharmaceutical industry. The ACA, among other things, (i) subjected therapeutic biologics to potential competition by lower-cost biosimilars by creating a licensure framework for follow on biologic products, (ii) proscribed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs and therapeutic biologics that are inhaled, infused, instilled, implanted or injected, (iii) increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extended the rebate program to individuals enrolled in Medicaid managed care organizations, (iv) established annual non-deductible fees and taxes on manufacturers of certain branded prescription drugs and therapeutic biologics apportioned among these entities according to their market share in certain government healthcare programs, (v) established a new Medicare Part D coverage gap discount program, in which manufacturers must now agree to offer 70% point-of-sale discounts off negotiated prices of applicable brand drugs and therapeutic biologics to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs and therapeutic biologics to be covered under Medicare Part D, (vi) expanded 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 individuals with income at or below 133% of the federal poverty level, thereby potentially increasing manufacturers' Medicaid rebate liability, (vii) expanded the entities eligible for discounts under the Public Health program (viii) created 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 (ix) established a Center for Medicare Innovation at the Centers for Medicare & Medicaid Services, or CMS, to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

The current U.S. presidential administration and U.S. Congress have sought, and we expect they will continue to, seek to modify, repeal, or otherwise invalidate all, or certain provisions of, the ACA. Since January 2017, the current U.S. presidential administration has issued two executive orders and other directives designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. For example, on October 12, 2017, the current U.S. presidential administration issued an executive order that expands the use of association health plans and allows anyone to purchase short-term health plans that provide temporary, limited insurance. This executive order also calls for the halt of federal payments to health insurers for cost-sharing reductions previously available to lower-income Americans to afford coverage. There is still uncertainty with respect to the impact this executive order could have on coverage and reimbursement for healthcare items and services covered by plans that were authorized by the ACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the ACA have been signed into law. The Tax Cuts and Jobs Act of 2017, or the Tax Reform Act, among other things, includes a provision that repealed, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." Additionally, on January 22, 2018, the current U.S. presidential administration signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain ACA-mandated fees, including the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices. Further, the Bipartisan Budget Act of 2018, or the BBA, among other things, amended the ACA, effective January 1, 2019, to increase from 50 percent to 70 percent the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole". More recently, in July 2018, CMS published a final rule permitting further collections and payments to and from certain ACA qualified health plans and health insurance issuers under the ACA risk adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. On December 14, 2018, a Texas U.S. District Court Judge ruled that the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Reform Act. While the Texas

U.S. District Court Judge, as well as the current U.S. presidential administration and CMS, have stated that the ruling will have no immediate effect pending appeal of the decision, it is unclear how this decision, subsequent appeals, and other efforts to repeal and replace the ACA will impact the ACA. There is still uncertainty with respect to the impact the current U.S. presidential administration and Congress may have, if any, and any changes will likely take time to unfold, and could have an impact on coverage and reimbursement for healthcare items and services covered by plans that were authorized by the ACA. However, we cannot predict the ultimate content, timing or effect of any healthcare reform legislation or the impact of potential legislation on us.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted to reduce healthcare expenditures. U.S. federal government agencies also currently face potentially significant spending reductions, which may further impact healthcare expenditures. On August 2, 2011, the Budget Control Act of 2011 among other things, created measures for spending reductions by Congress. A joint select committee on deficit reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers of 2% per fiscal year. These reductions went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, including the BBA, will remain in effect through 2027 unless additional Congressional action is taken. Moreover, on January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. If federal spending is further reduced, anticipated budgetary shortfalls may also impact the ability of relevant agencies, such as the FDA or the National Institutes of Health to continue to function at current levels. Amounts allocated to federal grants and contracts may be reduced or eliminated. These reductions may also impact the ability of relevant agencies to timely review and approve research and development, manufacturing, and marketing activities, which may delay our ability to develop, market and sell any products we may develop.

Moreover, payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives. For example, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or MMA, changed the way Medicare covers and pays for pharmaceutical products. The legislation expanded Medicare coverage for drug purchases by the elderly and introduced a new reimbursement methodology based on average sales prices for physician-administered drugs. In addition, this legislation provided authority for limiting the number of drugs that will be covered in any therapeutic class. While the MMA only applies to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates. Therefore, any reduction in reimbursement that results from the MMA may result in a similar reduction in payments from private payors.

Recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. At the federal level, the current U.S. presidential administration's budget proposal for fiscal year 2019 contains further drug price control measures that could be enacted during the 2019 budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid, and to eliminate cost sharing for generic drugs for low-income patients. Additionally, on May 11, 2018, the current U.S. presidential administration laid out the administration's "Blueprint" to reduce the cost of prescription medications while preserving innovation and cures. While the Department of Health and Human Services, or HHS, is soliciting feedback on some of these measures, other actions may be immediately implemented by HHS under existing authority. Further, on January 31, 2019, the HHS Office of Inspector General, proposed modifications to the federal Anti-Kickback Statute discount safe harbor for the purpose of reducing the cost of drug products to consumers which, among other things, if finalized, will affect discounts paid by manufacturers to Medicare Part D plans, Medicaid managed care organizations and pharmacy benefit managers working with these organizations. Although a number of these, and other potential, proposals will require additional authorization to become effective, Congress and the current U.S. presidential administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. At the state level, legislatures are

increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our product candidates or companion diagnostics or additional pricing pressures.

Additionally, on May 30, 2018, the Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2017 was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational new drug products that have completed a Phase I clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA authorization under an FDA expanded access program; however, manufacturers are not obligated to provide investigational new drug products under the current federal right to try law.

We expect that the ACA, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our products.

Our operations and relationships with healthcare providers, healthcare organizations, customers and third-party payors will be subject to applicable anti-bribery, anti-kickback, fraud and abuse, transparency and other healthcare and privacy laws and regulations, which could expose us to, among other things, enforcement actions, criminal sanctions, civil penalties, contractual damages, reputational harm, administrative burdens and diminished profits and future earnings.

Our current and future arrangements with healthcare providers, healthcare organizations, third-party payors and customers expose us to broadly applicable anti-bribery, fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we research, market, sell and distribute our product candidates. In addition, we may be subject to patient data privacy and security regulation by the U.S. federal government and the states and the foreign governments in which we conduct our business. Restrictions under applicable federal and state anti-bribery and healthcare laws and regulations, include the following:

- § the federal Anti-Kickback Statute, which prohibits, among other things, individuals and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a federal and state healthcare program such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- § the federal criminal and civil false claims and civil monetary penalties laws, including the federal False Claims Act, which can be enforced through civil whistleblower or qui tam actions against individuals or entities, prohibits, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. In addition, certain marketing practices, including off-label promotion, may also violate false claims laws. Moreover, the government may assert that a claim including items and services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act;

- § HIPAA, which imposes criminal and civil liability, prohibits, among other things, knowingly and willfully executing, or attempting to execute a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in

connection with the delivery of or payment for healthcare benefits, items or services; similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- HIPAA, as amended by HITECH, and their respective implementing regulations, including the Final Omnibus Rule published on January 25, 2013, which impose obligations on certain healthcare providers, health plans, and healthcare clearinghouses, known as covered entities, as well as their business associates that perform certain services involving the storage, use or disclosure of individually identifiable health information, including mandatory contractual terms, with respect to safeguarding the privacy, security, and transmission of individually identifiable health information, and require notification to affected individuals and regulatory authorities of certain breaches of security of individually identifiable health information; the federal legislation commonly referred to as Physician Payments Sunshine Act, enacted as part of the ACA, and its implementing regulations, which requires certain manufacturers of covered drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children's Health Insurance Program, with certain exceptions, to report annually to CMS information related to certain payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by the physicians described above and their immediate family members, with the information made publicly available on a searchable website;

- state privacy laws and regulations, such as those of California and Massachusetts, that impose restrictive requirements regulating the use and disclosure of health information and other personally identifiable information (for example, in June 2018, California enacted the California Consumer Privacy Act, or CCPA. (which will go into effect on January 1, 2020) that gives California residents expanded rights to access and delete their personal information, opt out of certain personal information sharing and receive detailed information about how their personal information is used, and provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation; resulting in increased compliance costs and potential liability);

- the U.S. Foreign Corrupt Practices Act of 1977, as amended, which prohibits, among other things, U.S. companies and their employees and agents from authorizing, promising, offering, or providing, directly or indirectly, corrupt or improper payments or anything else of value to foreign government officials, employees of public international organizations and foreign government owned or affiliated entities, candidates for foreign political office, and foreign political parties or officials thereof;

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

- certain state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to report information related to payments to physicians and other healthcare providers or marketing expenditures and drug pricing information, state and local laws that require the registration of pharmaceutical sales representatives, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

If we or our collaborators, manufacturers or service providers fail to comply with applicable federal, state or foreign laws or regulations, we could be subject to enforcement actions, which could affect our ability to develop, market and sell our products successfully and could harm our reputation and lead to reduced acceptance of our products by the market. These enforcement actions include, among others:

- exclusion from participation in government-funded healthcare programs; and

- exclusion from eligibility for the award of government contracts for our products.

Efforts to ensure that our current and future business arrangements with third parties comply with applicable healthcare laws and regulations could involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any such requirements, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, the curtailment or restructuring of our operations, loss of eligibility to obtain approvals from the FDA, exclusion from participation in government contracting, healthcare reimbursement or other government programs, including Medicare and Medicaid, integrity oversight and reporting obligations, or reputational harm, any of which could adversely affect our financial results. These risks cannot be entirely eliminated. Any action against us for an alleged or suspected violation could cause us to incur significant legal expenses and could divert our management's attention from the operation of our business, even if our defense is successful. In addition, achieving and sustaining compliance with applicable laws and regulations may be costly to us in terms of money, time and resources.

Even if we are able to commercialize any product candidate, such product candidate may become subject to unfavorable pricing regulations or third-party coverage and reimbursement policies, which would harm our business.

The regulations that govern regulatory approvals, pricing and reimbursement for new drugs vary widely from country to country. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing approval is granted. In some foreign markets, prescription biopharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain regulatory approval for a product in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods and negatively impact the revenues we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if our product candidates obtain regulatory approval.

Our ability to commercialize any products successfully also will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from third-party payors including government authorities, such as Medicare and Medicaid, private health insurers and other organizations. Patients who are provided medical treatment for their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Coverage and adequate reimbursement from third-party payors are critical to new product acceptance. Even if we succeed in bringing one or more products to the market, these products may not be considered cost-effective, and the amount reimbursed for any products may be insufficient to allow us to sell our products on a competitive basis. Because our programs are in the early stages of development, we are unable at this time to determine their cost effectiveness or the likely level or method of coverage and reimbursement. Increasingly, the third-party payors who reimburse patients or healthcare providers, such as government and private insurance plans, are requiring that drug companies provide them with predetermined discounts from list prices, and are seeking to reduce the prices charged or the amounts reimbursed for biopharmaceutical products. If the price we are able to charge for any products we develop, or the coverage and reimbursement provided for such products, is inadequate in light of our development and other costs, our return on investment could be affected adversely.

There may be significant delays in obtaining reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the FDA or similar foreign regulatory authorities. Moreover, eligibility for reimbursement does not imply that any drug or therapeutic biologic will be reimbursed in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution.

Interim reimbursement levels for new drugs, if applicable, may also be insufficient to cover our costs and may not be made permanent. Reimbursement rates may be based on payments allowed for lower cost drugs that are already reimbursed, may be incorporated into existing payments for other services and may reflect budgetary constraints or imperfections in Medicare data. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Further, no uniform policy for

coverage and reimbursement exists in the United States, and coverage and reimbursement can differ significantly from payor to payor. As a result, obtaining coverage and reimbursement approval of a product from a third-party payor is a time consuming and costly process that could require us to provide to each payor supporting scientific, clinical and cost effectiveness data for the use of our products on a payor-by-payor basis, with no assurance that coverage and adequate reimbursement will be obtained. There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement rates, but also have their own methods and approval process apart from Medicare determinations. Our inability to promptly obtain coverage and adequate reimbursement rates from both government-funded and private payors for new drugs that we develop and for which we obtain regulatory approval could have a material and adverse effect on our business, financial condition, results of operations and prospects.

If we decide to pursue a Fast Track Designation by the FDA, it may not lead to a faster development or regulatory review or approval process.

We may seek Fast Track Designation for one or more of our product candidates. If a drug is intended for the treatment of a serious or life-threatening condition and the drug demonstrates the potential to address unmet medical needs for this condition, the product sponsor may apply for FDA Fast Track Designation. The FDA has broad discretion whether or not to grant this designation, so even if we believe a particular product candidate is eligible for this designation, we cannot assure you that the FDA would decide to grant it. Even if we do receive Fast Track Designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may withdraw Fast Track Designation if it believes that the designation is no longer supported by data from our clinical development program.

If we decide to seek Orphan Drug Designation for some of our product candidates, we may be unsuccessful or may be unable to maintain the benefits associated with Orphan Drug Designation, including the potential for supplemental market exclusivity.

As part of our business strategy, we may seek Orphan Drug Designation for one or more of our product candidates, and we may be unsuccessful. Regulatory authorities in some jurisdictions, including the United States and Europe, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a drug as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. In the United States, Orphan Drug Designation entitles a party to financial incentives such as opportunities for grant funding toward clinical trial costs, tax advantages and user fee waivers. In addition, if a product that has Orphan Drug Designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications to market the same product for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity or where the manufacturer is unable to assure sufficient product quantity.

Even if we obtain Orphan Drug Designation for our product candidates in specific indications, we may not be the first to obtain marketing approval of these product candidates for the orphan-designated indication due to the uncertainties associated with developing pharmaceutical products. In addition, exclusive marketing rights in the United States may be limited if we seek approval for an indication broader than the orphan-designated indication or may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition. Further, even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs with different active moiety can be approved for the same condition. Even after an orphan product is approved, the FDA can subsequently approve the same drug with the same active moiety for the same condition if the FDA concludes that the later drug is safer, more effective or makes a major contribution to patient care. Orphan Drug Designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process. In addition, while we may seek Orphan Drug Designation for our product candidates, we may never receive such designations.

The recent tax reform legislation, which was signed into law on December 22, 2017 reduced the amount of the qualified clinical research costs for a designated orphan product that a sponsor may claim as a credit from 50% to 25%. Thus, further limiting the advantage and may impact our future business strategy of seeking the Orphan Drug Designation.

We are subject to U.S. and certain foreign export and import controls, sanctions, embargoes, anti-corruption laws, and anti-money laundering laws and regulations. Compliance with these legal standards could impair our ability to compete in domestic and international markets. We can face criminal liability and other serious consequences for violations, which can harm our business.

We are subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations, various economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Controls, the U.S. Foreign Corrupt Practices Act of 1977, as amended, or FCPA, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act, and other state and national anti-bribery and anti-money laundering laws in the countries in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, contractors, and other collaborators from authorizing, promising, offering, or providing, directly or indirectly, improper payments or anything else of value to recipients in the public or private sector. We may engage third parties to sell our products sell our products outside the United States, to conduct clinical trials, and/or to obtain necessary permits, licenses, patent registrations, and other regulatory approvals. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities, and other organizations. We can be held liable for the corrupt or other illegal activities of our employees, agents, contractors, and other collaborators, even if we do not explicitly authorize or have actual knowledge of such activities. Any violations of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences.

Governments outside the United States tend to impose strict price controls, which may adversely affect our revenue, if any.

In some countries, particularly member states of the European Union, or EU, the pricing of prescription drugs is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after receipt of marketing approval for a product. In addition, there can be considerable pressure by governments and other stakeholders on prices and reimbursement levels, including as part of cost containment measures. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various EU member states and parallel distribution, or arbitrage between low-priced and high-priced member states, can further reduce prices. To obtain coverage and reimbursement or pricing approvals in some countries, we or current or future collaborators may be required to conduct a clinical trial or other studies that compare the cost-effectiveness of our therapeutic candidates to other available therapies in order to obtain or maintain reimbursement or pricing approval. Publication of discounts by third-party payors or authorities may lead to further pressure on the prices or reimbursement levels within the country of publication and other countries. If reimbursement of any product candidate approved for marketing is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business, financial condition, results of operations or prospects could be materially and adversely affected. In addition, as a result of Brexit, there will be a transition period until a comprehensive trade agreement between the United Kingdom and European Union is negotiated by year-end 2020. It is not yet certain, if the European Union regulatory framework for medicinal products will continue to govern the relevant law in the United Kingdom during this transition. Brexit could lead to legal uncertainty and potentially divergent national laws and regulations, including those related to the pricing of prescription pharmaceuticals, as the United Kingdom determines which EU laws to replicate or replace. If the United Kingdom were to significantly alter its regulations affecting the pricing of prescription pharmaceuticals, we could face significant new costs. As a result, Brexit could impair our ability to transact business in the EU and the United Kingdom.

European data collection is governed by restrictive regulations governing the use, processing, and cross-border transfer of personal information.

The collection and use of personal health data in the EU is governed by the provisions of the Data Protection Directive, and as of May 2018, the General Data Protection Regulation, or GDPR. These directives impose several requirements relating to the consent of the individuals to whom the personal data relates, the information provided to the individuals, notification of data processing obligations to the competent national data protection authorities and the security and confidentiality of the personal data. The Data Protection Directive and GDPR also impose strict rules on the transfer of personal data out of the European Union to the United States. Failure to comply with the requirements of the Data Protection Directive, the GDPR, and the related national data protection laws of the EU Member States may result in fines (for example, of up to €20,000,000 or up to 4% of the total worldwide annual turnover of the preceding financial year (whichever is higher)) and other administrative penalties. The GDPR regulations may impose additional responsibility and liability in relation to personal data that we process and we may be required to put in place additional mechanisms ensuring compliance with the new data protection rules. This may be onerous and adversely affect our business, financial condition, results of operations and prospects. As a result of the implementation of the GDPR, we may be required to put in place additional mechanisms ensuring compliance with the new data protection rules. There is significant uncertainty related to the manner in which data protection authorities will seek to enforce compliance with GDPR is not yet clear. For example, it is not clear if the authorities will conduct random audits of companies doing business in the EU, or if the authorities will wait for complaints to be filed by individuals who claim their rights have been violated. Enforcement uncertainty and the costs associated with ensuring GDPR compliance be onerous and adversely affect our business, financial condition, results of operations and prospects. Further, Brexit, has created uncertainty with regard to data protection regulation in the United Kingdom. The United Kingdom enacted the Data Protection Act 2018 to directly enforce the GDPR. The government of the United Kingdom has also stated that when the United Kingdom leaves the European Union it will still abide with the provisions of the GDPR. However, in the event of a “no deal” Brexit, it is uncertain whether this commitment will still be met. In the case of a “no deal” Brexit, it is also uncertain whether clinical trial data and pharmacovigilance adverse event data originating from the United Kingdom will be compliant with European Union privacy legislation and whether the data will be incorporated by the EMA in the assessment of the ongoing benefit-risk profile and hence continued support of European Union marketing authorizations.

Risks Related to Ownership of Our Common Stock

Our quarterly operating results may fluctuate significantly or may fall below the expectations of investors or securities analysts, each of which may cause our stock price to fluctuate or decline.

We expect our operating results to be subject to quarterly fluctuations. Our net loss and other operating results will be affected by numerous factors, including:

- variations in the level of expense related to the ongoing development of our MInT Platform, product candidates or future development programs;
- results of preclinical and future clinical trials, or the addition or termination of future clinical trials or funding support by us, or existing or future collaborators or licensing partners;
- our execution of any additional collaboration, licensing or similar arrangements, and the timing of payments we may make or receive under existing or future arrangements or the termination or modification of any such existing or future arrangements;
- any intellectual property infringement lawsuit or opposition, interference or cancellation proceeding in which we may become involved;
- additions and departures of key personnel;
- strategic decisions by us or our competitors, such as acquisitions, divestitures, spin-offs, joint ventures, strategic investments or changes in business strategy;

- if any of our product candidates receives regulatory approval, the terms of such approval and market acceptance and demand for such product candidates;
- regulatory developments affecting our product candidates or those of our competitors; and
- changes in general market and economic conditions.

If our quarterly operating results fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. Furthermore, any quarterly fluctuations in our operating results may, in turn, cause the price of our common stock to fluctuate substantially. We believe that quarterly comparisons of our financial results are not necessarily meaningful and should not be relied upon as an indication of our future performance.

The market price of our stock may be volatile, and you could lose all or part of your investment.

The trading price of our common stock may be highly volatile and subject to wide fluctuations in response to various factors, some of which we cannot control. The market price for our common stock may be influenced by many factors, including the other risks described in this section and elsewhere in this report and the following:

- results of preclinical studies and future clinical trials of our product candidates, or those of our competitors or our existing or future collaborators;
- regulatory or legal developments in the United States and other countries, especially changes in laws or regulations applicable to our product candidates;
- the success of competitive products or technologies;
- introductions and announcements of new products by us, our future commercialization partners, or our competitors, and the timing of these introductions or announcements;
- actions taken by regulatory agencies with respect to our products, clinical studies, manufacturing process or sales and marketing terms;
- actual or anticipated variations in our financial results or those of companies that are perceived to be similar to us;
- the success of our efforts to acquire or in-license additional technologies, products or product candidates;
- developments concerning any future collaborations, including but not limited to those with development and commercialization partners;
- market conditions in the pharmaceutical and biotechnology sectors;
- announcements by us or our competitors of significant acquisitions, strategic collaborations, joint ventures or capital commitments;
- developments or disputes concerning patents or other proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our product candidates and products;
- our ability or inability to raise additional capital and the terms on which we raise it;
- the recruitment or departure of key personnel;
- changes in the structure of healthcare payment systems;

- actual or anticipated changes in earnings estimates or changes in stock market analyst recommendations regarding our common stock, other comparable companies or our industry generally;
- our failure or the failure of our competitors to meet analysts' projections or guidance that we or our competitors may give to the market;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- announcement and expectation of additional financing efforts;
- speculation in the press or investment community;
- share price and fluctuations of trading volume of our common stock, which may affect our trading liquidity and public float;
- sales of our common stock by us, insiders or our stockholders;
- the concentrated ownership of our common stock;
- changes in accounting principles;
- terrorist acts, acts of war or periods of widespread civil unrest;
- natural disasters and other calamities; and
- general economic, industry and market conditions.

In addition, the stock market in general, and the markets for pharmaceutical, biopharmaceutical and biotechnology stocks in particular, have experienced extreme price and volume fluctuations that have been often unrelated or disproportionate to the operating performance of the issuer. These broad market and industry factors may seriously harm the market price of our common stock, regardless of our actual operating performance. The realization of any of the above risks or any of a broad range of other risks, including those described in this "Risk Factors" section, could have a dramatic and adverse impact on the market price of our common stock. In addition, it may be more difficult for stockholders to sell a substantial number of shares for the same price at which stockholders could sell a smaller number of shares.

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for biopharmaceutical companies, which have experienced significant stock price volatility in recent years.

A sale of a substantial number of shares of our common stock may cause the price of our common stock to decline.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. If our stockholders sell, or the market perceives that our stockholders intend to sell, substantial amounts of our common stock in the public market the market price of our common stock could decline significantly.

We cannot predict what effect, if any, sales of our shares in the public market or the availability of shares for sale will have on the market price of our common stock. However, future sales of substantial amounts of our common stock in the public market, including shares issued upon exercise of our outstanding warrant or options, or the perception that such sales may occur, could adversely affect the market price of our common stock.

We also expect that significant additional capital may be needed in the future to continue our planned operations. To raise capital, we may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. To the extent that additional capital is raised through the sale

and issuance of shares or other securities convertible into shares, our stockholders will be diluted. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock.

If securities or industry analysts do not publish research or reports about our business, or if they issue an adverse or misleading opinion regarding our stock, our stock price and trading volume could decline.

The trading market for our common stock will be influenced by the research and reports that industry or securities analysts publish about us or our business. We do not have any control over the industry or securities analysts, or the content and opinions included in their reports. If any of the analysts who cover us issue an adverse or misleading opinion regarding us, our business model, our intellectual property or our stock performance, or if our preclinical studies and clinical trials and operating results fail to meet the expectations of analysts, our stock price would likely decline. If one or more of such analysts cease coverage of us or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause a decline in our stock price or trading volume.

Our principal stockholders and management own a significant percentage of our stock and will be able to control matters subject to stockholder approval.

Based on the beneficial ownership of our common stock as of December 31, 2019, our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates beneficially owned approximately 69% of our outstanding voting stock. As a result, these stockholders, if acting together, will continue to have control over the outcome of corporate actions requiring stockholder approval, including the election of directors, amendment of our organizational documents, any merger, consolidation or sale of all or substantially all of our assets and any other significant corporate transaction. The interests of these stockholders may not be the same as or may even conflict with your interests. For example, these stockholders could delay or prevent a change of control of our company, even if such a change of control would benefit our other stockholders, which could deprive our stockholders of an opportunity to receive a premium for their common stock as part of a sale of our company or our assets and might affect the prevailing market price of our common stock. The significant concentration of stock ownership may adversely affect the trading price of our common stock due to investors' perception that conflicts of interest may exist or arise.

We are an "emerging growth company" and a "smaller reporting company" and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies or smaller reporting companies will make our common stock less attractive to investors.

We are an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including (i) not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as amended, or the Sarbanes-Oxley Act, (ii) reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and (iii) exemptions from the requirements of holding nonbinding advisory stockholder votes on executive compensation and stockholder approval of any golden parachute payments not approved previously. In addition, as an emerging growth company, we are only required to provide two years of audited financial statements and two years of selected financial data in this report.

We will remain an emerging growth company until the earlier of (i) the last day of the fiscal year (a) following the fifth anniversary of the closing of our initial public offering – December 31, 2025, (b) in which we have total annual gross revenue of at least $1.07 billion or (c) in which we are deemed to be a large accelerated filer, which requires the market value of our common stock that is held by non-affiliates to exceed $700.0 million as of the prior June 30th, and (ii) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period.

Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have elected to take advantage of the benefits of this extended transition period. Our financial statements may therefore not be comparable to those of companies that comply with such new or revised accounting standards. Until the date that we are no longer an "emerging growth company" or

affirmatively and irrevocably opt out of the exemption provided by Section 7(a)(2)(B) of the Securities Act, upon issuance of a new or revised accounting standard that applies to our financial statements and that has a different effective date for public and private companies, we will disclose the date on which adoption is required for non-emerging growth companies and the date on which we will adopt the recently issued accounting standard.

We are also a "smaller reporting company," meaning that as of the date of our initial public offering, the market value of our stock held by non-affiliates was less than $700.0 million and our annual revenue was less than $100.0 million during the most recently completed fiscal year. We may continue to be a smaller reporting company until (i) the market value of our stock held by non-affiliates is less than $250.0 million as of the prior June 30th, or (ii) our annual revenue is less than $100.0 million during the most recently completed fiscal year and the market value of our stock held by non-affiliates is less than $700.0 million as of the prior June 30th. If we are a smaller reporting company at the time we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our share price may be more volatile.

Anti-takeover provisions in our charter documents and under Delaware law could prevent or delay an acquisition of us, which may be beneficial to our stockholders, and may prevent attempts by our stockholders to replace or remove our current management.

Our restated certificate of incorporation and our restated bylaws contain provisions that could delay or prevent a change in control of our company. These provisions could also make it difficult for stockholders to elect directors who are not nominated by current members of our board of directors or take other corporate actions, including effecting changes in our management. These provisions:

- § establish a classified board of directors so that not all members of our board are elected at one time;
- § permit only the board of directors to establish the number of directors and fill vacancies on the board;
- § provide that directors may only be removed "for cause" and only with the approval of two-thirds of our stockholders;
- § require super-majority voting to amend some provisions in our restated certificate of incorporation and restated bylaws;
- § authorize the issuance of "blank check" preferred stock that our board could use to implement a stockholder rights plan;
- § eliminate the ability of our stockholders to call special meetings of stockholders;
- § prohibit stockholder action by written consent, which requires all stockholder actions to be taken at a meeting of our stockholders;
- § prohibit cumulative voting; and
- § establish advance notice requirements for nominations for election to our board or for proposing matters that can be acted upon by stockholders at annual stockholder meetings.

The exclusive forum provision in our restated certificate of incorporation may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or any of our directors, officers, or other employees, which may discourage lawsuits with respect to such claims.

Our restated certificate of incorporation, to the fullest extent permitted by law, provides that the Court of Chancery of the State of Delaware is the exclusive forum for: any derivative action or proceeding brought on our behalf; any action asserting a breach of fiduciary duty; any action asserting a claim against us arising pursuant to the Delaware General Corporation Law, or the DGCL, our restated certificate of incorporation, or our restated bylaws; or any action asserting a claim against us that is governed by the internal affairs doctrine. This exclusive forum provision does not apply to suits brought to enforce a duty or liability created by the Exchange Act. It could apply, however, to a suit that falls within one or more of the categories enumerated in the exclusive forum provision and asserts claims under the Securities Act, inasmuch as Section 22 of 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 rule and regulations thereunder. There is uncertainty as to whether a court would enforce such provision with respect to claims under the Securities Act, and our stockholders will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder.

This choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or any of our directors, officers, or other employees, which may discourage lawsuits with respect to such claims. Alternatively, if a court were to find the choice of forum provisions contained in our restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business, results of operations and financial condition.

In addition, Section 203 of the DGCL may discourage, delay or prevent a change in control of our company. Section 203 imposes certain restrictions on mergers, business combinations and other transactions between us and holders of 0% or more of our common stock.

We will incur increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives and corporate governance practices.

As a public company, and particularly after we are no longer an emerging growth company, we will incur significant legal, accounting and other expenses that we did not incur as a private company. The Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of the Nasdaq Global Market and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, we expect these rules and regulations to substantially increase our legal and financial compliance costs and to make some activities more time consuming and costly. We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers. The increased costs may require us to reduce costs in other areas of our business or increase the prices of our services. Moreover, these rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

We are not currently required to comply with the SEC's rules that implement Section 404 of the Sarbanes-Oxley Act, and are therefore not required to make a formal assessment of the effectiveness of our internal control over financial reporting for that purpose. Pursuant to Section 404, we will be required to furnish a report by our management on our internal control over financial reporting. However, while we remain an emerging growth company, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with Section 404 within the prescribed period, we will be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In

this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. This process will be time-consuming, costly and complicated. Despite our efforts, there is a risk that we will not be able to conclude, within the prescribed timeframe or at all, that our internal control over financial reporting is effective as required by Section 404. If we identify one or more material weaknesses, it could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements. In addition, if we are not able to continue to meet these requirements, we may not be able to remain listed on the Nasdaq Global Market.

Because we do not anticipate paying any cash dividends on our capital 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 capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

ITEM 1B. UNRESOLVED STAFF COMMENTS.

None.

ITEM 2. PROPERTIES.

Our principal executive office is located in Waltham, Massachusetts, where we lease a total of approximately 35,000 square feet of office and laboratory space in three buildings that we use for our administrative, research and development and other activities. The lease under our Waltham buildings expires in May 2022, unless we exercise our option to extend the lease term through May 2025.

ITEM 3. LEGAL PROCEEDINGS.

From time to time, we may be involved in legal proceedings arising in the ordinary course of our business. We are not presently a party to any legal proceedings that, in the opinion of management, would have a material adverse effect on our business. Regardless of outcome, litigation can have an adverse impact on us due to defense and settlement costs, diversion of management resources, negative publicity and reputational harm, and other factors.

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 traded on the Nasdaq Capital Market under the symbol "MORF". Trading of our common stock commenced on June 26, 2019, following the completion of our initial public offering. Prior to that time, there was no established public trading market for our common stock.

Stockholders

As of February 27, 2020, there were approximately 54 stockholders of record of our common stock. This number does not include beneficial owners whose shares are held in street name.

Dividends

We have never declared or paid any dividends to our stockholders since our inception and we do not plan to declare or pay cash dividends in the foreseeable future. We currently anticipate that we will retain all available funds and any future earnings for the operation and expansion of our business. Any future determination related to dividend policy will be made at the discretion of our board of directors and will depend on, among other factors, our results of operations, financial condition, capital requirements, contractual restrictions, business prospects and other factors our board of directors may deem relevant. Investors should not purchase our common stock with the expectation of receiving cash dividends.

Use of Proceeds from Registered Securities

On June 26, 2019, our Registration Statement on Form S-1 (File No. 333-231837) relating to our initial public offering, or IPO, of our common stock was declared effective by the SEC. Pursuant to such Registration Statement, we sold an aggregate of 6,900,000 shares of our common stock at a price of $15.00 per share for aggregate cash proceeds of approximately $93.3 million, net of underwriting discounts and commissions and offering costs.

We intend to use the remaining net proceeds from our IPO to fund the further development of our oral small-molecule integrin therapeutics, the further development of our platform to broaden our pipeline of product candidates and for working capital and general corporate purposes.

Unregistered Sales of Securities

From January 1, 2019 through December 31, 2019, we sold and issued the following unregistered securities, which share numbers have been adjusted, as appropriate, to reflect the 5.8311-to-1 reverse stock split which became effective on June 13, 2019:

- Prior to filing our registration statement on Form S-8 in 2019, we granted options to our directors, officers, employees and consultants to purchase an aggregate of 2,047,556 shares of common stock under our 2018 Plan with per share exercise prices ranging from $4.32 to $7.76; no stock options were exercised.

- The issuances of the securities described above were deemed to be exempt from registration pursuant to Section 4(a)(2) of the Securities Act or Rule 701 promulgated under the Securities Act as transactions pursuant to compensatory benefit plans.

Issuer Purchases of Equity Securities

None.

ITEM 6. SELECTED FINANICAL DATA.

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

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

You should read the following discussion of our financial condition and results of operations in conjunction with our consolidated financial statements and the related notes and other financial information included elsewhere in this Annual Report on Form 10-K. This Annual Report on Form 10-K, including the following sections, contains forward-looking statements within the meaning of the federal securities laws. These statements are subject to risks and uncertainties that could cause actual results and events to differ materially from those expressed or implied by such forward-looking statements. For a detailed discussion of these risks and uncertainties, see the "Risk Factors" section in Item 1A of this Annual Report on Form 10-K. We caution the reader not to place undue reliance on these forward-looking statements, which reflect management's analysis only as of the date of this Form 10-K. We undertake no obligation to update forward-looking statements, which reflect events or circumstances occurring after the date of this Form 10-K.

Overview

We are a biopharmaceutical company applying our proprietary insights into integrins to discover and develop a pipeline of potentially first-in-class oral small-molecule integrin therapeutics. Integrins are a target class with multiple approved injectable blockbuster drugs for the treatment of serious chronic diseases, including autoimmune, cardiovascular and metabolic diseases, fibrosis and cancer. To date, no oral small-molecule integrin therapies have been approved by the FDA. Despite significant unsuccessful efforts, we believe tremendous untapped potential remains for us to develop oral integrin therapies. We created the Morphic integrin technology platform, or MInT Platform, by leveraging our unique understanding of integrin structure and biology to develop novel product candidates designed to achieve the potency, high selectivity, and pharmaceutical properties required for oral administration. We are advancing our preclinical pipeline, including our wholly-owned program MORF-057, a $\alpha_4\beta_7$ specific integrin inhibitor affecting inflammation, into clinical development for the treatment of inflammatory bowel disease, or IBD. We are also developing MORF-720, our selective oral $\alpha_v\beta_6$ specific integrin inhibitor affecting fibrosis, toward an Investigational New Drug application, or IND. We intend to advance MORF-057 and MORF-720 toward IND submissions by the middle of 2020 and the end of 2020, respectively. Beyond our current targets, we are using our MInT Platform to create a broad pipeline of programs across a variety of therapeutic areas, all of which aim to harness the potential of inhibition or activation.

We were formed as a limited liability company under the laws of the State of Delaware in August 2014 under the name Integrin Rock, LLC. We subsequently changed our name to Morphic Rock Holding, LLC in October 2014 and then to Morphic Holding, LLC in June 2016, and we subsequently converted to a corporation under the name Morphic Holding, Inc. in December 2018. In connection with the conversion to a Delaware corporation, or the Reorganization, each of the outstanding units of the members of the limited liability company were converted into shares of capital stock.

Upon consummation of the Reorganization, the historical consolidated financial statements of Morphic Holding, LLC became the historical consolidated financial statements of Morphic Holding, Inc. All information included in this Annual Report is presented after giving effect to the Reorganization.

On July 1, 2019, we completed the initial public offering, or IPO, of our common stock and issued and sold 6,900,000 shares of common stock at a public offering price of $15.00 per share, which included 900,000 shares sold upon full exercise of the underwriters' option to purchase additional shares of common stock resulting in net proceeds of $93.3 million after deducting underwriting discounts and commissions and offering expenses.

Since inception, our operations have focused on organizing and staffing our company, business planning, raising capital, establishing our intellectual property portfolio, and performing research to discover and develop oral small-molecule integrin therapeutics. Revenue generation activities have been limited to the following. In October 2018, pursuant to our collaboration and option agreement with AbbVie, or the AbbVie Agreement, we received an upfront payment of $100.0 million for research and development activities, and provided to AbbVie exclusive license options on product candidates directed at multiple targets. In March 2019, pursuant to the Janssen Agreement, we received an upfront payment of $10.0 million and provided Janssen with exclusive license options on product candidates directed at multiple targets. In addition, Janssen will reimburse us for research services at market rates. We do not have any products approved for sale and have not generated any revenue from product sales. Through December 31, 2019 in addition to the foregoing sources of revenue, we have funded our operations primarily through the sale and issuance of our convertible preferred equity securities, borrowings under a loan and security agreement, or the credit facility, with Silicon Valley Bank, or SVB, and an IPO. From inception through December 31, 2019 we raised an aggregate of approximately $242.6 million of gross proceeds through the issuance of equity and debt.

Since inception, we have incurred significant operating losses. Our net losses were $43.3 million and $23.8 million for the years ended December 31, 2019 and 2018 respectively. As of December 31, 2019, we had an accumulated deficit of $97.5 million. We expect to continue to incur significant and increasing expenses and operating losses for the foreseeable future, as we advance our current and future product candidates through preclinical and clinical development, seek regulatory approval for them, maintain and expand our intellectual property portfolio, hire additional research and development and business personnel, and operate as a public company.

We will not generate revenue from product sales unless and until we successfully complete clinical development and obtain regulatory approval for our product candidates. In addition, if we obtain regulatory approval for our product candidates and do not enter into a third-party commercialization partnership, we expect to incur significant expenses related to developing our commercialization capability to support product sales, marketing, manufacturing, and distribution activities.

As a result, we will need substantial additional funding to support our continuing operations and pursue our growth strategy. Until we can generate significant revenue from product sales, if ever, we expect to finance our operations through a combination of public or private equity offerings and debt financings or other sources, such as potential collaboration agreements. We may be unable to raise additional funds or enter into such other agreements or arrangements when needed on acceptable terms, or at all. Our failure to raise capital or enter into such agreements as, and when, needed, could have a material adverse effect on our business, results of operations, and financial condition.

As of December 31, 2019, we had cash, cash equivalents, and marketable securities of $237.0 million. We believe that our existing cash and cash equivalents, marketable securities will enable us to fund our operating expenses and capital expenditure requirements through at least the end of 2022.

Financial Operations Overview

Collaboration Revenue

We do not have any products approved for sale, and as a result, we have not generated any revenue from product sales and do not expect to generate any revenue from the sale of products in the foreseeable future.

To date, all of our collaboration revenue has been derived from our agreements with AbbVie and Janssen. We expect that until we have a marketed product, our revenue, if any, will be derived primarily from payments under our collaboration and option agreements with AbbVie and Janssen or other collaboration and license agreements that we may enter into in the future, if any.

Collaboration Revenue — AbbVie

In October 2018, we entered into a collaboration with AbbVie, an investor that held approximately 5% of our common stock common stock at the time of the agreement, designed to advance a number of our oral integrin therapeutics for fibrosis-related indications. Under the terms of the agreement, AbbVie paid us an upfront payment of $100.0 million for

research and development activities, and we provided to AbbVie exclusive license options on product candidates directed at multiple targets.

For each compound, we will conduct research and development activities through the completion of IND-enabling studies, at which point AbbVie may pay a license fee of $20.0 million, on a target-by-target basis, to exercise its exclusive license option and assume responsibility for global development and commercialization. Under the terms of the arrangement, we are responsible for generating at least one research product and one backup. We are also eligible for clinical and commercial milestone payments and tiered royalties from high single digit to low teens on worldwide net sales for each licensed product. In addition, for certain compounds for which we have completed IND-enabling studies and which meet certain advancement criteria for a liver indication, we have the option to commit to share development costs in exchange for an increased fixed royalty rate. We may exercise this option following completion of the first phase IIb clinical trial for the relevant product.

Collaboration Revenue — Janssen

In February 2019, we entered into the Janssen Agreement to discover and develop novel integrin therapeutics for patients with conditions not adequately addressed by current therapies. The Janssen Agreement focuses on three integrin targets, each target the subject of a research program, with the ability to substitute up to two integrin targets not explored by us. Upon completing IND-enabling studies, on a research program-by-research program basis, Janssen may exercise an exclusive option to obtain an exclusive license with respect to the target that is the subject of the research program, including all licensed compounds that are the subject of the applicable research program, and then Janssen will be responsible for global clinical development and commercialization. In consideration of the rights granted, Janssen paid us an upfront fee of $10.0 million for each of the first two research programs, will pay us an additional $5.0 million fee upon commencement of the third research program, and will fund research activities. Pursuant to the terms of the agreement, we are also eligible to receive additional milestone and royalty payments.

Expenses

Research and Development

Research and development expenses consist primarily of costs incurred for our research and development activities, including our product candidate discovery efforts and preclinical studies under our research programs, which include:

- employee-related expenses, including salaries, benefits, and equity-based compensation expense for our research and development personnel;
- costs of funding research performed by third parties that conduct research and development and preclinical activities on our behalf;
- costs of manufacturing clinical supply related to any of our current or future product candidates;
- costs of conducting preclinical studies of any of our current or future product candidates;
- consulting and professional fees related to research and development activities, including equity-based compensation to non-employees;
- costs of purchasing laboratory supplies and non-capital equipment used in our preclinical studies;
- costs related to compliance with clinical regulatory requirements;
- facility costs and other allocated expenses, which include expenses for rent and maintenance of facilities, insurance, depreciation and other supplies; and
- fees for maintaining licenses and other amounts due under our third-party licensing agreements.

Research and development costs are expensed as incurred. Costs for certain activities are recognized based on an evaluation of the progress to completion of specific tasks using data such as information provided to us by our vendors and analyzing the progress of our preclinical studies or other services performed. Significant judgment and estimates are made in determining the accrued expense balances at the end of any reporting period. Non-refundable advance payments for research and development goods or services to be received in the future from third parties are deferred and capitalized. The capitalized amounts are expensed as the related goods are delivered or the services are performed.

The successful development of our product candidates is highly uncertain. As such, at this time, we cannot reasonably estimate or know the nature, timing, and estimated costs of the efforts that will be necessary to complete our future product candidates. We are also unable to predict when, if ever, material net cash inflows will commence from the sale of our product candidates, if approved. This is due to the numerous risks and uncertainties associated with developing product candidates, including the uncertainty of:

- § the scope, rate of progress, and expenses of our ongoing research activities as well as any additional preclinical studies and clinical trials and other research and development activities;
- § establishing an appropriate safety profile;
- § successful enrollment in and completion of clinical trials;
- § whether our product candidates show safety and efficacy in our clinical trials;
- § receipt of marketing approvals from applicable regulatory authorities, if any;
- § establishing commercial manufacturing capabilities or making arrangements with third-party manufacturers;
- § obtaining and maintaining patent and trade secret protection and regulatory exclusivity for our product candidates;
- § commercializing the product candidates, if and when approved, whether alone or in collaboration with others; and
- § continued acceptable safety profile of the products following any regulatory approval.

A change in the outcome of any of these variables with respect to the development of our current and future product candidates would significantly change the costs and timing associated with the development of those product candidates.

Research and development activities are central to our business model. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We expect research and development costs to increase significantly for the foreseeable future as we continue the development of our product candidates. However, we do not believe that it is possible at this time to accurately project total program-specific expenses through commercialization. There are numerous factors associated with the successful commercialization of any of our product candidates, including future trial design and various regulatory requirements, many of which cannot be determined with accuracy at this time based on our stage of development. Additionally, future commercial and regulatory factors beyond our control will impact our clinical development programs and plans.

General and Administrative

General and administrative expenses consist primarily of employee-related expenses, including salaries, benefits, and equity-based compensation expenses for personnel in executive, finance, accounting, business development, legal, and human resources functions. Other significant general and administrative expenses include facility costs not otherwise

included in research and development expenses, legal fees relating to patent and corporate matters, and fees for accounting and consulting services.

We anticipate that our general and administrative expenses will increase in the future as our business expands to support expected growth in research and development activities, including our future clinical programs. These increases will likely include increased costs related to the hiring of additional personnel and fees to outside consultants, among other expenses. We also anticipate increased expenses associated with being a public company, including costs for audit, legal, regulatory, and tax-related services related to compliance with the rules and regulations of the Securities and Exchange Commission, or SEC, and listing standards applicable to companies listed on Nasdaq, director and officer compensation and insurance premiums, and investor relations costs. In addition, if we obtain regulatory approval for any of our product candidates and do not enter into a third-party commercialization collaboration, we expect to incur significant expenses related to building a sales and marketing team to support product sales, marketing and distribution activities.

Interest Income, Net

Interest income, net consists primarily of interest income earned on our cash and cash equivalents and marketable securities, partially offset by interest expense incurred on our credit facility, including amortization of debt discount and debt issuance costs.

Provision for Income Tax Expense

We recorded $0.9 million in income tax expense during the year ended December 31, 2019 primarily due to the current tax liability associated with the tax recognition of the upfront AbbVie collaboration payment received in 2018. A significant portion of the taxable income related to the collaboration payment was offset by the current year operating expenses as well as prior year accumulated losses and research and development credits. For additional details about the current year tax provision, refer to Note 9 in the Notes to the Consolidated Financial Statements appearing elsewhere in this Annual Report on Form 10-K.

Results of Operations

Comparison of the years ended December 31, 2019 and 2018

The following table summarizes our results of operations for years ended December 31, 2019 and 2018:

	Year Ended December 31,		Change	
	2019	2018	$	%
	(in thousands, except percentages)			
Collaboration revenue — AbbVie	$ 10,797	$ 3,358	$ 7,439	222 %
Collaboration revenue — Janssen	6,180	—	6,180	*
Total collaboration revenue	16,977	3,358	13,619	406 %
Operating expenses:				
Research and development	53,732	22,631	31,101	137 %
General and administrative	10,233	5,355	4,878	91 %
Total operating expenses	63,965	27,986	35,979	129 %
Loss from operations	(46,988)	(24,628)	(22,360)	91 %
Other income:				
Interest income, net	4,666	871	3,795	436 %
Other expense, net	(94)	(74)	(20)	27 %
Total other income, net	4,572	797	3,775	474 %
Loss before provision for income taxes	$ (42,416)	$ (23,831)	$ (18,585)	78 %
Provision for income taxes	(912)	—	(912)	*
Net loss	$ (43,328)	$ (23,831)	$ (19,497)	82 %

* Percentage not meaningful

Collaboration Revenue

Collaboration revenue increased to $17.0 million for the year ended December 31, 2019 from $3.4 million for the year ended December 31, 2018. The overall increase in revenue is attributable to $7.4 million increase in revenue recognized under our collaboration with AbbVie that we executed in October 2018 to advance several oral integrin therapeutics for fibrosis-related indications. Revenue we recognize from satisfaction of performance obligations under the AbbVie agreement is impacted by our estimates of the remaining costs to complete our obligations, which require significant judgment, and may cause fluctuation in the revenue recognized from period to period. Additionally, we recorded $6.2 million in revenue from our collaboration with Janssen that we executed in February 2019.

Research and Development Expenses

Research and development expense increased by $31.1 million, or 137%, from $22.6 million for the year ended December 31, 2018 to $53.7 million for the year ended December 31, 2019. A significant portion of our research and development costs have been external pre-clinical contract research organization (CRO) costs, which we track on a program-by-program basis related to a clinical product candidate that has been identified. Our internal research and development costs are primarily personnel-related costs, depreciation, and other indirect costs. The following table summarizes our research and development expense for the years ended December 31, 2019 and 2018:

	Year Ended December 31,		Change	
	2019	2018	$	%
	(in thousands, except percentages)			
External costs by program:				
MORF-720	$ 12,709	$ 6,763	$ 5,946	88%
Other AbbVie Agreement programs	5,273	—	5,273	*
MORF-057	12,995	3,997	8,998	225%
Janssen Agreement programs	1,992	—	—	*
Other early development candidates and unallocated costs	4,718	2,932	1,786	61%
Total external costs	37,687	13,692	23,995	175%
Internal costs:				
Employee compensation and benefits	14,349	7,754	6,595	85%
Facility and other	1,696	1,185	511	43%
Total internal costs	16,045	8,939	7,106	79%
Total research and development expense	$ 53,732	$ 22,631	$ 31,101	137%

* Percentage not meaningful

The increase in research and development expense was primarily attributable to the following:

- The $24.0 million increase in external costs primarily related to increased research and preclinical development and manufacturing costs associated with product candidates MORF-720 and MORF-057 targeting αvβ6 and α4β7, respectively, and other external research costs associated with our other early development candidates.

- The $7.1 million increase in internal costs was primarily attributable to a $4.4 million increase in employee compensation and benefits costs related to increased headcount to support increased activities in our research and development function, and a $1.6 million increase in stock-based compensation expenses.

General and Administrative Expenses

General and administrative expense increased by $4.9 million, or 91%, from $5.4 million for the year ended December 31, 2018 to $10.2 million for the year ended December 31, 2019.

The increase in general and administrative expense was primarily attributable to an increase of $1.5 million in employee compensation and benefits due to increased headcount, a $0.8 million increase in stock-based compensation expenses, an increase of $0.9 million in professional services and consulting fees primarily due to increases in legal fees related to business development, regulatory and patent costs, and expenses related to public company administrative costs, and a $1.7 million increase in other expenses.

Interest Income, Net

Interest income increased by $3.8 million from $0.9 million for the year ended December 31, 2018 to $4.7 million for the year ended December 31, 2019.

The increase in interest income, net was attributable to increased income earned on our investment portfolio, which increased significantly year-over-year due to the Series B financing, up-front payments pursuant to the AbbVie and the Janssen agreements, and receipt of the IPO proceeds in July 2019.

Provision for Income Tax

We recorded $0.9 million in income tax expense during the year ended December 31, 2019 primarily due to the current tax liability associated with the tax recognition of the upfront AbbVie collaboration payment received in 2018. No income tax expense was recorded during the year ended December 31, 2018 due to the net loss recorded during the period.

Liquidity and Capital Resources

Sources of Liquidity

From inception through December 31, 2019, we have funded our operations primarily with net proceeds of $93.3 million from the sale of common stock in our IPO, the gross proceeds of $138.1 million from sales of our convertible preferred equity securities and borrowings of $1.0 million under our credit facility with SVB, $100.0 million we received as an up-front, non-refundable payment from our collaboration with AbbVie, $10.0 million we received as an up-front, non-refundable payment from the Janssen Agreement, as well as on-going research funding from the Janssen Agreement.

The following table provides information regarding our total cash, cash equivalents, and marketable securities, each of which are stated at their respective fair values as of December 31, 2019 and of December 31, 2018:

	December 31,	
	2019	2018
	(in thousands)	
Cash and cash equivalents	$ 10,227	$ 225
Money market funds (included in cash equivalents)	91,332	185,676
Marketable securities	135,457	—
Total cash, cash equivalents, and marketable securities	$ 237,016	$ 185,901

In March 2016, we entered into a credit facility with SVB for an equipment line of credit of up to $1.5 million to finance the purchase of eligible equipment. Principal and interest payments commenced on January 1, 2017 for a period of 36 months. The loan and security agreement also included a final payment fee equal to 5.0% of the aggregate advances and a pre-payment fee of 0.5% to 1.0%, depending on when the prepayment occurs. In December 2018, we paid the entire balance back to SVB, including a prepayment penalty of 0.5% and terminated the credit facility. We had no balances outstanding due to SVB or any other lender as of December 31, 2019 or December 31, 2018.

In connection with the credit facility, we issued warrants to SVB to purchase 6,825 Series Seed convertible preferred units at a purchase price of $4.39 per unit, which became exercisable for 6,825 shares of common stock at a purchase

price of $4.39 per share in connection with the IPO. In August 2019, SVB exercised warrants via a cashless exercise which resulted in the issuance of 5,766 common shares.

Cash Flows

The following table provides information regarding our cash flows for the years ended December 31, 2019 and 2018:

	Year Ended December 31,	
	2019	2018
	(in thousands)	
Net cash (used in) provided by operating activities	$ (41,651)	$ 76,337
Net cash (used in) investing activities	(135,986)	(656)
Net cash provided by financing activities	93,295	89,470
Net decrease in cash and cash equivalents and restricted cash	$ (84,342)	$ 165,151

Net Cash Used in Operating Activities

Net cash used in operating activities was $41.7 million for year ended December 31, 2019 compared to $76.3 million in net cash provided by operating activities for the year ended December 31, 2018. The $118.0 million decrease in cash provided by operating activities was primarily due to the receipt of an upfront payment of $100 million from AbbVie in 2018, as well as the $19.5 million increase to net loss.

Net Cash Used in Investing Activities

Net cash used in investing activities was $136.0 million for year ended December 31, 2019 compared to net cash used in investing activities of $0.7 million for year ended December 31, 2018, an increase of $135.3 million. This increase was primarily due to the net purchases of $296.3 million in marketable securities, and a net increase of $1.5 million in capital expenditures, offset by $162.5 million in proceeds from maturities of marketable securities.

Net Cash Provided by Financing Activities

Net cash provided by financing activities was $93.3 million for year ended December 31, 2019 compared to $89.5 million in the comparable prior year period. The increase of $3.8 million was due to increase in funds raised from the Company’s IPO.

Funding Requirements

We expect our expenses to increase in connection with our ongoing activities, particularly as we continue research and development, initiate clinical trials, and seek marketing approval for our current and any of our future product candidates. In addition, if we obtain marketing approval for any of our current or our future product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution, which costs we might offset through entry into collaboration agreements with third parties. Furthermore, as a result of the IPO, we expect to incur additional costs associated with operating as a newly public company. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on acceptable terms, we would be forced to delay, reduce, or eliminate our research and development programs or future commercialization efforts.

We expect our existing cash and cash equivalents and marketable securities will enable us to fund our operating expenses and capital expenditure requirements through at least the end of 2022.

We have based this estimate on assumptions that may prove to be wrong, and we may use our available capital resources sooner than we currently expect. Our future capital requirements will depend on many factors, including:

- the costs of conducting preclinical studies and future clinical trials;
- the costs of future manufacturing;
- the scope, progress, results and costs of discovery, preclinical development, laboratory testing, and clinical trials for other potential product candidates we may develop, if any;
- the costs, timing, and outcome of regulatory review of our product candidates;
- our ability to establish and maintain collaborations on favorable terms, if at all;
- the achievement of milestones or occurrence of other developments that trigger payments under any collaboration agreements we might have at such time;
- the costs and timing of future commercialization activities, including product sales, marketing, manufacturing and distribution, for any of our product candidates for which we receive marketing approval;
- the amount of revenue, if any, received from commercial sales of our product candidates, should any of our product candidates receive marketing approval;
- the costs of preparing, filing and prosecuting patent applications, obtaining, maintaining and enforcing our intellectual property rights, and defending intellectual property-related claims;
- our headcount growth and associated costs as we expand our business operations and research and development activities; and
- the cost of operating as a public company.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances and licensing arrangements.

Critical Accounting Policies and Estimates

This management's discussion and analysis is based on our consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these consolidated financial statements requires us to make judgments and estimates that affect the reported amounts of assets, liabilities, revenues and expenses, and the disclosure of contingent assets and liabilities in our consolidated financial statements. We base our estimates on historical experience, known trends and events, and various other factors that we believe to be reasonable under the circumstances. Actual results may differ from these estimates under different assumptions or conditions. On an ongoing basis, we evaluate our judgments and estimates in light of changes in circumstances, facts, and experience. The effects of material revisions in estimates, if any, will be reflected in the consolidated financial statements prospectively from the date of change in estimates.

While our significant accounting policies are described in more detail in the notes to our consolidated financial statements included in this Annual Report on Form 10-K, we believe the following accounting policies used in the preparation of our consolidated financial statements require the most significant judgments and estimates.

Accrued Research and Development Expenses

As part of the process of preparing our consolidated financial statements, we are required to estimate our accrued expenses as of each balance sheet date. This process involves reviewing open contracts and purchase orders, communicating with our 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 the actual cost. The majority of our service providers invoice us monthly in arrears for services performed or when contractual milestones are met. We make estimates of our accrued expenses as of each balance sheet date 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. The significant estimates in our accrued research and development expenses include the costs incurred for services performed by our vendors in connection with research and development activities for which we have not yet been invoiced. In certain instances, we prepay for services to be provided in the future. These amounts are expensed as the services are performed.

We base our expenses related to research and development activities on our estimates of the services received and efforts expended pursuant to quotes and contracts with vendors that conduct research and development on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the research and development expense. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from our estimate, we adjust the accrual or prepaid balance accordingly. Non-refundable advance payments for goods and services that will be used in future research and development activities are expensed when the activity has been performed or when the goods have been received rather than when the payment is made.

Although we do not expect our estimates to be materially different from amounts incurred, if our estimates of the status and timing of services performed differ from the actual status and timing of services performed, it could result in us reporting amounts that are too high or too low in any particular period. To date, there have been no material differences between our estimates of such expenses and the amounts incurred.

Equity-Based Compensation

Prior to the Reorganization, we granted incentive units, which we accounted for as equity-classified awards. As part of the Reorganization, the incentive units were exchanged for shares of our common stock and restricted common stock, which we account for as equity-classified awards. In December 2018 and during year ended December 31, 2019, we granted stock options, which we account for as equity-classified awards.

We measure employee and nonemployee equity-based compensation based on the grant date fair value of the equity-based awards and recognize equity-based compensation expense on a straight-line basis over the requisite service period of the awards, which is generally the vesting period of the respective award. We recognize forfeitures as they occur.

We classify equity-based compensation expense in our consolidated statements of operations in the same manner in which the award recipient’s salary and related costs are classified or in which the award recipient’s service payments are classified. In future periods, we expect equity-based compensation expense to increase, due in part to our existing unrecognized stock-based compensation expense and as we grant additional stock-based awards to continue to attract and retain our employees.

We determine the fair value of restricted common stock awards granted based on the fair value of our common stock. We estimate the fair value of stock option awards and restricted stock granted using the Black-Scholes option-pricing model, which uses as inputs, the fair value of our common stock or unit and subjective assumptions we make, including the expected stock price volatility, the expected term of the award, the risk-free interest rate, and expected dividends. Due to insufficient company-specific historical data, we base the estimate of expected volatility on the historical volatility of a representative group of publicly traded companies for which historical information is available. The

historical volatility is generally calculated based on a period of time commensurate with the expected term assumption. We use the simplified method to calculate the expected term for options granted to employees and directors. We utilize this method as we do not have sufficient historical exercise data to provide a reasonable basis upon which to estimate the expected term. For options granted to non-employees, we utilize the expected term. The risk-free interest rate is based on a U.S. treasury instrument whose term is consistent with the expected term of the stock options. The expected dividend yield is assumed to be zero, as we have never paid dividends and do not have current plans to pay any dividends on our common stock.

Revenue from Contracts with Customers

As of December 31, 2019, all of our revenue to date has been generated from the AbbVie Agreement and Janssen Agreement. Effective January 1, 2018, we adopted the provisions of ASC Topic 606, *Revenue from Contracts with Customers*, or ASC 606, using the full retrospective transition method.

Under ASC 606, we recognize revenue when our 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 the appropriate amount of revenue to be recognized for arrangements determined to be within the scope of ASC 606, we perform the following five steps: (i) identification of the contract(s) with the customer, (ii) identification of the promised goods or services in the contract and determination of whether the promised goods or services are performance obligations, (iii) measurement of the transaction price, (iv) allocation of the transaction price to the performance obligations, and (v) recognition of revenue when (or as) we satisfy each performance obligation. We only apply the five-step model to contracts when it is probable that we will collect the consideration we are entitled to in exchange for the goods or services we transfer to our customer.

Identification of the Contracts with the Customers

We evaluate every contract to determine whether it in its entirety or in part represent a contract with a customer, or a collaboration agreement and, based on this determination, apply appropriate accounting guidance.

We account for a contract with a customer that is within the scope of ASC 606 when all of the following criteria are met: (i) the arrangement has been approved by the parties and the parties are committed to perform their respective obligations, (ii) each party's rights regarding the goods or services to be transferred can be identified, (iii) the payment terms for the goods or services to be transferred can be identified, (iv) the arrangement has commercial substance and (v) collection of substantially all of the consideration to which we will be entitled in exchange for the goods or services that will be transferred to the customer is probable.

Identification of the Performance Obligations

The promised goods or services in our collaboration and option arrangements consist of research and development services. The arrangements also have options for additional items (i.e., license rights). Options are considered to be marketing offers and are to be accounted for as separate contracts when the customer elects such options, unless we determine the option provides a material right which would not be provided without entering into the contract. The determination as to whether such options are material rights requires significant management judgment, and management considers factors such as other similar arrangements, market data and the terms of the contractual arrangement to make such conclusion. Performance obligations are promised goods or services in a contract to transfer a distinct good or service to the customer. Promised goods or services are considered distinct when: (i) the customer can benefit from the good or service on its own or together with other readily available resources and (ii) the promised good or service is separately identifiable from other promises in the contract. In assessing whether promised goods or services are distinct, we consider factors such as the stage of development of the underlying intellectual property, the capabilities of our customer to develop the intellectual property on their own and whether the required expertise is readily available.

Determination of the Transaction Price

We estimate the transaction price based on the amount of consideration we expect to receive for transferring the promised goods or services in the contract. The consideration may include both fixed consideration and variable consideration. At the inception of each arrangement that includes variable consideration, we evaluate the amount of the potential payments and the likelihood that the payments will be received. We utilize either the most likely amount method or expected value method to estimate the transaction price based on which method better predicts the amount of consideration expected to be received. If it is probable that a significant revenue reversal would not occur, the variable consideration is included in the transaction price.

All contingent future payments, which include research, development, regulatory, and sales-based royalty payments, have not been considered in the initial analysis, as they are contingent upon option(s) being exercised or are subject to significant risk of achievement.

Allocation of Transaction Price

We allocate the transaction price based on the estimated standalone selling price. We must develop assumptions that require judgment to determine the standalone selling price for each performance obligation identified in the contract. We utilize key assumptions to determine the standalone selling price, which may include other comparable transactions, pricing considered in negotiating the transaction, and the estimated costs. Certain variable consideration is allocated specifically to one or more performance obligations in a contract when the terms of the variable consideration relate to the satisfaction of the performance obligation and the resulting amounts allocated to each performance obligation are consistent with the amounts we would expect to receive for satisfying each performance obligation.

Recognition of Revenue

We recognize revenue as we perform the research and development services based on the costs incurred to date, as such costs have a direct relationship between our effort and the progress made towards satisfying its performance obligations to AbbVie and Janssen. Consideration allocated to material rights is recognized upon exercise or expiration of the related option.

As the Company progresses towards satisfaction of performance obligations under the AbbVie and Janssen agreements, the estimated costs associated with the remaining effort required to complete the performance obligations may change, which may materially impact revenue recognition. Factors that impact this estimate include but are not limted to inherhent uncertainty of early stage research, interactions with regulatory authorities and results of pre-clinical studies all of which may materially impact our estimates of the remaining costs to complete. The Company regularly evaluates and, when necessary, updates the costs associated with the remaining effort associated with each performance obligation under the AbbVie and Janssen agreements.

For example, during fiscal year 2019 we made certain changes to our estimated costs, including in November 2019 upon receiving feedback from the FDA which required us to conduct one additional toxicology study before submitting an IND for MORF-720. Additionally, we are pursuing a backup molecule for idiopathic pulmonary fibrosis, or IPF. As a result of these changes during fiscal year 2019, we reduced revenue by $2.0 million during fiscal year 2019.

Income Taxes

We record income taxes under the liability method. Deferred tax assets and liabilities reflect our estimation of the future tax consequences of temporary differences between the carrying amounts of assets and liabilities for book and tax purposes. We determine deferred income taxes based on the differences in accounting methods and timing between financial statement and income tax reporting. Accordingly, we determine the deferred tax asset or liability for each temporary difference based on the enacted tax rates expected to be in effect when we realize the underlying items of income and expense. We consider many factors when assessing the likelihood of future realization of our deferred tax assets, including our recent earnings experience, expectations of future taxable income, and the carryforward periods available to us for tax reporting purposes, as well as other relevant factors. We establish a valuation allowance to reduce

deferred tax assets to the amount we believe is more likely than not to be realized. Due to inherent complexities arising from the nature of our business, future changes in income tax law, or variances between our actual and anticipated operating results, we make certain judgments and estimates, including our ability to realize our deferred tax assets and our ability to use our operating loss carryforwards and tax credits to offset taxable income. Therefore, actual income taxes could materially vary from these estimates.

Despite the collaboration revenue, we continue to maintain a valuation allowance against all deferred tax assets. We believe that it is more likely than not that we will not realize a future tax benefit of these attributes, as the research programs continue to require significant investment and future revenue is subject to uncertainties. Ultimate realization of any deferred tax asset is dependent on our ability to generate sufficient future taxable income in the appropriate tax jurisdiction before the expiration of carryforward periods, if any.

As the company's research spending has increased in scope and complexity during fiscal year 2019, a detailed review of the current year R&D credit computation was undertaken to support the company's methodology and conclusions. We have not yet conducted a study of its research and development credit carryforwards for fiscal years prior to 2019. Such a study may result in an adjustment to our research and development credit carryforwards; however, until a study is completed and any adjustment is known, no amount is being presented as an uncertain tax position. A full valuation allowance has been provided against our research and development credits, and, if an adjustment is required, this adjustment would be offset by an adjustment to the valuation allowance. Thus, there would be no impact to the balance sheet or statement of operations and comprehensive loss if an adjustment were required.

Off-Balance Sheet Arrangements

We did not have, during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined under applicable SEC rules.

Contractual Obligations

The following table summarizes our significant contractual obligations by period presented according to the payment due date at December 31, 2019 (in thousands):

As of December 31, 2019	Total	Less than 1 Year	1 to 3 Years	3 to 5 Years	More than 5 Years
Operating lease obligations[1]	$ 2,792	$ 1,122	$ 1,670	$ —	$ —
Total	$ 2,792	$ 1,122	$ 1,670	$ —	$ —

(1) Represents future minimum repayments under our non-cancellable operating leases as of December 31, 2019.

We entered into contracts with a number of third parties, including external CROs, that require us to make upfront payments, some of which may be non-refundable. Under various licensing and related agreements with third parties, we have agreed to make milestone payments and pay royalties to third parties. Pursuant to an exclusive license agreement with Children's Medical Center Corporation, or CMCC, a holder of our common stock, we paid CMCC an annual license maintenance fee of $10,000 in each of 2015-2018. In 2018, we amended the agreement and this obligation increased to $80,000 per year, and continues until the agreement is terminated. We will also be responsible for up to $1.3 million of development milestone payments through the first regulatory approval of a licensed product, tiered royalty payments of low single-digit percentages on net sales of licensed products in the event that we realize sales from products covered by the license agreement, and between 10% and 20% of non-royalty income attributable to a sublicense of the CMCC rights. Amounts paid to CMCC are recorded as research and development expense in the statements of operations.

Pursuant to a collaboration agreement with Schrödinger, we may be required to pay Schrödinger certain development milestones, not to exceed in the aggregate, on a target-by-target basis, a low six-figure payment upon initiation of lead

optimization and $3.1 million on a compound-by-compound basis, as well as royalties in the low single digits on sales of products containing such compounds. In addition, we have agreed to pay Schrödinger a percentage, in the mid-single digits, of certain payments we receive from third parties in connection with the licensing or transfer of the rights to exploit such compounds to such third parties, including a one-time fee of $1.0 million paid in 2019.

We enter into agreements in the normal course of business with vendors for preclinical studies, preclinical and clinical supply and manufacturing services, professional consultants for expert advice, and other vendors for other services for operating purposes. We have not included these payments in the table of contractual obligations above since the contracts do not contain any minimum purchase commitments and are cancelable at any time by us, generally upon 30 days prior written notice, and therefore we believe that our non-cancelable obligations under these agreements are not material.

Emerging Growth Company and Smaller Reporting Status

We are an "emerging growth company," or EGC, under the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. Section 107 of the JOBS Act provides that an EGC can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act, for complying with new or revised accounting standards. Thus, an EGC can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to avail ourselves of delayed adoption of new or revised accounting standards and, therefore, we will be subject to the same requirements to adopt new or revised accounting standards as private entities.

As an EGC, we may take advantage of certain exemptions and reduced reporting requirements under the JOBS Act. Subject to certain conditions, as an EGC:

- we will avail ourselves of the exemption from providing an auditor's attestation report on our system of internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act;
- we will avail ourselves of the exemption from complying with any requirement that may be adopted by the Public Company Accounting Oversight Board, or PCAOB, regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements, known as the auditor discussion and analysis;
- we will provide reduced disclosure about our executive compensation arrangements; and
- we will not require nonbinding advisory votes on executive compensation or stockholder approval of any golden parachute payments.

We will remain an EGC until the earliest of (i) December 31, 2025 (the last day of the fiscal year following the fifth anniversary of the completion of our IPO), (ii) the last day of the fiscal year in which we have total annual gross revenues of $1.07 billion or more, (iii) the date on which we have issued more than $1.0 billion in non-convertible debt during the previous rolling three-year period, or (iv) the date on which we are deemed to be a large accelerated filer under the Securities Exchange Act of 1934, as amended, or the Exchange Act.

We are also a "smaller reporting company," meaning that the market value of our stock held by non-affiliates is less than $700.0 million and our annual revenue is less than $100.0 million during the most recently completed fiscal year. We may continue to be a smaller reporting company if either (i) the market value of our stock held by non-affiliates is less than $250.0 million or (ii) our annual revenue is less than $100.0 million during the most recently completed fiscal year and the market value of our stock held by non-affiliates is less than $700.0 million.

If we are a smaller reporting company at the time we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation.

Recent Accounting Pronouncements

We have reviewed all recently issued standards and have determined that, other than as disclosed in Note 2 to our consolidated financial statements appearing elsewhere in this Annual Report, such standards will not have a material impact on our financial statements or do not otherwise apply to our operations.

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

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

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.

MORPHIC HOLDING, INC.
INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and the Board of Directors of Morphic Holding, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Morphic Holding, Inc. (the Company) as of December 31, 2019 and 2018, the related consolidated statements of operations and comprehensive loss, stockholders' equity (deficit) and cash flows for each of the two years in the period ended December 31, 2019, 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, 2019 and 2018, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2019, in conformity with U.S. generally accepted accounting principles.

Basis for Opinion

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

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

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

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2017.
Boston, Massachusetts
February 27, 2020

MORPHIC HOLDING, INC.
CONSOLIDATED BALANCE SHEETS
(In thousands, except share and per share data)

	December 31, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 101,559	$ 185,901
Marketable securities	135,457	—
Accounts receivable	3,467	—
Prepaid expenses and other current assets	3,090	1,222
Total current assets	243,573	187,123
Property and equipment, net	3,446	1,843
Restricted cash	275	275
Other assets	141	64
Total assets	$ 247,435	$ 189,305
Liabilities		
Current liabilities:		
Accounts payable	$ 5,167	$ 1,745
Accrued expenses	6,639	3,239
Deferred revenue, current portion	23,450	29,862
Deferred rent, current portion	94	57
Total current liabilities	35,350	34,903
Long-term liabilities:		
Deferred revenue, net of current portion	70,954	66,781
Deferred rent, net of current portion	213	306
Other long-term liabilities	—	58
Total liabilities	106,517	102,048
Commitments and contingencies (Note 9)	—	—
Preferred shares:		
Series Seed preferred shares, $0.0001 par value, no shares authorized, issued, and outstanding as of December 31, 2019, and 11,967,689 shares authorized, 2,045,556 shares issued and outstanding as of December 31, 2018 (aggregate liquidation preference of $8,980 at December 31, 2018)	—	8,658
Series A preferred shares, $0.0001 par value, no shares authorized, issued, and outstanding as of December 31, 2019 and 49,047,619 shares authorized, 8,411,368 shares issued and outstanding as of December 31, 2018 (liquidation preference of $51,500 as of December 31, 2018)	—	51,320
Series B preferred shares, $0.0001 par value, no shares authorized, issued, and outstanding as of December 31, 2019 and 61,538,454 shares authorized, 10,553,483 shares issued and outstanding as of December 31, 2018 (liquidation preference of $80,000 as of December 31, 2018)	—	79,831
Stockholders' Equity (Deficit)		
Preferred shares, $0.0001 par value, 10,000,000 shares authorized, no shares issued and outstanding as of December 31, 2019 and December 31, 2018	—	—
Common shares, $0.0001 par value, 400,000,000 shares authorized, 30,110,251 shares issued and outstanding as of December 31, 2019 and 151,000,000 shares authorized and 1,832,923 shares issued and outstanding as of December 31, 2018	3	—
Additional paid-in capital	238,384	1,633
Accumulated deficit	(97,513)	(54,185)
Accumulated other comprehensive income	44	—
Total stockholders' equity (deficit)	140,918	(52,552)
Total liabilities, preferred shares, and stockholders' equity (deficit)	$ 247,435	$ 189,305

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

MORPHIC HOLDING, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(In thousands, except share and per share data)

	Year Ended December 31,	
	2019	2018
Collaboration revenue - AbbVie	$ 10,797	$ 3,358
Collaboration revenue - Janssen	6,180	—
	16,977	3,358
Operating expenses:		
Research and development	53,732	22,631
General and administrative	10,233	5,355
Total operating expenses	63,965	27,986
Loss from operations	(46,988)	(24,628)
Other income:		
Interest income, net	4,666	871
Other expense, net	(94)	(74)
Total other income, net	4,572	797
Loss before provision for income taxes	(42,416)	(23,831)
Provision for income taxes	(912)	—
Net loss	$ (43,328)	$ (23,831)
Net loss per share, basic and diluted	(2.69)	(22.28)
Weighted average common shares outstanding, basic and diluted	16,101,928	1,069,762
Comprehensive loss:		
Net loss	$ (43,328)	$ (23,831)
Other comprehensive income (loss):		
Unrealized holding gains on marketable securities, net of tax	44	—
Total other comprehensive income	44	—
Comprehensive loss	$ (43,284)	$ (23,831)

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

MORPHIC HOLDING, INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)
(In thousands, except unit and share data)

	Series Seed Convertible Preferred Units		Series Seed Preferred Shares		Series A Convertible Preferred Units		Series A Preferred Shares		Series B Convertible Preferred Units		Series B Preferred Shares		Common Units		Common Shares		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Deficit
	Units	Amount	Shares	Amount	Units	Amount	Shares	Amount	Units	Amount	Shares	Amount	Units	Amount	Shares	Amount			
Balance at December 31, 2017	**2,045,556**	**$ 8,658**	**—**	**$ —**	**6,729,096**	**$ 41,029**	**—**	**$ —**	**—**	**$ —**	**—**	**$ —**	**1,011,227**	**$ —**	**—**	**$ —**	**$ 661**	**$ (30,354)**	**$ (29,693**
Equity-based compensation expense	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	997	—	997
Net Loss	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	(23,831)	(23,831
Vesting of restricted shares	—	—	—	—	—	—	—	—	—	—	—	—	—	—	31,645	—	—	—	—
Issuance of Series A Preferred Units August 10, 2018, net of offering costs of $9	—	—	—	—	1,682,272	10,291	—	—	—	—	—	—	—	—	—		—	—	—
Issuance of Series B Preferred Units September 25, 2018, net of offering costs of $169	—	—	—	—	—	—	—	—	10,553,483	79,831	—	—	—	—	—	—	—	—	—
Effect of Reorganization	(2,045,556)	(8,658)	2,045,556	8,658	(8,411,368)	(51,320)	8,411,368	51,320	(10,553,483)	(79,831)	10,553,483	79,831	(1,011,227)	—	1,011,227	—	—	—	—
Exchange of incentive units for common stock in connection with the Reorganization	—	—	—	—	—	—	—	—	—	—	—	—	—	—	790,051	—	—	—	—
Reclassification of warrants to purchase preferred shares to liability	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	(25)	—	(25
Balance at December 31, 2018	**—**	**$ —**	**2,045,556**	**8,658**	**—**	**$ —**	**8,411,368**	**51,320**	**—**	**$ —**	**10,553,483**	**79,831**	**—**	**$ —**	**1,832,923**	**—**	**$ 1,633**	**$ (54,185)**	**$ (52,552**

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

MORPHIC HOLDING, INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT) (Continued)
(In thousands, except unit and share data)

	Series Seed Convertible Preferred Shares		Series A Convertible Preferred Shares		Series B Convertible Preferred Shares		Common Shares		Additional Paid-in	Accumulated	Accumulated Other Comprehensive	Total Stockholders'
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Capital	Deficit	Income	(Deficit)/Equity
Balance at December 31, 2018	**2,045,556**	**$ 8,658**	**8,411,368**	**$ 51,320**	**10,553,483**	**$ 79,831**	**1,832,923**	**$ —**	**$ 1,633**	**$ (54,185)**	**$ —**	**$ (52,552)**
Equity-based compensation expense	—	—	—	—	—	—	—	—	3,532	—	—	3,532
Net Loss	—	—	—	—	—	—	—	—	—	(43,328)	—	(43,328)
Vesting of restricted shares	—	—	—	—	—	—	354,660	—	—	—	—	—
Unrealized holding gains on marketable securities, net of tax	—	—	—	—	—	—	—	—	—	—	44	44
Conversion of convertible preferred stock into common stock	(2,045,556)	(8,658)	(8,411,368)	(51,320)	(10,553,483)	(79,831)	21,010,407	2	139,807	—	—	139,809
Reclassification of warrants to purchase preferred shares to stockholders' equity	—	—	—	—	—	—	—	—	118	—	—	118
Issuance of common shares at initial public offering, net of offering costs of $10.2 million	—	—	—	—	—	—	6,900,000	1	93,267	—	—	93,268
Issuance of common shares upon warrants exercise	—	—	—	—	—	—	5,766	—	—	—	—	—
Issuance of common shares upon stock option exercise	—	—	—	—	—	—	6,495	—	27	—	—	27
Balance at September 30, 2019	**—**	**$ —**	**—**	**— $ —**	**—**	**$ —**	**30,110,251**	**$ 3**	**$ 238,384**	**$ (97,513)**	**$ 44**	**$ 140,918**

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

MORPHIC HOLDING, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)

	Year Ended December 31, 2019	2018
Cash flows from operating activities:		
Net loss	$ (43,328)	$ (23,831)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	821	539
Premium amortization and discount accretion on marketable securities	(1,560)	—
Equity-based compensation	3,532	997
Non-cash interest expense	—	43
Loss on early debt extinguishment	—	28
Change in fair value of warrants	93	—
Other non-cash items	(22)	1
Change in operating assets and liabilities:		
Accounts receivable	(3,467)	—
Prepaid expenses and other current assets	(1,868)	(743)
Other assets	(77)	(51)
Accounts payable	3,164	862
Accrued expenses	3,389	1,888
Deferred revenue	(2,239)	96,643
Deferred rent	(56)	(27)
Other long-term liabilities	(33)	(12)
Net cash used in operating activities	(41,651)	76,337
Cash flows from investing activities:		
Purchases of marketable securities	(296,328)	—
Proceeds from maturities of marketable securities	162,500	—
Purchase of property and equipment	(2,158)	(659)
Proceeds from disposal of lab equipment	—	3
Net cash used in investing activities	(135,986)	(656)
Cash flows from financing activities:		
Repayment of debt	—	(652)
Proceeds from issuance of Common Stock pursuant to stock options exercise	27	
Proceeds from issuance of Common Stock, net	93,268	—
Proceeds from issuance of Preferred Stock, net	—	90,122
Net cash provided by financing activities	93,295	89,470
Net (decrease) increase in cash and cash equivalents and restricted cash	(84,342)	165,151
Cash and cash equivalents and restricted cash, beginning of period	186,176	21,025
Cash and cash equivalents and restricted cash, end of period	$ 101,834	$ 186,176
Non-cash financing activities:		
Purchases of property and equipment in accounts payable and accrued expenses	269	—
Reclassification of warrants to additional paid-in capital	118	—
Conversion of preferred shares to common stock	$ 139,809	$ —
Supplemental cash flow information:		
Cash paid for taxes	550	—
Cash paid for interest	$ —	$ 68

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

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Unaudited)

1. Nature of the Business and Basis of Presentation

Organization

Morphic Holding, Inc. was formed under the laws of the State of Delaware in August 2014 under the name Integrin Rock, LLC. The Company subsequently changed its name to Morphic Rock Holding, LLC in October 2014 and then to Morphic Holding, LLC in June 2016. On December 5, 2018, the Company completed a series of transactions (the "Reorganization") pursuant to which Morphic Holding, LLC was converted in a tax-free reorganization into Morphic Holding, Inc. and three wholly-owned subsidiaries, namely Lazuli, Inc., Tourmaline, Inc, and Phyllite, Inc, were merged with and into another wholly-owned subsidiary, Morphic Therapeutic, Inc. For further details regarding the tax-free reorganization, refer to Note 7 appearing elsewhere in this Annual Report on Form 10-K. At the time of the Reorganization, the Company created a Massachusetts Securities Corporation (the "Security Corporation") to take advantage of the favorable tax treatment of income earned on securities held within such entity. As of December 31, 2019, all of the Company's excess funds were invested through the Security Corporation.

The Company is a biopharmaceutical company applying proprietary insights into integrin medicine to discover and develop first-in-class oral small molecule integrin therapeutics. Integrins are a validated target class with multiple approved drugs for the treatment of serious chronic diseases. Despite significant biopharmaceutical industry investment, no oral integrin therapies have been approved. The Company has created the Morphic integrin technology platform, or MInT Platform, by leveraging our unique understanding of integrin structure and biology, to develop a pipeline of novel product candidates designed to achieve potency, high selectivity, and the pharmaceutical properties required for oral administration.

The Company is subject to risks and uncertainties common to early-stage companies in the biotechnology industry, including, but not limited to, development by competitors of new technological innovations, dependence on key personnel, protection of proprietary technology, compliance with government regulations and the ability to secure additional capital to fund operations. Product candidates currently under development will require significant additional research and development efforts, including extensive preclinical and clinical testing and regulatory approval prior to commercialization. These efforts require significant amounts of additional capital, adequate personnel and infrastructure and extensive compliance-reporting capabilities. Even if the Company's drug development efforts are successful, it is uncertain when, if ever, the Company will realize significant revenue from product sales. The Company expects to continue to incur losses from operations for the foreseeable future; the Company expects that its cash and cash equivalents and marketable securities will be sufficient to fund its operating expenses and capital expenditure requirements through at least the next 12 months from the date these financial statements were issued.

On July 1, 2019, the Company completed its initial public offering "IPO", in which the Company issued and sold 6,900,000 shares of its common stock at a public offering price of $15.00 per share, including 900,000 shares of common stock sold pursuant to the underwriters' exercise of their option to purchase additional shares of common stock, for aggregate gross proceeds of $103.5 million. The Company raised approximately $93.3 million in net proceeds after deducting underwriting discounts and commissions and offering expenses payable by the Company. Upon the closing of the IPO, all of the outstanding shares of convertible preferred stock automatically converted into 21,010,407 shares of common stock; the warrants to purchase 6,825 convertible preferred shares automatically converted into warrants to purchase 6,825 common shares. Subsequent to the closing of the IPO, there were no shares of preferred stock outstanding. In connection with the closing of the IPO, the Company amended and restated its Fourth Amended and Restated Certificate of Incorporation to change the authorized capital stock to 400,000,000 shares designated as common stock and 10,000,000 shares designated as preferred stock, all with a par value of $0.0001 per share.

Basis of Presentation

The consolidated financial statements include the accounts of Morphic Holding, Inc. and its wholly owned subsidiaries described above. All intercompany balances have been eliminated in consolidation.

These consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States (“GAAP”). Any reference in these notes to applicable guidance is meant to refer to the authoritative United States generally accepted accounting principles as found in the Accounting Standards Codification (“ASC”) and Accounting Standards Update (“ASU”) of the Financial Accounting Standards Board (“FASB”).

On June 10, 2019, the Company's board of directors and stockholders approved a 5.8311-to-one reverse stock split of the Company's issued and outstanding shares of common stock and convertible preferred stock. All unit, per unit, share and per share amounts in the consolidated financial statements and notes thereto have been retrospectively adjusted for all periods presented to give effect of the reverse stock split.

2. Summary of Significant Accounting Policies

Use of Estimates and Judgments

The preparation of financial statements in accordance with GAAP requires management to make estimates and judgments that may affect the reported amounts of assets and liabilities and related disclosures of contingent assets and liabilities at the date of the financial statements and the related reporting of revenues and expenses during the reporting period. Significant estimates of accounting reflected in these consolidated financial statements include, but are not limited to, estimates related to revenue recognition, accrued research and development expenses, the valuation of equity-based compensation, and income taxes. Actual results could differ from those estimates.

Concentration of Credit Risk and Off-Balance Sheet Risk

Financial instruments that potentially expose the Company to concentrations of credit risk consist primarily of cash and cash equivalents, marketable securities, and accounts receivable under Janssen agreement. The Company has all cash and cash equivalents at one accredited financial institution, in amounts that exceed federally insured limits. The Company does not believe that it is subject to unusual credit risk beyond the normal credit risk associated with commercial banking relationships.

The primary objectives for the Company’s investment portfolio are the preservation of capital and maintenance of liquidity. In 2019, the Company adopted its investment policy which allows funds to be held outside bank accounts, but to be invested only in readily marketable fixed income instruments with readily ascertainable market values, denominated and payable in U.S. dollars including obligations of the U.S. government and its agencies and money market funds registered according to Rule 2a-7 of the Investment Company Act of 1940. Investments in the money market fund shall be consistent with approved instruments and assets under management must be at least $1.0 billion.

Accounts receivable generally represent amounts due from Janssen. The Company monitors economic conditions to identify facts or circumstances that may indicate that any of its accounts receivable are at risk of collection.

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

Cash and Cash Equivalents and Restricted Cash

The Company considers highly liquid investments with a maturity of three months or less when purchased to be cash equivalents. At December 31, 2019 and 2018, cash and cash equivalents include bank demand deposits and money market funds that invest primarily in U.S. government-backed securities and treasuries. At December 31, 2019, cash equivalents also included one U.S. Treasury security with fair value of approximately $10.0 million. Cash equivalents are stated at cost, which approximates fair value.

Restricted cash consists of a letter of credit in the amount of $275,000 issued to the landlord of the Company's facility lease. The terms of the letter of credit extend beyond one year. The following table reconciles cash and cash equivalents and restricted cash per the balance sheet to the statements of cash flows:

	As of December 31,	
	2019	2018
Cash and cash equivalents	$ 101,559	$ 185,901
Restricted cash	275	275
Total cash, cash equivalents, and restricted cash	$ 101,834	$ 186,176

Marketable securities

The Company invests funds in the United States Treasury securities; those securities are included in the current assets based on their contractual maturities, classified as available-for-sale, and carried at fair value. Changes in fair value of marketable securities are recorded in other comprehensive income (loss) as net unrealized gains (losses) on marketable securities. The Company recognized $44,000 and $0 in unrealized gains for the years ended December 31, 2019 and 2018, respectively.

Interest income on investments

The Company recognizes interest income from investments in money market funds and available-for-sale securities, including amortization of premium/accretion of discount, on an accrual basis. For the years ended December 31, 2019 and 2018**,** the Company recognized $4.7 million and $0.9 million in interest income, respectively.

Interest income is included with other income on the consolidated statements of operations and comprehensive loss.

Property and Equipment, net

Property and equipment are recorded at cost. Expenditures for major renewals or betterments that extend the useful lives of property and equipment are capitalized; expenditures for maintenance and repairs are charged to expense as incurred. Depreciation is calculated on a straight-line basis over the estimated useful lives of the related asset. Property and equipment are depreciated as follows:

	Estimated Useful Life (in Years)
Laboratory equipment	5
Computers and software	3 - 5
Leasehold improvements	Shorter of the useful life or the remaining term of the lease

Impairment of Long-Lived Assets

Long-lived assets consist of property and equipment. Long-lived assets to be held and used are tested for recoverability whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. Factors that the Company considers in deciding when to perform an impairment review include significant underperformance of the business in relation to expectations, significant negative industry or economic trends, and significant changes or planned changes in the use of the assets. If an impairment review is performed to evaluate a long-lived asset for recoverability, the Company compares forecasts of undiscounted cash flows expected to result from the use and eventual disposition of the long-lived asset to its carrying value. An impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of an asset are less than its carrying amount. The impairment loss would be based on the excess of the carrying value of the impaired asset over its fair value,

determined based on discounted cash flows. To date, the Company has not recorded any impairment losses on long-lived assets.

Fair Value Measurements

ASC Topic 820, *Fair Value Measurement* ("ASC 820"), establishes a fair value hierarchy for instruments measured at fair value that distinguishes between assumptions based on market data (observable inputs) and the Company's own assumptions (unobservable inputs). Observable inputs are inputs that market participants would use in pricing the asset or liability based on market data obtained from sources independent of the Company. Unobservable inputs are inputs that reflect the Company's assumptions about the inputs that market participants would use in pricing the asset or liability and are developed based on the best information available in the circumstances. ASC 820 identifies fair value as the exchange price, or exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As a basis for considering market participant assumptions in fair value measurements, ASC 820 establishes a three-tier fair value hierarchy that distinguishes between the following:

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

Level 2 — Inputs other than Level 1 inputs that are either directly or indirectly observable, such as quoted market prices, interest rates and yield curves.

Level 3 — Unobservable inputs developed using estimates of assumptions developed by the Company, which reflect those that a market participant would use.

To the extent the valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair values requires more judgment. Accordingly, the degree of judgment exercised by the Company in determining fair value is greatest for instruments categorized as Level 3. A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement.

The Company believes that the carrying amounts of the Company's consolidated financial instruments, including prepaid expenses and other current assets, accounts receivable, accounts payable, and accrued expenses approximate fair value due to the short-term nature of those instruments.

Segment Information

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

Revenue Recognition

Effective January 1, 2018, the Company adopted the provisions of ASC 606 using the full retrospective transition method.

To date all revenue has been generated from the Company's agreements with AbbVie and Janssen, executed in October 2018 and February 2019, respectively. As a result, there was no impact of the adoption of ASC 606 to the Company's financial statements. Please refer to Note 12 below for details of ASC 606 application to the Company's agreements with AbbVie and Janssen.

The Company first evaluates collaboration arrangements to determine whether the arrangement (or part of the arrangement) represents a collaborative arrangement pursuant to ASC Topic 808, *Collaborative Arrangements*, based on the risks and rewards and activities of the parties pursuant to the contractual arrangement. The Company accounts for any collaborative arrangement or elements within the contract that are deemed to be a collaborative arrangement, and not

a customer relationship, in accordance with ASC 808. Through December 31, 2019, the Company entered into two agreements – with AbbVie and Janssen – that have been accounted for pursuant to ASC 606.

Under ASC 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. To determine the appropriate amount of revenue to be recognized for arrangements determined to be within the scope of ASC 606, the Company performs the following five steps: (i) identification of the contract(s) with the customer, (ii) identification of the promised goods or services in the contract and determination of whether the promised goods or services are performance obligations, (iii) measurement of the transaction price, (iv) allocation of the transaction price to the performance obligations, and (v) recognition of revenue when (or as) the Company satisfies each performance obligation. The Company only applies the five-step model to contracts when it is probable that the entity will collect consideration it is entitled to in exchange for the goods or services it transfers to the customer.

The Company accounts for a contract with a customer that is within the scope of ASC 606 when all of the following criteria are met: (i) the arrangement has been approved by the parties and the parties are committed to perform their respective obligations, (ii) each party's rights regarding the goods or services to be transferred can be identified, (iii) the payment terms for the goods or services to be transferred can be identified, (iv) the arrangement has commercial substance and (v) collection of substantially all of the consideration to which the Company will be entitled in exchange for the goods or services that will be transferred to the customer is probable.

Performance obligations are promised goods or services in a contract to transfer a distinct good or service to the customer. Promised goods or services are considered distinct when: (i) the customer can benefit from the good or service on its own or together with other readily available resources and (ii) the promised good or service is separately identifiable from other promises in the contract. Options to purchase additional goods or services are considered to be marketing offers and are to be accounted for as separate contracts when the customer elects such options, unless the Company determines the option provides a material right which would not be provided without entering into the contract. If, however, an option is determined to provide a material right that would not be provided without entering into a contract, a portion of the transaction price is allocated to such option.

The Company estimates the transaction price based on the amount of consideration the Company expects to receive for transferring the promised goods or services in the contract. The consideration may include both fixed consideration and variable consideration. At the inception of each arrangement that includes variable consideration, the Company evaluates the amount of the potential payments and the likelihood that the payments will be received. The Company utilizes either the most likely amount method or expected value method to estimate the transaction price based on which method better predicts the amount of consideration expected to be received. If it is probable that a significant revenue reversal would not occur, the variable consideration is included in the transaction price.

The Company also evaluates whether instances in which the timing of payments by customers do not match the timing of performance obligation satisfaction contain an element of financing and adjusts the transaction price for the effect of the financing component, if any.

The Company's transactions with customers may include development and regulatory milestone payments. The Company evaluates whether the milestones are considered probable of being reached and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within the Company's control or the customer's control, such as regulatory approvals, are not considered probable of being achieved until those approvals are received. At the end of each reporting period, the Company re-evaluates the probability of achievement of such milestones and any related constraint, and if necessary, adjusts the estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect collaboration revenue and net income (loss) in the period of adjustment.

For sales-based royalties, including milestone payments based on the level of sales, the Company determines whether the sole or predominant item to which the royalties relate is a license. When the license is the sole or predominant item to which the sales-based royalty relates, the Company recognizes revenue at the later of: (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied).

The Company allocates the transaction price based on the estimated standalone selling price of the identified performance obligations. The Company must develop assumptions that require judgment to determine the standalone selling price for each performance obligation identified in the contract. The Company utilizes key assumptions to determine the standalone selling price, which may include other comparable transactions, pricing considered in negotiating the transaction, and the estimated costs. Certain variable consideration is allocated specifically to one or more performance obligations in a contract when the terms of the variable consideration relate to the satisfaction of the performance obligation and the resulting amounts allocated to each performance obligation are consistent with the amounts the Company would expect to receive for each performance obligation.

We recognize as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) each performance obligation is satisfied, either at a point in time or over time. In particular, for the Company's collaborations with AbbVie and Janssen, revenue attributable to research services is recognized as those services are provided, based on the costs incurred to date.

The Company receives payments from customers based on billing schedules established in each contract. Up-front payments and fees are recorded as deferred revenue upon receipt or when due until the Company performs its obligations under these arrangements. Amounts are recorded as accounts receivable when the Company's right to consideration is unconditional.

Research and Development Expenses

Research and development expenses are expensed as incurred and consist of costs incurred in performing research and development activities, including compensation related expenses for research and development personnel, preclinical and clinical activities including cost of supply, overhead expenses including facilities expenses, materials and supplies, amounts paid to consultants and outside service providers, and depreciation of equipment. Upfront license payments related to acquired technologies which have not yet reached technological feasibility and have no alternative future use are also included in research and development expense.

Research Contract Costs and Accruals

The Company has entered into various research service arrangements under which vendors perform various services. The Company records accrued expenses for estimated costs incurred under the arrangements. When evaluating the adequacy of the accrued expenses, the Company analyzed the progress of the studies, trials or other services performed, including invoices received and contracted costs. Judgments and estimates are made in determining the accrued expense balances at the end of each reporting period.

Equity-Based Compensation

The Company accounts for equity awards, including restricted common stock, incentive units, and common stock options granted to employees and non-employees as equity award compensation in accordance with ASC Topic 718, *Compensation — Stock Compensation* ("ASC 718"). ASC 718 requires all equity-based payments to employees, which includes grants of employee equity awards, to be recognized as expense in the statements of operations based on their grant date fair values.

The fair value of each incentive unit and stock option award is estimated using the Black-Scholes option-pricing model, using inputs which include the fair value of the Company's common stock and certain subjective assumptions, the expected stock price volatility, the expected term of the award, the risk-free rate, and expected dividends. Expected volatility is calculated based on reported volatility data for a representative group of publicly traded companies for which historical information was available. The historical volatility is generally calculated based on a period of time commensurate with the expected term assumptions. The risk-free interest rate is based on the U.S. Treasury yield curve in effect at the time of grant commensurate with the expected term assumption. The Company uses the simplified method, under which the expected term is presumed to be the midpoint between the vesting date and the end of the contractual term. The Company utilizes this method due to lack of historical exercise data and the plain-vanilla nature of

its stock-based awards. The expected dividend yield is assumed to be zero as the Company has never paid dividends and has no current plans to pay any dividends on common stock.

Compensation expense related to equity awards to employees and non-employees that are subject to graded vesting is recognized on a straight-line basis, based on the grant date fair value, over the requisite service period of the award, which is generally the vesting term. All awards granted to employees and the Board members to date contain only service vesting conditions. The Company recognizes forfeitures when they occur.

All awards granted to date were equity-classified as of December 31, 2019 and 2018.

The Company classifies equity-based compensation expense in its consolidated statements of operations in the same manner in which the award recipient's salary and related costs are classified or in which the award recipient's service payments are classified.

Comprehensive Loss

Comprehensive loss is the change in equity of a business enterprise during a period from transactions and other events and circumstances from non-owner sources. Comprehensive loss includes net loss and the change in accumulated other comprehensive loss for the period. For the year ended December 31, 2019, comprehensive loss included $44,000 in unrealized holding gains, net on marketable securities; for the year ended December 31, 2018, comprehensive loss equaled net loss.

Net Loss per Share

The Company applies the two-class method to compute basic and diluted net loss per share because it has issued instruments that meet the definition of participating securities. The two-class method determines net income (loss) per share for each class of common and participating securities according to dividends declared or accumulated and participation rights in undistributed earnings. The two-class method requires income (losses) available to common unit holders and common stockholders for the period to be allocated between common and participating securities based upon their respective rights to share in the earnings as if all income (losses) for the period had been distributed. During periods of loss, there is no allocation required under the two-class method since the participating securities do not have a contractual obligation to fund the losses of the Company.

The Company calculates basic net loss per share by dividing net loss by the weighted average number of common shares outstanding, excluding unvested restricted common stock. The Company calculates diluted net loss per share by dividing net loss by the weighted average number of common shares outstanding, as applicable, after giving consideration to the dilutive effect of convertible preferred stock, restricted common stock, warrants, and stock options that are outstanding during the period. The Company has generated a net loss in all periods presented, so the basic and diluted net loss share are the same, as the inclusion of the potentially dilutive securities would be anti-dilutive.

Income Taxes

Since inception, the Company recorded income taxes in accordance with FASB Accounting Standards Codification Topic 740, *Income Taxes* ("ASC 740"), which provides for deferred taxes using an asset and liability approach. Under this method, deferred tax assets and liabilities are determined based on temporary differences between the financial statement basis and tax basis of assets and liabilities and net operating loss and credit carryforwards using enacted tax rates in effect for the year in which the differences are expected to reverse. 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 date. Valuation allowances are established when it is more likely than not that some portion of the deferred tax assets will not be realized.

The Company accounts for uncertainty in income taxes recognized in the financial statements by applying a two-step process to determine the amount of tax benefit to be recognized. First, the tax position must be evaluated to determine the likelihood that it will be sustained upon external examination by the taxing authorities. If the tax position is deemed

more-likely-than-not to be sustained, the tax position is then assessed to determine the amount of benefit to recognize in the financial statements. The amount of the benefit that may be recognized is the largest amount that has a greater than 50% likelihood of being realized upon ultimate settlement. At December 31, 2019 and 2018, the Company had not identified any significant uncertain tax positions.

Prior to the Reorganization, Morphic Holding, LLC elected to be treated under the partnership provisions of the Internal Revenue Service code. Accordingly, all income and deductions of Morphic Therapeutic, LLC were recorded on the members' individual tax returns and no taxes were recorded by Morphic Holding, LLC. The wholly-owned subsidiaries of Morphic Holding, LLC — Morphic Therapeutic, Inc., Lazuli, Inc., Tourmaline, Inc., and Phyllite, Inc. — were taxed as C-corporations for federal income tax purposes and filed separate corporate income tax returns from the LLC entity.

As part of the Reorganization, the parent Company made the election to be treated as C-corporation for federal and state income tax purposes and subsequently legally converted the parent Company to a corporation. Following the Reorganization, the Company has elected to file consolidated tax returns.

The Company is open to examination by the Internal Revenue Service for the tax years ended December 31, 2017 to December 31, 2019. The Company is currently not under examination by the Internal Revenue Service or any other jurisdictions for any tax years. The Company has not recorded any interest or penalties on any unrecognized tax benefits since its inception.

Subsequent Events

The Company considers events or transactions that occur after the balance sheet date but prior to the issuance of the consolidated financial statements for potential recognition or disclosure in the consolidated financial statements. Subsequent events have been evaluated through the date these consolidated financial statements were issued for potential recognition or disclosure in the consolidated financial statements.

Recently Issued Accounting Pronouncements not yet Adopted

In December 2019, the FASB issued ASU No. 2019-12, *Simplifying the Accounting for Income Taxes* ("ASU 2019-12"), which removes certain exceptions to the general principles in Topic 740 and also clarifies and amends existing guidance to improve consistent application. The guidance will be effective for the Company for the fiscal years beginning after December 15, 2021, and interim periods within fiscal years beginning after December 15, 2022. Provisions of ASU 2019-12 must be adopted using either full retrospective, modified retrospective, or prospective method, depending on the provision adopted, as specified within the guidance. Early adoption is permitted. The Company is evaluating the impact of the adoption of ASU 2019-12 on its consolidated financial statements but does not expect such adoption to have a material impact.

In November 2019, the FASB issued ASU 2019-10, *Financial Instruments—Credit Losses (Topic 326), Derivatives and Hedging (Topic 815), and Leases (Topic 842): Effective Dates* ("ASU 2019-10"), which finalizes effective date delays for private companies, not-for-profit organizations, and certain smaller reporting companies as follows:

- January 1, 2023 as the effective date for adoption of the Topic 326 for annual and interim reporting periods;
- January 1, 2021 and January 1, 2022 as the effective dates for adoption of the Topic 815 amendments for annual and interim periods, respectively; and
- January 1, 2021 and January 1, 2022 as the effective dates for adoption of the Topic 842 for annual and interim periods, respectively.

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments Credit Losses (Topic 326)* ("ASU 2016-13"), which requires consideration of a broader range of reasonable and supportable information in developing credit loss estimates. In April 2019, the FASB issued ASU 2019-04, *Financial Instruments-Credit Losses, Topic 815, Derivatives and Hedging, and Topic 825, Financial Instruments* ("ASU 2019-04"). Certain provisions of ASU 2019-04 amend the guidance of ASU 2016-13, are applicable to the Company's investments portfolio, and allow the Company to make

certain accounting policy elections regarding establishing allowance for credit losses for the accrued interest receivable and the corresponding disclosures. In November 2019, the FASB issued ASU No. 2019-11, *Codification Improvements to Topic 326, Financial Instruments – Credit Losses* ("ASU 2019-11"), which clarifies certain areas of the guidance to ensure all companies and organizations can make a smoother transition to the standard. Following the issuance of ASU 2019-10 described above, the guidance is effective for the Company for the fiscal years beginning after December 15, 2022, including interim periods within those fiscal years, and will be adopted using the modified retrospective approach. The Company is currently evaluating the impact of ASU 2019-11 and the related ASU 2019-04 and ASU 2016-13 on the consolidated financial statements, including the impact of the available accounting policy elections.

In February 2016, the FASB issued ASU 2016-02, Leases (Topic 842), with guidance regarding the accounting for and disclosure of leases. In general, for lease arrangements exceeding a twelve-month term, these arrangements must now be recognized as assets and liabilities on the balance sheet of the lessee. Under ASU 2016-02, a right-of-use asset and lease obligation will be recorded for all leases, whether operating or financing, while the income statement will reflect lease expense for operating leases and amortization/interest expense for financing leases. The balance sheet amount recorded for existing leases at the date of adoption of ASU 2016-02 must be calculated using the applicable incremental borrowing rate at the date of adoption. This update also requires lessees and lessors to disclose key information about their leasing transactions. In July 2018, the FASB issued ASU 2018-11, *Leases - Targeted Improvements*, intended to ease the implementation of the new lease standard for financial statement preparers by, among other things, allowing for an additional transition method. In lieu of presenting transition requirements to comparative periods, as previously required, an entity may now elect to show a cumulative effect adjustment on the date of adoption without the requirement to recast prior period financial statements or disclosures presented in accordance with ASU 2016-02.

The Company currently expects to elect the available package of practical expedients which allows the Company to not reassess previous accounting conclusions around whether arrangements are or contain leases, the classification of leases, and the treatment of initial direct costs. The Company also expects it will make an accounting policy election to keep leases with an initial term of 12 months or less off of the balance sheet. The Company is in the process of assessing the impact of the standard and while not complete, it expects that it will record a material asset and liability related to its current operating lease; however, the full impact of adoption to the Company's financial statements is yet to be determined. Effective with the issuance of ASU 2019-10, described above, this standard is effective for the Company for the annual periods beginning after December 15, 2021, which will be the initial date of application, and interim periods within fiscal years beginning after December 15, 2022.

The Company has considered other recent accounting pronouncements and concluded that they are either not applicable to the business, or that the effect is not expected to be material to the consolidated financial statements as a result of future adoption.

3. Fair Value of Financial Assets and Liabilities

The following tables summarize the assets and liabilities measured at fair value on a recurring basis at December 31, 2019 and 2018 (in thousands):

	Fair Value Measurements at December 31, 2019			
	Total	Level 1	Level 2	Level 3
Assets:				
Money market funds, included in cash and cash equivalents	$ 91,332	$ 91,332	$ —	$ —
U.S. Treasury obligations, included in cash and cash equivalents	9,995	—	9,995	—
U.S. Treasury obligations	135,457	—	135,457	—
Total assets	$ 236,784	$ 91,332	$ 145,452	$ —

	Fair Value Measurements at December 31, 2018			
	Total	Level 1	Level 2	Level 3
Assets:				
Money market funds, included in cash and cash equivalents	$ 185,676	$ 185,676	$ —	$ —
Total assets	$ 185,676	$ 185,676	$ —	$ —

The money market funds included in the table above invest in U.S. government securities that are valued using quoted market prices. Accordingly, money market funds are categorized as Level 1 as of December 31, 2019 and 2018. Marketable securities, included in the table above, consist exclusively of U.S. Treasury securities that are valued using prices provided by third party pricing vendors, using observable market inputs such as interest rates, yield curves, and credit risk. Accordingly, these securities are categorized as Level 2 as of December 31, 2019. The Company held no marketable securities as of December 31, 2018.

During the years ended December 31, 2019 and 2018, no assets were transferred between the fair value hierarchy categories.

4. Marketable securities

As of December 31, 2019, the Company had the following investments in marketable securities classified as available for sale (in thousands):

	Maturity	Amortized cost	Gross unrealized holding gains	Gross unrealized holding losses	Aggregate estimated fair value
U.S. Treasury securities	less than 1 year	$135,389	$ 70	$ (2)	$135,457

All of the Company's investments are classified as available-for-sale and are carried at fair value with unrealized gains and losses recorded as a component of accumulated other comprehensive income (loss), net of related income taxes. The Company recognized in accumulated other comprehensive income $44,000 in net unrealized holding gains related to changes in the securities' fair values, impacted by interest rates fluctuations. As of December 31, 2019, the aggregate fair value of three securities in an unrealized loss position was $30.2 million and the aggregate unrealized losses were $2,000. No securities have been in an unrealized loss position for more than one year. As of December 31, 2019, no securities are considered to be other than temporarily impaired because the impairments are not severe, have been for a short duration, and are due to normal market and interest rate fluctuations. Furthermore, the Company does not intend to sell the investment securities in an unrealized loss position and it is not more likely than not that the Company will be required to sell these securities before the recovery of the value. The Company did not have any investments in marketable securities at December 31, 2018.

5. Property and Equipment, Net

At December 31, 2019, property and equipment, net consists of the following (in thousands):

	As of December 31,	
	2019	2018
Laboratory equipment	$ 4,194	$ 2,415
Computers and software	280	163
Leasehold improvements	535	475
Construction in progress	465	—
	5,474	3,053
Less: Accumulated depreciation and amortization	(2,028)	(1,210)
	$ 3,446	$ 1,843

Depreciation and amortization expense was $821,000 and $539,000 for the years ended December 31, 2019 and 2018, respectively.

6. Accrued Expenses

At December 31, 2019 and 2018 accrued expenses consist of the following (in thousands):

	As of December 31,	
	2019	2018
Payroll and related expenses	3,159	2,012
Research and development activities	2,465	715
Other expenses	1,015	512
	$ 6,639	$ 3,239

7. Stockholders' Equity

Prior to the Reorganization described below, all interests of members in distributions and other amounts were represented by their units of membership in the Company as specified in its operating agreement. There were two classes of units: capital units and incentive units. Capital units were comprised of common units and convertible preferred units, which represent a capital interest in the Company, while incentive units represent profits interests within the meaning of IRS Revenue Procedures 93-27 and 2001-43. The various classes of capital units are described below.

Convertible Preferred Units and Shares

As of December 31, 2017, the total authorized capital units of the Company were 138,035,280 units, which consisted of 77,000,000 Common Units and 61,035,280 Preferred Units, of which 11,987,661 were designated Series Seed Preferred Units and 49,047,619 were designated Series A Preferred Units. During the year ended December 31, 2018, 61,538,454 units were designated Series B Preferred Units.

In August 2018, in accordance with the terms of the Series A Preferred Unit Purchase Agreement, the Company issued additional Series A Preferred Units to the Series A Investors for proceeds of $10,290,962, net of issuance costs of $9,038.

In September 2018, the Company issued Series B Preferred Units at $7.58 per unit for proceeds of $79,831,491, net of issuance costs of $168,499.

There were no additional convertible preferred units issued during the years ended December 31, 2018 and 2019.

Common Units

As of December 31, 2017, the Company had outstanding 1,011,227 common units. There were no additional common units issued during the years ended December 31, 2018 and 2019.

Reorganization and Convertible Preferred Stock

On December 5, 2018, the Company completed a series of transactions, or the Reorganization, pursuant to which Morphic Holding, LLC was converted in a tax-free exchange into Morphic Holding, Inc. and three subsidiaries, namely Lazuli, Inc., Tourmaline, Inc. and Phyllite, Inc. were merged with and into Morphic Therapeutic, Inc. In connection with the Reorganization:

- Holders of Morphic Holding, LLC Series B convertible preferred units received one share of Morphic Holding, Inc. Series B convertible preferred stock for each outstanding Series B convertible preferred unit

held immediately prior to the Reorganization, with an aggregate of 10,553,483 shares of Morphic Holding, Inc. Series B convertible preferred stock issued in the Reorganization;

- Holders of Morphic Holding, LLC Series A convertible preferred units received one share of Morphic Holding, Inc. Series A convertible preferred stock for each outstanding Series A convertible preferred unit held immediately prior to the Reorganization, with an aggregate of 8,411,368 shares of Morphic Holding, Inc. Series A convertible preferred stock issued in the Reorganization;

- Holders of Morphic Holding, LLC Series Seed convertible preferred units received one share of Morphic Holding, Inc. Series Seed convertible preferred stock for each outstanding Series Seed convertible preferred unit held immediately prior to the Reorganization, with an aggregate of 2,045,556 shares of Morphic Holding, Inc. Series Seed convertible preferred stock issued in the Reorganization;

- Holders of Morphic Holding, LLC common units received one share of Morphic Holding, Inc. common stock for each outstanding common unit held immediately prior to the Reorganization, with an aggregate of 1,011,227 shares of common stock issued in the Reorganization;

- Holders of Morphic Holding, LLC vested and unvested incentive units, exchanged one incentive unit for one share of common stock or restricted common stock, respectively. Threshold amounts on all vested and unvested incentive units were decreased to $0. The restricted common stock was issued with the same vesting terms as the unvested incentive units held immediately prior to the Reorganization. A total of 1,574,749 shares of common stock and restricted common stock were issued to the prior holders of incentive units; and

- The outstanding warrants to purchase 6,825 Series Seed convertible preferred units at an exercise price of $4.39 per unit were converted to warrants to purchase 6,825 shares of Series Seed convertible preferred stock at the same exercise price per share.

The Company's Series B convertible preferred stock, Series A convertible preferred stock, Series Seed convertible preferred stock were designated as convertible preferred stock under the amended and restated certificate of incorporation. All outstanding shares of convertible preferred stock were convertible into shares of common stock at a one-to-one conversion ratio and certain terms and preferences that made them senior to shares of common stock. The purpose of the Reorganization was to reorganize the Company's corporate structure so that Morphic Holding, Inc. would continue as a corporation and so that the Company's existing investors would own capital stock rather than equity interests in a limited liability company.

The Company evaluated the accounting for the Reorganization and specifically the exchange of (1) preferred and common units for preferred and common shares and (2) the modification to the terms of the incentive units. With respect to the exchange of preferred and common units for preferred and common shares, the Company considered that there were no changes to the ownership interest held by each unit/stockholder as a result of the Reorganization, there was no consideration exchanged to effect the exchange, and the significant terms of the preferred units and common units were substantially the same before and after the Reorganization. Based on these considerations, the Company determined that the exchange of shares occurring in the Reorganization should be accounted for as a modification of equity securities. The accounting for the modification to the terms of the incentive units is described in Note 8.

Immediately prior to the closing of the IPO on July 1, 2019, the Company had 21,010,407 convertible preferred shares outstanding, all of which automatically converted into 21,010,407 shares of common stock upon closing of the IPO.

As of December 31, 2019, the Company had 400,000,000 common shares authorized and 30,110,251 common shares issued and outstanding and 10,000,000 preferred shares authorized, none of which were outstanding.

Common Stock

The common stock has the following characteristics:

Voting

The holders of common stock are entitled to one vote for each share of common stock held.

Dividends

The holders of shares of common stock are entitled to receive dividends, if and when declared by the Company's board of directors. Cash dividends may not be declared or paid to holders of shares of common stock until all unpaid dividends on any preferred stock outstanding have been paid in accordance with their terms. As of December 31, 2019, no preferred stock was outstanding. No dividends have been declared or paid by the Company to the holders of common stock since the issuance of the common stock.

Liquidation

Holders of the common shares are entitled to receive distributions of cash, including in the event of a liquidation or dissolution of the Company, which preference is junior to the liquidation preference of any preferred stock holders. After any preferred stock holders have received their respective preferred distributions, any assets remaining for distribution shall be distributed to the holders of preferred or common shares determined on an as-converted basis.

Shares Reserved for Future Issuance

As of December 31, 2019, the Company had reserved common shares for exercise of outstanding stock options granted under the 2018 Stock Incentive Plan and the future issuance under the 2019 Stock Incentive Plan and the 2019 Employee Stock Purchase Plan (described in note 8 below) as follows:

	As of December 31, 2019
Common shares reserved for exercise of outstanding stock options under the 2018 Plan	2,028,233
Common shares reserved for issuance under the 2019 ESPP	300,000
Common shares reserved for exercise of outstanding stock options under the 2019 Plan	959,170
Common shares reserved for future issuance under the 2019 Plan	2,050,079
	5,337,482

8. Equity Based Compensation

Prior to the Reorganization, the Company's operating agreement, as amended and restated, provided for the granting of incentive units to employees, officers, directors, and consultants, as determined by the Board of Directors. At December 31, 2017, 1,586,907 incentive units were authorized to be granted of which 54,768 were available for the future grants.

The terms of the incentive units granted prior to the Reorganization were determined by the Board of Directors and included vesting, forfeiture, repurchase, and other provisions. Incentive units had rights to dividends and were entitled to distributions. Incentive unit holders were not required to purchase or "exercise" their incentive units in order to receive such distributions. However, distributions to incentive unit holders began only after the cumulative amount distributed to common unit holders exceeded the threshold amount with respect to such incentive unit. Distributions were entitled to be made to incentive unit holders whether vested or unvested. Distributions on unvested units were to be held by the Company until the incentive units vest, at which time they would be released to the incentive unit holder. Unless otherwise approved by the Board of Directors, the incentive units generally vested over a four-year period with the first 25% vesting following 12 months of employment or service and the remaining incentive units vesting in equal quarterly installments over the following 36 months. The incentive units had no contractual term.

In connection with the issuance of each incentive unit, the Board of Directors set a threshold amount based on the amount of distributions that the holders of a common unit would be entitled to receive in a hypothetical liquidation of the Company on the date of issuance of the incentive unit in which the Company sold its assets at fair market value, satisfied its liabilities, and distributed the net proceeds to the holders of units in liquidation of the Company.

A summary of the Company's incentive unit activity in 2018 prior to the Reorganization and related information is as follows:

	Number of Units	Weighted Average Grant Date Fair Value per Unit	Weighted Average Threshold Price per Unit
Outstanding at December 31, 2017	1,532,139	$ 1.34	$ 1.11
Granted	60,708	2.39	1.92
Forfeited	(18,098)	1.87	1.57
Exchanged for common stock and restricted common stock pursuant to the Reorganization	(1,574,749)	1.40	1.17
Outstanding at December 31, 2018	—	—	—

A summary of vested incentive units is as follows:

	Number of Units
Vested at December 31, 2017	439,332
Vested	350,719
Cancelled/Forfeited	—
Vested as of the Reorganization	790,051

The total fair value of incentive units vested during 2018 through the date of the Reorganization was $473,000.

Compensation Expense related to Incentive Units

The Company recorded equity-based compensation expense for incentive units granted to employees, directors and non-employees of $507,000 for the year ended December 31, 2018.

Reorganization

Pursuant to the Reorganization, all vested and unvested incentive units granted under the 2015 Compensatory Benefit Plan which were outstanding immediately prior to the Reorganization were exchanged for an equal number of shares of common stock or restricted common stock, respectively, under the 2018 Stock Incentive Plan, described below. The threshold amount per incentive unit was decreased to $0 for all vested and unvested units outstanding immediately prior to the Reorganization. A total of 35 active employees of the Company were subject to the exchange of the incentive units for common shares and restricted common shares. The restricted common stock was issued with the same vesting terms as the unvested incentive units held immediately prior to the Reorganization.

The Company accounted for the exchange of incentive units in Morphic Holding, LLC for common stock and restricted common stock of Morphic Therapeutic, Inc. as a modification in accordance with the requirements of ASC 718. Accordingly, the Company determined there was an excess fair value of the replacement awards over the fair value of the incentive units exchanged in connection with the Reorganization, which resulted in incremental compensation expense. The incremental fair value related to vested awards was recognized immediately as compensation expense. The incremental fair value of unvested awards and any remaining unrecognized compensation of the original awards will be recognized as compensation expense over the remaining vesting period. The incremental expense resulting from modification of awards totaled $968,000 of which $365,000, was recognized during the year ended December 31, 2018 and $255,000 during the year ended December 31, 2019.

Incentive Unit Compensation Expense Assumptions

The following weighted average assumptions were used in determining the fair value of incentive units granted to both employees and non-employees during 2018:

	Year ended December 31, 2018
Risk-free interest rate	2.79%
Expected dividend yield	—
Expected term (years to liquidity)	5.98
Expected volatility	76.63%

2018 Stock Incentive Plan

The 2018 Stock Incentive Plan (the "2018 Plan"), instituted as part of the Reorganization, provided for the grant of incentive stock options, non-qualified stock options, and restricted stock awards. The 2018 Plan was administered by the Board of Directors, or at the discretion of the Board of Directors, by a committee of the board. The exercise prices, vesting, and other restrictions were determined at the discretion of the Board of Directors, or a committee if so delegated, except that the exercise price per share of stock options may not be less than 100% of the fair market value of the share of common stock on the date of grant and the term of stock option may not be greater than ten years. The number of shares initially reserved for issuance under the 2018 Plan was 3,818,816 shares of common stock. The shares of common stock underlying any awards that are forfeited, cancelled, repurchased, or are otherwise terminated by the Company under the 2018 Plan were to be added back to the shares of common stock available for issuance under the 2018 Plan up to the number of shares of common stock subject to awards granted prior to the effectiveness of the 2018 Plan. Options generally vest over a four-year period with the first 25% vesting following 12 months of employment or service and the remaining award vesting in equal monthly installments over the following 36 months. All options have a contractual term of 10 years. As of December 31, 2018, there were 457,438 available for future issuance under the 2018 Plan.

Restricted Common Stock

The following table summarizes the common stock and restricted common stock issued as part of the Reorganization and restricted common stock activity under the 2018 Plan from the Reorganization to December 31, 2018:

	Number of Shares	Weighted Average Fair Value per Share at Issuance
Common stock and restricted common stock issued as part of the Reorganization	1,574,749	$ 4.32
Vested as of the Reorganization	790,051	4.32
Unvested restricted common stock as of the Reorganization	784,698	4.32
Granted	—	—
Vested	31,645	4.32
Forfeited	—	—
Unvested restricted common stock as of December 31, 2018	753,053	$ 4.32

The aggregate fair value of restricted stock awards that vested subsequent to the Reorganization during the year ended December 31, 2018, based on estimated fair values of stock underlying the restricted stock awards on the date of vesting was $137,000.

Stock Options

The following table summarizes the Company's stock option activity under the 2018 Plan during the year ended December 31, 2018:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding as of December 31, 2017	—	$ —	—	$ —
Granted	1,786,551	4.32	9.96	—
Exercised	—	—	—	—
Forfeited	—	—	—	—
Outstanding as of December 31, 2018	1,786,551	$ 4.32	9.96	$ —
Options exercisable as of December 31, 2018	—	$ —	—	$ —

The weighted average grant-date fair value per share of stock options granted to employees and non-employees for stock option awards with service-based vesting conditions through December 31, 2018 was $2.92 per share. The Company recorded equity-based compensation expense for the stock options granted to employees and non-employees of $312,000 for the year ended December 31, 2018.

The following table summarizes assumptions used in determining the fair value of the options granted in 2018:

	Year ended December 31, 2018
Risk-free interest rate	2.75%
Expected dividend yield	-
Expected term (in years)	6.03
Expected Volatility	75.33%

2019 Stock Incentive Plan

The 2019 Stock Incentive Plan (the "2019 Plan") was approved by the Board of Directors on June 10, 2019 and replaced the 2018 Stock Incentive Plan (the "2018 Plan"), previously instituted as part of the Reorganization. The 2018 Plan provided for the grant of incentive stock options, non-qualified stock options, and restricted stock awards. The 2019 Plan provides for the grant of stock options, restricted stock awards, stock bonus awards, cash awards, stock appreciation right, RSUs, and performance awards to purchase up to 2.8 million shares of common stock. The number of shares reserved for issuance under the Company's 2019 Plan will increase automatically on January 1 of each of 2020 through 2029 by the number of shares equal to the lesser of 4% of the aggregate number of outstanding shares of the Company's common stock as of the immediately preceding December 31, or a number as may be determined by the Company's board of directors. The 2019 Plan is administered by the Board of Directors, or at the discretion of the Board of Directors, by a committee of the board. The exercise prices, vesting, and other restrictions are determined at the discretion of the Board of Directors, or a committee if so delegated, except that the exercise price per share of stock options may not be less than 100% of the fair market value of the share of common stock on the date of grant and the term of stock option may not be greater than ten years. The shares of common stock underlying any awards that are forfeited, cancelled, repurchased, or are otherwise terminated by the Company under the 2019 Plan, and those previously granted under the 2018 Plan, will be added back to the shares of common stock available for issuance under the 2019 Plan. Options generally vest over a four-year period with the first 25% vesting following 12 months of employment or service and the remaining award vesting in equal monthly installments over the following 36 months. All options have a contractual term of 10 years.

Restricted Common Stock

The following table summarizes the restricted common stock activity under the 2018 Plan and the 2019 Plan during the year ended December 31, 2019:

	Number of Shares	Weighted Average Fair Value per Share at Issuance
Unvested restricted common stock as of December 31, 2018	753,053	$ 4.32
Granted	—	—
Vested	(354,660)	4.32
Forfeited	(18,623)	4.32
Unvested restricted common stock as of December 31, 2019	379,770	$ 4.32

As of December 31, 2019, the Company had unrecognized equity-based compensation expense of $959,000 which includes $336,000 related to the modification described above, for the restricted common shares issued to employees and non-employees, which is expected to be recognized over a weighted average period of 0.8 years. The Company recognized equity-based expense for the restricted common stock of $737,000 during the year ended December 31, 2019. The total fair value of shares vested during the year ended December 31, 2019 was approximately $1.5 million.

Stock Options

The following table summarizes the Company's stock option activity under the 2018 Plan and the 2019 Plan during the year ended December 31, 2019:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding as of December 31, 2018	1,786,551	$ 4.32	9.96	$ —
Granted	1,220,241	14.98	—	—
Exercised	(6,495)	4.32	—	89
Forfeited	(12,894)	4.32	—	—
Outstanding as of December 31, 2019	2,987,403	$ 8.67	9.22	$ 26,254
Options vested and expected to vest as of December 31, 2019	2,987,403	$ 8.67	9.22	$ 26,254
Options exercisable as of December 31, 2019	462,456	$ 4.49	8.96	$ 5,858

The weighted average grant-date fair value per share of stock options granted to employees and non-employees for stock option awards with service-based vesting conditions during the year ended December 31, 2019 was $9.95 per share.

The following table summarizes assumptions used in determining the fair value of the options granted in 2019:

	Year ended December 31, 2019
Risk-free interest rate	1.9%
Expected dividend yield	-
Expected term (in years)	6.01

Expected Volatility	75.45%

The Company determined the volatility for options granted in 2019 based on reported data for a guideline group of companies that issued options with substantially similar terms. The risk-free interest rate is based on a zero-coupon United States Treasury instrument with terms consistent with the expected life of the stock options. The expected term of options granted has been determined based upon the simplified method, because the Company does not have sufficient historical information regarding its options to derive the expected term. Under this approach, the expected term is the mid-point between the weighted average of vesting period and the contractual term. The Company has not paid and does not anticipate paying cash dividends on shares of common stock; therefore, the expected dividend yield is assumed to be zero.

Compensation Expense related to Stock Options

The Company recorded equity-based compensation expense for stock options granted to employees and non-employees of $2.5 million and $104,000 for the years ended December 31, 2019 and 2018, respectively.

As of December 31, 2019, the Company had unrecognized equity-based compensation expense of $14.6 million related to stock options issued to employees and non-employees, which is expected to be recognized over a weighted average period of 3.01 years.

2019 Employee Stock Purchase Plan

In June 2019, the Company adopted the 2019 Employee Stock Purchase Plan ("ESPP"), which became effective on June 26, 2019. The Company initially reserved 300,000 shares of common stock for sale under the ESPP. The number of shares reserved for issuance under the ESPP will increase automatically on January 1st of each of the first 10 calendar years following the first offering date by the number of shares equal to the lesser of 1% of the total outstanding shares of the Company's common stock as of the immediately preceding December 31 or an amount determined by the Company's board of directors. The aggregate number of shares issued over the term of the ESPP will not exceed 3,000,000 shares of the Company's common stock. The ESPP is a qualified, compensatory plan under Section 423 of the Internal Revenue Code and offers substantially all employees opportunity to purchase up to $25,000 of common stock per year at 15% discount to the lower of the beginning of the offering period price or the end of the offering period price.

Compensation expense for discounted purchases under the ESPP is measured using the Black-Scholes model to compute the fair value of the lookback provision plus the purchase discount and is recognized as compensation expense over the course of the offering period.

During the year ended December 31, 2019, the Company granted awards with the weighted average grant date fair value of $5.30 and recognized $246,000 in compensation expense related to the discount offered under the 2019 ESPP. The Company recognized no expense during the year ended December 31, 2018.

Total Equity-based Compensation Expense

The Company recorded equity-based compensation expense related to all equity-based awards for employees and non-employees, which was allocated as follows in the consolidated statements of operations (in thousands):

	Year Ended December 31,	
	2019	2018
Research and development expense	$ 2,241	$ 520
General and administrative expense	1,291	477
	$ 3,532	$ 997

9. Income Taxes

The components of the income tax expense for the years ended December 31, 2019 and 2018 were:

	Year Ended December 31,	
	2019	2018
Current		
Federal	$ 512	$ —
State	410	—
Total current tax provision	922	—
Deferred		
Federal	(6)	—
State	(4)	—
Total deferred tax provision	(10)	—
Total income tax provision	$ 912	$ —

The effective income tax rate differed from the amount computed by applying the federal statutory rate to the Company's loss before income taxes as follows:

	Year Ended December 31,	
	2019	2018
Tax effected at statutory rate	21.00 %	21.00 %
State taxes	8.39	2.89
Stock compensation	(1.09)	(0.84)
Non-deductible expenses	0.08	0.29
Federal research and development credits	5.09	1.89
Change in valuation allowance	(35.64)	(25.23)
	(2.17)%	— %

Deferred tax assets and liabilities consist of the following at December 31, 2019 and 2018 (in thousands):

	As of December 31,	
	2019	2018
Long-term net deferred tax assets:		
Net operating loss carryforwards	$ 1,170	$ 8,631
Deferred revenue	23,453	
Research and development credit carryforwards	1,091	938
Intangible assets	4,246	4,670
Reserves and accruals	195	692
Stock-based compensation	353	11
Total long-term deferred tax assets:	30,508	14,942
Valuation allowance	(29,618)	(14,710)
Subtotal	890	232
Fixed assets	(656)	(232)
Prepaid expense	(234)	
Total net deferred tax assets	$ —	$ —

As required by ASC 740, the Company has evaluated the positive and negative evidence bearing upon the realizability of its deferred tax assets, which is composed principally of collaboration revenue that has been recognized as taxable but remains deferred for book reporting purposes at year end. The Company has determined that it is more likely than not that the Company will not realize the benefits of its federal and state deferred tax assets, and, as a result, a valuation allowance of $29.6 million and $14.7 million has been established at 2019 and 2018, respectively. The change in the valuation allowance was $14.9 million and $5.8 million for the years ended December 31, 2019 and 2018.

The Company has incurred NOLs from inception. At December 31, 2019, the Company has federal and state NOL carryforwards of approximately $3.9 million and $5.6 million, respectively, available to reduce future taxable income, that expire beginning in 2037. As of December 31, 2019, the Company also has federal and state research and development tax credit carryforwards of approximately $1.0 million and $0.1 million, respectively, to offset future income taxes, which will begin to expire beginning in December 2032. The Company's NOL carryforwards are subject to review and possible adjustment by the appropriate taxing authorities. The Company has reviewed its historic ownership changes to determine if there are any IRC 382 limitations which would limit the annual utilization of the NOLs. The NOLs carryforwards remaining as of December 31, 2019 are subject to annual utilization limitation of approximately $0.6 milion.

On December 22, 2017, the Tax Cuts and Jobs Act ("the Act") was signed into law. The Act, among other things, contains significant changes to corporate taxation, including reduction of the corporate tax rate from a marginal rate of 34% to a flat rate of 21%, limitation of the tax deduction for interest expense to 30% of adjusted earnings (except for certain small businesses), limitation of the deduction for net operating losses to 80% of current year taxable income and elimination of net operating loss carrybacks, one time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, elimination of U.S. tax on foreign earnings (subject to certain important exceptions), immediate deductions for certain new investments instead of deductions for depreciation expense over time, and modifying or repealing many business deductions and credits.

The Company recognizes the changes in tax law, including the Act, in the period the law is enacted. Accordingly, the effects of the Act have been recognized in the financial statements for the year ended December 31, 2017. As a result of the change in law, the Company recorded a reduction to its deferred tax assets and a corresponding reduction to its valuation allowance. As a result, there was no impact to the Company's income statement due to the reduction in the U.S. corporate tax rate. The Company also had no investments in foreign corporations as of December 31, 2019 or 2018. The Company's reporting of the Act was complete as of December 31, 2018 and no adjustment to the provisional amounts recorded was recorded.

The Company follows the provisions of ASC 740-10, "Accounting for Uncertainty in Income Taxes," which specifies how tax benefits for uncertain tax positions are to be recognized, measured, and recorded in financial statements; requires certain disclosures of uncertain tax matters; specifies how reserves for uncertain tax positions should be classified on the balance sheet; and provides transition and interim period guidance, among other provisions. As of December 31, 2019 and 2018, the Company had no unrecognized tax benefits. As the Company's research spending has increased in scope and complexity during 2019, a detailed review of the current year R&D credit computation was undertaken to support the company's methodology and conclusions. The company has not identified any uncertain positions with respect to the credit computations. The Company's policy is to recognize interest and penalties accrued on any uncertain tax positions as a component of income tax expense, if any, in its statements of operations.

The Company files U.S. federal and state income tax returns and is generally subject to income tax examinations by these authorities for all tax years. Currently, no federal or state income tax returns are under examination by the respective income tax authorities.

Provision for Income Taxes

The Company recorded an income tax expense of $0.9 million and $0 for the years ended December 31, 2019 and 2018, respectively. In the year ended December 31, 2019, the income tax expense recorded was driven largely by the current

tax liability associated with the tax recognition of the upfront AbbVie collaboration payment received in 2018. A significant portion of the taxable income related to the collaboration payments was offset by current year expenses and prior year accumulated losses. A current tax liability has been calculated for the remaining taxable income. The Company reported no income tax provision in the year ended December 31, 2018, as the Company generated a taxable loss, offset by an increase to the Company's valuation allowance.

Despite the collaboration revenue, the Company continues to maintain a valuation allowance against all deferred tax assets. The Company believes that it is more likely than not that the Company will not realize a future tax benefit of these attributes, as the research programs continue to require significant investment and future revenue is subject to uncertainties. Ultimate realization of any deferred tax asset is dependent on the Company's ability to generate sufficient future taxable income in the appropriate tax jurisdiction before the expiration of carryforward periods, if any.

10. Commitments and Contingencies

Guarantees and Indemnifications

The Company entered, and intends to continue to enter, into separate indemnification agreements with directors, officers, and certain of key employees, in addition to the indemnification provided for in the restated certificate of incorporation and restated bylaws. These agreements, among other things, require the Company to indemnify directors, officers, and key employees for certain expenses, including attorneys' fees, judgments, penalties, fines, and settlement amounts actually incurred by these individuals in any action or proceeding arising out of their service to the Company or any of its subsidiaries or any other company or enterprise to which these individuals provide services at the Company's request. Subject to certain limitations, the indemnification agreements also require the Company to advance expenses incurred by directors, officers, and key employees for the defense of any action for which indemnification is required or permitted.

The Company has standard indemnification arrangements in its leases for laboratory and office space that require it to indemnify the landlord against any liability for injury, loss, accident, or damage from any claims, actions, proceedings, or costs resulting from certain acts, breaches, violations, or non-performance under the Company's lease.

Through December 31, 2019, the Company had not experienced any losses related to these indemnification obligations, and no material claims were outstanding. The Company does not expect significant claims related to these indemnifications' obligations and, consequently, concluded that the fair value of these obligations is negligible, and no related reserves were established.

Operating Leases

Facility Lease

Starting in June 2017, the Company leases office and laboratory space and obtains services (facilities management, office, and laboratory services) under an operating lease that expires in May 2022. The lease agreement provided for a fixed rental payment for the first 12 months with subsequent annual escalation of approximately 3%. The Company has an option to extend the lease by three years at a rate of at least the amount paid in the last year of the current lease or the then-current market rate, whichever is higher. In accordance with the lease, the Company entered into a cash-collateralized irrevocable standby letter of credit naming the landlord as beneficiary and the amount is included in restricted cash in the consolidated balance sheets.

The Company recognizes rent expense for the space it currently occupies and records a deferred rent obligation, representing the cumulative difference between actual rent payments and rent expense recognized ratably over the lease period, which is included in the Company's consolidated balance sheets as of December 31, 2019 and 2018.

Minimum annual rent payments under this lease for the remaining term of the amended lease, excluding operating expenses and taxes, which are not fixed for future periods as of December 31, 2019, are as follows (in thousands):

Year ending December 31,	Total Minimum Lease Payments
2020	1,122
2021	1,175
2022	495
Total minimum lease payments	$ 2,792

The Company recorded approximately $928,000 and $941,000 in rent expense for the years ended December 31, 2019 and 2018, respectively.

Legal Proceedings

The Company is not currently a party to any material legal proceedings.

11. Extinguishment of Notes Payable

In December 2018, the Company extinguished its obligation under the 2016 Loan and Security Agreement with Silicon Valley Bank (the “SVB Agreement”). As part of extinguishment, the Company paid the 5% of amounts drawn fee, originally agreed upon, certain other fees required by the Silicon Valley Bank, and recognized charges related to unaccreted issuance discount and unamortized debt issuance costs, resulting in the aggregate loss of $28,000. The Company had no outstanding obligations to SVB or another lender as of December 31, 2019.

In 2016, in connection with obtaining funding under the SVB Agreement, the Company issued a warrant to purchase 3,409 Series Seed Preferred Units at $4.39 per unit on March 31, 2016 and a warrant to purchase 3,416 Series Seed Preferred Units at $4.39 per unit on December 31, 2016. The warrants were outstanding on December 31, 2018 and were included in other long-term liabilities. SVB exercised the warrants during the year ended December 31, 2019, via cashless exercise, resulting in issuance of 5,766 common shares.

12. Option and License Agreements

AbbVie Agreement Overview

In October 2018, the Company entered into a 5-year collaboration and option agreement with AbbVie, “AbbVie agreement”, a research-based global biopharmaceutical company that held Series A and Series B Convertible Preferred Shares of the Company at the time the AbbVie agreement was executed. Pursuant to this agreement, AbbVie paid the Company an upfront, non-refundable amount of $100.0 million. In exchange, the Company: (i) assumed the obligation to perform research and development activities to identify and develop compounds directed at multiple fibrosis indications (grouped into four research programs) through completion of Investigational New Drug (IND)-enabling studies, and (ii) granted AbbVie options to license the results of R&D in exchange for separate upfront option-exercise fees.

At any time during the five-year period, AbbVie holds the right to exercise its license options for molecules with the selected pharmacological profiles by providing written notice to the Company and paying an option exercise fee of $20.0 million per option exercised (up to three in total). Morphic is solely responsible for performing the R&D activities and generating at least one research product and one backup research product for each research target. The Company’s obligations to perform R&D activities for the molecules with selected pharmacological profile cease after AbbVie exercises the option(s) and accepts the results of R&D activities. Upon exercise of an option, AbbVie assumes full responsibility for further development of the molecules at its sole cost, and the Company is obligated to transfer any and all manufacturing related activities to AbbVie at AbbVie’s cost. In addition, after AbbVie exercises its options, it is

obligated to pay the Company certain development milestones totaling up to $80.0 million per indication, launch milestones totaling up to $110.0 million per indication, and net sales milestones totaling up to $160.0 million per indication. Development milestones are triggered upon the initiation of various phases of clinical trials. Launch milestones are achieved by recording first commercial sale in each of the specified markets. The net sales milestones are achieved by reaching the agreed upon volume of sales in certain territories. The Company is also entitled to royalty payments ranging in high single digit to low teens percentage of sales in a calendar year. The Company retained cost-sharing rights in the development of compounds for the liver fibrosis indications, including non-alcoholic steatohepatitis, and may opt into paying a percentage of AbbVie's development costs in exchange for enhanced royalties. As of December 31, 2019, AbbVie has not exercised any options.

AbbVie Agreement Accounting Analysis

The Company has concluded that the performance obligations in the agreement include the research services for the four research programs. The Company has concluded that the unexercised license options were marketing offers as the options did not provide any discounts or other rights that would be considered a material right in the arrangement. All other performance obligations were determined to be immaterial in the context of the contract.

The Company estimated the standalone selling price of each research program based on internal and external costs to perform the research plus a reasonable profit margin of 10%. The total estimated cost of the research and development services reflects the nature of the services to be performed and the Company's best estimate of the length of time required to perform the services. The Company recognizes revenue as research and development services are provided based on the costs incurred to date, as such costs have a direct relationship between the Company's effort and the progress made towards satisfying its performance obligations to AbbVie. Changes to the estimated cost of internal and external development services are recognized in the period of change as a cumulative catch-up adjustment. The Company reassesses cost estimates which may change due to feedback from FDA, as well as the results and findings of any nonclinical activities performed under the agreement with AbbVie.

The Company determined that the transaction price included only the non-refundable up-front payment of $100.0 million and recorded this amount as deferred revenue as of December 31, 2018. The option exercise payments were not included in the transaction price, as the Company determined that the agreed upon fees represent fair value of such options. Exercise of any of the options will be accounted for as contract modification if and when AbbVie delivers the written exercise notice. The milestone payments were fully constrained, as a result of the uncertainty regarding whether AbbVie would exercise any of the options and whether any of the associated milestones would be achieved. There have been no changes to the transaction price in the years ended December 31, 2019 and 2018.

The Company also considered the existence of any significant financing component within the AbbVie Agreement given its upfront payment structure. Based upon this assessment, the Company concluded that the up-front payment was provided for valid business reasons and not for the purpose of providing financing. Accordingly, the Company has concluded that the upfront payment structure of the AbbVie Agreement does not result in the existence of a significant financing component.

The Company incurred approximately $20.0 million in research and development costs, and recognized revenue of $10.8 million related to research services performed during the year ended December 31, 2019. The Company incurred $3.2 million in research and development costs and recognized revenue of $3.4 million related to research services performed during year ended December 31, 2018. As of December 31, 2019 and December 31, 2018, the Company had $85.8 million and $96.6 million, respectively, of deferred revenue, which is classified as either current or net of current portion in the accompanying consolidated balance sheets based on the period over which the revenue is expected to be recognized. This deferred revenue balance represents the aggregate amount of the transaction price allocated to the performance obligations that are partially unsatisfied as of December 31, 2019 and 2018. The Company expects to recognize revenue related to these performance obligations through 2024.

On November 12, 2019, the Company announced that its selective oral $\alpha_v\beta_6$ - specific integrin inhibitor program for patients with fibrotic disease, MORF-720, conducted in collaboration with AbbVie, will require additional development activities, extending into the second half of 2020 based on feedback received during pre-IND interactions with the FDA.

As the Company progresses towards satisfaction of performance obligations under the AbbVie agreement, the estimated costs associated with the remaining effort required to complete the performance obligations may change, which may materially impact revenue recognition. The Company regularly evaluates and, when necessary, updates the costs associated with the remaining effort pursuant to each performance obligation under the AbbVie agreement. Accordingly, revenue may fluctuate from period to period due to revisions to estimated costs, resulting in a change in the measure of progress for a performance obligation. Such changes can also impact the allocation of deferred revenue between current and long term based on changes in expected timing of the satisfaction of performance obligations. During the year ended December 31, 2019, the Company made revisions to its estimated costs, which included estimated costs to conduct one additional toxicology study before submitting an IND for MORF-720 and to pursue a backup molecule for idiopathic pulmonary fibrosis (IPF) related to MORF-720. These revisions to the Company's estimated costs reduced the estimated completion of the related performance obligations as of December 31, 2019 and resulted in a $2 million reduction to revenue previously recognized, and corresponding increase to net loss by $2 million or approximately $0.13 per share during the year ended December 31, 2019.

Janssen Agreement — Overview

In February 2019, the Company entered into a research collaboration and option agreement with Janssen Pharmaceuticals, Inc. ("Janssen agreement"), a subsidiary of Johnson & Johnson, to discover and develop novel integrin therapeutics for patients with conditions not adequately addressed by current therapies. The Janssen agreement focuses on three integrin targets, each target the subject of a research program, with a limited ability to substitute integrin targets for others, not explored by the Company, if research results are not favorable. Under the terms of the agreement, Janssen paid the Company an upfront fee of $10.0 million for the first two research programs and will pay the Company an additional $5.0 million fee upon commencement of the third research program. In addition, Janssen will reimburse the Company for all internal and external costs and expenses incurred during the term of agreement at agreed-upon contractual rates. The Company invoices Janssen on a quarterly basis and payments are due within 60 days. Upon completing IND-enabling studies, on a research program-by-research program basis, Janssen, in exchange for one-time fee of $6.0 million per program, may exercise an exclusive option to obtain an exclusive license with respect to the target that is the subject of the research program, including all licensed compounds that are the subject of the applicable research program. Upon exercise of an option, Janssen will be responsible for global clinical development and commercialization of each licensed compound. Pursuant to the terms of the agreement, the Company is eligible to receive additional research and development milestone payments totaling $142.0 million per research program and net sales milestones payments totaling $90.0 million per research program. Research and development milestones are triggered upon the initiation of certain development activities and various phases of clinical trials. The net sales milestones are achieved by reaching the agreed upon volume of sales in certain territories. In addition, the Company is entitled to royalty payments in low-to-mid single digit percentage of sales in a calendar year.

Janssen Agreement — Accounting Analysis

The Company has concluded that the performance obligations in the agreement include the research services for the three research programs and three options to license the outcomes of those research programs, which were determined to provide Janssen with material rights. All other performance obligations were determined to be immaterial in the context of the contract.

The Company estimated the standalone selling price of each research program based on internal and external costs to perform the research plus a reasonable profit margin. The total estimated cost of the research and development services reflect the nature of the services to be performed and the Company's best estimate of the length of time required to perform the services. The Company estimated the standalone selling price of each material right by determining the discount provided to the estimated standalone selling price of comparable options and applying appropriate likelihood of exercise, which includes the appropriate probability of successfully completing the research efforts. Based on the standalone selling prices determined, the company allocates the total transaction price among the programs and material rights.

The Company recognizes revenue as research services are provided based on the costs incurred to date, as such costs have direct relationship between the Company's effort and the progress made towards satisfying its performance obligations to Janssen. Transaction price allocated to the material rights was deferred and will be recognized in revenue when Janssen exercises the options or the option period expires. Changes in estimates of total internal and external costs expected to be incurred are recognized in the period of change as a cumulative catch-up adjustment. There have been no material changes to the Company's estimates to date.

The Company determined that the transaction price included: the non-refundable up-front payment of $10.0 million for the first two programs, $5.0 million non-refundable up-front payment for the third program to be received at a later point, and the estimated reimbursement payments at agreed upon contractual rates to be received from Janssen for the Company's on-going research services. The option exercise payments were not included in the transaction price. Exercise of any of the options will be accounted for as a continuation of the current contract if and when Janssen delivers the written exercise notice. The milestone payments were fully constrained, as a result of the uncertainty regarding whether Janssen would exercise any of the options and whether any of the associated milestones would be achieved.

The Company also considered the existence of any significant financing component within the Janssen Agreement given its upfront payment structure. Based upon this assessment, the Company concluded that the up-front payment was provided for valid business reasons and not for the purpose of providing financing. Accordingly, the Company has concluded that the upfront payment structure of the Janssen Agreement does not result in the existence of a significant financing component.

During the year ended December 31, 2019, the Company recorded the $10.0 million upfront payment as deferred revenue, incurred $4.5 million in research and development costs and recognized revenue of $6.2 million, inclusive of $1.4 million of upfront payment received, related to research services performed. As of December 31, 2019 the Company had $3.5 million due from Janssen recorded in accounts receivable. As of December 31, 2019, $8.6 million of deferred revenue is classified as either current or net of current portion in the accompanying consolidated balance sheets based on the period over which the revenue is expected to be recognized. This deferred revenue balance represents the portion of the upfront payment received allocated to the performance obligations that are partially unsatisfied as of December 31, 2019. The Company expects to recognize revenue related to these performance obligations through 2024.

13. Net Loss per Unit and Share

Basic and diluted net loss per share is calculated as follows (in thousands, except share and per share data) for the year ended December 31, 2019 and 2018:

	Year Ended December 31, 2019	Year Ended December 31, 2018
Net loss	$ (43,328)	$ (23,831)
Weighted average common shares outstanding, basic and diluted	16,101,928	1,069,762
Net loss per share, basic and diluted	$ (2.69)	$ (22.28)

Following the Reorganization, the Company calculates net loss per share based on its outstanding shares of common stock.

The following table sets forth the outstanding common stock equivalents, presented based on amounts outstanding at each period end, that have been excluded from the calculation of diluted net loss per share for the periods indicated because their inclusion would have been anti-dilutive (in common stock equivalent shares, as applicable):

	Year Ended December 31,	
	2019	2018
Convertible preferred stock	—	21,010,407
Restricted common stock	379,770	753,053
Warrant	—	6,825

Stock options	2,987,403	1,786,551
	3,367,173	23,556,836

In addition to the securities listed in the table above, in June 2019, the Company adopted the ESPP (Note 8) and initially reserved 300,000 shares of common stock for sale under the ESPP, which, if issued, would be anti-dilutive if included in calculation of diluted net loss per share.

14. Employee Benefit Plan

In 2016, the Company adopted a qualified retirement plan, the Morphic Therapeutic, Inc. 401(k) Plan (the "Plan") to provide retirement income for eligible employees through employee contributions and employer matching contributions. The Company matches 50% up to the first 6% contributed by a participant. Contributions totaled $224,000 and $182,000 for the years ended December 31, 2019 and 2018, respectively.

15. Quarterly Financial Information (unaudited)

The following tables summarize the results of operations and earnings per share and per unit for the interim periods with the years ended December 31, 2019 and 2018:

	Three Months Ended			
	March 31, 2019	June 30, 2019	September 30, 2019	December 31, 2019
	(in thousands, except per share data) (unaudited)			
Revenue	$ 6,068	$ 5,567	$ 5,675	$ (333)*
Operating expenses	12,202	15,984	15,533	20,246
Loss from operations	(6,134)	(10,417)	(9,858)	(20,579)
Other (expense) income, net	1,063	1,119	1,298	1,092
Provision for income taxes	(129)	(135)	(304)	(344)
Net loss	$ (5,200)	$ (9,433)	$ (8,864)	$ (19,831)
Net loss per share - basic and diluted	$ (2.77)	$ (4.73)	$ (0.30)	$ (0.66)*

*Revisions to estimated costs under the AbbVie arrangement during Q4 2019, which principally related to FDA feedback provided in November 2019 on MORF-720, resulted in a $6 million reduction to revenue previously recognized and corresponding increase to net loss by $6 million or approximately $0.37 per share during the three months-ended December 31, 2019..

	Three Months Ended			
	March 31, 2018	June 30, 2018	September 30, 2018	December 31, 2018
	(in thousands, except per share and per unit data) (unaudited)			
Revenue	$ —	$ —	$ —	$ 3,358
Operating expenses	5,219	6,265	7,172	9,330
Loss from operations	(5,219)	(6,265)	(7,172)	(5,972)
Other (expense) income, net	39	34	95	629
Provision for income taxes	—	—	—	
Net loss	$ (5,180)	$ (6,231)	$ (7,077)	$ (5,343)
Net loss per share - basic and diluted				$ (4.27)
Net loss per unit - basic and diluted	$ (5.12)	$ (6.16)	$ (7.00)	

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

Under the supervision and with the participation of our management, including our Vice President of Finance and Operations and our Chief Executive Officer, we evaluated the effectiveness of the design and operation 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 (Exchange Act)) as of December 31, 2019. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate, to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on our management's evaluation (with the participation of our Chief Executive Officer and our Vice President of Finance and Operations), as of the end of the period covered by this report, our Chief Executive Officer and our Vice President of Finance and Operations have concluded that our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

There has been no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act) during the year ended December 31, 2019 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION.

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE.

The following table provides information regarding our executive officers and directors as of February 27, 2020:

Name	Age	Position
Executive Officers:		
Praveen P. Tipirneni	51	President, Chief Executive Officer and Director
Robert E. Farrell, Jr., CPA	54	Vice President of Finance and Operations, Treasurer
William D. DeVaul, Esq.	49	General Counsel and Secretary
Bruce N. Rogers, Ph. D.	51	Chief Scientific Officer
Alexey A. Lugovskoy, Ph.D.	46	Chief Development Officer
Non-Employee Directors:		
Gustav Christensen [(1)]	72	Chairman of the Board, Director
Norbert Bischofberger, Ph.D. [(1)]	64	Director
Vikas Goyal [(2)]	41	Director
Nilesh Kumar, Ph.D. [(2)(3)]	43	Director
Amir Nashat, Sc. D. [(3)]	46	Director
Joseph P. Slattery, CPA [(2)]	54	Chairman of the Audit Committee, Director
Timothy Springer, Ph.D.	71	Director
Otello Stampacchia, Ph.D. [(1)]	50	Director

(1) Member of the Compensation Committee

(2) Member of the Audit Committee

(3) Member of the Nominating and Governance Committee

Information About Our Executive Officers

Praveen P. Tipirneni, M.D. has served as our President and Chief Executive Officer and a member of our board of directors since July 2015. Previously, he served as the Senior Vice President of Corporate Development and Global Strategy at Cubist Pharmaceuticals, Inc., a biotechnology company focused on antibiotics, from November 2002 to February 2015. Prior to Cubist Pharmaceuticals, Dr. Tipirneni also held management positions at Sun Microsystems, Inc., Covad Communications Group and Deltagen, Inc. Dr. Tipirneni received a B.A. in Mechanical Engineering from Massachusetts Institute of Technology, an M.D. from McGill University and an M.B.A. from the Wharton School of Business of the University of Pennsylvania. We believe that Dr. Tipirneni is qualified to serve on our board of directors because of his experience with biotechnology companies, including working with and serving in various executive positions in life sciences companies.

Robert E. Farrell, Jr., CPA has served as our Vice President of Finance and Operations and Treasurer since June 2015. From March 2015 to June 2015, Mr. Farrell worked as an independent consultant. From April 2009 to March 2015, Mr. Farrell served as Vice President of Finance and Administration and Treasurer of Genocea Biosciences Inc. Previously, Mr. Farrell served in various senior level financial positions at Oscient Pharmaceuticals Corp., Magen Biosciences, Inc. and NeoGenesis Pharmaceuticals, Inc. Mr. Farrell received a B.S. in Accounting from Bentley University.

William D. DeVaul, Esq. has served as our General Counsel and Secretary since February 2019. From May 2015 to February 2019, he served as Vice President, Head of Intellectual Property at Evelo Biosciences, Inc., a biotechnology company. Prior to Evelo, Mr. DeVaul served Cubist Pharmaceuticals in various positions from December 2003 to February 2015, including most recently as Deputy Chief Intellectual Property Counsel. Mr. DeVaul earned a J.D. from Boston University School of Law and a B.A. in Biochemistry from Columbia University.

Bruce N. Rogers, Ph.D. has served as our Chief Scientific Officer since January 2016. From June 2014 to January 2016, Dr. Rogers served as the Head of Neuro-Opportunities at Pfizer Inc. Prior to that position, Dr. Rogers held positions of increasing responsibility within the medicinal chemistry organization at Pfizer Global R&D since August 2003. Dr. Rogers started his career in the private sector at Pharmacia & Upjohn Company LLC as a scientist from September 1998 to August 2003. Dr. Rogers received a B.A. in Chemistry from the University of Minnesota, a Ph.D. in Organic Chemistry from the University of California at Irvine and was a National Institutes of Health postdoctoral fellow at the University of California.

Alexey A. Lugovskoy, Ph.D. has served as our Chief Development Officer since January 2016. Previously, Dr. Lugovskoy served as a Vice President of Therapeutics of Merrimack Pharmaceuticals, Inc., a biopharmaceutical company, where he worked from June 2010 to January 2016. Prior to joining Merrimack, Dr. Lugovskoy served as Associate Director of Drug Discovery at Biogen Inc., a biotechnology company, where he worked from September 2001 to June 2010. Dr. Lugovskoy has been an Assistant Editor of the journal mAbs since December 2013. Dr. Lugovskoy received an Advanced Certificate for Executives in Management, Innovation and Technology from MIT Sloan School of Management, a Ph.D. in Biophysics from Harvard University and a M.Sc. in Molecular Biophysics and a B.Sc. in Mathematics and Physics from the Moscow Institute of Physics and Technology.

Information About Our Non-Employee Directors

Gustav Christensen has served as a member of our board of directors since January 2016. Mr. Christensen was most recently the President and Chief Executive Officer and director at Dyax Corp., a biopharmaceutical company, where he worked from April 2007 to February 2016. Prior to joining Dyax, Mr. Christensen was a Managing Director at Apeiron Partners, LLC, a boutique life sciences firm, where he worked from 2005 until 2007. Mr. Christensen received his M.Sc. in Economics from the University of Aarhus (Denmark) and his M.B.A. from Harvard Business School. We believe that Mr. Christensen is qualified to serve on our board of directors due to his extensive management and business experience in the life sciences industry and in the commercialization of pharmaceutical products.

Norbert Bischofberger, Ph.D. has served as a member of our board of directors since June 2019. Dr. Bischofberger has served as President and Chief Executive Officer of Kronos Bio, Inc., a biotechnology company, since August 2018. From August 1990 to August 2018, Dr. Bischofberger held various positions at Gilead Sciences, a biopharmaceutical company, and most recently served Gilead as Executive Vice President, Research and Development and Chief Scientific Officer. Prior to Gilead, Dr. Bischofberger served as a Senior Scientist in the DNA Synthesis group at Genentech, Inc., a biotechnology company, from 1986 to 1990. Dr. Bischofberger received a Ph.D. in Organic Chemistry from the Eidgenossische Technische Hochschule in Zurich, Switzerland and an M.S. in Chemistry from the University of Innsbruck. We believe that Dr. Bischofberger is qualified to serve on our board of directors because of his extensive management and research experience in the biopharmaceutical industry.

Vikas Goyal has served as a member of our board of directors since June 2016. Mr. Goyal is currently Senior Vice President, Business Development at Pandion Therapeutics. Prior to joining Pandion Therapeutics in August 2019, Mr. Goyal was a Principal at S.R. One, Limited since 2011, the corporate venture capital arm of GlaxoSmithKline plc, in Cambridge, Massachusetts, where he managed investments in innovative drug discovery and development companies. Prior to joining S.R. One, Limited, Mr. Goyal was a consultant in the pharmaceutical and medical products practice at McKinsey and Company, a co-founder of Extera Partners, where he advised public and private life sciences companies, and a business development manager at Infinity Pharmaceuticals, Inc. He received his B.A. in Neurobiology from Harvard University and his M.B.A. in Health Care Management from the Wharton School of the University of Pennsylvania. We believe that Mr. Goyal is qualified to serve on our board of directors because of his investing and operations experiences in the life sciences industry.

Nilesh Kumar, Ph.D. has served as a member of our board of directors since December 2018. Dr. Kumar has been a Partner at Novo Ventures (US), Inc., which provides consulting services to Novo Holdings A/S, a venture capital fund, since January 2017, and before that, a Senior Principle since April 2015. Prior to Novo Ventures, Dr. Kumar held various positions in the Merck KGaA family of companies since 2009, culminating in the position of Senior Investment Director, where he led venture investments and strategic licensing transactions in the field of oncology and autoimmune diseases. Dr. Kumar also serves on the boards of directors of several private companies and previously served on the board of Milestone Pharmaceuticals, Inc. Dr. Kumar received a B.A. in Natural Sciences from Cambridge University, a Ph.D. in Chemistry from Harvard University and an M.B.A. from Harvard Business School. We believe that Dr. Kumar is qualified to serve on our board of directors because of his venture capital experience, his extensive experience in the pharmaceutical industry and his educational background.

Amir Nashat, Sc.D. previously served as a member of our board of directors from June 2015 through June 2016 and has served as a member of our board of directors since June 2017. Dr. Nashat is a managing partner at Polaris Partners, a venture capital firm, where he has worked since 2002. Dr. Nashat was also the founding Chief Executive Officer of Living Proof, Inc. and Sun Catalytix Corporation. Dr. Nashat currently represents Polaris as a director of Fate Therapeutics, Inc., Selecta Biosciences Inc., Scholar Rock Holding Corporation, and Syros Pharmaceuticals, Inc., as well as on the boards of directors of several private companies. Dr. Nashat was previously a director of aTyr Pharma, Inc. Dr. Nashat also serves on the Partners Innovation Fund, the Investment Advisory Committee for The Engine at MIT, and helped launch the MIT Sandbox Innovation Fund as its active President. Dr. Nashat previously served on the Board of the New England Venture Capital Association. Dr. Nashat received an M.S. and B.S. in Materials Science and Mechanical Engineering from the University of California, Berkeley and a Sc.D. as a Hertz Fellow in Chemical Engineering at the Massachusetts Institute of Technology with a minor in Biology under Dr. Robert Langer. We believe that Dr. Nashat's biotechnology investment experience qualifies him to serve on our board of directors.

Joseph P. Slattery, CPA has served as a member of our board of directors since May 2019. From October 2013 through December 2019, he served as Executive Vice President and Chief Financial Officer of TransEnterix, Inc., a medical device company. Mr. Slattery served as Executive Vice President and Chief Financial Officer at Baxano Surgical Inc., a minimally invasive spinal surgery company, from April 2010 to September 2013. From February 1996 to August 2007, he served in finance and accounting roles including Chief Financial Officer and Senior Vice President of Finance and Information Systems of Digene Corp., a molecular diagnostics company acquired by Qiagen, N.V. in 2007. Currently, he serves on the boards of directors of Replimune Group, Inc. and certain private companies. Mr. Slattery earned a B.S. in Accounting from Bentley University and is a certified public accountant. We believe that Mr. Slattery is qualified to serve on our board of directors due to his extensive finance and business experience in the life sciences industry.

Timothy A. Springer, Ph.D. founded our company in August 2014 and has served as a scientific advisor to us and as a member of our board of directors since June 2015. Since 1989, Dr. Springer has served as the Latham Family Professor at Harvard Medical School. He has also served as Senior Investigator in the Program in Cellular and Molecular Medicine at Boston Children's Hospital since 2012, and as a Professor of Biological Chemistry and Molecular Pharmacology at Harvard Medical School and Professor of Medicine at Boston Children's Hospital since 2011. Dr. Springer was the Founder of LeukoSite, a biotechnology company acquired by Millennium Pharmaceuticals in 1999. Additionally, he is a founder and investor in Scholar Rock Holding Corporation and served as a member of its board from October 2012 to May 2019. He has also served Selecta Biosciences Inc. as a scientific advisor since December 2008 and as a member of its board since June 2016. Dr. Springer is a member of the National Academy of Sciences and his honors include the Crafoord Prize, the American Association of Immunologists Meritorious Career Award, the Stratton Medal from the American Society of Hematology, and the Basic Research Prize from the American Heart Association. Dr. Springer received a B.A. in Biochemistry from the University of California, Berkeley, and a Ph.D. in Biochemistry and Molecular Biology from Harvard University. We believe that Dr. Springer is qualified to serve on our board of directors because of his extensive knowledge of the integrin field and his investment, business and board experience with biopharmaceutical companies.

Otello Stampacchia, Ph.D. has served as a member of our board of directors since December 2018. He has served as founder and Managing Director of Omega Funds since 2004. Previously, Dr. Stampacchia was in charge of life sciences direct investments at AlpInvest Partners B.V. from 2001 to 2003, and from 2000 to 2001, Dr. Stampacchia was the portfolio manager of the Lombard Odier Immunology Fund. Previously, Dr. Stampacchia was a member of the healthcare corporate finance and mergers and acquisitions team at Goldman Sachs Group, Inc. from 1997 to 2000, Before joining Goldman Sachs, Dr. Stampacchia helped co-found the healthcare investment activities at Index Securities, now Index Ventures, Inc. Dr. Stampacchia is currently a member of the boards of directors of Replimune Group, Inc. and Kronos Bio, Inc. Dr. Stampacchia also serves on the board of directors of a private company and previously served on the boards of Gossamer Bio, Inc. and ESSA Pharma, Inc. He has a Ph.D. degree in Molecular Biology from the University of Geneva and a European Ph.D. in Biotechnology (EDBT) from the European Association for Higher Education in Biotechnology. He has an M.S. in Genetics from Universa' degli Studi di Pavia. We believe that Dr. Stampacchia is qualified to serve on our board of directors because of his experience investing in life sciences companies and working with and serving on the boards of directors of various life sciences companies.

Election of Officers

Our executive officers are appointed by, and serve at the discretion of, our board of directors. There are no family relationships among any of our directors or executive officers.

Committees of the Board of Directors

Our board of directors has an audit committee, a compensation committee, and a nominating and governance committee, each of which will have the composition and responsibilities described below. Each of the below committees has a written charter approved by our board of directors. Copies of each charter are posted on the investor relations section of our website. Members who serve on these committees will serve until their resignation or until otherwise determined by our board of directors.

Audit Committee

Our audit committee is comprised of Vikas Goyal, Nilesh Kumar, and Joseph P. Slattery, with Joseph P. Slattery as the chairman of our audit committee. Each member of our audit committee meets the requirements for independence under the current Nasdaq and SEC rules and regulations and is financially literate. In addition, our board of directors has determined that Joseph P. Slattery is an "audit committee financial expert" as defined in Item 407(d)(5)(ii) of Regulation S-K promulgated under the Securities Act of 1933, as amended. This designation does not impose on him any duties, obligations or liabilities that are greater than are generally imposed on members of our audit committee and our board of directors. Our audit committee is directly responsible for, among other things:

- selecting and hiring our independent registered public accounting firm;
- the qualifications, independence and performance of our independent auditors;
- the preparation of the audit committee report to be included in our annual proxy statement;
- our compliance with legal and regulatory requirements;
- our accounting and financial reporting processes, including our financial statement audits and the integrity of our financial statements; and
- reviewing and approving related-person transactions.

Compensation Committee

Our compensation committee is comprised of Norbert Bischofberger, Gustav Christensen and Otello Stampacchia, with Otello Stampacchia as the chairman of our compensation committee. Each member of our compensation committee is a non-employee director, as defined by Rule 16b-3 promulgated under the Exchange Act and meets the requirements for independence under the current Nasdaq listing standards and SEC rules and regulations. Our compensation committee is responsible for, among other things:

- evaluating, recommending, approving and reviewing executive officer compensation arrangements, plans, policies and programs;
- evaluating and recommending non-employee director compensation arrangements for determination by our board of directors;
- administering our cash-based and equity-based compensation plans; and
- overseeing our compliance with regulatory requirements associated with the compensation of directors, officers and employees.

Nominating and Governance Committee

Our nominating and governance committee is comprised of Nilesh Kumar and Amir Nashat, with Nilesh Kumar as the chairman of our nominating and governance committee. Each member of our nominating and governance committee meets the requirements for independence under the current Nasdaq listing standards. Our nominating and governance committee is responsible for, among other things:

- identifying, considering and recommending candidates for membership on our board of directors;
- overseeing the process of evaluating the performance of our board of directors; and

- advising our board of directors on other corporate governance matters.

Scientific Advisory Board

We have established a scientific advisory board composed of leading academic and industry scientists. We seek advice and input from these scientists on an ad hoc basis, individually or as a group, to provide scientific and clinical feedback and advice related to our research and development platform and programs. The members of our advisory board consist of experts across a range of key disciplines relevant to our programs. Other than Timothy A. Springer, our advisors are not our employees or directors and have no decision-making authority over our activities. Our advisors may have commitments to, or consulting or advisory contracts with, other entities that may limit their availability to us. In addition, our advisors may have arrangements with other companies to assist those companies in developing products or technologies that may compete with ours. All of our advisors are affiliated with other entities and devote only a small portion of their time to us. Our advisors are retained under consulting agreements and receive cash compensation based upon consulting services rendered. In addition, in the past we have granted stock options to purchase common stock to certain advisory members for their service.

Code of Business Conduct and Ethics

Our board of directors has adopted a code of business conduct and ethics that applies to all of our employees, officers and directors, including our Chief Executive Officer and other executive and senior officers. The full text of our code of business conduct and ethics will be posted on the investor relations section of our website. The reference to our website address in this prospectus does not include or incorporate by reference the information on our website into this prospectus. We intend to disclose future amendments to certain provisions of our code of business conduct and ethics, or waivers of these provisions, on our website or in public filings to the extent required by the applicable rules.

Non-Employee Director Compensation

The following table presents the total compensation earned by each of our non-employee directors in the year ended December 31, 2019. Our President and Chief Executive Officer, Dr. Tipirneni, receives no compensation for his service as a director. Other than as described below, none of our non-employee directors received any fees or reimbursement of any expenses (other than customary expenses in connection with the attendance of meetings of our board of directors) or any equity or non-equity awards in the year ended December 31, 2019.

Name	Fees Earned or Paid in Cash ($)	Option Awards ($) (1)	Total ($)
Norbert Bischofberger, Ph.D.	20,000	237,516	257,516
Gustav Christensen	55,000	237,516	292,516
Vikas Goyal	21,250	355,774	377,024
Nilesh Kumar, Ph.D.	-	-	-
Amir Nashat, Sc. D.[1]	19,500	237,516	257,016
Joseph P. Slattery, CPA	25,000	237,516	262,516
Timothy Springer, Ph.D.	50,833	1,209,672	1,260,505
Otello Stampacchia, Ph.D. [2]	22,500	237,516	260,016

(1) The amounts reported in the Option Awards column represent the grant date fair value of the stock options granted to the director during the year ended December 31, 2019 as computed in accordance with ASC 718. The assumptions used in calculating the grant date fair value of the stock options reported in the Option Awards column are set forth in Note 8 to the audited consolidated financial statements included in this Form 10-K. Note that the amounts reported in this column reflect the accounting cost for these stock options, and do not correspond to the actual economic value that may be received by the named executive officers from the options.

(2) Dr. Nashat earned compensation under our Non-Employee Director Compensation Policy which was paid directly to Dr. Nashat's employer.

(3) Dr. Stampacchia earned compensation under our Non-Employee Director Compensation Policy which was paid directly to Dr. Stampacchia's employer.

Prior to the IPO completed on July 1, 2019, we did not have a formal policy to provide any cash or equity compensation to our non-employee directors for their service on our board of directors or committees of our board of directors. In June 2019, our board of directors approved compensation for our non-employee directors, which became effective upon completion of the IPO.

Non-Employee Director Cash Compensation

Our non-employee directors receive annual cash compensation of $35,000 for service on the board, and additional cash compensation for the chairperson and committee members as set forth below. All cash payments will be made quarterly in arrears, and will be pro-rated for any partial quarters of service.

- Board Chairperson: $30,000
- Audit Committee Chair: $15,000
- Audit Committee Member (Non-Chair): $7,500
- Compensation Committee Chair: $10,000
- Compensation Committee Member (Non-Chair): $5,000
- Nominating and Corporate Governance Committee Chair: $8,000
- Nominating and Corporate Governance Committee Member (Non-Chair): $4,000

Non-Employee Director Equity Grants

Initial public offering option grant - In connection with the IPO, our board of directors approved the grant of an option to purchase 24,000 shares of our common stock to be made to each of our non-employee directors upon the effectiveness of the registration statement, referred to as the Initial IPO Grant. Each option has an exercise price per share equal to the per share price to the public, and will vest as follows: 25% will vest on the first anniversary of the date of grant and the remaining 75% will vest in 8 substantially equal quarterly installments on each quarterly anniversary of the first anniversary of the date of grant, such that the Initial IPO Grant will become fully vested and exercisable on the three-year anniversary of the date of grant, subject to the director's continued service on each applicable vesting date.

Initial appointment option grant - In addition, each non-employee director who is elected or appointed to our board of directors will, unless the board of directors determines that such grant will not be made automatically, be automatically granted an option to purchase 24,000 shares of our common stock (or such other number of shares of our common stock as may be determined by our board of directors from time to time, subject to the limits set forth in the 2019 Equity Incentive Plan) upon the director's initial appointment to our board of directors, referred to as the Initial Grant. The Initial Grant will vest as follows: 25% will vest on the first anniversary of the date of grant and the remaining 75% will vest in eight substantially equal quarterly installments on each quarterly anniversary of the first anniversary of the date of grant, such that the Initial Grant will become fully vested and exercisable on the three-year anniversary of the date of grant, subject to the director's continued service on each applicable vesting date.

Annual option grant - Each non-employee director who is serving on our board of directors immediately prior to, and will continue to service on our board of directors following, our annual meeting of stockholders, will, unless the board of directors determines that such grant will not be made automatically, be automatically granted an option to purchase 12,000 shares of our common stock (or such other number of shares of our common stock as may be determined by our board of directors from time to time, subject to the limits set forth in the 2019 Equity Incentive Plan) on the date of such

annual meeting of stockholders, referred to as the Annual Grant. Each Annual Grant will vest on the one-year anniversary of the date of grant, such that the Annual Grant will become fully vested and exercisable on the one-year anniversary of the date of grant, or if earlier, the next annual meeting of our stockholders, subject to the director's continued service on the applicable vesting date. The Initial IPO Grants, the Initial Grants and the Annual Grants will be subject to the terms and conditions of the 2019 Equity Incentive Plan and will fully vest and become exercisable upon the consummation of a corporate transaction (as defined in our 2019 Equity Incentive Plan and pursuant to the terms of our 2019 Equity Incentive Plan)

ITEM 11. EXECUTIVE COMPENSATION.

The following tables and accompanying narrative disclosure set forth information about the compensation earned by our named executive officers during the year ended December 31, 2019. Our named executive officers, who are our principal executive officer and the two most highly compensated executive officers (other than our principal executive officer) serving as executive officers as of December 31, 2019, were:

- Praveen P. Tipirneni, M.D., President and Chief Executive Officer;
- Bruce N. Rogers, Ph. D., Chief Scientific Officer;
- William DeVaul, Esq., General Counsel

Summary Compensation Table

The following table presents summary information regarding the total compensation for services rendered in all capacities that was awarded to and earned by our named executive officers during the year ended December 31, 2019 and 2018, all amounts are in dollars:

Name	Year	Salary	Bonus [a]	Stock Awards [b]	Option Awards [c]	Non-equity Incentive Plan Compensation [d]	All Other Compensation [e]	Total
Praveen P. Tipirneni, M.D. *President and Chief Executive Officer*	20192018	497,713402,097	- 110,000	- 329,708	- 1,351,500	282,150208,700	8,3688,250	788,2312,410,255
Bruce N. Rogers, Ph.D. *Chief Scientific Officer*	20192018	372,111320,671	- 60,000	111,533	- 643,500	148,200124,700	8,400 8,250	528,7111,268,654
William D. DeVaul, Esq. [1] *General Counsel*	2019	306,332	-	-	329,564	122,439	6,438	764,773

(1) Mr. DeVaul joined the Company as General Counsel during the year ended December 31, 2019 and was not an officer of the Company during the year ended December 31, 2018.

(a) The amounts reported in the Bonus column reflect special discretionary bonuses paid in January 2019 with respect to business development success in 2018; no special discretionary bonuses were awarded with respect to the 2019 activities.

(b) The amounts reported in the Stock Awards column for fiscal year 2018 reflect the incremental fair value associated with the December 5, 2018 exchange of incentive units in Morphic Holding, LLC previously awarded to our named executive officers into shares of our common stock and restricted stock in connection with the conversion of Morphic Holding, LLC into a corporation, or the Reorganization, with such value computed in accordance with Financial Accounting Standards Board Accounting Standards Codification Topic 718, or ASC 718. The assumptions used in calculating the incremental fair value of the stock awards reported in the Stock Awards column are set forth in Note 8 to the audited consolidated financial statements included in this Form 10-K.

(c) The amounts reported in the Option Awards column represent the grant date fair value of the stock options granted to the named executive officers during the years ended December 31, 2019 and 2018 as computed in accordance with ASC 718. The assumptions used in calculating the grant date fair value of the stock options reported in the Option Awards column are set forth in Note 8 to the audited consolidated financial statements included in this Form 10-K. Note that the amounts reported in this column reflect the accounting cost for these stock options, and do not correspond to the actual economic value that may be received by the named executive officers from the options.

(d) For additional information regarding the non-equity incentive plan compensation, see "— Non-equity Incentive Plan Awards."

(e) The amounts reported in the All Other Compensation column reflect 401(k) contributions paid by us on behalf of each named executive officer.

Non-equity Incentive Plan Awards

Annual bonuses for our executive officers are based on the achievement of corporate and, for all of the executive officers other than our Chief Executive Officer, individual performance objectives. For the 2019, the corporate performance objectives included advancing our MORF-057 and MORF-720 development candidates and raise capital. In December 2019, based on the achievement of these corporate performance objectives and satisfaction of individual performance goals, our board of directors determined to award bonuses equal to 95% of target.

For the 2018 bonuses, the corporate performance objectives included the delivery of a development candidate, the completion of a target level of financing, and the establishment of development infrastructure capable of supporting advancement of the development candidates into the clinic. In January 2019, based on the achievement of these corporate performance objectives and satisfaction of individual performance goals, our board of directors determined to award bonuses equal to 130% of target.

Outstanding Equity Awards at 2019 Fiscal Year-End Table

		Option Awards				Stock Awards[1]	
Name	**Vesting Commencement Date of Option Award or Stock Award**	**Number of Securities Underlying Unexercised Options Exercisable (#)**	**Number of Securities Underlying Unexercised Options Unexercisable (#)**	**Option Exercise Price ($)**	**Option Expiration date**	**Number of Shares of Stock That Have Not Vested (#)**	**Market Value of Shares of Restricted Stock That Have Not Vested ($)[3]**
Praveen P. Tipirneni, M.D.	12/14/2018[2]	115,895	347,655	4.32	12/14/2028	-	-
President and Chief	12/13/2016[5]					46,515	798,197
Executive Officer	12/11/2017[5]					40,728	698,892
Bruce N. Rogers, Ph.D.	12/14/2018[2]	55,186	165,528	4.32	12/14/2028	-	-
Chief Scientific Officer	1/18/2016[4]					1,124	19,288
	12/13/2016[5]					17,789	305,259
	12/11/2017[5]					35,328	606,228
William D. DeVaul, Esq.	12/14/2018[2]	60,5784,120	133,27728,840	4.32	12/14/2028	-	-
General Counsel	6/26/2019[6]			15.00	6/26/2029		

(1) Stock award totals represent shares of our restricted common stock received by each named executive officer upon the exchange of his incentive units in Morphic Holding, LLC in connection with the Reorganization. The shares of restricted common stock are subject to acceleration upon a qualifying termination of employment, which is described in greater detail in the Employee Offer Letters section below.

(2) The outstanding options were granted under our 2018 Plan and vest in 48 equal monthly installments over the four-year period following the vesting commencement date. The options are also subject to acceleration of vesting upon a qualifying termination of employment, which is described in greater detail in the Employee Offer Letters section below.

(3) Based on the closing price of our common stock on December 31, 2019 of $17.16 per share.

(4) The shares of restricted common stock vest as follows: 25% vest on the one-year anniversary of the vesting commencement date, with the remaining 75% vesting in equal monthly installments for the next 36 months thereafter.

(5) The shares of restricted common stock vest as follows: 1/48th of the shares vest in 48 equal monthly installments over the four-year period following the vesting commencement date.

(6) The outstanding options were granted under our 2019 Plan and vest in 48 equal monthly installments over the four-year period following the vesting commencement date. The options are also subject to acceleration of vesting upon a qualifying termination of employment, which is described in greater detail in the Employee Offer Letters section below.

Employee Offer Letters

Offer Letters

We have entered into amended and restated offer letters with each of our named executive officers effective on the day immediately prior to the effectiveness of the registration statement filed in connection with the IPO and which provide for at-will employment and include each named executive officer's base salary, discretionary annual incentive bonus opportunity, and standard employee benefit plan participation. The offer letters also provide that the executives will be eligible to receive certain benefits under the Change in Control and Severance Agreement entered into between us and each named executive officer, as described below.

Change in Control Severance Agreements

We have entered into Change in Control and Severance Agreements with each of our named executive officers, which Change in Control and Severance Agreements became effective on the day immediately prior to the effectiveness of the registration statement filed in connection with the IPO. The Change in Control and Severance Agreements superseded and replace any prior severance or acceleration protections to which the named executive officers were entitled.

These agreements provide for benefits upon either a termination by us of the executive officer's employment without "cause" or a resignation by the executive officer for "good reason" (each as defined in the Change in Control and Severance Agreement and as described below). We refer to either of these terminations as a "qualifying termination." The benefits provided under the Change in Control and Severance Agreements vary depending on whether the executive officer is subject to a qualifying termination within a period commencing three months prior to a "change in control" (as defined in the Severance and Change in Control Agreement) and ending 12 months following such change of control, which period we refer to as the change in control period.

If a qualifying termination occurs prior to or after the change of control period, subject to the executive officer's timely execution and nonrevocation of a release of claims, the executive officer will be entitled to:

- 12 months' continued payment of base salary, in the case of Mr. Tipirneni and 9 months' continued payment of base salary in the case of Messrs. Rogers and DeVaul; and

- if the executive officer elects to continue his health insurance coverage under the Consolidated Omnibus Budget Reconciliation Act of 1985, or COBRA, payment of the premiums for his continued health insurance

(or equivalent cash payment, if applicable law so requires) for up to 12 months in the case of Mr. Tipirneni and up to 9 months in the case of Messrs. Rogers and DeVaul.

If a qualifying termination occurs during the change of control period, subject to the executive officer's timely execution and non-revocation of a release of claims, the executive officer will be entitled to:

- 18 months of base salary, in the case of Mr. Tipirneni and 12 months of base salary in the case of Messrs. Rogers and DeVaul, payable in a lump sum on the first business day occurring after the 60th day following such termination of employment;
- 150% of the executive's target bonus, in the case of Mr. Tipirneni, and 100% of the executive's target bonus in the case of Messrs. Rogers and DeVaul, payable in a lump sum on the first business day occurring after the 60th day following such termination of employment;
- if the executive officer elects to continue his health insurance coverage under COBRA, payment of the premiums for his continued health insurance (or equivalent cash payment, if applicable law so requires) for up to 18 months in the case of Mr. Tipirneni and up to 12 months in the case of Messrs. Rogers and DeVaul; and
- full acceleration of each of the executive officer's then-outstanding but unvested equity awards, provided that the grant agreement for any performance-based equity awards may provide for alternative treatment upon a qualifying termination in the change in control period and, absent any such provision for alternative treatment, any performance-based awards, if any, will be deemed to have been achieved "at target."

Each named executive officer will also be entitled to any earned but unpaid bonus for any performance periods that have been completed as of the date of such executive officer's termination of employment, for any terminations of employment other than a termination of employment for cause.

The Change in Control and Severance Agreements will be in effect for three years from the effective date, unless renewed, or earlier terminated, subject to certain limitations.

For purposes of the Change in Control and Severance Agreements, "cause" generally means the following:

- engaging in theft, fraud and/or dishonesty which, in the judgement of the board of directors could be harmful to us;
- gross negligence or willful misconduct in the performance of the executive's assigned duties;
- gross neglect or willful refusal to attend to the material responsibilities assigned to the executive;
- the executive's material breach of the Change in Control and Severance Agreement or the Non-Disclosure, Non-Competition and Assignment of Intellectual Property Agreement between the executive and us;
- conviction (or a plea of no contest or similar plea or the entry of an order or judgement that requires a determination of guilt or responsibility) of a felony or for any crime involving moral turpitude or dishonesty;
- knowingly providing or making untruthful or misleading statement to us, whether by commission or omission;
- any willful failure to carry out a specific written directive of our board of directors; or
- an intentional violation of any of our material policies or procedures, including without limitation, any equal employment opportunity or anti-harassment policies.

For purposes of the Change in Control and Severance Agreements, "good reason" generally means the following without the executive's prior written consent:

- a reduction in the amount of the executive's then-current salary;
- a material diminution in the executive's position, authority, duties, or responsibilities;
- the relocation of our headquarters or the executive's assigned place of work more than 45 miles from Boston, MA; or
- any material failure by us to comply with any of the provisions of the Change in Control and Severance Agreement or any offer letter or employment agreement between the executive and us.

Restrictive Covenants

Each of our named executive officers has also entered into a Non-Disclosure, Non-Competition and Assignment of Intellectual Property Agreement with us, which agreement contains 12-month post-termination non-competition and non-solicitation covenants.

Other Benefits

Our named executive officers are eligible to participate in our employee benefit plans on the same basis as our other employees, including our health and welfare plans.

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

Equity Compensation Plan Table

The following table sets forth certain information, as of December 31, 2019, concerning securities authorized for issuance under all of our equity compensation plans: our 2018 Stock Incentive Plan, which terminated when we adopted the 2019 Equity Incentive Plan, or EIP, and the 2019 Employee Stock Purchase Plan, or the ESPP.

Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights (a)	Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights (b)	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column (a) (c)
Equity compensation plans approved by security holders	2,987,403	$ 8.67	2,350,079[(1)]
Equity compensation plans not approved by security holders	—	—	—
Total	2,987,403	$ 8.67	2,350,079

(1) The weighted average exercise price does not take into account the shares subject to outstanding RSUs and PSUs, which have no exercise price.

(2) Represents 2,050,079 shares available for issuance under our the EIP, which plan permits the grant of incentive and non-qualified stock options, stock appreciation rights, restricted stock, stock awards and restricted stock units; and 300,000 shares available for issuance under the ESPP. The EIP and ESPP each contain an “evergreen” provision, pursuant to which on January 1st of each year we automatically added 4% and 1% of our shares of common stock outstanding on the preceding December 31st to the shares reserved for issuance, respectively. In addition, pursuant to

a “pour over” provision in our EIP, options that were cancelled, expired or terminated under the 2018 Stock Incentive Plan were added to the number of shares reserved for issuance under our EIP.

Security Ownership Of Certain Beneficial Owners And Management

The following table and accompanying footnotes set forth certain information with respect to the beneficial ownership of our common stock at February 21, 2020 for:

- each of our directors;
- each of our named executive officers;
- all of our current directors and executive officers as a group; and
- each person, or group of affiliated persons, who beneficially owned more than 5% of our outstanding shares of common stock.

We have determined beneficial ownership in accordance with the rules of the Securities and Exchange Commission, and the information is not necessarily indicative of beneficial ownership for any other purpose. Except as indicated by the footnotes below, we believe, based on information furnished to us, that the persons and entities named in the table below have sole voting and sole investment power with respect to all shares of common stock that they beneficially owned, subject to applicable community property laws.

Beneficial ownership is based on 30,115,444 shares of common stock outstanding as of February 21, 2020. In computing the number of shares of common stock beneficially owned by a person and the percentage ownership of that person, we deemed to be outstanding all shares of common stock subject to options held by that person or entity that are currently exercisable or that will become exercisable within 60 days of February 21, 2020. We did not deem these shares outstanding, however, for the purpose of computing the percentage ownership of any other person.

Name of beneficial owner	Number of shares beneficially owned	Percentage of shares beneficially owned
5% Stockholders		
EcoR1 Capital, LLC [1]	2,154,845	7.2%
FMR LLC [2]	2,850,756	9.5%
Artal International S.C.A. [3]	1,819,186	6.0%
Novo Holdings A/S [4]	2,645,446	8.8%
Omega Fund V, L.P. [5]	2,969,582	9.9%
Pfizer Entities [6]	2,528,835	8.4%
Polaris Entities [7]	2,322,946	7.7%
Springer Entities [8]	5,198,530	17.3%
S.R. One, Limited [9]	1,533,772	5.1%
Executive Officers and Directors		
Praveen P. Tipirneni, M.D. [10]	842,389	2.8%
Bruce N. Rogers, Ph.D. [11]	273,642	*
William D. DeVaul, Esq. [12]	81,987	*
Norbert Bischofberger [13]	-	*
Gustav Christensen [14]	100,517	*
Vikas Goyal	-	*
Nilesh Kumar, Ph.D. [4]	-	*
Amir Nashat [7]	2,322,946	7.7%
Joseph P. Slattery [15]	6,667	*
Timothy A. Springer, Ph.D. [16]	4,984,163	16.6%
Otello Stampacchia, Ph.D. [5]	2,969,582	9.9%
All current executive officers and directors as a group (13 persons) [17]	11,907,380	39.5%

* Represents beneficial ownership of less than one percent.

(1) Based solely on information contained in Amendment No. 1 to Schedule 13G filed with the SEC on February 14, 2020 by EcoR1 Capital, LLC, or EcoR1 LLC. Represents (i) 382,133 shares of common stock held by EcoR1 LLC, and (ii) 1,772,712 shares of common stock held by EcoR1 Capital Fund Qualified, L.P., or EcoR1 Qualified. EcoR1 LLC, is the general partner of EcoR1 Qualified and may be deemed to indirectly beneficially own the shares held by EcoR1 Qualified. Oleg Nodelman is the managing member of EcoR1 LLC and may be deemed to have sole voting and dispositive power over the shares held by EcoR1 LLC and EcoR1 Qualified. Mr. Nodelman disclaims beneficial ownership of the shares held by EcoR1 LLC and EcoR1 Qualified except to the extent of his pecuniary interest therein. The address of EcoR1 LLC and EcoR1 Qualified is 409 Illinois Street, San Francisco, California 94158.

(2) Based solely on information contained in a Schedule 13G filed with the SEC on Febraury 7, 2020 by FMR LLC. Represents 2,850,756 shares of common stock held by FMR LLC as of December 31, 2019. The address of FMR LLC is 245 Summer Street, Boston, Massachusetts 02210.

(3) Based soley on information contained in Amendment No. 1 to Schedule 13G filed by Artal International S.C.A., or Artal S.C.A., and related entities. Represents 1,819,186 shares of common stock held by Invus Public Equities, L.P., or Invus Public Equities. Invus Public Equities Advisors, LLC, as the general partner of Invus Public Equities, controls Invus Public Equities and accordingly may be deemed to beneficially own the Shares held by Invus Public Equities. Artal Treasury Limited, or Artal Treasury, as the managing member of Invus PE Advisors, controls Invus PE Advisors, and accordingly may be deemed to beneficially own the Shares that Invus Public Equities may be deemed to beneficially own. Artal S.C.A., as its Geneva branch is the sole stockholder of Artal Treasury, may be deemed to beneficially own the Shares that Artal

Treasury may be deemed to beneficially own. Artal International Management S.A., or Artal International Management, as the managing partner of Artal S.C.A., controls Artal S.C.A. and, accordingly, may be deemed to beneficially own the Shares that Artal S.C.A. may be deemed to beneficially own. Artal Group S.A., or ARtal Group, as the parent company of Artal International Management, controls Artal International Management and, accordingly, may be deemed to beneficially own the Shares that Artal International Management may be deemed to beneficially own. Westend S.A., or Westend, as the parent company of Artal Group, controls Artal Group and, accordingly, may be deemed to beneficially own the Shares that Artal Group may be deemed to beneficially own. The Stichting Administratiekantoor Westend, or the Stichting, as the parent company of Westend, controls Westend and, accordingly, may be deemed to beneficially own the Shares that Westend may be deemed to beneficially own. Pascal Minne, the sole Director of Stichting, may be deemed to have sole voting and dispositive power over the shares held by Artal S.C.A. Mr. Minne disclaims beneficial ownership of the shares held by Artal S.C.A. except to the extent of his pecuniary interest therein. The address of Artal International S.C.A. is 44, rue de la Vallee, L-2661, Luxembourg.

(4) Based solely on information contained in a Schedule 13D filed with the SEC on July 1, 2019 by Novo Holdings A/S, or Novo. Represents 2,645,446 shares of common stock held by Novo, as of December 31, 2019. Nilesh Kumar, a member of our board of directors, is a partner of Novo Ventures (US) Inc., which is a wholly-owned subsidiary of Novo. Dr. Kumar has no voting or dispositive power over the shares held by Novo and is not deemed to beneficially own such shares. The Novo board, comprised of Viviane Monges, Jeppe Christiansen, Steen Riisgaard, Lars Rebien Sorensen, Jean-Luc Butel and Francis Cuss, exercises voting and dispositive power over these shares only with the support of a majority of the Novo board. As such, no individual member of the Novo board is deemed to beneficially own these shares. Each of such individuals disclaims beneficial ownership of all shares held by Novo. The address of Novo Holdings A/S is Tuborg Havnevej 19, 2900 Hellerup, Denmark.

(5) Based solely on information contained in a Schedule 13G filed with the SEC on February 13, 2020 by Omega Fund V, L.P., or Omega L.P., and related entities. Represents 2,969,582 shares of common stock held by Omega Fund V, L.P., or Omega L.P as of December 31, 2019. Otello Stampacchia, a member of our board of directors, Richard Lim, Claudio Nessi and Anne-Mari Paster are the directors of Omega Fund V GP Manager, Ltd., or Omega Manager, which is the sole general partner of Omega Fund GP, L.P., or Omega GP, which is the sole general partner of Omega L.P. Messrs. Stampacchia, Lim and Nessi and Ms. Paster may be deemed to share voting and dispositive power over the shares held by Omega L.P. Each of such individuals, together with Omega GP and Omega Manager, disclaims beneficial ownership of the shares held by Omega L.P. except to the extent of their pecuniary interest therein. The address of Omega Fund V, L.P. is 185 Dartmouth Street, Suite 502, Boston, Massachusetts 02116.

(6) Based solely on information contained in a Schedule 13G filed with the SEC on February 14, 2020 by Pfizer Inc., or Pfizer and Pfizer Ventures (US) Holdings, or Pfizer Ventures. Represents (i) 1,058,885 shares of common stock held by Pfizer, and (ii) 1,469,950 shares held by Pfizer Ventures, a wholly-owned subsidiary of Pfizer, as of December 31, 2019. The address of Pfizer is 235 East 42nd Street, New York, New York 10017.

(7) Based solely on information contained in a Schedule 13G filed with the SEC on February 12, 2020 by Polaris Partners VII, L.P., or PP VII, and related entities. Represents (i) 2,171,067 shares of common stock held by PP VII, and (ii) 151,879 shares of common stock held by Polaris Partners Entrepreneurs Fund VII, L.P., or PEF VII, as of December 31, 2019. Polaris Management Company VII, L.L.C., or PP GP VII, is the general partner of each of PP VII and PEF VII. PP GP VII may be deemed to have sole voting and investment power with respect to the shares owned by each of PP VII and PEF VII and disclaims beneficial ownership of these securities, except to the extent of its pecuniary interest therein. Amir Nashat, a member of our board of directors, Brian Chee, David Barrett, Bryce Youngren, Jonathan Flint and Terrance McGuire are the managing members of PP GP VII. Each of these managing members may be deemed to share voting and dispositive power over the shares held by each of PP VII and PEF VI. Each of these managing members disclaims beneficial ownership of such shares, except to the extent of their pecuniary

interests therein. The address of Polaris Partners is One Marina Park Drive, 10th Floor, Boston, Massachusetts 02210.

(8) Based solely on information contained in a Schedule 13G filed with the SEC on February 14, 2020 and in a Form 4 filed with the SEC on July 1, 2019 by Timothy A. Springer. Represents (i) 4,565,191 shares of common stock held directly, (ii) 42,873 shares of common stock held by Dr. Springer's spouse, (iii) 214,367 shares of common stock held by Springer-Lu Family 2004 Irrevocable Trust dated March 29, 2004, Fiduciary Trust Company of New England LLC, Trustee, over which shares Dr. Springer has no voting or dispositive control, (iv) 375,019 shares of common stock held by TAS Partners LLC, of which Dr. Springer is manager and has sole voting and dispositive control, and (v) 1,080 shares underlying option to purchase common stock that are exercisable within 60 days of February 21, 2020.

(9) Based solely on information contained in a Amedment No. 2 to Schedule 13 D filed with the SEC on February 18, 2020 by GlaxoSmithKline plc, or GSK plc. Represents 1,533,772 shares of common stock held by S.R. One, Limited, or S.R. One, a wholly-owned subsidiary of GlaxoSmithKline LLC, or GSK LLC. GSK LLC is an indirect wholly owned subsidiary of GSK plc. The address of S.R. One Limited is 161 Washington Street, Suite 500, Conshohocken, Pennsylvania 19428.

(10) Represents (i) 676,474 shares of common stock held by The Praveen P. Tipirneni Irrevocable Trust of 2019, the trustee of whom is Dr. Tipirneni's spouse, of which 76,098 shares are subject to a right of repurchase as of February 21, 2020, and (ii) 165,915 shares underlying options to purchase common stock that are exercisable within 60 days of February 21, 2020.

(11) Represents (i) 195,819 shares of common stock, of which 47,207 shares are subject to a right of repurchase as of February 21, 2020, and (ii) 77,823 shares underlying options to purchase common stock that are exercisable within 60 days of February 21, 2020.

(12) Represents 81,987 shares underlying options to purchase common stock that are exercisable within 60 days of February 21, 2020.

(13) Mr. Bischofberger did not hold any shares of common stock as of February 21, 2020.

(14) Represents 100,517 shares of common stock as of February 21, 2020.

(15) Represents 6,667 shares of common stock held as of February 21, 2020.

(16) Represents (i) 4,565,191 shares of common stock held directly, (ii) 42,873 shares of common stock held by Dr. Springer's spouse, (iii) 375,019 shares of common stock held by TAS Partners LLC, of which Dr. Springer is manager and has sole voting and dispositive control, and (iv) 1,080 shares underlying option to purchase common stock that are exercisable within 60 days of February 21, 2020.

(17) Includes 423,610 shares of common stock issuable upon the exercise of options exercisable within 60 days after February 21, 2020.

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

In addition to the compensation arrangements, including employment, termination of employment and change in control arrangements, with our directors and executive officers, including those discussed in the sections entitled "Management" and "Executive Compensation," the following is a description of each transaction since January 1, 2019 and each currently proposed transaction in which:

- we have been or are to be a participant;
- the amounts involved exceeded or will exceed the lesser of $120,000 and 1% of our total assets; and
- any of our directors, executive officers or holders of more than 5% of our capital stock, or an affiliate or immediate family member of the foregoing persons, had or will have a direct or indirect material interest.

Other than as described below, there have not been, nor are there any currently proposed, transactions or series of similar transactions to which we have been or will be a party other than compensation arrangements, which are described where required under the section entitled "Executive Compensation."

Transactions with Timothy A. Springer, Ph.D.

In June 2015, we entered into a consulting agreement, or the Springer Agreement, with Timothy A. Springer, Ph.D., a director on our Board, to provide advisory services related to our research and development programs, intellectual property development, strategic planning, our Scientific Advisory Board and other related services. Pursuant to the Springer Agreement, we paid an annual consulting fee of $80,000. The Springer Agreement expired on June 1, 2019.

In April 2019, we granted to Dr. Springer a stock option to purchase 4,287 shares of our common stock, with an exercise price of $7.76 per share, in connection with his services as a member of our Scientific Advisory Board.

In November 2019 we entered into a sponsored research agreement with Institute for Protein Innovation, Inc. (or “IPI”), a non-profit organization with which the executive officer is a member of the Company’s Board of Directors. Pursuant to the terms of the agreement, IPI will conduct agreed upon research activities; upon completion of the research activities, we will have the option to exclusively license IPI’s interest in any product invention resulting in such research. In connection with the research activities performed by IPI, it is anticipated that we will pay IPI up to $0.6 million over a two year period; as of December 31, 2019 we have paid $0.3 million.

In December 2019, we entered into a consulting agreement with Dr. Springer to provide advisory services related to our research and development programs for a period of three years. Pursuant to the terms of the consulting agreement, we granted Dr. Springer a stock option to purchase 90,000 shares of our common stock with an exercise price of $15.72 per share.

Partipation in our Initial Public Offering

Certain of our existing stockholders and their affiliated entities, including stockholders affiliated with certain of our directors, purchased an aggregate of 1,946,666 shares of our common stock in our initial public offering at the initial public offering price. The following table summarizes common stock purchased by affiliates of members of our board of directors and entities who held more than 5% of our outstanding capital stock at the time of the purchase:

Name of beneficial owner	Number of shares purchased in IPO
Artal Treasury Ltd.	500,000
Novo Holdings A/S	666,667
Omega Fund V, L.P.	133,333
Pfizer Entities	333,333
Polaris Entities	125,000
S.R. One, Limited	333,333

Policies and Procedures for Related Party Transactions

Our Board has adopted a written related person transactions policy that provides that our executive officers, directors, nominees for election as a director, beneficial owners of more than 5% of our common stock, and any members of the immediate family of and any entity affiliated with any of the foregoing persons, are not permitted to enter into a material related person transaction with us without the review and approval of our audit committee, or a committee composed solely of independent directors in the event it is inappropriate for our audit committee to review such transaction due to a

conflict of interest. The policy provides that any request for us to enter into a transaction with an executive officer, director, nominee for election as a director, beneficial owner of more than 5% of our common stock or with any of their immediate family members or affiliates in which the amount involved exceeds $120,000 will be presented to our audit committee (or the committee composed solely of independent directors, if applicable) for review, consideration and approval. In approving or rejecting any such proposal, we expect that our audit committee (or the committee composed solely of independent directors, if applicable) will consider the relevant facts and circumstances available and deemed relevant to the audit committee (or the committee composed solely of independent directors, if applicable), including, but not limited to, whether the transaction is on terms no less favorable than terms generally available to an unaffiliated third party under the same or similar circumstances and the extent of the related person's interest in the transaction.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES.

The following table summarizes the fees Ernst & Young LLP, our independent registered public accounting firm, billed to us for each of the last two fiscal years:

Fee Category	2019	2018
Audit Fees	525,000	244,037
Audit -Related Fees [(1)]	821,411	-
Tax Fees	-	-
All Other Fees	-	-
Total Fees	1,346,411	244,037

[(1)]Audit-related fees billed to us in 2019 relate to the IPO.

Policy on Audit Committee Pre-Approval of Audit and Permissible Non-Audit Services of Independent Registered Public Accounting Firm

Our Audit Committee generally pre-approves all audit and permissible non-audit services provided by the independent registered public accounting firm. These services may include audit services, audit-related services, tax services and other services. Pre-approval is detailed as to the particular service or category of services and is generally subject to a specific budget. The independent registered public accounting firm and management are required to periodically report to the Audit Committee regarding the extent of services provided by the independent registered public accounting firm in accordance with this pre-approval, and the fees for the services performed to date. Our Audit Committee may also pre-approve particular services on a case-by-case basis. All of the services relating to the fees described in the table above were approved by our Audit Committee.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES.

December 31, 2019 Financial Statements:

Our consolidated financial statements are set forth in Part II, Item 8 of this Annual Report on Form 10-K and are incorporated herein by reference.

(2) Financial Statement Schedules:

Schedules have been omitted since they are either not required or not applicable or the information is otherwise included herein

(3) Exhibits

The exhibits filed as part of this Annual Report on Form 10-K are listed below.

Exhibit Number	Description	Form	File No.	Exhibit	Filing Date	Filed/Furnished Herewith
3.1	Restated Certificate of Incorporation	10-Q	001-38940	3.1	August 13, 2019	
3.2	Restated Bylaws	10-Q	001-38940	3.2	August 13, 2019	
4.1	Form of Common Stock Certificate	S-1/A	333-231837	4.1	June 14, 2019	
4.2	Investors' Rights Agreement, dated December 5, 2018, by and among the Registrant and certain of its stockholders.	S-1/A	333-231837	4.2	June 14, 2019	
4.3	Warrant by and between the Registrant and Silicon Valley Bank.	S-1/A	333-231837	4.3	June 14, 2019	
4.4	Description of Registrant's Securities Registered under Section 12 of the Securities Exchange Act of 1934, as amended					X
10.1*	Form of Indemnity Agreement.	S-1/A	333-231837	10.1	June 14, 2019	
10.2*	2018 Stock Incentive Plan and forms of award agreements	S-1/A	333-231837	10.2	June 14, 2019	
10.3*	2019 Equity Incentive Plan and forms of award agreements	S-1/A	333-231837	10.3	June 14, 2019	
10.4*	2019 Employee Stock Purchase Plan and forms of award agreements	S-1/A	333-231837	10.4	June 14, 2019	
10.5*	Offer Letter, dated June 10, 2019, by and between the Registrant and Praveen P. Tipirneni, MD	S-1/A	333-231837	10.5	June 14, 2019	
10.6*	Offer Letter, dated June 10, 2019, by and between the Registrant and Bruce N. Rogers, Ph.D	S-1/A	333-231837	10.6	June 14, 2019	
10.7*	Offer Letter, dated June 10, 2019, by and between the Registrant and William DeVaul					X
10.8*	Consulting Agreement, dated December 5, 2019, by and between the Registrant and Timothy A. Springer, Ph.D					X
10.9	Lease, dated August 5, 2015, by and between the Registrant and AstraZeneca Pharmaceuticals Limited Partnership, as amended.	S-1/A	333-231837	10.9	June 14, 2019	
10.10†	Research Collaboration and Option Agreement, dated February 15, 2019, by and among Janssen Pharmaceuticals, Inc. and the Registrant.	S-1/A	333-231837	10.10	June 14, 2019	

10.11†	Collaboration and Option Agreement, dated October 16, 2018, by and between AbbVie Biotechnology Ltd and the Registrant.	S-1/A	333-231837	10.11	June 14, 2019	
10.12†	Collaboration Agreement, dated June 10, 2015, by and between Morphic Rock Therapeutic, Inc. and Schrödinger, LLC, as amended.	S-1/A	333-231837	10.12	June 14, 2019	
10.13†	Exclusive License Agreement, dated October 7, 2015, by and between Children's Medical Center Corporation and the Registrant, as amended.	S-1/A	333-231837	10.13	June 14, 2019	
10.14*	Change in Control and Severance Agreement, dated June 12, 2019, by and between the Registrant and Praveen P. Tipirneni, MD	S-1/A	333-231837	10.14	June 14, 2019	
10.15*	Change in Control and Severance Agreement, dated June 12, 2019, by and between the Registrant and Bruce N. Rogers	S-1/A	333-231837	10.15	June 14, 2019	
10.16*	Change in Control and Severance Agreement, dated June 12, 2019, by and between the Registrant and Alexey A. Lugovsky	S-1/A	333-231837	10.16	June 14, 2019	
10.17	Form of Stock Registration Agreement	S-1/A	333-231837	10.17	June 14, 2019	
21.1	Subsidiaries of the Registrant.					X
23.1	Consent of Independent Registered Public Accounting Firm.					X
24.1	Powers of Attorney. Reference is made to the signature page hereto.					X
31.1	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					X
31.2	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					X

32.1**	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.											X
32.2**	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.											X
101.INS	XBRL Instance Document											X
101.SCH	XBRL Taxonomy Extension Schema Document											X
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document											X
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document											X
101.LAB	XBRL Taxonomy Extension Label Linkbase Document											X
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document											X

* Executive compensation plan or agreement.

** The certifications furnished in Exhibits 32.1 and 32.2 hereto are deemed to accompany this Form 10-K and are not deemed "filed" for purposes of Section 18 of the Exchange Act, or otherwise subject to the liability of that section, nor shall they be deemed incorporated by reference into any filing under the Securities Act or the Exchange Act.

† Registrant has omitted portions of the exhibit as permitted under Item 601(b)(10) of Regulation S-K.

Item 16. FORM 10-K SUMMARY

None.

SIGNATURES

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

MORPHIC HOLDING, INC.

February 27, 2020 By: /s/ Praveen P. Tipirneni
Praveen P. Tipirneni, M.D.
President, Chief Executive Officer and Director
(Principal Executive Officer)

February 27, 2020 By: /s/ Robert E. Farrell Jr.
Robert E. Farrell Jr. CPA
Senior Vice President of Finance and Chief Accounting Officer
(Principal Financial & Accounting Officer)

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below hereby constitutes and appoints Praveen P. Tipirneni and William D. DeVaul, and each of them, with full power of substitution and resubstitution and full power to act without the other, as his or her true and lawful attorney-in-fact and agent to act in his or her name, place and stead and to execute in the name and on behalf of each person, individually and in each capacity stated below, and to file any and all amendments to this Annual Report on Form 10-K and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing, ratifying and confirming all that said attorneys-in-fact and agents or any of them or their or his substitute or substitutes may lawfully do or cause to be done by virtue thereof.

Pursuant to the requirements of the Securities Act of 1934, this Annual Report on Form 10-K has been signed by the following persons in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Praveen P. Tipirneni Praveen P. Tipirneni, M.D.	President, Chief Executive Officer and Director (Principal Executive Officer)	February 27, 2020
/s/ Robert E. Farrell, Jr. Robert E. Farrell, Jr., CPA	Senior Vice President of Finance and Chief Accounting Officer (Principal Accounting and Financial Officer)	February 27, 2020
/s/ Gustav Christensen Gustav Christensen	Director	February 27, 2020
/s/ Norbert Bischofberger Norbert Bischofberger	Director	February 27, 2020
/s/ Vikas Goyal Vikas Goyal	Director	February 27, 2020
/s/ Nilesh Kumar, Ph.D. Nilesh Kumar, Ph.D.	Director	February 27, 2020
/s/ Amir Nashat Amir Nashat	Director	February 27, 2020
/s/ Joseph P. Slattery Joseph P. Slattery, CPA	Director	February 27, 2020
/s/ Timothy A. Springer Timothy A. Springer, Ph.D.	Director	February 27, 2020
/s/ Otello Stampacchia Otello Stampacchia, Ph.D.	Director	February 27, 2020

DESCRIPTION OF CAPITAL STOCK

General

Our authorized capital stock consists of 400,000,000 shares of common stock, $0.0001 par value per share, and 10,000,000 shares of undesignated preferred stock, $0.0001 par value per share. The following description summarizes the most important terms of our capital stock. Because it is only a summary, it does not contain all the information that may be important to you. For a complete description, you should refer to our restated certificate of incorporation, our restated bylaws, and our investors' rights agreement, which are included as exhibits to our most recent Annual Report on Form 10-K and to the applicable provisions of Delaware law.

Common Stock

Dividend Rights

Subject to preferences that may apply to any shares of preferred stock outstanding at the time, the holders of our common stock are entitled to receive dividends out of funds legally available if our board of directors, in its discretion, determines to issue dividends and then only at the times and in the amounts that our board of directors may determine.

Voting Rights

Holders of our common stock are entitled to one vote for each share held on all matters submitted to a vote of stockholders. We have not provided for cumulative voting for the election of directors in our restated certificate of incorporation, which means that holders of a majority of the shares of our common stock will be able to elect all of our directors. Our restated certificate of incorporation establishes a classified board of directors, divided into three classes with staggered three-year terms. Only one class of directors will be elected at each annual meeting of our stockholders, with the other classes continuing for the remainder of their respective three-year terms.

No Preemptive or Similar Rights

Our common stock is not entitled to preemptive rights, and is not subject to conversion, redemption or sinking fund provisions.

Right to Receive Liquidation Distributions

Upon our liquidation, dissolution or winding-up, the assets legally available for distribution to our stockholders would be distributable ratably among the holders of our common stock and any participating preferred stock outstanding at that time, subject to prior satisfaction of all outstanding debt and liabilities and the preferential rights of and the payment of liquidation preferences, if any, on any outstanding shares of preferred stock.

Registration Rights

Certain of our common stock holders are entitled to certain registration rights with respect to the sale of such shares under the Securities Act. We refer to these shares as registrable securities. These rights are provided under the terms of an investors' rights agreement between us and the holders of these shares, which was entered into in connection with our preferred stock financings, and include demand registration rights, short-form registration rights and piggyback registration rights.

The registration rights terminate, with respect to any particular holder of these rights, on the earliest to occur of (a) the closing of a deemed liquidation event, as defined in our restated certificate of incorporation, (b) at such time that all of the holder's registrable securities can be sold without limitation in any three-month period without registration in compliance with Rule 144 or a similar exemption under the Securities Act 1933, as amended, and (c) seven years following the completion of our initial public offering.

Demand Registration Rights

Beginning 180 days after the completion of our initial public offering, if the holders of not less than 40% of the then-outstanding registrable securities may request the registration under the Securities Act of any registrable securities, if the anticipated aggregate offering price, net of selling expenses, would exceed $10.0 million, we are obligated to provide notice of such request to all holders of registration rights and, as soon as practicable and in any event within 60 days, file a Form S-1 registration statement under the Securities Act covering all registrable securities that the initiating holders requested to be registered and any additional registrable securities requested to be included in such registration by any other holders. We are only required to file two registration statements that are declared effective upon exercise of these demand registration rights. We may postpone taking action with respect to such filing not more than twice during any 12-month period for a period of not more than 120 days, if after receiving a request for registration, we furnish to the holders requesting such registration a certificate signed by our Chief Executive Officer stating that, in the good faith judgment of our board of directors, it would be materially detrimental to us and our stockholders.

Piggyback Registration Rights

If we register any of our securities for public sale, holders of then-outstanding registrable securities or their permitted transferees will have the right to include their registrable securities in the registration statement. However, this right does not apply to a registration relating to any of our employee benefit plans, a corporate reorganization or transaction under Rule 145 of the Securities Act, a registration that requires information that is not substantially the same, or a registration in which the only common stock being registered is common stock issuable upon conversion of debt securities that are also being registered. In an underwritten offering, if the total number of securities requested by stockholders to be included in the offering exceeds the number of securities to be sold (other than by the us) that the underwriters determine in their reasonable discretion is compatible with the success of the offering, then we will be required to include only that number of securities that the underwriters and us, in our sole discretion, determine will not jeopardize the success of the offering. If the underwriters determine that less than all the securities requested to be registered cab be included in the offering, the number of shares to be registered will be apportioned pro rata among the selling holders, according to the total number of registrable securities owned by each holder, or in a manner mutually agreed upon by all such selling holders. However, the number of shares to be registered by these holders cannot be reduced unless all other securities (other than the securities to be sold by us) are excluded entirely and may not be reduced below 30% of the total number of securities included in such offering, except for in connection with an initial public offering, in which case the underwriters may exclude these holders entirely.

Form S-3 Registration Rights

The holders of at least 10% of the then-outstanding registrable securities can request that we register all or part of their shares on Form S-3 if we are eligible to file a registration statement on Form S-3 and if the aggregate price to the public of the shares offered, net of selling expenses, is at least $3.0 million. The stockholders may only require us to effect two registration statements on Form S-3 in a 12-month period. We may postpone taking action with respect to such filing twice during any 12-month period for a period of not more than 120 days if our board of directors determines in its good faith judgment that the filing would be materially detrimental to us and our stockholders.

Anti-Takeover Provisions

The provisions of the DGCL, our restated certificate of incorporation and our restated bylaws could have the effect of delaying, deferring or discouraging another person from acquiring control of our company. These provisions, which are summarized below, may have the effect of discouraging takeover bids. They are also designed, in part, to encourage persons seeking to acquire control of us to negotiate first with our board of directors. We believe that the benefits of increased protection of our potential ability to negotiate with an unfriendly or unsolicited acquirer outweigh the disadvantages of discouraging a proposal to acquire us because negotiation of these proposals could result in an improvement of their terms.

Delaware Law

We are subject to the provisions of Section 203 of the DGCL regulating corporate takeovers. In general, DGCL 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 on which the person became an interested stockholder unless:

- prior to the date of the transaction, the board of directors of the corporation approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;

- the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the voting stock outstanding, but not the outstanding voting stock owned by the interested stockholder, (i) shares owned by persons who are directors and also officers and (ii) shares owned by employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or

- at or subsequent to the date of the transaction, the business combination is approved by the board of directors of the corporation and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least 66.67% of the outstanding voting stock that is not owned by the interested stockholder.

Generally, a business combination includes a merger, asset or stock sale, or other transaction or series of transactions together resulting in a financial benefit to the interested stockholder. 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 outstanding voting stock. We expect the existence of this provision to have an anti-takeover effect with respect to transactions our board of directors does not approve in advance. We also anticipate that Section 203 may also discourage attempts that might result in a premium over the market price for the shares of common stock held by stockholders.

Restated Certificate of Incorporation and Restated Bylaws Provisions

Our restated certificate of incorporation and our restated bylaws include a number of provisions that could deter hostile takeovers or delay or prevent changes in control of our company, including the following:

- ***Board of Directors Vacancies.*** Our restated certificate of incorporation and restated bylaws authorize only our board of directors to fill vacant directorships, including newly created seats. In addition, the number of directors constituting our board of directors is permitted to be set only by a resolution adopted by a majority vote of our entire board of directors. These provisions would prevent a stockholder from increasing the size of our board of directors and then gaining control of our board of directors by filling the resulting vacancies with its own nominees. This makes it more difficult to change the composition of our board of directors but promotes continuity of management.

- ***Classified Board.*** Our restated certificate of incorporation and restated bylaws provide that our board of directors is classified into three classes of directors, each with staggered three-year terms. A third party may be discouraged from making a tender offer or otherwise attempting to obtain control of us as it is more difficult and time consuming for stockholders to replace a majority of the directors on a classified board of directors.

- ***Stockholder Action; Special Meetings of Stockholders.*** Our restated certificate of incorporation provides that our stockholders may not take action by written consent, but may only take action at annual or special meetings of our stockholders. As a result, a holder controlling a majority of our capital stock would not be able to amend our restated bylaws or remove directors without holding a meeting of our stockholders called in accordance with our restated bylaws. Further, our restated bylaws provides that special meetings of our stockholders may be called only by a majority of our board of directors, the chairman of our board of directors, our Chief Executive Officer or our President, thus prohibiting a stockholder from calling a special meeting. These provisions might delay the ability of our stockholders to force consideration of a proposal or for stockholders controlling a majority of our capital stock to take any action, including the removal of directors.

- ***Advance Notice Requirements for Stockholder Proposals and Director Nominations.*** Our restated bylaws provides advance notice procedures for stockholders seeking to bring business before our annual meeting of stockholders or to nominate candidates for election as directors at our annual meeting of stockholders. Our restated bylaws also specifies certain requirements regarding the form and content of a stockholder's notice. These provisions might preclude our stockholders from bringing matters before our annual meeting of stockholders or from making nominations for directors at our annual meeting of stockholders if the proper procedures are not followed. We expect that these provisions might also discourage or deter a potential acquirer from conducting a solicitation of proxies to elect the acquirer's own slate of directors or otherwise attempting to obtain control of our company.

- ***No Cumulative Voting.*** The DGCL provides that stockholders are not entitled to the right to cumulate votes in the election of directors unless a corporation's certificate of incorporation provides otherwise. Our restated certificate of incorporation and restated bylaws do not provide for cumulative voting.

- ***Directors Removed Only for Cause.*** Our restated certificate of incorporation provides that stockholders may remove directors only for cause and only by the affirmative vote of the holders of at least two-thirds of our outstanding common stock.

- ***Amendment of Charter Provisions.*** Any amendment of the above provisions in our restated certificate of incorporation requires approval by holders of at least two-thirds of our outstanding common stock.

- ***Issuance of Undesignated Preferred Stock.*** Our board of directors has the authority, without further action by the stockholders, to issue up to 10,000,000 shares of undesignated preferred stock with rights and preferences, including voting rights, designated from time to time by our board of directors. The existence of authorized but unissued shares of preferred stock would enable our board of directors to render more difficult or to discourage an attempt to obtain control of us by means of a merger, tender offer, proxy contest or other means.

- ***Choice of Forum.*** Our restated certificate of incorporation provides that, to the fullest extent permitted by law, the Court of Chancery of the State of Delaware will be the exclusive forum for any derivative action or proceeding brought on our behalf; any action asserting a breach of fiduciary duty; any action asserting a claim against us arising pursuant to the DGCL, our restated certificate of incorporation or our restated bylaws; or any action asserting a claim against us that is governed by the internal affairs doctrine. The enforceability of similar choice of 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 inapplicable or unenforceable. This exclusive forum provision does not apply to suits brought to enforce a duty or liability created by the Exchange Act. It could apply, however, to a suit that falls within one or more of the categories enumerated in the exclusive forum provision and asserts claims under the Securities Act, inasmuch as Section 22 of 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. There is uncertainty as to whether a court would enforce such provision with respect to claims under the Securities Act, and our stockholders will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder.

Exchange Listing

Our common stock is listed on The Nasdaq Global Market under the symbol "MORF."

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is Computershare Trust Company, N.A.

December 10, 2018

William DeVaul, Esq.
35 Longmeadow Road
Milton, MA 02186

Dear Bill:

It is my pleasure to offer you employment with Morphic Therapeutic, Inc. (the "Company"). Your position will be General Counsel & Secretary, reporting directly to Praveen Tipirneni, Chief Executive Officer. Your effective date of hire as a regular, full-time employee is anticipated to occur no later than February 28, 2019 (your "Start Date").

Compensation: This is an exempt position. The Company will pay you salary at an annualized rate of $330,000, payable in accordance with the Company's regular payroll practices and subject to all applicable tax reporting and withholding requirements. As an employee, you will also be eligible to participate in the Company's standard employee benefit programs (health/dental/ life insurance, etc.) including 3 weeks paid vacation and holiday benefits.

Bonus: During employment, you will be eligible for an annual bonus target of 30% of your base salary as determined by the Board of Directors (the "Board") in its discretion, based on your performance as well as the Company's performance. Any bonus you receive will be paid at such time as determined by the Board and will require that you remain employed by the Company at the time of such payment.

Equity: Further, it is our intention that, subject to the approval of our Board of Directors, you will be granted a non-statutory stock option to purchase 1, 130,387 shares of the common stock of Morphic Holding In c., the Company's parent entity ("Parent"). The equity represents an approximately 0.75% ownership interest in the Parent as of the date of this offer letter, after accounting for our recent Series B financing. The stock option will be subject to a vesting period such that 25% will vest on September 30, 2019 and an additional 2.0833% shall vest every month thereafter, so that it will be fully vested on September 30, 2022, provided, however, the stock option shall be subject to customary double-trigger acceleration such that it shall vest fully in the event that your employment is terminated by the Company without cause, or you terminate your employment with the Company for good reason, in each case within six months following a sale of the Parent, as will be described in further detail in the applicable stock option agreement. The stock option will have an exercise price per share equal to no less than the fair market value per share on the date of grant as determined by the Board and shall have a term of ten years. The stock option will be subject in all respects to the Parent's stock incentive plan and form of non-statutory stock option agreement.

Term of Employment; Severance: Subject to the terms and conditions set forth on Exhibit A attached hereto, your employment at all times will be at will, meaning that you are not being offered employment for a definite period. Either you or the Company may terminate the employment relationship, in each case subject to and in accordance with the terms and conditions set forth on Exhibit A, in which case the obligations, if any, of the Company to make any severance payments to you shall be as set forth on Exhibit A.

Employment Eligibility: For purposes of federal immigration law, you will be required to provide to the Company documentary evidence of your identity and eligibility for employment in the United States. Such documentation must be provided to us within three (3) business days of your date of hire, or our employment

relationship with you may be terminated. Our offer is also subject to the completion of a customary background check.

Work Environment: The Company maintains a smoke-free, drug-free workplace policy and supports equal employment opportunities for all of its employees. As a Company employee, you will be expected to abide by the Company's rules and standards.

We also ask that, if you have not already done so, you disclose to the Company any and all agreements relating to your prior employment that may affect your eligibility to be employed by the Company or limit the manner in which you may be employed. It is the Company's understanding that any such agreements will not prevent you from performing the duties of your position and you represent that such is the case.
Moreover , you agree that during the tem1 of your full-time employment with the Company , you will not engage in any other employment, occupation , consulting or other business activity directly related to the business in which the Company is now involved or becomes involved during the term of your employment, nor will you engage in any other activities that conflict with your obligations to the Company. Similarly, you agree not to bring any third-party confidential information to the Company, including that of your former employer, and that in performing your duties for the Company you will not in any way utilize any such information.

As a condition of your employment, you are also required to sign and comply with a Non-Dis closure , Non Solicitation and Assignment of Intellectual Property Agreement which requires, among other provisions, the assignment of patent rights to any invention made as part of the scope of your employment at the Company, non-disclosure of Company proprietary information and an agreement not to solicit Company personnel or customers through the twelve-month period following the termination of your employment. Please note that we must receive your signed Agreement before your first day of employment.

Please indicate your acceptance of this offer by signing below and returning a signed copy of this letter to my attention on or before December 17, 2018.

The Company is incredibly excited about your joining and we are looking forward to working with you to build Morphic Therapeutic. Please contact me if you have any questions or need more information.

Sincere ly,

Morphic Therapeutic, Inc.

/s/ Robert E. Farrell Jr.CPA
By: Robert E. Farrell Jr.CPA
Its: VP Finance & Operations

Accepted and agreed:

/s/ William DeVaul
William DeVaul

Date December 17, 2018

Exhibit A

Termination, Severance

1. Termination.

1.1 Termination By the Company Without Cause: The Company may terminate your employment with the Company for any reason, which need not be disclosed to you, effective following 30 days' written notice. In the event of termination under this Section 1.1 of this Exhibit A, you shall be entitled to the compensation and benefits specified in Section 2, below. In its sole and exclusive discretion, the Company will determine whether to require that you perform your duties for the Company during that notice period. However, you shall receive your salary for the entire duration of the 30-day notice period.

1.2 Termination By the Company For Cause: The Company may terminate your employment for cause. For purposes of this Agreement, the tern "for cause" means: (i) engaging in theft, fraud and/or dishonesty which, in the judgment of the Board, could be harmful to the Company; (ii) gross negligence or willful misconduct in the performance of your assigned duties; (iii) gross neglect or willful refusal to attend to the material responsibilities assigned to you; (iv) your material breach of this Agreement; (v) conviction (or a plea of no contest or similar plea or the entry of an order or judgment that requires a determination of guilt or responsibility) of a felony or for any crime involving moral turpitude or dishonesty; (vi) knowingly providing or making untruthful or misleading statements to the Company, whether by commission or omission; (vii) any willful failure to carry out a specific written directive of the Board; or (viii) an intentional violation of any of the Company's material policies or procedures, including without limitation any equal employment opportunity or anti-harassment policies. In the event the Company believes that you have engaged in conduct that constitutes "cause" under clause (iv) above (a material breach of this Agreement), such conduct shall not be considered grounds for terminating your employment until the Company has provided you with written notice from the detailing the manner in which it believes your conduct violates such clause (iv) and you have been given 30 days in which to cure such violation. Nothing contained in this Section 1.2 shall in any way waive, restrict or prejudice the Company's rights and remedies in equity and at law with respect to the matter for which your employment under this Agreement may be terminated for cause. In the event of termination for cause under this Section 1.2, you shall not be entitled to any of the compensation or benefits described in Section 2 of this Exhibit A.

1.3 By You For Good Reason: You may terminate your employment with the Company for good reason upon providing 30 days written notice to the Board. For purposes of this Agreement, "good reason" shall mean any of the following: (i) a reduction in the amount of your then current salary without your prior written consent (exclusive of a reduction that is made in conjunction with a reduction for the Company's executives as a group or to its employees generally); (ii) a material diminution in your position, authority, duties, responsibilities or direct reporting relationship with the Board without your prior written consent; (iii) the relocation of the Company's headquarters or your assigned place of work more than 45 miles from Boston, MA; or (iv) any failure by the Company, without your prior written consent, to comply with any of the provisions of this Agreement which failure is not remedied by the Company within 30 days of receipt from you of written notice thereof In the event of termination of your employment with the Company for good reason under this Section 1.3 of this Exhibit A, you shall be entitled to the compensation and benefits specified in Section 2 of this Exhibit A.

1.4 Termination By You Without Good Reason: You may terminate your employment with the Company without good reason effective 30 days after providing written notice to the Board. In its sole and exclusive discretion, the Board will determine whether to require that you perform your duties for the Company during that notice period provided that you will be paid for the full notice period if relieved of your duties prior to the conclusion of the notice period. In the event of termination of your employment with the Company without good reason under this Section 1.4 of this Exhibit A, you shall not be entitled to any of the compensation or benefits described in Section 2 of this Exhibit A.

2. Severance. If this Agreement is terminated by the Company pursuant to Section 1.1 of this Exhibit A, or by you pursuant to Section 1.3 of this Exhibit A, subject to execution and delivery by you and the Company of a mutually agreed general release agreement and a mutually agreed non-competition agreement pursuant to which you will agree not to compete with the Company for the period of one year following the termination of your employment, you shall be entitled to receive payments equal to nine (9) months' base salary at the then current level (exclusive of payment of earned bonuses and any pro rata bonus payment based on your annual target bonus for that year, which bonuses, if any, shall be determined and paid in accordance with the terms and conditions of this Agreement) with such payments to be treated as post employment severance pay. In addition, the Company will pay any applicable COBRA premium for six additional months for you, after which you will assume responsibility for payment, if continuation is desired. Any post-employment severance pay shall be paid monthly except that the last such payment shall be no later than March 15 of the year following the year of termination of employment, with any remaining payments to be paid in a lump sum on or before such date. Post-employment severance pay shall not be treated as compensation for qualified plan or other employee benefit purposes.

3. Publicity. You and the Company will mutually agree upon any communications within the Company or to the public regarding the termination of your employment with the Company.

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MORPHIC HOLDING, INC.

CONSULTING AGREEMENT
(Timothy A. Springer, Ph.D.)

This Consulting Agreement (this "**Agreement**") is made effective as of December 5, 2019. In consideration for retaining Timothy A. Springer, Ph.D. ("**Consultant**") by Morphic Holding, Inc., (the "**Company**"), a Delaware corporation. For good and valuable consideration, the parties hereby agree as follows:

1. Retention as Consultant; Services. The Company hereby retains Consultant and Consultant hereby agrees to perform such consulting services for the Company (or for any of its subsidiaries designated by the Company to receive such services) as the Company or any such subsidiary may from time to time reasonably request (the "**Services**"), including the services specified on Schedule A attached hereto.

2. Availability; Time Commitment. Consultant will make himself available to render the Services, at such time or times and location or locations as may be mutually agreed, from time to time as requested by the Company or by its designated subsidiary, or as necessary to fulfill his duties. Consultant will devote his best efforts to performing the Services. Consultant will devote at least eight (8) days per year to performing the Services.

3. Compensation. Pursuant to the terms of the Company's 2019 Equity Incentive Plan (the "Plan") and a Notice of Stock Option Grant and Stock Option Agreement (the "Option Agreement"), the Company shall provide Consultant an option to purchase 90,000 shares of common stock of the Company (the "Option Award"). The Option Award shall vest 25% of the total number of shares on the first anniversary of the date of grant and the remaining 75% of the total number of shares will vest across eight (8) substantially equal quarterly installments on each quarterly anniversary of the first anniversary of the date of grant, such that the total number of shares would become fully vested and exercisable on the three-year anniversary of the date of grant, subject to the continued service of the Consultant on each applicable vesting date. The Option Agreement shall contain the specific terms and conditions for the Option Award provided for this Consulting Agreement and shall prevail in the event of any inconsistency with this Consulting Agreement.

4. Relationship of Consultant to Others.

4.1. The Company recognizes that as of the date first written above Consultant is a member of the faculty of Boston Children's Hospital ("**BCH**") and Harvard Medical School, and may become a member of or contributor to other not-for-profit institutions or associations in the future (the "**Institutions**"), and that Consultant's activities are and will be subject to the policies and regulations of the Institutions (the "**Applicable Policies**").

4.2. Consultant and Company agree to abide by the BCH Mandatory Uniform Consulting Terms as incorporated into this Agreement as Exhibit A and to provide Services which fall, at all times, outside the "Scope of BCH Activities" as set forth on Exhibit A.

4.3. Consultant agrees not to solicit employees of the Company or any Company subsidiary to become Consultant or BCH employees. Consultant further agrees not to enter into any agreement with an entity which may reasonably be considered a Company competitor, to the extent that the agreement would embrace services which would overlap with the Services described herein.

4.4. During the term of this Agreement, Consultant will not directly or indirectly (i) provide advice or services to any for-profit third party in the Field (as defined on Schedule A), or (ii) become an owner, partner, shareholder, consultant, agent, employee or co-venturer of any for-profit third party that has committed or intends to commit (by itself or through any affiliates or collaborators) resources to the Field (other than in Consultant's capacity as a holder of not more than one percent (1%) of the combined voting power of the outstanding stock of such a third party that is a publicly held company). The foregoing restrictions will not prohibit Consultant from providing any services, including but not limited to conducting research at or providing educational services to an Institution.

4.5. During the term of this Agreement and for one (1) year thereafter, Consultant will not (i) solicit, encourage, or take any other action which is intended to induce any employee of, or consultant to, the Company or any Company subsidiary to terminate his or her relationship with the Company or with such subsidiary, or (ii) solicit, endeavor to entice away from the Company or any Company Subsidiary or otherwise interfere with the relationship of the Company or any Company subsidiary with any third party who is, or was within the then-most recent twelve month period, a licensor to or customer, collaborator or licensee of the Company or any Company subsidiary.

5. Intellectual Property.

5.1. Subject to the BCH Mandatory Uniform Consulting Terms, Consultant will promptly disclose in confidence to the Company all inventions, discoveries, ideas, concepts, processes, products, formulas, trademarks, service marks, logos, computer programs or software, source codes, object codes, algorithms, machines, apparatuses, items of manufacture or compositions of matter, or any new uses therefor or improvements thereon, or any new designs or modifications or configurations of any kinds or works of authorship of any kind, including, without limitation, compilations and derivative works, whether or not patentable or copyrightable and know-how that Consultant makes, conceives, develops or reduces to practice, from the effective date of this Agreement through the expiration or termination of this Agreement and for six (6) months thereafter, and that (i) arise from the Services or other work performed by Consultant for the Company, or (ii) arise from use of facilities, equipment, supplies, materials or Confidential Information of the Company, (along with all patent and other intellectual property rights arising therefrom, collectively, "**Developments**"). Consultant will neither make any use of any funds, space, personnel, facilities, equipment or other resources of any Institution or other third party in performing the Services hereunder nor take any other action that would result in any Institution or other third party owning or having a right in any Developments under the Applicable Policies or otherwise.

5.2. Consultant will make and maintain adequate and current written records of all Developments, which records will be available to and remain the property of the Company at all times. All Developments will be the sole property of the Company. For purposes of the copyright laws of the United States, all Developments will constitute works made for hire as applicable. Consultant hereby assigns and, to the extent any such assignment cannot be made at present, hereby agrees to assign to the Company, without further compensation, all right, title and interest in and to all Developments.

5.3. Consultant will assist the Company in any reasonable manner to obtain for its own benefit patent and other intellectual property rights in any and all countries with respect to the Developments, and Consultant will execute and deliver, when requested, patent and other applications and assignments therefor. Consultant will further assist the Company in every way to enforce any such patent rights and other rights, including testifying in any suit or proceeding.

Consultant will perform Consultant's obligations under this Section without further compensation, except for reimbursement of expenses incurred at the Company's request and, with respect to any performance after the term of this Agreement or in excess of Consultant's time commitment during the term of this Agreement (other than reviewing and executing documents), compensation at a reasonable rate for time actually spent by Consultant at the Company's request. In the event the Company is unable after reasonable effort to obtain Consultant's signature on any document which Consultant may be required to sign pursuant to this Section, whether because of Consultant's physical or mental incapacity or for any other reason whatsoever, Consultant hereby irrevocably appoints each of the President and the Secretary of the Company (whether now or hereafter in office) as Consultant's attorney-in-fact to execute any such document on Consultant's behalf.

5.4. Consultant shall not, in connection with the Services to be performed under this Agreement, disclose to Company any information which is confidential or proprietary to Consultant or any third party including but not limited to any Institution.

6. Confidential Information.

6.1. As used in this Agreement, "**Confidential Information**" means all trade secrets, inventions, Developments and confidential or proprietary or other information owned, possessed or used by the Company or any Company subsidiary whether prepared, conceived or developed by a consultant or employee of the Company (including Consultant in the course of performing the Services), including (i) all Developments, know-how, technology, business strategies and plans, financial, technical or business information, personnel information and customer lists (an any tangible evidence, record or representation thereof) of the Company and its subsidiaries, (ii) all materials furnished by the Company or its subsidiaries, and (iii) all information of third parties that the Company or any Company subsidiary has an obligation to keep confidential. In addition, the terms and conditions of this Agreement will be treated by Consultant as Confidential Information hereunder, provided that such terms and conditions may be disclosed to an Institution upon its request.

6.2. During the term of this Agreement and at all times thereafter, Consultant will keep and hold all Confidential Information in strict confidence, and Consultant will not use or disclose any of such Confidential Information without the prior written consent, and with the authorization, of the Company, except as may be necessary to perform the Services. Consultant will not disclose to the Company or any Company Subsidiary, or induce the Company or any Company Subsidiary to use any confidential information or material belonging to any third party. In the event that Consultant is authorized to disclose any Confidential Information to anyone outside the Company or its subsidiaries in performing the Services, Consultant will take adequate steps, consistent with the policies and practices of the Company, to require that the recipient maintain the confidentiality of the Confidential Information.

6.3. The term "Confidential Information" hereunder will not include information that Consultant can establish by competent written evidence (i) is or becomes generally known within the Company's industry through no fault of Consultant; (ii) was known to Consultant at the time it was disclosed, (iii) is lawfully and in good faith made available to Consultant by a third party who did not derive it from the Company or any Company subsidiary and who imposes no obligation of confidence on Consultant; or (iv) is required to be disclosed by order of a governmental authority or a court of competent jurisdiction, provided that such disclosure is subject to all applicable governmental or judicial protection available for like material and reasonable advance notice of the pendency of any such order is given to the Company. For the purpose of this Section, Confidential Information will not be deemed to fall within any of the foregoing exceptions merely because such

information is embraced by general disclosures or because individual features or combinations thereof are publicly available.

6.4. Upon termination of this Agreement or at any other time upon the request of the Company, Consultant will promptly deliver to the Company all records and materials documenting, evidencing or embodying any Confidential Information.

7. No Conflicts.

7.1. Consultant agrees to the best of his knowledge that Consultant is permitted to enter into this Agreement and to perform the obligations contemplated hereby, and that this Agreement and the terms and obligations hereof are not inconsistent or otherwise in conflict with any other obligations Consultant may have, under and as modified by the Applicable Policies or otherwise. In addition, Consultant will not enter into any agreement or modification of any existing agreement (whether written or oral) that are inconsistent with or otherwise conflict with Consultant's obligations under this Agreement.

7.2. Consultant represents and warrants that Consultant has disclosed to the Institutions all aspects of Consultant's relationship with the Company which are required to be disclosed under the Applicable Policies, and that Consultant has obtained any required consents or approvals of the Institutions concerning such relationship and this Agreement.

8. Publication.

Consultant shall not publish Confidential Information.

9. Term and Termination.

9.1. Subject to earlier termination as expressly provided herein, this Agreement will commence on the date first written above and will continue until the third anniversary of that date. If either party breaches in any material respect any of its material obligations under this Agreement, in addition to any other right or remedy, the non-breaching party may terminate this Agreement in the event that the breach is not cured within thirty days after receipt by such party of written notice of such breach. Either party may terminate this Agreement for convenience, but only upon six months advance written notice to the other party.

9.2. No expiration or termination of this Agreement will relieve or affect any rights or liabilities of the parties which may have accrued prior to the date of expiration or termination. Notwithstanding anything herein to the contrary, upon any expiration or termination of this Agreement, the provisions of Sections 5, 6, 7, 8, 9 and 10 will survive such expiration or termination and continue in effect in accordance with their terms.

10. General.

10.1. Consultant recognizes that, in the event of a breach or threatened breach by Consultant of this Agreement, the Company may suffer irreparable harm, and Consultant therefore agrees that, in addition to all other rights and remedies available to the Company at law or in equity, the Company will be entitled to seek injunctive relief to restrain any such breach and to enforce the provisions hereof, without showing or proving any actual damage to the Company.

10.2. The Services to be rendered by Consultant are personal in nature, and Consultant may not assign or transfer this Agreement or any of Consultant's rights or obligations. In no event will Consultant assign or delegate responsibility for actual performance of the Services. Company may not assign or otherwise transfer this Agreement without the prior written consent of Consultant, except to any wholly owned subsidiary of the Company or in connection with the sale of substantially all of the Company's assets, including by way of merger, asset sale, stock sale, or other transaction type having the same purpose. This Agreement will be binding upon and inure to the benefit of the parties and their respective legal representatives, heirs, successors and permitted assigns.

10.3. All notices and other communications hereunder will be delivered by hand or sent by registered or certified mail, or by reputable package delivery service, return receipt requested, addressed to the Company at its regular place of business or to Consultant at the address set forth below, or to such other address as such party may designate in writing to the other.

10.4. This Agreement, together with Schedule A and Exhibit A attached hereto, constitutes the entire agreement between the parties as to the subject matter hereof, and supersedes any previous oral or written communications, representations, understandings, or agreements between them as to such subject matter. No provision of this Agreement will be waived, altered or canceled except in writing signed by the party against whom such waiver, alteration or cancellation is asserted. Any such waiver will be limited to particular instance and the particular time when and for which it is given.

10.5. It is understood and agreed that Consultant's relationship to the Company is that of an independent contractor and that neither this Agreement nor the Services to be rendered hereunder will for any purpose whatsoever or in any way or manner create any employer-employee relationship between the parties. Consultant understands that Consultant will not be entitled to participate in or to receive any benefit or right under any of the Company's employee benefit, welfare or like plans. Consultant will be responsible for paying all withholding and other taxes arising from consideration payable by Company hereunder when they become due and payable.

10.6. During the term of this Agreement and at all times thereafter, Consultant will execute and deliver all such documents and will perform all such lawful acts, as the Company considers necessary or advisable to secure its rights hereunder and to carry out the intent of this Agreement.

10.7. This Agreement will be governed by, and construed and enforced in accordance with, the laws of The Commonwealth of Massachusetts, without regard to its principles of conflicts of laws. All litigation arising from or relating to this Agreement will be filed and prosecuted before any court of competent subject matter jurisdiction in Boston, Massachusetts. Consultant hereby consents to the jurisdiction of such courts over him, stipulates to the convenience, efficiency and fairness of proceeding in such courts, and covenants not to allege or assert the inconvenience, inefficiency or unfairness of proceeding in such courts.

10.8. The invalidity or unenforceability of any provision hereof as to an obligation of a party will in no way affect the validity or enforceability of any other provision of this Agreement, provided that if such invalidity or unenforceability materially adversely affects the benefits the other party reasonably expected to receive hereunder, that party will have the right to terminate this Agreement. Moreover, if one or more of the provisions contained in this Agreement will for any reason be held to be excessively broad as to scope, activity or subject so as to be unenforceable at law, such provision or provisions will be construed by limiting or reducing it or them, so as to be enforceable to the extent compatible with the then-applicable law.

10.9. The titles and headings herein are for reference purposes only and will not in any manner limit the construction of this Agreement which will be considered as a whole. As used in this Agreement, "herein" and "hereof" will refer to this Agreement as a whole, and "including" and "include" means "including but not limited to" and "includes, without limitation", respectively. This Agreement will not be interpreted or construed against a party because that party or any attorney or representative for that party drafted or participated in the drafting of this Agreement.

IN WITNESS WHEREOF, the parties hereto have duly executed this Consulting Agreement under seal as of the date first set forth above.

Morphic Holding, Inc.		Consultant	
By:	/s/ Praveen Tipirneni	By:	/s/ Timothy A. Springer, Ph.D.
Name:	Praveen Tipirneni	Name:	Timothy A. Springer, Ph.D.
Title:	President		

SCHEDULE A
SERVICES AND FIELD

"**Field**" means research, discovery, design, manufacture, clinical development, seeking of regulatory approvals, marketing and/or commercialization of small molecules that target any member of the integrin family of cell adhesion molecules.

Specific Services will include:

- Contribute to the development of the R&D plan of the Company or its designated subsidiaries
- Contribute to the development of the patent rights and other intellectual property of the Company or its designated subsidiaries
- At the Company's request, participate in the Company's strategic planning (or that of its designated subsidiaries) and attend Scientific Advisory Board meetings of the Company or its designated subsidiaries, including as co-chair of the Scientific Advisory Board meetings
- Be available to represent the Company or its designated subsidiaries to investors and potential partners

EXHIBIT A – BCH Mandatory Uniform Consulting Terms.

1. Mandatory and superseding nature of these terms

These terms must be attached to and incorporated into any personal Consulting Agreement that involves services by any member of the medical or research staff, or any officer or employee, of Boston Children's Hospital or its supporting affiliated foundations (collectively referred to as BCH). They apply regardless of the nature of the consulting services, and regardless of the corporate or other nature of the other party to the consulting agreement. They are incorporated in and enforceable as a term and condition of the Consulting Agreement; supersede any conflicting provisions; and may not be limited, amended or superseded by any other agreement. They are not negotiable.

2. Definitions

(a) Consultant: the BCH staff member, officer of employee who is a party to the consulting agreement.
(b) Consulting Agreement: the set of agreements, oral and written, that together comprise the complete set of rights and obligations between the Consultant and the Company.
(c) Company: the party or parties retaining the Consultant, and any other third party referred to in the Consulting Agreement as the recipient of Consultant services or legal obligations.
(d) Services: the services included within the Consulting Agreement.
(e) HMS: Harvard Medical School.
(f) Scope of BCH Activities: (1) any activities undertaken by Consultant at BCH or using BCH resources (excluding de minimis uses of BCH computer resources, e-mail, calendaring, and telephone); and (2) any activities described within the professional role of the Consultant at BCH, or by BCH, its departments or divisions, as reflected in (i) activities actually or historically undertaken by Consultant at their request or direction or on their behalf; (ii) obligations, whether or not currently undertaken, under directives and assignments of the pertinent chief, the terms of appointment, the Consultant's job description, sponsored research agreements, customary responsibilities, and other indicators of expectations for the scope of Consultant's BCH or HMS role.
(g) BCH and HMS Policies: Policies of BCH, its departments and divisions, and of HMS if Consultant is a member of the HMS faculty, concerning ethical conduct, conflicts of interest, intellectual property, confidentiality, compliance with federal and state laws, regulations and policies, and any other matter relating to the Consultant's appointment or employment.

3. Supremacy of Consultant's BCH and HMS Obligations

Company acknowledges that Consultant has pre-existing and on-going obligations to HMS, BCH, and the sponsors of research at BCH (including obligations under BCH and HMS Policies, grants, contracts, collaborative agreements, and a "participation agreement" assigning to BCH all inventions within the Scope of BCH Activities). In order to enter into this Consulting Agreement, Company therefore acknowledges and agrees that in the event that any conflict should arise between the Consulting Agreement and Consultant's obligations to HMS, BCH or sponsors of research at BCH, Consultant shall necessarily notify BCH immediately, and that Consultant's obligations to BCH, HMS and sponsors of research at BCH shall take precedence over the terms of the Consulting Agreement. Without limiting the foregoing, Company shall have no rights in any publication, invention, discovery, improvement, or other intellectual property whatsoever, whether or not publishable, patentable, or copyrightable, developed by

Consultant *in whole or in part* within the Scope of BCH Activities, even if arising in part from Services. It is understood that the Scope of BCH Activities may change from time to time, and the Consulting Agreement may not restrict such changes. Services shall exclude disclosure of information derived from the Scope of BCH Activities of Consultant, and information that is confidential under BCH and HMS Policy. Services for the Company shall consist only of the exchange of ideas and provision of advice. Consultant shall not conduct research for or on behalf of the Company, act as a Company executive, or take a position with Company that entails fiduciary obligations to Company in conflict with primary obligations to BCH.

4. Assignment of Consultant Intellectual Property

Subject to the terms of paragraph 3, above, it is the Consultant's own choice whether to assign, or to decline to assign, to the Company any right, title and interest the Consultant may have in any invention, discovery, improvement, or other intellectual property that Consultant develops in the course of and arising from Consultant performing Services for the Company under the Consulting Agreement.

5. Confidentiality and Disclosure

The Consulting Agreement shall not restrict the Consultant from disclosing to BCH, Consultant's department or division chief, and other staff or employees of BCH to whom disclosure of Consulting Agreements is required, any aspect of the Consulting Agreement, including an unredacted copy of the Consulting Agreement, compensation and reimbursement paid to Consultant in any form, the nature of Services actually provided, and, for purposes of assessing compliance with paragraph 3 of Exhibit A, any intellectual property disclosed by Consultant to Company. BCH, and all BCH staff and employees to whom it is disclosed, shall treat such information as confidential business information under BCH policies.

6. No Consultant Warranties.

Any provision of the Consulting Agreement purporting to impose a warranty obligation on Consultant is superseded and void. Without limiting the foregoing: Consultant shall use reasonable efforts not to use any facilities, funds, or equipment owned or administered by BCH in the performance of the Services. Any provision of the Consultant Agreement which imposes a higher obligation is void and superseded by this provision.

7. Non-competition

Company and Consultant may agree on provisions which restrict Consultant from soliciting Company's employees to become Consultant employees. However, any provision requiring Consultant to refrain from entering into agreements with competing organizations, to the extent it relates to or overlaps the present or future Scope of BCH Activities, is void.

8. Use of names, depictions and logos

Company shall not use Consultant's name or depiction, or the name, logos, trademarks, or depictions of BCH, HMS, or any officer, director, employee, appointee, medical staff member or employee of either, or any adaptation thereof, in any promotional, advertising or marketing literature, or in any other way without the prior written consent of BCH, the individual, or HMS, as appropriate, provided however that in neutral circumstances that do not imply endorsement or advocacy, or otherwise misrepresent the terms of the Consulting Agreement or Consultant's role, Company may accurately state that Consultant is a consultant to Company, and list his or her professional degrees and titles.

9. Consultant's personal activity.

Each party to the Consulting Agreement acknowledges that Consultant is entering into the Agreement, and providing Services, in the Consultant's personal capacity and not as an employee or agent of BCH; BCH is not a party to the Consulting Agreement and has no liability or obligation thereunder except as its own policies create an obligation of confidentiality as described in paragraph 5; and BCH is an intended, third-party beneficiary of this Agreement, and certain provisions of this Agreement are for the benefit of BCH and are enforceable by BCH in its own name.

10. Termination

In addition to any provision for termination, the Consulting Agreement shall be terminable without cause on thirty days notice at the request of the BCH Office of General Counsel, operating on the request of the Consultant's department or division chief or supervisor.

Exhibit 21.1

Subsidiaries of Morphic Holding, Inc.

Name of Subsidiary	Jurisdiction
Morphic Therapeutic, Inc.	Delaware
Morphic Security Corporation	Massachusetts

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the Registration Statement (Form S-8, File No. 333-232372) pertaining to the 2019 Equity Incentive Plan, 2019 Employee Stock Purchase Plan, and the 2018 Stock Incentive Plan of Morphic Holding, Inc. of our report dated February 27, 2020, with respect to the consolidated financial statements of Morphic Holding Inc. included in this Annual Report (Form 10-K) for the year ended December 31, 2019.

/s/ Ernst & Young LLP

Boston, Massachusetts
February 27, 2020

EXHIBIT 31.1

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

I, Praveen P. Tipirneni, certify that:

1. I have reviewed this annual report on Form 10-K of Morphic Holding, 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)) 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) 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

   (c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 27, 2020

/s/ Praveen P. Tipirneni
Praveen P. Tipirneni, M.D.
President, Chief Executive Officer and Director
(Principal Executive Officer)

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

I, Robert E. Farrell, Jr., certify that:

1. I have reviewed this annual report on Form 10-K of Morphing Holding, 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)) 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) 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

   (c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 27, 2020

/s/ Robert E. Farrell, Jr.
Robert E. Farrell, Jr., CPA
Senior Vice President of Finance and Chief Accounting Officer
(Principal Accounting and Financial Officer)

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

I, Praveen P. Tipirneni, Chief Executive Officer of Morphic Holding, Inc. (the "Company"), do hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

1. the Annual Report on Form 10-K of the Company for the fiscal year ended December 31, 2019 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

2. the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: February 27, 2020

/s/ Praveen P. Tipirneni
Praveen P. Tipirneni, M.D.
President, Chief Executive Officer and Director
(Principal Executive Officer)

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

I, Robert E. Farrell, Jr., Senior Vice President of Finance and Chief Accounting Officer of Morphic Holding, Inc. (the "Company"), do hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

1. the Annual Report on Form 10-K of the Company for the fiscal year ended December 31, 2019 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

2. the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: February 27, 2020

/s/ Robert E. Farrell, Jr.
Robert E. Farrell, Jr., CPA
Senior Vice President of Finance and Chief Accounting Officer
(Principal Accounting and Financial Officer)