UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

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

For the fiscal year ended December 31, 2018

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)	**(Zip Code)**

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

Securities registered pursuant to Section 12(b) of the Act: Common Stock, Par Value $0.001 Per Share; Common stock traded on the Nasdaq stock market

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

Indicate by check mark if the Registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. YES x NO ☐

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

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

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405) is not contained herein, and will not be contained, to the best of Registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. x

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 definition of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

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

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

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

The aggregate market value of voting common equity held by non-affiliates of the Registrant was $1,518,810,407 as of June 30, 2018.

The number of shares of Registrant's Common Stock outstanding was 26,986,584 as of February 25, 2019.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's Definitive Proxy Statement relating to the 2019 Annual Meeting of Shareholders, scheduled to be held on June 11, 2019, 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, 2018.

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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 (Exchange Act), and section 27A of the Securities Act of 1933, as amended (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 candidates etokimab for patients with severe allergic and atopic diseases and ANB019 for patients with generalized pustular psoriasis, or GPP, and palmoplantar pustulosis, or PPP;
- the likelihood that the clinical data generated in any study we are performing or plan to perform in a non-US jurisdiction will be subsequently accepted by the U.S. Food and Drug Administration, or 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 etokimab and ANB019 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 United States, 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 antibody product candidates focused on unmet medical needs in inflammation. We develop our product candidates to address emerging biological targets 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, or SHM, and replicates this natural process of antibody generation *in vitro*. Our strategy is to advance the development and commercialization of our proprietary product candidates, and for certain programs, establish partnerships with leading biopharmaceutical companies where we retain certain development and commercialization rights in the United States. Our most advanced wholly-owned antibody programs, etokimab and ANB019, neutralize therapeutic targets that are genetically associated with severe inflammatory disorders in humans.

Etokimab, our anti-IL-33 antibody drug candidate previously referred to as ANB020, inhibits the activity of the interleukin-33 cytokine, or IL-33, which we believe is broadly applicable to the treatment of atopic inflammatory disorders, such as moderate-to-severe atopic dermatitis, eosinophilic asthma, chronic rhinosinusitis with nasal polyps, or CRSwNP, and potentially other allergic conditions.

We completed a Phase 2a proof-of-concept trial of etokimab in 12 moderate-to-severe adult atopic dermatitis patients in late 2017 and believe the data from this trial, presented at the 2018 American Academy of Dermatology, or AAD, and 2018 European Academy of Allergy and Clinical Immunology, or EAACI, demonstrate proof-of-concept for etokimab in moderate-to-severe adult atopic dermatitis and suggest that etokimab may provide meaningful differentiation in terms of patient convenience. We are conducting a Phase 2b randomized, double-blinded, placebo-controlled, multi-dose study in 300 adult patients with moderate-to-severe atopic dermatitis, also referred to as the ATLAS trial, to assess different dose levels and dosing frequencies of subcutaneously-administered etokimab for a 16-week treatment period followed by an eight-week monitoring period, with top-line data expected in the second half of 2019.

We recently completed a Phase 2a randomized, placebo-controlled, single dose study of etokimab in 25 severe adult eosinophilic asthma patients. We announced top-line data from an interim analysis of this Phase 2a trial in September 2018, which we believe demonstrated proof-of-concept for etokimab in severe adult eosinophilic asthma patients with rapid and sustained Forced Expiratory Volume in One Second, or FEV1, improvement. We plan to report full data from this trial, including data subsequent to the Day 64 time point, at a medical conference in 2019. We believe the interim analysis of this trial supports the continued development of etokimab in eosinophilic asthma and plan to initiate, during 2019, a multi-dose Phase 2b randomized, double-blinded, placebo-controlled trial. We may also conduct clinical studies in other severe asthma subset(s) in the future.

We are conducting a randomized, placebo-controlled Phase 2 trial of etokimab in approximately 100 adult patients with CRSwNP, also referred to as the ECLIPSE trial, which is a debilitating atopic disorder associated with elevated IL-33 pathway signaling. We anticipate top-line data from this trial to be available in the second half of 2019.

ANB019 inhibits the interleukin-36 receptor, or IL-36R, for the treatment of rare inflammatory diseases including generalized pustular psoriasis, or GPP, and palmoplantar pustulosis, or PPP, previously referred to as palmo-plantar pustular psoriasis. We completed a Phase 1 clinical trial in healthy volunteers which was presented at EAACI 2018, where ANB019 was well-tolerated by all subjects, no dose-limiting toxicities were observed, and no serious adverse events were reported among any subjects in the trial. We have subsequently initiated a 10-patient open-label, multi-dose, single-arm Phase 2 trial of ANB019 in GPP patients, also referred to as the GALLOP trial, where top-line data are anticipated in mid-2019. We have also initiated a randomized, double-blind, placebo-controlled approximately 50-patient multi-dose trial of ANB019 in PPP, also referred to as the POPLAR trial, where top-line data are anticipated in the second half of 2019.

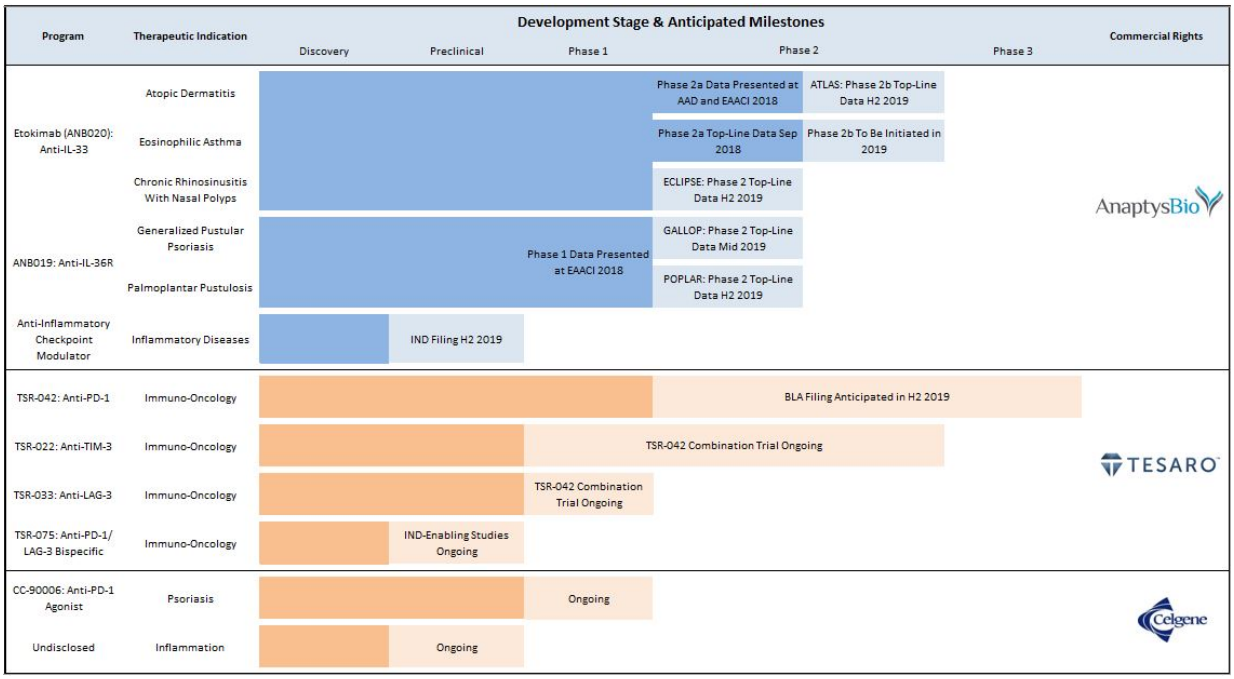
In addition to etokimab and ANB019, our wholly-owned pipeline includes novel anti-inflammatory checkpoint receptor modulator antibodies that we believe are applicable for treatment of certain autoimmune diseases where immune checkpoint receptors are insufficiently activated. We anticipate an Investigational New Drug Application, or IND, for the first such antibody in the second half of 2019.

In addition to our wholly-owned antibody programs, multiple AnaptysBio-developed antibody programs have been advanced to preclinical and clinical milestones under our collaborations. Our collaborations include an immuno-oncology-focused collaboration with TESARO, Inc. and TESARO Development, Ltd., or collectively TESARO, and an inflammation-

focused collaboration with Celgene Corporation, or Celgene. For more information about these collaborations, see "— Collaborations".

Our Product Candidates

We have developed, and will continue to develop, antibody product candidates that leverage emerging insights into biological mechanisms to treat severe diseases with unmet medical need. The following table summarizes certain key information about our wholly-owned and partnered product candidates:



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, and have completed a Phase 1 trial of etokimab in healthy volunteers, which we believe has demonstrated favorable safety and *ex vivo* pharmacodynamic properties. We have completed a Phase 2a trial of etokimab in patients with moderate-to-severe adult atopic dermatitis where top-line data efficacy was announced in October 2017 and completed trial data was presented at the 2018 AAD Annual Meeting and EAACI 2018. We are currently conducting an on-going Phase 2b randomized, double-blinded, placebo-controlled, multi-dose study in 300 adults patients with moderate-to-severe atopic dermatitis, also referred to as the ATLAS trial, to assess different dose levels and dosing frequencies of subcutaneously-administered etokimab for a 16-week treatment period followed by an eight-week monitoring period, with top-line data expected in the second half of 2019. We have completed a severe adult eosinophilic asthma Phase 2a trial where interim analysis top-line data was announced during September 2018, which we believe supports the continued development of etokimab in eosinophilic asthma and plan to initiate a multi-dose Phase 2b randomized, double-blinded, placebo-controlled trial during 2019. We have initiated a Phase 2 trial of etokimab in patients with CRSwNP, also referred to as the ECLIPSE trial, and anticipate top-line data from this trial to be available in the second half of 2019. We have conducted a Phase 1 clinical trial in healthy volunteers to assess the safety, pharmacokinetics and pharmacodynamics of ANB019 and have announced top-line data from this trial in November 2017 and complete data at EAACI 2018. We have subsequently initiated two Phase 2 studies of ANB019 in GPP and PPP patients during 2018, also referred to as the GALLOP and POPLAR trials, respectively, where top-line data are anticipated in mid-2019 and in the second half of 2019, respectively.
- **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. We may build sales and marketing capabilities in the United States with a focused commercial organization. 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, etokimab and ANB019, are described below:

Etokimab: Anti-IL-33 Antibody

Overview

Etokimab is a potentially first-in-class antibody that inhibits the activity of IL-33 and is being developed to treat atopic diseases, including moderate-to-severe adult atopic dermatitis, severe adult peanut allergy and severe adult eosinophilic asthma. Despite the key role of IL-33 in atopic diseases, it has been historically difficult for other antibody technologies to generate a functional anti-IL-33 therapeutic agent. We believe etokimab is the most advanced antibody therapeutic candidate in development targeting the IL-33 cytokine. We have completed a Phase 1 trial of etokimab in healthy volunteers, completed a Phase 2a clinical trial of etokimab in moderate-to-severe atopic dermatitis, completed a Phase 2a clinical trial of etokimab in severe peanut allergy patients, completed a Phase 2a trial of etokimab in severe adult eosinophilic asthma patients and are currently enrolling a Phase 2b clinical trial of etokimab in patients with moderate-to-severe atopic dermatitis and a Phase 2 clinical trial of etokimab in patients with CRSwNP.

IL-33 Target Biology

IL-33 is a pro-inflammatory cytokine that signals through the ST2 receptor, which multiple studies suggest serves as a central mediator of various immune responses leading to Th2-type inflammatory disorders, including atopic dermatitis, food allergies, asthma and other atopic diseases. In response to pathogens, viruses, toxins or allergens, IL-33 is rapidly released from mucosal epithelial and endothelial cells. For example, a recent scientific study has indicated that individuals with asthma symptoms express higher levels of IL-33 than healthy control subjects. IL-33 initiates a diverse array of cellular immune responses, including the activation of mast cells, basophils and eosinophils, leading to production of downstream cytokines, such as IL-4, IL-5 and IL-13, which are associated with atopic diseases. IL-33 also acts on T helper 2, or Th2, effector cells and Innate Lymphoid Cell Type 2, or ILC2, two types of white blood cells that initiate and orchestrate atopic responses.

Because etokimab inhibits IL-33 function and acts upstream of key cell types involved in atopy and the subsequent release of Th2 cytokines, we believe that its mechanism has advantages over that of competing therapeutic antibodies which block only a subset of IL-4, IL-5 or IL-13 cytokines.

Genetic studies support the importance of the IL-33 pathway in atopic diseases. These studies have demonstrated that certain ST2 mutations reduce IL-33 mediated signaling and thereby protect individuals with mutated ST2 from asthma. Certain studies also demonstrate that mutation that increases IL-33 mediated signaling increases incidence of asthma and atopic dermatitis. This supports the hypothesis that an anti-IL-33 antibody, such as etokimab, has the potential to benefit asthma, atopic dermatitis and CRSwNP patients.

We believe that targeting IL-33 activity is a more promising therapeutic intervention strategy than targeting its receptor, ST2, because (i) ST2 is present in significantly larger quantities, in comparison to IL-33, which will likely require high anti-ST2 antibody dosing levels, (ii) anti-ST2 antibodies are likely to be internalized *in vivo*, which will likely require frequent

dosing and (iii) soluble ST2 inhibits IL-33 function, therefore blocking ST2, and likely leading to the release of additional IL-33, thereby exacerbating atopic disease.

Etokimab Description

Etokimab, which is a potential first-in-class therapeutic antibody, is our wholly-owned anti-IL-33 antibody product candidate generated using our SHM technology platform. The potency and functional activity of etokimab for human and cynomolgus monkey IL-33 was measured using standard *in vitro* assays: equilibrium dissociation constant, or KD, and half-maximal inhibitory concentration values, or IC50. Etokimab demonstrated highly potent KD values of approximately 1 pM and 37 pM for human and cynomolgus monkey IL-33, respectively. Etokimab inhibits secretion of IL-5 from primary basophils purified from peripheral blood of healthy human subjects with an IC50 of approximately 1.5 nM, which is approximately 15-fold greater than that of the soluble ST2 antagonist. Lower KD and IC50 values indicate higher potency and functional activity, respectively.

Using peripheral blood mononuclear cells, or PBMC, etokimab inhibited human and cynomolgus monkey interferon-gamma release with an IC50 of approximately 1.1 nM and approximately 20.4 nM, respectively. We have developed a whole blood version of the PBMC assay, which we used in our Phase 1 trial to understand the pharmacodynamic activity of etokimab in clinical trials.

Our preclinical development has also demonstrated that etokimab has favorable manufacturability, pharmacokinetics and toxicology to support development. Studies have demonstrated desirable manufacturing properties for etokimab, including robust expression from Chinese hamster ovary cells, or CHO cells, efficient purification using standard downstream techniques and stable formulation up to concentrations required for subcutaneous dosing in humans. Etokimab demonstrated a half-life of approximately seven days in cynomolgus monkeys, retained full functional activity when incubated in normal human serum at 37 °C for one week and proved to be fully active in cynomolgus monkey sera two weeks after dosing. We have conducted preclinical toxicology studies under good laboratory practices, or GLPs, for etokimab. In addition, we have conducted manufacturing under good manufacturing practice to produce etokimab in quantities for clinical use.

Clinical Development Plan

We have completed a Phase 1 trial of etokimab in healthy volunteers in Australia under an approved Clinical Trial Notification, or CTN. Our Phase 1 trial assessed, in single ascending doses, or SAD, and multiple ascending doses, or MAD, safety, tolerability and pharmacokinetic characteristics of etokimab. The SAD cohorts of this Phase 1 trial have been completed and, subsequent to review of the clinical data generated under the SAD, the Australian regulatory authority approved the initiation of MAD cohorts, which have also been completed. In the double-blind, placebo- controlled Phase 1 trial, 96 healthy volunteer subjects were dosed with either a single subcutaneous or intravenous dose of etokimab ranging between 10 mg and 750 mg, or four multiple doses of etokimab ranging between 40 mg and 300 mg over a period of four consecutive weeks. In the SAD portion of our Phase 1 clinical trial of etokimab, 51 subjects (80%) experienced at least one treatment-emergent adverse events, or AE, however the occurrence of AEs was similar between etokimab (38 of 48; 79%) versus placebo (13 of 16, 81%) dosed individuals, and the most common AEs were upper respiratory tract infection (etokimab 48% vs. placebo 50%) and headache (etokimab 27% vs. placebo 31%). The only serious adverse event reported in the SAD portion of the trial was severe neutropenia 22 days post single dose of intravenous 750 mg etokimab in a single subject. Neutrophil levels in this subject returned to normal by 29 days post-dose and this event was preceded by prodromal viral symptoms consistent with an on-going viral infection. In the MAD portion of the Phase 1 clinical trial of etokimab, 24 subjects (75%) experienced an AE, however there was no difference in the percentage of AEs observed amongst subjects dosed with etokimab (18 of 24, 75%) versus placebo (6 of 8, 75%), and the most common AEs were upper respiratory tract infections (etokimab 21% versus placebo 38%) and headache (etokimab 33% versus placebo 38%). No severe adverse events were reported in the MAD portion of the clinical trial. None of these adverse events were determined to be drug-related and no dose-limiting toxicities were observed at any dose level. We concurrently evaluated the pharmacodynamics of etokimab in the SAD portion of the Phase 1 study using a whole blood *ex vivo* assay upon stimulation with IL-33/IL-12, where etokimab inhibition of IFN-gamma release was measured. Persistent and nearly complete inhibition was observed at 1032 hours (day 43) post-dosing for all SAD cohorts dosed with 40 mg etokimab or greater, regardless of whether such dose was through a subcutaneous or intravenous route of administration. In the 300 mg and 750 mg IV dosed cohorts of the SAD portion of the study, the pharmacodynamic assay was also performed at 2040 hours (day 85) post-dosing, and nearly complete IFN-gamma inhibition was observed through this time point. Pharmacokinetic testing indicated that the terminal half-life of etokimab among the SAD cohorts was approximately 372 hours (15–16 days) with comparable values across all doses and regardless of intravenous or subcutaneous route of administration. Anti-drug antibodies were detected at only low titer levels, and were observed in 5 of 48 etokimab dosed subjects in the SAD cohorts and 2 of 24 etokimab dosed subjects in the MAD cohorts, and no effect was observed on pharmacokinetic parameters

in any of the subjects with anti-drug antibody titers. All safety information generated under the single-ascending dose segment of our Phase 1 clinical trial was included in the US IND and UK Clinical Trial Authorisation, or CTA, submissions which have been subsequent cleared. There were no adverse events that were determined to be drug-related, and no dose-limiting toxicities were observed at any dose level. We have concurrently utilized a whole blood *ex vivo* assay to evaluate pharmacodynamics, and we believe the results of this assay suggest that the pharmacodynamic activity of etokimab can, at certain dose levels, extend to three months subsequent to a single administration. We disclosed detailed data from this Phase 1 trial at the AAD and AAAAI conferences in early March 2017.

We have subsequently completed a Phase 2a trial of etokimab in 12 moderate-to-severe adult atopic dermatitis patients, under an approved CTA with the U.K. Medicines and Healthcare Products Regulatory Agency, or MHRA, announced top-line data from an interim analysis of this trial in October 2017 and presented data upon completion of this trial at the 2018 AAD Annual Meeting on February 17, 2018, and EAACI 2018.

The Phase 2a proof-of-concept trial enrolled 12 moderate-to-severe adult atopic dermatitis patients, who were initially administered a single intravenous dose of placebo within 14 days of enrollment, followed by a single intravenous 300mg dose of etokimab one week subsequent to placebo. Prior to enrollment in the study, patients were not permitted any systemic or topical medications during a wash-out period. Patients were permitted to take a monitored amount of topical corticosteroids as rescue therapy during the course of the study. Clinical response was assessed by a number of endpoints, including the improvement of each patient's Eczema Area Severity Index, or EASI, score, a tool used to measure the extent and severity of atopic dermatitis, at key time points following etokimab administration relative to their enrollment baseline. The average baseline EASI score at enrollment amongst all 12 patients was 32. Other efficacy endpoints measured during the trial included the 5-D pruritus scale which measures itchiness, the 5-point Investigator's Global Assessment, or IGA, scale, the Dermatology Life Quality Index, or DLQI, and the SCORing Atopic Dermatitis, or SCORAD, scale. Exploratory mechanistic biomarkers included granulocyte infiltration and cytokine levels in localized skin lesions measured five days after placebo administration and five days after etokimab administration.

Trial data indicated rapid and sustained clinical achievement of EASI-50, which is 50% or better improvement in EASI score relative to enrollment baseline, in 83% of patients at Day 29, and the 5-D pruritus score was reduced by 32% relative to enrollment baseline. As early as Day 15 post-etokimab administration, 75% of patients reached EASI-50 and pruritus was reduced by 28%, which was sustained until Day 57 when 75% of patients achieved EASI-50; pruritus was reduced by 21% at Day 57. All 12 patients achieved EASI-50 on or before Day 57 post-etokimab administration. Efficacy was sustained in some patients by Day 140 post-etokimab administration where 42% of patients achieved EASI-50. etokimab efficacy was not limited by disease severity as etokimab had similar EASI score improvement in the 7 of 12 enrolled patients treated with systemic immuno-modulators pre-study, which exhibited an average EASI baseline score of 36 upon enrollment, relative to the remaining 5 of 12 enrolled patients that did not require systemic immuno-modulators pre-study, which exhibited an average EASI baseline score of 27. Twenty five percent of patients enrolled in this study achieved an IGA score of 0 or 1, indicating clear or almost clear skin, subsequent to a single etokimab administration. Average DLQI score was maximized at 55% on Day 78 following etokimab dosing and sustained to 43% at Day 140 relative to baseline. SCORAD efficacy was maximized at 40% at Day 29 following etokimab dosing and sustained to 32% at Day 140 relative to baseline. Exploratory biomarker assessment indicated reduction of granulocyte infiltration into localized skin lesions by an average of 30% amongst all patients and 60% among the 10 patients achieving EASI-50 at 29 days post-etokimab administration, while exploratory cytokine biomarker levels were below detection limit and therefore inconclusive. Etokimab was generally well-tolerated by all patients and no drug-related safety signals were observed. The most frequent adverse events reported were dizziness in 17% of patients post-placebo and headache in 25% of patients post-etokimab administration, while one serious adverse event of severe depression was reported by a single patient on Day 140 post-etokimab, which was deemed not drug related since the patient had a 10 year pre-trial history of severe depression.

We believe the data from this trial demonstrate proof-of-concept for etokimab in moderate-to-severe adult atopic dermatitis and suggest that etokimab may provide meaningful differentiation in terms of patient convenience. We are conducting a Phase 2b randomized, double-blinded, placebo-controlled, multi-dose study in 300 adult patients with moderate-to-severe atopic dermatitis, also referred to as the ATLAS trial, to assess different dose levels and dosing frequencies of subcutaneously-administered etokimab in the US and Europe. Efficacy will be assessed at week 16 post-subcutaneous dosing, with an eight week monitoring period, using percentage change in EASI and we anticipate top-line data from this trial to be available in the second half of 2019. Sixty patients are being randomized into each of five arms in this trial, where dosing will occur as follows: (i) initial 600mg loading dose followed by 300mg monthly doses of etokimab, (ii) initial 300mg loading dose followed by 150mg monthly doses of etokimab, (iii) initial 300mg loading dose followed by 150mg doses of etokimab every eight weeks, (iv) monthly 20mg doses of etokimab and (v) monthly doses of placebo.

We recently completed, under a CTA with the MHRA in the United Kingdom and under an IND, with the U.S. Food and Drug Administration, or FDA, a randomized, placebo-controlled Phase 2a trial of etokimab in 25 severe adult eosinophilic asthma patients who were randomized between a single 300mg intravenous dose of etokimab or placebo upon enrollment (Day 1) at six sites located in the United States and the United Kingdom. Upon screening, which occurred 7 to 14 days prior to enrollment, patients were required to have a blood eosinophil count of at least 300 per microliter, confirmed clinical diagnosis of severe asthma according to the Global Initiative for Asthma, or GINA, 2016, pre-bronchodilator Forced Expiratory Volume in One Second, or FEV1, of less than 80% of predicted and at least one asthma exacerbation within the past 12 months requiring use of rescue medication. Patients were required to be stably maintained on high-dose inhaled corticosteroids, or ICS, and long-acting beta-2- agonists, or LABA, for at least three months prior to screening and were required to continue ICS/LABA therapy during the course of this trial. Baseline clinical assessments were conducted for each patient on Day 1 prior to etokimab or placebo dose, and patients completed follow-up clinical assessments on Days 2, 8, 22, 36 and 64 as of an interim analysis. The last monitoring visit for each patient occurred on Day 127 post-dose. Baseline parameters of etokimab-dosed patients (n=12) were 545 blood eosinophils per microliter, 2.5 liters FEV1 and 65% predicted FEV1, while placebo-dosed patients (n=13) had 705 blood eosinophils per microliter, 2.5 liters FEV1 and 66% predicted FEV1. Nine of 12 (75%) etokimab-dosed patients were male with an average age of 41, while nine of 13 (69%) placebo-dosed patients were male with an average age of 36.

We announced top-line data an interim analysis of this Phase 2a trial in September 2018, which we believe demonstrated proof-of-concept for etokimab in severe adult eosinophilic asthma patients with rapid and sustained FEV1 improvement. Etokimab-dosed patients rapidly improved lung function by Day 2, where FEV1 increased by 8% over placebo. FEV1 increase was sustained at Day 64, where etokimab-dosed patients demonstrated 11% increase over placebo. Blood eosinophil reduction, which is a biomarker illustrative of etokimab's mechanistic breadth, was observed at 31% over placebo at Day 2 and sustained to 46% over placebo at Day 64. This reduction correlated with FEV1 improvement and was consistent with the blood eosinophil effects observed in a prior single dose etokimab trial in moderate-to-severe atopic dermatitis patients. Etokimab was generally well-tolerated by all patients and no serious adverse events have been reported to date. No treatment-emergent adverse events were deemed to be etokimab-related, and the most frequent treatment-emergent adverse events reported were single occurrences of moderate strep throat in two etokimab-dosed patients and single occurrences of mild vomiting in two placebo-dosed patients. No exacerbations or rescue therapy usage has been reported as of the interim analysis. We plan to report full data from this trial, including data subsequent to the Day 64 timepoint, at a medical conference in 2019. We believe the interim analysis of this trial supports the continued development of etokimab in eosinophilic asthma and plan to initiate, during 2019, a multi-dose Phase 2b randomized, double-blinded, placebo-controlled trial. We may also conduct clinical studies in other severe asthma subset(s) in the future.

We are conducting, under an IND to the FDA a randomized, placebo-controlled Phase 2 trial of etokimab in approximately 100 adult patients with CRSwNP which is a debilitating atopic disorder associated with elevated IL-33 pathway signaling. Patients in this trial, also known as the ECLIPSE trial, will be randomized between three subcutaneous dosing cohorts, each in combination with mometasone furoate nasal spray as background therapy, as follows: (i) initial 300mg loading dose followed by 150mg monthly doses of etokimab, (ii) initial 300mg loading dose followed by 150mg doses of etokimab every eight weeks, and (iii) monthly doses of placebo. Efficacy will be assessed at week 16 post-dosing, with an eight week monitoring period, using the bilateral endoscope Nasal Polyp Score and Sino-Nasal Outcome Test and we anticipate top-line data from this trial to be available in the second half of 2019.

Each of the aforementioned clinical trials are subject to regulatory review by the respective regulatory authority applicable to the jurisdiction of the trial.

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.

Etokimab Market Opportunity

A significant portion of individuals in the U.S. population experiences at least one atopic disease during their lifetime, and it is well understood that most patients with one type of atopic condition tend to present with other allergic conditions. While we believe etokimab may be effective across atopic diseases, we have prioritized our development efforts based on unmet medical need and potential market opportunity. We have chosen to focus our etokimab program initially on three indications: moderate-to-severe atopic dermatitis, eosinophilic asthma, and CRSwNP.

Atopic Dermatitis. Atopic dermatitis is a chronic inflammatory skin disease that affects approximately 1.4 million adults in the United States. Human studies have demonstrated that IL-33 is highly expressed in atopic dermatitis lesions and

leads to the recruitment of downstream cytokines (IL-4, IL-5 and IL-13) and eosinophils to the disease site in patients. By inhibiting IL-33 function in patients, we believe etokimab will suppress the production of the aforementioned downstream cytokines and lead to therapeutic benefit in patients with moderate to severe adult atopic dermatitis.

Current therapies for atopic dermatitis include the topical use of non-biologic small molecules and anti-IL-4/13 receptor antibody known as dupilumab (Dupixent®). Dupilumab has been approved for the treatment of adults with moderate-to-severe atopic dermatitis that is not well controlled with prescription topical therapies or for those who cannot use topical therapies. While dupilumab has shown some benefit in disease remission, it requires the administration of a substantial antibody dose (300 mg) every other week, which we believe may not be convenient for atopic dermatitis patients. In addition, a significant number of atopic dermatitis patients taking dupilumab have reported conjunctivitis as a drug-related side effect.

Based upon public data analyses and discussions with physicians and key opinion leaders in the field, we believe approximately 280,000 atopic dermatitis patients in the United States are diagnosed with a moderate-to- severe form of this disease that significantly impairs their daily professional and social lifestyle.

Asthma. We estimate, based on our analysis of publicly available data sources and interviews with physicians and key opinion leaders in the field that asthma affects approximately 7.7% of the adult U.S. population, or 19.0 million individuals, of which 1.1 million individuals have severe disease that cannot be controlled by standard-of-care therapy, of which 50% are believed to be eosinophilic patients. As a chronic inflammatory disorder, severe asthma can lead to permanent structural damage to the airways and long-term reductions in lung function. Although many mild-to-moderate asthmatics respond well to currently available treatments, which include inhaled corticosteroids, or ICS, and long-acting beta agonists, or LABA, severe asthma in patients is generally not adequately controlled by such available therapies.

We believe that etokimab may have therapeutic benefit across a broad range of ICS-refractory severe adult eosinophilic asthma patients, and plan to differentiate etokimab's therapeutic efficacy, dosing frequency and safety relative to competitors.

Chronic Rhinosinusitis with Nasal Polyps. We estimate that CRSwNP, based on our analysis of publicly available data sources and interviews with physicians and key opinion leaders in the field, affects approximately 1.3 million adults in the United States and we estimate that 400,000 of these patients are inadequately controlled with standard-of-care. CRSwNP is a debilitating chronic atopic condition associated with elevated IL-33 expression. Patients with CRSwNP that do not respond to standard-of-care are likely to undergo recurring surgeries to remove nasal polyps that block airflow through the nasal passages and often lead to recurring infections and related discomfort.

ANB019: Anti-IL-36R Antibody

Overview

ANB019 is an antibody that inhibits the function of IL-36R, which we are initially developing as a potential first-in-class therapy for GPP and PPP patients. GPP is a life-threatening, rare systemic inflammatory disorder reported to affect approximately 3,000 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 also plan to develop ANB019 for other IL-36R driven inflammatory conditions, including PPP, which is reported to affect approximately 150,000 patients in the United States. We plan to seek FDA Orphan Drug Designation for ANB019 for the treatment of GPP and PPP, which we believe may be differentiated from the non-rare plaque psoriasis, or psoriasis vulgaris, based upon distinctive genetic and translational features unique to GPP and/or PPP. We have completed a Phase 1 trial of ANB019 in healthy volunteers in Australia under an approved CTN, have received clearance of a CTA filing to the MHRA and an IND filing with the FDA, and have initiated a 10-patient open-label, multi-dose, single-arm Phase 2 trial of ANB019 in GPP patients, also referred to as the GALLOP trial, where top-line data are anticipated in mid-2019 and have cleared an IND with the FDA and have initiated, in the United States, a randomized, double-blind, placebo-controlled approximately 50-patient multi-dose trial of ANB019 in PPP, also referred to as the POPLAR trial, where top-line data are anticipated in the second half of 2019.

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 conducted by AnaptysBio 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 ANB019 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 disease, including GPP and PPP.

ANB019 Description

ANB019 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.

ANB019 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 ANB019 for human and cynomolgus monkey IL-36R was measured using standard *in vitro* assays to determine KD, and IC 50 values. ANB019 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 ANB019 is at least 100-fold greater than IL-36RA in human systems, which is measured as the IC 50 of inhibition of interleukin-8, or IL-8, release from human keratinocytes.

ANB019 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 K D and IC 50 values indicate higher potency and functional activity, respectively. Similar IC 50 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 ANB019 in cynomolgus monkeys is more than nine days. ANB019 is well-expressed from CHO mammalian 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 CTN, a Phase 1 clinical trial in healthy volunteers for which we announced positive top-line results from an interim analysis of this trial and subsequently presented completed data from this trial at EAACI 2018. In the double-blinded, placebo-controlled healthy volunteer Phase 1 trial, 36 subjects were administered a single subcutaneous or intravenous dose of ANB019 ranging between 10 mg and 750 mg, 18 subjects were administered multiple ascending doses of ANB019 intravenously ranging between 40 mg and 300 mg weekly for four consecutive weeks and 18 subjects were dosed with placebo. ANB019 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 ANB019 versus six of 12 (50%) subjects dosed with placebo, and headache in 10 of 36 (28%) subjects dosed with ANB019 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 ANB019 versus one of six (17%) subjects dosed with placebo. No serious adverse events were reported among any subjects in the trial. The *in vivo* half-life of ANB019 was approximately 28 days for both subcutaneous and intravenous routes of administration, with bioavailability of approximately 90 percent. A single dose of ANB019 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 ANB019 and other results demonstrated by this Phase 1 trial support advancement of ANB019 into Phase 2 studies for GPP and PPP.

We have received clearance of a CTA filing to the MHRA and an IND filing with the FDA, and have initiated a 10-patient open-label, multi-dose, single-arm Phase 2 trial of ANB019 in GPP patients, also referred to as the GALLOP trial, where top-line data are anticipated in mid 2019. All patients in the GALLOP study are dosed with a 750mg intravenous loading dose of ANB019 upon enrollment, followed by 100mg subcutaneously-administered monthly doses of ANB019 for a treatment period of up to 16 weeks post enrollment and then monitored for a total of 8 weeks. We have cleared an IND with the FDA and have initiated, in the United States, a randomized, double-blind, placebo-controlled approximately 50-patient multi-dose trial of ANB019 in PPP, also referred to as the POPLAR trial, where patients are randomized between two subcutaneous dosing cohorts, as follows: (i) an initial loading dose of 200mg followed by 100mg monthly doses of ANB019 and (ii) monthly doses of placebo, for a treatment period of 16 weeks post enrollment, with a subsequent monitoring period of 8 weeks. We anticipate top-line data from the POPLAR trial in the second half of 2019.

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.

ANB019 Market Opportunity

IL-36R cytokine dysfunction is implicated in multiple inflammatory disorders including GPP and PPP.

Generalized Pustular Psoriasis. 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.

Through assessment of public literature and primary key opinion leader discussions, we estimate GPP affects approximately 3,000 individuals in the United States. We have conducted, and will continue to conduct, translational studies to identify GPP patients for potential enrollment in our ongoing clinical trials in this indication. Given the limited size of this patient population in the United States, we plan to seek Orphan Drug Designation from the FDA for ANB019 for the treatment of GPP. The FDA may grant Orphan Drug Designation to a product intended to treat a rare disease or condition—generally one that affects fewer than 200,000 individuals in the United States. If we obtain Orphan Drug Designation for ANB019 for the treatment of GPP and subsequently are the first Biologics License Application, or BLA applicant to receive FDA approval for a product containing the same active molecular structure as ANB019, ANB019 would be entitled to a seven-year exclusive marketing period in the United States for the treatment of GPP. Although the GPP patient population is small, we believe there is an unmet medical need that ANB019 may be able to address.

Palmoplantar Pustulosis. PPP is a non-fatal form of pustular psoriasis that we estimate affects approximately 2% of total psoriasis cases, 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 ANB019 in this indication as well.

Checkpoint Receptor Agonist Programs

Our strategy includes the discovery and development of therapeutic antibodies targeting emerging opportunities in inflammation. We are developing checkpoint receptor agonist antibodies to multiple different novel anti-inflammatory checkpoint receptor modulator antibodies for the treatment of certain autoimmune diseases where we believe checkpoint receptor function is insufficiently activated. Known human immune checkpoint receptors include CTLA-4, PD-1, LAG-3, BTLA and TIGIT. We anticipate an Investigational New Drug Application, or IND, for the first such antibody in the second half of 2019.

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 10 9 or 10 10 range, 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

TESARO

In March 2014, we entered into a collaboration and exclusive license agreement with TESARO. We executed an amendment in November 2014 to add an additional dual-reactive antibody product candidate. Under the terms of the amended agreement, we granted TESARO 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 TESARO 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 amended agreement, 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. TESARO 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 TESARO 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, both TESARO 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 agreement as of December 31, 2016 to generate and develop antibodies to certain defined stages of preclinical development.

Under the terms of this agreement, TESARO made up-front, non-creditable and non-refundable cash payments aggregating $19.0 million to us during 2014. TESARO 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 TESARO is granted exclusive rights, TESARO 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. TESARO will also be required to pay us tiered single-digit royalties, 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.

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

On December 3, 2018, GlaxoSmithKline plc announced an agreement to acquire TESARO. This acquisition closed on January 22, 2019.

Celgene

In December 2011, we entered into a collaboration agreement with Celgene, or the Collaboration Agreement, to develop human therapeutic antibodies against multiple biological targets. We completed our responsibilities under the terms of

the agreement to generate antibodies against various mutually agreed biological targets during fiscal 2014. On a target-by-target basis, we provided Celgene 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 Celgene has exercised its option with respect to antibodies against three targets. Celgene 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 trial, while the other program is currently in preclinical development.

Upon execution of the Collaboration Agreement in 2011, Celgene paid us a one-time, non-refundable, non- creditable initial fee of $6.0 million. Celgene has reimbursed us for specified research costs in accordance with the research plans. Celgene 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. Celgene 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 ten years after the first commercial sale of the product in such country.

The Collaboration Agreement continues until our royalty rights on any Celgene 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 Celgene may terminate the agreement in the event of an uncured material breach by the other party.

On January 3, 2019, Bristol-Myers Squibb Co. announced an agreement to acquire Celgene Corp. This acquisition is expected to close in the third quarter of 2019.

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 million and 1% of annual net sales of products worldwide above $750 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 19 patents and three pending patent applications 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 ANB019. We believe our Australian subsidiary will be eligible for certain financial incentives made available by the Australian government for biotech research and development expenses. Specifically, Australia provides a refundable tax credit in the form of a cash rebate equal to 43.5% of qualified expenditures on biotech research and development projects to Australian companies that operate the majority of their research and development activities associated with such projects in Australia. A wholly-owned Australian subsidiary of a non-Australian parent company is eligible to receive the refundable tax credit, provided that the Australian subsidiary retains the rights to the data and intellectual property generated in Australia, and provided that the total revenues of the parent company and its consolidated subsidiaries during the period for which the refundable tax credit is claimed are less than $20.0 million Australian dollars.

In addition, 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 and patents licensed from Kyoto University, consisted of approximately 44 issued patents and 109 pending patent applications as of December 31, 2018.

For our product candidates, generally we initially pursue patent protection covering compositions of matter, antibody sequence diversity, epitopes, functional activity and methods of use. Throughout the development of our product candidates, we seek to identify additional means of obtaining patent protection that would potentially enhance commercial success, including through additional methods of use and biomarker and companion diagnostic related claims.

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

Etokimab

As of December 31, 2018, we owned approximately 34 patent applications in various countries directed to the antibody sequence of etokimab and its variants, epitopes, 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 October 2038.

ANB019

As of December 31, 2018, we owned 15 patent applications in various countries directed to the antibody sequence of ANB019 and its variants, epitopes, 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 April 2036.

Platform Technology

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

Our wholly-owned portfolio includes patents and patent applications 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 February 2034.

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, in the United States, 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 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 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, ANB019 and etokimab, including major pharmaceutical companies. For atopic dermatitis, our competitors include dupilumab (Dupixent, Regeneron, Sanofi), which has been approved by the FDA, crisaborole (EUCRISA, Pfizer), which has been approved by the FDA, VTP-38543 (Vitae, acquired by Allergan), JAK inhibitors such as baricitinib, PF-04965842 and upadacitinib under development by Lilly/Incyte, Pfizer and Abbvie, respectively, an IL-33 program by Regeneron (REGN3500) in a Phase 2 clinical trial for atopic dermatitis, a recently announced IL-33 related program by Pfizer (PF-06817024) in a Phase 1 clinical trial indicated for various indications, a recently announced IL-33 related program by Lilly in a Phase 1 clinical trial indicated for autoimmune disorders, an IL-1 alpha antibody, bermekimab (XBiotech) and antibodies that bind to IL-13 such as lebrikizumab (Dermira) and tezepelumab (AMG157, MEDI9929, Amgen/AstraZeneca).

For asthma, our competitors include omalizumab (Xolair; Roche), which has received FDA approval and functions by inhibiting the binding between free IgE and FceRI; antibodies that bind IL-5 and inhibit its interaction with the IL-5 receptor such as mepolizumab (Nucala; Glaxosmithkline) and reslizumab (Cinqair; Teva), both of which the FDA has approved for the

add-on maintenance treatment in patients with severe eosinophilic asthma; antibodies such as benralizumab (FASENRA, AstraZeneca) that bind the IL-5 receptor; antibodies that bind the IL-4 receptor and inhibit its signaling through IL-4 and IL-13 cytokines such as dupilumab (Dupixent; Regeneron/Sanofi), which has been approved by the FDA for use with other asthma medicines for the maintenance treatment of moderate-to-severe asthma in patients aged 12 years and older whose asthma is not controlled with their current asthma medicines; antibodies that bind to IL-13 such as lebrikizumab (Dermira), tralokinumab (AstraZeneca, LEO Pharma) and anrukinzumab (Pfizer), which are in clinical testing; antibodies that bind the IL-4 receptor alpha chain, such as AMG 317 (Amgen) in clinical testing; ST2-binding antibodies including Roche's RG6149, GSK's GSK3772847 and Regeneron's IL-33 antibody (REGN3500), each in clinical development for asthma and related conditions; a recently announced IL-33 related program by AstraZeneca (MEDI3506) in a Phase 1 clinical trial indicated for chronic obstructive pulmonary disease; DP-2 antagonists including fevipiprant (Novartis) under development for asthma and GB001 (Gossamer Bio) under development for moderate-to-severe eosinophilic asthma; and an anti-TSLP antibody called tezepelumab (AMG 157, MEDI9929) being developed by Amgen and AstraZeneca for asthma.

Our competitors in CRSwNP include dupilumab (Regeneron/Sanofi), mepolizumab (GSK), benralizumab (AstraZeneca), omalizumab (Novartis), GB001 (Gossamer Bio) and PF-06817024 (Pfizer), each of which are in clinical testing.

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; Glaxosmithkline), 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 the IL-1 receptor antagonist, and an anti-IL-36 receptor antibody called BI-655130 (Boehringer Ingelheim).

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 pre-market approval requirements typically takes many years and the actual time required may vary substantially based upon the type, complexity, and novelty of the product or disease.

Preclinical tests include laboratory evaluation of product chemistry, formulation, and toxicity, as well as animal trials to assess the characteristics and potential safety and efficacy of the product. The conduct of the preclinical tests must comply with federal regulations and requirements, including 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 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 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 trial with other confirmatory evidence may be sufficient in rare instances where the trial is a large multicenter 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 trial would be practically or ethically impossible.

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 accepted for filing, 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 ten 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 affects fewer than 200,000 individuals in the United States, or if it affects more than 200,000 individuals in the United States, there is no reasonable expectation that the cost of developing and making 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 trials can be delayed in certain circumstances for up to two years after the date of completion of the trial. Competitors may use this publicly available information to gain knowledge regarding the progress of development programs.

Pediatric information

Under the Pediatric Research Equity Act, or PREA, NDAs or 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 designation has been granted.

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, creates 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 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. To date, a handful of biosimilar products 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.

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.

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
pre-market 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 United States.

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, the 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

Government and other third-party payers (including pharmacy benefit management companies) are challenging the prices charged for health care products and increasingly limiting, and attempting to limit, both coverage and level of reimbursement for prescription drugs, such as by requiring outcomes-based or other pay-for-performance pricing arrangements. They are also imposing restrictions on eligible patient populations and the reimbursement process (including by means of required prior authorizations and utilization management criteria). 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 in the United States. This legislation imposes cost-containment and other measures that are likely to adversely affect the amount of reimbursement for our current and future products. The full effects of this legislation depend on a number of factors, many of which are beyond our control, including new regulations and guidance issued by CMS and other federal and state agencies. Some states are also considering legislation that would control the prices and reimbursement of prescription drugs, and state Medicaid programs are increasingly requesting manufacturers to pay supplemental rebates and requiring prior authorization by the state program for use of any prescription drug for which supplemental rebates are not being paid. It is likely that federal and state legislatures and health agencies will continue to focus

on additional health care reform measures in the future that will impose additional constraints on prices and reimbursements for our products.

Some of the provisions of the ACA have yet to be implemented and there have been judicial and Congressional challenges to certain aspects of the ACA. In addition, the current administration and Congress have previously sought, and will likely continue to seek, legislative and regulatory changes, including repeal and replacement of all or certain provisions of the ACA. While Congress has not passed repeal legislation, the Tax Cuts and Jobs Act of 2017 includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate". Additionally, the current administration signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain ACA-mandated fees, including the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices. Further, the Bipartisan Budget Act of 2018, among other things, amends the ACA, effective January 1, 2019, to increase from 50% to 70% the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole". Congress may consider other legislation to repeal or replace elements of the ACA.

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 and other countries in the EU, for example, a 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 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, with the exception of, among other things, country-specific document requirements. For other countries outside of the EU, 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 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 organisation at which the trial will be conducted, referred to as the "Approving Authority" gives the final approval for the conduct of the trial at the site, having due regard to the advice from the HREC; and
- CTN trials cannot commence until the 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 trial until written advice has been received from the TGA regarding the application and approval for the conduct of the trial has been obtained from an ethics committee and the institution at which the 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 trial is submitted directly to the HREC of each institution at which the 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 Harmonization 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

As of December 31, 2018, we had 78 full-time employees. Of these employees, 60 were primarily engaged in research and development activities and 24 have an M.D. or a Ph.D. None of our employees are represented by a labor union or covered by collective bargaining agreements, and we believe our relationship with our employees is good.

Financial Information

We manage our operations and allocate resources as a single reporting segment. Financial information regarding our operations, assets and liabilities, including our net loss for the years ended December 31, 2018, 2017 and 2016 and our total assets as of December 31, 2018 and 2017, is included in our Consolidated Financial Statements in Part II Item 8 of this Annual Report on Form 10-K.

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.

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 Phase 2a clinical trials of etokimab may not be representative of the results we will experience in later Phase 2b and registration 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 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 trials of etokimab may not be representative of the results we will experience in later Phase 2b and registration trials. If our later clinical trials are unsuccessful, etokimab may be delayed in development or fail entirely, which would have a material adverse impact on our business.

We have elected to structure our initial Phase 2a clinical trials with etokimab as investigational studies that enroll a relatively limited number of patients and are intended to allow us to better assess patient responses and potential efficacy results before designing and commencing Phase 2b clinical trials. We believe the results we have observed in the initial Phase 2a clinical trials of etokimab in atopic dermatitis and severe adult eosinophilic asthma suggest a reasonable basis for continuing development of etokimab in these indications through larger Phase 2b clinical trials. However, our Phase 2a trials involve relatively small patient populations, for example 12 patients in our Phase 2a trial in atopic dermatitis and 25 patients in our Phase 2a trial in severe adult eosinophilic asthma. The results we have observed in these smaller patient populations may not be predictive of results we will experience in later studies. Furthermore, the average results reported from our Phase 2a trials (for example, the average change in FEV1 reported in connection with our Phase 2a trial in severe adult eosinophilic asthma) are subject to significant variability due to the small number of patients enrolled, and are not expected to be, and are unlikely to be, statistically significant. In addition, we have elected to structure our initial Phase 2a clinical trials as single dose studies, which may not be representative of the efficacy and/or safety observed in subsequent multi-dose Phase 2, Phase 2b or Phase 3 clinical trials.

In addition, later studies may also include different design elements that could contribute to us experiencing different results than we have observed in our Phase 2a trials. One such design element may be differences in efficacy endpoints between Phase 2a trials and subsequent Phase 2, Phase 2b or Phase 3 clinical trials. For instance, while our single dose Phase 2a clinical trial of etokimab demonstrated efficacy in terms of FEV1 improvement versus placebo, we did not structure this trial to assess efficacy in terms of exacerbation reduction, which is the endpoint historically used by the FDA for drug approval in asthma, and hence our future Phase 2, Phase 2b or Phase 3 trials in asthma may not demonstrate efficacy in exacerbation reduction leading to potential delays or failure to obtain approval of etokimab in asthma. In addition, the initial results we have reported from our completed Phase 2a clinical trials have included interim analyses and top-line results at early timepoints, which may not accurately predict the final results of this clinical trial or the results of future clinical trials. For instance, our single dose Phase 2a trial of etokimab in atopic dermatitis demonstrated certain levels of EASI-50 response upon interim analysis at Day 29, but this EASI-50 response level was not maintained at the end of this clinical trial at Day 140. In another example, interim analysis data from our Phase 2a study of severe adult eosinophilic asthma demonstrated FEV1 improvement over placebo at Day 64, but may not demonstrate the same FEV1 efficacy upon study completion at the Day 127 timepoint.

If our later clinical trials of etokimab are unsuccessful, whether for one of the reasons mentioned above or otherwise, etokimab 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 U.S. Food and Drug Administration, or FDA, or foreign regulatory authorities. More specifically, some of our product candidates, including ANB019, 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.

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 early Phase 1 and Phase 2a clinical trials for etokimab, and subsequent patient trials with etokimab are currently ongoing. We also have only recently completed a Phase 1 clinical trial with ANB019. 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, none of which were determined to be drug related. The most frequent treatment-emergent adverse events reported were mild dizziness or vomiting in patients subsequent to placebo dosing, and mild headache, strep throat, upper respiratory tract infection, or in one case, severe neutropenia which was acute and not persistent in patients post-etokimab administration. 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 2a 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 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 IRB, may suspend clinical trials of a product candidate at any time for various reasons, including a belief that subjects in such trials are being exposed to unacceptable health risks or adverse side effects. Some potential therapeutics developed in the biotechnology industry that initially showed therapeutic promise in early-stage studies have later been found to cause side effects that prevented their further development. Even if the side effects do not preclude the drug 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 products 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 CTA to conduct clinical trials for both etokimab and ANB019 in the United States and United Kingdom, respectively, 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, the Therapeutic Goods Administration in Australia 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 Biologics License Application, or 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 Australia, the United States and United Kingdom, we have not yet discussed with the FDA or foreign regulatory authorities 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 trial designs or product development for our target indications. For example, we believe a small pivotal trial, potentially with approximately 100 patients, may be sufficient to demonstrate substantial evidence of efficacy of ANB019 in generalized pustular psoriasis, or GPP, patients. However, we have not yet discussed clinical trial design for this indication with the FDA, and the FDA may disagree with our proposed trial design, including the number of patients necessary to demonstrate efficacy and/or may require us to conduct more than one pivotal study 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. Products, 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 contract research organizations, or CROs, or failure by such CROs or trials sites to carry out the clinical trial in accordance with our agreed-upon terms;
- 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 etokimab and ANB019, and have no other history of conducting clinical trials or 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 new 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 atopic dermatitis, our competitors include dupilumab (Dupixent, Regeneron, Sanofi), which has been approved by the FDA, crisaborole (EUCRISA, Pfizer), which has been approved by the FDA, VTP-38543 (Vitae, acquired by Allergan), JAK inhibitors such as baricitinib, PF-04965842 and upadacitinib under development by Lilly/Incyte, Pfizer and Abbvie, respectively, an IL-33 program by Regeneron (REGN3500) in a Phase 2 clinical trial for atopic dermatitis, a recently announced IL-33 related program by Pfizer (PF-06817024) in a Phase 1 clinical trial indicated for various indications, a recently announced IL-33 related program by Lilly in a Phase 1 clinical trial indicated for autoimmune disorders, an IL-1 alpha antibody, bermekimab (XBiotech) and antibodies that bind to IL-13 such as lebrikizumab (Dermira) and tezepelumab (AMG157, MEDI9929, Amgen/AstraZeneca).

For asthma, our competitors include omalizumab (Xolair; Roche), which has received FDA approval and functions by inhibiting the binding between free IgE and FceRI; antibodies that bind IL-5 and inhibit its interaction with the IL-5 receptor such as mepolizumab (Nucala; Glaxosmithkline) and reslizumab (Cinqair; Teva), both of which the FDA has approved for the add-on maintenance treatment in patients with severe eosinophilic asthma; antibodies such as benralizumab (FASENRA, AstraZeneca) that bind the IL-5 receptor; antibodies that bind the IL-4 receptor and inhibit its signaling through IL-4 and IL-13 cytokines such as dupilumab (Dupixent; Regeneron/Sanofi), which has been approved by the FDA for use with other asthma medicines for the maintenance treatment of moderate-to-severe asthma in patients aged 12 years and older whose asthma is not controlled with their current asthma medicines; antibodies that bind to IL-13 such as lebrikizumab (Dermira), tralokinumab (AstraZeneca, LEO Pharma) and anrukinzumab (Pfizer), which are in clinical testing; antibodies that bind the IL-4 receptor alpha chain, such as AMG 317 (Amgen) in clinical testing; ST2-binding antibodies including Roche's RG6149, GSK's GSK3772847 and Regeneron's IL-33 antibody (REGN3500) each in clinical development for asthma and related conditions; a recently announced IL-33 related program by AstraZeneca (MEDI3506) in a Phase 1 clinical trial indicated for chronic obstructive pulmonary disease; DP-2 antagonists including fevipiprant (Novartis) under development for asthma and GB001 (Gossamer Bio) under development for moderate-to-severe eosinophilic asthma; and an anti-TSLP antibody called tezepelumab (AMG 157, MEDI9929) being developed by Amgen and AstraZeneca for asthma.

Our competitors in CRSwNP include dupilumab (Regeneron/Sanofi), mepolizumab (GSK), benralizumab (AstraZeneca), omalizumab (Novartis), GB001 (Gossamer Bio) and PF-06817024 (Pfizer), each of which are in clinical testing.

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; Glaxosmithkline), 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 the IL-1 receptor antagonist and an anti-IL-36 receptor antibody called BI-655130 (Boehringer Ingelheim).

With the enactment of the Biologics Price Competition and Innovation Act of 2009, or 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, as well as in 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, or 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 ANB019 for the treatment of GPP or PPP by designing our pivotal trial or trials of ANB019 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 ANB019, 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, or 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. 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 product sales.

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 TESARO and Celgene 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, 2018, our collaboration revenue was $5.0 million and our net loss was $61.7 million. As of December 31, 2018, we had an accumulated deficit of $146.7 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 two 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 products;

- 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 trials in addition to those that we currently anticipate. Even if ANB019 and etokimab, or any of our other product candidates, are 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 through the end of 2020. 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, or our collaborators may not elect to pursue the development and commercialization of any of our product candidates that are subject to their respective agreements with us. 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 product collaborations 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;
- 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 or equity 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 significant 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 conduct certain operations through our Australian wholly-owned subsidiary. If we lose our ability to operate in Australia, or if our subsidiary is unable to receive the research and development tax credit allowed by Australian regulations, our business and results of operations will suffer.

In March 2015, we formed a wholly-owned Australian subsidiary, AnaptysBio Pty Ltd, or AnaptysBio Pty, to develop and commercialize our ANB019 and etokimab antibody program in Australia. Due to the geographical distance and lack of employees currently in Australia, as well as our lack of experience operating in Australia, we may not be able to efficiently or successfully monitor, develop and commercialize our lead products or antibody program in Australia, including conducting clinical trials. Furthermore, we have no assurance that the results of any clinical trials that we conduct for our product candidates in Australia will be accepted by the FDA or foreign regulatory authorities for development and commercialization approvals.

In addition, current Australian tax regulations provide for a refundable research and development tax credit equal to 43.5% of qualified expenditures. If we are ineligible or unable to receive the research and development tax credit, required to repay all or a portion of the credit, lose our ability to operate AnaptysBio Pty in Australia, or if the Australian government significantly reduces or eliminates the tax credit, our business and results of operation would be adversely affected.

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 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 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 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 TESARO and Celgene, 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 TESARO and Celgene to develop several of our product candidates. We have also entered into antibody generation and/or development collaborations with various collaborators, including TESARO and Celgene, under which we have generated therapeutic quality antibodies using our technology platform and conducted certain preclinical studies in collaboration. We are currently aware that TESARO and Celgene 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.

Moreover, both TESARO and Celgene recently announced agreements to be acquired by large pharmaceutical companies. On December 3, 2018, GlaxoSmithKline plc announced an agreement to acquire TESARO, which closed on January 22, 2019, and on January 3, 2019, Bristol-Myers Squibb Co. announced an agreement to acquire Celgene Corp, which is expected to close during the third quarter of 2019. There can be no assurance that these collaborators, following their respective acquisitions by third parties, or such third-party acquirers, will continue to develop and commercialize these product candidates consistent with and with similar timelines as done previous to the acquisitions or that they will comply with the covenants, restrictions, sub-license and other agreement provisions, which, if they don’t comply, could lead us into disputes and potentially trigger breaches of our agreements with other partners.

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.

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

In addition to our current licensing arrangements with TESARO and Celgene, a part of our strategy is to enter into additional strategic product development 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 development 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 development collaborations, the terms that we agree upon may not be favorable to us, and we may not be able to maintain such development 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 development 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 development 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 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, contract research organizations (for non-clinical and clinical activities), or CROs, contract manufacturing organizations, or 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, or GCPs, 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. Since 2004, these 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. 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 ANB019 or 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.

We plan to seek Orphan Drug Designation for ANB019 or certain of our other product candidates. Regulatory authorities in some jurisdictions, including the United States and the European Union, or 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. 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, in the United States, or the European Medicines Agency, or EMA, in 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 ANB019 for any indication, and may not be able to obtain designation or any of the potential benefits associated with it. For example, we plan to seek FDA Orphan Drug Designation for ANB019 for the treatment of GPP and PPP, which will likely require that we demonstrate to FDA that GPP and PPP are distinct diseases from psoriasis generally (a non-rare disease) or that use of ANB019 may be appropriate for the treatment of GPP and PPP but not appropriate for use in the general psoriasis population.

Even if we obtain Orphan Drug Designation, 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, or 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.

Recently enacted legislation 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.

Some of the provisions of the ACA have yet to be implemented, and there have been judicial and Congressional challenges to certain aspects of the ACA. In addition, the current administration and Congress have previously sought, and will likely continue to seek, legislative and regulatory changes, including repeal and replacement of all or certain provisions of the ACA. While Congress has not passed repeal legislation, the Tax Cuts and Jobs Act of 2017 includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the “individual mandate”. Additionally, the current administration signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain ACA-mandated fees, including the so-called “Cadillac” tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices. Further, the Bipartisan Budget Act of 2018, among other things, amends the ACA, effective January 1, 2019, to increase from 50% to 70% the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and to close the coverage gap in most Medicare drug plans, commonly referred to as the “donut hole”. Congress may consider other legislation to repeal or replace elements of the ACA.

We may face difficulties from changes to current regulations and future legislation.

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.

More recently, President Trump has signed an executive order and made statements that suggest he plans to seek repeal of all or portions of the ACA. There is uncertainty with respect to which legislation, if any, will be enacted and the impact President Trump's Administration may have, if any, and any changes likely will take time to unfold, and could have an impact on coverage and reimbursement for health care items and services covered by plans that were authorized by the ACA. However, we cannot predict the ultimate content, timing or effect of any health care reform legislation or the impact of potential legislation on us. In addition, other legislative changes have been proposed and adopted since the ACA was enacted. These changes included aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, effective April 1, 2013, which, due to subsequent legislative amendments, will stay in effect through 2027 unless additional Congressional action is taken. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, reduced Medicare payments to several providers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new 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.

Likewise, the annual Medicare Physician Fee Schedule update, which, until recently, was based on a target-setting formula system called the Sustainable Growth Rate, or SGR, was adjusted to reflect the comparison of actual expenditures to target expenditures. Because one of the factors for calculating the SGR was linked to the growth in the U.S. gross domestic product, or GDP, the SGR formula often resulted in a negative payment update when growth in Medicare beneficiaries' use of services exceeded GDP growth. Congress repeatedly intervened to delay the implementation of negative SGR payment updates. For example, on April 1, 2014, with the enactment of the Protecting Access to Medicare Act of 2014, Congress prevented the 24 percent cut that was to occur by continuing the previously implemented 0.5 percent payment increase through December 31, 2014 and maintaining a zero percent payment update from January 1, 2015 through March 31, 2015. However, on April 14, 2015, Congress passed the Medicare Access and CHIP Reauthorization Act of 2015, which was signed into law by President Obama on April 16, 2015. This law repeals the SGR methodology from the physician payment formula, institutes a 0% update to the Medicare Physician Fee Schedule for the January 1 to July 1, 2015 period, a 0.5% payment update for July 2015 through the end of 2019, and a 0% payment update for 2020 through 2025, along with a merit-based incentive payment system beginning January 1, 2019, that will replace current incentive programs. For 2026 and subsequent years, the payment update will be either 0.75% or 0.25%, depending on which Alternate Payment Model the physician participates.

We expect that the ACA, as well as other health care reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. 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 the U.S. 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, or 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.

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, or prohibit prescription drug price gouging. And states such as California, Connecticut, Nevada, and Massachusetts require pharmaceutical companies to implement compliance programs and/or marketing codes. Other states are considering similar proposals. 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 is governed by the General Data Protection Regulation (GDPR), which became fully applicable in May 2018. 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 new 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. 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 GDPR is new and the pending EU ePrivacy Regulation is expected to establish, new requirements applicable to the handling of personal data and imposes penalties for non-compliance of up to the greater of €20 million or 4% of worldwide revenue. Additionally, in June 2018, California passed the California Consumer Privacy Act, or CCPA, which provides new data privacy rights for consumers and new operational requirements for companies effective in 2020. 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, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with 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 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, or 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' 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 or collaborators may not be able to prevent third parties from practicing our and our licensors' or collaborators' inventions in all countries outside the United States, or from selling or importing products made using our and our licensors' or collaborators' inventions in and into the United States or other jurisdictions. Competitors may use our and our licensors' 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 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' 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 or collaborators to stop the infringement of our and our licensors' or collaborators' patents or marketing of competing products in violation of our and our licensors' or collaborators' proprietary rights generally. Proceedings to enforce our and our licensors' or collaborators' patent rights in foreign jurisdictions could result in substantial costs and divert our and our licensors' or collaborators' efforts and attention from other aspects of our business, could put our and our licensors' or collaborators' patents at risk of being invalidated or interpreted narrowly and our and our licensors' or collaborators' patent applications at risk of not issuing and could provoke third parties to assert claims against us or our licensors or collaborators. We or our licensors or collaborators may not prevail in any lawsuits that we or our licensors or collaborators initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful.

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' or collaborators' patent applications and the enforcement or defense of our or our licensors' or collaborators' issued patents. On September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act 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 Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents.

The USPTO has developed new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and, in particular, the first to file provisions, only became effective in 2013. It is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our or our licensors' or collaborators' patent applications and the enforcement or defense of our or our licensors' or collaborators' issued patents, all of which could have an adverse effect on our business and financial condition. Moreover, in recent years, the 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. (Myriad I), BRCA1- & BRCA2-Based Hereditary Cancer Test Patent Litig., (Myriad II), 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' or collaborators' ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on 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' or collaborators' ability to obtain new patents or to enforce existing patents and patents that we and our licensors 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 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, either 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' or collaborators' patents or misappropriate or otherwise violate our or our licensors' or collaborators' intellectual property rights. In the future, we or our licensors or collaborators may initiate legal proceedings to enforce or defend our or our licensors' or collaborators' intellectual property rights, to protect our or our licensors' 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 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' 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 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' 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' or collaborators' patents at risk of being invalidated, held unenforceable or interpreted narrowly.

Accordingly, despite our or our licensors' or collaborators' efforts, we or our licensors 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 or collaborators to protect or enforce our or our licensors' 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' or collaborators' patent applications. An unfavorable outcome in any such proceedings could require us or our licensors 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 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 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 or collaborators.

In addition, if the breadth or strength of protection provided by our or our licensors' 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 and collaborators, to develop, manufacture, market and sell our product candidates and use our and our licensors' 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 our licensors and us and our 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 or collaborators alleging that we or our licensors or collaborators infringe their intellectual property rights, or we or our licensors 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, 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' 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 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 or collaborators to cease using the related technology or 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 or collaborators a license on commercially reasonable terms or at all. Even if we or our licensors 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 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, referred to as 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. 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 may be the target of this type of litigation in the future. Securities litigation against us could result in substantial costs and divert our management’s attention from other business concerns, which could seriously harm our business.

We incur increased costs and devote substantial management time as a result of operating as a public company.

As a public company, we incur significant legal, accounting and other expenses that we did not incur as a private company, and these expenses have increased and will continue to increase even more after we are no longer an “emerging growth company.” 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. Moreover, these rules and regulations substantially increase our legal and financial compliance costs and make some activities more time-consuming and costly. The increased costs increase our net loss. 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 of 2002 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. Irrespective 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 may discourage, delay or prevent a change in control of our company. Section 203 imposes certain restrictions on mergers, business combinations and other transactions between us and holders of 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, or 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, or 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 Internal Revenue 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, 2018, we have federal NOLs of approximately $145.3 million, which expire beginning December 31, 2028 through December 31, 2037,

if not used to reduce income taxes payable in the future. The federal net operating loss carryover includes $85.2 million of net operating losses generated in 2018. Federal net operating losses generated in 2018 carryover indefinitely and may generally be used to offset up to 80% of future taxable income in the year it is utilized.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

Our principal executive office is located 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 for an additional 18,000 square feet of office space in San Diego, California, this lease will expire on October 31, 2021.

Item 3. Legal Proceedings

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

Item 4. Mine Safety Disclosures

Not applicable.

PART II

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

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 25, 2019, we had approximately 17 holders of record of our common stock. This number does not include beneficial owners whose shares were held in street name.

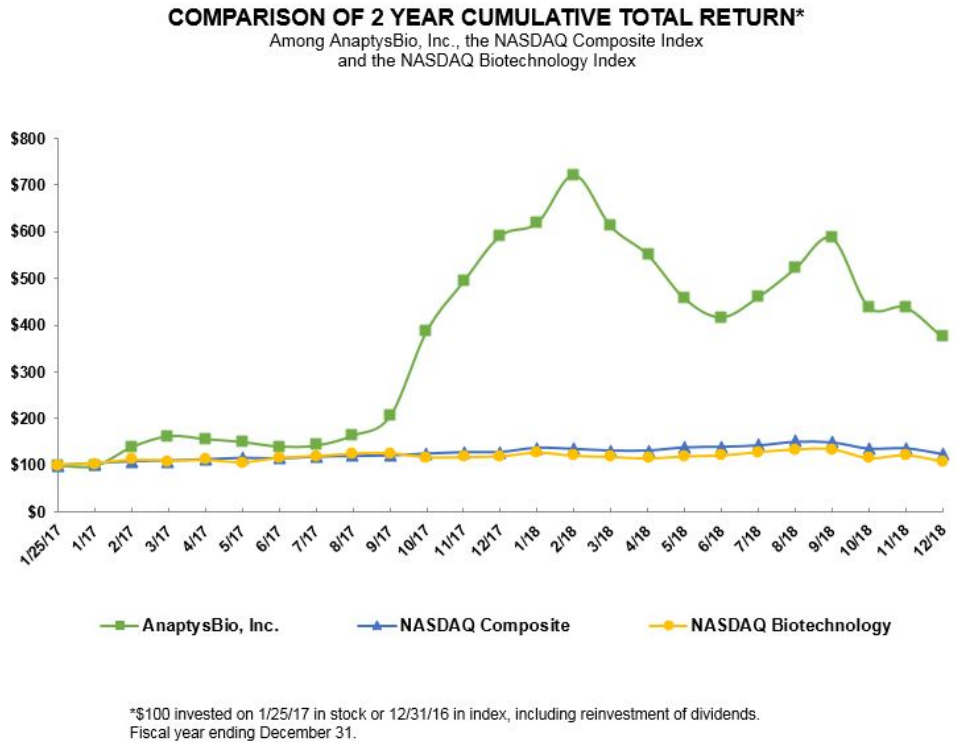
Dividend Policy

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. In addition, under the terms of our current credit facility, we are prohibited from paying cash dividends without the consent of our lenders.

Stock Performance Graph

The following performance graph and related information shall not be deemed to be "soliciting material" or to be "filed" with the Securities and Exchange Commission, or SEC, for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or the Exchange Act, nor shall such information be incorporated by reference into any future filing under the Exchange Act or Securities Act of 1933, as amended, or the Securities Act, except to the extent that we specifically incorporate it by reference into such filing.

The following performance graph compares the performance of our common stock to the Nasdaq Composite Index and to the Nasdaq Biotechnology Index from January 26, 2017 (the first date that shares of our common stock were publicly traded) through December 31, 2018. The comparison assumes $100 was invested in our common stock and in each of the aforementioned indices after the market closed on December 31, 2018, and it assumes reinvestment of dividends, if any. The stock price performance included in this graph is not necessarily indicative of future stock price performance.



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

The selected financial data set forth below for the years ended December 31, 2018, 2017, and 2016 and as of December 31, 2018 and 2017 are derived from and should be read in conjunction with our audited financial statements, including the notes thereto, included elsewhere in this report. The selected financial data for the years ended December 31, 2015 and 2014 and as of December 31, 2016, 2015 and 2014 are derived from our audited financial statements not included in this report.

Our historical results are not necessarily indicative of the results that may be expected in the future. You should read the selected consolidated financial data below in conjunction with Part II Item 7—Management's Discussion and Analysis of Financial Condition and Results of Operations and our audited consolidated financial statements and the related notes included in this Annual Report on Form 10-K.

	Year Ended December 31,				
(in thousands)	**2018**	**2017**	**2016**	**2015**	**2014**
Collaboration revenue	$ 5,000	$ 10,000	$ 16,684	$ 17,571	$ 15,838
(Loss) income from operations	(66,722)	(28,781)	(3,025)	(3,322)	4,870
Net (loss) income	(61,848)	(30,070)	(4,259)	(5,405)	3,532
Net (loss) income attributed to common stockholders	(61,656)	(30,070)	(4,259)	(5,405)	232
Net (loss) income per common share: Basic and diluted	(2.50)	(1.52)	(1.62)	(2.12)	0.09

(in thousands)	December 31, 2018	December 31, 2017	December 31, 2016	December 31, 2015	December 31, 2014
Total assets	$ 508,997	$ 329,364	$ 62,180	$ 56,280	$ 25,065
Notes payable, net of current portion	625	7,553	13,809	4,903	4,793
Deferred rent	171	140	154	115	94
Preferred stock warrant liabilities	—	—	3,241	1,549	569
Commitments and contingencies					
Series B convertible preferred stock	—	—	28,220	28,220	28,220
Series C convertible preferred stock	—	—	6,452	6,452	6,452
Series C-1 convertible preferred stock	—	—	2,156	2,156	2,156
Series D convertible preferred stock	—	—	40,688	40,688	—
Stockholders' equity (deficit):					
Preferred stock	—	—	—	—	—
Common stock	27	24	3	3	2
Additional paid in capital	633,251	393,017	16,672	15,482	14,422
Accumulated other comprehensive loss	(223)	(426)	—	—	—
Accumulated deficit	(146,690)	(85,034)	(54,923)	(50,664)	(45,259)
Total liabilities, convertible preferred stock and stockholders' equity	$ 508,997	$ 329,364	$ 62,180	$ 56,280	$ 25,065

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 antibody product candidates focused on unmet medical needs in inflammation. We develop our product candidates to address emerging biological targets 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, or SHM, and replicates this natural process of antibody generation *in vitro*. Our strategy is to advance the development and commercialization of our proprietary product candidates, and for certain programs, establish partnerships with leading biopharmaceutical companies where we retain certain development and commercialization rights in the United States. Our most advanced wholly-owned antibody programs, etokimab and ANB019, neutralize therapeutic targets that are genetically associated with severe inflammatory disorders in humans.

Etokimab, our anti-IL-33 antibody drug candidate previously referred to as ANB020, inhibits the activity of the interleukin-33 cytokine, or IL-33, which we believe is broadly applicable to the treatment of atopic inflammatory disorders, such as moderate-to-severe atopic dermatitis, eosinophilic asthma, chronic rhinosinusitis with nasal polyps, or CRSwNP, and potentially other allergic conditions.

We completed a Phase 2a proof-of-concept trial of etokimab in 12 moderate-to-severe adult atopic dermatitis patients in late 2017 and believe the data from this trial, presented at the 2018 American Academy of Dermatology, or AAD, and 2018 European Academy of Allergy and Clinical Immunology, or EAACI, demonstrate proof-of-concept for etokimab in moderate-to-severe adult atopic dermatitis and suggest that etokimab may provide meaningful differentiation in terms of patient convenience. We are conducting a Phase 2b randomized, double-blinded, placebo-controlled, multi-dose study in 300 adult patients with moderate-to-severe atopic dermatitis, also referred to as the ATLAS trial, to assess different dose levels and dosing frequencies of subcutaneously-administered etokimab for a 16-week treatment period followed by an eight-week monitoring period, with top-line data expected in the second half of 2019.

We recently completed a Phase 2a randomized, placebo-controlled, single dose study of etokimab in 25 severe adult eosinophilic asthma patients. We announced top-line data from an interim analysis of this Phase 2a trial in September 2018, which we believe demonstrated proof-of-concept for etokimab in severe adult eosinophilic asthma patients with rapid and sustained Forced Expiratory Volume in One Second, or FEV1, improvement. We plan to report full data from this trial, including data subsequent to the Day 64 time point, at a medical conference in 2019. We believe the interim analysis of this trial supports the continued development of etokimab in eosinophilic asthma and plan to initiate, during 2019, a multi-dose Phase 2b randomized, double-blinded, placebo-controlled trial. We may also conduct clinical studies in severe asthma subset(s) in the future.

We are conducting a randomized, placebo-controlled Phase 2 trial of etokimab in approximately 100 adult patients with CRSwNP, also referred to as the ECLIPSE trial, which is a debilitating atopic disorder associated with elevated IL-33 pathway signaling. We anticipate top-line data from this trial to be available in the second half of 2019.

ANB019 inhibits the interleukin-36 receptor, or IL-36R, for the treatment of rare inflammatory diseases including generalized pustular psoriasis, or GPP, and palmoplantar pustulosis, or PPP, previously referred to as palmo-plantar pustular psoriasis. We completed a Phase 1 clinical trial in healthy volunteers, which was presented at EAACI 2018, where ANB019 was well-tolerated by all subjects, no dose-limiting toxicities were observed, and no serious adverse events were reported among any subjects in the trial. We have subsequently initiated a 10-patient open-label, multi-dose, single-arm Phase 2 trial of ANB019 in GPP patients, also referred to as the GALLOP trial, where top-line data are anticipated in mid-2019. We have also initiated a randomized, double-blind, placebo-controlled approximately 50-patient multi-dose trial of ANB019 in PPP, also referred to as the POPLAR trial, where top-line data are anticipated in the second half of 2019.

In addition to etokimab and ANB019, our wholly-owned pipeline includes novel anti-inflammatory checkpoint receptor modulator antibodies that we believe are applicable for treatment of certain autoimmune diseases where immune checkpoint receptors are insufficiently activated. We anticipate an Investigational New Drug Application, or IND, for the first such antibody in the second half of 2019.

In addition to our wholly-owned antibody programs, multiple AnaptysBio-developed antibody programs have been advanced to preclinical and clinical milestones under our collaborations. Our collaborations include an immuno-oncology-focused collaboration with TESARO, Inc. and TESARO Development, Ltd., or collectively TESARO, and an inflammation-focused collaboration with Celgene Corporation, or Celgene. For more information about these collaborations, see "- Collaboration Revenue" below.

As of December 31, 2018, we had an accumulated deficit of $146.7 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.

Public Offerings

On January 31, 2017, we completed an initial public offering, or IPO, selling 5,750,000 shares of common stock at $15.00 per share, which included 750,000 shares sold pursuant to the exercise of the underwriters' options to purchase additional shares. Proceeds from our initial public offering net of underwriting discounts and commissions were $80.2 million.

On October 17, 2017, we completed an underwritten public offering of 3,000,000 shares of common stock. All shares were offered by us at a price to the public of $68.50 per share. The aggregate net proceeds received by us from the offering were $194.7 million, net of underwriting discounts and commissions. As part of the underwritten public offering, on November 14, 2017, the underwriters exercised an additional 271,380 shares of common stock at a discounted price to the public of $68.50 per share for aggregate net proceeds of $17.6 million, net of underwriting discounts and commissions.

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.

Financial Overview

Collaboration Revenue

We have not generated any revenue from product sales. Our revenue has been derived from amortization of upfront payments, research and development funding and milestone payments under collaboration and license agreements with our collaborators. From inception through December 31, 2018, we have received $81.6 million in cash in non-dilutive funding from our collaborators.

Collaboration and Exclusive License Agreement with TESARO

In March 2014, we entered into an exclusive worldwide license and collaboration agreement with TESARO 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 TESARO in March 2014, and in November 2014, we amended the agreement with TESARO 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 agreement in February 2016. From inception of the agreement through December 31, 2018, we have recognized $59.3 million in total revenue from TESARO.

For each of the four targets under the TESARO 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, TESARO is obligated to pay us tiered single-digit royalties on annualized net sales of each antibody commercialized from the collaboration.

Milestones achieved through December 31, 2018 under the TESARO Agreement are as follows:

	Anti-PD-1 (TSR042)		Anti-TIM-3 (TSR022)		Anti-LAG-3 (TSR033)	
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	—	—
Phase 3 clinical trial initiation	$5.0M	Q3'18	—	—	—	—

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.

On December 3, 2018, GlaxoSmithKline plc announced an agreement to acquire TESARO. This acquisition closed on January 22, 2019.

Antibody Generation Agreement with Celgene Corporation

In December 2011, we entered into a license and collaboration agreement with Celgene to develop therapeutic antibodies against multiple targets. We granted Celgene 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 agreement provided for an upfront payment of $6.0 million from Celgene, which we received in 2011, 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, 2018, we have recognized $10.0 million in total revenue from Celgene.

	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, 2018 or 2017.

On January 3, 2019, Bristol-Myers Squibb Co. announced an agreement to acquire Celgene Corp. This acquisition is expected to close in the third quarter of 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, or CROs, consultants, members of our scientific and therapeutic advisory boards, and Contract Manufacturing Organizations, or 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 recognize the Australian Research and Development Tax Incentive, or the Tax Incentive, as a reduction of research and development expense. The amounts are determined on a cost reimbursement basis based on our eligible research and development expenditures and are non-refundable, provided that in order to qualify for the Australian benefits we must have revenue of less than AUD $20.0 million during the reimbursable period and cannot be controlled by income tax exempt entities. The Tax Incentive is recognized when there is reasonable assurance that the Tax Incentive will be received, the relevant expenditure has been incurred, and the amount can be reliably measured.

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 and 2a trials for etokimab and Phase 1 trials for ANB019 and have ongoing Phase 2 and 2b clinical trials as well. 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, which we refer to as the Loan Agreement.

Change in Fair Value of Liability for Preferred Stock Warrants

Income and expense from the change in fair value of our liability for preferred stock warrants results from the valuation of our outstanding warrants to purchase shares of our preferred stock, which are valued at each period end. Upon the closing of our initial public offering on January 31, 2017, the warrants to purchase shares of preferred stock converted into warrants to purchase shares of common stock, the preferred stock warrant liabilities were reclassified to additional paid-in capital and periodic fair value adjustments are no longer required. All warrants were exercised as of December 31, 2018.

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 TESARO 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, 2018, we had federal and state NOL carryforwards of $145.3 million and $59.1 million, respectively. The federal and state NOLs will both begin to expire in 2028, respectively, unless previously utilized. The federal NOL includes $85.2 million of net operating losses generated in 2018. Federal net operating losses generated in 2018 carryover indefinitely and may generally be used to offset up to 80% of future taxable income in the year it is utilized. At December 31

, 2018, we had federal and California research tax credit carryforwards of $6.1 million and $5.9 million, respectively. The federal research tax credit carryforward will begin to expire in 2026 and the California state credits carry forward indefinitely.

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.

On December 22, 2017, the President of the United States, signed into law the Tax Reform Act. The legislation significantly changed 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 and no longer allows deductions for compensation in excess of $1 million for certain employees, even if paid as commissions or performance-based compensation. The SEC staff issued Staff Accounting Bulletin No. 118, or “SAB 118” to address the application of U.S. GAAP in situations when a registrant does not have the necessary information available, prepared or analyzed (including computations) in reasonable detail to complete the accounting for certain income tax effects of the Tax Reform Act. We recognized provision tax impacts related to the revaluation of deferred tax assets and liabilities and included this amount in its consolidated financial statements for the year ended December 31, 2017. The accounting was completed upon filing of the 2017 U.S. corporate income tax return in 2018, and had no impact on our consolidated financial statements.

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, or 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 our accrued expenses 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.

Accounting Pronouncements Recently Adopted

In May 2014, the Financial Accounting Standards Board "FASB" issued Accounting Standard Update (ASU) 2014-09, Revenue from Contracts with Customers, which outlines a single comprehensive model for entities to use in accounting for revenue from contracts with customers and supersedes most current revenue recognition guidance, including industry-specific guidance. This standard is based on the principle that an entity should recognize revenue to depict the transfer of goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. This standard also requires additional disclosure about the nature, amount, timing and uncertainty of assets recognized from costs incurred to fulfill a contract and became effective for our annual reporting period beginning January 1, 2018, including interim periods within that reporting period. Entities have the option of using either a full retrospective or a modified retrospective approach for the adoption of the new standard. We assessed all potential impacts of the standard, and the most significant impacts relate to our accounting for variable consideration including revenues related to contingent "milestone" based payments and our disclosures required under the new standard as it relates to our two ongoing collaboration agreements, TESARO and Celgene. Application of the new standard requires that variable consideration be recognized to the extent that it is probable that a significant reversal in the amount of revenue will not occur when the uncertainty associated with the variable consideration is subsequently resolved. Accordingly, we may be required to recognize milestone payments earlier in the period in which we determine a significant reversal will not occur, rather than when the milestone is achieved. However, we have reviewed the TESARO and Celgene agreements and have determined that given the nature of potential milestones owed to us under these agreements, and the inherent risk involved in developing drugs, and have determined that these potential milestones were not recognizable as of the standard adoption date. Additionally, while we currently disaggregate our revenue disclosures by collaborative agreement, additional discussion surrounding significant estimates made by management was required in our disclosure and included in Note 4 below. We adopted this standard using the modified retrospective approach for our annual reporting period beginning January 1, 2018, and did not record any adjustments upon adoption of this standard.

In January 2016, the FASB issued ASU 2016-01, *Financial Instruments—Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities*, which intends to enhance the reporting model for financial instruments by providing users of financial instruments with more decision-useful information. The standard also addresses certain aspects of the recognition, measurement, presentation, and disclosure of financial instruments and requires additional disclosure about the nature, amount, timing and uncertainty of assets recognized from costs incurred to fulfill a contract and became effective for our annual reporting period beginning January 1, 2018, including interim periods within that reporting period; early adoption is permitted. We adopted this standard as of January 1, 2018 and there was no material impact on our consolidated financial statements. We did not record any adjustments upon adoption of this standard and have consistently applied our accounting policies to all periods presented in the consolidated financial statements.

In May 2017, the FASB issued ASU 2017-09, *Compensation - Stock Compensation (Topic 718)*, which provides further guidance as to what constitutes a modification to the terms of shared based compensation, in order to create consistency in practice amongst all entities. ASU 2017-09 became effective for annual reporting periods beginning after December 15, 2017, including interim periods thereafter; early adoption is permitted, including adoption in an interim period. We adopted this standard as of January 1, 2018, and the impact was not material on our consolidated financial statements. We did not record any adjustments upon adoption of this standard.

Recent Accounting Pronouncements

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842)*, which requires that lessees recognize a right-of-use, or "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, *Codification Improvements to Topic 842, Leases*; and ASU 2018-11, *Targeted Improvements*. ASU 2016-02 becomes effective for our annual reporting period beginning January 1, 2019, including interim periods thereafter; early adoption is permitted. 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 the new standard on January 1, 2019 and used the effective date as our date of initial application. The new standard provides a number of optional practical expedients in transition, and we elected the 'package of practical expedients', which permits us not to reassess under the new standard our prior conclusions about lease identification, lease classification and initial direct costs. 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 will not have a material impact on our consolidated statements of operations or cash flows.

Results of Operations

Comparison of the Years Ended December 31, 2018 and 2017

Collaboration Revenue

Collaboration revenue was $5.0 million compared to $10.0 million for the years ended December 31, 2018 and 2017, respectively. A comparison of revenue by collaborator is as follows:

	Year Ended December 31,		Increase
(in thousands)	**2018**	**2017**	**(Decrease)**
TESARO-milestones	$ 5,000	$ 10,000	$ (5,000)
Total collaboration revenue	$ 5,000	$ 10,000	$ (5,000)

Collaboration revenue during the year ended December 31, 2018 decreased $5.0 million compared to the year ended December 31, 2017 primarily due to 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 $56.2 million during the year ended December 31, 2018 compared to $29.4 million during the year ended December 31, 2017, for an increase of approximately $26.8 million. The increase is primarily attributable to a $11.9 million increase in outside services for preclinical and manufacturing expenses, a $7.4 million increase in clinical expenses, and a $4.6 million increase in salaries and related expenses, including stock compensation expense.

We do not track fully burdened research and development costs separately for each of our drug 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
(in thousands)	**2018**	**2017**	**(Decrease)**
External Costs			
Etokimab	$ 20,935	$ 12,267	$ 8,668
ANB019	12,738	3,460	9,278
Preclinical and other unallocated costs	9,057	4,862	4,195
Total External Costs	$ 42,730	$ 20,589	$ 22,141
Internal Costs	13,466	8,854	4,612
Total Costs	$ 56,196	$ 29,443	$ 26,753

We expect our research and development expenses to increase substantially for the foreseeable future as we continue to invest in research and development activities related to developing our product candidates, including investments in manufacturing, as our programs advance into later stages of development and as we conduct additional clinical trials.

General and Administrative Expenses

General and administrative expenses were $15.5 million during the year ended December 31, 2018 compared to $9.3 million during the year ended December 31, 2017, for an increase of approximately $6.2 million. The increase is primarily due to a $4.7 million increase in salaries and related expenses, which includes stock compensation expense, as well as a $0.7 million increase in professional fees, including consultants.

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 $1.7 million during the year ended December 31, 2018 and represents effective interest of approximately 13.32% on our outstanding Term Loans, as defined in Part II Item 8—5. Notes Payable, which have a principal balance of $8.1 million as of December 31, 2018. Interest expense was $1.8 million during the year ended December 31, 2017 and primarily represents effective interest of approximately 12.25% on an outstanding principal balance of $15.0 million.

Change in Fair Value of Liabilities for Preferred Stock Warrants

The change in fair value of the liabilities for stock warrants resulted in no expense compared to $1.4 million of expense during the year ended December 31, 2018 and 2017, respectively. As discussed in Part II Item 8 —1. Description of the Business below, all of the outstanding warrants to purchase shares of preferred stock automatically converted into warrants to purchase shares of common stock in connection with the IPO and are accounted for as equity from the conversion date forward.

Interest Income and Other Income (Expense), Net

Interest income and other income (expense), net was $6.5 million during the year ended December 31, 2018 and primarily consisted of interest income of approximately $6.7 million from our short-term and long-term investments net of foreign exchange losses of approximately $0.2 million related to our Australian subsidiary. Other income (expense), net was $1.8 million during the year ended December 31, 2017 and primarily consisted of interest income of approximately $1.6 million from our short-term and long-term investments and foreign exchange gains of approximately $0.2 million related to our Australian subsidiary.

Provision for Income Taxes

The income tax benefit was $0.2 million during the year ended December 31, 2018, primarily related to a credit for alternative minimum taxes, or AMT, which is eligible for refund under the Tax Cuts and Jobs Act. There was no provision for income taxes during the year ended December 31, 2017.

Comparison of the Years Ended December 31, 2017 and 2016

Collaboration Revenue

Collaboration revenue was $10.0 million and $16.7 million during the years ended December 31, 2017 and 2016, respectively. A comparison of revenue by collaborator is as follows:

	Year Ended December 31,		Increase
(in thousands)	**2017**	**2016**	**(Decrease)**
TESARO-amortization of upfront payments	$ —	$ 2,634	$ (2,634)
TESARO-funding of research and development	—	3,242	(3,242)
TESARO-milestones	10,000	9,308	692
Celgene-milestone	—	1,500	(1,500)
Total	$ 10,000	$ 16,684	$ (6,684)

Collaboration revenue during the year ended December 31, 2017 decreased $6.7 million compared to the year ended December 31, 2016 primarily due to a decrease in upfront fees and research reimbursement revenue which we recognized in full upon the completion of the research services under the TESARO contract in December 31, 2016, as well as a decrease in milestone revenue.

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 and other payments from our existing collaborations.

Research and Development Expenses

Research and development expenses were $29.4 million during the year ended December 31, 2017 compared to $15.4 million during the year ended December 31, 2016, for an increase of approximately $14.0 million. The increase is primarily due to a $5.7 million decrease in Australian tax incentives recognized. The decrease in the Australian tax incentives related to the timing of the initial recognition of 2015 and 2016 tax incentives as well as a reduction in reimbursable expenses during 2017. The increase is also attributable to a $3.4 million increase in clinical expenses, a $2.3 million increase in outside services for preclinical and manufacturing expenses, and a $2.2 million increase in salaries and related expenses, including stock compensation expense.

We do not track fully burdened research and development costs separately for each of our drug 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 (in thousands):

	Year Ended December 31,		Increase
(in thousands)	**2017**	**2016**	**(Decrease)**
External Costs			
Etokimab	$ 12,267	$ 389	$ 11,878
ANB019	3,460	3,474	(14)
Preclinical and other unallocated costs	4,862	4,871	(9)
Total External Costs	$ 20,589	$ 8,734	$ 11,855
Internal Costs	8,854	6,685	2,169
Total Costs	$ 29,443	$ 15,419	$ 14,024

We expect our research and development expenses to increase as we further advance our development programs and, in particular, as we enter into additional clinical trials.

General and Administrative Expenses

General and administrative expenses were $9.3 million during the year ended December 31, 2017 compared to $4.3 million during the year ended December 31, 2016, for an increase of approximately $5.0 million. The increase is primarily due to a $3.5 million increase in salaries and related expenses, which includes stock compensation expense and recruiting fees, as well as a $0.7 million increase in professional fees including public company costs.

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. Also, we 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 $1.8 million during the year ended December 31, 2017 and represents effective interest of approximately 12.25% on our outstanding Term Loans, as defined in Part II Item 8—5. Notes Payable, which have a principal balance of $15.0 million as of December 31, 2017. Interest expense was $0.5 million during the year ended December 31, 2016 respectively, and primarily represents effective interest of approximately 9.25% through December 30, 2016, the date at which the Term B Loans and the Term C Loans were drawn. Subsequent to the draw, the effective interest rate was 11.70% for each of the Term Loans, with an outstanding cumulative principal balance of $15.0 million as of December 31, 2016.

Change in Fair Value of Liabilities for Preferred Stock Warrants

The change in fair value of the liabilities for stock warrants resulted in $1.4 million of expense compared to $0.8 million of income during the year ended December 31, 2017 and 2016, respectively, due to changes in the valuation of our Series C convertible preferred stock which impacts the estimated fair value of the warrants. As discussed in Part II Item 8 —1. Description of the Business below, all of the outstanding warrants to purchase shares of preferred stock automatically converted into warrants to purchase shares of common stock in connection with the IPO and are accounted for as equity from the conversion date forward.

Interest Income and Other Income (Expense), Net

Interest income and other income (expense), net was $1.8 million during the year ended December 31, 2017 and primarily consisted of interest income of approximately $1.6 million from our short-term and long-term investments and foreign exchange gains of approximately $0.2 million related to our Australian subsidiary. Other income (expense), net was less than $0.1 million during the year ended December 31, 2016 and primarily consisted of interest income of approximately $0.1 million from our money market fund, offset by foreign exchange losses of approximately $0.1 million related to our Australian subsidiary.

Liquidity and Capital Resources

From our inception through December 31, 2018, we have received an aggregate of $717.5 million to fund our operations which included $616.8 million from the sale of equity securities, $81.6 million from our collaboration agreements and $19.1 million from venture debt. As of December 31, 2018, we had $500.2 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 and is uncertain at this time. Our rights to payments under our collaboration agreements are our only committed external source of funds.

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.

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.

Under our original Loan Agreement, as defined in Part II Item 8—5. Notes Payable, we could borrow up to $15.0 million in three separate draws of $5.0 million each. In January 2016, we amended the Loan Agreement to combine Term B Loans and Term C Loans for a total of $10.0 million available for draw and delay the principal repayments for our Term A Loans from February 1, 2016 until February 1, 2017.

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; principal repayments began in February 2018. As of December 31, 2018, there are 13 equal monthly principal and interest payments remaining on the Term Loans, with final maturity in January 2020. The Term Loans bear interest equal to the greater of 3-month U.S. LIBOR plus 6.37% or 7.3%. The interest rate was 8.93% as of December 31, 2018.

Funding Requirements

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.

As a publicly traded company, we incur significant legal, accounting and other expenses that were not required as a private company. In addition, the Sarbanes-Oxley Act of 2002, as well as rules adopted by the SEC and The Nasdaq Global

Stock Market, requires public companies to implement specified corporate governance practices that were inapplicable to us as a private company. These rules and regulations have increased our legal and financial compliance costs, have made and will continue to make certain activities more time-consuming and costly.

Cash, cash equivalents and investments totaled $500.2 million as of December 31, 2018, compared to $324.3 million as of December 31, 2017. We believe that our existing cash, cash equivalents and investments will fund our current operating plan at least through the end of 2020. 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 drug 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, 2018, 2017 and 2016:

(in thousands)	Year Ended December 31,		
	2018	2017	2016
Net cash (used in) provided by:			
Operating activities	$ (48,506)	$ (19,438)	$ (9,030)
Investing activities	(142,451)	(243,058)	(50)
Financing activities	223,364	292,453	8,628
Net increase (decrease) in cash, cash equivalents and restricted cash	$ 32,407	$ 29,957	$ (452)

Operating Activities

Net cash used in operating activities during the year ended December 31, 2018 of $48.5 million was primarily due to our net loss of $61.7 million, adjusted for addbacks for non-cash items of $9.7 million which includes stock-based compensation and income from marketable securities and increases in working capital of $3.3 million. Net cash used in operating activities during the year ended December 31, 2017 of $19.4 million was primarily due to our net loss of $30.1 million, offset by non-cash expenses of $6.6 million which includes stock-based compensation and warrant liability fair value adjustments and increases in working capital of $4.1 million. Net cash used in operating activities during the year ended December 31, 2016 of $9.0 million was primarily due to decreases in working capital of $7.0 million offset by non-cash addbacks of $2.3 million and net loss of $4.3 million.

Investing Activities

Cash used in investing activities during the year ended December 31, 2018 and 2017 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. Cash used in investing activities during the year ended December 31, 2016 was due to our purchases of property and equipment.

Financing Activities

The cash provided by financing activities during the year ended December 31, 2018 of $223.4 million was primarily related to proceeds of $227.5 million from our follow-on public offerings, net of underwriting discounts and commissions, as well as proceeds of $2.9 million from the issuance of common stock as a result of option and warrant exercises, offset by $6.9 million in repayments on our outstanding Term Loan. Cash provided by financing activities during the year ended December 31, 2017 of $292.5 million was primarily related to proceeds of $292.5 million from our IPO and follow-on public offering, net of underwriting discounts and commissions, as well as proceeds of $1.5 million from the issuance of common stock as a result of option and warrant exercises, offset by $1.6 million in payments related to offering costs. Cash provided by financing activities during the year ended December 31, 2016 of $8.6 million was primarily related to the draw down of our Term B & C loans of $10.0 million, offset by $1.4 million in payments for debt issuance costs and deferred offering costs.

Contractual Obligations

The following table summarizes our contractual obligations as of December 31, 2018:

(in thousands)	Total[1]	Payments Due by Period: Less Than 1 Year	1-3 Years	3-5 Years	More Than 5 Years
Notes payable, including interest and final payment fee	$ 9,304	$ 7,924	$ 1,380	$ —	$ —
Operating lease obligation[2]	2,632	937	1,695	—	—
Total	$ 11,936	$ 8,861	$ 3,075	$ —	$ —

(1) Future minimum annual obligations for license payments under all collaborative in-license agreements at December 31, 2018 were $0.2 million in fiscal 2019 and in the years thereafter. These obligations are excluded from the table above as the annual minimum payments 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.

(2) Operating lease obligation includes future rent payments under our office leases, which both expire in 2021.

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 cancelable contracts and not included in the table above.

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, 2018, we held $386.6 million in debt securities with for which the accumulated other comprehensive loss was $0.2 million. As such, we believe that should a 10.0% change in interest rates were to have occurred on December 31, 2018, this change would not have had a material effect on the fair value of our investment portfolio as of that date.

We are also subject to interest expense fluctuations through our Term Loans, as discussed in Part II Item 8—5. Notes Payable, which as of December 31, 2018 bear interest equal to the greater of 3-month U.S. LIBOR plus 6.37% or 7.3% and are therefore exposed to changes in interest rates through their maturity date of January 2020. The rate was 8.93% as of December 31, 2018 on a remaining balance of $8.1 million. If interest rates had been 10% higher/lower and all other variables were held constant, operating income would decrease/increase by less than $0.1 million. Therefore we do not believe that our financial condition or results of operations would be materially impacted by an immediate change of 10% in interest rates.

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 totaled approximately $0.2 million during the year ended December 31, 2018. 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, 2018 from a low of 0.7102 to a high of 0.7950 with a net impact of approximately $0.2 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, 2018, we had no 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, 2018, 2017 or 2016.

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, 2018 and 2017, the related consolidated statements of operations and comprehensive loss, convertible preferred stock and stockholders' equity (deficit), and cash flows for each of the years in the three-year period ended December 31, 2018, 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, 2018 and 2017, and the results of its operations and its cash flows for each of the years in the three-year period ended December 31, 2018, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2018, based on criteria established in *Internal Control - Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission, and our report dated February 28, 2019 expressed an unqualified opinion on the effectiveness of the Company's internal control over financial reporting.

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

/s/ KPMG LLP

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

San Diego, California
February 28, 2019

ANAPTYSBIO, INC.
CONSOLIDATED BALANCE SHEETS
(in thousands, except par value)

	December 31, 2018	December 31, 2017
ASSETS		
Current assets:		
Cash and cash equivalents	$ 113,596	$ 81,189
Australian tax incentive receivable	174	1,601
Short-term investments	313,486	167,218
Prepaid expenses and other current assets	6,960	2,688
Total current assets	434,216	252,696
Property and equipment, net	1,445	665
Long-term investments	73,128	75,897
Other long-term assets	148	46
Restricted cash	60	60
Total assets	$ 508,997	$ 329,364
LIABILITIES, PREFERRED STOCK AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 5,443	$ 2,323
Accrued expenses	8,761	4,875
Notes payable, current portion	7,574	6,875
Other current liabilities	58	17
Total current liabilities	21,836	14,090
Notes payable, net of current portion	625	7,553
Deferred rent	171	140
Stockholders' equity:		
Preferred stock, $0.001 par value, 10,000 shares authorized and no shares, issued or outstanding at December 31, 2018 and December 31, 2017, respectively	—	—
Common stock, $0.001 par value, 500,000 shares authorized, 26,922 shares and 23,791 shares issued and outstanding at December 31, 2018 and December 31, 2017, respectively	27	24
Additional paid in capital	633,251	393,017
Accumulated other comprehensive loss	(223)	(426)
Accumulated deficit	(146,690)	(85,034)
Total stockholders' equity	486,365	307,581
Total liabilities, preferred stock and stockholders' equity	$ 508,997	$ 329,364

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,		
	2018	**2017**	**2016**
Collaboration revenue	$ 5,000	$ 10,000	$ 16,684
Operating expenses:			
Research and development	56,196	29,443	15,419
General and administrative	15,526	9,338	4,290
Total operating expenses	71,722	38,781	19,709
Loss from operations	(66,722)	(28,781)	(3,025)
Other income (expense), net:			
Interest expense	(1,652)	(1,775)	(458)
Change in fair value of liability for preferred stock warrants	—	(1,366)	(756)
Interest income	6,685	1,623	127
Other (expense) income, net	(159)	229	(147)
Total other income (expense), net	4,874	(1,289)	(1,234)
Loss before income taxes	(61,848)	(30,070)	(4,259)
Provision for income taxes	192	—	—
Net loss	(61,656)	(30,070)	(4,259)
Other comprehensive income (loss):			
Unrealized income (loss) on available for sale securities	258	(426)	—
Income tax expense related to other comprehensive income	(55)	—	—
Other comprehensive income (loss), net of tax	203	(426)	—
Comprehensive loss	$ (61,453)	$ (30,496)	$ (4,259)
Net loss per common share:			
Basic and diluted	$ (2.50)	$ (1.52)	$ (1.62)
Weighted-average number of shares outstanding:			
Basic and diluted	24,673	19,782	2,637

See accompanying notes to consolidated financial statements.

ANAPTYSBIO, INC.
CONSOLIDATED STATEMENTS OF CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)
(in thousands)

	Series B Convertible Preferred Stock		Series C Convertible Preferred Stock		Series C-1 Convertible Preferred Stock		Series D Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive (Loss) Income	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount				
Balance, January 1, 2016	3,963	$ 28,220	1,593	$ 6,452	474	$ 2,156	5,491	$ 40,688	2,630	$ 3	$ 15,482	$ —	$ (50,664)	$ (35,179)
Shares issued under employee stock plans									23		31			31
Repurchase of shares									(2)		(1)			(1)
Stock-based compensation											1,160			1,160
Net loss													(4,259)	(4,259)
Balance, December 31, 2016	3,963	28,220	1,593	6,452	474	2,156	5,491	40,688	2,651	3	16,672	—	(54,923)	(38,248)
Shares issued for public offerings, net of underwriters' fees									9,021	9	292,528		—	292,537
Total offering costs											(4,228)			(4,228)
Shares issued under employee stock plans									199		979			979
Conversion of preferred stock	(3,963)	(28,220)	(1,593)	(6,452)	(474)	(2,156)	(5,491)	(40,688)	11,521	12	77,504			77,516
Warrants exercised									399		536			536
Reclassification of warrants											4,607			4,607
Forfeiture rate adjustment											41		(41)	—
Stock-based compensation											4,378			4,378
Comprehensive loss												(426)		(426)
Net loss													(30,070)	(30,070)
Balance, December 31, 2017	—	—	—	—	—	—	—	—	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

See accompanying notes to consolidated financial statements.

ANAPTYSBIO, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)

	Year Ended December 31,		
	2018	**2017**	**2016**
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net loss	$ (61,656)	$ (30,070)	$ (4,259)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	315	183	233
Stock-based compensation	9,961	4,378	1,160
Change in fair value of liability for preferred stock warrants	—	1,366	756
(Income) loss from investments	(1,233)	11	—
Non-cash interest expense	646	619	105
Loss on disposal of property and equipment	—	—	1
Changes in operating assets and liabilities:			
Receivable from collaborative partners	—	1,225	1
Australian tax incentive receivable	1,427	2,517	(4,118)
Prepaid expenses and other assets	(5,188)	(1,885)	(1,079)
Accounts payable and other liabilities	7,083	2,218	1,251
Income taxes	139	—	(139)
Deferred revenue	—	—	(2,942)
Net cash used in operating activities	(48,506)	(19,438)	(9,030)
CASH FLOWS FROM INVESTING ACTIVITIES:			
Acquisition of investments	(347,537)	(290,905)	—
Sales and maturities of investments	206,149	48,137	—
Purchases of property and equipment	(1,063)	(290)	(50)
Net cash used in investing activities	(142,451)	(243,058)	(50)
CASH FLOWS FROM FINANCING ACTIVITIES:			
Proceeds from public offerings, net of underwriters' fees	227,476	292,537	—
Proceeds from issuance of common stock, upon the exercise of stock options	2,869	979	31
Proceeds from issuance of common stock, upon the exercise of warrants	76	536	—
Payments on notes payable	(6,875)	—	—
Proceeds from debt	—	—	10,000
Payments for repurchase of common stock	—	—	(1)
Payments for offering costs, net	(182)	(1,599)	(1,147)
Payments for debt issuance costs	—	—	(255)
Net cash provided by financing activities	223,364	292,453	8,628
Net increase (decrease) in cash, cash equivalents, and restricted cash	32,407	29,957	(452)
Cash, cash equivalents and restricted cash, beginning of period	81,249	51,292	51,744
Cash, cash equivalents and restricted cash, end of period	$ 113,656	$ 81,249	$ 51,292
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION			
Interest paid	$ 1,043	$ 1,089	$ 354
Non-cash investing and financing activities:			
Fair value of warrants issued with debt	$ —	$ —	$ 936
Amounts accrued for property and equipment	$ 159	$ 191	$ 104
Amounts accrued for offering costs	$ —	$ 37	$ 849
Reclassification of warrants to equity	$ —	$ 4,607	$ —

See accompanying 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 biotechnology company developing first-in-class antibody product candidates focused on unmet medical needs in inflammation. We develop our product candidates using our proprietary, antibody discovery technology platform, which is designed to replicate, *in vitro*, the natural process of antibody generation. We currently generate revenue from milestones achieved under our collaborative research and development arrangements.

Since our inception, we have devoted our primary effort to raising capital and 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, proceeds from our Term Loans as discussed in Note 5 below, and the issuance of convertible debt. 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. Management believes its currently available resources will provide sufficient funds to enable the Company to meet its 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.

Public Offerings and Related Transactions

Initial Public Offering

On January 31, 2017, we completed an initial public offering, or IPO, selling 5,750,000 shares, which included the exercise of the underwriters' option to purchase an additional 750,000 shares of common stock, at $15.00 per share. Proceeds from our initial public offering net of underwriting discounts and commissions were $80.2 million.

In addition, each of the following occurred in connection with the completion of the IPO on January 31, 2017:

- the conversion of all outstanding shares of convertible preferred stock into 11,520,698 shares of common stock; and
- the conversion of warrants to purchase 377,195 shares of convertible preferred stock into warrants to purchase 377,195 shares of common stock and the resultant reclassification of the warrant liability to additional paid-in capital.

Reverse Stock Split

On January 13, 2017, we amended and restated our certificate of incorporation to effect a one for seven reverse stock split of every outstanding share of our preferred and common stock. The financial statements and accompanying footnotes have been retroactively restated to reflect the reverse stock split.

Follow-on Public Offerings

On October 17, 2017, we completed an underwritten public offering selling 3,000,000 shares of common stock. All shares were offered by us at a price to the public of $68.50 per share. The aggregate net proceeds received by us from the offering were $194.7 million, net of underwriting discounts and commissions. As part of the underwritten public offering, on November 14, 2017, the underwriters exercised an additional 271,380 shares of common stock at a discounted price to the public of $68.50 per share for aggregate net proceeds of $17.6 million, net of underwriting discounts and commissions.

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, or 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 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. 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, 2018 and 2017, respectively, which we used to secure a letter of credit provided as security for our 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. Unrealized gains and losses, deemed temporary in nature, are reported as a component of accumulated other comprehensive income (loss). A decline in the fair value of any security below cost that is deemed other than temporary results in a charge to earnings and the corresponding establishment of a new cost basis for the security. 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.

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, 2018, 2017, or 2016.

Leases, Deferred Rent and Operating Lease Incentives

Our office leases are classified as operating leases. Rent expense is recognized on a straight-line basis over the terms of the leases and, accordingly, we record the cumulative difference between cash rent payments and the recognition of rent expense as a deferred rent liability. When an operating lease includes lease incentives, such as a rent abatements or leasehold improvement allowances, or requires fixed escalations of the minimum lease payments, the aggregate rental expense, including such incentives or increases, is recognized on a straight-line basis over the term of the lease.

Debt Issuance Costs

Debt issuance costs incurred to obtain debt financing are deferred and are amortized over the term of the debt using the effective interest method. The costs are recorded as a reduction to the carrying value of the debt and the amortization expense is included in interest expense in the statements of operations.

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

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, fringe benefits, 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. 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.

Australian Research and Development Tax Incentive

We are eligible under the Australian Research and Development Tax Incentive Program, or the Tax Incentive, to obtain a cash refund from the Australian Taxation Office for eligible research and development expenditures. However, we must have revenue of less than AUD $20.0 million during the reimbursable period and cannot be controlled by income tax exempt entities. The Tax Incentive is recognized as a reduction to research and development expense when there is reasonable assurance that the Tax Incentive will be received, the relevant expenditure has been incurred, and the amount can be reliably measured. The Tax Incentive is denominated in Australian dollars and, therefore, the related receivable is remeasured into U.S. dollars as of each reporting date.

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.

Warrants for Shares of Preferred Stock

In January 2017, upon completion of our IPO, all warrants were reclassified to additional paid-in capital. Prior to this, we accounted for warrants for shares of preferred stock with conversion features that provide for reductions in the warrant price as derivative liabilities in the accompanying balance sheets at their fair value on the date of issuance. The derivative liabilities were revalued at each balance sheet date, with changes in the fair value between reporting periods recorded as other income or expense in the consolidated statement of operations.

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. For each period presented, there is no difference in the number of shares used to calculate basic and diluted net loss per share.

The following table sets forth the 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)	**2018**	**2017**	**2016**
Convertible preferred stock	—	—	11,521
Options to purchase common stock	2,451	2,478	1,969
Warrants to purchase preferred stock	—	—	295
Warrants to purchase common stock	—	161	117
Total	2,451	2,639	13,902

Accounting Pronouncements Recently Adopted

In May 2014, the Financial Accounting Standards Board, or FASB, issued Accounting Standard Update (ASU) 2014-09, *Revenue from Contracts with Customers (Topic 606)*, which outlines a single comprehensive model for entities to use in accounting for revenue from contracts with customers and supersedes most current revenue recognition guidance, including industry-specific guidance. This standard is based on the principle that an entity should recognize revenue to depict the transfer of goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. This standard also requires additional disclosure about the nature, amount, timing and uncertainty of assets recognized from costs incurred to fulfill a contract and became effective for our annual reporting period beginning January 1, 2018, including interim periods within that reporting period. Entities have the option of using either a full retrospective or a modified retrospective approach for the adoption of the new standard. We assessed all potential impacts of

the standard, and the most significant impacts relate to our accounting for variable consideration including revenues related to contingent “milestone” based payments and our disclosures required under the new standard as it relates to our two ongoing collaboration agreements, TESARO and Celgene. Application of the new standard requires that variable consideration be recognized to the extent that it is probable that a significant reversal in the amount of revenue will not occur when the uncertainty associated with the variable consideration is subsequently resolved. Accordingly, we may be required to recognize milestone payments earlier in the period in which we determine a significant reversal will not occur, rather than when the milestone is achieved. However, we reviewed the TESARO and Celgene agreements and determined that given the nature of potential milestones owed to us under these agreements, and the inherent risk involved in developing drugs, these potential milestones were not recognizable as of the standard adoption date. Additionally, while we currently disaggregate our revenue disclosures by collaborative agreement, additional discussion surrounding significant estimates made by management was required in our disclosure and included in Note 4 below. We adopted this standard using the modified retrospective approach for our annual reporting period beginning January 1, 2018, and did not record any adjustments upon adoption of this standard.

In January 2016, the FASB issued ASU 2016-01, *Financial Instruments—Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities*, which intends to enhance the reporting model for financial instruments by providing users of financial instruments with more decision-useful information. The standard also addresses certain aspects of the recognition, measurement, presentation, and disclosure of financial instruments and requires additional disclosure about the nature, amount, timing and uncertainty of assets recognized from costs incurred to fulfill a contract and became effective for our annual reporting period beginning January 1, 2018, including interim periods within that reporting period; early adoption is permitted. We adopted this standard as of January 1, 2018 and there was no material impact on our consolidated financial statements. We did not record any adjustments upon adoption of this standard and have consistently applied our accounting policies to all periods presented in the consolidated financial statements.

In May 2017, the FASB issued ASU 2017-09, *Compensation - Stock Compensation (Topic 718)*, which provides further guidance as to what constitutes a modification to the terms of shared based compensation, in order to create consistency in practice amongst all entities. ASU 2017-09 became effective for annual reporting periods beginning after December 15, 2017, including interim periods thereafter; early adoption is permitted, including adoption in an interim period. We adopted this standard as of January 1, 2018, and the impact was not material on our consolidated financial statements. We did not record any adjustments upon adoption of this standard.

Recent Accounting Pronouncements

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842)*, which requires that lessees recognize a right-of-use, or “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, *Codification Improvements to Topic 842, Leases*; and ASU 2018-11, *Targeted Improvements*. ASU 2016-02 becomes effective for our annual reporting period beginning January 1, 2019, including interim periods thereafter; early adoption is permitted. 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 expect to adopt the new standard on January 1, 2019 and use the effective date as our date of initial application. The new standard provides a number of optional practical expedients in transition. We expect to elect the ‘package of practical expedients’, which permits us not to reassess under the new standard our prior conclusions about lease identification, lease classification and initial direct costs. Adoption of the new standard will result 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 will 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, 2018	December 31, 2017
Laboratory equipment	$ 4,287	$ 3,687
Office furniture and equipment	780	605
Leasehold improvements	575	351
Property and equipment, gross	5,642	4,643
Less: accumulated depreciation and amortization	(4,197)	(3,978)
Total property and equipment, net	$ 1,445	$ 665

Accrued Expenses

Accrued expenses consist of the following:

(in thousands)	December 31, 2018	December 31, 2017
Accrued compensation and related expenses	$ 2,421	$ 1,588
Accrued research and contract manufacturing expenses	5,577	2,961
Other	763	326
Total accrued expenses	$ 8,761	$ 4,875

4. Collaborative Research and Development Agreements

TESARO Collaboration

In March 2014, we entered into a Collaboration and Exclusive License Agreement, or the TESARO Agreement, with TESARO, Inc. and TESARO Development, Inc., or collectively, TESARO, an oncology-focused biopharmaceutical company. Under the terms of the 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 TESARO. Under the terms of the agreement, TESARO 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, we and TESARO entered into Amendment No. 1 to the Agreement 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 TESARO, 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 agreement will terminate, with respect to each specific developed product, upon the latter 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 Topic 606, we determined that the upfront license fees and research funding under the 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 December 2015, 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 milestones were recognized was extended through December 31, 2016, and have been recognized in full.

We assessed this arrangement in accordance with ASC Topic 606 and concluded that the contract counterparty, TESARO, is a customer. We identified the following material promises under the TESARO Agreement: (1) the licenses under certain patent rights relating to six discovery programs (four targets) and transfer of certain development and regulatory information, (2) R&D services and (3) Joint Steering Committee meetings. We considered the research and discovery capabilities of TESARO for these specific programs, TESARO'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 the 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 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.

As of December 31, 2018, the transaction price includes the upfront payment, research reimbursement revenue, and milestones earned to date, which are allocated in their entirety to the single performance obligation. We earned and recognized one clinical milestone for $5.0 million during the year ended December 31, 2018. 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 the licensees' 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 IP license granted to TESARO 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, 2018 under the TESARO Agreement are as follows:

	Anti-PD-1 (TSR042)		Anti-TIM-3 (TSR022)		Anti-LAG-3 (TSR033)	
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	—	—
Phase 3 clinical trial initiation	$5.0M	Q3'18	—	—	—	—

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 $5.0 million in revenue under this agreement during the year ended December 31, 2018 related to one milestone and recognized $10.0 million during the year ended December 31, 2017 related to three milestones. We recognized aggregated revenue under this agreement of $15.2 million during the year ended December 31, 2016, which includes $9.3 million related to milestones earned, $3.2 million in funding for research and development services and $2.6 million for the amortization of the upfront fee.

Antibody Generation Agreement with Celgene Corporation

In December 2011, we entered into a license and collaboration agreement with Celgene, or the Celgene Agreement, to develop therapeutic antibodies against multiple targets. We granted Celgene 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 agreement provided for an upfront payment of $6.0 million from Celgene, 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, Celgene, is a customer. We identified the following material promises under the Celgene 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 Celgene, Celgene'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 the 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, 2018, the transaction price 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 the licensees' 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 IP license granted to Celgene 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, 2018 under the Celgene 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

Milestones achieved during fiscal 2016 were recognized as revenue in the period earned, while 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, 2018 and 2017. Revenue recognized under this agreement aggregated $1.5 million during the year ended December 31, 2016 related to two milestones earned.

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 connection with the issuance of the Term A Loans, we issued detachable, fully vested warrants to purchase an aggregate of 41,208 shares of Series C Preferred Stock at an exercise price of $4.55 per share to the lenders. The grant-date fair value of the warrants of $0.1 million was recorded as a liability, with a reduction to the carrying value of the Term A Loans, and which is recognized as additional interest expense over the remaining term of the Loans. The initial fair value of the warrants was determined using the Black-Scholes option pricing model with the following assumptions: a stock price volatility of 70.2%, an expected life equal to the contractual term of the warrants of ten years and a risk-free interest rate of 1.97%.

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 as of December 31, 2018, there are 13 monthly principal and interest payments remaining on the Term Loans, with final maturity in January 2020. The Term Loans bear interest equal to the greater of 3-month U.S. LIBOR plus 6.37% or 7.3%. The interest rate was 8.93% as of December 31, 2018.

In connection with the issuance of the Term B & C Loans, we issued detachable, fully vested warrants to purchase an aggregate of 82,416 shares of Series C Preferred Stock at an exercise price of $4.55 per share to the lenders. The grant-date fair value of the warrants of $0.9 million was recorded as a liability, with a reduction to the carrying value of the Term B & C

Loans, and which is recognized as additional interest expense over the remaining term of the Loans. The initial fair value of the warrants was determined using the Black-Scholes option pricing model with the following assumptions: a stock price volatility of 79.2%, an expected life equal to the contractual term of the warrants of ten years and a risk-free interest rate of 2.45%. As discussed in Note 7 below, all of the outstanding warrants to purchase shares of preferred stock automatically converted into warrants to purchase shares of common stock in connection with the IPO and were accounted for as equity from the conversion date forward. All warrants related to Term Loans were exercised during the year ended December 31, 2017.

The costs incurred to issue the Term Loans were deferred and are included in the discount to the carrying value of the Term Loans in the accompanying balance sheet. The Term Loans also include 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 are being amortized to interest expense over the expected term of the Term A Loans using the effective interest method.

As of December 31, 2018, the carrying amount of the Term Loans was $8.2 million, which includes amortized final payment fees of $0.1 million and of which $7.6 million is classified as current liabilities as of December 31, 2018. The effective interest rate on the Term Loans at December 31, 2018 was 13.32%. As of December 31, 2018, future principal maturities of the Term Loans were $7.5 million, and $0.6 million in 2019 and 2020, respectively.

The Term Loans are secured by a first priority interest in most of our assets, excluding intellectual property. As of December 31, 2018, we were in compliance with the covenants contained in the Loan Agreement.

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, notes payable and, through January 31, 2017, preferred stock warrant liabilities. 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, 2018				
Money market funds[1]	$ 87,213	$ 87,213	$ —	$ —
Mutual funds[1]	7,967	7,967	—	—
U.S. treasury securities[2]	164,245	164,245	—	—
Certificates of deposit[2]	4,784	—	4,784	—
Agency securities[1][2]	81,296	—	81,296	—
Commercial and corporate obligations[1][2]	153,983	—	153,983	—
At December 31, 2017				
Money market funds[1]	$ 41,318	$ 41,318	$ —	$ —
Mutual funds[1]	28,817	28,817	—	—
U.S. treasury securities[2]	79,397	79,397	—	—
Agency securities [2]	59,948	—	59,948	—
Commercial and corporate obligations[2]	111,660	—	111,660	—

(1) Included in cash and cash equivalents, and 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.

Warrant Liabilities. Our preferred stock warrants were accounted for as derivative liabilities and measured at fair value on a recurring basis through January 31, 2017 as they contained features that were either not afforded equity classification or embodied risks that were not clearly and closely related to host contracts. We estimated the fair value of these derivatives utilizing the Black-Scholes option-pricing model, which required Level 3 inputs.

As discussed in Note 7 below, all of the outstanding warrants to purchase shares of preferred stock automatically converted into warrants to purchase shares of common stock in connection with the IPO and are accounted for as equity from the conversion date forward. Prior to the conversion, we estimated the fair value of convertible preferred stock warrants at the time of issuance and upon subsequent remeasurement using the Black-Scholes option-pricing model at each reporting date.

The following weighted-average assumptions were utilized in estimating the value of the liabilities for Series C preferred stock warrants using the Black-Scholes option-pricing model as of January 31, 2017, the conversion date:

	January 31, 2017
Fair value of preferred stock	$ 16.95
Exercise price	$ 4.55
Risk-free interest rate	1.4%
Volatility	88.8%
Dividend Yield	—%
Contractual term (in years)	3.8
Weighted-average measurement date fair value per share	$ 13.71

The following table summarizes the activity in liabilities measured at fair value on a recurring basis using significant unobservable inputs (Level 3 Inputs):

(in thousands)	Year Ended December 31, 2017
Preferred Stock Warrant Liabilities:	
Beginning balance	$ (3,241)
Net gains (losses) included in other expense	(1,366)
Reclassification of warrant liabilities to equity	4,607
Ending balance	$ —

Fair Value of Other Financial Instruments

The fair value of our other financial instruments estimated as of December 31, 2018 and December 31, 2017 are presented below:

	December 31, 2018		December 31, 2017	
	Carrying Amount	Fair Value	Carrying Amount	Fair Value
Notes payable	$ 8,199	$ 8,806	$ 14,428	$ 15,650

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, Australian tax incentive receivable, 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, 2018 are as follows:

(in thousands)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Total Fair Value
Agency securities[1]	$ 81,371	$ 62	$ (137)	$ 81,296
Certificates of deposit[2]	4,784	—	—	4,784
Commercial and corporate obligations[3]	154,070	62	(149)	153,983
US Treasury securities[4]	164,251	96	(102)	164,245
Total available-for-sale investments	$ 404,476	$ 220	$ (388)	$ 404,308

(1) Of our outstanding agency securities, $67.4 million have maturity dates of less than one year and $13.9 million have a maturity date of between one to two years as of December 31, 2018.

(2) All of our outstanding certificates of deposit have a maturity date of between one to two years as of December 31, 2018.

(3) Of our outstanding commercial and corporate obligations, $126.8 million have maturity dates of less than one year and $27.2 million have a maturity date of between one to two years as of December 31, 2018.

(4) Of our outstanding U.S. Treasury securities $137.0 million have maturity dates of less than one year and $27.3 million have a maturity date of between one to two years as of December 31, 2018.

7. Stockholders' Equity

Common and Preferred Stock

On January 31, 2017, upon completion of our IPO, we amended our Certificate of Incorporation to increase the number of authorized shares of common stock to 500,000,000 with a par value of $0.001 and decrease the number of authorized shares of preferred stock to 10,000,000 with a par value of $0.001 per share.

Common Stock

Of the 500,000,000 shares of common stock authorized, 26,921,822 shares were issued and outstanding as of December 31, 2018. Common stock reserved for future issuance upon the exercise, issuance or conversion of the respective equity instruments at December 31, 2018 are as follows:

Issued and Outstanding:	
Stock options	2,152,455
Shares Reserved For:	
2017 Equity Incentive Plan	2,021,019
2017 Employee Stock Purchase Plan	455,193
Total	4,628,667

Warrant Exercises

During the year ended December 31, 2018, 16,770 shares of common stock were issued as a result of warrant exercises. During the year ended December 31, 2017, warrants for the purchase of 477,908 shares of common stock were exercised, of which 359,999 were exercised by a net exercise method. As a result, we issued 398,837 shares of common stock. As of December 31, 2018, all warrants have been exercised.

Repurchase of Common Stock

Certain stock option grants under our 2006 Equity Incentive Plan, or the 2006 Plan, were subject to an early exercise provision. Shares of common stock obtained upon early exercise of unvested options are subject to repurchase by us at the applicable original issue price. During the year ended December 31, 2016, we repurchased 1,457 shares of common stock. No shares were repurchased during the years ended December 31, 2018 or 2017.

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, or 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, or the 2006 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 951,656 shares as of January 1, 2018.

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 237,913 shares as of January 1, 2018.

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 have a maximum term of ten 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, 2018 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, 2018	2,425,903	$ 12.03		
Granted	368,607	$ 98.19		
Exercises	(583,660)	$ 4.92		
Forfeitures and cancellations	(58,395)	$ 55.13		
Outstanding at December 31, 2018	2,152,455	$ 27.55	7.07	$ 90,143
Exercisable at December 31, 2018	1,265,626	$ 13.01	6.30	$ 65,718

Total cash received from the exercise of stock options was approximately $2.9 million during the year ended December 31, 2018.

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,		
	2018	2017	2016
Risk-free interest rate	2.7%	2.0%	1.4%
Expected volatility	67.7%	64.3%	70.5%
Expected dividend yield	—%	—%	—%
Expected term (in years)	6.25	6.25	6.25
Weighted average grant date fair value per share	$ 61.41	$ 14.82	$ 4.35

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 director 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. The weighted average expected term for non-employee stock-based awards is the remaining contractual life of the award. Estimated volatility incorporates historical volatility of 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.

There were 368,607, 1,099,806 and 330,622 stock options granted during the years ended December 31, 2018, 2017 and 2016, respectively.

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:

	Year Ended December 31,		
(in thousands)	**2018**	**2017**	**2016**
Research and development	$ 3,371	$ 1,347	$ 420
General and administrative	6,590	3,031	740
Total	$ 9,961	$ 4,378	$ 1,160

At December 31, 2018, there was $25.6 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 2.36 years.

9. Australia Research and Development Tax Incentive

Our Australian subsidiary, which conducts core research and development activities on our behalf, is eligible to receive a 43.5% refundable tax incentive for qualified research and development activities during fiscal 2018 and fiscal 2017, and 45.0% during fiscal 2016. For the years ended December 31, 2018, 2017 and 2016, $0.1 million, $1.5 million and $7.2 million, respectively, were recorded as a reduction to research and development expenses in the consolidated statements of operations and comprehensive loss. As of December 31, 2018 our tax incentive receivable from the Australian government was $0.2 million. We received approximately $1.5 million and $4.6 million in cash during the years ended December 31, 2018 and 2017, respectively, related to the tax incentive.

10. Employee Benefit Plan

We have a defined-contribution 401(k) plan for our employees. Employees are eligible to participate in the plan beginning on the first day of the month following date of hire. Under the terms of the plan, employees may make voluntary contributions as a percentage of compensation and we have the option to make a discretionary match as determined by the board of directors, within prescribed limits. There were no employer contributions to the plan during the years ended December 31, 2018, 2017 and 2016.

11. Commitments and Contingencies

Operating Leases

In May 2018, we entered into a three-year non-cancellable sub-lease agreement for an additional 18,000 square feet of office space, which we determined to be an operating lease. This lease has three renewal options, each for one year, which we currently do not anticipate exercising. We also continue to lease our headquarters under a non-cancellable operating lease for which we early exercised our option to renew for an additional five-year period in fiscal 2015. Both leases expire in 2021.

Rent expense was $0.7 million, $0.5 million and $0.5 million during the years ended December 31, 2018, 2017 and 2016, respectively. At December 31, 2018, deferred rent aggregated $0.2 million, which is included in both current and noncurrent liabilities in the accompanying consolidated balance sheets. At December 31, 2018, the future minimum annual obligations under non-cancellable operating lease commitments are as follows:

Years Ending December 31, (in thousands)		
2019	$	937
2020		969
2021		726
2022		—
2023		—
Thereafter		—
Total minimum payments required	$	2,632

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 $0.3 million, $0.5 million and $0.3 million during the years ended December 31, 2018, 2017 and 2016, respectively. Total cash paid under these agreements was $0.2 million, $0.6 million, and $0.2 million during the years ended December 31, 2018, 2017, and 2016, respectively.

Future minimum annual obligations under all such license agreements will be $0.2 million in aggregate during 2019, 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, 2018 and 2017, 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

We are, from time to time, involved in legal proceedings, regulatory actions, claims and litigation arising in the ordinary course of business. Currently, we are not involved in any legal proceeding that we expect to have a material effect on our business, financial condition, results of operations and cash flows.

12. Income Taxes

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

	Year Ended December 31,		
(in thousands)	**2018**	**2017**	**2016**
U.S.	$ (61,193)	$ (27,494)	$ (632)
Foreign	(655)	(2,576)	(3,627)
Consolidated net loss before income taxes	$ (61,848)	$ (30,070)	$ (4,259)

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

	December 31,	
(in thousands)	**2018**	**2017**
Deferred Tax Assets:		
Net operating loss carryforwards	$ 35,499	$ 17,408
Research and development credits	9,190	4,773
Other, net	2,948	1,686
Total deferred tax assets	47,637	23,867
Deferred Tax Liabilities:		
Fixed assets	(49)	(57)
Total deferred tax liabilities	(49)	(57)
Net deferred tax assets	47,588	23,810
Less: valuation allowance	(47,588)	(23,810)
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, 2018, we had federal and state net operating loss carryforwards, or NOLs, of $145.3 million and $59.1 million, respectively. The federal and state NOLs will both begin to expire in 2028, unless previously utilized. The federal NOLs include $85.2 million of net operating losses generated in 2018. Federal net operating losses generated in 2018 carryforward indefinitely and may generally be used to offset up to 80% of future taxable income in the year it is utilized. At December 31, 2018 we had federal and California research tax credit carryforwards of $6.1 million and $5.9 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 $2.7 million, which will carry forward indefinitely, subject to a continuity of ownership test.

The above NOLs 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, 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 through December 31, 2018, noting an ownership change in 2017 that may limit the utilization of Federal and State NOLs. Our use of federal NOLs 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 NOLs may be similarly limited. If limited, 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 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:

	Year Ended December 31,		
(in thousands)	**2018**	**2017**	**2016**
Expected income tax benefit at federal statutory tax rate	$ (12,988)	$ (10,223)	$ (1,448)
State income taxes, net of federal benefit	(166)	(787)	(174)
Permanent items	17	13	12
Equity compensation [(1)]	(6,693)	(739)	163
Change in fair value of preferred stock warrant liabilities	—	464	257
Research and development expenditure	63	679	789
Refundable AMT credit	(139)	—	—
Return to provision adjustment	60	11	1,957
Rate differential	155	297	52
Federal rate adjustment - tax reform	—	7,595	—
Research credits	(4,393)	(1,554)	(814)
Change in the valuation allowance	23,892	4,244	(794)
Income tax benefit	$ (192)	$ —	$ —

[(1)] Includes non-deductible stock-based compensation and, beginning in 2017, excess tax benefits from stock-based compensation. During fiscal 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. During fiscal 2017, our tax provision includes $0.4 million of excess tax benefits associated with the exercise of non-qualified stock options and $0.7 million associated with the disqualifying dispositions of incentive stock options.

The Tax Cuts and Jobs Act, or the 2017 Act, was enacted on December 22, 2017, and includes a number of changes to existing U.S. tax laws that impact us, most notably a reduction of the U.S. corporate income tax rate from 35% to 21% for tax years beginning after December 31, 2017. The 2017 Act also provides for a one-time transition tax on certain foreign earnings and the acceleration of depreciation for certain assets placed in service after September 27, 2017 as well as prospective changes beginning in 2018, including additional limitations on: executive compensation; the deductibility of interest; the usage of NOLs against taxable income; the capitalization of research and development expenditures. While the 2017 Act provides for a territorial tax system, beginning in 2018, it includes two new U.S. tax base erosion provision, the global intangible low-taxed income, or GILTI provisions and the base-erosion and anti-abuse tax, or BEAT, provisions.

We completed our analysis of the 2017 Act income tax effects and remeasured our deferred tax assets and liabilities to reflect the reduction in the U.S. corporate income tax rate from 35% to 21% percent, resulting in a $7.6 million increase in tax expense for the year ended December 31, 2017 and a corresponding $7.6 million decrease in net deferred tax assets for the year ended December 31, 2017. The impact was fully offset by a valuation allowance.

On December 22, 2017, the SEC staff issued Staff Accounting Bulletin No. 118 to address the application of U.S. GAAP in situations when a registrant does not have the necessary information available, prepared, or analyzed, including computations, in reasonable detail to complete the accounting for certain income tax effects of the 2017 Act. We applied the guidance in SAB 118 when accounting for all of the enactment-date income tax effects of the Act under ASC 740, Income Taxes, related to the remeasurement of deferred tax assets and liabilities. As of December 31, 2018, we have completed our accounting for all of the enactment-date income tax effects of the Act and no adjustments were made to the provisional amounts recorded at December 31, 2017.

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, 2018 and 2017, 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:

	Year Ended December 31,	
(in thousands)	**2018**	**2017**
Balance at the beginning of the year	$ 591	$ 409
Increase related to prior year tax positions	9	—
Increase related to current year tax positions	1,212	182
Balance at the end of the year	$ 1,812	$ 591

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, 2018, 2017 and 2016, 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. Selected Quarterly Financial Data (Unaudited)

The following is a summary of our quarterly results for the years ended December 31, 2018 and 2017 (in thousands, except for per share data):

	Quarter				
2018	**First**	**Second**	**Third**	**Fourth**	**Year Ended December 31, 2018**
Operating loss	$ (15,757)	$ (14,415)	$ (16,887)	$ (19,663)	$ (66,722)
Net loss	$ (15,086)	$ (13,618)	$ (15,958)	$ (16,994)	$ (61,656)
Per common share:					
Loss per share, basic	$ (0.63)	$ (0.57)	$ (0.66)	$ (0.64)	$ (2.50)
Loss per share, diluted	$ (0.63)	$ (0.57)	$ (0.66)	$ (0.64)	$ (2.50)

	Quarter				
2017	**First**	**Second**	**Third**	**Fourth**	**Year Ended December 31, 2017**
Operating loss	$ (9,988)	$ (2,555)	$ (9,087)	$ (7,151)	$ (28,781)
Net loss	$ (11,435)	$ (2,684)	$ (9,090)	$ (6,861)	$ (30,070)
Per common share:					
Loss per share, basic	$ (0.75)	$ (0.13)	$ (0.45)	$ (0.30)	$ (1.52)
Loss per share, diluted	$ (0.75)	$ (0.13)	$ (0.45)	$ (0.30)	$ (1.52)

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, 2018, our management, with the participation of our Chief Executive Officer and Chief 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 Securities and Exchange Commission's rules and forms, and that such information is accumulated and communicated to our management, including the Chief Executive Officer and the Chief Financial Officer, to allow timely decisions regarding required disclosures. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of December 31, 2018, 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, 2018. 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, 2018 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. The effectiveness of our internal control over financial reporting as of December 31, 2018 has been audited by KPMG LLP, an independent registered public accounting firm, as stated in their report which is included herein.

The certifications of our Chief Executive Officer and Chief Financial Officer required under Section 302 of the Sarbanes-Oxley Act have been filed as Exhibits 31.1 and 31.2 to this report.

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, 2018 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.

Report of Independent Registered Public Accounting Firm

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

Opinion on Internal Control Over Financial Reporting

We have audited AnaptysBio, Inc. and subsidiary (the Company) internal control over financial reporting as of December 31, 2018, based oncriteria established in *Internal Control - Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission. In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2018, based on criteria established in *Internal Control - Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets of the Company as of December 31, 2018 and 2017, the related consolidated statements of operations and comprehensive loss, convertible preferred stock and stockholders' equity (deficit), and cash flows for each of the years in the three-year period ended December 31, 2018, and the related notes (collectively, the consolidated financial statements), and our report dated February 28, 2019 expressed an unqualified opinion on those consolidated financial statements.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Annual Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audit also included performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control Over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

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

/s/ KPMG LLP

San Diego
February 28, 2019

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 “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 2019 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 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 2019 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 2019 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 2019 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 2019 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 at 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	
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, to become effective on the date the registration statement is declared effective, and forms of award agreements.	S-1	333-206849	10.3	January 17, 2017	
10.4*	2017 Employee Stock Purchase Plan, to become effective on the date the registration statement is declared effective, 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*	Employment Agreement, effective as of March 22, 2016, by and between the Registrant and Matthew Moyle.	S-1	333-206849	10.6	December 28, 2016	
10.7*	Employment Agreement, effective as of October 20, 2014, by and between the Registrant and Marco Londei, as amended.	10-K	001-37985	10.7	March 5, 2018	
10.8*	Employment Agreement, effective as of January 9, 2017, by and between the Registrant and Dominic Piscitelli, as amended.	10-K	001-37985	10.8	March 5, 2018	
10.9	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	
10.10	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	

Exhibit Number	Description of Document	Incorporated by reference				Filed Herewith
		Form	File No.	Exhibit	Filing Date	
10.11+	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	
10.12+	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	
10.13+	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	
10.14	Loan and Security Agreement, dated December 24, 2014, by and among the Registrant, Oxford Finance LLC and Silicon Valley Bank, as amended.	S-1	333-206849	10.13	February 2, 2016	
10.15*	Employment Agreement, effective August 6, 2018, by and between Registrant and Eric Loumeau	10-Q	001-37985	10.15	November 8, 2018	
10.16	Investor Rights Agreement.	10-Q	001-37985	4.1	November 8, 2018	
10.17	Sub-lease Agreement.	10-Q	001-37985	10.1	November 8, 2018	
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					
101.SCH	XBRL Taxonomy Extension Schema Document					
101.CAL	XBRL Taxonomy Calculation Linkbase Document					
101.LAB	XBRL Taxonomy Label Linkbase Document					
101.PRE	XBRL Presentation Linkbase Document					
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document					

* 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 28, 2019

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 Dominic G. Piscitelli, 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 28, 2019
/s/ Dominic G. Piscitelli Dominic G. Piscitelli	Chief Financial Officer (Principal Accounting and Financial Officer)	February 28, 2019
/s/ Dennis Fenton Dennis Fenton, Ph.D.	Director	February 28, 2019
/s/ Nicholas B. Lydon Nicholas B. Lydon, Ph.D., FRS	Director	February 28, 2019
/s/ Hollings Renton Hollings Renton	Director	February 28, 2019
/s/ John Schmid John Schmid	Director	February 28, 2019
/s/ James N. Topper James N. Topper, M.D., Ph.D.	Director	February 28, 2019
/s/ J. Anthony Ware J. Anthony Ware, M.D.	Director	February 28, 2019

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 (No. 333-222868) on Form S-3ASR, and registration statement (Nos. 333-215741, 333-223446) on Form S-8 of AnaptysBio, Inc. of our report dated February 28, 2019, with respect to the consolidated balance sheets of AnaptysBio, Inc. as of December 31, 2018 and 2017, and the related consolidated statements of operations and comprehensive loss, convertible preferred stock and stockholders' equity (deficit), and cash flows for each of the years in the three-year period ended December 31, 2018, and the related notes (collectively, the "consolidated financial statements"), and the effectiveness of internal control over financial reporting as of December 31, 2018, which reports appear in the December 31, 2018 annual report on Form 10-K of AnaptysBio, Inc.

/s/ KPMG LLP

San Diego, California
February 28, 2019

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 28, 2019

/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, Dominic G. Piscitelli, 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 28, 2019

/s/ Dominic G. Piscitelli

Dominic G. Piscitelli

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, 2018 (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 28, 2019

/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, Dominic G. Piscitelli, 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, 2018 (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 28, 2019

/s/ Dominic G. Piscitelli

Dominic G. Piscitelli
Chief Financial Officer
(Principal Financial Officer)