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

FORM 10-K

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

For the fiscal year ended December 31, 2020

OR

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

FOR THE TRANSITION PERIOD FROM____ TO____

Commission File Number: 001-37985

ANAPTYSBIO, INC.
(Exact name of registrant as specified in its charter)

Delaware	**20-3828755**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification Number)**

10421 Pacific Center Court, Suite 200
San Diego, CA 92121
(Address of principal executive offices and zip code)

(858) 362-6295
(Registrant's telephone number, including area code)

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.001 par value	ANAB	The Nasdaq Stock Market LLC

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

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

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 (§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 has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

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

The aggregate market value of voting common equity held by non-affiliates of the registrant was $555,993,474 as of June 30, 2020.

The number of shares of Registrant's Common Stock outstanding was 27,366,405 as of February 23, 2021.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's Definitive Proxy Statement relating to the 2021 Annual Meeting of Shareholders, scheduled to be held on June 17, 2021, are incorporated by reference into Part III of this Annual Report on Form 10-K to the extent stated herein. The Definitive Proxy Statement will be filed within 120 days of the Registrant's fiscal year ended December 31, 2020. Except with respect to information specifically incorporated by reference in this Form 10-K, the Proxy Statement is not deemed to be filed as part of this Form 10-K.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K ("Annual Report") contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and section 27A of the Securities Act of 1933, as amended (the "Securities Act"). The words "believe," "may," "will," "potentially," "estimate," "continue," "anticipate," "intend," "could," "would," "project," "plan," and "expect," and similar expressions that convey uncertainty of future events or outcomes, are intended to identify forward-looking statements.

The forward-looking statements in this report include, among other things, statements about:

- the success, cost, and timing of our product candidate development activities and ongoing and planned clinical trials;
- our plans to develop and commercialize antibodies, including our lead product candidate: imsidolimab for patients with generalized pustular psoriasis ("GPP") and palmoplantar pustulosis ("PPP");
- the impact of the coronavirus ("COVID-19") pandemic on our business and the United States ("U.S.") and global economies;
- the likelihood that the clinical data generated in any study we performed, are performing, or plan to perform in a non-U.S. jurisdiction will be subsequently accepted by the U.S. Food and Drug Administration ("FDA") and/or by foreign regulatory authorities outside of the jurisdiction where the study was being performed;
- the timing and ability of our collaborators to develop and commercialize our partnered product candidates;
- the potential benefits and advantages of our product candidates and approaches versus those of our competitors;
- our ability to execute on our strategy, including advancing our lead product candidates, identifying emerging opportunities in key therapeutic areas, continuing to expand our wholly-owned pipeline, and retaining rights to strategic products in key commercial markets;
- our ability to obtain funding for our operations, including funding necessary to complete further development and commercialization of our product candidates;
- the timing of and our ability to obtain and maintain regulatory approvals for imsidolimab and our other product candidates;
- our ability to develop our product candidates;
- the rate and degree of market acceptance and clinical utility of any approved product candidates;
- the size and growth potential of the markets for any approved product candidates, and our ability to serve those markets;
- our commercialization, marketing, and manufacturing capabilities and strategy;
- our expectations regarding our ability to obtain and maintain intellectual property protection for our product candidates;
- regulatory developments in the U.S., the United Kingdom, Australia, and other foreign countries;
- the success of competing therapies that are or may become available;
- our ability to attract and retain key scientific or management personnel;
- our use of the net proceeds from our public offerings;
- our ability to identify additional products or product candidates with significant commercial potential that are consistent with our commercial objectives; and
- our estimates regarding expenses, future revenue, capital requirements, and needs for additional financing.

These forward-looking statements are subject to a number of risks, uncertainties, and assumptions, including those described in Item 1A, "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 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.

Unless the context indicates otherwise, as used in this Annual Report, the terms "AnaptysBio," "company," "we," "us" and "our" refer to AnaptysBio, Inc., a Delaware corporation, and its subsidiaries taken as a whole, unless otherwise noted. AnaptysBio is our common law trademark. 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.

PART I

Item 1. Business

Overview

We are a clinical stage biotechnology company developing first-in-class immunology therapeutic product candidates focused on emerging immune control mechanisms applicable to inflammation and immuno-oncology indications. We develop our product candidates using our proprietary antibody discovery technology platform, which is based upon a breakthrough understanding of the natural process of antibody generation, known as somatic hypermutation ("SHM"), and replicates this natural process of antibody generation *in vitro*. Our strategy is to advance the development of our proprietary product candidates, and where applicable, establish partnerships with leading biopharmaceutical companies where we retain certain development and commercialization rights. Our most advanced wholly-owned antibody programs, imsidolimab, ANB030 and ANB032, are designed to modulate therapeutic targets that are genetically associated with human inflammatory disorders.

Imsidolimab, our IL-36R antibody previously referred to as ANB019, inhibits the interleukin-36 receptor ("IL-36R"), and is being developed for the treatment of multiple dermatological inflammatory diseases. We completed a Phase 1 clinical trial in healthy volunteers, which was presented at the European Academy of Allergy and Clinical Immunology in 2018, where imsidolimab was well-tolerated by all subjects, no dose-limiting toxicities were observed, and no serious adverse events were reported among any subjects in the clinical trial. In July 2020, the U.S. Food and Drug Administration (the "FDA") granted Orphan Drug Designation for imsidolimab for the treatment of patients with GPP. We are conducting an open-label, multi-dose, single-arm Phase 2 clinical trial of imsidolimab in 8 GPP patients, also referred to as the GALLOP clinical trial, where we announced positive topline data in October 2020. Six of 8 (75%) patients treated with imsidolimab monotherapy achieved the primary endpoint of improvement in the clinical global impression scale ("CGI") on Day 29. Two of 8 (25%) patients were considered to have not met the primary endpoint because they dropped out of the clinical trial prior to Day 29. The modified Japanese Dermatology Association Severity Index ("mJDA-SI") score, which incorporates both dermatological and systemic aspects of GPP, decreased on average by 29% on Day 8 and 54% on Day 29. Erythema with skin pustules, which clinically defines GPP, decreased by 60% on Day 8 and 94% on Day 29. Serum c-reactive protein ("CRP"), which is an indicator of systemic inflammation, was normal (less than 5 mg/L) for 5 of the 6 patients achieving the primary endpoint on Day 29. Genotypic testing indicated homozygous wild-type IL-36RN, CARD14 and AP1S3 alleles for all 8 patients. We believe this suggests that imsidolimab may be broadly applicable to pustular diseases irrespective of genetic drivers. Anti-drug antibodies were not detected as of Day 29 in any patient. Imsidolimab was generally well-tolerated, and most treatment-emergent adverse events were mild to moderate in severity and resolved without sequelae. No infusion or injection site reactions were observed. One patient dropped out of the trial due to a diagnosis of Staphylococcal aureus bacteremia in the first week, which was a serious adverse event deemed to be possibly drug-related. Because the patient was symptomatic prior to dosing and had a prior medical history of bacteremia, a common comorbidity of GPP, we do not believe this event is likely attributable to imsidolimab. Another patient dropped out of the study on Day 22 due to investigator reported inadequate efficacy. One patient contracted COVID-19 during the course of the clinical trial, which was mild, unrelated to imsidolimab, and did not lead to study discontinuation. Data from the first two patients to have completed the Day 113 treatment period under this clinical trial, which we announced in September 2019, indicated sustained efficacy in these two patients through Day 113. We plan to report full data from the GALLOP clinical trial at a medical conference in 2021. While initial GPP epidemiology studies suggested at least 3,000 patients in the United States, recent medical claims analyses suggest GPP prevalence in the United States of at least 10,000 patients. We met with the FDA during the fourth quarter of 2020 to review an orphan disease registration plan for imsidolimab for the treatment of GPP and anticipate initiating a Phase 3 clinical trial in mid-2021 following completion of protocol alignment and review of 16-week data from the GALLOP clinical trial by the FDA.

We are also conducting a randomized, double-blind, placebo-controlled 59-patient multi-dose clinical trial of imsidolimab in PPP, also referred to as the POPLAR clinical trial, where enrollment was completed in 2020 and top-line data are anticipated in the first quarter of 2021. The primary endpoint of this clinical trial is change in palmo-plantar pustulosis area severity index (PPPASI) at week 16 relative to baseline. PPP is a non-fatal form of pustular psoriasis that we estimate affects approximately 150,000 patients in the United States alone. We have initiated a global registry of GPP and PPP patients, also referred to as the RADIANCE study, which we anticipate will improve understanding of the patient journey in these two indications and assist in enrollment of future GPP and PPP clinical trials.

We have initiated clinical development of imsidolimab for the treatment of skin toxicities associated with treatments with inhibitors of epidermal growth factor ("EGFRi") and MAPK/ERK kinase ("MEKi"). Treatment of solid tumors with EGFRi and/or MEKi is frequently limited by the occurrence of skin toxicities, including acneiform or papulopustular rash. Recent translational data has suggested that these skin toxicities are mediated by excess IL-36 signaling, leading to IL-8-mediated cutaneous neutrophilia and acneiform rash. Based on existing claims data, approximately 60,000 patients are prescribed EGFRi and/or MEKi treatments annually, and the vast majority of these patients experience skin toxicity, which in some cases leads to dose reduction and/or discontinuation of treatment. Current standard-of-care treatments are generally

ineffective in patients with the most severe grades of EGFRi and/or MEKi mediated skin toxicity. During the fourth quarter of 2020, we initiated a Phase 2 clinical trial, called EMERGE, of imsidolimab in combination with EGFRi inhibitors, for the treatment of patients diagnosed with a certain baseline severity of skin toxicity, where 45 patients are randomized 2:1 between imsidolimab and placebo arms, to assess the efficacy of imsidolimab in the treatment of this indication. We anticipate interim top-line data from this clinical trial at the end of 2021.

We have also initiated clinical development of imsidolimab in ichthyosis, which is a family of rare, inherited, dermatological disorders characterized by dry, scaling and thickened skin. Recent human translational studies have suggested that the underlying skin inflammation responsible for ichthyosis is mediated by dysregulated IL-36 signaling, and we believe that imsidolimab treatment may be efficacious in treatment of this condition. Approximately 6,000 patients in the United States are affected with moderate-to-severe levels of ichthyosis, and no approved therapies are available for this disease. We have initiated a Phase 2 clinical trial, called INSPIRE, of imsidolimab in patients with certain baseline severity of ichthyosis, where 24 patients are randomized 2:1 between imsidolimab and placebo arms, and interim top-line data is anticipated in 2022.

We plan to initiate clinical development of imsidolimab in hidradenitis suppurativa, also known as acne inversa, which is a chronic inflammatory skin disease characterized by painful nodules in intertriginous areas that can progress to abscesses, sinus tracks and scarring. Current treatment options for hidradenitis suppurativa, including antibiotics, corticosteroids and anti-TNF therapy, have variable efficacy in moderate-to-severe patients, which often leads to surgery for removal of hidradenitis suppurativa nodules. Human translational studies have demonstrated elevated IL-36 cytokine expression in hidradenitis suppurativa skin biopsies, and we believe treatment of moderate-to-severe hidradenitis suppurativa with imsidolimab may lead to therapeutic benefit for this patient population. Moderate-to-severe hidradenitis suppurativa affects approximately 150,000 adults in the United States. We intend to initiate a Phase 2 clinical trial of imsidolimab in hidradenitis suppurativa, called HARP, in the second quarter of 2021.

We plan to initiate clinical development of imsidolimab in acne, which is the most common skin disorder in the United States, with approximately 7 million patients diagnosed with moderate-to-severe disease. Moderate-to-severe acne typically presents with painful papules, pustules, nodules, cysts and scarring. A key contributing factor to the pathogenesis of acne is the immune response to p. acnes, which is associated with upregulated IL-36 cytokine activity, localized inflammation and neutrophil infiltration of the skin. Existing therapies, including isotretinoin and systemic antibiotics, provide variable efficacy for moderate-to-severe acne patients and have practical limitations to their use given potential for clinically meaningful side effects. We anticipate initiating a Phase 2 clinical trial of imsidolimab, called ACORN, for the treatment of moderate-to-severe acne in the second quarter of 2021.

Our second wholly-owned program, ANB030, is an anti-PD-1 agonist antibody program designed to augment PD-1 signaling through ANB030 treatment to suppress T-cell driven human inflammatory diseases. Genetic mutations in the PD-1 pathway are known to be associated with increased susceptibility to human inflammatory diseases, and hence we believe that ANB030 is applicable to diseases where PD-1 checkpoint receptor function may be under-represented. We presented preclinical data for ANB030 at the Festival of Biologics Annual Meeting in March 2020, including translational data demonstrating i*n vitro* activity of ANB030 in alopecia areata patient samples. We initiated a Phase 1 healthy volunteer clinical trial in the first half of 2020, which is designed to assess the safety, pharmacokinetics and pharmacodynamics of ANB030 in single and multiple ascending dose cohorts. We anticipate top-line data from this Phase 1 clinical trial in mid-2021. We plan to initiate Phase 2 clinical trials of ANB030 in alopecia areata and vitiligo in the second half of 2021.

Our third wholly-owned program is an anti-BTLA modulator antibody, known as ANB032, which is broadly applicable to human inflammatory diseases associated with lymphoid and myeloid immune cell dysregulation. Mutations in the BTLA signaling pathway are associated with human inflammatory disease, and we believe ANB032 silences pro-inflammatory signaling by modulating BTLA binding to HVEM. We filed a Clinical Trial Notification (“CTN”) in Australia for ANB032 during the first quarter of 2021 and anticipate initiating a healthy volunteer Phase 1 trial in the first half of 2021 upon clearance of the CTN. We presented preclinical data regarding ANB032 at the 2020 Federation of Clinical Immunology Societies (FOCIS) Virtual Annual Meeting in October 2020.

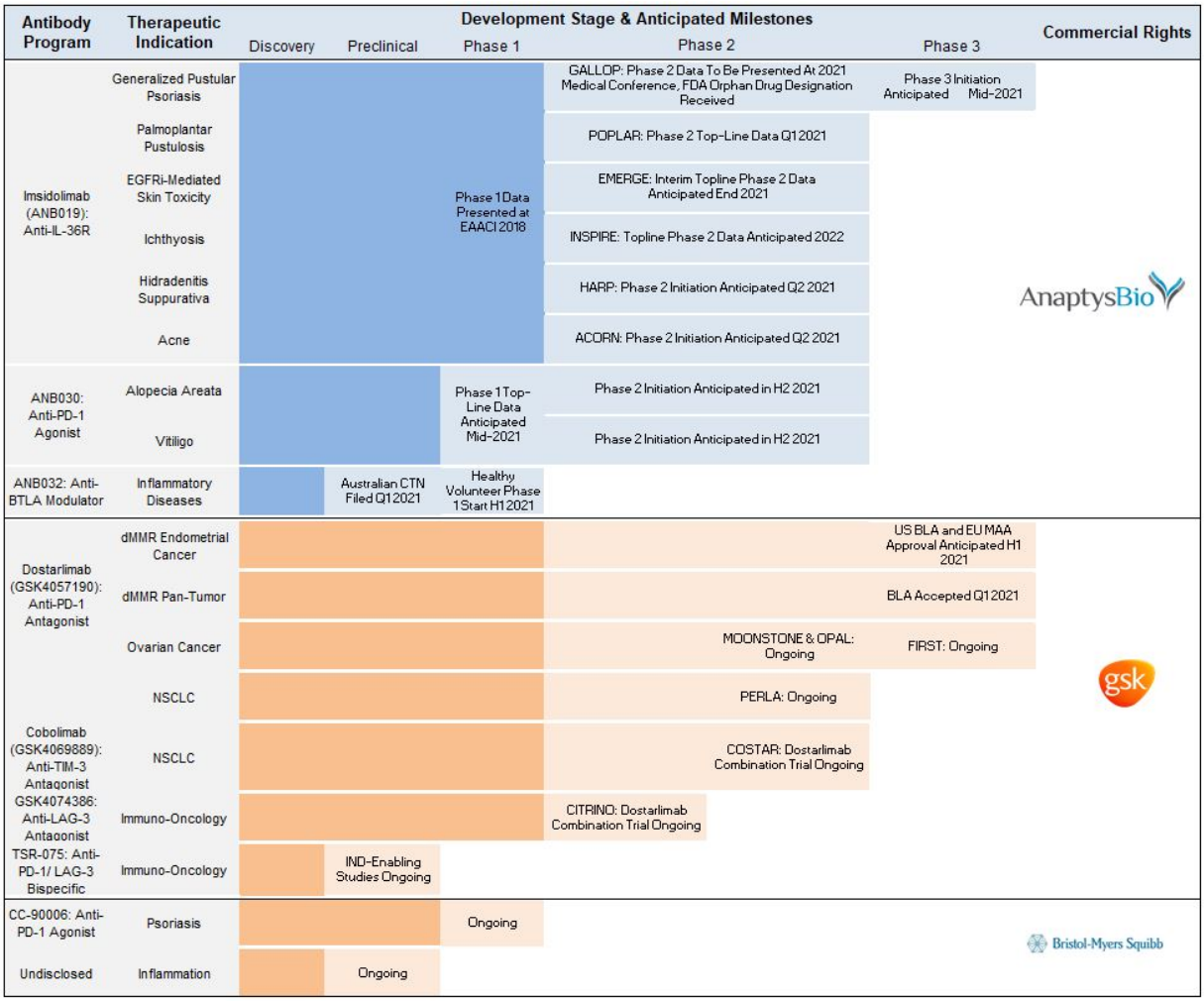
Etokimab, our anti-IL-33 antibody previously referred to as ANB020, inhibits the activity of the interleukin-33 cytokine (“IL-33”). We have conducted a randomized, placebo-controlled Phase 2 clinical trial of etokimab in approximately 100 adult patients with CRSwNP (a debilitating atopic disorder associated with elevated IL-33 pathway signaling), also referred to as the ECLIPSE clinical trial. We recently reported top-line data from a week 16 analysis of the ECLIPSE clinical trial. Patients dosed with etokimab every four (q4w) or eight weeks (q8w) failed to achieve the co-primary endpoints of statistically significant improvement in their bilateral nasal polyps score (“NPS”), an endoscopic measure of nasal occlusion, and in their sino-nasal outcome test (“SNOT-22”), a patient reported quality-of-life assessment, versus placebo at the week 8 time point. Both endpoints demonstrated statistically significant improvement over baseline levels of NPS and SNOT-22. Blood eosinophil levels, which are a biomarker of etokimab’s mechanism, demonstrated statistically significant reduction relative to

baseline in both etokimab treatment arms. Following this data, we have decided to discontinue further development of etokimab.

In addition to our wholly-owned antibody programs, multiple Company-developed antibody programs have been advanced to preclinical and clinical milestones under our collaborations. We have received to date approximately $164.6 million in cash receipts from collaborations. Our collaborations include an immuno-oncology-focused collaboration with GlaxoSmithKline, Inc. (“GSK”) and an inflammation-focused collaboration with Bristol-Myers Squibb (“BMS”). A Biologics License Application (“BLA”) for our most advanced partnered program, which is an anti-PD-1 antagonist antibody called dostarlimab, was submitted by GSK and accepted by the FDA for the treatment of advanced or recurrent deficient mismatch repair endometrial cancer (“dMMREC”), and FDA approval is anticipated in this indication during the first half of 2021. This FDA approval is dependent on a pre-approval inspection of the dostarlimab manufacturing site by the FDA and is therefore contingent on easing of the coronavirus (“COVID-19”) pandemic travel restrictions. In addition, the European Medicines Agency (“EMA”) recently accepted GSK’s Marketing Authorization Application (“MAA”) for dostarlimab in the European Union (“EU”) for dMMREC, and EMA approval is anticipated in this indication during the first half of 2021. A second BLA submitted by GSK was accepted by the FDA during the first quarter of 2021 for dostarlimab in pan-deficient mismatch repair tumors (“PdMMRT”). We received a $10.0 million cash milestone payment upon the FDA acceptance of GSK’s first BLA for dostarlimab and anticipate an additional $20.0 million cash milestone payment upon first FDA approval of dostarlimab during the first half of 2021. We also received a $5.0 million milestone payment for the EMA acceptance of GSK’s first MAA for dostarlimab and anticipate an additional $10.0 million cash milestone payment upon first EMA approval of dostarlimab during the first half of 2021. An additional $10.0 million cash milestone payment is anticipated by the end of the first quarter of 2021 for acceptance of the second FDA BLA referred to above. Dostarlimab is currently in clinical development for various solid tumor indications, including dMMREC, PdMMRT, colorectal cancer, ovarian cancer, non-small cell lung cancer, cervical cancer, rectal cancer, clear cell sarcoma and head-and-neck squamous cell carcinoma. We anticipate receiving additional milestones from GSK, of equal magnitude to the milestone payments outlined above, upon approval of the BLA and acceptance and approval of the EMA filings of dostarlimab for the PdMMRT indication. Depending upon the timing of the aforementioned dostarlimab regulatory acceptance and approval milestones, we anticipate a total of $75.0 million in such milestone payments over the upcoming 18 months. An additional $165.0 million in sales milestones is anticipated upon achievement of certain dostarlimab annual sales revenues. In October 2020, we amended our GSK collaboration to increase royalties on global net sales of dostarlimab to 8-25%, add 1% royalty rate on GSK’s global net sales of Zejula and received a one-time cash payment of $60.0 million. For more information about these collaborations, see “—Collaborations”.

Our Product Candidates

The following table summarizes certain key information about our wholly-owned and partnered product candidates:



The outbreak of the novel coronavirus and the COVID-19 disease that continues to be a global pandemic. The full impact of the COVID-19 pandemic is inherently uncertain at the time of this Annual Report. The COVID-19 pandemic has resulted in travel restrictions and, in some cases, prohibitions of non-essential activities, disruption and shutdown of businesses, and greater uncertainty in global financial markets. As COVID-19 has spread, it has significantly impacted the health and economic environment around the world, and many governments have closed most public establishments, including restaurants, workplaces and schools. Our ongoing clinical trials have been, and may continue to be, affected by the closure of offices, or country borders, among other measures being put in place around the world. The inability to travel and conduct face-to-face meetings can also make it more difficult to enroll new patients in ongoing or planned clinical trials. Any of these circumstances will potentially have a negative impact on our financial results and the timing of our clinical trials.

The COVID-19 pandemic has caused us to modify our business practices (including but not limited to curtailing or modifying employee travel, moving to full remote work, and cancelling physical participation in meetings, events and conferences), and we may take further actions as may be required by government authorities or that we determine are in the best interests of our employees, patients and business partners.

The extent of the impact of the COVID-19 pandemic on our future liquidity and operational performance will depend on certain developments, including the duration and spread of the outbreak, the availability and effectiveness of vaccines, the impact on our clinical trials, patients and collaboration partners, and the effect on our suppliers.

Our Strategy

We are a leading antibody development company with a pipeline of novel therapeutic antibodies, which is being further expanded by applying our technology platform to emerging biological targets. The key elements of our strategy include:

- **Advancing our wholly-owned lead product candidates to clinical milestones.** We are working to demonstrate the safety and efficacy of our wholly-owned pipeline programs. We are currently developing three wholly-owned programs to key 2021 milestones, including data from our Phase 2 imsidolimab clinical trial in PPP during the first quarter of 2021, initiation of a Phase 3 clinical trial in GPP during mid-2021, data from our Phase 2 imsidolimab clinical trial in EGFRi/MEKi during the fourth quarter of 2021, top-line data from our Phase 1 clinical trial of ANB030 in mid-2021 and initiation of Phase 2 clinical trials in alopecia areata and vitiligo during the second half of 2021 and initiation of a healthy volunteer Phase 1 trial for ANB032 in the first half of 2021.
- **Continuing to expand our proprietary pipeline by generating new product candidates using our technology platform.** Using our proprietary SHM antibody generation platform, we are able to rapidly develop novel antibodies against biological targets. Our goal is to continue expanding our wholly-owned new therapeutic antibody program pipeline by innovating additional wholly-owned novel pipeline antibodies to potentially first-in-class immune-related targets.
- **Identifying emerging opportunities in key therapeutic areas.** We intend to remain at the forefront of discovery and development of new therapeutic opportunities in inflammation by understanding and translating biological breakthroughs into first-in-class therapeutic antibodies. Our approach includes translational biology assessments, such as human genetics, *ex vivo* tissue pathology and target expression patterns, to understand the relevance of emerging targets to patients with unmet medical needs. We plan to leverage this knowledge to create new product candidates and position our current and future programs for initial efficacy assessment.
- **Retaining rights to strategic products in key commercial markets.** We intend to retain ownership and control of our pipeline programs to key preclinical and clinical data inflection points. For certain programs, we plan to seek strategic collaborations that provide us with funding, infrastructure and marketing resources to advance through development and commercialization.

Our Wholly-Owned Product Pipeline

Our most advanced, wholly-owned pipeline programs, imsidolimab, ANB030 and ANB032, are described below:

Imsidolimab: Anti-IL-36R Antibody

Overview

Imsidolimab is an antibody that inhibits the function of IL-36R, which we are initially developing as a potential first-in-class therapy for multiple inflammation-mediated dermatological patient populations. GPP is a life-threatening, rare systemic inflammatory disorder reported by literature to affect at least 3,000 patients while recent medical claims analysis indicates at least 10,000 patients in the United States alone, with no currently approved therapies. Studies have shown that GPP can be associated with mutations in the gene encoding the IL-36R antagonist, or IL-36RA, or can be caused by excessive IL-36 cytokine levels, that lead to abnormally high signaling through the IL-36R and thereby cause the systemic inflammatory condition, GPP. We are also developing imsidolimab for PPP which is reported to affect approximately 150,000 patients, EGFRi/MEKi-mediated skin toxicity which is estimated to affect 60,000 patients, certain IL-36 mediated ichthyosis subtypes that affect 6,000 patients, hidradenitis suppurativa affecting 150,000 patients and moderate-to-severe acne which affects 7 million patients, all in the United States. We have obtained FDA Orphan Drug Designation for imsidolimab for the treatment of GPP, and plan to seek Orphan Drug Designation for additional indications in the future. We anticipate initiating a Phase 3 clinical trial in GPP starting mid-2021, reporting top-line data from the POPLAR Phase 2 clinical trial of PPP in the first quarter of 2021, reporting interim top-line data from the EMERGE Phase 2 trial in EGFRi/MEKi mediated skin toxicity by the end of 2021, reporting top-line data from the INSPIRE Phase 2 clinical trial in ichthyosis in 2022, and initiating the HARP Phase 2 clinical trial in hidradenitis suppurativa and the ACORN Phase 2 clinical trial in moderate-to-severe acne in the second quarter of 2021.

IL-36R Target Biology

The IL-36 subfamily of proteins consists of the IL-36 receptor antagonist, or IL-36RA, as well as three cytokines, IL-36 alpha, IL-36 beta and IL-36 gamma, each of which have agonistic characteristics and signal through IL-36R. These IL-36 proteins are mainly expressed in keratinocytes, the predominant cell type in the epidermis. The role of the IL-36RA is to dampen the inflammatory effects of IL-36 alpha, IL-36 beta and IL-36 gamma.

Studies have demonstrated the relevance of IL-36 in regulating inflammation in the skin. Mice over-expressing the IL-36 alpha cytokine undergo a psoriasis-like condition when challenged with an inflammatory stimulus. Additionally, immuno-deficient mice transplanted with human psoriatic skin have been shown to require the IL-36R signaling to maintain disease.

Recent human studies have demonstrated that mutations in the IL-36RA can lead to the occurrence of GPP by dysregulating the IL-36R signaling pathway. However, translational studies that we conducted have also demonstrated that a significant number of GPP patients do not have mutations in the IL-36RA but are likely to have excessive levels of IL-36 cytokines leading to the same disease as patients with mutations. These findings support our hypothesis that IL-36 signaling plays a significant role in GPP.

In addition, studies have demonstrated that humans with genetic mutations that downregulate IL-36 receptor activity are otherwise normal with no specific clinical phenotype.

We believe that imsidolimab has the potential to be the first-in-class therapeutic antibody targeting IL-36R, serving as a therapeutic opportunity for patients with IL-36 signaling mediated inflammatory diseases. Translational studies have indicated that IL-36 signaling is upregulated in GPP, PPP, EGFRi/MEKi-mediated skin toxicity, ichthyosis, hidradenitis suppurativa and acne.

Imsidolimab Non-Clinical Development

Imsidolimab was generated using our SHM technology platform and has demonstrated high functional potency in blocking human and cynomolgus monkey IL-36 signaling in preclinical studies.

Imsidolimab blocks signal transduction through the human IL-36R and cynomolgus monkey IL-36R by inhibiting the interaction between the receptor and IL-36 alpha, IL-36 beta, and IL-36 gamma cytokines. The high potency and functional activity of imsidolimab for human and cynomolgus monkey IL-36R was measured using standard *in vitro* assays to determine equilibrium dissociation constant, or KD, and half-maximal inhibitory concentration values, or IC50. Imsidolimab has demonstrated potent KD values of approximately of 71 pM and 209 pM for human IL-36R and cynomolgus monkey IL-36R, respectively. The antibody exhibits high specificity for IL-36R, displaying no detectable binding to related proteins. Functional potency of imsidolimab is at least 100-fold greater than IL-36RA in human systems, which is measured as the IC50 of inhibition of interleukin-8, or IL-8, release from human keratinocytes.

Imsidolimab functional activity has been demonstrated through inhibition of IL-8 secretion from human primary keratinocytes when stimulated by IL-36 gamma of approximately 0.15 nM and 1.2 nM, respectively. Lower KD and IC50 values indicate higher potency and functional activity, respectively. Similar IC50 values were observed in those same preclinical studies when keratinocytes were stimulated with IL-36 alpha or beta.

To date, we have demonstrated that the half-life of imsidolimab in cynomolgus monkeys is more than nine days. Imsidolimab is well-expressed from Chinese hamster ovary cells, or CHO cells, and is readily purified using standard methodologies. In addition, the antibody retained full functional activity when incubated in normal human serum at 37 °C for one week.

Clinical Development Plan

We have completed, under an approved Clinical Trial Notification, or CTN, a Phase 1 clinical trial in healthy volunteers for which we announced positive top-line results from an interim analysis of this clinical trial and subsequently presented completed data from this clinical trial at the 2018 European Academy of Allergy and Clinical Immunology Congress. In the double-blinded, placebo-controlled healthy volunteer Phase 1 clinical trial, 36 subjects were administered a single subcutaneous or intravenous dose of imsidolimab ranging between 10 mg and 750 mg, 18 subjects were administered multiple ascending doses of imsidolimab intravenously ranging between 40 mg and 300 mg weekly for four consecutive weeks and 18 subjects were dosed with placebo. Imsidolimab was well-tolerated by all subjects, and no dose-limiting toxicities were observed. The most frequent treatment-emergent adverse events observed in the single ascending dose cohorts were upper respiratory tract infections in 10 of 36 (28%) subjects dosed with imsidolimab versus six of 12 (50%) subjects dosed with placebo and headache in 10 of 36 (28%) subjects dosed with imsidolimab versus three of 12 (25%) subjects dosed with placebo. In the multiple ascending dose cohorts, the most frequent treatment-emerging adverse events observed were headache in seven of 18 (39%) subjects dosed with imsidolimab versus one of six (17%) subjects dosed with placebo. No serious adverse events were reported among any subjects in the clinical trial. The *in vivo* half-life of imsidolimab was approximately 28 days for both subcutaneous and intravenous routes of administration, with bioavailability of approximately 90 percent. A single dose of imsidolimab at certain dose levels was able to completely suppress IL-36 cytokine function for 85 days, as measured by IL-36 cytokine-mediated release of IL-8 using an *ex vivo* pharmacodynamic assay. The favorable pharmacokinetics and pharmacodynamic

properties of imsidolimab and other results demonstrated by this Phase 1 clinical trial supported advancement of imsidolimab into Phase 2 studies.

We are conducting an open-label, multi-dose, single-arm Phase 2 clinical trial of imsidolimab in 8 GPP patients, also referred to as the GALLOP clinical trial, where we announced positive topline data in October 2020. Six of 8 (75%) patients treated with imsidolimab monotherapy achieved the primary endpoint of improvement in the clinical global impression scale ("CGI") on Day 29. Two of 8 (25%) patients were considered to have not met the primary endpoint because they dropped out of the clinical trial prior to Day 29. The modified Japanese Dermatology Association Severity Index ("mJDA-SI") score, which incorporates both dermatological and systemic aspects of GPP, decreased on average by 29% on Day 8 and 54% on Day 29. Erythema with skin pustules, which clinically defines GPP, decreased by 60% on Day 8 and 94% on Day 29. Serum c-reactive protein ("CRP"), which is an indicator of systemic inflammation, was normal (less than 5 mg/L) for 5 of the 6 patients achieving the primary endpoint on Day 29. Genotypic testing indicated homozygous wild-type IL-36RN, CARD14 and AP1S3 alleles for all 8 patients. We believe this suggests that imsidolimab may be broadly applicable to pustular diseases irrespective of genetic drivers. Anti-drug antibodies were not detected as of Day 29 in any patient. Imsidolimab was generally well-tolerated, and most treatment-emergent adverse events were mild to moderate in severity and resolved without sequelae. No infusion or injection site reactions were observed. One patient dropped out of the clinical trial due to a diagnosis of *Staphylococcal aureus* bacteremia in the first week, which was a serious adverse event deemed to be possibly drug-related. Because the patient was symptomatic prior to dosing and had a prior medical history of bacteremia, a common comorbidity of GPP, we do not believe this event is likely attributable to imsidolimab. Another patient dropped out of the study on Day 22 due to investigator reported inadequate efficacy. One patient contracted COVID-19 during the course of the clinical trial, which was mild, unrelated to imsidolimab, and did not lead to study discontinuation. Data from the first two patients to have completed the Day 113 treatment period under this clinical trial, which we announced in September 2019, indicated sustained efficacy in these two patients through Day 113. We plan to report full data from the GALLOP clinical trial at a medical conference in 2021. We met with the FDA during the fourth quarter of 2020 to review an orphan disease registration plan for imsidolimab for the treatment of GPP and anticipate initiating a Phase 3 clinical trial in mid-2021 following completion of protocol alignment and review of 16-week data from the GALLOP clinical trial by the FDA.

In July 2020, the FDA granted Orphan Drug Designation for imsidolimab for the treatment of patients with GPP. GPP is a chronic, life-threatening, rare disease with no currently approved therapies. GPP is a systemic inflammatory disease characterized by the development of widespread pustules marked by idiopathic exacerbations. In severe cases, GPP patients can die from cardio-pulmonary failure, exhaustion, toxicity and/or infection subsequent to occurrences of pustular flares. Patients with GPP suffer without robust therapeutic options because currently approved psoriasis management therapies have not demonstrated clear efficacy in the treatment of this condition. While initial GPP epidemiology studies suggested at least 3,000 patients in the United States, recent medical claims analyses suggest GPP prevalence in the United States of at least 10,000 patients.

We are also conducting a randomized, double-blind, placebo-controlled 59-patient multi-dose clinical trial of imsidolimab in PPP, also referred to as the POPLAR clinical trial, where enrollment was completed in 2020 and top-line data are anticipated in the first quarter of 2021. The primary endpoint of this clinical trial is change in palmo-plantar pustulosis area severity index (PPPASI) at week 16 relative to baseline. PPP is a non-fatal form of pustular psoriasis that we estimate affects approximately 150,000 patients in the United States alone. Patients experience a chronic occurrence of sterile pustules on their hands and feet, while systemic levels of IL-36 cytokines and other inflammatory disease biomarkers are also elevated. Patients with severe symptoms may have significant pain and be unable to stand, walk or do manual work, resulting in greatly diminished quality of life. Existing anti-inflammatory therapeutic options to our knowledge have not proven to be consistently effective in treating PPP. As we believe the PPP patient population to be less than 200,000 individuals in the United States, we plan to seek Orphan Drug Designation from the FDA for imsidolimab in this indication as well.

We have initiated a global registry of GPP and PPP patients, also referred to as the RADIANCE study, which we anticipate will improve understanding of the patient journey in these two indications and assist in enrollment of future GPP and PPP clinical trials.

We have initiated clinical development of imsidolimab for the treatment of skin toxicities associated with treatments with inhibitors of epidermal growth factor ("EGFRi") and MAPK/ERK kinase ("MEKi"). Treatment of solid tumors with EGFRi and/or MEKi is frequently limited by the occurrence of skin toxicities, including acneiform or papulopustular rash. Recent translational data has suggested that these skin toxicities are mediated by excess IL-36 signaling, leading to IL-8-mediated cutaneous neutrophilia and acneiform rash. Based on existing claims data, approximately 60,000 patients are prescribed EGFRi and/or MEKi treatments annually, and the vast majority of these patients experience skin toxicity, which in some cases leads to dose reduction and/or discontinuation of treatment. Current standard-of-care treatments are generally ineffective in patients with the most severe grades of EGFRi and/or MEKi mediated skin toxicity. During the fourth quarter of

2020, we initiated a Phase 2 clinical trial, called EMERGE, of imsidolimab in combination with EGFRi inhibitors, for the treatment of patients diagnosed with a certain baseline severity of skin toxicity, where 45 patients are randomized 2:1 between imsidolimab and placebo arms, to assess the efficacy of imsidolimab in the treatment of this indication. We anticipate interim top-line data from this clinical trial at the end of 2021.

We have also initiated clinical development of imsidolimab in ichthyosis, which is a family of rare, inherited, dermatological disorders characterized by dry, scaling and thickened skin. Recent human translational studies have suggested that the underlying skin inflammation responsible for ichthyosis is mediated by dysregulated IL-36 signaling, and we believe that imsidolimab treatment may be efficacious in treatment of this condition. Approximately 6,000 patients in the United States are affected with moderate-to-severe levels of ichthyosis, and no approved therapies are available for this disease. We have initiated a Phase 2 clinical trial, called INSPIRE, of imsidolimab in patients with certain baseline severity of ichthyosis, where 24 patients are randomized 2:1 between imsidolimab and placebo arms, and interim top-line data is anticipated in 2022.

We plan to initiate clinical development of imsidolimab in hidradenitis suppurativa, also known as acne inversa, which is a chronic inflammatory skin disease characterized by painful nodules in intertriginous areas that can progress to abscesses, sinus tracks and scarring. Current treatment options for hidradenitis suppurativa, including antibiotics, corticosteroids and anti-TNF therapy, have variable efficacy in moderate-to-severe patients, which often leads to surgery for removal of hidradenitis suppurativa nodules. Human translational studies have demonstrated elevated IL-36 cytokine expression in hidradenitis suppurativa skin biopsies, and we believe treatment of moderate-to-severe hidradenitis suppurativa with imsidolimab may lead to therapeutic benefit for this patient population. Moderate-to-severe hidradenitis suppurativa affects approximately 150,000 adults in the United States. We intend to initiate a Phase 2 clinical trial of imsidolimab in hidradenitis suppurativa, called HARP, in the second quarter of 2021.

We plan to initiate clinical development of imsidolimab in acne, which is the most common skin disorder in the United States, with approximately 7 million patients diagnosed with moderate-to-severe disease. Moderate-to-severe acne typically presents with painful papules, pustules, nodules, cysts and scarring. A key contributing factor to the pathogenesis of acne is the immune response to p. acnes, which is associated with upregulated IL-36 cytokine activity, localized inflammation and neutrophil infiltration of the skin. Existing therapies, including isotretinoin and systemic antibiotics, provide variable efficacy for moderate-to-severe acne patients and have practical limitations to their use given potential for clinically meaningful side effects. We anticipate initiating a Phase 2 clinical trial of imsidolimab, called ACORN, for the treatment of moderate-to-severe acne in the second quarter of 2021.

As described in the section titled “Risk Factors” and elsewhere in this report, the clinical development of drug product candidates is subject to a wide range of risks and uncertainties, any of which could cause our actual development strategy or timeframes to vary.

Checkpoint Receptor Modulator Programs

We are developing anti-inflammatory checkpoint receptor antibodies to PD-1 and BTLA, each of which are genetically associated with inflammatory disease when dysregulated in humans.

ANB030 is an antibody that binds PD-1 in an agonistic manner, leading to reduced T cell activity and anti-inflammatory effects *in vivo*. PD-1 is a key inhibitory immune checkpoint receptor expressed by activated T cells. PD-1 activity contributes to downregulation of T cell mediated immune responses in healthy individuals. We believe insufficient PD-1 activity may be a key biological defect associated with human inflammatory diseases. According to a 2007 study, genetic mutations in the PD-1 pathway are associated with increased susceptibility to various inflammatory conditions. We hypothesize that augmenting PD-1 signaling by ANB030 treatment has the potential to broadly suppress human inflammatory diseases. ANB030 was developed using our proprietary antibody discovery platform. We believe PD-1 agonist antibodies are challenging to discover due to the unique binding properties required to augment signaling through checkpoint receptors. ANB030 has been preclinically tested for key pharmacological properties (including binding potency, functional activity, epitope specificity, *in vivo* efficacy and pharmacokinetics) and manufacturability attributes (including expression and stability). Through translational biology, we plan to focus the clinical development of ANB030 upon certain human autoimmune diseases where PD-1 checkpoint receptor function may be under-represented. We presented preclinical data for ANB030 at the Festival of Biologics Annual Meeting in March 2020, including translational data demonstrating *in vitro* activity of ANB030 in alopecia areata patient samples. We initiated a Phase 1 healthy volunteer clinical trial in the first half of 2020, which is designed to assess the safety, pharmacokinetics and pharmacodynamics of ANB030 in single and multiple ascending dose cohorts. We anticipate top-line data from this Phase 1 clinical trial in mid-2021. We plan to initiate Phase 2 clinical trials of ANB030 in alopecia areata and vitiligo in the second half of 2021.

ANB032 is an antibody that modulates BTLA in a manner that results in anti-inflammatory effects *in vivo*. BTLA is broadly expressed upon lymphoid (including T and B) cells and myeloid cells (including dendritic cells) and therefore involved in a spectrum of inflammatory responses. We believe that the binding of BTLA with LIGHT, a receptor also known as TSFSR14, results in pro-inflammatory signaling across various immune cells, and that stabilization of BTLA's binding to HVEM, which is mediated by ANB032 treatment, leads to an anti-inflammatory effect *in vivo*. Genetic studies have demonstrated that dysregulated BTLA signaling, which favors pro-inflammatory activity, is associated with certain human inflammatory diseases (Lin et al. J Biomed Sci. 2006). ANB032 has demonstrated *in vivo* efficacy in an animal disease model. We filed a CTN in Australia for ANB032 during the first quarter of 2021 and anticipate initiating a healthy volunteer Phase 1 trial in the first half of 2021 upon clearance of the CTN. We presented preclinical data regarding ANB032 at the 2020 FOCIS Virtual Annual Meeting in October 2020.

Our SHM Antibody Discovery Platform

Antibody Overview

Antibodies are complex proteins naturally generated by the immune system to neutralize foreign pathogens such as bacteria or viruses. B cells, a white blood cell type responsible for the generation of antibodies in response to pathogens, secrete billions of antibodies with different specificities into the bloodstream. Antibodies are structurally distinct Y-shaped proteins formed through the combination of two long proteins, called heavy chains, and two short proteins, called light chains. Each heavy and light chain pair forms a binding site where the antibody specifically binds its target, otherwise known as an antigen, at the Fab domain of the antibody molecule. The specificity of each antibody to a target, and the potency of its binding strength to that target are defined by the amino acid sequences of heavy and light chains in the Fab domain of the antibody molecule. The other end of the antibody, called the Fc domain, is responsible for communication between the antibody and the rest of the immune system. Fc domains bind to various receptors and cause immune system effector responses.

Therapeutic antibodies are typically non-naturally occurring, or recombinant, antibodies specifically developed to treat human diseases by binding to certain proteins, and thereby modulating key biological processes. Therapeutic antibodies are injectable products that are typically dosed subcutaneously or intravenously, unlike synthetic chemistry-based "small molecule" therapeutics that may also be administered orally. Therapeutic antibodies have the following key features that we believe make them more predictable than small molecules:

- **Target Specificity.** Due to the large size and complex nature of the antibody Fab domain, antibodies generally bind with high specificity to the desired therapeutic target and tend to exhibit less off-target binding to unrelated proteins, which lowers the risk of unintended biological side effects such as toxicity.
- **Pharmacokinetics and Dosing Frequency**. As complex proteins, antibodies are metabolized and distributed differently than small molecules. Full length antibodies tend to exhibit serum half-lives of seven to 24 days in humans, leading to bi-weekly or monthly dosing as typical practice for therapeutic antibodies.
- **Potency and Dose Quantities.** Antibodies are typically highly potent in binding to their desired target, with binding dissociation constants in the low nanomolar to picomolar range. Hence, antibodies tend to be dosed at low amounts (less than 1 gram quantities per course of therapy).

We believe that therapeutic antibodies can be significantly de-risked pre-clinically for specificity, toxicology and pharmacokinetics, which is not generally true for small molecule drugs.

Limitations of Competing Antibody Technologies

Despite the promise of antibodies as a therapeutic modality, historically it has been difficult and time consuming to generate therapeutic-grade antibodies utilizing competing antibody discovery technologies. Such technologies have relied primarily on mouse immunization methodologies (such as wild-type or engineered mice), microbial antibody display libraries (such as phage or yeast cell display) or human B cell screening to generate antibodies against therapeutic targets of interest. We believe the key limitations of these competitive approaches include:

- **Insufficient Diversity**. Each of the prior technologies has limited, and often static, diversity of antibodies available for selection. The number of therapeutic targets that can be addressed by the available antibodies is therefore limited. It is particularly difficult for mouse immunization approaches to identify therapeutics against conserved proteins that are homologous between human and mouse species;

- **Lack of Functional Activity Selection.** Competing technologies have not been able to drive antibody selection on the basis of functional activity. Even if antibodies are available against a certain target, they may not bind the correct region or epitope of the protein to achieve the intended functional therapeutic effects;
- **Low Potency.** Antibodies from competing technologies tend to demonstrate low binding potencies against their targets. Such incomplete binding may not result in therapeutic effect that is sufficient to change disease outcomes, or require impractically high doses to convey therapeutic benefit; and
- **Unpredictable Manufacturing Properties.** Using microbial display systems such as phage and yeast display libraries has resulted in unpredictable expression, stability and formulation when manufacturing is initiated using mammalian cells, thus leading to poor production yields and product stability.

Mouse immunization methodologies. Mouse immunization methodologies involve the administration of human target antigen to mice with wild-type or engineered immune systems, with the assumption that their immune systems will generate antibodies with sufficient potency against the desired human antigen epitope to convey biological effect. A key limitation of this approach is that when the mouse is dosed with an antigen that is similar in the human and mouse, the antigen is seen by the mouse immune system as one of its own proteins, and very few, if any, antibodies are generated. In addition, the mouse immune system often generates mouse antibodies to epitopes that are not therapeutically relevant to humans, leading the resulting antibodies to bind the human target but failing to convey therapeutic effect.

Microbial antibody display systems. Microbial antibody display systems require screening of antibodies, typically formatted as antibody fragments, from a static library diversity displayed on a bacterial or yeast microbial cell surface. The static nature of these libraries limits the range of antibody specificities to values around 10^9 or 10^{10}, which is generally insufficient to avail high-affinity antibodies against many antigens. This can lead to suboptimal potency and subsequently require phage/yeast antibodies to be matured significantly, typically with random mutagenesis, to obtain therapeutic level potencies, which is a labor-intensive and inefficient process. In addition, antibodies selected using this approach are expressed through the microbial cell expression machinery, which differs significantly in terms of manufacturability (expression level, glycosylation, formulation and stability) from mammalian cell expression typically utilized for clinical and commercial manufacturing of therapeutic antibodies. Such differences typically lead to difficulties in mammalian cell manufacturing of microbial display-derived antibodies.

Human B cell screening methodologies. Human B cell screening methodologies involve the screening and isolation of antibodies from peripheral human blood against therapeutic antigens of interest. The key limitation of this approach is that circulating human B cells generally do not develop antibodies against endogenous proteins because their function is to develop humoral immunity against foreign pathogens, such as bacteria and viruses. Therefore, it is challenging to obtain therapeutic antibodies against human antigens through this approach.

Our Technology Solution

Our innovative platform is designed to replicate the natural process of SHM embedded within the human immune system to rapidly develop a diverse range of therapeutic-grade antibodies *in vitro*. SHM is a critical, endogenous process that generates the essential antibody diversity required to develop a natural immune response to pathogens. Human genomes encode a limited number of antibody genes, which are insufficient to generate antibodies against the wide variety of foreign pathogens encountered from the external environment. SHM enables the human immune system to expand the limited diversity encoded within human genomes to the billions of antibody specificities required to defend against external pathogens.

The key enzyme required for SHM is called activation-induced cytidine deaminase, or AID. AID has been genetically conserved throughout mammalian biology and is required for the non-random mutagenesis pattern associated with SHM. AID is specifically expressed by B cells after contact with a foreign pathogen and modifies antibody sequences in a non-random fashion. Through SHM, B cells evolve antibodies with the potency and specificity required to clear the foreign pathogen. However, within the *in vivo* environment, SHM does not generally progress to the creation of high potency antibodies or develop antibodies against the body's own proteins.

By coupling *in vitro* SHM with our mammalian cell system that simultaneously displays and secretes antibodies, we believe SHM is able to rapidly identify and mature antibodies with desired functional activity to high potency while simultaneously mitigating the risks associated with manufacturing. We introduce AID into mammalian cells to replicate the non-random mutagenesis SHM pattern observed within B cells *in vivo*. Starting with a library of either fully-human or humanized antibodies, our platform generates AID-based variants of the starting antibody library throughout the process. We have demonstrated that the pattern of mutagenesis we observe *in vitro* using our platform technology closely mimics the pattern

observed among *in vivo* generated antibodies, thereby increasing confidence that antibodies generated by our platform will be tolerated when used as therapeutic drugs in humans.

By selecting antibodies based on their antigen binding from the broad antibody library population SHM develops, we are able to evolve in an iterative fashion the binding potency and function of antibodies to levels that we believe will be required for therapeutic use. We believe this approach allows us to rapidly generate antibodies with high binding potency against a target. Through this approach, we have successfully generated therapeutic antibody product candidates to more than 25 targets, including targets that we believe have been challenging for competing antibody technology platforms to generate.

Each evolving antibody is expressed within the SHM-active mammalian cell to concurrently display the evolved antibody on the cell surface to permit cell sorting selection for potency properties while the same antibody is secreted into the extracellular media at sufficient quantities to permit functional assays to be conducted. In this manner, the evolving antibodies expressed by each transfected cell are assessed in a high-throughput fashion for the desired functional activity relevant to the therapeutic mechanism.

We believe our antibody discovery platform, as described above, has the following advantages over competing approaches:

- **Diversity against difficult targets.** We are able to generate an unprecedented diversity of antibodies by applying SHM-based diversification outside of the constraints of an *in vivo* environment. This enables us to develop antibodies against human targets that we believe have not otherwise been accessible to prior technologies.
- **High potency.** Because our platform generates highly-potent antibodies, we are potentially able to modulate every extracellular target associated with human disease, and believe only small therapeutic doses may be required to mediate therapeutic effect *in vivo*.
- **Functional activity selection.** Our mammalian cell system simultaneously displays and secretes antibodies during the antibody discovery process, allowing us to incorporate functional assays throughout the process and focus on producing product candidates that are optimized for the desired therapeutic activity.
- **Speed.** Our platform technology has enabled us to generate therapeutic-grade antibodies and initiate subsequent preclinical manufacturing and toxicology studies, typically in less than 12 months. We believe this timeline is significantly shorter than conventional approaches based upon mouse immunization and microbial display systems.
- **Manufacturability.** By utilizing our mammalian cell display system, we believe our approach increases the probability of success in manufacturing and commercialization by mitigating the risks associated with antibody expression, formulation and stability during the antibody generation process.

Collaborations

GlaxoSmithKline

In March 2014, we entered into a Collaboration and Exclusive License Agreement (the "GSK Agreement") with TESARO, Inc. ("Tesaro"), an oncology-focused biopharmaceutical company now a part of GlaxoSmithKline (Tesaro and GlaxoSmithKline are hereinafter referred to, collectively, as "GSK"). We executed an amendment in November 2014 to add an additional dual-reactive antibody product candidate. Under the terms of the GSK Agreement, as amended, we granted GSK an exclusive, royalty-bearing, sub-licensable worldwide license to research, develop, manufacture, market and sell products based on our proprietary technology for the discovery, generation and optimization of certain specified immunotherapy antibodies. We have granted GSK exclusive rights to three monospecific antibody product candidates targeting TIM-3 (TSR-022), LAG-3 (TSR-033) and PD-1 (TSR-042) and a bispecific antibody product candidates targeting PD-1 and LAG-3. Under the GSK Agreement, as amended, we are responsible for performing initial discovery and development of therapeutic antibodies with the goal of generating immunotherapy antibodies for use in the treatment of cancer. GSK is responsible for all subsequent preclinical, clinical, regulatory, manufacturing and other activities necessary to develop and commercialize antibodies selected under each of six development programs, and GSK is obligated to use commercially reasonable efforts to research, develop and commercialize at least one product to each of the four targets. During the term, other than under the collaboration, and except as amended by the October 23, 2020 amendment of the GSK Agreement (described below), both GSK and we are prohibited from developing and commercializing, independently or with a third party, any agents targeting LAG-3, PD-1 or TIM- 3, as single agents or in combination with other therapies. We have completed our responsibilities under the terms of the GSK Agreement as of December 31, 2016 to generate and develop antibodies to certain defined stages of preclinical development.

Under the terms of the GSK Agreement, as amended, GSK made up-front, non-creditable and non-refundable cash payments aggregating $19.0 million to us during 2014. GSK was also required to reimburse us on a quarterly basis for specified costs incurred by us in our initial discovery and development activities covered by the agreement. For each of the targets for which GSK is granted exclusive rights, GSK is required to make milestone payments to us of up to $18.0 million if certain research and development milestone events are achieved, up to an additional $90.0 million of milestone payments if certain U.S. and non-U.S. regulatory submissions and approvals occur in initial and subsequent indications, and up to an additional $165.0 million upon the achievement of specified levels of annual worldwide net sales. GSK will also be required to pay us tiered royalties ranging from 4% to 8%, for each product developed under the agreement, except in the case of dostarlimab where the royalties payable will be 8% to 25% (as explained in more detail below in connection with the October 23, 2020 amendment of the GSK Agreement), on a product- by-product basis, on worldwide annual net sales, and additional commercial milestone payments if specified levels of annual net sales of a product are attained.

On October 23, 2020, we again amended the GSK Agreement (the "2020 Amendment"). Under the 2020 Amendment, we agreed to permit GSK to conduct development and commercialization of Zejula in combination with any third-party molecules. Zejula is an oral, once-daily poly (ADP-ribose) polymerase (PARP) inhibitor, which has received U.S. approval for the maintenance treatment of adult patients with advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to first-line platinum-based chemotherapy, has been approved for certain other indications, and is under development for additional cancer indications as well. In addition, under the 2020 Amendment, we were granted increased royalties upon sales of dostarlimab, an anti-PD-1 antagonist antibody under development by GSK for multiple oncological disorders, including endometrial cancer, non-small cell lung cancer, ovarian cancer, colorectal cancer and mismatch repair deficient solid tumors, equal to 8% of Net Sales (as defined in the GSK Agreement) below $1.0 billion and from 12% up to 25% of Net Sales above $1.0 billion. The 2020 Amendment also provided for a one-time non-refundable cash payment of $60.0 million that we received in the fourth quarter of 2020. GSK also agreed, starting January 1, 2021, to pay us a 1% royalty on all GSK Net Sales of Zejula. The $1.1 billion in cash milestone payments due under the GSK Agreement remain unchanged. Additionally, under the terms of the 2020 Amendment, GSK has agreed to certain diligence commitments with respect to the future development of dostarlimab, and the parties have agreed to review such commitments under regular joint review committee meetings going forward.

This GSK Agreement, as amended, expires when no further payments are due to us, unless earlier terminated. Either party may terminate the GSK Agreement, as amended, in the event of an uncured material breach by the other party. GSK may terminate the GSK Agreement, as amended, at any time upon 90 days' prior written notice to us.

Bristol-Myers Squibb

In December 2011, we entered into a license and collaboration agreement (the "BMS Agreement") with Celgene, now a part of Bristol-Myers Squibb (Celgene and Bristol-Myers Squibb are hereinafter referred to, collectively, as "BMS"), to develop therapeutic antibodies against multiple targets. We completed our responsibilities under the terms of the BMS Agreement to generate antibodies against various mutually agreed biological targets during fiscal 2014. On a target-by-target basis, we provided BMS an option to obtain rights to develop and commercialize a defined number of antibodies against each target. We were successful in generating antibodies against multiple targets and BMS has exercised its option with respect to antibodies against three targets. BMS is currently advancing two anti-inflammatory antibodies, of which an anti-PD-1 agonist antibody, also known as CC-90006, is currently in a Phase 1 clinical trial, while the other program is currently in preclinical development.

Upon execution of the BMS Agreement in 2011, BMS paid us a one-time, non-refundable, non-creditable initial fee of $6.0 million. BMS has reimbursed us for specified research costs in accordance with the research plans. BMS is also obligated, on a project-by-project basis, to pay us up to a total of an additional $18.0 million if certain research and development milestone events are achieved under such project and up to a total of an additional $35.0 million if certain regulatory milestone events are achieved under such project. BMS will also be required to pay us single digit royalties on net sales of products containing the delivered antibodies on a product-by-product and country-by-country basis until the later of the expiration of the last patent right that covers manufacture, use or sale of such product in such country, and in any case at least 10 years after the first commercial sale of the product in such country.

The BMS Agreement continues until our royalty rights on any BMS product resulting from the collaboration expire, which period will last at least ten years after any such product first goes to market. Either we or BMS may terminate the BMS Agreement in the event of an uncured material breach by the other party.

In-Licensing Agreements License Agreement with UKRI

In 2006, we entered into an exclusive worldwide license agreement with the Medical Research Council, which has subsequently been acquired by United Kingdom Research and Innovation, or UKRI, to obtain rights to multiple patents and patent applications relating to fundamental discoveries with respect to SHM and AID by Dr. Michael Neuberger and his colleagues. We since amended this license agreement to include additional subject matter and reflect the change in ownership. Under the terms of the agreement, or the UKRI Agreement, we obtained an exclusive, worldwide, sub-licensable license under specified patent rights to manufacture, use, sell and commercialize products and methods covered by such patents for all fields of use. We are responsible for prosecution of the licensed patents and the development of therapeutic products covered by the intellectual property. We are obligated to research and develop licensed methods and licensed products for the purpose of commercializing such methods and products at least as diligently as we research and develop our other products of similar market potential and stages of development.

We are responsible for paying UKRI an annual fee of $55,000. Additionally, for each product developed and commercialized under the UKRI Agreement, we are obligated to pay UKRI up to an additional $175,000 upon the achievement of specified development milestone events and up to an additional $275,000 upon the achievement of specified regulatory milestone events. In addition we owe UKRI royalties at 0.25% of annual net sales for worldwide sales on a product-by-product at or below $750.0 million and 1% of annual net sales of products worldwide above $750.0 million, payable on a country-by-country basis until the expiration of the last licensed patent covering such product in such country. Under this license agreement, we have rights to 16 patents worldwide.

Unless earlier terminated, the UKRI Agreement will expire upon expiration of all royalty payment obligations under the UKRI Agreement. Either party may terminate the UKRI Agreement in the event of an uncured material breach by the other party or upon the occurrence of specified bankruptcy events for the other party. We may terminate the UKRI Agreement upon 60 days' notice to UKRI.

License Agreement with Millipore

In May 2009, we signed a non-exclusive research and commercial license agreement with Millipore Corporation, or Millipore, to obtain a non-exclusive license to patents and patent applications directed to the ubiquitous chromatin opening elements technology for the expression of proteins, particularly antibodies, generated by us, which license may be sublicensed to our contractors and partners. Under the terms of the agreement, or the Millipore Agreement, we are obligated to pay Millipore $87,500 in annual license fees, adjusted annually for inflation using the Consumer Price Index. Additionally, for each product developed and commercialized under the Millipore Agreement, we are obligated to pay Millipore up to an additional $750,000 upon the achievement of specified development milestone events and up to an additional $4.4 million upon the achievement of specified commercial milestone events. We do not owe Millipore any royalties on net sales of products commercialized under the Millipore Agreement.

Unless affirmatively terminated by one of the parties, the Millipore Agreement will continue in effect. Either party may terminate the Millipore Agreement in the event of an uncured material breach by the other party. We may terminate the Millipore Agreement upon 90 days' notice to Millipore.

Australian Operations

In March 2015, we established a wholly-owned Australian subsidiary called AnaptysBio Pty Ltd, in order to conduct various preclinical and clinical activities for etokimab and imsidolimab. By establishing operations in Australia, we are able to access an established network of manufacturing and clinical development support contractors located in Australia and benefit from Australia's streamlined approval processes for the initiation of first-in human studies. We have few employees with experience advancing product candidates through the Australian regulatory review process and have therefore engaged Australian consultants with expertise in the regulatory requirements and clinical development of therapeutic products in Australia. We are also working with established manufacturing and clinical development support contractors located in Australia, who are familiar with Australian regulatory and product development processes.

Intellectual Property

Our intellectual property is critical to our business and we strive to protect it, including by obtaining and maintaining patent protection in the United States and internationally for our technology platform, product candidates, novel biological discoveries, epitopes, new therapeutic approaches and potential indications, and other inventions that are important to our business. In total, our patent portfolio, including patents to our technology platform licensed from UKRI, as well as patents co-owned with GSK consisted of approximately 49 issued patents and 138 pending patent applications as of December 31, 2020.

For our product candidates, generally we initially pursue patent protection covering compositions of matter including antibody sequences, methods of use, and methods of production. Throughout the development of our product candidates, we seek to identify additional means of obtaining patent protection that would potentially enhance commercial success.

The patent portfolios for our internal programs and platform technology are outlined below:

Imsidolimab

As of December 31, 2020, we owned 18 patents and patent applications in various countries directed to the antibody sequence of imsidolimab and its variants, methods of use and related matters. We also intend to prosecute our pending applications and pursue patent issuance and protection in key commercial markets where significant product sales may occur. Patents that may issue from our pending applications would provide protection until July 2041.

ANB030

As of December 31, 2020, we owned two U.S. patent applications directed to the antibody sequence of ANB030 and its variants, methods of use and related matters. We also intend to prosecute our pending applications and pursue patent issuance and protection in key commercial markets where significant product sales may occur. Patents that may issue from our pending applications would provide protection until June 2040.

ANB032

As of December 31, 2020, we owned one U.S. patent application directed to the antibody sequence of ANB032 and its variants, methods of use and related matters. We intend to prosecute this pending application and, perhaps, other patent applications, and pursue patent issuance and protection in key commercial markets where significant product sales may occur. Patents that may issue from our pending application would provide protection until October 2041.

Dostarlimab (GSK4057190)

As of December 31, 2020, we owned or co-owned 40 patents and patent applications in various countries directed to the antibody sequence of GSK4057190 (dostarlimab), an anti-PD-1 antagonist, and its variants, methods of use and related matters. We intend to prosecute our pending applications and pursue patent issuance and protection in key commercial markets where significant product sales may occur. Patents that may issue from our pending applications would provide protection until November 2037.

Cobolimab (GSK4069889)

As of December 31, 2020, we owned or co-owned 39 patents and patent applications in various countries directed to the antibody sequence of GSK4069889 (cobolimab), an anti-TIM-3 antagonist, and its variants, methods of use and related matters. We intend to prosecute our pending applications and pursue patent issuance and protection in key commercial markets where significant product sales may occur. Patents that may issue from our pending applications would provide protection until November 2037.

GSK4074386

As of December 31, 2020, we owned or co-owned 35 patents and patent applications in various countries directed to the antibody sequence of GSK4074386, an anti-LAG-3 antagonist, and its variants, methods of use and related matters. We intend to prosecute our pending applications and pursue patent issuance and protection in key commercial markets where significant product sales may occur. Patents that may issue from our pending applications would provide protection until April 2038.

Platform Technology

Our platform technology is covered by U.S. and foreign issued patents, emanating from our in-licensed portfolio and wholly-owned portfolio, in various jurisdictions.

Our portfolio includes patents directed to platform technology related inventions associated with antibody library design, antibody humanization, mammalian cell display and secretion, and other technical attributes relating to the discovery, maturation and optimization of antibodies using our technology platform. Patents relating to our platform technology that have been issued to date provide protection through May 2033.

The patent positions of biotechnology companies like ours are generally uncertain and involve complex legal, scientific and factual questions. In addition, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Consequently, we may not obtain or maintain adequate patent protection for any of our product candidates or for our technology platform. We cannot predict whether the patent applications we are currently pursuing will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient proprietary protection from competitors. Any patents that we hold may be challenged, circumvented or invalidated by third parties. For a more comprehensive discussion of the risks related to our intellectual property, please see "Risk Factors— Risks Related to Our Intellectual Property."

The term of individual patents depends upon the legal term of the patents in the countries in which they are 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 related to the patent. A U.S. patent also may be accorded a patent term adjustment, or PTA, under certain circumstances to compensate for delays in obtaining the patent from the U.S. Patent and Trademark Office, or USPTO. In some instances, such a PTA may result in a U.S. patent term extending beyond 20 years from the earliest date of filing a non-provisional patent application related to the U.S. patent. In addition, the term of a U.S. patent that covers an FDA-approved drug may also be eligible for patent term extension, which permits patent term restoration as compensation for the patent term lost during the FDA regulatory review process. The Hatch-Waxman Act permits a patent term extension of up to five years beyond the expiration of the patent. The length of the patent term extension is related to the length of time the 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. Similar provisions are available in Europe and other foreign jurisdictions to extend the term of a patent that covers an approved drug. In the future, if and when 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 FDA in the United States, will agree with our assessment of whether such extensions should be granted, and if granted, the length of such extensions.

We also rely on trade secrets relating to our technology platform and product candidates and seek to protect and maintain the confidentiality of proprietary information to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection. 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 during the course of the individual's relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances. Our agreements with employees also provide that all inventions conceived by the employee in the course of employment with us or from the employee's use of our confidential information are our exclusive property.

Manufacturing

We must manufacture drug product for clinical trial use in compliance with current good manufacturing practices, or cGMP. The cGMP regulations include requirements relating to organization of personnel, buildings and facilities, equipment, control of components and drug product containers and closures, production and process controls, packaging and labeling controls, holding and distribution, laboratory controls, records and reports, and returned or salvaged products. The manufacturing facilities for our product candidates must meet cGMP requirements and FDA satisfaction before any product is approved and we can manufacture commercial products. Our third-party manufacturers will also be subject to periodic inspections of facilities by the FDA and other authorities, including procedures and operations used in the testing and manufacture of our products to assess our compliance with applicable regulations.

Our internal manufacturing capabilities include non-cGMP antibody and reagent production using small scale quantities for characterization and *in vitro* and *in vivo* preclinical assessment of product candidates. We do not have and we do not currently plan to acquire or develop the facilities or capabilities to manufacture cGMP drug substance or filled drug product for use in human clinical trials.

We rely on third-party manufacturers to generate cGMP-grade cell lines and will rely on them to produce cGMP drug product required for our planned clinical trials, and we expect to continue to rely on third parties to manufacture clinical trial

drug supplies for the foreseeable future. We also contract with additional third parties for the filling, labeling, packaging, storage and distribution of investigational drug products. We have personnel with significant technical, manufacturing, analytical, quality, including cGMP, and project management experience to oversee our third-party manufacturers and to manage manufacturing and quality data and information for regulatory compliance purposes. While our contract manufacturers have not yet produced commercially-approved cGMP batches of our product candidates, they have previously manufactured products for other companies in compliance with cGMP and have been previously inspected by regulatory authorities for compliance with cGMP standards. Similarly, our personnel have had experience with cGMP at previous positions.

Failure to comply with statutory and regulatory requirements subjects a manufacturer to possible legal or regulatory action, including warning letters, the seizure or recall of products, injunctions, consent decrees placing significant restrictions on or suspending manufacturing operations and civil and criminal penalties. These actions could have a material impact on the availability of our products. Contract manufacturers often encounter difficulties involving production yields, quality control and quality assurance, as well as shortages of qualified personnel.

Competition

The biotechnology and pharmaceutical industries are characterized by continuing technological advancement and significant competition. While we believe that our product candidates, technology, 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 existing 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 and the ease of use and effectiveness of any companion diagnostics. The level of generic competition and the availability of reimbursement from government and other third-party payors will also significantly affect the pricing and competitiveness of our products. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market.

Many of the companies against which we may compete have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

Specifically, there are several companies developing or marketing treatments that may be approved for the same indications and/or diseases as our lead product candidates, imsidolimab and etokimab, including major pharmaceutical companies.

For GPP and PPP, our competitors include marketed therapies such as secukinumab (Cosentyx; Novartis), which binds IL-17A; ustekinumab (Stelara; Janssen), which blocks IL-12 and 23 cytokine function; and acitretin (Soriatane; GSK), as well as therapies in development such as guselkumab (Janssen), which blocks IL-23 cytokine function, gevokizumab (Xoma 052) and canakinumab (Ilaris, Novartis), which binds IL-1 beta, anakinra (Kineret; Swedish Orphan Biovitrum AB), a recombinant form of the IL-1 receptor antagonist and an anti-IL-36 receptor antibody called BI-655130 (Boehringer Ingelheim).

For ichthyosis, systemically administered competitors include secukinumab (Cosentyx; Novartis), liarozole (GSK), dupilumab (Dupixent; Regeneron/Sanofi), and adalimumab (Humira; Abbvie). Various topical treatments may also be used off-label for treatment of ichthyosis related symptoms.

For hidradenitis suppurativa, our competitors include adalimumab (Humira; Abbvie) which is approved for the treatment of moderate to severe hidradenitis suppurativa for patients 12 years of age or older.

For acne, our competitors include retinoids and retinoid-like drugs, including tretinoin (Avita, Retin-A, adapalene (Differin) and tazarotene (Tazorac, Avage), antibiotics including clindamycin (Benzaclin, Duac) and erythromycin (Benzamycin) and isotretinoin (Amnesteem, Claravis, Accutane) and oral antibiotics including sarecycline (Seysara).

For our anti-inflammatory checkpoint modulator antibody programs, our competitors include CC-90006 (BMS), which is an anti-PD-1 agonist antibody developed under our partnership with BMS, a BTLA modulator antibody called LY3361237 being developed by Eli Lilly, a PD-1 agonist antibody called LY3462817 also being developed by Eli Lilly and two PD-1 agonist antibodies called PT627 and PT001 being developed by Pandion Therapeutics. Our competitors in moderate-to-severe alopecia areata and vitiligo include topical and oral corticosteroids, topical immunotherapy (diphencyprone,

dinitrochlorobenzene, squaric acid dibutyl ester), calcineurin inhibitors (tacrolimus, pmecrolimus), light therapy, prostaglandins and janus kinase inhibitors (tofacitinib, rixolitinib) currently in development.

Government Regulation and Product Approval

Government authorities in the United States, at the federal, state and local level, and in other countries and jurisdictions, including the European Union, extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, marketing, 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 the FDA. The Federal Food, Drug, and Cosmetic Act, or the FDC 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. Biological products used for the prevention, treatment, or cure of a disease or condition of a human being are subject to regulation under the FDC Act, except the section of the FDC Act which governs the approval of new drug applications, or NDAs. Biological products are approved for marketing under provisions of the Public Health Service Act, or PHSA, via a BLA. However, the application process and requirements for approval of BLAs are similar to those for NDAs, and biologics are associated with similar approval risks and costs as drugs. Failure to comply with applicable U.S. requirements may subject a company to a variety of administrative or judicial sanctions, such as clinical hold, FDA refusal to approve pending NDAs or BLAs, warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties, and criminal prosecution.

Biological product development for a new product or certain changes to an approved product in the United States typically involves preclinical laboratory and animal tests, the submission to the FDA of an IND, which must become effective before clinical testing may commence in the United States, 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 premarket 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, or GLPs. The results of preclinical testing are submitted to the 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 the 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 biologic 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 practices, or GCPs, 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 the FDA as part of the IND.

The 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 trial protocol and informed consent information for patients in clinical trials must also be submitted to an institutional review board, or IRB, 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 BLAs for marketing approval are typically conducted in three sequential phases, but the phases may overlap. In Phase 1, the initial introduction of the biologic into healthy human subjects or patients, the product is tested to assess metabolism, pharmacokinetics, pharmacological actions, side effects associated with increasing doses, and, if possible, early evidence on effectiveness. Phase 2 usually involves clinical trials in a limited patient population to determine the

effectiveness of the drug or biologic for a particular indication, dosage tolerance, and optimal dosage, and to identify common adverse effects and safety risks. If a compound demonstrates evidence of effectiveness and an acceptable safety profile in Phase 2 evaluations, Phase 3 clinical 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 the FDA to evaluate the overall benefit risk relationship of the drug or biologic and to provide adequate information for the labeling of the product. In most cases, the FDA requires two adequate and well-controlled Phase 3 clinical trials to demonstrate the efficacy of the biologic. A single Phase 3 clinical trial may be sufficient in rare instances, including (i) where the clinical trial is a large multicenter clinical trial demonstrating internal consistency and a statistically 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 clinical trial would be practically or ethically impossible or (ii) when in conjunction with other confirmatory evidence.

After completion of the required clinical testing, a BLA is prepared and submitted to the FDA. FDA approval of the BLA is required before marketing of the product may begin in the United States. The BLA 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 a BLA is substantial. The submission of most BLAs is additionally subject to a substantial application user fee, and the applicant under an approved BLA is also subject to annual product and establishment user fees. These fees are typically increased annually. The FDA has 60 days from its receipt of a BLA 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 filed, the FDA begins an in-depth review. The FDA has agreed to certain performance goals in the review of BLAs. Most such applications for standard review biologic products are reviewed within 10 months of the date the BLA is filed with the FDA; most applications for priority review biologics are reviewed within six months of the date the BLA is filed with the FDA. Priority review can be applied to a biologic that the FDA determines has the potential to treat a serious or life-threatening condition and, if approved, would be a significant improvement in safety or effectiveness compared to available therapies. The review process for both standard and priority review may be extended by the FDA for three additional months to consider certain late-submitted information or information intended to clarify information already provided in the submission.

The FDA may also refer applications for novel biologic products, or biologic products that present difficult questions of safety or efficacy, to an 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. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations. Before approving a BLA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP. Additionally, the FDA will inspect the facility or the facilities at which the biologic product is manufactured. The FDA will not approve the product unless compliance with cGMP is satisfactory and the BLA contains data that provide substantial evidence that the biologic is safe, pure, potent and effective in the indication studied.

After the FDA evaluates the BLA 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 the FDA to reconsider the application. If, or when, those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the BLA, the FDA will issue an approval letter. The FDA has committed to reviewing such resubmissions in two or six months depending on the type of information included. An approval letter authorizes commercial marketing of the biologic with specific prescribing information for specific indications. As a condition of BLA approval, the FDA may require a risk evaluation and mitigation strategy, or REMS to help ensure that the benefits of the biologic outweigh the potential risks. REMS can include medication guides, communication plans for health care 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 product. Moreover, product approval may require substantial post-approval testing and surveillance to monitor the product'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 BLA or BLA supplement before the change can be implemented. A BLA supplement for a new indication typically requires clinical data similar to that in the original application, and the FDA uses the same procedures and actions in reviewing BLA supplements as it does in reviewing BLAs.

Foreign clinical studies to support an IND

The FDA will accept as support for an IND a well-designed, well-conducted, non-IND foreign clinical study if it was conducted in accordance with GCP and the FDA is able to validate the data from the study through an onsite inspection, if necessary. A sponsor or applicant who wishes to rely on a non-IND foreign clinical study to support an IND must submit the following supporting information to the FDA to demonstrate that the study conformed to GCP:

- the investigator's qualifications;
- a description of the research facilities;
- a detailed summary of the protocol and study results and, if requested, case records or additional background data;
- a description of the drug substance and drug product, including the components, formulation, specifications, and, if available, the bioavailability of the drug product;
- information showing that the study is adequate and well controlled;
- the name and address of the independent ethics committee that reviewed the study and a statement that the independent ethics committee meets the required definition;
- a summary of the independent ethics committee's decision to approve or modify and approve the study, or to provide a favorable opinion;
- a description of how informed consent was obtained;
- a description of what incentives, if any, were provided to subjects to participate;
- a description of how the sponsors monitored the study and ensured that the study was consistent with the protocol;
- a description of how investigators were trained to comply with GCP and to conduct the study in accordance with the study protocol; and
- a statement on whether written commitments by investigators to comply with GCP and the protocol were obtained.

Orphan Drug Designation

Under the Orphan Drug Act, the FDA may grant Orphan Drug Designation to biological products intended to treat a rare disease or condition—generally a disease or condition that (i) affects fewer than 200,000 individuals in the United States, or (ii) affects more than 200,000 individuals in the United States and there is no reasonable expectation that the cost of developing and making a product available in the United States for such disease or condition will be recovered from sales of the product.

Orphan Drug Designation must be requested before submitting a BLA. After the FDA grants Orphan Drug Designation, the generic identity of the biological product and its potential orphan use are disclosed publicly by the FDA. Orphan Drug Designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. The first BLA applicant to receive FDA approval for a biological product containing a particular active moiety to treat a particular disease with FDA Orphan Drug Designation is entitled to a seven-year exclusive marketing period in the United States for that product for that indication. During the seven-year exclusivity period, the FDA may not approve any other applications to market a biological product containing the same active moiety for the same disease, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity. A product is clinically superior if it is safer, more effective or makes a major contribution to patient care. Orphan drug exclusivity does not prevent the FDA from approving a different drug or biological product for the same disease or condition, or the same biological product for a different disease or condition. Among the other benefits of Orphan Drug Designation are tax credits for certain research and a waiver of the BLA user fee.

Disclosure of clinical trial information

Sponsors of clinical trials of FDA-regulated products, including biological products, are required to register and disclose certain clinical trial information. Information related to the product, patient population, phase of investigation, trial 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 clinical trials can be delayed in certain circumstances for up to two years after the date of completion of the clinical 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 BLAs or supplements to NDAs or BLAs must contain data to assess the safety and effectiveness of the biological product for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the biological product is safe and effective. The FDA may grant full or partial waivers, or deferrals, for submission of data. Unless otherwise required by regulation, the PREA does not apply to any biological product for an indication for which Orphan Drug Designation has been granted.

The Best Pharmaceuticals for Children Act, or BPCA, provides sponsors of NDAs with an additional six-month period of market exclusivity for all unexpired patent or non-patent exclusivity on all forms of the drug containing the active moiety if the sponsor submits results of pediatric studies specifically requested by the FDA under BPCA within required timeframes. The BPCA provides sponsors of BLAs an additional six-month extension for all unexpired non-patent market exclusivity on all forms of the biological containing the active moiety pursuant to the BPCA if the conditions under the BPCA are met.

Additional controls for biologics

To help reduce the increased risk of the introduction of adventitious agents, the PHSA emphasizes the importance of manufacturing controls for products whose attributes cannot be precisely defined. The PHSA also provides authority to the FDA to immediately suspend licenses in situations where there exists a danger to public health, to prepare or procure products in the event of shortages and critical public health needs, and to authorize the creation and enforcement of regulations to prevent the introduction or spread of communicable diseases in the United States and between states.

After a BLA is approved, the product may also be subject to official lot release as a condition of approval. As part of the manufacturing process, the manufacturer is required to perform certain tests on each lot of the product before it is released for distribution. If the product is subject to official release by the FDA, the manufacturer submits samples of each lot of product to the FDA together with a release protocol showing a summary of the history of manufacture of the lot and the results of all of the manufacturer's tests performed on the lot. The FDA may also perform certain confirmatory tests on lots of some products, such as viral vaccines, before releasing the lots for distribution by the manufacturer.

In addition, the FDA conducts laboratory research related to the regulatory standards on the safety, purity, potency, and effectiveness of biological products. As with drugs, after approval of biologics, manufacturers must address any safety issues that arise, are subject to recalls or a halt in manufacturing, and are subject to periodic inspection after approval.

Patent term restoration

After approval, owners of relevant drug or biologic 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 or BLA submission—and all of the review phase—the time between NDA or BLA 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.

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 USPTO 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 or biologic for which an NDA or BLA has not been submitted.

Biosimilars

The Biologics Price Competition and Innovation Act of 2009, or BPCIA, created an abbreviated approval pathway for biological products shown to be highly similar to or interchangeable with an FDA licensed reference biological product. Biosimilarity sufficient to reference a prior FDA-approved product requires that there be no differences in conditions of use, route of administration, dosage form, and strength, and no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency. Biosimilarity must be shown through analytical trials, animal trials, and a clinical trial or trials, unless the Secretary of the U.S. Department of Health and Human Services waives a required element. A biosimilar product may be deemed interchangeable with a prior approved product if it meets the higher hurdle of demonstrating that it can be expected to produce the same clinical results as the reference product and, for products administered multiple times, the biologic and the reference biologic may be switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic. The first biosimilar was approved by the FDA in 2015, and no interchangeable products have been approved under the BPCIA.

Complexities associated with the larger, and often more complex, structures of biological products, as well as the process by which such products are manufactured, pose significant hurdles to implementation, which is still being evaluated by the FDA.

A reference biologic is granted 12 years of exclusivity from the time of first licensure of the reference product, and no application for a biosimilar can be submitted for four years from the date of licensure of the reference product. The first biologic product submitted under the abbreviated approval pathway that is determined to be interchangeable with the reference product has exclusivity against a finding of interchangeability for other biologics for the same condition of use for the lesser of (i) one year after first commercial marketing of the first interchangeable biosimilar, (ii) 18 months after the first interchangeable biosimilar is approved if there is no patent challenge, (iii) 18 months after resolution of a lawsuit over the patents of the reference biologic in favor of the first interchangeable biosimilar applicant, or (iv) 42 months after the first interchangeable biosimilar's application has been approved if a patent lawsuit is ongoing within the 42-month period.

Post-approval requirements

Once a BLA is approved, a product will be subject to certain post-approval requirements. For instance, the FDA closely regulates the post-approval marketing and promotion of biologics, including standards and regulations for direct-to-consumer advertising, off-label promotion, industry-sponsored scientific and educational activities and promotional activities involving the internet.

Biologics may be marketed only for the approved indications and in accordance with the provisions of the approved labeling. Changes to some of the conditions established in an approved application, including changes in indications, labeling, or manufacturing processes or facilities, may require a submission to and approval by the FDA before the change can be implemented. A BLA supplement for a new indication typically requires clinical data similar to that in the original application and similar procedures and actions in reviewing BLA or supplements as in reviewing BLAs.

Adverse event reporting and submission of periodic reports is required following FDA approval of a BLA. The FDA also may require post-marketing testing, known as Phase 4 testing, REMS, and surveillance to monitor the effects of an approved product, or the FDA may place conditions on an approval that could restrict the distribution or use of the product. In addition, quality control, biological product manufacture, packaging, and labeling procedures must continue to conform to cGMPs after approval. Biologic manufacturers and certain of their subcontractors are required to register their establishments with the FDA and certain state agencies. Registration with the FDA subjects entities to periodic unannounced inspections by the 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. In addition, biological product manufacturers in the U.S. must comply with applicable provisions of the Drug Supply Chain Security Act and provide and receive product tracing information, maintain appropriate licenses, ensure they only work with other properly licensed entities and have procedures in place to identify and properly handle suspect and illegitimate products.

FDA regulation of companion diagnostics

If use of an *in vitro* diagnostic is essential for safe and effective use of a drug or biologic product, then the FDA generally will require approval or clearance of the diagnostic, known as a companion diagnostic, at the same time that the FDA approves the therapeutic product. The review of an *in vitro* companion diagnostic in conjunction with the review of a biologic involves coordination of review by the FDA's Center for Biologics Evaluation and Research and by the FDA's Center for Devices and Radiological Health. Pursuing FDA approval of an *in vitro* companion diagnostic would require us to obtain a
premarket approval, or PMA. The PMA process, including the gathering of clinical and preclinical data and the submission to and review by the FDA, can take several years or longer. It involves a rigorous premarket review during which the applicant must prepare and provide the FDA with reasonable assurance of the device's safety and effectiveness and information about the device and its components regarding, among other things, device design, manufacturing and labeling. PMA applications are subject to an application fee, which exceeds $250,000 for most PMAs. In addition, PMAs for certain devices must generally include the results from extensive preclinical and adequate and well-controlled clinical trials to establish the safety and effectiveness of the device for each indication for which FDA approval is sought. In particular, for a diagnostic, the applicant must demonstrate that the diagnostic produces reproducible results when the same sample is tested multiple times by multiple users at multiple laboratories. As part of the PMA review, the FDA will typically inspect the manufacturer's facilities for compliance with the Quality System Regulation, or QSR, which imposes elaborate testing, control, documentation and other quality assurance requirements.

PMA approval is not guaranteed, and the FDA may ultimately respond to a PMA application submission with a not approvable determination based on deficiencies in the application and require additional clinical trial or other data that may be expensive and time-consuming to generate and that can substantially delay approval. If the FDA's evaluation of the PMA application is favorable, the FDA typically issues an approvable letter requiring the applicant's agreement to specific conditions, such as changes in labeling, or specific additional information, such as submission of final labeling, in order to secure final approval of the PMA. If the FDA concludes that the applicable criteria have been met, the FDA will issue a PMA for the approved indications, which can be more limited than those originally sought by the applicant. The PMA can include post-approval conditions that the FDA believes necessary to ensure the safety and effectiveness of the device, including, among other things, restrictions on labeling, promotion, sale and distribution.

After a device is placed on the market, it remains subject to significant regulatory requirements. Medical devices may be marketed only for the uses and indications for which they are cleared or approved. Device manufacturers must also establish registration and device listings with the FDA. A medical device manufacturer's manufacturing processes and those of its suppliers are required to comply with the applicable portions of the QSR, which cover the methods and documentation of the design, testing, production, processes, controls, quality assurance, labeling, packaging and shipping of medical devices. Domestic facility records and manufacturing processes are subject to periodic unscheduled inspections by the FDA. The FDA also may inspect foreign facilities that export products to the U.S.

Other U.S. health care laws and compliance requirements

In the United States, our activities are potentially subject to regulation by various federal, state and local authorities in addition to the FDA, including but not limited to, the Centers for Medicare and Medicaid Services, or CMS, other divisions of the U.S. Department of Health and Human Services (such as the Office of Inspector General), the U.S. Department of Justice, or DOJ, and individual U.S. Attorney offices within the DOJ, and state and local governments. For example, sales, marketing and scientific/educational grant programs may have to comply with the anti-fraud and abuse provisions of the Social Security Act, anti-kickback statutes, false claims laws, the privacy and security provisions of the Health Insurance Portability and Accountability Act, or HIPAA, and similar state laws, each as amended, as applicable.

The federal Anti-Kickback Statute prohibits, among other things, any person or entity, from knowingly and willfully offering, paying, soliciting or receiving any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or in return for purchasing, leasing, ordering or arranging for the purchase, lease or order of any item or service reimbursable under Medicare, Medicaid or other federal health care programs. The term remuneration has been interpreted broadly to include anything of value. The Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand and prescribers, purchasers, and formulary managers on the other. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution. The exceptions and safe harbors are drawn narrowly and practices that involve remuneration that may be alleged to be intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exception or safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all of its facts and circumstances. Our practices may not in all cases meet all of the criteria for protection under a statutory exception or regulatory safe harbor.

Additionally, the intent standard under the Anti-Kickback Statute was amended by the Patient Protection and Affordable Care Act, or ACA, to a stricter standard such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. In addition, the ACA codified case law that a claim including items or 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 (discussed below).

The civil monetary penalties statute imposes penalties against any person or entity that, among other things, is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent.

Federal false claims and false statement laws, including the federal False Claims Act, prohibit, among other things, any person or entity from knowingly presenting, or causing to be presented, a false or fraudulent claim for payment to, or approval by, the federal health care programs, including Medicare and Medicaid, or knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government. As a result of a modification made by the Fraud Enforcement and Recovery Act of 2009, a claim includes "any request or demand" for money or property presented to the U.S. government. Recently, several pharmaceutical and other health care companies have been prosecuted under these laws for allegedly providing free product to customers with the expectation that the customers would bill federal

programs for the product. Other companies have been prosecuted for causing false claims to be submitted because of the companies' marketing of the product for unapproved, and thus generally non-reimbursable, uses.

HIPAA created additional federal criminal statutes that prohibit, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud or to obtain, by means of false or fraudulent pretenses, representations or promises, any money or property owned by, or under the control or custody of, any health care benefit program, including private third-party payors, willfully obstructing a criminal investigation of a health care offense, and knowingly and willfully falsifying, concealing or covering up by trick, scheme or device, a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for health care benefits, items or services. Like the Anti-Kickback Statute, the ACA amended the intent standard for certain health care fraud statutes under HIPAA such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

Also, many states have similar fraud and abuse statutes or regulations that apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor. Additionally, to the extent that our product is sold in a foreign country, we may be subject to similar foreign laws.

We may be subject to data privacy and security regulations by both the federal government and the states in which we conduct our business. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and its implementing regulations, imposes requirements relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH makes HIPAA's privacy and security standards directly applicable to business associates, independent contractors or agents of covered entities that receive or obtain protected health information in connection with providing a service on behalf of a covered entity. HITECH also created four new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce HIPAA and seek attorneys' fees and costs associated with pursuing federal civil actions. In addition, many state laws govern the privacy and security of health information in specified circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

Additionally, the federal Physician Payments Sunshine Act within the ACA, and its implementing regulations, require that certain manufacturers of drugs, devices, biological and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) report annually to CMS information related to certain payments or other transfers of value made or distributed to physicians and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of, the physicians and teaching hospitals and to report annually certain ownership and investment interests held by physicians and their immediate family members. Moreover, the Drug Supply Chain Security Act imposes new obligations on manufacturers of pharmaceutical products related to product tracking and tracing. Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products.

In order to distribute products commercially, we must comply with state laws that require the registration of manufacturers and wholesale distributors of drug and biological products in a state, including, in certain states, manufacturers and distributors who ship products into the state even if such manufacturers or distributors have no place of business within the state. Some states also impose requirements on manufacturers and distributors to establish the pedigree of product in the chain of distribution, including some states that require manufacturers and others to adopt new technology capable of tracking and tracing product as it moves through the distribution chain. Several states have enacted legislation requiring pharmaceutical and biotechnology companies to establish marketing compliance programs, file periodic reports with the state, make periodic public disclosures on sales, marketing, pricing, clinical trials and other activities, and/or register their sales representatives, as well as to prohibit pharmacies and other health care entities from providing certain physician prescribing data to pharmaceutical and biotechnology companies for use in sales and marketing, and to prohibit certain other sales and marketing practices. All of our activities are potentially subject to federal and state consumer protection and unfair competition laws.

If our operations are found to be in violation of any of the federal and state health care laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including without limitation, civil, criminal and/or administrative penalties, damages, fines, disgorgement, exclusion from participation in government programs, such as Medicare and Medicaid, injunctions, private "qui tam" actions brought by individual whistleblowers in the name of the government, or refusal to allow us to enter into government contracts, contractual damages, reputational harm, administrative burdens, diminished profits and future earnings, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

Coverage, pricing and reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any product candidates for which we obtain regulatory approval. In the United States and markets in other countries, sales of any products for which we receive regulatory approval for commercial sale will depend, in part, on the extent to which third- party payors provide coverage, and establish adequate reimbursement levels for such products. In the United States, third-party payors include federal and state health care programs, private managed care providers, health insurers and other organizations. The process for determining whether a third-party payor will provide coverage for a product may be separate from the process for setting the price of a product or for establishing the reimbursement rate that such a payor will pay for the product. Third-party payors may limit coverage to specific products on an approved list, also known as a formulary, which might not include all of the FDA-approved products for a particular indication. Third-party payors are increasingly challenging the price, examining the medical necessity and reviewing the cost-effectiveness of medical products, therapies and services, in addition to questioning their safety and efficacy. We may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of our products, in addition to the costs required to obtain the FDA approvals. Our product candidates may not be considered medically necessary or cost-effective. A payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Further, one payor's determination to provide coverage for a product does not assure that other payors will also provide coverage for the product. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development.

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

The marketability of any product candidates for which we receive regulatory approval for commercial sale may suffer if the government and third-party payors fail to provide adequate coverage and reimbursement. In addition, emphasis on managed care in the United States has increased and we expect will continue to increase the pressure on health care pricing. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Health care reform

In the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs. The pharmaceutical industry has been significantly affected by major legislative initiatives. For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively the ACA, was enacted, which was intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhanced 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. The ACA 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% 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, which has since been increased to 70% by the Bipartisan Budget Act of 2018, or BBA, (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.

There have been judicial and Congressional efforts to repeal, replace or change certain aspects of the ACA, including measures taken during the Trump administration. The Tax Cuts and Jobs Act of 2017, or 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." In November 2020, the United States Supreme Court held oral arguments on the Fifth Circuit U.S. Court of Appeals decision that held that the individual mandate is unconstitutional. It is uncertain how the United States Supreme Court will rule on this case or how healthcare measures of the Biden administration will impact the ACA and our business. Additionally, the 2020 federal spending package permanently eliminated, effective January 1, 2020, the ACA-mandated "Cadillac" tax on certain high cost employer-sponsored insurance plans and the medical device excise tax, and effective January 1, 2021, also eliminates the health insurer tax. The BBA, among other things, also amended the ACA, effective January 1, 2019, by increasing from 50% to 70% the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and closing the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole." In addition, CMS published a final rule that would give states greater flexibility, effective January 1, 2020, in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the ACA for plans sold through such marketplaces.

Other legislative changes have been proposed and adopted since the ACA was enacted. 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 to Medicare payments to providers of 2% per fiscal year, which went into effect in 2013 and will remain in effect through 2030, with the exception of a temporary suspension implemented under various COVID-19 relief legislation from May 1, 2020 through March 31, 2021, unless additional Congressional action is taken. The American Taxpayer Relief Act of 2012, among other things, 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. These laws may result in additional reductions in Medicare and other health care funding.

There have been 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, reduce the costs of drugs under Medicare and reform government program reimbursement methodologies for drug products. At the federal level, the Trump administration's budget proposal for fiscal year 2021 included a $135 billion allowance to support legislative proposals seeking to reduce drug prices, increase competition, lower out-of-pocket drug costs for patients, and increased patient access to lower cost generic and biosimilar drugs. In particular, on July 24, 2020 and September 13, 2020, the Trump administration announced several executive orders related to prescription drug pricing that seek to implement several of the administration's proposals. The FDA also released a final rule in September 2020 providing guidance for states to build and submit importation plans for drugs from Canada. The Trump and Biden administrations both issued executive orders intended to favor government procurement from domestic manufacturers. In addition, the Trump administration issued an executive order specifically aimed at the procurement of pharmaceutical products, which instructed the federal government to develop a list of "essential" medicines and then buy those and other medical supplies that are manufactured, including the manufacture of the API, in the United States. It is unclear whether this executive order or something similar will be implemented by the Biden Administration.

Further, in November 2020, HHS finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers. The CMS also issued an interim final rule implementing President Trump's Most Favored Nation executive order, which would tie Medicare Part B payments for certain physician-administered drugs to the lowest price paid in other economically advanced countries, effective January 1, 2021. On December 28, 2020, the United States District Court in Northern California issued a nationwide preliminary injunction against implementation of the interim final rule. In December 2020, CMS issued a final rule implementing significant manufacturer price reporting changes under the Medicaid Drug Rebate Program, including regulations that affect manufacturer-sponsored patient assistance programs subject to pharmacy benefit manager accumulator programs and Best Price reporting related to certain value-based purchasing arrangements.

The Foreign Corrupt Practices Act

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

Additional regulation

In addition to the foregoing, we are also subject to numerous federal, state and local laws relating to such matters as safe working conditions, manufacturing practices, environmental protection, fire hazard control, and disposal of hazardous or potentially hazardous substances, including the Occupational Safety and Health Act, the Resource Conservancy and Recovery Act and the Toxic Substances Control Act. These and other laws govern our use, handling and disposal of various biological, chemical and radioactive substances used in, and wastes generated by, our operations. If our operations result in contamination of the environment or expose individuals to hazardous substances, we could be liable for damages and governmental fines. We believe that we are in material compliance with applicable environmental laws and that continued compliance therewith will not have a material adverse effect on our business. We cannot predict, however, how changes in these laws may affect our future operations.

Europe / rest of world government regulation

In addition to regulations in the United States, we will be subject to a variety of regulations in other jurisdictions governing, among other things, clinical trials and any commercial sales and distribution of our products. Whether or not we obtain FDA approval of a product, we must obtain the requisite approvals from regulatory authorities in foreign countries prior to the commencement of clinical trials or marketing of the product in those countries. Certain countries outside of the United States have a similar process that requires the submission of a clinical trial application much like the IND prior to the commencement of human clinical trials. In the United Kingdom ("UK") and countries in the EU, for example, a Clinical Trial Authorisation, or CTA, must be submitted to each country's national health authority and an independent ethics committee, much like the FDA and IRB, respectively. Once the CTA is approved in accordance with a country's requirements, clinical trial development may proceed. Because biologically sourced raw materials are subject to unique contamination risks, their use may be restricted in some countries. The requirements and process governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. In all cases, the clinical trials are conducted in accordance with GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

To obtain regulatory approval of an investigational drug or biological product under EU and UK regulatory systems, we must submit a marketing authorization application. The application used to file the BLA in the United States is similar to that required in the EU and the UK, with the exception of, among other things, country-specific document requirements. For other countries outside of the EU and the UK, such as countries in Eastern Europe, Latin America or Asia, the requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. In all cases, again, the clinical trials are conducted in accordance with GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

If we or our potential collaborators fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

Australia

Conducting clinical trials for therapeutic drug candidates in Australia is subject to regulation by Australian governmental entities. Approval for inclusion in the Australian Register of Therapeutic Goods, or the ARTG, is required before a pharmaceutical drug product may be marketed in Australia.

Typically, the process of obtaining approval of a new therapeutic drug product for inclusion in the ARTG requires compilation of clinical trial data. Clinical trials conducted using "unapproved therapeutic goods" in Australia, being those which have not yet been evaluated by the Therapeutic Goods Administration, or the TGA, for quality, safety and efficacy must occur pursuant to either the Clinical Trial Notification, or CTN, or Clinical Trial Exemption, or CTX, process.

The CTN process broadly involves:

- completion of pre-clinical laboratory and animal testing;
- submission to a Human Research Ethics Committee, or the HREC, of all material relating to the proposed clinical trial, including the trial protocol. The TGA does not review any data relating to the clinical trial;
- the institution or organization at which the clinical trial will be conducted, referred to as the "Approving Authority" gives the final approval for the conduct of the clinical trial at the site, having due regard to the advice from the HREC; and
- CTN clinical trials cannot commence until the clinical trial has been notified to the TGA.

Under the CTX process:

- a sponsor submits an application to conduct a clinical trial to the TGA for evaluation and comment; and
- a sponsor cannot commence a CTX clinical trial until written advice has been received from the TGA regarding the application and approval for the conduct of the clinical trial has been obtained from an ethics committee and the institution at which the clinical trial will be conducted.

In each case, it is required that:

- adequate and well-controlled clinical trials demonstrate the quality, safety and efficacy of the therapeutic product;
- evidence is compiled which demonstrates that the manufacture of the therapeutic drug product complies with the principles of cGMP;
- manufacturing and clinical data is derived to submit to the Australian Committee on Prescription Medicines, which makes recommendations to the TGA as to whether or not to grant approval to include the therapeutic drug product in the ARTG; and
- an ultimate decision is made by the TGA whether to include the therapeutic drug product in the ARTG.

Pre-clinical studies include laboratory evaluation of the therapeutic drug product as well as animal studies to assess the potential safety and efficacy of the drug. The results of the pre-clinical studies form part of the materials submitted to the investigators HREC in the case of a CTN trial and part of the application to the TGA in the case of a CTX trial.

Clinical trials involve administering the investigational product to healthy volunteers or patients under the supervision of a qualified principal investigator. The TGA has developed guidelines for a CTN. Under the CTN process, all material relating to the proposed clinical trial is submitted directly to the HREC of each institution at which the clinical trial is to be conducted. An HREC is an independent review committee set up under guidelines of the Australian National Health and Medical Research Council. The role of an HREC is to ensure the protection of rights, safety and wellbeing of human subjects involved in a clinical trial by, among other things, reviewing, approving and providing continuing review of trial protocols and amendments, and of the methods and material to be used in obtaining and documenting informed consent of the trial subjects. The TGA is formally notified by submission of a CTN application but does not review the safety of the drug or any aspect of the proposed trial. The approving authority of each institution gives the final approval for the conduct of the clinical trial, having due regard to advice from the HREC. Following approval, responsibility for all aspects of the trial conducted under a CTN application remains with the HREC of each investigator's institution.

The standards for clinical research in Australia are set by the TGA and the National Health and Medical Research Council, and compliance with GCP is mandatory. Guidelines, such as those promulgated by the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use, or ICH, are required across all fields, including those related to pharmaceutical quality, nonclinical and clinical data requirements and study designs. The basic requirements for preclinical data to support a first-in- human study under ICH guidelines are applicable in Australia. Requirements related to adverse event reporting in Australia are similar to those required in other major jurisdictions.

Employees and Human Capital Resources

As of December 31, 2020, we had 94 full-time employees. Of these employees, 74 were primarily engaged in research and development activities and 27 have an M.D. or a Ph.D. None of our employees are represented by a labor union or covered by collective bargaining agreements. We have never experienced a work stoppage and believe that we have good employee relations.

We view our diverse employee population and our culture as key to our success. Our company culture prioritizes learning, supports growth and empowers us to reach new heights. We recruit employees with the skills and training relevant to succeed and thrive in their functional responsibilities. We assess the likelihood that a particular candidate will contribute to the Company's overall goals, and beyond their specifically assigned tasks. Depending on the position, our recruitment reach can be local as well as national. We provide competitive compensation and best in class benefits that are tailored specifically to the needs and requests of our employees. During 2020, we worked to manage through the effects of the COVID-19 pandemic and entered 2021 stronger than ever. During 2020 all employees were retained at full salary and lab employees' productivity and safety were a top priority. As appropriate, others were provided the option of working remotely or at our facilities with appropriate safeguards. We uphold our commitment to shareholders by working hard, being thoughtful about how we use resources and doing the right thing for the company at every turn.

Corporate Information

We were incorporated under the laws of the State of Delaware in November 2005. Our principal executive offices are located at 10421 Pacific Center Court, Suite 200, San Diego, California 92121, and our telephone number is (858) 362-6295. Our website address is www.anaptysbio.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 report.

Available Information

We file Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and other information with the Securities and Exchange Commission (SEC). Our filings with the SEC are available free of charge on the SEC's website at *www.sec.gov* and on our website under the "Investors" tab as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC.

Item 1A. Risk Factors

Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below, as well as the other information in this report, including our consolidated financial statements and the related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations," before deciding whether to invest in our common stock. The occurrence of any of the events or developments described below could harm our business, financial condition, results of operations, and growth prospects. In such an event, the market price of our common stock could decline, and you may lose all or part of your investment.

Summary of Risk Factors

An investment in our common stock involves various risks, and prospective investors are urged to carefully consider the matters discussed in the section titled "Risk Factors" prior to making an investment in our common stock. These risks include, but are not limited to, the following:

- Our product candidates are in early stages of development and may fail in development or suffer delays that adversely affect their commercial viability. Results from our initial clinical trials may not be representative of the results we will experience in later clinical trials. 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.
- The COVID-19 pandemic has had a material impact on the U.S. and global economies and could have a material adverse impact on our employees, contractors, and patients, which could adversely and materially impact our business, financial condition, and results of operations.
- We have only limited data regarding the safety profile of our wholly-owned product candidates when dosed in humans. Our ongoing and planned clinical trials or those of our collaborators may reveal significant adverse events, toxicities or other side effects and may result in a safety profile that could inhibit regulatory approval or market acceptance of any of our product candidates.
- We and/or our collaborators may be unable to obtain, or may be delayed in obtaining, required regulatory approvals in the United States or in foreign jurisdictions, which would materially impair our ability to commercialize and generate revenue from our product candidates.
- We may not be successful in our efforts to use our technology platform to expand our pipeline of product candidates and develop marketable products.

- We have recently commenced clinical development of imsidolimab, ANB030 and ANB032 and have a limited history of conducting clinical trials and no history of commercializing biotechnology products, which may make it difficult to evaluate the prospects for our future viability.
- We face significant competition, and if our competitors develop and market products that are more effective, safer or less expensive than our product candidates, our commercial opportunities will be negatively impacted.
- Our product candidates may not achieve adequate market acceptance among physicians, patients, health care payors and others in the medical community necessary for commercial success.
- If companion diagnostics for our product candidates, for which such diagnostics are required, are not successfully, and in a timely manner, validated, developed or approved, we may not achieve marketing approval or realize the full commercial potential of our product candidates.
- The manufacture of biologics is complex, and our third-party manufacturers may encounter difficulties in production. If 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.
- We have limited operating revenue and a history of operational losses and may not achieve or sustain profitability.
- We have no products approved for commercial sale, and to date we have not generated any revenue or profit from sales of our product candidates.
- We will require additional capital to finance our operations, which may not be available to us on acceptable terms, or at all. As a result, we may not complete the development and commercialization of our product candidates or develop new product candidates.
- We must attract and retain highly skilled employees in order to succeed.
- The manufacture of biotechnology products is complex, and manufacturers often encounter difficulties in production. If we or any of our third-party manufacturers encounter any loss of our master cell banks or if any of our third-party manufacturers encounter other difficulties, or otherwise fail to comply with their contractual obligations, our ability to provide product candidates for clinical trials or our products to patients, once approved, could be delayed or stopped.
- We currently have no marketing and sales force. If we are unable to establish effective sales or marketing capabilities or enter into agreements with third parties to sell or market our product candidates, we may not be able to effectively sell or market our product candidates, if approved, or generate product revenue.
- Our existing collaborations, including those with GSK and BMS, are important to our business, and future collaborations may also be important to us. If we are unable to maintain any of these collaborations, or if these collaborations are not successful, our business could be adversely affected.
- We may not succeed in establishing and maintaining additional development and commercialization collaborations, which could adversely affect our ability to develop and commercialize product candidates.
- Even if our product candidates receive regulatory approval, they will be subject to significant post-marketing regulatory requirements.
- If we are unable to obtain or protect intellectual property rights, we may not be able to compete effectively in our market.
- We may not be able to protect our intellectual property rights throughout the world.
- The market price of our stock has been and may continue to be volatile, and you could lose all or part of your investment.

Risks Related to Discovery and Development of Our Product Candidates

Our product candidates are in early stages of development and may fail in development or suffer delays that adversely affect their commercial viability. Results from our initial clinical trials may not be representative of the results we will experience in later clinical trials. 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 are using our proprietary technology platform to develop therapeutic antibodies, including our wholly-owned product candidates, as well as other programs that are being developed by our collaborators. However, all of our wholly-owned

and most of partnered product candidates are in the early stages of development, and, for a wide variety of reasons discussed below, may fail in development or suffer delays that adversely affect their commercial viability.

A product candidate can unexpectedly fail at any stage of preclinical and clinical development. The historical failure rate for product candidates is high due to scientific feasibility, safety, efficacy, changing standards of medical care, and other variables. The results from preclinical testing or early clinical trials of a product candidate may not predict the results that will be obtained in later phase clinical trials of the product candidate. For example, results from our initial Phase 2a clinical trial of etokimab in moderate-to-severe atopic dermatitis patients were not representative of the results we experienced in our later etokimab moderate-to-severe atopic dermatitis Phase 2b clinical trial called "ATLAS" and we ultimately discontinued development of etokimab.

Furthermore, our rationale for conducting clinical trials of imsidolimab in multiple indications is that we believe imsidolimab's mechanism of action, the inhibition of IL-36R, has the potential be effective for treatment of a range of dermatological inflammatory diseases. However, it is possible that our assumptions regarding the effectiveness of imsidolimab's mechanism of action may be incorrect and that imsidolimab may be ineffective in certain dermatological inflammatory diseases or in treating inflammatory disorders generally. If this were the case, then the results from any clinical trials of imsidolimab that we conduct are less likely to be positive.

If our later clinical trials of imsidolimab are unsuccessful, whether for one of the reasons mentioned above or otherwise, imsidolimab may be delayed in development or fail entirely, which would have a material adverse impact on our business.

The success of our current product candidates, and any other product candidates we may develop in the future, will depend on many factors, including the following:

- obtaining regulatory permission to initiate clinical trials;
- successful enrollment of patients in, and the completion of, our planned clinical trials;
- receiving marketing approvals from applicable regulatory authorities;
- establishing commercial manufacturing capabilities and/or making 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 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 harm our business.

Furthermore, delays or difficulties in patient enrollment or difficulties in retaining trial participants can result in increased costs, longer development times, or termination of a clinical trial. Clinical trials of a new product candidate require the enrollment of a sufficient number of patients, including patients who are suffering from the disease the product candidate is intended to treat and who meet other eligibility criteria. Rates of patient enrollment are affected by many factors, including the size of the patient population, the eligibility criteria for the clinical trial, the age and condition of the patients, the stage and severity of disease, the nature of the protocol, the proximity of patients to clinical sites, and the availability of effective treatments for the relevant disease. We may not be able to initiate our planned clinical trials if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or foreign regulatory authorities. More specifically, some of our product candidates, including imsidolimab, initially target indications that are very rare, which can prolong the clinical trial timeline for the regulatory process if sufficient patients cannot be enrolled in a timely manner.

The COVID-19 pandemic has had a material impact on the U.S. and global economies and could have a material adverse impact on our employees, contractors and patients, which could adversely and materially impact our business, financial condition and results of operations.

The COVID-19 pandemic and mitigation measures have had, and may continue to have, an adverse impact on global economic conditions, which could have an adverse effect on our business and financial condition, including impairing our ability to raise capital when needed. The extent to which the COVID-19 pandemic impacts our business and operations will depend on future developments that are highly uncertain and cannot be predicted, including new information that may emerge concerning the severity of the virus and the actions to contain its impact.

The COVID-19 pandemic has caused us to modify our business practices (including but not limited to curtailing or modifying employee travel, moving to full remote work, and cancelling physical participation in meetings, events and conferences), and we may take further actions as may be required by government authorities or that we determine are in the best interests of our employees and patients. In response to the COVID-19 pandemic, we limited our office to only those employees completing laboratory-based tasks essential to our development efforts, and are starting to allow other employees to work in our office with certain precautions in place that we believe will ensure our employees' safety and wellbeing. "Essential" employees that are unable to telework continue to work at our facilities, and we have implemented appropriate safety measures, including social distancing, face covering and increased sanitation standards. We are following guidance from the Center for Disease Control and the Occupational Safety and Health Administration regarding suspension of nonessential travel, self-isolation recommendations for employees returning from certain geographic areas, confirmed reports of any COVID-19 diagnosis among our employees and the return of such employees to our workplace. Pursuant to updated guidance from the Equal Employment Opportunity Commission, we are engaging in limited and appropriate inquiries of employees regarding potential COVID-19 exposure based on the direct threat that such exposure may present to our workforce. We continue to address other unique situations that arise among our workforce due to the COVID-19 pandemic on a case-by-case basis. While we believe that we have taken appropriate measures to ensure the health and well-being of our "essential" employees, there can be no assurances that our measures will be sufficient to protect our employees in our workplace, and they may be exposed to COVID-19 outside of our workplace. If a number of our essential employees become ill, incapacitated or are otherwise unable to continue working during the current or any future epidemic, our operations may be adversely impacted.

A prolonged disruption or any further unforeseen delay in our operations or within any of our business activities could continue to result in reduced participation in ongoing clinical trials or delays in enrolling our planned clinical trials because we rely on contract research organizations (for non-clinical and clinical activities) ("CROs") and contract manufacturing organizations ("CMOs") to conduct our clinical trials and to manufacture our product candidates. If our CROs are unable to continue ongoing clinical trials or to enroll new patients for new clinical trials, or if our CMOs are unable to obtain sufficient quantities of reagents or manufacture adequate drug quantities, our clinical trials could be materially delayed or disrupted. We may also encounter delays from the FDA, EMA or other health authorities in our clinical development efforts. Any elongation or de-prioritization of our preclinical or clinical studies or delay in regulatory review resulting from such disruptions could materially affect the development and study of our product candidates. Further, in reaction to the spread of COVID-19 in the United States and internationally, many patients and medical facilities are delaying or canceling elective procedures, adding further strain to health care budgets globally.

The COVID-19 pandemic may result in the inability of our suppliers to deliver supplies to us on a timely basis. We currently utilize third parties to, among other things, manufacture components of our product candidates and, in the future, intend to utilize third parties to conduct our preclinical and clinical studies. If either we or any third-party parties in the supply chain for materials used in the production of our product candidates are adversely impacted by restrictions resulting from the COVID-19 pandemic, our supply chain may be disrupted, limiting our ability to manufacture our product candidates for our preclinical or clinical studies.

Both the health and economic aspects of the COVID-19 virus are highly fluid, and the future course of each is uncertain. For these reasons and other reasons that may come to light if the COVID-19 pandemic and associated protective or preventative measures expand, we may experience a material adverse effect, either directly or indirectly through our CROs, CMOs, collaboration partners or patients, on our business operations, revenues and financial condition; however, its ultimate impact is highly uncertain and subject to change.

We have only limited data regarding the safety profile of our wholly-owned product candidates when dosed in humans. Our ongoing and planned clinical trials or those of our collaborators may reveal significant adverse events, toxicities or other side effects and may result in a safety profile that could inhibit regulatory approval or market acceptance of any of our product candidates.

In order to obtain marketing approval for any of our product candidates, we must demonstrate the safety and efficacy of the product candidate for the relevant clinical indication or indications through preclinical studies and clinical trials as well as

additional supporting data. If our product candidates are associated with undesirable side effects in preclinical studies or clinical trials or have characteristics that are unexpected, we may need to interrupt, delay or abandon their development or limit development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective.

We have conducted various preclinical studies of our product candidates, but we do not know the predictive value of these studies for humans, and we cannot guarantee that any positive results in preclinical studies will successfully translate to human patients. We have only completed a Phase 1 clinical trial with imsidolimab, and subsequent clinical trials with imsidolimab are currently ongoing. It is not uncommon to observe results in human clinical trials that are unexpected based on preclinical testing, or to observe results in later stage clinical trials that are unexpected based on early clinical trials. Many product candidates fail in clinical trials despite promising preclinical and early clinical results. In addition, top-line results of a clinical trial, which generally reflect preliminary reviews of primary efficacy and/or safety results, do not necessarily predict final results, and any top-line findings or assessments are subject to change pending the completion of final data review procedures. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval for their products.

Some patients in our clinical trials have experienced adverse events, including serious adverse events. We reported that one patient dropped out of the GALLOP Phase 2 clinical trial for imsidolimab due to diagnosis with Staphylococcal aureus bacteremia on Day 3 post-imsidolimab administration, which was a serious adverse event deemed to be possibly drug-related. Subjects in our ongoing and planned clinical trials may in the future suffer significant adverse events or other side effects not observed in our preclinical studies or in our Phase 1 or Phase 2 clinical trials. The observed potency and kinetics of our product candidates in preclinical studies may not be observed in human clinical trials. We have tested the dosing frequency and route of administration of our product candidates in preclinical studies, which will inform our dosing strategy for future clinical trials, however such dose and route of administration may not result in sufficient exposure or pharmacological effect in humans and may lead to unforeseen toxicity not previously observed in preclinical testing. If preclinical studies of our product candidates fail to provide preliminary evidence of safety to the satisfaction of regulatory authorities or do not otherwise produce satisfactory results, we may incur additional costs or experience delays in initiating and/or advancing the development and commercialization of our product candidates. Further, if clinical trials of our product candidates fail to demonstrate safety and efficacy to the satisfaction of regulatory authorities or do not otherwise produce positive results, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.

If further significant adverse events or other side effects are observed in any of our current or future clinical trials, we may have difficulty recruiting patients to the clinical trial, patients may drop out of our trial, or we may be required to abandon the trial or our development efforts of that product candidate altogether. We, the FDA, or other applicable regulatory authorities, or an institutional review board or ethics committee, may suspend clinical trials of a product candidate at any time for various reasons, including a belief that subjects in such clinical 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 studies have later been found to cause side effects that prevented their further development. Even if the side effects do not preclude a 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.

Further, if any of our product candidates obtain marketing approval, toxicities associated with our product candidates may also develop after such approval and lead to a requirement to conduct additional clinical safety trials, additional warnings being added to the labeling, significant restrictions on the use of the product or the withdrawal of the product from the market. We cannot predict whether our product candidates will cause toxicities in humans that would preclude or lead to the revocation of regulatory approval based on preclinical studies or early stage clinical testing.

We and/or our collaborators may be unable to obtain, or may be delayed in obtaining, required regulatory approvals in the United States or in foreign jurisdictions, which would materially impair our ability to commercialize and generate revenue from our product candidates.

Our ability to continue to develop our product candidates, and to have the potential to achieve and sustain profitability, depends on the FDA and foreign regulatory authorities permitting us to conduct human clinical trials and, if our product candidates are safe and effective, obtaining approval from the FDA and foreign regulatory authorities to market them and subsequently successfully commercializing them, either alone or with our collaborators. The research, testing, manufacturing, labeling, approval, selling, marketing and distribution of drug and biologic products are subject to extensive regulation by the FDA and foreign regulatory authorities. Though we have cleared an IND and clinical trial application (“CTA”) to conduct

clinical trials for imsidolimab in the United States and certain foreign jurisdictions and we have cleared an IND to conduct a clinical trial for ANB030 in the United States, before commencing clinical trials in the United States for any other product candidate, we must submit an IND to the FDA; foreign regulatory authorities enforce similar requirements for initiation of clinical trials in other countries. An IND or foreign equivalent requires extensive preclinical studies, and there is no guarantee that the FDA or foreign regulatory authorities will allow clinical trials to proceed based on the IND or equivalent submission. For example, although we have initiated toxicology studies for our product candidates, the FDA in the United States, or other foreign regulatory authorities, as applicable, may not allow our clinical trials to proceed in the regulatory authority's jurisdiction if we are unable to show safety margins acceptable to the particular regulatory authority in appropriate animal species in our preclinical toxicology studies.

Even if we or our collaborators initiate and complete clinical trials for our product candidates, these product candidates will not be permitted to be marketed in the United States until approval of a BLA from the FDA is received, and will not be permitted to be marketed in other countries without marketing approval from foreign regulatory authorities. Obtaining approval of a BLA or other marketing approvals is often a lengthy, expensive and uncertain process over which the FDA and foreign regulatory authorities have substantial discretion. Other than submitting and receiving acceptance for initiation of our previous and current clinical trials in the United States and certain foreign jurisdictions, we have had only limited discussions with the FDA and no discussions with foreign regulatory authorities regarding the development plans for any of our product candidates or the designs of any of our later-stage clinical studies. We thus may not have the full benefit of the FDA's or foreign regulatory authorities' current thinking on clinical trial designs or product development for our target indications. For example, we believe a small pivotal clinical trial, potentially with less than 100 patients, may be sufficient to demonstrate substantial evidence of efficacy of imsidolimab in GPP patients. However, the FDA may disagree with our proposed clinical trial design, including the number of patients necessary to demonstrate efficacy, and/or may require us to conduct more than one pivotal clinical trial in order to obtain approval of a BLA.

Preclinical studies and clinical trials are expensive, difficult to design and implement, can take many years to complete, and are uncertain as to outcome. Product candidates, on average, take 10 to 15 years to be developed from the time they are discovered to the time they are approved and available for treating patients. The start or end of a clinical trial is often delayed or halted for many reasons, including:

- imposition of a clinical hold for safety reasons or following an inspection of clinical trial operations or site by the FDA or other regulatory authorities;
- manufacturing challenges;
- insufficient supply or quality of product candidates or other materials necessary to conduct clinical trials;
- delays in reaching or failure to reach agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites and CROs or failure by such CROs or trials sites to carry out the clinical trial in accordance with our agreed-upon terms;
- non-clinical or clinical sites becoming unavailable due to political, economic, or public health events, such as the COVID-19 pandemic;
- clinical sites electing to terminate their participation in one of our clinical trials;
- inability or unwillingness of patients or medical investigators to follow clinical trial protocols;
- required clinical trial administrative actions;
- slower than anticipated patient enrollment;
- changing standards of care;
- safety concerns;
- availability or prevalence of use of a comparative drug or required prior therapy; or
- clinical outcomes or financial constraints.

Our product candidates may not be effective, may be only moderately effective, or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use. Regulatory authorities may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical or other studies or clinical trials. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent marketing approval of a product candidate. Moreover, regulatory authorities may determine that the clinical and other benefits of a product candidate do not outweigh the safety or other risks. Changes in marketing approval policies during the development period, changes in or the enactment of

additional statutes or regulations, or changes in regulatory review for each submitted product application may also cause delays in or prevent the approval of an application.

If we experience any of the issues described above, or other similar or related issues, we may:

- be delayed in obtaining marketing approval for our product candidates;
- not obtain marketing approval at all;
- obtain marketing approval in some countries and not in others;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings, including boxed warnings;
- be subject to additional post-marketing testing requirements; or
- have the product removed from the market after obtaining marketing approval.

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

Because we have limited financial and managerial resources, we focus on research programs and product candidates that we identify for specific indications. Our business depends on our successful development and commercialization of the limited number of internal product candidates we have in preclinical and early-stage clinical development. Even if we are successful in continuing to build our pipeline, development of the potential product candidates that we identify will require substantial investment in additional clinical development, management of clinical, preclinical and manufacturing activities, regulatory approval in multiple jurisdictions, building a commercial organization, and significant marketing efforts before we generate any revenue from product sales. Furthermore, such product candidates may not be suitable for clinical development, including as a result of their harmful side effects, limited efficacy or other characteristics that indicate that they are unlikely to be products that will receive marketing approval and achieve market acceptance. If we cannot validate our technology platform by successfully developing and commercializing product candidates based upon our technological approach, we may not be able to obtain product or partnership revenue in future periods, which would adversely affect our business, prospects, financial condition and results of operations.

As a result of our current focus on our lead product candidates, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products. Our understanding and evaluation of biological targets for the discovery and development of new product candidates may fail to identify challenges encountered in subsequent preclinical and clinical development. 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.

We have recently commenced clinical development of imsidolimab, ANB030 and ANB032 and have a limited history of conducting clinical trials and no history of commercializing biotechnology products, which may make it difficult to evaluate the prospects for our future viability.

Our operations to date have been largely limited to financing and staffing our company, developing our technology, and developing our wholly-owned product candidates and other product candidates in partnerships with our collaborators. As a company, we have only very limited experience conducting clinical trials and have not had previous experience commercializing product candidates, including submitting a BLA to the FDA. In part because of this lack of experience, we cannot be certain that planned clinical trials will begin or be completed on time, if at all, that our planned development programs would be acceptable to the FDA or other regulatory authorities, or that, if approval is obtained, such product candidates can be successfully commercialized. Clinical trials and commercializing our wholly-owned product candidates will require significant additional financial and management resources, and reliance on third-party clinical investigators, CROs, consultants or collaborators. Relying on third-party clinical investigators, CROs or collaborators may result in delays that are outside of our control.

Furthermore, we may not have the financial resources to continue development of, or to enter into collaborations for, a product candidate if we experience any problems or other unforeseen events that delay or prevent regulatory approval of, or our ability to commercialize, product candidates, including:

- 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;
- delays in submitting INDs or comparable foreign applications or delays or failure 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 foreign regulatory authorities regarding the number, scope or design of our clinical trials;
- delays in enrolling research subjects in clinical trials;
- high drop-out rates of research subjects;
- inadequate supply or quality of clinical trial materials or other supplies necessary for the conduct of our clinical trials;
- greater than anticipated clinical trial costs;
- poor effectiveness or unacceptable side effects of our product candidates during clinical trials;
- unfavorable FDA or other regulatory agency inspection and review of a clinical trial site;
- 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;
- serious and unexpected drug-related side effects experienced by participants in our planned clinical trials or by individuals using drugs similar to our product candidates;
- 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 data by the FDA and foreign regulatory authorities.

Consequently, any predictions you make about our future success or viability based on our short operating history may not be as accurate as they could be if we had a longer operating history or an established track record in conducting clinical trials or commercializing products.

Further, as a clinical stage business, we may encounter unforeseen expenses, difficulties, complications, delays, and other known and unknown factors. We will need to transition from a company with a research focus to a company capable of supporting commercial activities. We may not be successful in such a transition.

We face significant competition, and if our competitors develop and market products that are more effective, safer or less expensive than our product candidates, our commercial opportunities will be negatively impacted.

The biotechnology industry is highly competitive and subject to rapid and significant technological change. Products we may develop in the future are also likely to face competition from other drugs and therapies, some of which we may not currently be aware. We have competitors both in the United States and internationally, including major multinational pharmaceutical and biotechnology companies, established biotechnology companies, specialty biotechnology companies, emerging and start-up companies, universities and other research institutions. Many of our competitors have significantly greater financial, manufacturing, marketing, drug development, technical and human resources and commercial expertise than we do. Large pharmaceutical and biotechnology companies, in particular, have extensive experience in clinical testing, obtaining regulatory approvals, recruiting patients and manufacturing biotechnology products. These companies also have significantly greater research and marketing capabilities than we do and may also have products that have been approved or are in late stages of development and collaborative arrangements in our target markets with leading companies and research institutions. Established pharmaceutical and biotechnology companies may also invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make the product candidates that we develop obsolete. As a result of all of these factors, our competitors may succeed in obtaining patent protection and/or approval from the FDA or foreign regulatory authorities or discovering, developing and commercializing products in our field before we do.

For GPP and PPP, our competitors include marketed therapies such as secukinumab (Cosentyx; Novartis), which binds IL-17A; ustekinumab (Stelara; Janssen), which blocks IL-12 and 23 cytokine function; and acitretin (Soriatane; GSK), as well as therapies in development such as guselkumab (Janssen), which blocks IL-23 cytokine function, gevokizumab (Xoma 052) and canakinumab (Ilaris, Novartis), which binds IL-1 beta, anakinra (Kineret; Swedish Orphan Biovitrum AB), a recombinant form of the IL-1 receptor antagonist and an anti-IL-36 receptor antibody called BI-655130 (Boehringer Ingelheim).

For ichthyosis, systemically administered competitors include secukinumab (Cosentyx; Novartis), liarozole (GSK), dupilumab (Dupixent; Regeneron/Sanofi), and adalimumab (Humira; Abbvie). Various topical treatments may also be used off-label for treatment of ichthyosis related symptoms.

For hidradenitis suppurativa, our competitors include adalimumab (Humira; Abbvie) which is approved for the treatment of moderate to severe hidradenitis suppurativa for patients 12 years of age or older.

For acne, our competitors include retinoids and retinoid-like drugs, including tretinoin (Avita, Retin-A, adapalene (Differin) and tazarotene (Tazorac, Avage), antibiotics including clindamycin (Benzaclin, Duac) and erythromycin (Benzamycin) and isotretinoin (Amnesteem, Claravis, Accutane) and oral antibiotics including sarecycline (Seysara).

For our anti-inflammatory checkpoint modulator antibody programs, our competitors include CC-90006 (BMS), which is an anti-PD-1 agonist antibody developed under our partnership with BMS, a BTLA modulator antibody called LY3361237 being developed by Eli Lilly, a PD-1 agonist antibody called LY3462817 also being developed by Eli Lilly and two PD-1 agonist antibodies called PT627 and PT001 being developed by Pandion Therapeutics. Our competitors in moderate-to-severe alopecia areata and vitiligo include topical and oral corticosteroids, topical immunotherapy (diphencyprone, dinitrochlorobenzene, squaric acid dibutyl ester), calcineurin inhibitors (tacrolimus, pmecrolimus), light therapy, prostaglandins and janus kinase inhibitors (tofacitinib, rixolitinib) currently in development.

With the enactment of the Biologics Price Competition and Innovation Act of 2009 (“BPCIA”), an abbreviated pathway for the approval of biosimilar and interchangeable biological products was created. The abbreviated regulatory pathway establishes legal authority for the FDA to review and approve biosimilar biologics, including the possible designation of a biosimilar as interchangeable based on its similarity to an existing reference product. Under the BPCIA, an application for a biosimilar product cannot be approved by the FDA until 12 years after the original branded product is approved under a BLA. To date, several biosimilar products have been approved under the BPCIA, but no interchangeable biological products have been approved. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation, and meaning are subject to uncertainty. While it is uncertain when such processes intended to implement BPCIA may be fully adopted by the FDA, any such processes could have a material adverse effect on the future commercial prospects for our biological products.

We believe that if any of our product candidates are approved as a biological product under a BLA it should qualify for the 12-year period of exclusivity. However, there is a risk that the FDA will not consider any of our product candidates to be reference products for competing products, potentially creating the opportunity for biosimilar competition sooner than anticipated. Additionally, this period of regulatory exclusivity does not apply to companies pursuing regulatory approval via their own traditional BLA, rather than via the abbreviated pathway. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe effects, are more convenient, are less expensive or capture significant market share prior to or during our commercialization. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. In addition, our ability to compete may be affected in many cases by insurers or other third party payors seeking to encourage the use of biosimilar products. Even if our product candidates achieve marketing approval, they may be priced at a significant premium over competitive biosimilar products if any have been approved by then.

Smaller and other early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These companies compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for planned clinical trials and acquiring technologies complementary to, or necessary for, our programs. In addition, the biotechnology industry is characterized by rapid technological change. If we fail to stay at the forefront of technological change, we may be unable to compete effectively. Technological advances or products developed by our competitors may render our technologies or product candidates obsolete, less competitive or not economical.

Our product candidates may not achieve adequate market acceptance among physicians, patients, health care payors and others in the medical community necessary for commercial success.

Even if our product candidates receive regulatory approval, they may not gain adequate market acceptance among physicians, patients, health care payors and others in the medical community. The degree of market acceptance of any of our approved product candidates will depend on a number of factors, including:

- the efficacy and safety profile as demonstrated in planned clinical trials;
- the timing of market introduction of the product candidate as well as competitive products;
- the clinical indications for which the product candidate is approved;
- restrictions on the use of our products, if approved, such as boxed warnings or contraindications in labeling or a risk evaluation and mitigation strategy ("REMS"), if any, which may not be required of alternative treatments and competitor products;
- acceptance of the product candidate as a safe and effective treatment by physicians, clinics and patients;
- the potential and perceived advantages of product candidates over alternative treatments, including any similar generic treatments;
- the cost of treatment in relation to alternative treatments;
- the availability of coverage and adequate reimbursement and pricing by third parties and government authorities;
- relative convenience and ease of administration;
- the frequency and severity of adverse events;
- the effectiveness of sales and marketing efforts; and
- unfavorable publicity relating to the product candidate.

If any product candidate is approved but does not achieve an adequate level of acceptance by physicians, hospitals, health care payors and patients, we may not generate or derive sufficient revenue from that product candidate and may not become or remain profitable.

If companion diagnostics for our product candidates, for which such diagnostics are required, are not successfully, and in a timely manner, validated, developed or approved, we may not achieve marketing approval or realize the full commercial potential of our product candidates.

If companion diagnostics are developed in conjunction with clinical programs, the FDA may require regulatory approval of a companion diagnostic as a condition to approval of the product candidate. For example, if we use a genetic test to determine which patients are most likely to benefit from imsidolimab for the treatment of GPP or PPP by designing our pivotal clinical trial or clinical trials of imsidolimab in that indication to require that subjects test positive for specific genetic mutations as a criterion for enrollment, then we will likely be required to obtain FDA approval or clearance of a companion diagnostic, concurrent with approval of imsidolimab, to test for those genetic mutations; we may also be required to demonstrate to the FDA the predictive utility of the companion diagnostic—namely, that the diagnostic selects for patients in whom the biologic therapy will be effective or more effective compared to patients not selected for by the diagnostic. We do not have experience or capabilities in developing or commercializing diagnostics and plan to rely in large part on third parties to perform these functions. We do not currently have any agreement in place with any third party to develop or commercialize companion diagnostics for any of our product candidates. Companion diagnostics are subject to regulation by the FDA and foreign regulatory authorities as medical devices and require separate regulatory approval or clearance prior to commercialization.

If we or our partners, or any third party, are unable to successfully develop companion diagnostics for our product candidates, or experience delays in doing so:

- the development of our product candidates may be adversely affected if we are unable to appropriately select patients for enrollment in our planned clinical trials;
- our product candidates may not receive marketing approval if their safe and effective use depends on a companion diagnostic; and
- we may not realize the full commercial potential of any product candidates that receive marketing approval if, among other reasons, we are unable to appropriately identify patients with the specific genetic alterations targeted by our product candidates.

In addition, although we believe genetic testing is becoming more prevalent in the diagnosis and treatment of various diseases and conditions, our product candidates may be perceived negatively compared to alternative treatments that do not require the use of companion diagnostics, either due to the additional cost of the companion diagnostic or the need to complete additional procedures to identify genetic markers prior to administering our product candidates.

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

The manufacture of biologics is complex, and our third-party manufacturers may encounter difficulties in production. If 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.

The process of manufacturing biologics is complex, highly-regulated and subject to multiple risks. Manufacturing biologics 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 the facilities of our manufacturer, 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 manufacturer is not in compliance with FDA laws and regulations, including those governing current good manufacturing practices ("cGMPs"), the FDA may deny BLA approval until the deficiencies are corrected or we replace the manufacturer in our BLA 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 good manufacturing practices, lot consistency and timely availability of raw materials. Even if we or 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. Moreover, we source certain of the raw materials needed for our product candidates from outside the U.S.. Although we have not experienced any material supply interruptions to date, it is possible that the COVID-19 pandemic could cause such interruptions in the future. 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 growth prospects.

Scaling up a biologic manufacturing process is a difficult and uncertain task, and we may not be successful in transferring our production system or the manufacturer may not have the necessary capabilities to complete the implementation and development process. If we are unable to adequately validate or scale-up the manufacturing process with our current manufacturers, we will need to transfer to other manufacturers and complete the manufacturing validation process, which can be lengthy and costly. If we are able to adequately validate and scale-up the manufacturing process for our product candidates with contract manufacturers, we will still need to negotiate with such contract manufacturers agreements for commercial supply, and it is not certain we will be able to come to agreement on terms acceptable to us.

Risks Related to Our Financial Position and Capital Needs

We have limited operating revenue and a history of operational losses and may not achieve or sustain profitability. We have no products approved for commercial sale, and to date we have not generated any revenue or profit from sales of our product candidates.

We are an early-stage biotechnology company with a limited operating history. We have no approved products. To date, our revenue has been primarily derived from our GSK and BMS research collaboration and license agreements, and we are significantly dependent on such collaborators for the successful development of product candidates in these collaborations. Our ability to generate revenue and become profitable depends upon our ability, alone or with our collaborators, to successfully complete the development of our product candidates for our target indications and to obtain necessary regulatory approvals.

Since our inception, we have incurred significant operating losses in every year except fiscal year 2014. For the year ended December 31, 2020, our collaboration revenue was $75.0 million and our net loss was $19.9 million. As of December 31, 2020, we had an accumulated deficit of $264.0 million.

We have financed our operations primarily through our initial public offering of common stock in January 2017, our follow-on public offerings of common stock in October 2017 and September 2018, private placements of our preferred stock and the issuance of debt. We have devoted substantially all of our efforts to research and development. We have only recently initiated clinical development for three of our product candidates and expect that it will be many years, if ever, before we have a product candidate ready for commercialization. We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future, and the net losses we incur may fluctuate significantly from quarter to quarter. Our revenue has been historically derived from amortization of upfront payments, research and development funding and milestone payments under collaboration and license agreements with our collaborators. Our ability to generate future product revenue from our current or future product candidates depends on a number of additional factors, including our ability (or as applicable our collaborators' ability) to:

- continue research and preclinical development of our product candidates;
- identify additional product candidates;
- maintain existing and enter into new collaboration agreements;
- conduct additional preclinical studies and initiate clinical trials for our product candidates;
- obtain approvals for the product candidates we develop or developed under our collaboration arrangements;
- establish a sales, marketing and distribution infrastructure to commercialize any product candidates for which we may obtain marketing approval;
- maintain, expand and protect our intellectual property portfolio;
- hire additional executive, clinical, quality control and scientific personnel;
- add operational, financial and management information systems and personnel, including personnel to support our product development and commercialization efforts;
- establish and maintain supply and manufacturing relationships with third parties and ensure adequate and legally compliant manufacturing of our product candidates;
- obtain coverage and adequate product reimbursement from third-party payors, including government payors;
- acquire or in-license other product candidates and technologies; and
- achieve market acceptance for our or our collaborators' products, if any.

We are unable to predict the timing or amount of increased expenses, or when, or if, we will be able to achieve or maintain profitability because of the numerous risks and uncertainties associated with product development. In addition, our expenses could increase significantly beyond expectations if we are required by the FDA or other regulatory authorities to perform studies or clinical trials in addition to those that we currently anticipate. Even if imsidolimab, or any of our other product candidates, is approved for commercial sale, we anticipate incurring significant costs associated with the commercial launch of any product candidate.

We are currently only in the clinical development stages for our most advanced product candidates. In order to become and remain profitable we must, alone or with our collaborators, develop and eventually commercialize a product or products with significant market potential. This may require us to be successful in a range of challenging activities, including completing clinical trials of our product candidates, successfully developing companion diagnostics, obtaining marketing approval for these product candidates and manufacturing, marketing and selling those products for which we may obtain marketing approval. We may never succeed in these activities and, even if we do, may never generate revenues that are significant or large enough to achieve profitability. If we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would decrease the value of our company and could impair our ability to raise capital, maintain or expand our research and development efforts, expand our business or continue our operations. A decline in the value of our company would also cause you to lose part or even all of your investment.

We will require additional capital to finance our operations, which may not be available to us on acceptable terms, or at all. As a result, we may not complete the development and commercialization of our product candidates or develop new product candidates.

As a research and development company, our operations have consumed substantial amounts of cash since our inception. We expect our research and development expenses to increase substantially in connection with our ongoing activities, particularly as we continue our discovery and preclinical development to identify new clinical candidates, and we and

our collaborators conduct clinical trials of, and seek marketing approval for, our product candidates. In addition, if we obtain marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution. Furthermore, we incur additional costs associated with operating as a public company. We believe that our existing cash, cash equivalents and investments will fund our current operating plan at least into 2024. However, circumstances may cause us to consume capital more rapidly than we currently anticipate. For example, as we continue to move our product candidates through preclinical studies, submit INDs or foreign equivalents and conduct clinical development, we may have adverse results requiring us to find new product candidates. Any of these events may increase our development costs more than we expect. We may need to raise additional funds or otherwise obtain funding through collaboration agreements to continue development of our product candidates.

If we need to secure additional financing, such additional fundraising efforts may divert our management from our day-to-day activities, which may adversely affect our ability to develop and commercialize our product candidates. In addition, we cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. If we do not raise additional capital when required or on acceptable terms, we may need to:

- significantly delay, scale back or discontinue the development or commercialization of our product candidates or cease operations altogether;
- seek strategic alliances for research and development programs at an earlier stage than we would otherwise desire or on terms less favorable than might otherwise be available;
- relinquish, or license on unfavorable terms, our rights to technologies or future product candidates that we otherwise would seek to develop or commercialize ourselves; or
- eliminate staff to conserve resources.

If we need to conduct additional fundraising activities and we do not raise additional capital in sufficient amounts or on terms acceptable to us, we may be prevented from pursuing development and commercialization efforts, which will have a material adverse effect on our business, operating results and prospects. Our forecast of the period of time through which our financial resources will adequately support our operations is a forward-looking statement and involves risks and uncertainties, and actual results could vary as a result of a number of factors, including the factors discussed elsewhere in this “Risk Factors” section. We have based this estimate on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Our future funding requirements, both short and long-term, will depend on many factors, including:

- the initiation, progress, timing, costs and results of preclinical studies and clinical trials for our product candidates and future product candidates we may develop;
- the number and size of clinical trials needed to show safety, efficacy and an acceptable risk/benefit profile for any of our product candidates;
- the outcome, timing and cost of seeking and obtaining regulatory approvals from the FDA and foreign regulatory authorities, including the potential for such authorities to require that we perform more studies or trials than those that we currently expect;
- the commercial success or failure of products sold by our collaborators, such as dostarlimab and Zejula by GSK, and the timing thereof;
- our ability to maintain existing and enter into new collaboration agreements;
- the cost to establish, maintain, expand and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make, or that we may receive, in connection with licensing, preparing, filing, prosecuting, defending and enforcing of any patents or other intellectual property rights;
- the effect of competing technological and market developments;
- market acceptance of any approved product candidates;
- the costs of acquiring, licensing or investing in additional businesses, products, product candidates and technologies;
- the cost of recruiting and retaining key employees;
- the costs and fees associated with any delays or cancellations of forecasted manufacturing batches;
- the cost and timing of selecting, auditing and potentially validating manufacturing sites for commercial-scale manufacturing; and

- the cost of establishing sales, marketing and distribution capabilities for our product candidates for which we may receive regulatory approval and that we determine to commercialize ourselves or in collaboration with our collaborators.

If we cannot expand our operations or otherwise capitalize on our business opportunities due to a lack of capital, our business, financial condition and results of operations could be adversely affected.

Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our product candidates on unfavorable terms to us.

We may seek additional capital through a variety of means, including through public or private equity, debt financings or other sources, including up-front payments and milestone payments from strategic collaborations. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a stockholder. Such financing may result in dilution to stockholders, imposition of debt covenants, increased fixed payment obligations, or other restrictions that may affect our business. If we raise additional funds through up-front payments or milestone payments pursuant to strategic collaborations 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. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans.

Risks Related to Managing Growth, Operations and Macroeconomic Conditions

We must attract and retain highly skilled employees in order to succeed.

To succeed, we must recruit, retain, manage and motivate qualified clinical, scientific, technical and management personnel, and we face significant competition for experienced personnel. This is especially critical as we ramp up our hiring needs entering into later-stage product development of our product candidates. If we do not succeed in attracting and retaining qualified personnel, particularly at the management level, it could adversely affect our ability to execute our business plan, harm our operating results and adversely affect our ability to successfully commercialize our product candidates. In particular, we believe that our future success is highly dependent upon the contributions of our senior management, particularly our President and Chief Executive Officer, as well as our senior scientists. The loss of services of any of these individuals, who all have at-will employment arrangements with us, could delay or prevent the successful development of our product pipeline, completion of our planned clinical trials or the commercialization of our product candidates, if approved. The competition for qualified personnel in the biotechnology field is intense and, as a result, we may be unable to continue to attract and retain qualified personnel necessary for the development of our business or to recruit suitable replacement personnel. In addition, certain members of our senior management team have worked together for only a relatively short period of time, and it may be difficult to evaluate their effectiveness, on an individual or collective basis, and ability to address future challenges to our business.

Many of the other biotechnology companies that we compete against for qualified personnel have greater financial and other resources, different risk profiles and a longer history in the industry than we do. They also may provide more diverse opportunities and better chances for career advancement. Some of these characteristics may be more appealing to high-quality candidates than what we have to offer. If we are unable to continue to attract and retain high-quality personnel, the rate and success at which we can discover and develop product candidates and our business will be limited.

The manufacture of biotechnology products is complex, and manufacturers often encounter difficulties in production. If we or any of our third-party manufacturers encounter any loss of our master cell banks or if any of our third-party manufacturers encounter other difficulties, or otherwise fail to comply with their contractual obligations, our ability to provide product candidates for clinical trials or our products to patients, once approved, could be delayed or stopped.

The manufacture of biotechnology products is complex and requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. We and our contract manufacturers must comply with cGMP regulations and guidelines for the manufacturing of biologics used in clinical trials and, if approved, marketed products. Manufacturers of biotechnology products often encounter difficulties in production, particularly in scaling up and validating initial production. Furthermore, if microbial, viral or other contaminations are discovered in our products or in the manufacturing facilities in which our products are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. Delays in raw materials availability and supply may also extend the period of time required to develop our products.

All of our therapeutic antibodies are manufactured by starting with cells which are stored in a cell bank. We have one master cell bank for each antibody manufactured in accordance with cGMP and multiple working cell banks and believe we would have adequate backup should any cell bank be lost in a catastrophic event. However, it is possible that we could lose multiple cell banks and have our manufacturing severely impacted by the need to replace the cell banks.

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. Additionally, our manufacturers may experience manufacturing difficulties due to resource constraints or as a result of labor disputes or unstable political environments. If our manufacturers were to encounter any of these difficulties, or otherwise fail to comply with their contractual obligations, our ability to provide 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 our product candidates or products and could have an adverse effect on our business, prospects, financial condition and results of operations.

We currently have no marketing and sales force. If we are unable to establish effective sales or marketing capabilities or enter into agreements with third parties to sell or market our product candidates, we may not be able to effectively sell or market our product candidates, if approved, or generate product 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. In order to commercialize any product candidates, we must build on a territory-by-territory basis marketing, sales, distribution, managerial and other non-technical capabilities or make arrangements 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. 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.

We expect to expand our development and regulatory capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

We expect to experience growth in the number of our employees and the scope of our operations, particularly in the areas of product candidate development and growing our capability to conduct clinical trials. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

We may be vulnerable to disruption, damage and financial obligation as a result of system failures.

Despite the implementation of security measures, any of the internal computer systems belonging to us, our collaborators or our third-party service providers are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failure. Any system failure, accident or security breach that

causes interruptions in our own, in collaborators' or in third-party service vendors' operations could result in a material disruption of our drug discovery and development programs. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our or our collaborators' regulatory approval efforts and significantly increase our costs in order to recover or reproduce the lost data. To the extent that any disruption or security breach results in a loss or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we may incur liability as a result, our drug discovery programs and competitive position may be adversely affected, and the further development of our product candidates may be delayed. Furthermore, we may incur additional costs to remedy the damages caused by these disruptions or security breaches.

Our operations, or the third parties upon whom we depend, are vulnerable to interruption by fire, earthquake, power loss, telecommunications failure, terrorist activity, health epidemics or pandemics and other events beyond our control, which could harm our business.

Our facilities are located in San Diego, California, which is a seismically active region, and has also historically been subject to wildfires and electrical blackouts as a result of a shortage of available electrical power. We have not undertaken a systematic analysis of the potential consequences to our business and financial results from a major earthquake, fire, power loss, terrorist activity, health epidemics or pandemics such as the COVID-19 pandemic or other disasters and do not have a recovery plan for such disasters. In addition, we do not carry sufficient insurance to compensate us for actual losses from interruption of our business that may occur, and any losses or damages incurred by us could harm our business. We maintain multiple copies of each of our antibody sequences and electronic data records, most of which we maintain at our headquarters. If our facility was impacted by a seismic or wildfire event, we could lose some of our antibody sequences, which would have an adverse effect on our ability to perform our obligations under our collaborations and discover new targets.

Furthermore, integral parties in our supply chain are geographically concentrated and operating from single sites, increasing their vulnerability to natural disasters or other sudden, unforeseen and severe and/or serious adverse events. If such an event were to affect our supply chain, it could have a material adverse effect on our business.

Risks Related to Our Dependence on Third Parties

Our existing collaborations, including those with GSK and BMS, are important to our business, and future collaborations may also be important to us. If we are unable to maintain any of these collaborations, or if these collaborations are not successful, our business could be adversely affected.

We have entered into collaborations with GSK and BMS to develop several of our product candidates. We have also entered into antibody generation and/or development collaborations with various collaborators, including GSK and BMS, under which we have generated therapeutic quality antibodies using our technology platform and conducted certain preclinical studies in collaboration. We are currently aware that GSK and BMS have advanced multiple antibodies generated through our collaboration into clinical trials. If our collaborators terminate any of our collaborations, we may not receive all or any of this funding, which would adversely affect our business or financial condition. Our operational obligations under each of our collaborations has ended.

We are unable to predict the success of our collaborations. Our collaborators have discretion in determining and directing the efforts and resources, including the ability to discontinue all efforts and resources, they apply to the development and, if approval is obtained, commercialization and marketing of the product candidates covered by such collaborations. As a result, our collaborators may elect to de-prioritize our programs, change their strategic focus or pursue alternative technologies in a manner that results in reduced, delayed or no revenue to us. Our collaborators may have other marketed products and product candidates under collaboration with other companies, including some of our competitors, and their corporate objectives may not be consistent with our best interests. Our collaborators may also be unsuccessful in developing or commercializing our products. If our collaborations are unsuccessful, our business, financial condition, results of operations and prospects could be adversely affected. In addition, any dispute or litigation proceedings we may have with our collaborators in the future could delay development programs, create uncertainty as to ownership of intellectual property rights, distract management from other business activities and generate substantial expense. For example, in August 2020, we served notice on GSK related to an alleged breach of our collaboration agreement in connection with GSK's use of certain antibodies originally developed by us for the development of a drug not covered by the agreement. We subsequently settled this matter in October 2020, but there can be no assurance that we will not encounter such issues under our collaborations with GSK or other parties in the future.

We may not succeed in establishing and maintaining additional development and commercialization collaborations, which could adversely affect our ability to develop and commercialize product candidates.

In addition to our current licensing arrangements with GSK and BMS, a part of our strategy is to enter into additional strategic product development and commercialization collaborations in the future, including collaborations to broaden and accelerate clinical development and potential commercialization of our product candidates. We may face significant competition in seeking appropriate development partners, and the negotiation process is time-consuming and complex. Moreover, we may not succeed in our efforts to establish collaborations or other alternative arrangements for any of our other existing or future product candidates and programs because our research and development pipeline may be insufficient, our product candidates and programs may be deemed to be at too early a stage of development for collaborative effort, and/or third parties may not view our product candidates and programs as having the requisite potential to demonstrate safety and efficacy or to be commercially viable. Even if we are successful in our efforts to establish new collaborations, the terms that we agree upon may not be favorable to us, and we may not be able to maintain such collaborations if, for example, development or approval of a product candidate is delayed or sales of an approved product candidate are disappointing. Any delay in entering into new collaboration agreements related to our product candidates could delay the development and commercialization of our product candidates and reduce their competitiveness if they reach the market.

Moreover, if we fail to establish and maintain additional collaborations related to our product candidates:

- the development of certain of our current or future product candidates may be terminated or delayed;
- our cash expenditures related to development of certain of our current or future product candidates would increase significantly and we may need to seek additional financing;
- we may be required to hire additional employees or otherwise develop expertise, such as sales and marketing expertise, for which we have not budgeted; and
- we will bear all of the risk related to the development and commercialization of any such product candidates.

If third parties on which we depend to conduct our planned preclinical studies and clinical trials do not perform as contractually required, fail to satisfy regulatory or legal requirements or miss expected deadlines, our development program could be delayed with adverse effects on our business, financial condition, results of operations and prospects.

We rely on third party clinical investigators, CROs, CMOs and consultants to design, conduct, supervise and monitor key activities relating to, discovery, manufacturing, non-clinical studies and clinical trials of our product candidates, and we intend to do the same for future activities relating to existing and future programs. Because we rely on third parties and do not have the ability to conduct all required discovery, manufacturing, preclinical studies or clinical trials independently, we have less control over the timing, quality and other aspects of discovery, manufacturing, preclinical studies and clinical trials than we would if we conducted them on our own. These investigators, CROs, CMOs and consultants are not our employees, and we 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 we contract with might not be diligent, careful or timely in conducting our discovery, manufacturing, preclinical studies or clinical trials, resulting in discovery, manufacturing, preclinical studies or clinical trials being delayed or unsuccessful, in whole or in part.

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 are responsible for ensuring that each of our preclinical studies and clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Our reliance on third parties that we do not control does not relieve us of these responsibilities and requirements. Any such event could have an adverse effect on our business, financial condition, results of operations and prospects.

We rely completely on third parties to manufacture our nonclinical, clinical and future commercial drug supplies of any approved products.

We outsource the manufacture of our product candidates. We do not currently have the infrastructure or internal capability to manufacture supplies of our product candidates for use in development and commercialization. If we were to experience an unexpected loss of supply of our product candidates for any reason, whether as a result of manufacturing, supply or storage issues or otherwise, our business would be harmed, and we could experience delays, disruptions, suspensions or terminations of, or be required to restart or repeat, any pending or ongoing clinical trials. Although we generally do not begin a clinical trial unless we believe we have a sufficient supply of a product candidate to complete the clinical trial, we may be required to manufacture additional supplies of our product candidates to the extent our estimates of the amounts required prove inaccurate, we suffer unexpected losses of product candidate supplies, or we are required to have fresh product candidate

supplies manufactured to satisfy regulatory requirements or specifications. Any significant delay or discontinuation in the supply of a product candidate, or the raw material components thereof, due to the need to replace a contract manufacturer or other third-party manufacturer, could considerably harm our business and ability to generate revenue and delay completion of our clinical trials, product testing and potential regulatory approval of our product candidates.

Any delays in our preclinical or clinical development could lead to delays or cancellations of forecasted manufacturing batches, which would typically result in significant fees owed by us to the manufacture and an uncertainty as to when the manufacturer will have the availability for a new time slot to manufacture the batch, which could lead to further delays in the development of the product candidate and have an adverse effect on our business.

Reliance on third-party manufacturers entails additional risks, including the possible breach of the manufacturing agreement by the third party and the possible termination or nonrenewal of the agreement by the manufacturer at a time that is costly or inconvenient for us. If our contract manufacturers were to breach or terminate their manufacturing arrangements with us, the development or commercialization of the affected product candidates could be significantly delayed, which could have an adverse effect on our business. Any change in our manufacturers could be costly because the commercial terms of any new arrangement could be less favorable and because the expenses relating to the transfer of necessary technology and processes could be significant.

We depend on a small number of suppliers for the raw materials necessary to produce our product candidates. The loss of these suppliers, or their failure to supply us with these raw materials, would materially and adversely affect our business.

We depend on the availability of key raw materials for our product candidates from a small number of third-party suppliers. Because there are a limited number of suppliers for the raw materials that we use to manufacture our product candidates, we may need to engage alternate suppliers to prevent a possible disruption of the manufacture of the materials necessary to produce our product candidates for our clinical trials. We do not have any control over the availability of raw materials. If we or our manufacturers are unable to purchase these raw materials on acceptable terms, at sufficient quality levels, or in adequate quantities, if at all, the development of our product candidates would be delayed or there would be a shortage in supply, which would impair our ability to meet our development objectives for our product candidates or generate revenues from the sale of any approved products.

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

Even if our product candidates receive regulatory approval, they will be subject to significant post-marketing regulatory requirements.

Any regulatory approvals that we may receive for our product candidates will require surveillance to monitor the safety and efficacy of the product candidate, may contain significant limitations related to use restrictions for specified age groups, warnings, precautions or contraindications, and may include burdensome post-approval study or risk management requirements. For example, the FDA may require a risk evaluation and mitigation strategy in order to approve our product candidates, which could entail requirements for a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA or foreign regulatory authorities approve our product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for our product candidates will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMPs and good clinical practices for any clinical trials that we conduct post-approval. In addition, manufacturers of drug products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP regulations and standards. If we or a regulatory agency discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facilities where the product is manufactured, a regulatory agency may impose restrictions on that product, the manufacturing facility or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing. In addition, failure to comply with FDA and foreign regulatory requirements may, either before or after product approval, if any, subject our company to administrative or judicially imposed sanctions, including:

- restrictions on our ability to conduct clinical trials, including full or partial clinical holds on ongoing or planned trials;
- restrictions on the products, manufacturers or manufacturing process;
- warning or untitled letters;

- civil and criminal penalties;
- injunctions;
- suspension or withdrawal of regulatory approvals;
- product seizures, detentions or import bans;
- voluntary or mandatory product recalls and publicity requirements;
- total or partial suspension of production;
- imposition of restrictions on operations, including costly new manufacturing requirements; and
- refusal to approve pending BLAs or supplements to approved BLAs.

The occurrence of any event or penalty described above may inhibit our ability to commercialize our product candidates and generate revenue.

Advertising and promotion of any product candidate that obtains approval in the United States will be heavily scrutinized by the FDA, the Department of Justice, the Department of Health and Human Services' Office of Inspector General, state attorneys general, members of Congress and the public. Violations, including promotion of our products for unapproved (or off-label) uses, are subject to enforcement letters, inquiries and investigations, and civil and criminal sanctions by the government. Additionally, comparable foreign regulatory authorities will heavily scrutinize advertising and promotion of any product candidate that obtains approval outside of the United States.

In the United States, engaging in the impermissible promotion of our products for off-label uses can also subject us to false claims litigation under federal and state statutes, which can lead to civil and criminal penalties and fines and agreements that materially restrict the manner in which a company promotes or distributes drug products. These false claims statutes include the federal False Claims Act, which allows any individual to bring a lawsuit against a biotechnology company on behalf of the federal government alleging submission of false or fraudulent claims, or causing to present such false or fraudulent claims, for payment by a federal program such as Medicare or Medicaid. If the government prevails in the lawsuit, the individual will share in any fines or settlement funds. Such False Claims Act lawsuits against biotechnology companies have increased significantly in volume and breadth, leading to several substantial civil and criminal settlements regarding certain sales practices promoting off-label drug uses involving fines in excess of $1.0 billion. This growth in litigation has increased the risk that a biotechnology company will have to defend a false claim action, pay settlement fines or restitution, agree to comply with burdensome reporting and compliance obligations, and be excluded from Medicare, Medicaid and other federal and state health care programs. In addition, we may incur liability from claims initiated under the Lanham Act or other federal and state unfair competition laws with respect to how our products are marketed and promoted. Furthermore, the off-label use of our products may increase the risk of product liability claims. If we do not lawfully promote our approved products, we may become subject to such litigation and, if we do not successfully defend against such actions, those actions may have an adverse effect on our business, financial condition and results of operations.

Our failure to obtain regulatory approval in international jurisdictions would prevent us from marketing our product candidates outside the United States.

In order to market and sell our products in other jurisdictions, we must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The regulatory approval process outside the United States generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside the United States, we must secure product reimbursement approvals before regulatory authorities will approve the product for sale in that country. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries.

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 prospects could decline.

We plan to seek Orphan Drug Designation for imsidolimab and certain of our other product candidates, and we may not be able to obtain or maintain Orphan Drug Designation or obtain the benefits associated with Orphan Drug status, including market exclusivity.

Regulatory authorities in some jurisdictions, including the United States and the European Union ("EU") may designate biologics for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a biologic as an Orphan Drug if it is 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. We recently received Orphan Drug Designation from the FDA for imsidolimab for our GPP indication and plan to seek Orphan Drug Designation for imsidolimab in other indications and for certain of our other product candidates. Generally, if a biologic with an Orphan Drug Designation subsequently receives the first marketing approval for the indication for which it has such designation, the biologic is entitled to a period of marketing exclusivity, which precludes the FDA with respect to the United States or the EMA with respect to the EU from approving another marketing application for a drug containing the same active moiety for the same indication for that time period. The applicable period is seven years in the United States and ten years in the EU. The EU exclusivity period can be reduced to six years if a biologic no longer meets the criteria for Orphan Drug Designation or if the biologic is sufficiently profitable so that market exclusivity is no longer justified. Orphan Drug exclusivity may be lost if the FDA or EMA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition. In addition, the Orphan Drug Designation does not convey any advantage in, or shorten the duration of, the regulatory review or approval process. Also, regulatory approval for any product candidate may be withdrawn and other candidates may obtain approval before us.

We have not been granted Orphan Drug Designation for imsidolimab for any indication other than GPP, and there can be no assurance that any of our other product candidates will be designated as an orphan drug. For example, we plan to seek FDA Orphan Drug Designation for imsidolimab for the treatment of PPP, which will likely require that we demonstrate to FDA that PPP is a distinct disease from psoriasis generally (a non-rare disease) or that use of imsidolimab may be appropriate for the treatment of PPP but not appropriate for use in the general psoriasis population.

Even if we obtain Orphan Drug Designation for imsidolimab in indications other than GPP, or for any of our other product candidates, we may not receive Orphan Drug exclusivity, and such exclusivity, if obtained, may not effectively protect the candidate from competition because different drugs or biologics can be approved for the same condition and only the first biologic with an Orphan Drug Designation to receive regulatory approval for a particular indication will receive marketing exclusivity. Even after a drug or biological with Orphan Drug Designation is approved, the FDA can subsequently approve another biologic containing the same active moiety (which in the case of an antibody is the principal molecular structure) for the same condition if the FDA concludes that the later biologic is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care.

Any drugs we develop may become subject to unfavorable third-party reimbursement practices and pricing regulations.

The availability and extent of coverage and adequate reimbursement by governmental and private payors is essential for most patients to be able to afford expensive treatments. Sales of any of our product candidates that receive marketing approval will depend substantially, both in the United States and internationally, on the extent to which the costs of our product candidates will be paid by health maintenance, managed care, pharmacy benefit and similar health care management organizations or reimbursed by government health administration authorities, private health coverage insurers and other third-party payors. If reimbursement is not available, or is available only to limited levels, we may not be able to successfully commercialize our product candidates. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize a sufficient return on our investment. Coverage and reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. If coverage and reimbursement are not available or reimbursement is available only at limited levels, we may not successfully commercialize any product candidate for which we obtain marketing approval.

There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. In the United States, the principal decisions about reimbursement for new products are typically made by the Centers for Medicare & Medicaid Services ("CMS"), an agency within the U.S. Department of Health and Human Services, because CMS decides whether and to what extent a new product will be covered and reimbursed under Medicare. Private payors often follow CMS's decisions regarding coverage and reimbursement to a substantial degree. However, one payor's determination to provide coverage for a drug product does not assure that other payors will also provide coverage for the drug product. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance.

Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. Further, such payors are increasingly examining the medical necessity and reviewing the cost effectiveness of medical drug products. There may be especially significant delays in obtaining coverage and reimbursement for newly approved drugs. Third-party payors may limit coverage to specific drug products on an approved list, known as a formulary, which might not include all FDA-approved drugs for a particular indication. We or our collaborators may need to conduct expensive pharmaco-economic studies to demonstrate the medical necessity and cost effectiveness of our products. Nonetheless, our product candidates may not be considered medically necessary or cost effective. We cannot be sure that coverage and reimbursement will be available for any product that we commercialize and, if reimbursement is available, what the level of reimbursement and the timing of achieving a reimbursement determination will be.

Outside the United States, international operations are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost containment initiatives in Europe, Canada and other countries has and will continue to put pressure on the pricing and usage of therapeutics, including our product candidates. In many countries, particularly the countries of the EU, the prices of medical products are subject to varying price control mechanisms as part of national health systems. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost effectiveness of our product candidate to other available therapies. In general, the prices of products under such systems are substantially lower than in the United States. Other countries allow companies to fix their own prices for products but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our product candidates. Accordingly, in markets outside the United States, the reimbursement for our products may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenue and profits.

Moreover, increasing efforts by governmental and third-party payors, in the United States and internationally, to cap or reduce health care costs may cause such organizations to limit both coverage and level of reimbursement for new products approved, and, as a result, they may not cover or provide adequate payment for our product candidates. We expect to experience pricing pressures in connection with the sale of any of our product candidates due to the trend toward managed health care, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on health care costs in general, particularly prescription drugs and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products into the health care market.

In addition to CMS and private payors, professional organizations such as the American Medical Association can influence decisions about reimbursement for new products by determining standards for care. In addition, many private payors contract with commercial vendors who sell software that provide guidelines that attempt to limit utilization of, and therefore reimbursement for, certain products deemed to provide limited benefit to existing alternatives. Such organizations may set guidelines that limit reimbursement or utilization of our product candidates.

Furthermore, some of our target indications, such as GPP, are rare diseases with small patient populations. In order for therapeutics that are designed to treat smaller patient populations to be commercially viable, the reimbursement for such therapeutics must be higher, on a relative basis, to account for the low volume of sales. Accordingly, we will need to implement a coverage and reimbursement strategy for any approved product candidate that accounts for the smaller potential market size.

If we are unable to establish or sustain coverage and adequate reimbursement for any future product candidates from third-party payors, the adoption of those products and sales revenue will be adversely affected, which, in turn, could adversely affect the ability to market or sell those product candidates, if approved. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we or our collaborators receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Healthcare legislative reform measures may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates and affect the prices we may obtain.

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. 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 Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively, the "ACA") was enacted, which was intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhanced 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. The ACA 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% 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, which has since been increased to 70% by the Bipartisan Budget Act of 2018 ("BBA"), (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.

There have been judicial and Congressional efforts to repeal, replace or change certain aspects of the ACA, including measures taken during the Trump administration. 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." In November 2020, the United States Supreme Court held oral arguments on the Fifth Circuit U.S. Court of Appeals decision that held that the individual mandate is unconstitutional. It is uncertain how the United States Supreme Court will rule on this case or how healthcare measures of the Biden administration will impact the ACA and our business. Additionally, the 2020 federal spending package permanently eliminated, effective January 1, 2020, the ACA-mandated "Cadillac" tax on certain high cost employer-sponsored insurance plans and the medical device excise tax, and effective January 1, 2021, also eliminates the health insurer tax. The BBA, among other things, also amended the ACA, effective January 1, 2019, by increasing from 50% to 70% the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and closing the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole." In addition, CMS published a final rule that would give states greater flexibility, effective January 1, 2020, in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the ACA for plans sold through such marketplaces.

Other legislative changes have been proposed and adopted since the ACA was enacted. 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 to Medicare payments to providers of 2% per fiscal year, which went into effect in 2013 and will remain in effect through 2030, with the exception of a temporary suspension implemented under various COVID-19 relief legislation from May 1, 2020 through March 31, 2021, unless additional Congressional action is taken. The American Taxpayer Relief Act of 2012, among other things, 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. These laws may result in additional reductions in Medicare and other health care funding, which could have a material adverse effect on customers for our drugs, if approved, and accordingly, our financial operations.

There have been 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, reduce the costs of drugs under Medicare and reform government program reimbursement methodologies for drug products. At the federal level, the Trump administration's budget proposal for fiscal year 2021 included a $135 billion allowance to support legislative proposals seeking to reduce drug prices, increase competition, lower out-of-pocket drug costs for patients, and increased patient access to lower cost generic and biosimilar drugs. In particular, on July 24, 2020 and September 13, 2020, the Trump administration announced several executive orders related to prescription drug pricing that seek to implement several of the administration's proposals. The FDA also released a final rule in September 2020 providing guidance for states to build and submit importation plans for drugs from Canada. The Trump and Biden administrations both issued executive orders intended to favor government procurement from domestic manufacturers. In addition, the Trump administration issued an executive order specifically aimed at the procurement of pharmaceutical products, which instructed the federal government to develop a list of "essential" medicines and then buy those and other medical supplies that are manufactured, including the manufacture of the API, in the United States. It is unclear whether this executive order or something similar will be implemented by the Biden Administration.

Further, in November 2020, HHS finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers. The CMS also issued an interim final rule implementing President Trump's Most Favored Nation executive order, which would tie Medicare Part B payments for certain physician-administered drugs to the lowest price paid in other economically advanced countries, effective January 1, 2021. On December 28, 2020, the United States District Court in Northern California issued a nationwide preliminary injunction against implementation of the interim final rule. In December 2020, CMS issued a final rule implementing significant manufacturer price reporting changes under the Medicaid Drug Rebate Program, including regulations that affect manufacturer-sponsored patient assistance programs subject to pharmacy benefit manager accumulator programs and Best Price reporting related to certain value-based purchasing arrangements. It is unclear to what extent these new regulations will be implemented and to what extent these or any future legislation or regulation by the Biden administration will have on our business, including our ability to generate revenue and achieve profitability. We expect 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 additional pricing pressures.

The implementation of cost containment measures or other health care reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our product candidates.

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

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

Our business exposes us 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, injury to our reputation, costs to defend the related litigation, a diversion of management's time and our resources, substantial monetary awards to trial participants or patients and a decline in our stock price. We currently have product liability insurance that we believe is appropriate for our stage of development and may need to obtain higher levels prior to 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 an adverse effect on our business.

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

Health care providers and third-party payors play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our future arrangements with third-party payors and customers may expose us to broadly applicable fraud and abuse and other health care laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute our products for which we obtain marketing approval. Restrictions under applicable federal and state health care laws and regulations include the following:

- the federal Anti-Kickback Statute prohibits, among other things, persons 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 health care program such as Medicare and Medicaid;
- the federal false claims and civil monetary penalties laws, including the civil False Claims Act, impose criminal and civil penalties, including civil whistleblower or qui tam actions, against individuals or entities for, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA") imposes criminal and civil liability for, among other things, executing or attempting to execute a scheme to defraud any health care benefit program or making false statements relating to health care matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and its implementing regulations, also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- the federal Physician Payments Sunshine Act requires applicable manufacturers of covered drugs, devices, biologics, and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program, with specific exceptions, to report to CMS annually information regarding payments and other transfers of value to physicians and teaching hospitals as well as information regarding ownership and investment interests held by physicians and their immediate family members. The information was initially made publicly available on a searchable website in September 2014 and is disclosed on an annual basis; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving health care items or services reimbursed by non-governmental third-party payors, including private insurers.

The ACA, among other things, amended the intent standard of the federal Anti-Kickback Statute and criminal health care fraud statutes to a stricter standard such that a person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it. In addition, the ACA codified case law that a claim including items or 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.

Some state laws require biotechnology companies to comply with the biotechnology industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and may require drug manufacturers to report information related to payments and other transfers of value to physicians and other health care providers or marketing expenditures. For example, 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 health care 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 pricing information, including information pertaining to and justifying price increases. Some states further require pharmaceutical companies to implement compliance programs and/or marketing codes. Compliance with these laws is difficult and time consuming, and companies that do not comply with these state laws face civil penalties.

State and foreign laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts. For example, the collection and use of health data in the EU and the UK is governed by the General Data Protection Regulation ("GDPR"), which became fully applicable in May 2018 and has been incorporated into the UK's data protection laws following

Brexit. The GDPR extends the geographical scope of EU data protection law to non-EU entities under certain conditions, tightens existing EU data protection principles and creates new obligations for companies and new rights for individuals. The GDPR is complex, and guidance, interpretation and application under the GDPR are still developing. Failure to comply with the GDPR may result in substantial fines and other administrative penalties of up to the greater of €20 million or 4% of worldwide revenue. The GDPR may increase our 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 GDPR. The pending EU ePrivacy Regulation is also expected to establish new requirements applicable to the handling of personal data and imposes penalties for non-compliance. In addition, the GDPR increases the scrutiny of transfers of personal data from clinical trial sites located in the European Economic Area to the United States and other jurisdictions that the European Commission does not recognize as having "adequate" data protection laws. For example, in July 2016, the European Commission adopted the EU-U.S. Privacy Shield Framework (the "Privacy Shield Framework"), which replaced the prior U.S. Safe Harbor scheme. On July 16, 2020, the Court of Justice of the European Union issued a decision, known as Schrems II, that declared the Privacy Shield Framework invalid. The Schrems II decision also resulted in substantial additional compliance obligations for companies that implement standard contractual clauses to ensure a valid basis for the transfer of personal data outside of Europe. The European Commission has also published draft updates to its standard contractual clauses that impose substantial additional obligations on the companies that wish to use the clauses as the basis for their data transfers. Additionally, California enacted the California Consumer Privacy Act ("CCPA"), which became effective on January 1, 2020, and the California Privacy Rights Act ("CPRA"), which modifies the CCPA and creates additional obligations beginning on January 1, 2022. The CCPA and CPRA provide 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. The costs of compliance with, and other burdens imposed by, the GDPR, CCPA and other U.S., EU and worldwide laws may impose onerous requirements on our business and, if our efforts to comply with such laws are not successful, our business could be adversely affected.

Efforts to ensure that our current and future business arrangements with third parties will comply with applicable health care laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other health care laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government funded health care programs, such as Medicare and Medicaid, contractual damages, reputational harm, diminished profits and future earnings, and the curtailment or restructuring of our operations. Defending against any such actions can be costly, time-consuming and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. Further, if any of the physicians or other health care providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded health care programs.

Our employees may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements and insider trading.

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include failures to comply with FDA regulations, to provide accurate information to the FDA, to comply with federal and state health care fraud and abuse laws and regulations, to report financial information or data accurately or to disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the health care industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, 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. We have adopted a code of conduct, but it is not always possible to identify and deter employee misconduct. 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 these 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 significant impact on our business, including the imposition of significant fines or other sanctions.

Risks Related to Intellectual Property

If we are unable to obtain or protect intellectual property rights, we may not be able to compete effectively in our market.

Our success depends in significant part on our and our licensors', licensees' or collaborators' ability to establish, maintain and protect patents and other intellectual property rights and operate without infringing the intellectual property rights of others. We have filed numerous patent applications both in the United States and in foreign jurisdictions to obtain patent rights to inventions we have discovered. We have also licensed from third parties rights to patent portfolios. Some of these licenses give us the right to prepare, file and prosecute patent applications and maintain and enforce patents we have licensed, and other licenses may not give us such rights. The patent prosecution process is expensive and time-consuming, and we and our current or future licensors, licensees or collaborators may not be able to prepare, file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we or our licensors, licensees or collaborators will fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. Moreover, in some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology that we license from or license to third parties and are reliant on our licensors, licensees or collaborators. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. If our current or future licensors, licensees or collaborators fail to establish, maintain or protect such patents and other intellectual property rights, such rights may be reduced or eliminated. If our licensors, licensees or collaborators are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised.

The patent position of biotechnology companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our and our current or future licensors', licensees' or collaborators' patent rights are highly uncertain. Our and our licensors', licensees' or collaborators' pending and future patent applications may not result in patents being issued which protect our technology or products, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. The patent examination process may require us or our licensors, licensees or collaborators to narrow the scope of the claims of our or our licensors', licensees' or collaborators' pending and future patent applications, which may limit the scope of patent protection that may be obtained. In the past, we have not always been able to obtain the full scope of patent protection we have initially sought in our patent applications, and as described above and as is typical for most biotechnology patent prosecution, we have been required to narrow or eliminate patent claims as part of the patent prosecution process. In addition, some patent applications that we or our licensors have filed have not resulted in issued patents because we or our licensors have abandoned those patent applications as changes in business and/or legal strategies dictated.

We cannot assure you that all of the potentially relevant prior art relating to our patents and patent applications has been found. If such prior art exists, it can invalidate a patent or prevent a patent from issuing from a pending patent application. Even if patents do successfully issue and even if such patents cover our product candidates, third parties may initiate opposition, interference, re-examination, post-grant review, inter partes review, nullification or derivation action in court or before patent offices or similar proceedings challenging the validity, enforceability or scope of such patents, which may result in the patent claims being narrowed or invalidated. Our and our licensors', licensees' or collaborators' patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications, and then only to the extent the issued claims cover the technology.

Because patent applications in the United States and most other countries are confidential for a period of time after filing, and some remain so until issued, we cannot be certain that we or our licensors, licensees, or collaborators were the first to file any patent application related to a product candidate. Furthermore, if third parties have filed such patent applications on or before March 15, 2013, an interference proceeding in the United States can be initiated by such third parties to determine who was the first to invent any of the subject matter covered by the patent claims of our applications. If third parties have filed such applications after March 15, 2013, a derivation proceeding in the United States can be initiated by such third parties to determine whether our invention was derived from theirs. Even where we have a valid and enforceable patent, we may not be able to exclude others from practicing our invention where the other party can show that they used the invention in commerce before our filing date or the other party benefits from a compulsory license. In addition, 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. filing date. Various 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 for a product, we may be open to competition from competitive medications, including biosimilar or generic medications.

Furthermore, 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. We expect to seek extensions of patent terms where these are available in any countries where we are prosecuting patents. This includes in the United States under the Drug Price Competition and Patent

Term Restoration Act of 1984, which permits a patent term extension of up to five years beyond the expiration of the patent. However the applicable authorities, including the FDA and the U.S. Patent and Trademark Office ("USPTO") in the United States, and any equivalent foreign regulatory authority, may not agree with our assessment of whether such extensions are available and may refuse to grant extensions to our patents or may grant more limited extensions than we request. If this occurs, our competitors may take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case.

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

Filing, prosecuting, enforcing and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our or our licensors', licensees' 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 addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we and our licensors, licensees or collaborators may not be able to prevent third parties from practicing our and our licensors', licensees' or collaborators' inventions in all countries outside the United States or from selling or importing products made using our and our licensors', licensees' or collaborators' inventions in and into the United States or other jurisdictions. Competitors may use our and our licensors', licensees' or collaborators' technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we and our licensors, licensees or collaborators have patent protection but enforcement is not as strong as that in the United States. These products may compete with our product candidates, and our and our licensors', licensees' or collaborators' patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biotechnology, which could make it difficult for us and our licensors, licensees or collaborators to stop the infringement of our and our licensors', licensees' or collaborators' patents or marketing of competing products in violation of our and our licensors', licensees' or collaborators' proprietary rights generally. Proceedings to enforce our and our licensors', licensees' or collaborators' patent rights in foreign jurisdictions could result in substantial costs and divert our and our licensors', licensees' or collaborators' efforts and attention from other aspects of our business, could put our and our licensors', licensees' or collaborators' patents at risk of being invalidated or interpreted narrowly and our and our licensors', licensees' or collaborators' patent applications at risk of not issuing and could provoke third parties to assert claims against us or our licensors, licensees or collaborators. We or our licensors, licensees or collaborators may not prevail in any lawsuits that we or our licensors, licensees or collaborators initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful.

Changes in patent law could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involve technological and legal complexity, and obtaining and enforcing biopharmaceutical patents is costly, time-consuming, and inherently uncertain.

Patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our and our licensors', licensees' or collaborators' patent applications and the enforcement or defense of our or our licensors', licensees' or collaborators' issued patents. On September 16, 2011, the Leahy-Smith America Invents Act (the "AIA") was signed into law. The AIA includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted and may also affect patent litigation.

An important change introduced by the AIA is that, as of March 16, 2013, the United States transitioned to a "first-to-file" system for deciding which party should be granted a patent when two or more patent applications are filed by different parties claiming the same invention. A third party that files a patent application in the USPTO after that date but before us could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by the third party. This will require us to be cognizant going forward of the time from invention to filing of a patent application, but circumstances could prevent us from promptly filing patent applications on our inventions.

Among some of the other changes introduced by the AIA are changes that limit where a patentee may file a patent infringement suit and providing opportunities for third parties to challenge any issued patent in the USPTO. This applies to all of our U.S. patents, even those issued before March 16, 2013. Because of a lower evidentiary standard in USPTO proceedings

compared to the evidentiary standard in United States federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. The AIA and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents.

Moreover, future and recent past changes in the patent laws in the U.S. and abroad could impact or could increase the uncertainties and costs surrounding the prosecution of our and our licensors', licensees' or collaborators' patent applications and the enforcement or defense of our or our licensors', licensees' or collaborators' issued patents, which could have an impact on our business and financial conditions. For example, over the past decade, the U.S. Supreme Court and the U.S. Court of Appeals for the Federal Circuit have rendered decisions in several patent cases such as *Association for Molecular Pathology v. Myriad Genetics, Inc., BRCA1- & BRCA2-Based Hereditary Cancer Test Patent Litig.*, Mayo Collaborative Services v. Prometheus Laboratories, Inc., and Alice Corporation Pty. Ltd. v. CLS Bank International, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our and our licensors', licensees' or collaborators' ability to obtain patents in the future, these type of changes in the patent laws have created uncertainty with respect to the value of patents, once obtained. Depending on decisions by Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our and our licensors', licensees' or collaborators' ability to obtain new patents or to enforce existing patents and patents that we and our licensors, licensees or collaborators may obtain in the future.

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 and annuity fees on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance 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. Non-compliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we or our licensors, licensees or collaborators fail to maintain the patents and patent applications covering our product candidates, our competitors might be able to enter the market, which would have an adverse effect on our business.

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.

Because we collaborate with various collaborators on the development and commercialization of one or more of our product candidates and because we rely on third parties to manufacture our product candidates, we must, at times, share trade secrets with them. We seek to protect our wholly-owned technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, consulting agreements or other similar agreements with our advisors, employees, third-party contractors and consultants prior to disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, including our trade secrets. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's discovery of our trade secrets or other unauthorized use or disclosure would impair our competitive position and may have an adverse effect on our business.

In addition, these agreements typically restrict the ability of our advisors, employees, third-party contractors and consultants to publish data potentially relating to our trade secrets, although our agreements may contain certain limited publication rights. For example, any academic institution that we may collaborate with in the future may be granted rights to publish data arising out of such collaboration, provided that we are notified in advance and given the opportunity to delay publication for a limited time period in order for us to secure patent protection of intellectual property rights arising from the collaboration, in addition to the opportunity to remove confidential or trade secret information from any such publication. Our existing collaborative research and development programs may require us to share trade secrets under the terms of our research and development collaborations or similar agreements. Despite our efforts to protect our trade secrets, our competitors may

discover our trade secrets through breach of our agreements with third parties, independent development or publication of information by any of our third-party collaborators. A competitor's discovery of our trade secrets would impair our competitive position and have an adverse impact on our business.

We may become involved in lawsuits to protect or enforce our intellectual property, which could be expensive, time-consuming and unsuccessful and have an adverse effect on the success of our business.

Third parties may infringe our or our licensors', licensees' or collaborators' patents or misappropriate or otherwise violate our or our licensors', licensees' or collaborators' intellectual property rights. In the future, we or our licensors, licensees or collaborators may initiate legal proceedings to enforce or defend our or our licensors', licensees' or collaborators' intellectual property rights, such as the litigation we initiated in August 2020 to enforce our rights under our collaboration with GSK, to protect our or our licensors', licensees' or collaborators' trade secrets or to determine the validity or scope of intellectual property rights we own or control. Also, third parties may initiate legal proceedings against us or our licensors, licensees or collaborators to challenge the validity or scope of intellectual property rights we own or control. These proceedings can be expensive and time-consuming, and many of our or our licensors', licensees' or collaborators' adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these legal actions than we or our licensors, licensees or collaborators. In addition, in an infringement proceeding, a court may decide that a patent owned by or licensed to us is invalid or unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our or our licensors', licensees' or collaborators' patents do not cover the technology in question. Furthermore, an adverse result in any litigation or administrative proceeding could put one or more of our or our licensors', licensees' or collaborators' patents at risk of being invalidated, held unenforceable or interpreted narrowly.

Accordingly, despite our or our licensors', licensees' or collaborators' efforts, we or our licensors, licensees or collaborators may not prevent third parties from infringing upon or misappropriating intellectual property rights we own or control, particularly in countries where the laws may not protect those rights as fully as in the United States. In addition, litigation and administrative proceedings could result in substantial costs and diversion of management resources, which could harm our business and financial results.

Within and outside of the United States, there has been a substantial amount of litigation and administrative proceedings regarding patent and other intellectual property rights in the pharmaceutical industry including opposition, derivation, reexamination, inter partes review or interference proceedings, or other preissuance or post-grant proceedings. Such proceedings may be provoked by third parties or by us or our licensors, licensees or collaborators to protect or enforce our or our licensors', licensees' or collaborators' patents or patent applications. Additionally, third-party preissuance submission of prior art to the USPTO or other foreign jurisdictions may jeopardize the issuance or scope of our or our licensors', licensees' or collaborators' patent applications. An unfavorable outcome in any such proceedings could require us or our licensors, licensees or collaborators 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 or our licensors, licensees or collaborators a license on commercially reasonable terms or at all, and we could be forced to stop commercializing our product candidates. Even if we or our licensors, licensees or collaborators obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us or our licensors, licensees or collaborators.

In addition, if the breadth or strength of protection provided by our or our licensors', licensees' or collaborators' patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates. Even if we successfully defend such litigation or proceeding, we may incur substantial costs, and it may distract our management and other employees. We could be found liable for monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent.

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

If we breach the license agreements related to our product candidates, we could lose the ability to continue the development and commercialization of our product candidates.

Our commercial success depends upon our ability, and the ability of our licensors, licensees and collaborators, to develop, manufacture, market and sell our product candidates and use our and our licensors', licensees' or collaborators' wholly-owned technologies without infringing the proprietary rights of third parties. A third party may hold intellectual

property, including patent rights that are important or necessary to the development of our products. As a result, we are a party to a number of technology licenses that are important to our business and expect to enter into additional licenses in the future. For example, we have in-licensed the rights to certain intellectual property relating to SHM under our in-license agreement with the Medical Research Council, which is the subject of issued patents and pending patent applications in certain countries. If we fail to comply with the obligations under these agreements, including payment and diligence terms, our licensors may have the right to terminate these agreements, in which event we may not be able to develop, manufacture, market or sell any product that is covered by these agreements or may face other penalties under the agreements. Such an occurrence could adversely affect the value of the product candidate being developed under any such agreement. Termination of these agreements or reduction or elimination of our rights under these agreements may result in our having to negotiate new or reinstated agreements, which may not be available to us on equally favorable terms, or at all, or cause us to lose our rights under these agreements, including our rights to intellectual property or technology important to our development programs.

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 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 any collaboration relationships we might enter into in the future;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by us and our licensors, licensees or collaborators; and
- the priority of invention of patented technology.

If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates.

Third parties may initiate legal proceedings against us alleging that we infringe their intellectual property rights, or we may initiate legal proceedings against third parties to challenge the validity or scope of intellectual property rights controlled by third parties, the outcome of which would be uncertain and could have an adverse effect on the success of our business.

Third parties may initiate legal proceedings against us or our licensors, licensees or collaborators alleging that we or our licensors, licensees or collaborators infringe their intellectual property rights or that we or our licensors, licensees or collaborators may initiate legal proceedings against third parties to challenge the validity or scope of intellectual property rights controlled by third parties, including in oppositions, interferences, reexaminations, post-grant reviews, inter partes reviews or derivation proceedings in the United States or other jurisdictions. These proceedings can be expensive and time-consuming, and many of our or our licensors', licensees' or collaborators' adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these legal actions than we or our licensors, licensees or collaborators.

Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of management and employee resources from our business. An unfavorable outcome could require us or our licensors, licensees or collaborators to cease using the related technology, to cease developing or commercializing our product candidates 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 or our licensors, licensees or collaborators a license on commercially reasonable terms or at all. Even if we or our licensors, licensees or collaborators obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us or our licensors, licensees or collaborators. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could harm our business.

We may be subject to claims by third parties asserting that our employees or we have misappropriated their intellectual property or claiming ownership of what we regard as our own intellectual property.

Many of our employees, including our senior management, were previously employed at universities or at other 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 we try to ensure that our employees do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these employees have used or disclosed confidential information or intellectual property, including trade secrets or other proprietary information, of any such employee's former employer. Litigation may be necessary to defend against these claims.

If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel or sustain damages. Such intellectual property rights could be awarded to a third party, and we could be required to obtain a license from such third party to commercialize our technology or products, which license could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. Such a license may not be available on commercially reasonable terms or at all. Even if we successfully prosecute or defend against such claims, litigation could result in substantial costs and distract management.

Our inability to protect our confidential information and trade secrets would harm our business and competitive position.

In addition to seeking patents for some of our technology and products, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. We seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. 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 both within and outside the United States may be less willing or unwilling to protect trade secrets. Furthermore, if a competitor lawfully obtained or independently developed any of our trade secrets, we would have no right to prevent such competitor from using that technology or information to compete with us, which could harm our competitive position. Additionally, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating the trade secret.

If we do not obtain protection under the Hatch-Waxman Amendments and similar foreign legislation for extending the term of patents covering each of our product candidates, our business may be harmed.

Depending upon the timing, duration and conditions of FDA marketing approval of our product candidates, one or more of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Amendments"). The Hatch-Waxman Amendments permit a patent term extension of up to five years for a patent covering an approved product as compensation for effective patent term lost during product development and the FDA regulatory review process. However, we may not receive an extension if we fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Moreover, the length of the extension could be less than we request. If we are unable to obtain patent term extension or the term of any such extension is less than we request, the period during which we can enforce our patent rights for that product will be shortened, and our competitors may obtain approval to market competing products sooner. As a result, our revenue from applicable products could be reduced, possibly materially.

Risks Related to Ownership of Our Common Stock

The market price of our stock has been and may continue to 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. In addition to the factors discussed in this "Risk Factors" section and elsewhere in this report, these factors include:

- the success of competitive products;
- regulatory actions with respect to our products or our competitors' products;
- actual or anticipated changes in our growth rate relative to our competitors;
- announcements by us or our competitors of significant acquisitions, strategic collaborations, joint ventures, collaborations or capital commitments;

- results of preclinical studies and clinical trials of our product candidates or those of our competitors;
- regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- the level of expenses related to any of our product candidates or clinical development programs;
- developments with respect to our existing collaboration agreements and announcements of new collaboration agreements;
- disputes, breaches and terminations of our manufacturing agreements, collaborations agreements or other important agreements;
- the results of our efforts to in-license or acquire additional product candidates or products;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- variations in our financial results or those of companies that are perceived to be similar to us;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- share price and volume fluctuations attributable to inconsistent trading volume levels of our shares;
- announcement or expectation of additional financing efforts;
- sales of our common stock by us, our insiders or our other stockholders;
- changes in the structure of health care payment systems;
- market conditions in the biotechnology sector; and
- general economic, industry and market conditions.

In addition, the stock market in general, and the Nasdaq Global Select Market and biotechnology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. In the past, following periods of volatility in the overall market and the market price of a particular company's securities, securities class action litigation has often been instituted against these companies. We are currently subject to securities litigation, which is described in Item 3, "Legal Proceedings." This or any future securities litigation could result in substantial costs and a diversion of our management's attention and resources. 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.

We have broad discretion in the use of the net proceeds from our public offerings and may not use them effectively.

Our management has broad discretion in the application of the net proceeds from our public offerings, and you will be relying on the judgment of our management regarding the application of these proceeds. Our management might not apply the net proceeds from our public offerings in ways that ultimately increase the value of your investment. If we do not invest or apply the net proceeds from our public offerings in ways that enhance stockholder value, we may fail to achieve expected financial results, which could cause our stock price to decline.

We may be subject to securities litigation, which is expensive and could divert management attention.

The market price of our common stock is volatile and, in the past, companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. We have been, and may in the future be, the target of this type of litigation. We are currently subject to securities litigation, which is described in Item 3, "Legal Proceedings." Regardless of the outcome, these matters or future litigation against us could result in substantial costs and divert our management's attention from other business concerns, which could seriously harm our business.

The requirements of being a public company may strain our resources, divert management's attention, and affect our ability to attract and retain additional executive management and qualified board members.

We are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Protection Act, as well as rules adopted, and to be adopted, by the SEC and the Nasdaq Global Select Market. Our management and other personnel devote a substantial amount of time to these compliance initiatives. In addition, changing laws, regulations, and standards relating to corporate governance and public disclosure are creating uncertainty for public companies, increasing legal and financial compliance costs, and making some activities more time consuming. We intend to continue to invest resources to comply with evolving laws, regulations, and standards, and this investment may result in increased general and administrative expenses and a diversion of management's time and attention. If our efforts to comply with new laws, regulations, and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to their application and practice, regulatory authorities may initiate legal proceedings against us and our business may be adversely affected. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to incur substantial costs to maintain sufficient coverage. We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these and future 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.

In addition, we are required to maintain internal control over financial reporting and to report any material weaknesses in such internal control. Section 404 of the Sarbanes-Oxley Act requires that we evaluate and determine the effectiveness of our internal control over financial reporting and provide a management report on our internal controls on an annual basis. If we have material weaknesses in our internal control over financial reporting, we may not detect errors on a timely basis and our financial statements may be materially misstated. We have only recently compiled the systems, processes and documentation necessary to comply with Section 404 of the Sarbanes-Oxley Act. We will need to maintain and enhance these processes and controls as we grow, and we may require additional management and staff resources to do so. Additionally, even if we conclude our internal controls are effective for a given period, we may in the future identify one or more material weaknesses in our internal controls, in which case our management will be unable to conclude that our internal control over financial reporting is effective. Regardless of compliance with Section 404, any failure of our internal control over financial reporting could have a material adverse effect on our reported operating results and harm our reputation. Internal control deficiencies could also result in a restatement of our financial results.

Future sales and issuances of our common stock or rights to purchase common stock, including pursuant to our equity incentive plans, could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall.

We expect that significant additional capital may be needed in the future to continue our planned operations, including conducting clinical trials, commercialization efforts, expanded research and development activities and costs associated with operating a public company. 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. If we sell common stock, convertible securities or other equity securities, investors may be materially diluted by subsequent sales. We also have registered all shares of common stock that we may issue under our equity incentive plans or that are issuable upon exercise of outstanding options. These shares can be freely sold in the public market upon issuance and once vested, subject to volume limitations applicable to affiliates. If any of these additional shares are sold, or if it is perceived that they will be sold, in the public market, the market price of our common stock could decline. Such sales may also result in material dilution to our existing stockholders, and new investors could gain rights, preferences and privileges senior to the holders of our common stock.

Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

We are subject to the periodic reporting requirements of the Exchange Act. We designed our disclosure controls and procedures to reasonably assure that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management and recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

These inherent limitations include the realities that judgments in decision-making can be faulty and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

We do not intend to pay dividends on our common stock, so any returns will be limited to the value of our stock.

We have never declared or paid any cash dividend on our common stock. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any return to stockholders will therefore be limited to the appreciation of their stock.

Provisions in our restated certificate of incorporation and restated bylaws and Delaware law might discourage, delay or prevent a change in control of our company or changes in our management and, therefore, depress the market price of our common stock.

Our restated certificate of incorporation and restated bylaws contain provisions that could depress the market price of our common stock by acting to discourage, delay or prevent a change in control of our company or changes in our management that the stockholders of our company may deem advantageous. These provisions, among other things:

- 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 (also known as a "poison pill");
- 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.

In addition, Section 203 of the Delaware General Corporation Law ("DGCL") may discourage, delay or prevent a change in control of our company. Section 203 of the DGCL imposes certain restrictions on mergers, business combinations and other transactions between us and holders of 15% or more 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 is influenced by the research and reports that industry or securities analysts publish about us or our business. 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 clinical trial results or operating results fail to meet the expectations of analysts, our stock price would likely decline. If one or more of these 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 our stock price or trading volume to decline.

We plan to use potential future operating losses and our federal and state net operating loss ("NOL") carryforwards to offset taxable income from revenue generated from operations or corporate collaborations. However, our ability to use NOL carryforwards could be limited as a result of additional issuances of equity securities.

We plan to use our current year operating losses to offset taxable income from any revenue generated from operations or corporate collaborations. To the extent we have taxable income, we plan to use our NOL carryforwards to offset income that would otherwise be taxable. However, under the Tax Reform Act of 1986, the benefits from the use of our NOL carryforwards may be impaired or limited under Section 382 of the Internal Revenue Code of 1984, as amended (the "Code"), if we incur a cumulative ownership change of more than 50%, as interpreted by the U.S. Internal Revenue Service, over a three-year period. In September 2015, we completed a Section 382 and 383 ownership change analysis through December 31, 2014 and determined that there was an ownership change in 2007 that may limit the utilization of approximately $5.3 million and $5.4 million in federal and state NOLs, respectively, and $0.2 million in both federal and state research tax credits. We extended the analysis period of the study through December 31, 2018, noting an additional ownership change during fiscal 2017 that may limit the utilization of federal and state NOLs. Our use of federal NOL carryforwards could be limited further by the provisions of Section 382 of the Code depending upon the timing and amount of additional equity securities that we have issued or will

issue. State NOL carryforwards may be similarly limited. Any such disallowances may result in greater tax liabilities than we would incur in the absence of such a limitation, and any increased liabilities could adversely affect our business, results of operations, financial condition and cash flow.

On December 22, 2017, the President of the United States signed into law the Tax Reform Act. The legislation significantly changes U.S. tax law by, among other things, lowering the corporate income tax rates. The Tax Reform Act permanently reduces the U.S. corporate income tax rate from a maximum of 35% to a flat 21% rate, effective January 1, 2018. Additionally, the Tax Reform Act will no longer allow deductions for compensation in excess of $1 million for certain employees, even if paid as commissions or performance-based compensation. We may be subject to these limitations as provided for under Section 162(m) of the Code in the future. The Tax Reform Act also limits the amount taxpayers are able to deduct for federal NOL carryforwards generated in taxable years beginning after December 31, 2017 to 80% of the taxpayer's taxable income. The law also generally repeals all carrybacks. However, any NOLs generated in taxable years after December 31, 2017 can be carried forward indefinitely. Losses arising in taxable years beginning before December 31, 2017 may still be carried back two years and are subject to their current expiration period. As of December 31, 2020, we have federal NOLs of approximately $248.4 million, which expire beginning December 31, 2028 through December 31, 2037, if not used to reduce income taxes payable in the future.

We are a smaller reporting company and may elect to comply with reduced public company reporting requirements applicable to smaller reporting companies, which could make our common stock less attractive to investors.

We are a "smaller reporting company," meaning that we are not an investment company, an asset-backed issuer, or a majority-owned subsidiary of a parent company that is not a "smaller reporting company," and have either: (i) a public float of less than $250 million or (ii) annual revenues of less than $100 million during the most recently completed fiscal year and (A) no public float or (B) a public float of less than $700 million. As a "smaller reporting company," we are subject to reduced disclosure obligations in our SEC filings compared to other issuers, including with respect to disclosure obligations regarding executive compensation in our periodic reports and proxy statements. Until such time as we cease to be a "smaller reporting company," such reduced disclosure in our SEC filings may make it harder for investors to analyze our operating results and financial prospects.

If some investors find our common stock less attractive as a result of any choices to reduce future disclosure we may make, there may be a less active trading market for our common stock and our stock price may be more volatile.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

Our principal executive office is located at 10421 Pacific Center Court in San Diego, California, and consists of approximately 25,000 square feet of leased office and laboratory space under a lease which will expire on August 31, 2021. We use these facilities for our administrative, research and development and other activities.

In May 2018, we entered into a three-year sublease agreement with Trex Enterprises Corporation, a California corporation, for an additional 18,000 square feet of office space in the building at 10455 Pacific Center Court in San Diego, California (the "10455 Building"). The terms of the original sublease with Trex provided for a November 12, 2021 lease expiration. On November 11, 2020, we entered into a termination agreement of the sublease with Trex (the "Sublease Termination"). Under the Sublease Termination, we agreed to early terminate the sublease agreement for the 10455 Building on December 15, 2020.

On May 4, 2020, we entered into a lease agreement (the "Lease Agreement") with Wateridge Property Owner, LP, with respect to facilities in the building at 10770 Wateridge Circle, San Diego, California 92121 (the "10770 Wateridge Circle Building"). Under the Lease Agreement, we agreed to lease approximately 45,000 square feet of space in the 10770 Wateridge Circle Building for a term of 124 months, beginning on April 1, 2021 (or on such later date as described in the Lease Agreement).

Item 3. Legal Proceedings

On March 25, 2020, a putative securities class action was filed in the United States District Court for the Southern District of California naming the Company and certain of its current or former officers as defendants. The complaint purports to assert claims under Section 10(b) of the Exchange Act Rule 10b-5, and Section 20(a) of the Exchange Act, on behalf of persons and entities who acquired our common stock between October 10, 2017 and November 7, 2019 (the "Class Period"). An amended complaint was filed on September 30, 2020 alleging that, during the Class Period, the defendants made material misrepresentations or omissions regarding our etokimab product candidate that artificially inflated our stock price. The plaintiff seeks, among other things, damages in an unspecified amount, as well as costs and expenses. We believe that the plaintiff's allegations are without merit and intend to vigorously defend against the claims. Because the Company is in the early stages of this litigation matter, we are unable to estimate a reasonably possible loss or range of loss, if any, that may result from these matters. On September 1, 2020, a related shareholder derivative complaint was filed based on allegations substantially similar to those in the class action, and asserting claims against current or former officers and directors for contribution under Sections 10(b) and 21D of the Exchange Act, breach of fiduciary duty, unjust enrichment and corporate waste. On January 28, 2021, this derivative action was voluntarily dismissed without prejudice.

From time to time, we may be involved in legal proceedings arising in the ordinary course of our business. We investigate these claims as they arise and accrue estimates for resolution of legal and other contingencies when losses are probable and estimable. 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

Trading Symbol and Holders

Our common stock has been listed on the Nasdaq Global Select market under the symbol "ANAB" since January 26, 2017. As of February 23, 2021, we had approximately 13 holders of record of our common stock. This number does not include beneficial owners whose shares were held in street name.

Dividend Policy

We have never declared or paid cash or stock dividends on our common stock. We currently intend to retain all available funds and any future earnings for use in the operation of our business and do not anticipate paying any dividends on our common stock in the foreseeable future. Any future determination to declare dividends on common stock will be made at the discretion of our board of directors and will depend on our financial condition, operating results, capital requirements, general business conditions and other factors that our board of directors may deem relevant.

Issuer Purchases of Equity Securities

We did not purchase any of our registered equity securities during the period covered by this Annual Report on Form 10-K.

Item 6. Selected Consolidated Financial Data

Not applicable.

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

You should read the following discussion and analysis of our financial condition and results of operations together with the historical consolidated financial statements and the notes thereto included in Part II, Item 8—Consolidated Financial Statements and Supplementary Data of this Annual Report on Form 10-K. This discussion and other sections of this Annual Report contain forward-looking statements that involve risks and uncertainties, such as our plans, objectives, expectations, intentions, and beliefs. Our actual results could differ materially from those discussed in these forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those identified below and those discussed in the section entitled "Risk Factors" included in Part I, Item 1A of this Annual Report. You should also carefully read "Special Note Regarding Forward-Looking Statements".

Overview

We are a clinical stage biotechnology company developing first-in-class immunology therapeutic product candidates focused on emerging immune control mechanisms applicable to inflammation and immuno-oncology indications. We develop our product candidates using our proprietary antibody discovery technology platform, which is based upon a breakthrough understanding of the natural process of antibody generation, known as somatic hypermutation ("SHM"), and replicates this natural process of antibody generation *in vitro*. Our strategy is to advance the development of our proprietary product candidates, and where applicable, establish partnerships with leading biopharmaceutical companies where we retain certain development and commercialization rights. Our most advanced wholly-owned antibody programs, imsidolimab, ANB030 and ANB032, are designed to modulate therapeutic targets that are genetically associated with human inflammatory disorders.

Imsidolimab, our IL-36R antibody previously referred to as ANB019, inhibits the interleukin-36 receptor ("IL-36R"), and is being developed for the treatment of multiple dermatological inflammatory diseases. We completed a Phase 1 clinical trial in healthy volunteers, which was presented at the European Academy of Allergy and Clinical Immunology in 2018, where imsidolimab was well-tolerated by all subjects, no dose-limiting toxicities were observed, and no serious adverse events were reported among any subjects in the clinical trial. In July 2020, the U.S. Food and Drug Administration (the "FDA") granted Orphan Drug Designation for imsidolimab for the treatment of patients with GPP. We are conducting an open-label, multi-dose, single-arm Phase 2 clinical trial of imsidolimab in 8 GPP patients, also referred to as the GALLOP clinical trial, where we announced positive topline data in October 2020. Six of 8 (75%) patients treated with imsidolimab monotherapy achieved the primary endpoint of improvement in the clinical global impression scale ("CGI") on Day 29. Two of 8 (25%) patients were considered to have not met the primary endpoint because they dropped out of the clinical trial prior to Day 29. The modified Japanese Dermatology Association Severity Index ("mJDA-SI") score, which incorporates both dermatological and systemic aspects of GPP, decreased on average by 29% on Day 8 and 54% on Day 29. Erythema with skin pustules, which clinically defines GPP, decreased by 60% on Day 8 and 94% on Day 29. Serum c-reactive protein ("CRP"), which is an indicator of systemic inflammation, was normal (less than 5 mg/L) for 5 of the 6 patients achieving the primary endpoint on Day 29. Genotypic testing indicated homozygous wild-type IL-36RN, CARD14 and AP1S3 alleles for all 8 patients. We believe this suggests that imsidolimab may be broadly applicable to pustular diseases irrespective of genetic drivers. Anti-drug antibodies were not detected as of Day 29 in any patient. Imsidolimab was generally well-tolerated, and most treatment-emergent adverse events were mild to moderate in severity and resolved without sequelae. No infusion or injection site reactions were observed. One patient dropped out of the clinical trial due to a diagnosis of Staphylococcal aureus bacteremia in the first week, which was a serious adverse event deemed to be possibly drug-related. Because the patient was symptomatic prior to dosing and had a prior medical history of bacteremia, a common comorbidity of GPP, we do not believe this event is likely attributable to imsidolimab. Another patient dropped out of the study on Day 22 due to investigator reported inadequate efficacy. One patient contracted COVID-19 during the course of the clinical trial, which was mild, unrelated to imsidolimab, and did not lead to study discontinuation. Data from the first two patients to have completed the Day 113 treatment period under this clinical trial, which we announced in September 2019, indicated sustained efficacy in these two patients through Day 113. We plan to report full data from the GALLOP clinical trial at a medical conference in 2021. While initial GPP epidemiology studies suggested at least 3,000 patients in the United States, recent medical claims analyses suggest GPP prevalence in the United States of at least 10,000 patients. We met with the FDA during the fourth quarter of 2020 to review an orphan disease registration plan for imsidolimab for the treatment of GPP and anticipate initiating a Phase 3 clinical trial in mid-2021 following completion of protocol alignment and review of 16-week data from the GALLOP clinical trial by the FDA.

We are also conducting a randomized, double-blind, placebo-controlled 59-patient multi-dose clinical trial of imsidolimab in PPP, also referred to as the POPLAR clinical trial, where enrollment was completed in 2020 and top-line data are anticipated in the first quarter of 2021. The primary endpoint of this clinical trial is change in palmo-plantar pustulosis area severity index (PPPASI) at week 16 relative to baseline. PPP is a non-fatal form of pustular psoriasis that we estimate affects approximately 150,000 patients in the United States alone. We have initiated a global registry of GPP and PPP patients, also referred to as the RADIANCE study, which we anticipate will improve understanding of the patient journey in these two indications and assist in enrollment of future GPP and PPP clinical trials.

We have initiated clinical development of imsidolimab for the treatment of skin toxicities associated with treatments with inhibitors of epidermal growth factor ("EGFRi") and MAPK/ERK kinase ("MEKi"). Treatment of solid tumors with EGFRi and/or MEKi is frequently limited by the occurrence of skin toxicities, including acneiform or papulopustular rash. Recent translational data has suggested that these skin toxicities are mediated by excess IL-36 signaling, leading to IL-8-mediated cutaneous neutrophilia and acneiform rash. Based on existing claims data, approximately 60,000 patients are prescribed EGFRi and/or MEKi treatments annually, and the vast majority of these patients experience skin toxicity, which in some cases leads to dose reduction and/or discontinuation of treatment. Current standard-of-care treatments are generally ineffective in patients with the most severe grades of EGFRi and/or MEKi mediated skin toxicity. During the fourth quarter of 2020, we initiated a Phase 2 clinical trial, called EMERGE, of imsidolimab in combination with EGFRi inhibitors, for the treatment of patients diagnosed with a certain baseline severity of skin toxicity, where 45 patients are randomized 2:1 between imsidolimab and placebo arms, to assess the efficacy of imsidolimab in the treatment of this indication. We anticipate interim top-line data from this clinical trial at the end of 2021.

We have also initiated clinical development of imsidolimab in ichthyosis, which is a family of rare, inherited, dermatological disorders characterized by dry, scaling and thickened skin. Recent human translational studies have suggested that the underlying skin inflammation responsible for ichthyosis is mediated by dysregulated IL-36 signaling, and we believe that imsidolimab treatment may be efficacious in treatment of this condition. Approximately 6,000 patients in the United States are affected with moderate-to-severe levels of ichthyosis, and no approved therapies are available for this disease. We have initiated a Phase 2 clinical trial, called INSPIRE, of imsidolimab in patients with certain baseline severity of ichthyosis, where 24 patients are randomized 2:1 between imsidolimab and placebo arms, and interim top-line data is anticipated in 2022.

We plan to initiate clinical development of imsidolimab in hidradenitis suppurativa, also known as acne inversa, which is a chronic inflammatory skin disease characterized by painful nodules in intertriginous areas that can progress to abscesses, sinus tracks and scarring. Current treatment options for hidradenitis suppurativa, including antibiotics, corticosteroids and anti-TNF therapy, have variable efficacy in moderate-to-severe patients, which often leads to surgery for removal of hidradenitis suppurativa nodules. Human translational studies have demonstrated elevated IL-36 cytokine expression in hidradenitis suppurativa skin biopsies, and we believe treatment of moderate-to-severe hidradenitis suppurativa with imsidolimab may lead to therapeutic benefit for this patient population. Moderate-to-severe hidradenitis suppurativa affects approximately 150,000 adults in the United States. We intend to initiate a Phase 2 clinical trial of imsidolimab in hidradenitis suppurativa, called HARP, in the second quarter of 2021.

We plan to initiate clinical development of imsidolimab in acne, which is the most common skin disorder in the United States, with approximately 7 million patients diagnosed with moderate-to-severe disease. Moderate-to-severe acne typically presents with painful papules, pustules, nodules, cysts and scarring. A key contributing factor to the pathogenesis of acne is the immune response to p. acnes, which is associated with upregulated IL-36 cytokine activity, localized inflammation and neutrophil infiltration of the skin. Existing therapies, including isotretinoin and systemic antibiotics, provide variable efficacy for moderate-to-severe acne patients and have practical limitations to their use given potential for clinically meaningful side effects. We anticipate initiating a Phase 2 clinical trial of imsidolimab, called ACORN, for the treatment of moderate-to-severe acne

Our second wholly-owned program, ANB030, is an anti-PD-1 agonist antibody program designed to augment PD-1 signaling through ANB030 treatment to suppress T-cell driven human inflammatory diseases. Genetic mutations in the PD-1 pathway are known to be associated with increased susceptibility to human inflammatory diseases, and hence we believe that ANB030 is applicable to diseases where PD-1 checkpoint receptor function may be under-represented. We presented preclinical data for ANB030 at the Festival of Biologics Annual Meeting in March 2020, including translational data demonstrating *in vitro* activity of ANB030 in alopecia areata patient samples. We initiated a Phase 1 healthy volunteer clinical trial in the first half of 2020, which is designed to assess the safety, pharmacokinetics and pharmacodynamics of ANB030 in single and multiple ascending dose cohorts. We anticipate top-line data from this Phase 1 clinical trial in mid-2021. We plan to initiate Phase 2 clinical trials of ANB030 in alopecia areata and vitiligo in the second half of 2021.

Our third wholly-owned program is an anti-BTLA modulator antibody, known as ANB032, which is broadly applicable to human inflammatory diseases associated with lymphoid and myeloid immune cell dysregulation. Mutations in the BTLA signaling pathway are associated with human inflammatory disease, and we believe ANB032 silences pro-inflammatory signaling by modulating BTLA binding to HVEM. We filed a Clinical Trial Notification ("CTN") in Australia for ANB032 during the first quarter of 2021 and anticipate initiating a healthy volunteer Phase 1 trial in the first half of 2021 upon clearance of the CTN. We presented preclinical data regarding ANB032 at the 2020 Federation of Clinical Immunology Societies (FOCIS) Virtual Annual Meeting in October 2020.

Etokimab, our anti-IL-33 antibody previously referred to as ANB020, inhibits the activity of the interleukin-33 cytokine ("IL-33"). We have conducted a randomized, placebo-controlled Phase 2 clinical trial of etokimab in approximately 100 adult patients with CRSwNP (a debilitating atopic disorder associated with elevated IL-33 pathway signaling), also referred to as the

ECLIPSE clinical trial. We recently reported top-line data from a week 16 analysis of the ECLIPSE clinical trial. Patients dosed with etokimab every four (q4w) or eight weeks (q8w) failed to achieve the co-primary endpoints of statistically significant improvement in their bilateral nasal polyps score ("NPS"), an endoscopic measure of nasal occlusion, and in their sino-nasal outcome test ("SNOT-22"), a patient reported quality-of-life assessment, versus placebo at the week 8 time point. Both endpoints demonstrated statistically significant improvement over baseline levels of NPS and SNOT-22. Blood eosinophil levels, which are a biomarker of etokimab's mechanism, demonstrated statistically significant reduction relative to baseline in both etokimab treatment arms. Following this data, we have decided to discontinue further development of etokimab.

In addition to our wholly-owned antibody programs, multiple Company-developed antibody programs have been advanced to preclinical and clinical milestones under our collaborations. We have received to date approximately $164.6 million in cash receipts from collaborations. Our collaborations include an immuno-oncology-focused collaboration with GlaxoSmithKline, Inc. ("GSK") and an inflammation-focused collaboration with Bristol-Myers Squibb ("BMS"). A Biologics License Application ("BLA") for our most advanced partnered program, which is an anti-PD-1 antagonist antibody called dostarlimab, was submitted by GSK and accepted by the FDA for the treatment of advanced or recurrent deficient mismatch repair endometrial cancer ("dMMREC"), and FDA approval is anticipated in this indication during the first half of 2021. This FDA approval is dependent on a pre-approval inspection of the dostarlimab manufacturing site by the FDA and is therefore contingent on easing of the coronavirus ("COVID-19") pandemic travel restrictions. In addition, the European Medicines Agency ("EMA") recently accepted GSK's Marketing Authorization Application ("MAA") for dostarlimab in the European Union ("EU") for dMMREC, and EMA approval is anticipated in this indication during the first half of 2021. A second BLA submitted by GSK was accepted by the FDA during the first quarter of 2021 for dostarlimab in pan-deficient mismatch repair tumors ("PdMMRT"). We received a $10.0 million cash milestone payment upon the FDA acceptance of GSK's first BLA for dostarlimab and anticipate an additional $20.0 million cash milestone payment upon first FDA approval of dostarlimab during the first half of 2021. We also received a $5.0 million milestone payment for the EMA acceptance of GSK's first MAA for dostarlimab and anticipate an additional $10.0 million cash milestone payment upon first EMA approval of dostarlimab during the first half of 2021. An additional $10.0 million cash milestone payment is anticipated by the end of the first quarter of 2021 for acceptance of the second FDA BLA referred to above. Dostarlimab is currently in clinical development for various solid tumor indications, including dMMREC, PdMMRT, colorectal cancer, ovarian cancer, non-small cell lung cancer, cervical cancer, rectal cancer, clear cell sarcoma and head-and-neck squamous cell carcinoma. We anticipate receiving additional milestones from GSK, of equal magnitude to the milestone payments outlined above, upon approval of the BLA and acceptance and approval of the EMA filings of dostarlimab for the PdMMRT indication. Depending upon the timing of the aforementioned dostarlimab regulatory acceptance and approval milestones, we anticipate a total of $75.0 million in such milestone payments over the upcoming 18 months. An additional $165.0 million in sales milestones is anticipated upon achievement of certain dostarlimab annual sales revenues. In October 2020, we amended our GSK collaboration to increase royalties on global net sales of dostarlimab to 8-25%, add 1% royalty rate on GSK's global net sales of Zejula and received a one-time cash payment of $60.0 million. For more information about these collaborations, see "—Collaborations".

As of December 31, 2020, we had an accumulated deficit of $264.0 million, primarily as a result of losses incurred since our inception in 2005. We expect to continue to incur net operating losses for at least the next several years as we advance our products through clinical development, seek regulatory approval, prepare for and, if approved, proceed to, commercialization, expand our operations and facilities and grow in new and existing markets, territories and industries.

For our discussion related to the results of our operations and liquidity and capital resources for fiscal year ended December 31, 2019 compared to the year ended December 31, 2018, please refer to Part II, Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our Annual Report on Form 10-K for the year ended December 31, 2019.

COVID-19

In December 2019, a strain of coronavirus was reported in Wuhan, China and began to spread globally, including to the United States and Europe, in the following months. The World Health Organization has declared COVID-19 to be a global pandemic. The full impact of the COVID-19 pandemic is inherently uncertain at the time of this Annual Report. The COVID-19 pandemic has resulted in travel restrictions and, in some cases, prohibitions of non-essential activities, disruption and shutdown of businesses, and greater uncertainty in global financial markets. As COVID-19 has spread, it has significantly impacted the health and economic environment around the world, and many governments have closed most public establishments, including restaurants, workplaces, and schools. Our ongoing clinical trials have been, and may continue to be, affected by the closure of offices, or country borders, among other measures being put in place around the world. The inability to travel and conduct face-to-face meetings can also make it more difficult to enroll new patients in ongoing or planned clinical trials. Any of these circumstances will potentially have a negative impact on our financial results and the timing of our clinical trials.

The COVID-19 pandemic has caused us to modify our business practices (including but not limited to curtailing or modifying employee travel, moving to full remote work, and cancelling physical participation in meetings, events, and conferences), and we may take further actions as may be required by government authorities or that we determine are in the best interests of our employees, patients, and business partners.

The extent of the impact of the COVID-19 pandemic on our future liquidity and operational performance will depend on certain developments, including the duration and spread of the outbreak, the availability and effectiveness of vaccines, the impact on our clinical trials, patients, and collaboration partners, and the effect on our suppliers.

Financial Overview

Collaboration Revenue

We have not generated any revenue from product sales. Our revenue has been derived from amortization of upfront license payments, research and development funding and milestone payments under collaboration and license agreements with our collaborators. From inception through December 31, 2020, we have received $164.6 million in cash in non-dilutive funding from our collaborators.

Collaboration and Exclusive License Agreement with GSK

In March 2014, we entered into a Collaboration and Exclusive License Agreement GSK (the "GSK Agreement") for the development and commercialization of therapeutic monospecific and bispecific antibodies that antagonize PD-1, TIM-3, LAG-3 and/or a fourth undisclosed checkpoint receptor. We received $17.0 million in upfront fees from GSK in March 2014, and in November 2014, we amended the agreement with GSK to include the development and commercialization of bispecific antibodies to another undisclosed target, for an additional upfront fee of $2.0 million. Both upfront fees were recognized over the same period that our research and development services for which we were reimbursed were performed, which was extended through December 31, 2016 by amendment of the GSK Agreement in February 2016.

For each of the four targets under the GSK agreement, we are eligible to receive up to $273.0 million in milestone payments, which are comprised of $18.0 million for preclinical and clinical development milestone payments, $90.0 million upon certain regulatory events and $165.0 million upon worldwide commercial sales thresholds. In addition, GSK is obligated to pay us tiered royalties, ranging from 4% to 8%, for each product developed under the agreement, except in the case of dostarlimab where the royalties payable will be 8% to 25% as amended below, on annualized net sales of each antibody commercialized from the collaboration.

On October 23, 2020, we amended the GSK Agreement (the "Amendment"). Under the Amendment, we agreed to permit GSK to conduct development and commercialization of Zejula, an oral, once-daily poly (ADP-ribose) polymerase (PARP) inhibitor, which has received US approval for the maintenance treatment of adult patients with advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to first-line platinum-based chemotherapy and is under development for additional cancer indications. In addition, under the Amendment, we were granted increased royalties upon sales of dostarlimab, an anti-PD-1 antagonist antibody under development by GSK for multiple oncological disorders, including endometrial cancer, non-small cell lung cancer, ovarian cancer, colorectal cancer, and mismatch repair deficient solid tumors, equal to 8% of Net Sales (as defined in the GSK Agreement) below $1.0 billion and from 12% up to 25% of Net Sales above $1.0 billion. The Amendment also provided for a one-time non-refundable cash payment of $60.0 million that we received in the fourth quarter of 2020. GSK also agreed, starting January 1, 2021, to pay us a 1% royalty on all GSK Net Sales of Zejula. The $1.1 billion in cash milestone payments due under the GSK Agreement remain unchanged. Additionally, under the terms of the Amendment, GSK has agreed to certain diligence commitments with respect to the future development of dostarlimab, and the parties have agreed to review such commitments under regular joint review committee meetings going forward. From inception of the agreement through December 31, 2020, we have recognized $142.3 million in total revenue from GSK.

Milestones achieved through December 31, 2020 under the GSK Agreement are as follows:

	Anti-PD-1 (GSK4057190A/Dostarlimab)		Anti-TIM-3 (GSK4069889A/Cobolimab)		Anti-LAG-3 (GSK40974386)	
Milestone Event	**Amount**	**Quarter Recognized**	**Amount**	**Quarter Recognized**	**Amount**	**Quarter Recognized**
Initiated *in vivo* toxicology studies using good laboratory practices (GLPs)	$1.0M	Q2'15	$1.0M	Q4'15	$1.0M	Q3'16
IND clearance from the FDA	$4.0M	Q1'16	$4.0M	Q2'16	$4.0M	Q2'17
Phase 2 clinical trial initiation	$3.0M	Q2'17	$3.0M	Q4'17	$3.0M	Q4'19
Phase 3 clinical trial initiation - first indication	$5.0M	Q3'18	—	—	—	—
Phase 3 clinical trial initiation - second indication	$5.0M	Q2'19	—	—	—	—
Filing of the first NDA - first indication	$10.0M	Q1'20	—	—	—	—
Filing of the first MAA - first indication	$5.0M	Q1'20	—	—	—	—

Milestones achieved during the discovery period were recognized as revenue pro-rata through December 31, 2016. Milestones achieved during fiscal 2017 were recognized as revenue in the period earned, while milestones after December 31, 2017 were recognized upon determination that a significant reversal of revenue would not be probable. Cash is generally received within 30 days of milestone achievement.

Antibody Generation Agreement with Bristol-Myers Squibb

In December 2011, we entered into a license and collaboration agreement (the "BMS Agreement") with Celgene, now a part of Bristol-Myers Squibb (Celgene and Bristol-Myers Squibb are hereinafter referred to, collectively, as "BMS"), to develop therapeutic antibodies against multiple targets. We granted BMS the option to obtain worldwide commercial rights to antibodies generated against each of the targets under the agreement, which option was triggered on a target-by-target basis by our delivery of antibodies meeting certain pre-specified parameters pertaining to each target under the agreement.

The BMS Agreement provided for an upfront payment of $6.0 million from BMS, which we received in 2011, and recognized through 2014, milestone payments of up to $53.0 million per target, low single-digit royalties on net sales of antibodies against each target, and reimbursement of specified research and development costs. From inception of the agreement through December 31, 2020, we have recognized $10.0 million in total revenue from BMS.

	Anti-PD-1 (CC-90006)	
Milestone Event	**Amount**	**Quarter Recognized**
Completion of first *in vivo* toxicology studies using GLPs	$0.5M	Q2'16
Phase 1 clinical trial initiation	$1.0M	Q4'16

Milestones were recognized as revenue in the period earned. There was no revenue recognized under this agreement during the years ended December 31, 2020 or 2019.

Research and Development Expense

Research and development expenses consist of costs associated with our research and development activities, including drug discovery efforts, preclinical and clinical development of our programs, and manufacturing. Our research and development expenses include:

- External research and development expenses incurred under arrangements with third parties, such as contract research organizations ("CROs"), consultants, members of our scientific and therapeutic advisory boards, and contract manufacturing organizations ("CMOs");
- Employee-related expenses, including salaries, benefits, travel, and stock-based compensation;
- Facilities, depreciation and other allocated expenses, which include direct and allocated expenses for rent and maintenance of facilities, depreciation of leasehold improvements and equipment, and laboratory supplies; and
- License and sub-license fees.

We expense research and development costs as incurred. We account for nonrefundable advance payments for goods and services that will be used in future research and development activities as expense when the service has been performed or when the goods have been received.

We are conducting research and development activities primarily on inflammation programs. We have a research and development team that conducts antibody discovery, characterization, translational studies, IND-enabling preclinical studies, and clinical development. We conduct some of our early research and preclinical activities internally and plan to rely on third parties, such as CROs and CMOs, for the execution of certain of our research and development activities, such as *in vivo* toxicology and pharmacology studies, drug product manufacturing, and clinical trials.

We have completed Phase 1 clinical trials and have ongoing Phase 2 clinical trials for imsidolimab and an ongoing Phase 1 clinical trial for ANB030. We expect our research and development expenses to be higher for the foreseeable future as we continue to advance our product candidates.

General and Administrative Expense

General and administrative expenses consist primarily of salaries and related benefits, including stock-based compensation for our executive, finance, legal, business development, human resource, and support functions. Other general and administrative expenses include allocated facility-related costs not otherwise included in research and development expenses, travel expenses, and professional fees for auditing, tax, and legal services.

Interest Expense

Interest expense consists of floating interest payments and amortization of discounts on our outstanding notes payable relating to our Loan and Security Agreement with Oxford Finance LLC and Silicon Valley Bank, as amended (the "Loan Agreement"). On January 1, 2020, the Loan Agreement was paid in full, without penalty or premium.

Interest Income

Interest income consists primarily of interest earned on our short-term and long-term investments and is recognized when earned.

Net Operating Loss and Research and Development Tax Credit Carryforwards

Since inception, we have accumulated net operating losses, or NOLs in all years except December 31, 2015 and 2014, in which we generated taxable income as a result of our collaboration agreement with GSK as well as expenses incurred by our Australian subsidiary which are not deductible for U.S. income tax purposes. While we utilized NOLs in 2015 and 2014, we have since incurred losses and therefore continue to have a valuation allowance against our net deferred tax assets due to the uncertainty of the realization of such assets.

At December 31, 2020, we had federal and state net operating loss carryforwards ("NOLs"), of $248.4 million and $64.2 million, respectively. The federal and state NOLs will begin to expire in 2028, unless previously utilized. The federal NOLs includes $188.4 million of net operating losses generated in 2018 and after. Federal net operating losses generated in 2018 and after carryover indefinitely and may generally be used to offset up to 80% of future taxable income. At December 31, 2020, we had federal and California research tax credit carryforwards of approximately $14.3 million and $8.9 million, respectively. The federal research tax credit carryforwards will begin to expire in 2026 and the California state credits carryforward indefinitely. We also have foreign tax losses of $3.4 million, which will carry forward indefinitely, subject to a continuity of ownership test.

The NOL carryforward and the research tax credit carryforwards may be subject to an annual limitation under Section 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code, and similar state provisions if we experience one or more ownership changes which would limit the amount of NOL and tax credit carryforwards that can be utilized to offset future taxable income and tax, respectively. In general, an ownership change, as defined by Section 382 and 383 of the Code, results from transactions increasing ownership of certain stockholders or public groups in the stock of the corporation by more than 50 percentage points over a three-year period. In September 2015, we completed a Section 382 and 383 of the Code ownership change analysis through December 31, 2014 and determined that there was an ownership change in 2007 that may limit the utilization of approximately $5.3 million and $5.4 million in Federal and state NOLs, respectively, and $0.2 million in both Federal and state research tax credits. We extended the analysis period of the study through December 31, 2018, noting one additional ownership changes during fiscal 2017 that may limit the utilization of Federal and State NOLs. Limitations on our ability to use NOL carryforwards and research and development tax credits to offset future taxable income could require us to pay U.S. federal income tax earlier than would be required if such limitations were not in effect. Similar rules and limitations may apply for state income tax purposes.

Critical Accounting Policies and Use of Estimates

Our management's discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles ("GAAP"). The preparation of these 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 financial statements. We base our estimates on historical experience, known trends and events, and various other factors that are believed 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.

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

Revenue Recognition

Revenue is recognized in accordance with revenue recognition accounting guidance, which utilizes five basic steps to determine whether revenue can be recognized and to what extent: (i) identify the contract with a customer; (ii) identify the performance obligation; (iii) determine the transaction price; (iv) allocate the transaction price; and (v) determine the recognition period.

Performance Obligations. We evaluate deliverables on a contract-by-contract basis to determine whether each deliverable represents a good or service that is distinct or has the same pattern of transfer as other deliverables. A deliverable is considered distinct if the customer can benefit from the good or service independently of other goods/services either in the contract or that can be obtained elsewhere, without regard to contract exclusivity, and the entity's promise to transfer the good or service to the customer is separately identifiable from other promises in the contact. If the deliverable is not considered distinct, we combine such deliverables and account for them as a single performance obligation. We allocate the consideration to each deliverable at the inception of the arrangement based on the transaction price.

Our performance obligations may include the following:

- License Arrangements. The performance obligations under our collaboration and license agreements generally include exclusive or nonexclusive licenses to one or more products generated using our technologies. Licenses for multiple antibodies within a single contract are generally combined as they have substantially the same pattern of transfer to the customer. Historically, our licenses have held no value to the customer, as the antibodies were in the discovery phase and required our expertise for further development. Accordingly, licenses are not considered distinct.
- Research and Development Services. The performance obligations under our collaboration and license agreements generally include research and development services we perform on behalf of or with our collaborators. As discussed within license arrangements above, our licenses have historically held no value without the research and development services we provide. As we generally only provide research and development services for internally generated antibodies that require a license to be utilized by a third party, our research and development services are not considered distinct.
- Steering Committee Meetings. The performance obligations under our collaboration and license agreements may also include our participation in a steering committees, which allows us to direct the progression of our discovery programs. As these steering committees would not occur or benefit the customer without the use of our licenses, these are not considered distinct.

We recognize consideration allocated to a performance obligation as the performance obligation is satisfied, and the determination as to whether consideration is recognized over time or at a point in time is made upon contract inception. For our collaboration agreements, this is generally over the period in which research and development services have been performed.

Transaction Price. Our collaboration and license agreements generally include both fixed and variable consideration. Fixed payments, such as those for upfront fees are included in the transaction price at contract value, while variable consideration such as reimbursement for research and development services, milestone and royalty payments are estimated and then evaluated for constraints upon inception of the contract and evaluated on a quarterly basis thereafter. Research and development services are updated for actual invoices. Given the nature of our agreements, milestones are estimated using the most likely amount and are evaluated on a quarterly basis. Upon commercialization, royalty payments are recognized in the period incurred.

Research and Development Expenses

As part of the process of preparing our financial statements, we are required to estimate research and development costs incurred during the period, which impacts the amount of accrued expenses and prepaid balances related to such costs as of each balance sheet date. This process involves reviewing open contracts and purchase orders, communicating with our personnel and service providers 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.

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 accordingly. 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 actually 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 actually incurred.

Recently Issued Accounting Pronouncements

For further information on recently issued accounting pronouncements, see Note 2 — Summary of Significant Accounting Policies in the accompanying notes to the consolidated financial statements included in Part II, Item 8, “Consolidated Financial Statements and Supplementary Data” of this Annual Report on Form 10-K.

Results of Operations

Collaboration Revenue

Collaboration revenue was $75.0 million compared to $8.0 million for the years ended December 31, 2020 and 2019, respectively. A comparison of collaboration revenue is as follows:

	Year Ended December 31,		Increase
(in thousands)	2020	2019	(Decrease)
GSK Amendment No. 3 Payment	$ 60,000	$ —	$ 60,000
GSK milestones	15,000	8,000	7,000
Total collaboration revenue	$ 75,000	$ 8,000	$ 67,000

Collaboration revenue during the year ended December 31, 2020 increased $67.0 million compared to the year ended December 31, 2019 primarily due to payment received related to an amendment to the GSK Agreement during 2020 and the timing of milestones achieved.

We expect that any collaboration revenue we generate will continue to fluctuate from period to period as a result of the timing and amount of milestones from our existing collaborations.

Research and Development Expenses

Research and development expenses were $80.0 million during the year ended December 31, 2020 compared to $99.3 million during the year ended December 31, 2019, for a decrease of approximately $19.3 million. The decrease is primarily

attributable to a $14.1 million decrease in outside services for preclinical and manufacturing expenses, a $3.7 million decrease in clinical expenses, a $1.1 million decrease in salaries and related expenses, including stock compensation expense, and a $0.4 million decrease in other research and development expenses.

We do not track fully burdened research and development costs separately for each of our product candidates. We review our research and development expenses by focusing on external development and internal development costs. External development expenses consist of costs associated with our external preclinical and clinical trials, including pharmaceutical development and manufacturing. Included in preclinical and other unallocated costs are external corporate overhead costs that are not specific to any one program. Internal costs consist of salaries and wages, share-based compensation and benefits, which are not tracked by product candidate as several of our departments support multiple product candidate research and development programs. The following table summarizes the external costs attributable to each program and internal costs:

	Year Ended December 31,		Increase/(Decrease)
(in thousands)	**2020**	**2019**	
External Costs			
Imsidolimab	$ 25,577	$ 18,570	$ 7,007
Etokimab	14,483	41,872	(27,389)
ANB030	4,563	9,261	(4,698)
ANB032	9,447	2,216	7,231
Preclinical and other unallocated costs	8,143	8,564	(421)
Total External Costs	$ 62,213	$ 80,483	$ (18,270)
Internal Costs	17,812	18,855	(1,043)
Total Costs	$ 80,025	$ 99,338	$ (19,313)

General and Administrative Expenses

General and administrative expenses were $18.9 million during the year ended December 31, 2020 compared to $16.1 million during the year ended December 31, 2019, for an increase of approximately $2.8 million. The increase is primarily due to a $1.5 million increase in legal expenses, a $1.3 million increase in personnel costs including stock compensation expense, and a $0.7 million increase in insurance expense, offset by a $0.4 million decrease in professional fees, a $0.1 million decrease in travel expense, and $0.2 million decrease in other general and administrative expense.

We expect that our general and administrative expenses will increase for the foreseeable future as we incur additional costs associated with being a publicly traded company, including legal, auditing and filing fees, additional insurance premiums, investor relations expenses and general compliance and consulting expenses. We also expect our intellectual property related legal expenses, including those related to preparing, filing, prosecuting and maintaining patent applications, to increase as our intellectual property portfolio expands.

Interest Expense

Interest expense was $0.0 million during the year ended December 31, 2020. Interest expense was $1.0 million during the year ended December 31, 2019 and primarily represents effective interest of approximately 12.67% on our outstanding Term Loans on an outstanding principal balance of $0.6 million as of December 31, 2019. The decrease in interest expense during the periods is due to the final payment made on the Loan Agreement on January 1, 2020.

Interest Income

Interest income was $4.0 million and $11.0 million during the years ended December 31, 2020 and 2019, respectively, which primarily related to our short-term and long-term investments, the balance of which decreased during the periods as a result of funding our clinical trial programs. The decrease in interest income is also attributable to lower interest rates during the year ended December 31, 2020.

Provision for Income Taxes

The income tax benefit was $0.0 million and $0.2 million during the year ended December 31, 2020 and 2019, respectively. The income tax benefit for the year ended December 31, 2019 is primarily related to the allocation of tax benefit to continuing operations offsetting income tax expense recorded in other comprehensive income that is related to unrealized gains.

Liquidity and Capital Resources

From our inception through December 31, 2020, we have received an aggregate of $804.0 million to fund our operations, which included $620.3 million from the sale of equity securities, $164.6 million from our collaboration agreements and $19.1 million from venture debt. As of December 31, 2020, we had $411.2 million in cash, cash equivalents and investments.

In addition to our existing cash, cash equivalents and investments, we are eligible to earn milestone and other contingent payments for the achievement of defined collaboration objectives and certain nonclinical, clinical, regulatory and sales-based events, and royalty payments under our collaboration agreements. Our ability to earn these milestone and contingent payments and the timing of achieving these milestones is primarily dependent upon the outcome of our collaborators' research and development activities. Our rights to payments under our collaboration agreements are our only committed external source of funds.

Specific to our collaboration agreement with GSK, dostarlimab is currently in clinical development for various solid tumor indications. We anticipate receiving additional milestones from GSK, of equal magnitude to the milestone payments outlined above, upon acceptance and approval of BLA and EMA filings of dostarlimab for the PdMMRT indication. Depending upon the timing of the aforementioned dostarlimab regulatory acceptance and approval milestones, we anticipate a total of $75.0 million in such milestone payments over the upcoming 18 months. An additional $165.0 million in sales milestones is anticipated upon achievement of certain dostarlimab annual sales revenues. Our amended GSK Agreement also includes a royalty to GSK's global net sales of Zejula that began in 2021.

Funding Requirements

We may seek to obtain additional financing in the future through equity or debt financings or through collaborations or partnerships with other companies. If we are unable to obtain additional financing on commercially reasonable terms, our business, financial condition and results of operations will be materially adversely affected.

Our primary uses of capital are, and we expect will continue to be, third-party clinical and preclinical research and development services, including manufacturing, laboratory and related supplies, compensation and related expenses, legal, patent and other regulatory expenses, and general overhead costs. We have entered into agreements with certain vendors for the provision of services, including services related to commercial manufacturing, that we are unable to terminate for convenience. Under such agreements, we are contractually obligated to make certain minimum payments to the vendors with the amounts to be based on the timing of the termination and the specific terms of the agreement.

Cash, cash equivalents and investments totaled $411.2 million as of December 31, 2020, compared to $428.5 million as of December 31, 2019. We believe that our existing cash, cash equivalents and investments will fund our current operating plan at least into 2024. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we expect. Additionally, the process of testing product candidates in clinical trials is costly, and the timing of progress and expenses in these trials is uncertain.

Cash Flows

The following table summarizes our cash flows for the years ended December 31, 2020 and 2019:

(in thousands)	Year Ended December 31, 2020	2019
Net cash (used in) provided by:		
Operating activities	$ (14,157)	$ (69,517)
Investing activities	94,475	131,431
Financing activities	(879)	(4,493)
Net increase in cash, cash equivalents and restricted cash	$ 79,439	$ 57,421

Operating Activities

Net cash used in operating activities during the year ended December 31, 2020 of $14.2 million was primarily due to our net loss of $19.9 million, adjusted for addbacks for non-cash items of $12.5 million which includes stock-based compensation and income from marketable securities and decreases in working capital of $6.8 million.

Net cash used in operating activities during the year ended December 31, 2019 of $69.5 million was primarily due to our net loss of $97.3 million, adjusted for addbacks for non-cash items of $11.0 million which includes stock-based compensation and income from marketable securities and increases in working capital of $16.9 million.

Investing Activities

Cash provided by and used in investing activities during the year ended December 31, 2020 and 2019 was primarily due to the acquisition of investments upon receipt of the proceeds from our IPO and follow-on public offerings, offset by investment maturities.

Financing Activities

Cash used in financing activities during the year ended December 31, 2020 of $0.9 million was primarily related to $1.4 million in repayments on our outstanding Term Loan, offset by proceeds of $0.5 million from the issuance of common stock as a result of option exercises.

Cash used in financing activities during the year ended December 31, 2019 of $4.5 million was primarily related to $7.5 million in repayments on our outstanding Term Loan, offset by proceeds of $3.0 million from the issuance of common stock as a result of option exercises.

Contractual Obligations

We have entered into agreements with certain vendors for the provision of goods and services, which includes manufacturing services with contract manufacturing organizations and development services with contract research organizations. These agreements may include certain provisions for purchase obligations and termination obligations that could require payments for the cancellation of committed purchase obligations or for early termination of the agreements. The amount of the cancellation or termination payments vary and are based on the timing of the cancellation or termination and the specific terms of the agreement and therefore are cancellable contracts.

For further information related to our operating lease and future minimum annual obligations for license payments under our collaboration in-license agreements, see Note 11 — Commitments and Contingencies in the accompanying notes to the consolidated financial statements included in Part II, Item 8, “Consolidated Financial Statements and Supplementary Data” of this Annual Report on Form 10-K.

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 in the rules and regulations of the SEC.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Interest Rate Risk

We hold certain financial instruments for which a change in prevailing interest rates may cause the principal amount of the marketable securities to fluctuate. Financial instruments that potentially subject us to significant concentrations of credit risk consist primarily of cash and cash equivalents, short-term and long-term investments. We invest our excess cash primarily in money market funds, commercial paper and debt instruments of financial institutions, corporations, U.S. government-sponsored agencies and the U.S. Treasury. The primary objectives of our investment activities are to ensure liquidity and to preserve principal while at the same time maximizing the income we receive from our marketable securities without significantly increasing risk. Additionally, we established guidelines regarding approved investments and maturities of investments, which are designed to maintain safety and liquidity. For marketable investment securities with short-term maturities, we do not believe that an increase or decrease in market rates would have a significant impact on the realized values or the statements of operations and comprehensive loss. As of December 31, 2020, we held $160.7 million in debt securities with for which the accumulated other comprehensive loss was less than $0.1 million. As such, we believe that should a 10.0% change in interest rates were to have occurred on December 31, 2020, this change would not have had a material effect on the fair value of our investment portfolio as of that date.

Foreign Currency Exchange Risk

In March 2015, we formed a wholly-owned subsidiary in Australia, which exposes us to foreign currency exchange risk. The functional currency of our subsidiary in Australia is the United States dollar. Assets and liabilities of our foreign subsidiary that are not denominated in the functional currency are remeasured into U.S. dollars at foreign currency exchange rates in effect at the balance sheet date except for nonmonetary assets and capital accounts, which are remeasured at historical foreign currency exchange rates in effect at the date of transaction. Expenses are generally remeasured at monthly foreign currency exchange rates which approximate average rates in effect during each period. Net realized and unrealized gains and losses from foreign currency transactions and remeasurement are reported in other income (expense), net, in the consolidated statements of operations and were less than $0.1 million during the year ended December 31, 2020. We believe that our foreign currency exposure is limited at this time as the value of transactions and the asset and liability balances denominated in foreign currencies are relatively small. Further, we do not believe that our financial condition or results of operations would be materially impacted by an immediate change of 10% in exchange rate of the foreign currencies in which we have transactions denominated, as exchange rates have fluctuated over 10% throughout the year ended December 31, 2020 from a low of 0.5724 to a high of 0.7707 with a net impact of less than $0.1 million to the consolidated statement of operations.

We conduct a portion of our business with CROs in currencies other than our U.S. dollar functional currency. These transactions give rise to monetary assets and liabilities that are denominated in currencies other than the U.S. dollar. The value of these monetary assets and liabilities are subject to changes in currency exchange rates from the time the transactions are originated until settlement in cash. Our foreign currency exposures are primarily concentrated in the euro, British pound, Australian dollar, and Canadian dollar. Both realized and unrealized gains or losses on the value of these monetary assets and liabilities are included in the determination of net income. We do not hedge our foreign currency exchange rate risk, however, we may do so in the future. As of December 31, 2020, we had no material accounts payable or receivable denominated in foreign currencies, and a hypothetical 10% change in foreign currency exchange rates applicable to our business would not have had a material impact on our consolidated financial statements.

Inflation Risk

Inflation generally affects us by increasing our clinical trial costs. We do not believe that inflation has had a material effect on our business, financial condition or results of operations during the years ended December 31, 2020, 2019 or 2018.

Item 8. Consolidated Financial Statements and Supplementary Data

AnaptysBio, Inc.
Annual Report on Form 10-K
Index to Audited Consolidated Financial Statements

Report of Independent Registered Public Accounting Firm

To the Stockholders and Board of Directors
AnaptysBio, Inc.:

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of AnaptysBio, Inc. and subsidiary (the Company) as of December 31, 2020 and 2019, the related consolidated statements of operations and comprehensive loss, stockholders' equity, and cash flows for each of the years in the three-year period ended December 31, 2020, and the related notes (collectively, the consolidated financial statements). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2020 and 2019, and the results of its operations and its cash flows for each of the years in the three-year period ended December 31, 2020, in conformity with U.S. generally accepted accounting principles.

Basis for Opinion

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

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

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

Critical Audit Matters

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

Evaluation of Research and Development Costs

As discussed in Note 2 to the consolidated financial statements, the Company has entered into various contracts with third parties to perform research and development, including clinical manufacturing. When billing terms under these contracts do not coincide with the timing of when the work is performed, the Company makes estimates of the costs incurred by third parties during the period and the outstanding obligations to those third parties as of period end. Estimates of costs incurred during the period that are included in period-end prepaid or accrued expense balances are based on a number of factors, including the Company's knowledge of the research and development programs and clinical manufacturing activities associated with project status and milestones, invoicing to date, and the provisions in the contract. Significant judgments and estimates are made by the Company in determining the costs incurred during the period that are included in prepaid or accrued expense balances at the end of each reporting period.

We identified the evaluation of research and development costs as a critical audit matter. These estimates are based on certain assumptions and inputs that were challenging to assess, including the Company's knowledge of the status of research and development programs and associated completion status, project milestones achieved, raw materials used

in manufacturing, and, for larger clinical trials, per patient costs, patient enrollment status, project costs, and site costs. Significant auditor judgment, subjectivity, and effort were required to evaluate the assumptions and inputs to these estimates.

The following are the primary procedures we performed to address this critical audit matter. On a sample basis, we examined contracts, invoices, and third-party confirmations and compared them to the assumptions and inputs that are described above. We also examined certain invoices received after December 31, 2020 and evaluated whether services received prior to December 31, 2020 were included in the Company's estimate of costs incurred as of December 31, 2020.

Assessment of the Presentation of GlaxoSmithKline Payment as Revenue

As discussed in Note 4 to the consolidated financial statements, the Company entered into an amendment to an agreement with GlaxoSmithKline (GSK) in October 2020. Under the amended agreement, the Company received a one-time, non-refundable cash payment of $60.0 million (the GSK payment) that was recognized as revenue for the year ended December 31, 2020.

We identified the assessment of the presentation of the GSK payment as revenue as a critical audit matter. The determination of the presentation of the GSK payment on the consolidated statement of operations and comprehensive loss was complex and involved subjective auditor judgment because of the terms of the amendment with GSK.

The following are the primary procedures we performed to address this critical audit matter. We evaluated the design of an internal control over the Company's process for accounting for modifications of collaboration arrangements. We evaluated the Company's assessment of the accounting treatment for this transaction, including the determination that presentation of the GSK payment as revenue was appropriate by obtaining and reading management's technical analysis and the amendment to the GSK agreement. We inquired of key executives involved in the negotiations with GSK as well as the board of directors.

/s/ KPMG LLP

We have served as the Company's auditor since 2009.

San Diego, California
February 25, 2021

AnaptysBio, Inc.
Consolidated Balance Sheets
(in thousands, except par value)

	December 31, 2020	December 31, 2019
ASSETS		
Current assets:		
Cash and cash equivalents	$ 250,456	$ 171,017
Short-term investments	143,197	203,210
Prepaid expenses and other current assets	2,908	3,506
Total current assets	396,561	377,733
Property and equipment, net	1,783	1,618
Long-term investments	17,546	54,305
Other long-term assets	602	1,481
Restricted cash	60	60
Total assets	$ 416,552	$ 435,197
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 4,217	$ 16,237
Accrued expenses	15,262	11,052
Notes payable, current portion	—	1,375
Other current liabilities	342	871
Total current liabilities	19,821	29,535
Other long-term liabilities	—	654
Stockholders' equity:		
Preferred stock, $0.001 par value, 10,000 shares authorized and no shares, issued or outstanding at December 31, 2020 and December 31, 2019, respectively	—	—
Common stock, $0.001 par value, 500,000 shares authorized, 27,356 shares and 27,255 shares issued and outstanding at December 31, 2020 and December 31, 2019, respectively	27	27
Additional paid in capital	660,665	648,669
Accumulated other comprehensive (loss) income	(4)	338
Accumulated deficit	(263,957)	(244,026)
Total stockholders' equity	396,731	405,008
Total liabilities and stockholders' equity	$ 416,552	$ 435,197

See accompanying notes to consolidated financial statements.

AnaptysBio, Inc.
Consolidated Statements of Operations and Comprehensive Loss
(in thousands, except per share data)

	Year Ended December 31,		
	2020	**2019**	**2018**
Collaboration revenue	$ 75,000	$ 8,000	$ 5,000
Operating expenses:			
Research and development	80,025	99,338	56,196
General and administrative	18,854	16,094	15,526
Total operating expenses	98,879	115,432	71,722
Loss from operations	(23,879)	(107,432)	(66,722)
Other income (expense), net:			
Interest expense	—	(1,041)	(1,652)
Interest income	3,959	10,984	6,685
Other (expense) income, net	(11)	1	(159)
Total other income (expense), net	3,948	9,944	4,874
Loss before income taxes	(19,931)	(97,488)	(61,848)
Provision for income taxes	—	152	192
Net loss	(19,931)	(97,336)	(61,656)
Other comprehensive (loss) income:			
Unrealized (loss) income on available for sale securities, net of tax of $0, $153, and $55, respectively	(342)	561	203
Comprehensive loss	$ (20,273)	$ (96,775)	$ (61,453)
Net loss per common share:			
Basic and diluted	$ (0.73)	$ (3.60)	$ (2.50)
Weighted-average number of shares outstanding:			
Basic and diluted	27,302	27,059	24,673

See accompanying notes to consolidated financial statements.

AnaptysBio, Inc.
Consolidated Statements of Stockholders' Equity
(in thousands)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive (Loss) Income	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance, January 1, 2018	23,791	$ 24	$ 393,017	$ (426)	$ (85,034)	$ 307,581
Shares issued for public offerings, net of underwriters' fees	2,530	3	227,473	—	—	227,476
Total offering costs	—	—	(145)	—	—	(145)
Shares issued under employee stock plans	584	—	2,869	—	—	2,869
Warrants exercised	17	—	76	—	—	76
Stock-based compensation	—	—	9,961	—	—	9,961
Comprehensive income	—	—	—	203	—	203
Net loss	—	—	—	—	(61,656)	(61,656)
Balance, December 31, 2018	26,922	27	633,251	(223)	(146,690)	486,365
Shares issued under employee stock plans	333	—	3,007	—	—	3,007
Stock-based compensation	—	—	12,411	—	—	12,411
Comprehensive income	—	—	—	561	—	561
Net loss	—	—	—	—	(97,336)	(97,336)
Balance, December 31, 2019	27,255	27	648,669	338	(244,026)	405,008
Shares issued under employee stock plans	101	—	497	—	—	497
Stock-based compensation	—	—	11,499	—	—	11,499
Comprehensive loss	—	—	—	(342)	—	(342)
Net loss	—	—	—	—	(19,931)	(19,931)
Balance, December 31, 2020	27,356	$ 27	$ 660,665	$ (4)	$ (263,957)	$ 396,731

See accompanying notes to consolidated financial statements.

AnaptysBio, Inc.
Consolidated Statements of Cash Flows
(in thousands)

	Year Ended December 31,		
	2020	**2019**	**2018**
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net loss	$ (19,931)	$ (97,336)	$ (61,656)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	559	514	315
Stock-based compensation	11,499	12,411	9,961
Accretion/amortization of investments, net	461	(2,633)	(1,233)
Non-cash interest expense	—	676	646
Income taxes	—	—	139
Loss on disposal of property and equipment, net of gain on lease termination	26	—	—
Changes in operating assets and liabilities:			
Australian tax incentive receivable	—	174	1,427
Prepaid expenses and other assets	2,106	2,178	(5,188)
Accounts payable and other liabilities	(8,877)	14,499	7,083
Net cash used in operating activities	(14,157)	(69,517)	(48,506)
CASH FLOWS FROM INVESTING ACTIVITIES:			
Acquisition of investments	(194,927)	(251,815)	(347,537)
Sales and maturities of investments	289,971	384,051	206,149
Purchases of property and equipment	(569)	(805)	(1,063)
Net cash provided by (used in) investing activities	94,475	131,431	(142,451)
CASH FLOWS FROM FINANCING ACTIVITIES:			
Proceeds from public offerings, net of underwriters' fees	—	—	227,476
Proceeds from issuance of common stock, upon the exercise of stock options	496	3,007	2,869
Proceeds from issuance of common stock, upon the exercise of warrants	—	—	76
Payments on notes payable	(1,375)	(7,500)	(6,875)
Payments for offering costs, net	—	—	(182)
Net cash (used in) provided by financing activities	(879)	(4,493)	223,364
Net increase in cash, cash equivalents, and restricted cash	79,439	57,421	32,407
Cash, cash equivalents and restricted cash, beginning of period	171,077	113,656	81,249
Cash, cash equivalents and restricted cash, end of period	$ 250,516	$ 171,077	$ 113,656
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION			
Interest paid	$ 4	$ 424	$ 1,043
Non-cash investing and financing activities:			
Amounts accrued for property and equipment	$ 279	$ 41	$ 159

See accompanying notes to consolidated financial statements.

AnaptysBio, Inc.
Notes to Consolidated Financial Statements

1. Description of the Business

AnaptysBio, Inc. ("we," "us," "our," or the "Company") was incorporated in the state of Delaware in November 2005. We are a clinical-stage biotechnology company developing first-in-class immunology therapeutic product candidates focused on emerging immune control mechanisms applicable to inflammation and immuno-oncology indications. We develop our product candidates using our proprietary antibody discovery technology platform, which is based upon a breakthrough understanding of the natural process of antibody generation, known as somatic hypermutation, and replicates this natural process of antibody generation *in vitro*. We currently generate revenue from milestones achieved under our collaborative research and development arrangements.

Since our inception, we have devoted our primary effort to research and development activities. Our financial support has been provided primarily from the sale of our common and preferred stock, as well as through funds received under our collaborative research and development agreements. Going forward, as we continue our expansion, we may seek additional financing and/or strategic investments. However, there can be no assurance that any additional financing or strategic investments will be available to us on acceptable terms, if at all. If events or circumstances occur such that we do not obtain additional funding, we will most likely be required to reduce our plans and/or certain discretionary spending, which could have a material adverse effect on our ability to achieve our intended business objectives. Our management believes our currently available resources will provide sufficient funds to enable us to meet our operating plans for at least the next twelve months. The accompanying consolidated financial statements do not include any adjustments that might be necessary if we are unable to continue as a going concern.

Follow-on Public Offering

On September 28, 2018, we completed an underwritten public offering of 2,530,000 shares of common stock, which included the exercise of the underwriters' option to purchase an additional 330,000 shares of common stock. All shares were offered by us at a price to the public of $94.46 per share. The aggregate net proceeds received by us from the offering were $227.5 million, net of underwriting discounts and commissions.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying consolidated financial statements have been prepared pursuant to the rules and regulations of the Securities and Exchange Commission (the "SEC"). The accompanying consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America, or U.S. GAAP.

Basis of Consolidation

The accompanying consolidated financial statements include us and our wholly-owned Australian subsidiary. All intercompany accounts and transactions have been eliminated in consolidation. We operate in one reportable segment, and our functional and reporting currency is the U.S. dollar.

Use of Estimates

The preparation of the accompanying consolidated financial statements in conformity with U.S. GAAP requires our management to make estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities at the date of the financial statements, and reported amounts of revenues and expenses during the reporting periods. Actual results could differ from those estimates. We base our estimates and assumptions on historical experience when available and on various factors that we believe to be reasonable under the circumstances. We evaluate our estimates and assumptions on an ongoing basis. The full extent to which the COVID-19 pandemic will directly or indirectly impact our business, results of operations, and financial condition, including expenses, reserves and allowances, manufacturing, clinical trials, research and development costs, and employee-related amounts, will depend on future developments that are highly uncertain, including as a result of new information that may emerge concerning COVID-19 and the actions taken to contain or treat it, as well as the economic impact on local, regional, national and international markets. Our actual results could differ from these estimates under different assumptions or conditions.

Cash and Cash Equivalents

We consider all highly liquid investments with a maturity at date of purchase of three months or less to be cash equivalents. Cash equivalents consist primarily of money market and mutual funds with original maturities of 90 days or less.

Restricted Cash

We held restricted cash of $60,000 at December 31, 2020 and 2019, respectively, which we used to secure a letter of credit provided as security for the operating lease for our corporate headquarters.

Short-Term and Long-Term Investments

All investments have been classified as "available-for-sale" and are carried at fair value as determined based upon quoted market prices or pricing models for similar securities at period end. Investments with contractual maturities less than 12 months at the balance sheet date are considered short-term investments. Those investments with contractual maturities 12 months or greater at the balance sheet date are considered long-term investments. Dividend and interest income are recognized when earned. Realized gains and losses are included in earnings and are derived using the specific identification method for determining the cost of securities sold. Unrealized gains and losses are reported as a component of accumulated other comprehensive income (loss). We review our portfolio of available-for-sale debt securities, using both quantitative and qualitative factors, to determine if declines in fair value below cost have resulted from a credit-related loss or other factors. If the decline in fair value is due to credit-related factors, a loss is recognized in net income, whereas if the decline in fair value is not due to credit-related factors, the loss is recorded in other comprehensive income (loss).

Concentration of Credit Risk

Financial instruments that potentially subject us to a concentration of credit risk consist of cash and cash equivalents and certain investments in money market funds, certificates of deposit, agency securities, commercial obligations and U.S. Treasury securities. Bank deposits are diversified between three financial institutions and these deposits may exceed insured limits. We are exposed to credit risk in the event of default by the financial institutions holding our cash and cash equivalents and issuers of investments that are recorded on our consolidated balance sheets. We mitigate our risk by investing in high-grade instruments and limiting the concentration in any one issuer, which limits our exposure.

Property and Equipment

Property and equipment are stated at cost, less accumulated depreciation. Expenditures for major additions and betterments are capitalized. Maintenance and repairs are charged to operations as incurred. Depreciation and amortization are calculated using the straight-line method over the estimated useful lives of the assets, which range from three to seven years. Leasehold improvements are amortized using the straight line method over the term of the lease. Upon sale or retirement of property and equipment, the related cost and accumulated depreciation are removed from the accounts and any gain or loss is reflected in operations.

Long Lived Assets

Long-lived assets, consisting of property and equipment, are reviewed for impairment whenever events or changes in circumstances indicate that the carrying value of an asset may not be recoverable based on undiscounted cash flows. If long-lived assets are impaired, an impairment loss is recognized and is measured as the amount by which the carrying value exceeds the estimated fair value of the assets. No impairment charges were recorded during the years ended December 31, 2020, 2019, or 2018.

Leases

Our leases consist of leases for office space that are classified as operating leases. We determine if an arrangement is a lease at inception. Rent expense is recognized on a straight-line basis. When an operating lease includes rent abatements or requires fixed escalations of the minimum lease payments, the aggregate rental expense is recognized on a straight-line basis over the term of the lease. When an operating lease includes lease incentives such as leasehold improvement allowances, the lease incentive is included in the right-of-use ("ROU") asset. For leases that have greater than a 12-month lease term, the ROU assets and lease liabilities are recognized based on the present value of the future minimum lease payments over the lease term. For this purpose, we consider only payments that are fixed and determinable at the time of commencement.

As our leases do not provide an implicit rate, we use our incremental borrowing rate based on the information available at commencement date in determining the present value of future payments. We account for fixed lease components separately from non-lease components.

We keep leases with an initial term of 12 months or less off the balance sheet and recognize the associated lease payments in the consolidated statements of operations on a straight-line basis over the lease term.

Results and disclosure requirements for reporting periods beginning after January 1, 2019 are presented under ASC 842, while prior period amounts have not been adjusted and continue to be reported under ASC 840.

Revenue Recognition

Revenue is recognized in accordance with revenue recognition accounting guidance, which utilizes five basic steps to determine whether revenue can be recognized and to what extent: (i) identify the contract with a customer; (ii) identify the performance obligation; (iii) determine the transaction price; (iv) allocate the transaction price; and (v) determine the recognition period.

Performance Obligations. We evaluate deliverables on a contract-by-contract basis to determine whether each deliverable represents a good or service that is distinct or has the same pattern of transfer as other deliverables. A deliverable is considered distinct if the customer can benefit from the good or service independently of other goods/services either in the contract or that can be obtained elsewhere, without regard to contract exclusivity, and the entity's promise to transfer the good or service to the customer is separately identifiable from other promises in the contact. If the deliverable is not considered distinct, we combine such deliverables and account for them as a single performance obligation. We allocate the consideration to each deliverable at the inception of the arrangement based on the transaction price.

Our performance obligations may include the following:

- License Arrangements. The performance obligations under our collaboration and license agreements generally include exclusive or nonexclusive licenses to one or more products generated using our technologies. Licenses for multiple antibodies within a single contract are generally combined as they have substantially the same pattern of transfer to the customer. Historically, our licenses have held no value to the customer, as the antibodies were in the discovery phase and required our expertise for further development. Accordingly, licenses are not considered distinct.
- Research and Development Services. The performance obligations under our collaboration and license agreements generally include research and development services we perform on behalf of or with our collaborators. As discussed within license arrangements above, our licenses have historically held no value without the research and development services we provide. As we generally only provide research and development services for internally generated antibodies that require a license to be utilized by a third party, our research and development services are not considered distinct.
- Steering Committee Meetings. The performance obligations under our collaboration and license agreements may also include our participation in a steering committees, which allows us to direct the progression of our discovery programs. As these steering committees would not occur or benefit the customer without the use of our licenses, these are not considered distinct.

We recognize consideration allocated to a performance obligation as the performance obligation is satisfied, and the determination as to whether consideration is recognized over time or at a point in time is made upon contract inception. For our collaboration agreements, this is generally over the period in which research and development services have been performed.

Transaction Price. Our collaboration and license agreements generally include both fixed and variable consideration. Fixed payments, such as those for upfront fees are included in the transaction price at contract value, while variable consideration such as reimbursement for research and development services, milestone and royalty payments are estimated and then evaluated for constraints upon inception of the contract and evaluated on a quarterly basis thereafter. Research and development services are updated for actual invoices. Given the nature of our agreements, milestones are estimated using the most likely amount and are evaluated on a quarterly basis. Upon commercialization, royalty payments will be recognized in the period incurred.

Research and Development Expenses

Research and development costs primarily include third-party clinical and preclinical research and development services such as manufacturing, laboratory and related supplies, salaries and personnel-related costs, in-licensing fees, outside services, and an allocation of information technology, and facility overhead costs.

Costs associated with research and development activities are expensed as incurred. We account for nonrefundable advance payments for goods and services that will be used in future research and development activities as expense when the service has been performed or when the goods have been received. We estimate research and development costs incurred during the period, which impacts the amount of accrued expenses and prepaid balances related to such costs as of each balance sheet date. This process involves reviewing open contracts and purchase orders, communicating with our personnel and service providers 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.

Upfront and milestone payments incurred under our in-licensing agreements are expensed as acquired in-process research and development in the period in which they are incurred, provided that the technology or method has no alternative future use.

Stock-Based Compensation

We recognize stock-based compensation expense using a fair-value-based method for costs related to all share-based payments, including stock options. Stock-based compensation cost for stock options granted to our employees and directors is measured at the grant date based on the fair-value of the award which is estimated using the Black-Scholes option-pricing model, and is recognized as expense over the requisite service period on a straight-line basis. We recognize forfeitures in the period in which forfeiture occur and record stock-based compensation expense as though all awards are expected to vest.

No tax benefits for stock-based compensation have been recognized in the statements of changes in stockholders' equity or cash flows. We have not recognized, and do not expect to recognize in the near future, any tax benefit related to stock-based compensation cost as a result of our full valuation allowance on net deferred tax assets and net operating loss carryforwards.

Income Taxes

We account for income taxes under the asset and liability method. Under this method, deferred tax assets and liabilities are determined based on differences between financial reporting and tax basis of assets and liabilities and are measured using enacted tax rates and laws that are expected to be in effect when the differences are expected to be recovered or settled. Realization of deferred tax assets is dependent upon future taxable income. A valuation allowance is recognized if it is more likely than not that some portion or all of a deferred tax asset will not be realized based on the weight of available evidence, including expected future earnings.

We recognize an uncertain tax position in our consolidated financial statements when we conclude that a tax position is more likely than not to be sustained upon examination based solely on technical merits. Only after a tax position passes the first step of recognition will measurement be required. Under the measurement step, the tax benefit is measured as the largest amount of benefit that is more likely than not to be realized upon effective settlement. This is determined on a cumulative probability basis. The full impact of any change in recognition or measurement is reflected in the period in which such change occurs. We have elected to accrue any interest or penalties related to income taxes as part of our income tax expense.

Functional Currency of Foreign Operations

Our Australian subsidiary operates in a U.S. dollar functional currency environment. Assets and liabilities of our foreign subsidiary that are not denominated in the functional currency are remeasured into U.S. dollars at foreign currency exchange rates in effect at the balance sheet date except for nonmonetary assets and capital accounts, which are remeasured at historical foreign currency exchange rates in effect at the date of transaction. Expenses are generally remeasured at monthly foreign currency exchange rates which approximate average rates in effect during each period. Net realized and unrealized gains and losses from foreign currency transactions and remeasurement are reported in other income (expense), net, in the consolidated statements of operations.

Comprehensive Income (Loss)

Comprehensive income (loss) represents all changes in stockholders' equity except those resulting from distributions to stockholders. Our unrealized gain and losses on available for sale investments represent the only component of other comprehensive income (loss) that is excluded from the reported net income (loss).

Net Loss Per Common Share

Basic net loss per common share is computed by dividing net loss by the weighted-average number of common shares outstanding during the period. Diluted net loss per share is computed by dividing net loss by the weighted-average number of common equivalent shares outstanding for the period, as well as any dilutive effect from outstanding stock options and warrants using the treasury stock method.

The following table sets forth the weighted-average outstanding potentially dilutive securities that have been excluded in the calculation of diluted net loss per share because to do so would be anti-dilutive (in common stock equivalent shares):

	Year Ended December 31,		
(in thousands)	**2020**	**2019**	**2018**
Options to purchase common stock	2,901	2,462	2,451

Accounting Pronouncements Recently Adopted

In December 2019, the Financial Accounting Standards Board (the "FASB") issued ASU 2019-12, *Income Taxes (Topic 740)* intended to simplify the accounting for income taxes. The guidance removes the following exceptions: (1) exception to the incremental approach for intraperiod tax allocation when there is a loss from continuing operations and income or a gain from other items, (2) exception to the requirement to recognize a deferred tax liability for equity method investments when a foreign subsidiary becomes an equity method investment, (3) exception to the ability not to recognize a deferred tax liability for a foreign subsidiary when a foreign equity method investment becomes a subsidiary, and (4) exception to the general methodology for calculating income taxes in an interim period when a year-to-date loss exceeds the anticipated loss for the year. Additionally, the guidance simplifies the accounting for income taxes by: (1) requiring that an entity recognize a franchise tax (or similar tax) that is partially based on income as an income-based tax and account for any incremental amount incurred as a non-income-based tax, (2) requiring that an entity evaluate when a step up in the tax basis of goodwill should be considered part of the business combination in which the book goodwill was originally recognized and when it should be considered a separate transaction, (3) specifying that an entity is not required to allocate the consolidated amount of current and deferred tax expense to a legal entity that is not subject to tax in its separate financial statements (although the entity may elect to do so (on an entity-by-entity basis) for a legal entity that is both not subject to tax and disregarded by the taxing authority), (4) requiring that an entity reflect the effect of an enacted change in tax laws or rates in the annual effective tax rate computation in the interim period that includes the enactment date, and (5) making minor improvements for income tax accounting related to employee stock ownership plans and investments in qualified affordable housing projects accounted for using the equity method. The guidance will be effective for fiscal years and interim periods beginning after December 15, 2020. Different components of the guidance require retrospective, modified retrospective or prospective adoption, and early adoption is permitted. We early adopted this standard on January 1, 2020, and the adoption of the standard did not have a material impact to our consolidated financial statements.

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments - Credit Losses: Measurement of Credit Losses on Financial Instruments (Topic 326)*, which changes the accounting treatment for recognizing the impairment of financial assets. Under the new guidance, credit losses for certain types of financial instruments will be estimated based on expected losses. The new guidance also eliminates the other-than-temporary impairment model for available-for-sale ("AFS") debt securities. Entities will begin to recognize credit losses on AFS debt securities as allowances rather than as reductions in the carrying value of the securities. Impairment that is not credit-related impairment will continue to be recognized in other comprehensive income and entities will no longer consider the length of time a security has been in an unrealized loss position when determining whether a credit loss exists. ASU 2016-13 becomes effective for annual and interim periods beginning after December 15, 2019. We adopted this standard prospectively on January 1, 2020, and the adoption of the standard did not have a material impact to our consolidated financial statements as credit losses are not expected to be significant based on historical trends, the financial condition of our investments and external market factors. We will continue to actively monitor the impact of the COVID-19 pandemic on expected credit losses.

In February 2016, the FASB, issued ASU 2016-02, *Leases (Topic 842)*, which requires that lessees recognize a ROU asset and a related lease liability on the balance sheet for all leases with a term longer than 12 months. Topic 842 was subsequently amended by ASU 2018-01, *Land Easement Practical Expedient for Transition to Topic 842*; ASU 2018-10, C*odification Improvements to Topic 842, Leases*; ASU 2018-11, *Targeted Improvements*; and ASU 2019-01, *Leases (Topic 842): Codification Improvements*. ASU 2016-02 became effective for our annual reporting period beginning January 1, 2019, including interim periods thereafter. A modified retrospective transition approach is required, applying the new standard to all leases existing at the date of initial application. An entity may choose to use either (i) its effective date or (ii) the beginning of

the earliest comparative period presented in the financial statements as its date of initial application. We adopted this standard on January 1, 2019 and used the effective date as our date of initial application. Upon adoption, we elected the package of transition practical expedients, which allowed us to carry forward prior conclusions related to whether any expired or existing contracts are or contain leases, the lease classification for any expired or existing leases and initial direct costs for existing leases. We also made an accounting policy election to not recognize leases with an initial term of 12 months or less within our consolidated balance sheets and to recognize those lease payments on a straight-line basis in our consolidated statements of operations over the lease term. Adoption of the new standard resulted in the recording of operating lease ROU assets and lease liabilities of approximately $2.1 million and $2.3 million as of January 1, 2019, respectively related to our real estate leases. Adoption of this new standard did not have a material impact on our consolidated statements of operations or cash flows.

3. Balance Sheet Accounts and Supplemental Disclosures

Property and Equipment

Property and equipment consist of the following:

(in thousands)	December 31, 2020	December 31, 2019
Laboratory equipment	$ 5,225	$ 4,911
Office furniture and equipment	976	811
Leasehold improvements	527	575
Property and equipment, gross	6,728	6,297
Less: accumulated depreciation and amortization	(4,945)	(4,679)
Total property and equipment, net	$ 1,783	$ 1,618

We recorded a loss of approximately $0.1 million in other income (expense), net, related to the disposal of tenant improvements and certain equipment in connection with the termination of the 10455 Building Lease. The $0.1 million loss is recorded in the consolidated statements of cash flows net of the gain from the termination of the 10455 Building Lease (see Note 11).

Accrued Expenses

Accrued expenses consist of the following:

(in thousands)	December 31, 2020	December 31, 2019
Accrued compensation and related expenses	$ 3,688	$ 2,152
Accrued professional fees	408	435
Accrued research and development expenses	10,936	8,196
Other	230	269
Total accrued expenses	$ 15,262	$ 11,052

4. Collaborative Research and Development Agreements

GlaxoSmithKline Collaboration

In March 2014, we entered into a Collaboration and Exclusive License Agreement (the “GSK Agreement”) with TESARO, Inc. (“Tesaro”), an oncology-focused biopharmaceutical company now a part of GlaxoSmithKline (Tesaro and GlaxoSmithKline are hereinafter referred to, collectively, as “GSK”). Under the terms of the GSK Agreement, we agreed to perform certain discovery and early preclinical development of therapeutic antibodies with the goal of generating immunotherapy antibodies for subsequent preclinical, clinical, regulatory, and commercial development to be performed by GSK. Under the terms of the GSK Agreement, GSK paid an upfront license fee of $17.0 million in March 2014 and agreed to provide funding to us for research and development services related to antibody discovery programs for three specific targets. In November 2014, Amendment No. 1 to the GSK Agreement was agreed by both parties to add an antibody discovery program against an undisclosed fourth target for an upfront license fee of $2.0 million.

For each development program, we are eligible to receive milestone payments of up to $18.0 million if certain preclinical and clinical trial events are achieved by GSK, up to an additional $90.0 million if certain U.S. and European

regulatory submissions and approvals in multiple indications are achieved, and up to an additional $165.0 million upon the achievement of specified levels of annual worldwide net sales. We will also be eligible to receive tiered single-digit royalties related to worldwide net sales of products developed under the collaboration. Unless earlier terminated by either party upon specified circumstances, the GSK Agreement will terminate, with respect to each specific developed product, upon the later of the 12th anniversary of the first commercial sale of the product or the expiration of the last to expire of any patent. Prior to the adoption of ASC 606, *Revenue from Contracts with Customers*, we determined that the upfront license fees and research funding under the GSK Agreement, as amended, should be accounted for as a single unit of accounting and that the upfront license fees should be deferred and recognized as revenue over the same period that the research and development services are performed. In February 2016, Amendment No. 2 to the GSK Agreement was agreed by both parties to define the effective dates of the development programs of the GSK Agreement. We determined that the research and development services would be extended through December 31, 2016. As a result, the period over which the unrecognized license fees and discovery milestones were recognized was extended through December 31, 2016 and have since been recognized in full.

We assessed these arrangements in accordance with ASC 606 and concluded that the contract counterparty, GSK, is a customer. We identified the following material promises under the GSK Agreement: (1) the licenses under certain patent rights relating to six discovery programs (four targets) and transfer of certain development and regulatory information, (2) research and development ("R&D") services, and (3) joint steering committee meetings. We considered the research and discovery capabilities of GSK for these specific programs, GSK's inability to sub-license, and the fact that the discovery and optimization of these antibodies is proprietary and could not, at the time of contract inception, be provided by other vendors, to conclude that the license does not have stand-alone functionality and is therefore not distinct. Additionally, we determined that the joint steering committee participation would not have been provided without the R&D services and license agreement. Based on these assessments, we identified all services to be interrelated and therefore concluded that the promises should be combined into a single performance obligation at the inception of the arrangement.

On October 23, 2020, Amendment No. 3 to the GSK Agreement (the "Amendment") was agreed to by both parties to permit GSK to conduct development and commercialization of Zejula, an oral, once-daily poly (ADP-ribose) polymerase (PARP) inhibitor, which has received US approval for the maintenance treatment of adult patients with advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to first-line platinum-based chemotherapy, and is under development for additional cancer indications. In addition, under the Amendment, we were granted increased royalties upon sales of dostarlimab, an anti-PD-1 antagonist antibody under development by GSK for multiple oncological disorders. The Amendment also provided for a one-time, non-refundable cash payment of $60.0 million that we received and recognized as revenue in the fourth quarter of 2020. GSK also agreed, starting January 1, 2021, to pay us a 1% royalty on all GSK Net Sales of Zejula. The $1.1 billion in cash milestone payments due under the GSK Agreement remain unchanged. Additionally, under the terms of the Amendment, GSK has agreed to certain diligence commitments with respect to the future development of dostarlimab, and the parties have agreed to review such commitments under regular joint review committee meetings going forward.

We assessed this Amendment in accordance with ASC 606 and concluded the Amendment was a contract modification to the GSK Agreement. Based on our assessment, we identified the terms of the Amendment to be interrelated to the GSK Agreement's single performance obligation, noting completion and delivery of terms under the Amendment were satisfied by both parties with the execution of the Amendment.

As of December 31, 2020, the transaction price for the GSK Agreement and Amendment includes the upfront payment, research reimbursement revenue, one-time payment associated to Amendment No. 3, and milestones earned to date, which are allocated in their entirety to the single performance obligation. We earned and recognized two clinical milestones for $15.0 million during the year ended December 31, 2020. No other future clinical or regulatory milestones have been included in the transaction price, as all milestone amounts were subject to the revenue constraint. As part of the constraint evaluation, we considered numerous factors including the fact that the receipt of milestones is outside of our control and contingent upon success in future clinical trials, an outcome that is difficult to predict, and GSK's efforts. Any consideration related to sales-based milestones, including royalties, will be recognized when the related sales occur as they were determined to relate predominantly to the intellectual property license granted to GSK and therefore have also been excluded from the transaction price. We will re-evaluate the variable transaction price in each reporting period and as uncertain events are resolved or other changes in circumstances occur.

Milestones recognized through December 31, 2020 under the GSK Agreement are as follows:

Milestone Event	Anti-PD-1 (GSK4057190A/Dostarlimab)		Anti-TIM-3 (GSK4069889A/Cobolimab)		Anti-LAG-3 (GSK40974386)	
	Amount	Quarter Recognized	Amount	Quarter Recognized	Amount	Quarter Recognized
Initiated *in vivo* toxicology studies using good laboratory practices (GLPs)	$1.0M	Q2'15	$1.0M	Q4'15	$1.0M	Q3'16
IND clearance from the FDA	$4.0M	Q1'16	$4.0M	Q2'16	$4.0M	Q2'17
Phase 2 clinical trial initiation	$3.0M	Q2'17	$3.0M	Q4'17	$3.0M	Q4'19
Phase 3 clinical trial initiation - first indication	$5.0M	Q3'18	—	—	—	—
Phase 3 clinical trial initiation - second indication	$5.0M	Q2'19	—	—	—	—
Filing of the first NDA - first indication	$10.0M	Q1'20	—	—	—	—
Filing of the first MAA - first indication	$5.0M	Q1'20	—	—	—	—

Milestones achieved during the discovery period were recognized as revenue pro-rata through December 31, 2016. Milestones achieved during fiscal 2017 were recognized as revenue in the period earned, while milestones after December 31, 2017 are recognized upon determination that a significant reversal of revenue would not be probable. Cash is generally received within 30 days of milestone achievement.

We recognized $75.0 million in revenue under this agreement during the year ended December 31, 2020, of which $60.0 million is related to terms under Amendment No. 3 to the GSK Agreement that were satisfied and $15.0 million in milestone revenue related to two milestones. We recognized $8.0 million during the year ended December 31, 2019 related to two milestones. We recognized $5.0 million during the year ended December 31, 2018 related to one milestone.

Antibody Generation Agreement with Bristol-Myers Squibb

In December 2011, we entered into a license and collaboration agreement (the "BMS Agreement") with Celgene, now a part of Bristol-Myers Squibb (Celgene and Bristol-Myers Squibb are hereinafter referred to, collectively, as "BMS"), to develop therapeutic antibodies against multiple targets. We granted BMS the option to obtain worldwide commercial rights to antibodies generated against each of the targets under the agreement, which option was triggered on a target-by-target basis by our delivery of antibodies meeting certain pre-specified parameters pertaining to each target under the agreement.

The BMS Agreement provided for an upfront payment of $6.0 million from BMS, which we received in 2011 and recognized through 2014, milestone payments of up to $53.0 million per target, low single-digit royalties on net sales of antibodies against each target, and reimbursement of specified research and development costs.

We assessed this arrangement in accordance with ASC Topic 606 and concluded that the contract counterparty, BMS, is a customer. We identified the following material promises under the BMS Agreement: (1) the licenses under certain patent rights relating to four targets and transfer of certain development and regulatory information, (2) R&D services, (3) a written report documenting findings, and (4) steering committee meetings. We considered the research and discovery capabilities of BMS, BMS's inability to sub-license the four targets, and the fact that the discovery and optimization of these antibodies is proprietary and could not, at the time of contract inception, be provided by other vendors, to conclude that the license does not have stand-alone functionality and is therefore not distinct. Additionally, we determined that the report of findings and steering committee participation would not have been provided without the R&D services and license agreement. Based on these assessments, we identified all services to be interrelated, and therefore concluded that the promises should be combined into a single performance obligation at the inception the arrangement.

As of December 31, 2020, the transaction price of the BMS Agreement includes the upfront payment, success fees, expense reimbursement, and milestones earned to date, which are allocated in their entirety to the single performance obligation. None of the future clinical or regulatory milestones have been included in the transaction price, as all milestone amounts were subject to the revenue constraint. As part of the constraint evaluation, we considered numerous factors, including the fact that the receipt of milestones is outside of our control and contingent upon success in future clinical trials and BMS's efforts. Any consideration related to sales-based milestones, including royalties, will be recognized when the related sales occur as they were determined to relate predominantly to the intellectual property license granted to BMS and therefore have also been excluded from the transaction price. We will re-evaluate the transaction price in each reporting period and as uncertain events are resolved or other changes in circumstances occur.

Milestones achieved through December 31, 2020 under the BMS Agreement are as follows:

	Anti-PD-1 (CC-90006)	
Milestone Event	**Amount**	**Quarter Recognized**
Completion of first *in vivo* toxicology studies using GLPs	$0.5M	Q2'16
Phase 1 clinical trial initiation	$1.0M	Q4'16

Revenue from future contingent milestone payments will be recognized when it is more likely than not that the revenue will not be reversed in future periods. Cash is generally received within 30 days of milestone achievement.

There was no revenue recognized under this agreement during the years ended December 31, 2020, 2019, and 2018.

5. Notes Payable

On December 24, 2014, we entered into a Loan and Security Agreement, as amended from time to time (the "Loan Agreement"), with a bank and a financial institution whereby we may borrow up to $15.0 million in three separate draws of $5.0 million each. The Term A Loans, for an aggregate of $5.0 million, were drawn on December 24, 2014 with a fixed interest rate of 6.97%.

In January 2016, the Loan Agreement was amended to combine Term B Loans and Term C Loans for a total of $10.0 million available for draw through December 31, 2016 and delay the beginning of our Term A Loans' principal repayments from February 1, 2016 until February 1, 2017. The Term B Loans and Term C Loans became available for draw on July 1, 2016. In December 2016, we further amended the Loan Agreement to (i) allow for the Term B Loans and Term C Loans to be drawn on December 30, 2016, (ii) delay principal repayments of all Term Loans until February 1, 2018, and (iii) amend the interest rate for each Term Loan. The Term B Loans and the Term C Loans were drawn on December 30, 2016, and Term A, B and C Loans are now collectively referred to as the Term Loans. Principal repayments began in February 2018, and the Term Loans were paid in full, without penalty or premium, on January 1, 2020.

The costs incurred to issue the Term Loans were deferred and were included in the discount to the carrying value of the Term Loans in the accompanying balance sheet. The Term Loans also included a final payment fee of $0.8 million due at the earlier of prepayment or the maturity date of the Term Loans. The deferred costs and the final payment fee were amortized to interest expense over the expected term of the Term A Loans using the effective interest method.

6. Fair Value Measurements and Available for Sale Investments

Fair Value Measurements

Our financial instruments consist principally of cash, cash equivalents, restricted cash, short-term and long-term investments, receivables, accounts payable, and notes payable. Certain of our financial assets and liabilities have been recorded at fair value in the consolidated balance sheet in accordance with the accounting standards for fair value measurements.

Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants on the measurement date. Accounting guidance also establishes a fair value hierarchy that requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. The standard describes three levels of inputs that may be used to measure fair value:

Level 1 - Observable inputs that reflect quoted prices (unadjusted) for identical assets or liabilities in active markets.

Level 2 - Inputs are observable, unadjusted quoted prices in active markets for similar assets or liabilities, unadjusted quoted prices for identical or similar assets or liabilities in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the related assets or liabilities; and

Level 3 - Unobservable inputs that are supported by little or no market activities, therefore requiring an entity to develop its own assumptions.

Assets and Liabilities Measured at Fair Value on a Recurring Basis

The following table summarizes our assets and liabilities that require fair value measurements on a recurring basis and their respective input levels based on the fair value hierarchy:

		Fair Value Measurements at End of Period Using:		
(in thousands)	**Fair Value**	**Quoted Market Prices for Identical Assets (Level 1)**	**Significant Other Observable Inputs (Level 2)**	**Significant Unobservable Inputs (Level 3)**
At December 31, 2020				
Money market funds[1]	$ 188,297	$ 188,297	$ —	$ —
Mutual funds[1]	57,153	57,153	—	—
U.S. Treasury securities[2]	107,697	107,697	—	—
Certificates of deposit[2]	2,436	—	2,436	—
Agency securities[2]	21,169	—	21,169	—
Commercial and corporate obligations[2]	29,441	—	29,441	—
At December 31, 2019				
Money market funds[1]	$ 162,928	$ 162,928	$ —	$ —
Mutual funds[1]	7,619	7,619	—	—
U.S. Treasury securities[2]	96,434	96,434	—	—
Certificates of deposit[2]	5,428	—	5,428	—
Agency securities[2]	33,623	—	33,623	—
Commercial and corporate obligations[2]	122,030	—	122,030	—

[1] Included in cash and cash equivalents or restricted cash in the accompanying consolidated balance sheets.

[2] Included in short-term or long-term investments in the accompanying consolidated balance sheets depending on the respective maturity date.

The following methods and assumptions were used to estimate the fair value of our financial instruments for which it is practicable to estimate that value:

Marketable Securities. For fair values determined by Level 1 inputs, which utilize quoted prices in active markets for identical assets, the level of judgment required to estimate fair value is relatively low. For fair values determined by Level 2 inputs, which utilize quoted prices in less active markets for similar assets, the level of judgment required to estimate fair value is also considered relatively low.

Fair Value of Other Financial Instruments

The fair value of our other financial instruments estimated as of December 31, 2020 and December 31, 2019 are presented below:

	December 31, 2020		December 31, 2019	
(in thousands)	**Carrying Amount**	**Fair Value**	**Carrying Amount**	**Fair Value**
Notes payable	$ —	$ —	$ 1,375	$ 1,365

The following methods and assumptions were used to estimate the fair value of our notes payable:

Notes Payable—We use the income approach to value the aforementioned debt instrument. We use a present value calculation to discount principal and interest payments and the final maturity payment on these liabilities using a discounted cash flow model based on observable inputs. We discount these debt instruments based on what the current market rates would offer us as of the reporting date. Based on the assumptions used to value these liabilities at fair value, these debt instruments are categorized as Level 2 in the fair value hierarchy.

The carrying amounts of certain of our financial instruments, including cash and cash equivalents, accounts payable, and accrued expenses approximate fair value due to their short-term nature.

Available for Sale Investments

We invest our excess cash in agency securities, debt instruments of financial institutions and corporations, commercial obligations, and U.S. Treasury securities, which we classify as available-for-sale investments. These investments are carried at fair value and are included in the tables above. The aggregate market value, cost basis, and gross unrealized gains and losses of available-for-sale investments by security type, classified in cash equivalents, short-term and long-term investments as of December 31, 2020 are as follows:

(in thousands)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Total Fair Value
Agency securities[1]	$ 21,169	$ 1	$ (1)	$ 21,169
Certificates of deposit[2]	2,427	9	—	2,436
Commercial and corporate obligations[3]	29,414	28	(1)	29,441
US Treasury securities[4]	107,530	170	(3)	107,697
Total available-for-sale investments	$ 160,540	$ 208	$ (5)	$ 160,743

(1) Of our outstanding agency securities, $10.0 million have maturity dates of less than one year and $11.2 million have a maturity date of between one to two years as of December 31, 2020.

(2) Of our outstanding certificates of deposit, $1.1 million have a maturity date of less than one year and $1.3 million have a maturity date of between one to two years as of December 31, 2020.

(3) Of our outstanding commercial and corporate obligations, $29.4 million have maturity dates of less than one year and $0.0 million have a maturity date of between one to two years as of December 31, 2020.

(4) Of our outstanding U.S. Treasury securities, $102.7 million have maturity dates of less than one year and $5.0 million have a maturity date of between one to two years as of December 31, 2020.

The aggregate market value, cost basis, and gross unrealized gains and losses of available-for-sale investments by security type, classified in cash equivalents, short-term and long-term investments as of December 31, 2019 are as follows:

(in thousands)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Total Fair Value
Agency securities[1]	$ 33,543	$ 80	$ —	$ 33,623
Certificates of deposit[2]	5,381	47	—	5,428
Commercial and corporate obligations[3]	121,809	225	(4)	122,030
US Treasury securities[4]	96,236	200	(2)	96,434
Total available-for-sale investments	$ 256,969	$ 552	$ (6)	$ 257,515

(1) Of our outstanding agency securities, $16.5 million have maturity dates of less than one year and $17.1 million have a maturity date of between one to two years as of December 31, 2019.

(2) Of our outstanding certificates of deposit, $4.6 million have a maturity date of less than one year and $0.8 million have a maturity date of between one to two years as of December 31, 2019.

(3) Of our outstanding commercial and corporate obligations, $111.1 million have maturity dates of less than one year and $10.9 million have a maturity date of between one to two years as of December 31, 2019.

(4) Of our outstanding U.S. Treasury securities, $70.9 million have maturity dates of less than one year and $25.5 million have a maturity date of between one to two years as of December 31, 2019.

The following tables present gross unrealized losses and fair values for those investments that were in an unrealized loss position as of December 31, 2020 and December 31, 2019, aggregated by investment category and the length of time that individual securities have been in a continuous loss position:

	December 31, 2020					
	Less than 12 Months		12 Months or Greater		Total	
(in thousands)	Fair Value	Gross Unrealized Losses	Fair Value	Gross Unrealized Losses	Fair Value	Gross Unrealized Losses
Agency securities	$ 4,999	$ (1)	$ —	$ —	$ 4,999	$ (1)
Commercial and corporate obligations	6,503	(1)	2,399	—	8,902	(1)
US Treasury Securities	35,211	(3)	—	—	35,211	(3)
Total	$ 46,713	$ (5)	$ 2,399	$ —	$ 49,112	$ (5)

	December 31, 2019					
	Less than 12 Months		12 Months or Greater		Total	
(in thousands)	Fair Value	Gross Unrealized Losses	Fair Value	Gross Unrealized Losses	Fair Value	Gross Unrealized Losses
Commercial and corporate obligations	$ 5,986	$ (4)	$ —	$ —	$ 5,986	$ (4)
US Treasury Securities	17,608	(2)	—	—	17,608	(2)
Total	$ 23,594	$ (6)	$ —	$ —	$ 23,594	$ (6)

As of December 31, 2020 and 2019, unrealized losses on available-for-sale investments were not material, and accordingly, no allowance for credit losses were recorded.

7. Stockholders' Equity

Common Stock

Of the 500,000,000 shares of common stock authorized, 27,355,575 shares were issued and outstanding as of December 31, 2020. Common stock reserved for future issuance upon the exercise, issuance or conversion of the respective equity instruments at December 31, 2020 are as follows:

Issued and Outstanding:	
Stock options	2,920,700
Shares Reserved For:	
2017 Equity Incentive Plan	2,986,101
2017 Employee Stock Purchase Plan	997,682
Total	6,904,483

8. Equity Incentive Plans

2017 Equity Incentive Plan

On January 12, 2017, our board of directors and stockholders approved and adopted the 2017 Equity Incentive Plan (the "2017 Plan"). The 2017 Plan became effective upon the execution and delivery of the underwriting agreement for our initial public offering on January 26, 2017, and replaced our existing 2006 Equity Incentive Plan. Under the 2017 Plan, we may grant stock options, stock appreciation rights, restricted stock, restricted stock units and other awards to individuals who are then our employees, officers, directors or consultants. In addition, the number of shares of stock available for issuance under the 2017 Plan will be automatically increased each January 1, beginning on January 1, 2018, by 4% of the aggregate number of outstanding shares of our common stock as of the immediately preceding December 31 or such lesser number as determined by our board of directors. The 2017 Plan automatically increased by 1,090,203 shares as of January 1, 2020.

Employee Stock Purchase Plan

On January 12, 2017, our board of directors and stockholders approved and adopted the 2017 Employee Stock Purchase Plan or the ESPP. The ESPP became effective upon the execution and delivery of the underwriting agreement for our initial public offering on January 26, 2017. In addition, the number shares of stock available for issuance under the ESPP will be automatically increased each January 1, beginning on January 1, 2018, by 1% of the aggregate number of outstanding shares of our common stock as of the immediately preceding December 31 or such lesser number as determined by our board of directors. The ESPP automatically increased by 272,550 shares as of January 1, 2020.

Stock Options

Stock options granted to employees and non-employees generally vest over a four-year period while stock options granted to directors vest over a one-year period. Each stock option award has a maximum term of 10 years from the date of grant, subject to earlier cancellation prior to vesting upon cessation of service to us. A summary of the activity related to stock option awards during the year ended December 31, 2020 is as follows:

	Shares Subject to Options	Weighted-Average Exercise Price per Share	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding at January 1, 2020	3,039,880	$ 29.40		
Granted	539,825	$ 19.13		
Exercises	(100,493)	$ 4.94		
Forfeitures and cancellations	(558,512)	$ 38.13		
Outstanding at December 31, 2020	2,920,700	$ 26.67	7.29	$ 17,434
Exercisable at December 31, 2020	1,606,744	$ 26.56	5.93	$ 12,326

Total cash received from the exercise of stock options was approximately $0.5 million during the year ended December 31, 2020.

Stock-Based Compensation Expense

The estimated fair values of stock option awards granted to employees were determined on the date of grant using the Black-Scholes option valuation model with the following weighted-average assumptions:

	Year Ended December 31,		
	2020	2019	2018
Risk-free interest rate	0.5 %	2.0 %	2.7 %
Expected volatility	90.2 %	77.98 %	67.7 %
Expected dividend yield	— %	— %	— %
Expected term (in years)	6.25	6.25	6.25
Weighted average grant date fair value per share	$ 14.51	$ 21.99	$ 61.41

We determine the appropriate risk-free interest rate, expected term for employee stock-based awards, contractual term for non-employee stock-based awards, and volatility assumptions. The weighted-average expected option term for employee and non-employee stock-based awards reflects the application of the simplified method, which defines the life as the average of the contractual term of the options and the weighted-average vesting period for all option tranches. Estimated volatility incorporates historical volatility of our stock price as well as similar entities whose share prices are publicly available. The risk-free interest rate is based upon U.S. Treasury securities with remaining terms similar to the expected or contractual term of the stock-based payment awards. The assumed dividend yield is based on our expectation of not paying dividends in the foreseeable future.

Total non-cash stock-based compensation expense for all stock awards that was recognized in the consolidated statements of operations and comprehensive loss is as follows:

(in thousands)	Year Ended December 31, 2020	2019	2018
Research and development	$ 4,122	$ 5,564	$ 3,371
General and administrative	7,377	6,847	6,590
Total	$ 11,499	$ 12,411	$ 9,961

At December 31, 2020, there was $22.9 million of unrecognized compensation cost related to unvested stock option awards, which is expected to be recognized over a remaining weighted average vesting period of 2.92 years.

9. Australia Research and Development Tax Incentive

Our Australian subsidiary, which conducts core research and development activities on our behalf, was eligible to receive a 43.5% refundable tax incentive for qualified research and development activities during fiscal years 2019 and 2018. We were no longer eligible to receive the refundable tax incentive during fiscal year ending 2020. For the years ended December 31, 2019 and 2018, $0.0 million and $0.1 million, respectively, were recorded as a reduction to research and development expenses in the consolidated statements of operations and comprehensive loss. We received approximately $0.0 million and $0.2 million in cash during the years ended December 31, 2020 and 2019, respectively, related to the tax incentive. As of December 31, 2020, we had no remaining tax incentive receivable from the Australian government.

10. Employee Benefit Plan

We have a defined contribution 401(k) plan available to eligible employees. Employee contributions are voluntary and are determined on an individual basis, limited to the maximum amount allowable under U.S. federal tax regulations. During 2020 and 2019, we elected to match 50% of an employee's contributions up to 6% of the employees' eligible salary with a maximum annual match limit of $6,000. For the years ended December 31, 2020, and 2019, we incurred approximately $0.5 million and $0.3 million, respectively of costs related to the 401(k) plan. There were no employer contributions to the plan during the year ended December 31, 2018.

11. Commitments and Contingencies

Operating Leases

On November 11, 2020, we entered into an agreement to terminate our sublease (the "Sublease Termination") with Trex Enterprises Corporation, with respect to facilities in the building at 10455 Pacific Center Court in San Diego, California (the "10455 Building"). The terms of the original sublease with Trex provided for a November 12, 2021 lease expiration. Under the Sublease Termination, we agreed to terminate the sublease agreement on December 15, 2020 with no associated penalty. We recorded a non-cash gain of approximately $0.1 million as other income (expense), in connection with the write-off of the lease liability and corresponding ROU asset. As of December 31, 2020, there was no lease liability and corresponding ROU asset related to the 10455 Building Lease.

As of December 31, 2020, we still maintain the non-cancellable office lease for our facilities at 10421 Pacific Center Court in San Diego, California, which expires on August 31, 2021. Our lease payments are fixed, and we recognize lease expense for leases on a straight-line basis over the lease term. Operating lease ROU assets and lease liabilities are recorded based on the present value of the future minimum lease payments over the lease term at commencement date. As our leases do not provide an implicit rate, we used our incremental borrowing rate based on the information available at effective date of adoption in determining the present value of future payments. The weighted-average discount rate used was 8.59%.

Our balance sheet includes our ROU assets and lease liabilities as follows (in thousands):

Leases	Classification on the Balance Sheet	December 31, 2020	December 31, 2019
Operating ROU assets	Other long-term assets	$ 344	$ 1,402
Operating lease liabilities	Other current liabilities	342	871
Operating lease liabilities	Other long-term liabilities	—	654

The following costs are included in our cash flow statement (in thousands):

Leases	Classification on the Cash Flow	Year Ended December 31, 2020	Year Ended December 31, 2019
Operating lease cost	Operating	$ 865	$ 879
Cash paid for amounts included in the measurement of lease liabilities	Operating	938	937

Rent expense was $0.7 million during the year ended December 31, 2018 under ASC 840.

At December 31, 2020, the future minimum annual obligations under non-cancellable operating lease commitments in excess of one year are as follows:

Years Ending December 31, (in thousands)	
2021	$ 352
2022	—
2023	—
2024	—
2025	—
Thereafter	—
Total minimum payments required	$ 352
Less: Imputed interest	(10)
Present value of lease liabilities	$ 342

On May 4, 2020, we entered into a lease agreement (the “Lease Agreement”) with Wateridge Property Owner, LP, with respect to facilities in the building at 10770 Wateridge Circle, San Diego, California 92121. Under the Lease Agreement, we agreed to lease approximately 45,000 square feet of space for a term of 124 months, beginning on April 1, 2021 or at the completion of leasehold improvements. The Lease liability and corresponding ROU asset will be recorded at lease commencement date, which we anticipate to be April 1, 2021. The terms of the Lease Agreement provide us with an option to extend the term of the lease for an additional five years, as well as a one-time option to terminate the lease after seven years with the payment of a termination fee. The monthly base rent will be $4.20 per rentable square foot and will be increased by 3% annually. Under the Lease Agreement, we are also responsible for our pro rata share of real estate taxes, building insurance, maintenance, direct expenses, and utilities. As of December 31, 2020, we have recorded $0.2 million in prepaid rent and $0.3 million as a security deposit in accordance with the terms of the Lease Agreement.

At December 31, 2020, the future minimum annual obligations for the Lease Agreement in excess of one year are as follows (in thousands):

Years Ending December 31,		
2021	$	568
2022		2,328
2023		2,397
2024		2,469
2025		2,543
Thereafter		15,420
Total minimum payments required	$	25,725

License Agreements

We have certain obligations under licensing agreements with third parties that are contingent upon achieving various development, regulatory and commercial milestones. Pursuant to these license agreements, we are required to make milestone payments if certain development, regulatory and commercial sales milestones are achieved. Also, pursuant to the terms of each of these license agreements, when and if commercial sales of a product commence, we will pay royalties to our licensors on net sales of the respective products.

Certain of the licensing agreements require guaranteed minimum annual payments. Terms of the licensing agreements generally range from the remaining life of the patent up to 19 years and, in some cases, may be subject to earlier termination by either party upon specified circumstances.

Total expense incurred under all collaborative licensing agreements for upfront, milestone and royalty payments were $0.2 million, $0.5 million and $0.3 million during the years ended December 31, 2020, 2019 and 2018, respectively. Total cash paid under these agreements was $0.3 million, $0.1 million, and $0.2 million during the years ended December 31, 2020, 2019, and 2018, respectively.

Future minimum annual obligations under all such license agreements will be $0.2 million in aggregate during 2021, and thereafter. These obligations are payable through ten years from the first commercial sale, if any, or expiration of the last patent to expire, the dates of which are not determinable at this time.

Other Commitments and Contingencies

We have entered into agreements with certain vendors for the provision of goods and services, which includes manufacturing services with contract manufacturing organizations and development services with contract research organizations. These agreements may include certain provisions for purchase obligations and termination obligations that could require payments for the cancellation of committed purchase obligations or for early termination of the agreements. The amount of the cancellation or termination payments vary and are based on the timing of the cancellation or termination and the specific terms of the agreement.

Guarantees and Indemnifications

We enter into standard indemnification arrangements in the ordinary course of business. Pursuant to certain of these arrangements, we indemnify, hold harmless, and agree to reimburse the indemnified parties for losses suffered or incurred by the indemnified party for third-party claims in connection with our breach of the agreement, our negligence or willful misconduct in connection with the agreement, or any trade secret, copyright, patent or other intellectual property infringement claim with respect to our technology. The term of these indemnification arrangements is generally perpetual. The maximum potential amount of future payments we could be required to make under these agreements is not determinable because it involves claims that may be made against us in the future, but have not yet been made.

We indemnify our officers and directors for certain events or occurrences, subject to certain limits, while the officer or director is or was serving in such capacity, as permitted under Delaware law, in accordance with our certificate of incorporation and bylaws, and pursuant to agreements providing for indemnification entered into with our officers and directors. The term of the indemnification period lasts as long as an officer or director may be subject to any proceeding arising out of acts or omissions of such officer or director in such capacity.

The maximum amount of potential future indemnification of directors and officers is unlimited; however, we currently hold director and officer liability insurance. This insurance allows the transfer of risk associated with our exposure and may enable us to recover a portion of any future amounts paid.

We believe that the fair value of these indemnification obligations is minimal. Accordingly, we have not recognized any liabilities relating to these obligations for any period presented.

Letter of Credit

At December 31, 2020 and 2019, we were contingently liable for a standby letter of credit issued by a commercial bank for $60,000 for security on our lease. A restricted cash account with these amounts was held as cash collateral for the letter of credit.

Litigation

On March 25, 2020, a putative securities class action was filed in the United States District Court for the Southern District of California naming the Company and certain of its current or former officers as defendants. The complaint purports to assert claims under Section 10(b) of the Exchange Act Rule 10b-5, and Section 20(a) of the Exchange Act, on behalf of persons and entities who acquired our common stock between October 10, 2017 and November 7, 2019 (the "Class Period"). An amended complaint was filed on September 30, 2020 alleging that, during the Class Period, the defendants made material misrepresentations or omissions regarding our etokimab product candidate that artificially inflated our stock price. The plaintiff seeks, among other things, damages in an unspecified amount, as well as costs and expenses. We believe that the plaintiff's allegations are without merit and intend to vigorously defend against the claims. Because the Company is in the early stages of this litigation matter, we are unable to estimate a reasonably possible loss or range of loss, if any, that may result from these matters. On September 1, 2020, a related shareholder derivative complaint was filed based on allegations substantially similar to those in the class action, and asserting claims against current or former officers and directors for contribution under Sections 10(b) and 21D of the Exchange Act, breach of fiduciary duty, unjust enrichment and corporate waste. On January 28, 2021, this derivative action was voluntarily dismissed without prejudice.

From time to time, we may be involved in legal proceedings arising in the ordinary course of our business. We investigate these claims as they arise and accrue estimates for resolution of legal and other contingencies when losses are probable and estimable. 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.

12. Income Taxes

The components of loss before income tax benefit consist of the following:

	Year Ended December 31,		
(in thousands)	**2020**	**2019**	**2018**
U.S.	$ (19,832)	$ (97,187)	$ (61,193)
Foreign	(99)	(301)	(655)
Consolidated net loss before income taxes	$ (19,931)	$ (97,488)	$ (61,848)

Significant components of our deferred tax assets and liabilities are as follows:

(in thousands)	December 31, 2020	2019
Deferred Tax Assets:		
Net operating loss carryforwards	$ 57,772	$ 55,722
Research and development credits	17,614	14,244
Equity compensation	5,329	4,067
Other, net	769	799
Total deferred tax assets	81,484	74,832
Deferred Tax Liabilities:		
Fixed assets	(150)	(349)
Total deferred tax liabilities	(150)	(349)
Net deferred tax assets	81,334	74,483
Less: valuation allowance	(81,334)	(74,483)
Deferred tax assets, net of valuation allowance	$ —	$ —

We have recorded a full valuation allowance against our net deferred tax assets due to the uncertainty surrounding the realization of such assets. Management has determined it more likely than not that the deferred tax assets are not realizable due to our historical loss position.

At December 31, 2020, we had federal and state net operating loss carryforwards, or NOLs, of $248.4 million and $64.2 million, respectively. The federal and state NOLs generated prior to 2018 will both begin to expire in 2028, unless previously utilized. The federal NOL includes $188.4 million of net operating losses generated in 2018 and after. Federal net operating losses generated in 2018 and after carryover indefinitely and may generally be used to offset up to 80% of future taxable income. At December 31, 2020, we had federal and California research tax credit carryforwards of approximately $14.3 million and $8.9 million, respectively. The federal research tax credit carryforwards will begin to expire in 2026 and the California state credits carryforward indefinitely. We also have foreign tax losses of $3.4 million, which will carry forward indefinitely, subject to a continuity of ownership test.

The above NOL carryforward and the federal and state research tax credit carryforwards may be subject to an annual limitation under section 382 and 383 of the Internal Revenue Code of 1986, as amended (the “Code”), and similar state provisions if we experience one or more ownership changes which would limit the amount of NOL and tax credit carryforwards that can be utilized to offset future taxable income and tax, respectively. In general, an ownership change as defined by Section 382 and 383, results from transactions increasing ownership of certain stockholders or public groups in the stock of the corporation by more than 50 percentage points over a three-year period. In September 2015, we completed a Section 382 analysis through December 31, 2014 and determined that there was an ownership change in 2007 that may limit the utilization of approximately $5.3 million and $5.4 million in federal and state NOLs, respectively, and $0.2 million in both federal and state research tax credits. We extended the analysis period of the study through December 31, 2018, noting an ownership change in 2017 which may limit the use of our net operating losses. Our use of federal NOL carryforward could be limited further by the provisions of Section 382 of the U.S. Internal Revenue Code of 1986, as amended, depending upon the timing and amount of additional equity securities that we have issued or will issue. State NOL carryforwards may be similarly limited. If a change in ownership were to have occurred, NOL and tax credits carryforwards could be eliminated or restricted. If eliminated the related asset would be removed from the deferred tax asset schedule with a corresponding reduction in the valuation allowance. Due to the existence of the valuation allowance, limitations created by ownership changes, if any, will not impact our effective tax rate.

The following is a reconciliation of the expected statutory federal income tax provision to our actual income tax provision:

(in thousands)	Year Ended December 31, 2020	2019	2018
Expected income tax benefit at federal statutory tax rate	$ (4,186)	$ (20,473)	$ (12,988)
State income taxes, net of federal benefit	(21)	(377)	(166)
Permanent items	18	34	17
Equity compensation [1]	871	(1,122)	(6,693)
Research and development expenditure	—	—	63
Refundable AMT credit	—	—	(139)
Return to provision adjustment	(11)	(661)	60
Rate differential	40	(53)	155
Research credits	(3,389)	(4,405)	(4,393)
Change in the valuation allowance	6,678	26,905	23,892
Income tax benefit	$ —	$ (152)	$ (192)

[1] Includes non-deductible stock-based compensation and excess tax benefits from stock-based compensation. During 2020, our tax provision includes $0.0 of excess tax benefits associated with the exercise of non-qualified stock options and $0.2 associated with the disqualifying dispositions of incentive stock options. During 2019, our tax provision includes $1.1 million of excess tax benefits associated with the exercise of non-qualified stock options and $0.3 million associated with the disqualifying dispositions of incentive stock options. During 2018, our tax provision includes $4.9 million of excess tax benefits associated with the exercise of non-qualified stock options and $2.2 million associated with the disqualifying dispositions of incentive stock options.

We recognize a tax benefit from an uncertain tax position when it is more likely than not that the position will be sustained upon examination, including resolutions of any related appeals or litigation processes, based on the technical merits. Income tax positions must meet a more likely than not recognition at the effective date to be recognized. At December 31, 2020 and 2019, we had no unrecognized tax benefits that, if recognized and realized, would affect the effective tax rate due to the valuation allowance against deferred tax assets. The following table summarizes the activity related to our unrecognized tax benefits:

(in thousands)	Year Ended December 31, 2020	2019
Balance at the beginning of the year	$ 3,146	$ 1,812
Increase related to prior year tax positions	—	168
Increase related to current year tax positions	898	1,166
Balance at the end of the year	$ 4,044	$ 3,146

If recognized, these amounts would not affect our effective tax rate, since they would be offset by an equal corresponding adjustment in the deferred tax asset valuation allowance. We do not anticipate there will be a significant change in unrecognized tax benefits within the next 12 months.

Our policy is to recognize interest and penalties related to income tax matters in the provision for income taxes. At December 31, 2020 and 2019, there were no interest or penalties on uncertain tax benefits.

We file income tax returns in the United States, California and Australia. Due to our losses incurred, we are essentially subject to income tax examination by tax authorities from inception to date.

13. Subsequent Event

A second BLA submitted by GSK was accepted by the FDA during the first quarter of 2021 for dostarlimab in pan-deficient mismatch repair tumors (“PdMMRT”),” triggering a milestone payment to us of $10.0 million.

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

None.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

As of December 31, 2020, our management, with the participation of our principal executive officer and principal financial officer, performed an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act. Our disclosure controls and procedures are designed to ensure that information required to be disclosed in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, to allow timely decisions regarding required disclosures. Based on this evaluation, our principal executive officer and principal financial officer concluded that, as of December 31, 2020, the design and operation of our disclosure controls and procedures were effective at a reasonable assurance level.

Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rule 13a-15(f) of the Exchange Act. Management assessed the effectiveness of our internal control over financial reporting as of December 31, 2020. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control—Integrated Framework issued in 2013. Based upon the assessments, management has concluded that as of December 31, 2020 our internal control over financial reporting was effective to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with GAAP.

This Annual Report on Form 10-K does not include an attestation report on internal control over financial reporting issued by our independent registered accounting firm. Our auditors will not be required to formally opine on the effectiveness of our internal control over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act of 2002 until we are no longer a smaller reporting company.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the quarter ended December 31, 2020 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations on Effectiveness of Controls

Internal control over financial reporting may not prevent or detect all errors and all fraud. Any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objective and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Item 9B. Other Information

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

Information required by this Item is incorporated herein by reference to the sections titled “Information about our Executive Officers,” “Election of Class I Directors,” “Corporate Governance Standards and Director Independence” and “Security Ownership of Certain Beneficial Owners and Management” in our Definitive Proxy Statement with respect to our 2021 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

With regard to the information required by this item regarding compliance with Section 16(a) of the Exchange Act, we will provide disclosure of delinquent Section 16(a) reports, if any, in our Proxy Statement related to the 2021 Annual Meeting of Shareholders, and such disclosure, if any, is incorporated herein by reference.

Item 11. Executive Compensation

Information required by this Item is incorporated herein by reference to the section titled “Executive Compensation,” “Election of Class I Directors,” and “Corporate Governance Standards and Director Independence” in our Definitive Proxy Statement with respect to our 2021 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

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

Information required by this Item is incorporated herein by reference to the section titled “Security Ownership of Certain Beneficial Owners and Management” and “Equity Compensation Plan Information” in our Definitive Proxy Statement with respect to our 2021 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

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

Information required by this Item is incorporated herein by reference to the section titled “Certain Relationships and Related Party Transactions” and “Corporate Governance Standards and Director Independence” in our Definitive Proxy Statement with respect to our 2021 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

Item 14. Principal Accounting Fees and Services

Information required by this Item is incorporated herein by reference to the section titled “Ratification of Independent Registered Public Accounting Firm” in our Definitive Proxy Statement with respect to our 2021 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

PART IV

Item 15. Exhibits, Consolidated Financial Statement Schedules

(a) The following documents are filed as part of this report:

1. Consolidated Financial Statements

See Index to Consolidated Financial Statements under Part II, Item 8 herein.

2. Consolidated Financial Statement Schedules

No consolidated financial statement schedules are provided because the information called for is not required or is shown either in the consolidated financial statements or notes thereto.

3. Exhibits

EXHIBIT INDEX

Exhibit Number	Description of Document	Incorporated by reference				Filed Herewith
		Form	File No.	Exhibit	Filing Date	
3.1	Amended and Restated Certificate of Incorporation, as currently in effect.	10-Q	001-37985	3.1	May 12, 2017	
3.2	Restated Bylaws, as currently in effect.	S-1	333-206849	3.4	September 9, 2015	
4.1	Form of Common Stock Certificate.	S-1	333-206849	4.1	December 23, 2015	
4.2	Fourth Amended and Restated Investors' Rights Agreement, dated July 13, 2015, by and among the Registrant and certain of its stockholders.	S-1	333-206849	4.2	September 9, 2015	
4.3	Description of the Registrant's Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934	10-K	001-37985	4.3	March 2, 2020	
10.1*	Form of Indemnity Agreement.	S-1	333-206849	10.1	September 9, 2015	
10.2*	Amended and Restated 2006 Equity Incentive Plan and forms of award agreements.	S-1	333-206849	10.2	January 17, 2017	
10.3*	2017 Equity Incentive Plan, and forms of award agreements.	S-1	333-206849	10.3	January 17, 2017	
10.4*	2017 Employee Stock Purchase Plan, and forms of award agreements.	S-1	333-206849	10.4	January 17, 2017	
10.5*	Employment Agreement, effective as of January 1, 2012, by and between the Registrant and Hamza Suria, as amended.	10-K	001-37985	10.5	March 5, 2018	
10.6	Office Lease, dated April 19, 2011, by and between the Registrant and Kilroy Realty, L.P., as amended.	S-1	333-206849	10.8	December 23, 2015	
10.7	Antibody Generation Agreement, dated December 22, 2011, by and between the Registrant and Celgene Corporation, as modified.	S-1	333-206849	10.9	December 28, 2016	
10.8+	Collaboration and Exclusive License Agreement, dated March 10, 2014, by and among the Registrant, TESARO, Inc. and TESARO Development, Ltd., as amended.	S-1	333-206849	10.10	May 10, 2016	
10.9+	License Agreement, dated August 30, 2006, by and between the Registrant and Medical Research Council, as amended.	S-1	333-206849	10.12	September 9, 2015	
10.10 +	Non-Exclusive Research and Commercial License Agreement, dated May 15, 2009, by and between the Registrant and Millipore Corporation.	S-1	333-206849	10.13	September 9, 2015	

Exhibit Number	Description of Document	Incorporated by reference				Filed Herewith
		Form	File No.	Exhibit	Filing Date	
10.11	Amendment No. 1 to Investor Rights.	10-Q	001-37985	4.1	November 8, 2018	
10.12	Wateridge Lease Agreement.	10-Q	001-37985	10.16	May 6, 2020	
10.13*	Amended and Restated Employment Agreement, effective July 15, 2020, by and between Registrant and Eric Loumeau	10-Q	001-37985	10.17	November 4, 2020	
10.14*	Employment Agreement, effective July 15, 2020, by and between Registrant and Dennis Mulroy	10-Q	001-37985	10.18	November 4, 2020	
10.15*	Employment Agreement, effective July 31, 2020, by and between Registrant and Paul Lizzul	10-Q	001-37985	10.19	November 4, 2020	
10.16	Amendment No. 3 to the Collaboration and Exclusive License Agreement					X
10.17	Termination of Sublease					X
10.18	Confidential Settlement and Modification Agreement dated as of October 23, 2020					X
21.1	Subsidiaries of the Registrant.					X
23.1	Consent of KPMG LLP, an independent registered public accounting firm.					X
24.1	Power of Attorney					X
31.1	Certification of Principal Executive Officer, pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					X
31.2	Certification of Principal Financial Officer, pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					X
32.1**	Certification of Chief Executive Officer, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.					X
32.2**	Certification of Chief Financial Officer, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.					X
101.INS	XBRL Report Instance Document - The instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.					
101.SCH	Inline XBRL Taxonomy Extension Schema Document					
101.CAL	Inline XBRL Taxonomy Calculation Linkbase Document					
101.LAB	Inline XBRL Taxonomy Label Linkbase Document					
101.PRE	Inline XBRL Presentation Linkbase Document					
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document					
104	Cover Page Interactive Data File (formatted as inline XBRL and contained in Exhibit 101)					

* Executive compensation plan or agreement.

** This certification is deemed not filed for purpose of section 18 of the Exchange Act or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference into any filing under the Securities Act or the Exchange Act.

+ Registrant has omitted and filed separately with the SEC portions of the exhibit pursuant to a confidential treatment request under Rule 406 promulgated under the Securities Act.

Item 16. Form 10-K Summary

None.

SIGNATURES

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

Date: February 25, 2021

AnaptysBio, Inc.

By: /s/ Hamza Suria
Hamza Suria
Chief Executive Officer

POWER OF ATTORNEY

Each person whose individual signature appears below hereby authorizes and appoints Hamza Suria and Eric Loumeau, and each of them, with full power of substitution and re-substitution 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 Exchange Act of 1934, as amended, this Report has been signed below by the following persons on behalf of the Registrant in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Hamza Suria Hamza Suria	President, Chief Executive Officer and Director *(Principal Executive Officer)*	February 25, 2021
/s/ Dennis Mulroy Dennis Mulroy	Chief Financial Officer *(Principal Accounting and Financial Officer)*	February 25, 2021
/s/ Dennis Fenton Dennis Fenton, Ph.D.	Director	February 25, 2021
/s/ Laura J. Hamill Laura J. Hamill	Director	February 25, 2021
/s/ Magda Marquet Magda Marquet, Ph.D.	Director	February 25, 2021
/s/ Hollings Renton Hollings Renton	Director	February 25, 2021
/s/ John Schmid John Schmid	Director	February 25, 2021
/s/ James N. Topper James N. Topper, M.D., Ph.D.	Director	February 25, 2021
/s/ J. Anthony Ware J. Anthony Ware, M.D.	Director	February 25, 2021

CERTAIN CONFIDENTIAL INFORMATION MARKED [***] HAS BEEN EXCLUDED FROM THE EXHIBIT BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED.

AMENDMENT NO. 3

TO COLLABORATION AND EXCLUSIVE LICENSE AGREEMENT

This Amendment No. 3 to the Collaboration and Exclusive License Agreement (this "**Amendment**") effective as of October 23, 2020 (the "**Amendment Date**"), is entered into is made by and between (i) **AnaptysBio, Inc.**, a Delaware corporation, having a place of business at 10421 Pacific Center Court, Suite 200, San Diego, California 92121 ("**AnaptysBio**"), and (ii) **TESARO, Inc.**, a Delaware corporation, having a place of business at 1000 Winter Street, Suite 3300, Waltham, Massachusetts 02541 ("**TESARO US**") and **TESARO Development, Ltd.**, a Bermuda corporation, having its principal office at Clarendon House, 2 Church Street, Hamilton HM 11, Bermuda (together with TESARO US, "**TESARO** Collectively, AnaptysBio and TESARO are referred to as the "Parties" and, individually, as a "Party".

WHEREAS, the Parties previously entered into that certain Collaboration and Exclusive License Agreement dated as of March 10, 2014 and as amended by Amendment No. 1 dated November 28, 2014 and Amendment No. 2 dated February 29, 2016 (the "**Agreement**");

WHEREAS, AnaptysBio and TESARO US are also parties (along with GlaxoSmithKline LLC ("**GSK**")) to that certain Confidential Settlement Agreement of even date herewith (the "**Settlement Agreement**");

WHEREAS, AnaptysBio, TESARO US, and GSK are contemporaneously entering into the Settlement Agreement, of which this Amendment is an exhibit and integral component; and

WHEREAS, the Parties wish to amend the Agreement in certain respects on the terms and conditions set forth herein.

NOW THEREFORE, capitalized terms not defined in this Amendment shall have the meaning ascribed in the Agreement, and the Parties hereby agree as follows:

1. **Amendment of the Collaboration Agreement.** The following Sections of the Agreement are hereby amended as follows:

1.1 "Development Program Meetings. Section 4.6 of the Agreement is hereby rescinded and replaced in its entirety as follows:

"4.6 Joint Review Committee.

(a) Within [*] days after the Amendment Date, the Parties will establish a Joint Review Committee ("JRC") comprised of equal representation from AnaptysBio and TESARO or TESARO Affiliates.

(b) The purpose of the JRC is for TESARO:

(i) to inform AnaptysBio regarding future activities planned by TESARO and TESARO Affiliates with respect to the ongoing Development Programs and Products, including [*];

(ii) to update AnaptysBio regarding the conduct by TESARO or TESARO Affiliates clinical trials involving Products that have [*], and

(iii) to update AnaptysBio regarding commercialization of Products worldwide. The JRC will meet once every [*] months (unless otherwise agreed) and all updates and information provided will be subject to TESARO's or TESARO's Affiliates' confidentiality obligations to Third Parties. TESARO will advise AnaptysBio with regard to any material changes to the Development Programs and commercialization of Products anticipated relative to the updates provided at the most recent prior JRC meeting.

(c) [*]

(d) In the event of the [*], as to which AnaptysBio shall give Tesaro prompt notice there will be no further obligation for the JRC to address matters pertaining to that Product. Should there no longer be any Product as to which AnaptysBio or its Affiliates has the right to receive the royalties of Net Sales from TESARO, then the JRC shall be disbanded and the obligations of TESARO and its Affiliates under this Section 4.6 (a) to (c) shall cease. No purchaser of AnaptysBio's royalty rights will be entitled to participate in the JRC. In addition, the JRC will terminate at such time as TESARO or its Affiliates ceases research, development, or commercialization efforts for all Products."

1.2 Exclusivity.

1.2.1 Section 5.3(b) of the Agreement is hereby rescinded and replaced in its entirety as follows:

"5.3(b) During the Exclusivity Period, and except with respect to a Product pursuant to this Agreement and/or niraparib, TESARO shall not [*] For the sake of clarity, any research, development, manufacturing and/or commercialization by TESARO and/or its Affiliates of a Target Antagonist that is not a Product in combination with or otherwise with respect to niraparib or a Product is permitted under the Agreement."

1.2.2 Section 5.3(e) of the Agreement is hereby rescinded and replaced in its entirety as follows:[*]

1.4 Earned Royalties. Section 6.4(a) of the Agreement is hereby rescinded and replaced in its entirety as follows:

"With respect to Net Sales of dostarlimab, TESARO shall pay AnaptysBio a royalty on Net Sales as follows:

Worldwide Annual Net Sales of a Product (on a Product-by Product basis) during the applicable calendar year during the Royalty Term:	Royalty Rate Applicable to a Product:
Portion less than or equal to $1 billion:	8%
Portion greater than $1 billion, but less than or equal to $1.5 billion:	12%
Portion greater than $1.5 billion, but less than or equal to $2.5 billion:	20%
Portion greater than $2.5 billion:	25%

With respect to Net Sales of Product resulting from a Development Antibody other than dostarlimab, on a Product-by-Product basis, TESARO shall pay AnaptysBio a royalty on Net Sales as follows:

Worldwide Annual Net Sales of a Product (other than dostarlimab) (on a Product-by Product basis) during the applicable calendar year during the Royalty Term:	Royalty Rate Applicable to a Product:
Portion less than or equal to $[*]:	[*]%
Portion greater than $[*], but less than or equal to $[*]:	[*]%
Portion greater than $[*], but less than or equal to $[*]:	[*]%
Portion greater than $[*], but less than or equal to $[*]:	[*]%
Portion greater than $[*]:	[*]%

1.5 Royalty Payments and Reports. Section 7.3 of the Agreement is hereby rescinded and replaced in its entirety as follows:

"TESARO or its Affiliates shall make written reports and quarterly royalty payments under this Agreement to AnaptysBio within [*] days after the end of each calendar quarter covering Net Sales of Products during such calendar quarter, each such written report in reasonable detail [*]. Concurrent with the delivery of each such report, TESARO or its Affiliates shall make the royalty payment due to AnaptysBio for the calendar quarter covered by such report."

1.6 Section 8.1 of the Agreement is hereby amended by adding the following to the end of Section 8.1:

"Dostarlimab Clinical Trials. An agreed-upon list of clinical trials that TESARO and GSK plan to conduct or are currently conducting involving dostarlimab is attached to this Agreement as Exhibit D. [*]"

1.7 Exhibit D. The Agreement is hereby amended by adding Exhibit D attached to this Amendment.

2. **Payment to AnaptysBio.** TESARO or its Affiliates shall pay AnaptysBio the sum of sixty million US Dollars (US$60 million) by wire transfer within 30 days of the Amendment Date to the following account:

[*]

Upon request, AnaptysBio shall promptly provide TESARO with an invoice reflecting the amount and date due. [*] The Parties agree that it is a condition precedent to the payment obligation of this Paragraph 2 AnaptysBio shall have first dismissed the Delaware Chancery Court case captioned, *AnaptysBio, Inc. v. Tesaro, Inc. and GlaxoSmithKline LLC*, C.A. No. 2020-0690-KSJM with prejudice as set forth in Paragraph 3 of the Settlement Agreement.

3. **Press Release**. Public disclosure of the terms of this Amendment are subject to Section 11.2 of the Agreement and Sections 13 and 14 of the Settlement Agreement.

4. **Authority.** The Parties each represent and warrant that (i) this Amendment, and all terms and conditions thereof, have been duly authorized by all required corporate action on behalf of such party, and (ii) the individual executing this Amendment below on behalf of such party has been duly authorized to do so, and has the authority necessary to bind such party. The Parties further acknowledge, agree, and confirm that each has relied upon the foregoing representations in entering into this Amendment.

5. **Miscellaneous**. This Amendment shall be effective after both of the following occur: (i) this Amendment is executed by the Parties (such executions may be in separate counterparts and by original signature or copy); and (ii) the Settlement Agreement is executed by AnaptysBio, TESARO US, and GSK; and the Amendment once effective shall have an effective date for all purposes as of the Amendment Date. Except as expressly modified herein, the Agreement shall continue to remain in full force and effect in accordance with its terms. This Amendment may be executed in counterparts, each of which shall be deemed to be an original and together shall be deemed to be one and the same document.

IN WITNESS WHEREOF, the Parties have caused this Amendment No. 3 to Collaboration and Exclusive License Agreement to be duly executed by their respective duly authorized representatives effective as of the Amendment Date.

TESARO, INC.

By: /s/ Justin T. Huang
Name: Justin T. Huang
Title: Vice President & Secretary

ANAPTYSBIO, INC.

By: /s/ Hamza Suria
Name: Hamza Suria
Title: President & CEO

TESARO, DEVELOPMENT, LTD.

By: /s/ Justin T. Huang
Name: Justin T. Huang
Title: Director

Exhibit D

Clinical Trials Involving Dostarlimab

Name of Study	Clinicaltrials.gov Description
[*]	[*]
[*]	[*]
[*]	[*]
[*]	[*]
[*]	[*]
[*]	[*]

TERMINATION OF SUBLEASE
(Early Termination)

THIS TERMINATION OF SUBLEASE (this "**Agreement**") is dated as of November 11, 2020, between TREX ENTERPRISES CORPORATION, a California corporation ("**Sublessor**"), and ANAPTYSBIO, INC., a Delaware Corporation ("**Sublessee**") (collectively "**Parties**").

RECITALS

A. Sublessor and Sublessee are parties to a sublease dated May 18, 2018 (the "**Sublease**"), pursuant to which Sublessee subleases from Sublessor certain premises (the "**Premises**") commonly known as Suite 200 and which is an approximately 18,322 rentable square foot portion of 10455 Pacific Center Court, San Diego, CA 92121, part of the Master Premises leased by Sublessor.

B. The Sublease is subordinate to, and the Parties are subject to rights and obligations as provided in, the Lease, dated April 21, 2016 and the First Amendment thereto dated January 20, 2017 (together, the "**Master Lease**") as defined and acknowledged in the Sublease.

C. Sublessor and Sublessee desire to terminate the Sublease early in accordance with the terms and conditions set forth below. Sublessor and Sublessee desire that all other terms of the Sublease which survive the expiration or early termination of the Sublease remain in full force and effect.

NOW, THEREFORE, in consideration of the foregoing, the parties hereto agree as follows:

1. Recitals; Defined Terms. Sublessor and Sublessee hereby acknowledge and agree that all of the foregoing Recitals are true and correct and are fully incorporated herein. Except for those terms expressly defined in this Agreement, all initially capitalized terms will have the meanings ascribed to them in the Sublease.

2. Termination of Lease. The Sublease shall terminate as of 11:59 P.M. on December 15, 2020 (the "**Termination Date**"), and all rights, liabilities and duties of the parties under the Sublease and with respect to the Premises shall terminate effective as of the Termination Date as if it were the expiration date under Section 5 of the Sublease, except as provided herein. Prior to the Termination Date, all rights and obligations under the Sublease remain in full force and effect, including without limitation Sublessee's rent obligations, direct expense obligations, and other obligations.

3. Surrender Conditions. On or prior to the Termination Date, Sublessee shall (i) remove all furniture, signage, and other personal property from the Premises, (ii) return the Sublessor FF&E, including without limitation the items described in Exhibit A, and (iii) surrender the Premises, returning the vacant Premises to Sublessor in broom clean condition, and otherwise in accordance with the terms and conditions of the Sublease (as amended hereby) and Master Lease (collectively, the "**Surrender Conditions**").

4. Security Deposit. Sublessor and Sublessee acknowledge and agree that Sublessor currently holds a Security Deposit in the amount of Thirty-three thousand thirty-four and 56/100ths Dollars ($33,034.56), and that Sublessor shall return the full amount of the Security Deposit to Sublessee within five (5) business days following the Termination Date and completion of the Surrender Conditions.

5. Release. The date which is the later of (i) the Termination Date, or (ii) the date on which Sublessee surrenders the Premises to Sublessor in the Surrender Condition shall be referred to herein as

the "Surrender Date". Effective as of the Surrender Date, Sublessor and Sublessee each releases the other from all obligations and liabilities relating to the Premises accruing under the Sublease from and after the Surrender Date, excluding any obligations expressly set forth in this Agreement and obligations that are intended to survive the expiration or earlier termination of the Sublease. Notwithstanding the foregoing, nothing contained herein is intended to release either Sublessor or Sublessee from their respective obligations accruing under the Sublease prior to the Surrender Date. Without limitation of the foregoing, Sublessor's and Sublessee's respective obligations to indemnify, defend and hold the other party harmless contained in the Sublease or Master Lease shall survive the termination of the Sublease with respect to all claims, liabilities, damages, costs and expenses, including attorneys' fees, arising from or connected with circumstances, actions or omissions that occurred prior to the Termination Date.

6. Waiver. With respect to the releases set forth in Section 5 above, the Parties acknowledge that they have been advised by legal counsel and are familiar with the provisions of California Civil Code Section 1542 which provides as follows:

"A GENERAL RELEASE DOES NOT EXTEND TO CLAIMS THAT THE CREDITOR OR RELEASING PARTY DOES NOT KNOW OR SUSPECT TO EXIST IN HIS OR HER FAVOR AT THE TIME OF EXECUTING THE RELEASE AND THAT, IF KNOWN BY HIM OR HER, WOULD HAVE MATERIALLY AFFECTED HIS OR HER SETTLEMENT WITH THE DEBTOR OR RELEASED PARTY."

THE UNDERSIGNED, BEING AWARE OF SAID CODE SECTION, HEREBY EXPRESSLY WAIVE ALL RIGHTS THEY MAY HAVE THEREUNDER, AS WELL AS ANY OTHER STATUTES OR COMMON LAW PRINCIPLES OF SIMILAR EFFECT PERTAINING TO THE RELEASES SET FORTH HEREIN.

Sublessee and Sublessor each specifically acknowledges that it has carefully reviewed the provisions of this Agreement, including without limitation, Sections 5 and 6 hereof, and discussed their import with skilled legal counsel, and further acknowledge that the provisions of Sections 5 and 6 are a material part of this Agreement.

EL DD
Sublessee's Initials Sublessor's Initials

Eric Loumeau, COO Deborah A. Doyle, COO/CFO
Name/Title Name/Title

7. Brokers. Sublessor and Sublessee each represents and warrants to the other that Sublessor and Sublessee, respectively, have not authorized or employed, or acted by implication to authorize or to employ, any real estate broker or salesman to act for Sublessor or Sublessee, respectively, in connection with this Agreement. Sublessor and Sublessee shall each indemnify, defend and hold the other harmless from and against any and all claims as a result of a breach by the indemnifying party of the foregoing representation (including reasonable attorneys' fees, court costs and any commissions, if ultimately owed).

8. Attorneys' Fees. If Sublessor or Sublessee shall take any action or commence any legal proceedings against the other arising out of or in connection with this Sublease, the prevailing party shall be entitled to recover its costs of suit and reasonable attorneys' fees.

9. Miscellaneous. Except as provided above, after the Surrender Date, Sublessee shall have no further rights of any kind with respect to the Premises. Notwithstanding the foregoing, those provisions of the Sublease which, by their terms, survive the termination of the Sublease shall survive the surrender of the Premises and termination of the Sublease provided for herein.. The Parties may execute several copies of this Agreement. All copies of this Agreement bearing signatures of the Parties shall constitute one and the same Agreement, binding upon all parties. The Parties may exchange counterpart signatures by facsimile or electronic transmission and the same shall constitute delivery of this Agreement with respect to the delivering party. This Agreement contains the entire agreement and understanding between Sublessor and Sublessee concerning the subject matter of this Agreement and supersedes all prior agreements, terms, understandings, conditions, representations and warranties, whether written or oral, made by Sublessor or Sublessee concerning the Sublease or the other matters which are the subject of this Agreement.

[*signature page to follow*]

IN WITNESS WHEREOF, the parties hereto have executed this Agreement as of the date and year first above written above.

SUBLESSEE:

ANAPTYSBIO, INC.,
a Delaware corporation

By: /s/ Eric Loumeau
Name: Eric Loumeau
Title: COO

SUBLESSOR:

TREX ENTERPRISES CORPORATION,
a California corporation

By: /s/ Deborah A. Doyle
Name: Deborah A. Doyle
Title: COO/CFO

EXHIBIT A
(TERMINATION OF LEASE)

SUBLESSOR'S FF&E: (To Remain in Premises)

1. Board Room Table
2. Board Room Chairs – 15
3. Board Room Refrigerator
4. Board Room TV and Stand
5. Conference Room Installed TV
6. Conference Room Installed Whiteboard
7. Conference Room Table – No Chairs
8. Conference Room Table – No Chairs

CERTAIN CONFIDENTIAL INFORMATION MARKED [***] HAS BEEN EXCLUDED FROM THE EXHIBIT BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED.

CONFIDENTIAL SETTLEMENT AND MODIFICATION AGREEMENT

This Confidential Settlement and Modification Agreement (the "Agreement") is made and entered into on the date that it is signed by the last of the signatories identified below (the "Effective Date"), by and between (i) AnaptysBio, Inc., a Delaware corporation having its principal place of business at 10421 Pacific Center Court, Suite 200, San Diego, CA 92121 ("AnaptysBio"), (ii) Tesaro, Inc., a Delaware corporation having its principal place of business in 1000 Winter Street, Waltham, Massachusetts 02451, (iii) Tesaro Development, Ltd., a Bermuda corporation having its principal office at Clarendon House, 2 Church Street, Hamilton HM 11, Bermuda (together with Tesaro, Inc., "Tesaro"), and (iv) GlaxoSmithKline LLC, a Delaware limited liability corporation having its principal place of business at 5 Crescent Drive, Philadelphia, PA 19112 ("GSK") (Tesaro and GSK, collectively, "Defendants") (each individually the "Party" or collectively the "Parties").

RECITALS

WHEREAS, AnaptysBio and Tesaro are parties to a Collaboration and Exclusive License Agreement entered into in March 2014 as amended (the "Collaboration Agreement");

WHEREAS, Sections 14.2 and 14.4(e) of the Collaboration Agreement provide that upon material breach by Tesaro, AnaptysBio may terminate a specific Development Program (as defined in the Collaboration Agreement);

WHEREAS, AnaptysBio contends that Tesaro has materially breached the Collaboration Agreement, and AnaptysBio provided Tesaro with notice of material breach on August 20, 2020;

WHEREAS, AnaptysBio filed suit against Tesaro, Inc. and GSK in Delaware Chancery Court in a case captioned, *AnaptysBio, Inc. v. Tesaro, Inc. and GlaxoSmithKline LLC*, C.A. No. 2020-0690-KSJM (the "Action"), and Tesaro and GSK deny the allegations and claims in the Action and have asserted a number of defenses thereto;

WHEREAS, the Parties, without any admission of wrongdoing or culpability as to the Action or any of the facts relating to any claim asserted in connection with the Action, desire to avoid further disputes or litigation and fully settle their differences relating to the Action and the Collaboration Agreement;

WHEREAS, the Parties, in addition to fully settling their differences relating to the Action, and in consideration of financial payments to be made by Defendants under this Agreement and Exhibit A hereto, wish to modify the exclusivity arrangements set forth in Paragraph 5.3 of the Collaboration Agreement.

NOW, THEREFORE, in consideration of the mutual terms, obligations, covenants, and conditions contained herein, the receipt and sufficiency of which is hereby acknowledged, the Parties agree as follows:

1. **Amendment of the Collaboration Agreement.** As reflected in Amendment No. 3 to the Collaboration Agreement (the "Third Amendment"), a true and correct copy of the fully executed version of which is attached hereto as Exhibit A, the Parties have amended the Collaboration Agreement to revise the exclusivity provision of Section 5.3, the royalty table in Section 6.4(a), the payment and reporting of royalties in Section 7.3, and management of the Parties' relationship in Section 4. With respect to the interpretation of the Collaboration Agreement to the extent there is any conflict between this Agreement and the Third Amendment, the Third Amendment shall control. With respect to the interpretation of this Agreement, this Agreement will control.

2. **Zejula™ Royalties.**

2.1 Defendants hereby agree to pay AnaptysBio a royalty at a rate of 1% on (a) aggregate annual global Net Sales (as defined below) of the product known as of the Effective Date as Zejula™, and (b) [*]. For the avoidance of doubt, amounts received under (b) above shall not include [*].

2.2 "Affiliate(s)" shall mean any corporation or other entity, whether de jure or de facto, which is directly or indirectly controlling, controlled by or under common control of a Party hereto for so long as such control exists. For the purposes of this definition of Affiliate(s), "control" shall mean the direct or indirect ownership of at least fifty percent (50%) of the outstanding shares or other voting rights of the subject entity having the power to vote, or if not meeting the preceding, the maximum voting right that may be held by the particular Party under the laws of the country where such entity exists, or the power to otherwise direct the affairs of the entity.

2.3 "Net Sales" means gross invoiced sales price of Zejula™ sold by Defendants or their Affiliates (or (sub)licensees (other than the Existing Sublicensees), successors, or assigns) (The "Selling Party") in arm's length transactions to third parties, less deductions allowed to the third party customer by the Selling Party, to the extent actually taken by the third party customer, on such sales for the following [*]:

[*].

2.4 [*].

2.5 [*].

2.6 If Defendants pay royalties to any third party in a country in order to make, use, sell, offer for sale or import Zejula™ in such country, then Defendants shall have the right to credit [*] percent ([*]%) of such third

party royalty payments against the royalties owing to AnaptysBio under this Agreement with respect to sales of Zejula™ in such country; provided, however, that Defendants shall not reduce the amount of royalties owing to AnaptysBio under this Agreement to less than [*] percent ([*]%) of the royalties that would otherwise be due under this Agreement with respect to Zejula™ in such country.

2.7 All royalty payments due under this Agreement shall be made from a bank located in the United States or United Kingdom by bank wire transfer in immediately available funds to a bank account designated by AnaptysBio. All payments hereunder shall be made in U.S. dollars. [*]. In the event that any payment under this Agreement is due on a Saturday, Sunday, or national holiday, such payment may be made on the following business day.

2.8 Taxes.

Defendants will make all payments to AnaptysBio under this Agreement without deduction or withholding for taxes except to the extent that any such deduction or withholding is required by applicable law in effect at the time of payment. The Parties shall reasonably cooperate with one another to reduce or minimize any such deduction or withholding required by applicable law, including by providing any forms or other certifications necessary to reduce the amount of such withholding. If AnaptysBio, on or prior to the Effective Date, provides Defendants with an applicable, duly completed, IRS Form W-9 or applicable IRS Form W-8 (and in the case of each IRS Form W-8 certifying qualification for any applicable tax treaty of the United States), Defendants shall apply the reduced rate of withholding, or not withhold, as the case may be, provided that Defendants are in receipt of evidence, in a form reasonably satisfactory to Defendants. If, in accordance with the foregoing, Defendants withhold any amount, then they will pay to AnaptysBio the balance when due, timely remit to the proper taxing authority of the withheld amount, and send AnaptysBio proof of such remittance within [*] days following AnaptysBio's request for such proof of remittance.

2.9 Royalty Payments and Reports. Defendants shall make written reports and quarterly payments to AnaptysBio within [*] ([*]) days after the end of each calendar quarter covering Net Sales of Zejula™ by Defendants or their Affiliates during such calendar quarter, each such written report in reasonable detail [*]. Concurrent with the delivery of each such report, Defendants shall make the royalty payment due to AnaptysBio for the calendar quarter covered by such report.

Amounts due to AnaptysBio under Section 2.1(b) shall be reported and paid to AnaptysBio within [*] ([*]) days after the end of the calendar quarter in which the royalties or milestone payments are received from the Existing Sublicensees.

2.10 Any undisputed payments that are not paid on the date such payments are due under this Agreement shall bear interest to the extent permitted by applicable law [*].

2.11 Defendants shall maintain complete and accurate books and records, in accordance with their then-current accounting standards (which as of the Effective Date is GSK Accounting Standards), which are relevant to royalty payments to be made to AnaptysBio under this Agreement, which books and records shall be sufficient in detail to verify all payment amounts due to AnaptysBio hereunder. AnaptysBio shall have the right, at its own expense and not more than once in any calendar year during the term of this Agreement, to have an independent, certified public accountant selected by AnaptysBio, and under an obligation of confidence, audit the books and records of Defendants in the location(s) where such books and records are maintained upon reasonable notice (which shall be no less than sixty (60) days prior written notice) and during regular business hours, and for the sole purpose of verifying the basis and accuracy of payments required and made under this Agreement. The report and communication of such accountant with respect to such an audit shall be limited to a certificate stating whether any royalty report or payment submitted during such period is accurate or inaccurate and, if a discrepancy is identified, shall also indicate the amount and if applicable, with respect to any report, the nature of any discrepancy, and the correct information with respect to the applicable period. Such accountant shall provide the Parties with a copy of each such report simultaneously. If the audit leads to the discovery of a discrepancy: (i) to AnaptysBio's detriment, then Defendants shall pay to AnaptysBio the amount of the discrepancy within thirty (30) days of Defendants' receipt of the report and an invoice for such amount, if requested; or (ii) to Defendants' detriment, Defendants may, as applicable, credit the amount of the discrepancy against future payments payable to AnaptysBio under this Agreement, and if there are no such payments payable, then AnaptysBio shall pay to Defendants the amount of the discrepancy within thirty (30) days of AnaptysBio's receipt of the report and an invoice for such amount, if requested. Additionally, if the discrepancy is to AnaptysBio's detriment and is greater than five percent (5%) of the amount due for such audited period, then Defendants shall pay or reimburse the reasonable cost charged by such accountant for such audit. Once AnaptysBio has conducted an audit permitted by this Section 2.11 in respect of any period, it may not re-inspect Defendants' books and records in respect of such period, unless a

subsequent audit of a separate reporting period uncovers fraud on the part of Defendants that is reasonably expected to have been occurring during the prior audited period. For clarity, however, if a discrepancy is identified by the accountant during the course of an audit and the Parties do not agree upon a resolution of such discrepancy, then AnaptysBio's accountant may re-inspect the books and records to the extent reasonably relevant to resolving such discrepancy. Notwithstanding anything herein to the contrary, upon the expiration of three (3) years following the end of any calendar year, the right to audit the books and records for such calendar year shall expire and such Party shall be released from any liability or accountability with respect to the calculation of royalties payable with respect to each such calendar year. The Parties shall no longer be required to retain such books and records for any calendar year after the expiration of the third (3rd) calendar year following such calendar year.

2.12 The Parties agree that it is a condition precedent to the payment obligation of this Paragraph 2 and its subparts the Parties shall have first (i) executed the Third Amendment attached as Exhibit A and (ii) dismissed this lawsuit with prejudice as set forth in Paragraph 3.

3. **Dismissal of the Action.** Within three (3) business days of the Effective Date, and after execution of the Third Amendment, AnaptysBio shall file a stipulated notice of dismissal with prejudice of the Action pursuant to Delaware Chancery Court Rule 41(a)(1)(ii), with each Party to bear its own fees and costs.

4. **Release**

4.1 Release by AnaptysBio. Except for any claims arising from a breach of this Agreement or the Third Amendment, AnaptysBio on behalf of itself, its past, present, and/or future parents, subsidiaries, divisions, brother and sister corporations, affiliates, general and limited partners, shareholders, members, and other direct or indirect beneficial and legal owners, and each of its or their predecessors, successors, licensees, sub-licensees, and assigns (except for the Defendants); and each of all of the foregoing's past, present, or future heirs, executors, administrators, and/or purchasers; and each of all the foregoing's past, present, or future representatives, attorneys, agents, officers, directors, employees, contractors, and/or trustees, all acting in their capacity as such (collectively, the "AnaptysBio Release Parties"); hereby forever release and discharge the Tesaro/GSK Release Parties (defined below) of and from any and all manner of action, claim or cause of action, in law or in equity, suits, debts, liens, contracts, agreements, promises, liabilities, demands, losses, damages, costs or expenses, known or unknown, which exist at the time of the Effective Date of this Agreement, and which arise out of or relate (directly or

indirectly) to the claims asserted in the Action, including but not limited to (i) claims that were alleged or could have been alleged in the Action, (ii) claims related in any way to alleged violations of Tesaro's obligations under the Collaboration Agreement; and (iii) claims related in any way to liability by GSK or any other released party (e.g. affiliates) relating to Tesaro's obligations under the Collaboration Agreement or any obligations by GSK or any other released party ostensibly due AnaptysBio.

4.2 Release by Defendants. Except for any claims arising from a breach of this Agreement or the Third Amendment, Defendants on behalf of themselves, their past, present, and/or future parents, subsidiaries, divisions, brother and sister corporations, affiliates, general and limited partners, shareholders, members, and other direct or indirect beneficial and legal owners, and each of its or their predecessors, successors, licensees, sub-licensees, and assigns; and each of all of the foregoing's past, present, or future heirs, executors, administrators, and/or purchasers; and each of all the foregoing's past, present, or future representatives, attorneys, agents, officers, directors, employees, contractors, and/or trustees, all acting in their capacity as such (collectively, the "Tesaro/GSK Release Parties"); hereby forever release and discharge the AnaptysBio Release Parties of and from any and all manner of action, claim or cause of action, in law or in equity, suits, debts, liens, contracts, agreements, promises, liabilities, demands, losses, damages, costs or expenses, known or unknown, which exist at the time of the Effective Date of this Agreement, and which arise out of or relate (directly or indirectly) to the claims asserted in the Action, including but not limited to (i) claims that were alleged or could have been alleged in the Action, and (ii) claims related in any way to alleged violations of AnaptysBio's obligations under the Collaboration Agreement; and (iii) claims related in any way to liability by AnaptysBio or any other released party (e.g. affiliates) relating to AnaptysBio's obligations under the Collaboration Agreement or any obligations by any other released party ostensibly due Defendants.

4.3 "Released Claims" refers to any and all claims released pursuant to Paragraphs 4.1 and/or 4.2 of this Agreement.

4.4 To the extent necessary to fully release the Released Claims, the AnaptysBio Release Parties and Tesaro/GSK Release Parties hereby expressly waive and release any and all provisions, rights and benefits conferred by § 1542 of the California Civil Code, which reads:

> Section 1542. Certain Claims Not Affected By General Release. A general release does not extend to claims that the creditor or releasing party does

not know or suspect to exist in his or her favor at the time of executing the release, and that, if known by him or her must have materially affected his or her settlement with the debtor or released party;

or rights and benefits conferred by any law of any state or territory of the United States or any other jurisdiction or principle of common law, which is similar, comparable or equivalent to §1542 of the California Civil Code. AnaptysBio Release Parties and Tesaro/GSK Release Parties may hereafter discover facts other than or different from those which they know or believe to be true with respect to the claims that are the subject matter of Paragraphs 4.1 and 4.2, but the AnaptysBio Release Parties and Tesaro/GSK Release Parties hereby expressly waive and fully, finally and forever settle and release any known or unknown, suspected or unsuspected, contingent or non-contingent claim that would otherwise fall within the definition of Released Claims, whether or not concealed or hidden, without regard to the subsequent discovery or existence of such different or additional facts. The AnaptysBio Release Parties and Tesaro/GSK Release Parties also hereby expressly waive and fully, finally and forever settle and release any claim under federal or state law relating to the Released Claims or other proceedings of findings related thereto that they may have against the other Release Parties under §17200, et seq., of the California Business and Professions Code, or any similar, comparable or equivalent provision of the law of any other state or territory of the United States or other jurisdiction or principle of common law, which claims are hereby expressly incorporated into the definition of Released Claims. For the sake of clarity, inclusion of this subparagraph 4.4 is not intended to release known or unknown claims on any subject matter except those relating to the Released Claims.

4.5 For the avoidance of doubt, the releases provided in Paragraphs 4.1 and 4.2 above are intended to provide the broadest release permitted as a matter of law relating to the Released Claims.

4.6 Except for enforcing this Agreement or the Third Amendment, the AnaptysBio Release Parties and Tesaro/GSK Release Parties hereby mutually covenant and agree that neither shall, hereafter, seek to establish liability against the other Release Parties based, in whole or in part, on any of the Released Claims.

5. **Costs and Fees.** Each Party agrees that it shall bear its own costs and attorneys' fees associated with the Action, and its resolution through this Agreement.

6. **Authority.** Each Party represents and warrants that it has the sole right and exclusive authority to execute and perform this Agreement and that it has not

sold, assigned, transferred, conveyed, or otherwise disposed of any of the Released Claims, or any portion of or interest in any Released Claims or demand, relating to any matter covered by this Agreement.

7. **Agreement Binding.** This Agreement shall be binding upon and inure to the benefit of the Parties and their respective owners, shareholders, affiliates, partners and subsidiaries, and successors in interest and title.

8. **No Waiver.** The failure of either Party at any time to demand strict performance by the other Party of any of the terms or conditions of this Agreement shall not be construed as a continuing waiver or relinquishment thereof and each may at any time demand strict and complete performance by the other of said terms and conditions. To be enforceable, a waiver must be in writing and signed by an authorized representative of the waiving Party.

9. **No Third-Party Beneficiaries.** This Agreement shall not expand the rights of any persons who are not members of AnaptysBio, the Defendants, the AnaptysBio Release Parties, or the Tesaro/GSK Release Parties, and any such person shall not acquire any rights hereunder, whether as a purported third-party beneficiary or otherwise, except that each of the AnaptysBio Release Parties, or the Tesaro/GSK Release Parties shall be entitled to assert the release as to it.

10. **Entire Agreement.** This Agreement, together with all exhibits hereto, contains the entire, complete, and integrated statement of each and every term and provision of the settlement, and supersedes any prior negotiations, representations, promises, or warranties (oral or otherwise) made by any Party or its agents, attorneys, employees, or representatives concerning the subject of this Agreement. All understandings and agreements, if any, previously reached between the Parties are merged into this Agreement. No Party shall be liable or bound to any other Party for any prior negotiation, representation, promise, or warranty (oral or otherwise) except for those expressly set forth in this Agreement, nor has any Party relied on any such prior negotiation, representation, promise, or warranty (oral or otherwise) except for those expressly set forth in this Agreement, in entering this Agreement. For the sake of clarity, other than as set forth in Exhibit A (Third Amendment), this Agreement does not modify the Collaboration Agreement, and is a stand-alone agreement, the breach of which does not constitute a breach of the Collaboration Agreement.

11. **No Oral Modification.** No amendment or modification of this Agreement shall be valid or binding upon the Parties hereto unless made in writing and executed by authorized representatives of both Parties.

12. **No Reliance on Representations.** Each Party represents and acknowledges that in executing this Agreement, it does not rely and has not relied on any representation or statement made by the other Party or by the other Party's agents, representatives or attorneys with regard to the subject matter, basis or effect of

this Agreement, except for representations set forth in this Agreement. This Agreement is intended to be and is final and binding between the Parties regardless of any claims of misrepresentation, promise made without the intention of performing, concealment of fact, mistake of fact or law, or of any other circumstance whatsoever.

13. **Public Disclosure.** GSK and Tesaro agree to permit AnaptysBio to publicly disclose, together or individually, the items included in Exhibit B hereto.

14. **Confidentiality.** [*].

15. **No Admissions.** Nothing in this Agreement shall constitute an admission of liability, wrongdoing, or culpability by any Party.

16. **No Construction Against Drafter.** Each Party has had an opportunity to participate in the negotiation of this Agreement. If any ambiguity or question of intent arises, this Agreement shall be construed as if the Parties drafted it jointly, and any rule of construction to the effect that ambiguities are to be resolved against the drafting Party shall not apply in interpreting this Agreement.

17. **Disputes.** Any dispute arising out of or relating to the Agreement, or the breach, termination or validity thereof (a "Dispute"), shall be finally resolved pursuant to the following provisions:

17.1 [*].

18. **Territory.** The territorial scope of terms of this Agreement shall be worldwide. In any proceeding to enforce or interpret the terms of this Agreement, the prevailing Party shall be entitled to its reasonable attorneys' fees and costs.

19. **Governing Law.** This Agreement and any dispute arising from the construction, performance, or breach hereof shall be governed by and construed, and enforced in accordance with, the laws of the State of Delaware, without reference to conflicts of laws principles thereof that would remain in the application of any other law.

20. **Severability.** In the event that any provision of this Agreement or the application of any provision of this Agreement is held invalid by any competent authority, such invalidity will not affect the enforceability of other provisions, and in such event, the parties agree that such provision will be replaced with a new provision that accomplishes the original business purpose.

21. **Headings/Recitals.** The headings contained in this Agreement are for reference only. The Parties incorporate the above Recitals into this Agreement.

22. **Execution in Counterparts.** This Agreement may be executed in any number of counterparts, each of which shall be considered an original, and both of which together constitute one and the same instrument. Signature may be by DocuSign, PDF copy, or facsimile.

[*signature page follows*]

IN WITNESS WHEREOF, the authorized representatives of the Parties hereto duly execute this Agreement.

ANAPTYSBIO, INC. Dated: October 22, 2020

By: /s/ Hamza Suria

Title: President & CEO

TESARO, INC. Dated: October 23, 2020

By: /s/ Justin T. Huang

Title: Vice President & Secretary

TESARO DEVELOPMENT, LTD. Dated: October 23, 2020

By: /s/ Justin T. Huang

Title: Director

GLAXOSMITHKLINE LLC Dated: October 23, 2020

By: /s/ Justin T. Huang

Title: Secretary

Exhibit A

AMENDMENT NO. 3

TO COLLABORATION AND EXCLUSIVE LICENSE AGREEMENT

[Insert]

Exhibit B

Permitted Disclosures

GSK and Tesaro agree to permit AnaptysBio to publicly disclose, together or individually, each of the following, solely to the extent such disclosures are determined by counsel for AnaptysBio to be necessary as a matter of law:

- Revised royalty rates on dostarlimab under the Collaboration Agreement as set forth below. Royalty rates on other products resulting from a Development Antibody (TIM-3 and LAG-3) are unchanged.
    - Previous royalty rate on dostarlimab of 4-8%, where annual net sales above $1B were subject to 8% while annual sales up to $1B were subject to 4-7% royalty;
    - Amended royalty rate on dostarlimab of 8-25%, as follows:

Worldwide Annual Net Sales of a Product (on a Product-by Product basis) during the applicable calendar year during the Royalty Term:	**Royalty Rate Applicable to a Product:**
Portion less than or equal to $1 billion;	8%
Portion greater than $1 billion, but less than or equal to $1.5 billion;	12%
Portion greater than $1.5 billion, but less than or equal to $2.5 billion;	20%
Portion greater than $2.5 billion;	25%

For the sake of clarity, any reference to the royalty rates to be paid on dostarlimab shall describe the Net Sales thresholds to be met before each royalty rate is triggered.

- Tesaro agrees to pay AnaptysBio a royalty at a rate of 1% on aggregate, annual global Net Sales of Zejula™ by Tesaro or GSK and its Affiliates;
- No modification to previously disclosed milestone payments associated with dostarlimab (or other Products), including:
    - dMMR Endometrial: $20 million upon 1st US Regulatory Approval;
    - dMMR Endometrial: $10 million upon 1st EU Regulatory Approval;
    - dMMR Pan-Tumor: $10 million upon 2nd FDA BLA Acceptance;

    - dMMR Pan-Tumor: $5 million upon 2nd MAA acceptance by EMA;
    - dMMR Pan-Tumor: $20 million upon 2nd US Regulatory Approval;
    - dMMR Pan-Tumor: $10 million upon 2nd EU Regulatory Approval;

- Payment of $60 million in cash within 30 days;
- AnaptysBio has granted Tesaro the right to conduct research and development and commercialization activities as to Zejula™ regarding the categories of antagonists covered by their collaboration.
- The Parties are convening a Joint Review Committee to review the development and commercialization of dostarlimab; and
- AnaptysBio has settled its legal dispute with Tesaro and GSK and released all claims against Tesaro and GSK. Tesaro and GSK have also released all claims against Tesaro in connection with the legal dispute.

NOTE: The bullet points contained in this Exhibit B shall not be used to interpret the meaning of the Collaboration Agreement, its Amendments, or the Settlement Agreement, which shall speak for themselves.

EXHIBIT 21.1

SUBSIDIARIES OF THE REGISTRANT

Name of Subsidiary	**Jurisdiction of Incorporation or Organization**
AnaptysBio Pty Ltd	Australia

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

The Board of Directors
AnaptysBio, Inc.:

We consent to the incorporation by reference in the registration statement (Nos. 333-215741, 333-223446, 333-229927, and 333-236805) on Form S-8 of AnaptysBio, Inc. of our report dated February 25, 2021, with respect to the consolidated balance sheets of AnaptysBio, Inc. as of December 31, 2020 and 2019, the related consolidated statements of operations and comprehensive loss, stockholders' equity, and cash flows for each of the years in the three-year period ended December 31, 2020, and the related notes (collectively, the consolidated financial statements), which report appears in the December 31, 2020 annual report on Form 10-K of AnaptysBio, Inc.

/s/ KPMG LLP

San Diego, California
February 25, 2021

EXHIBIT 31.1

CERTIFICATION OF PERIODIC REPORT UNDER SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Hamza Suria, certify that:

1. I have reviewed this annual report on Form 10-K of AnaptysBio, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 25, 2021

/s/ Hamza Suria

Hamza Suria
Chief Executive Officer
(Principal Executive Officer*)*

EXHIBIT 31.2

CERTIFICATION OF PERIODIC REPORT UNDER SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Dennis Mulroy, certify that:

1. I have reviewed this annual report on Form 10-K of AnaptysBio, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 25, 2021

/s/ Dennis Mulroy

Dennis Mulroy

Chief Financial Officer
(Principal Financial Officer)

EXHIBIT 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350
AS ADOPTED PURSUANT TO SECTION 906
OF THE SARBANES-OXLEY ACT OF 2002

I, Hamza Suria, Chief Executive Officer of AnaptysBio, Inc. (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:

- the Annual Report on Form 10-K of the Company for the year ended December 31, 2020 (the "Report"), as filed with the Securities and Exchange Commission, fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company for the periods presented therein.

Date: February 25, 2021

/s/ Hamza Suria
Hamza Suria
Chief Executive Officer
(Principal Executive Officer*)*

EXHIBIT 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350
AS ADOPTED PURSUANT TO SECTION 906
OF THE SARBANES-OXLEY ACT OF 2002

I, Dennis Mulroy, Chief Financial Officer of AnaptysBio, Inc. (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:

- the Annual Report on Form 10-K of the Company for the year ended December 31, 2020 (the "Report"), as filed with the Securities and Exchange Commission, fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company for the periods presented therein.

Date: February 25, 2021

/s/ Dennis Mulroy

Dennis Mulroy
Chief Financial Officer
(Principal Financial Officer)