

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

**FORM 10-K**

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

For the fiscal year ended December 31, 2016

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**  
(State or other jurisdiction of  
incorporation or organization)  
10421 Pacific Center Court, Suite 200  
San Diego, CA  
(Address of principal executive offices)

20-3828755  
(I.R.S. Employer  
Identification Number)

92121  
{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  NO

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

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

Indicate by check mark whether the Registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the Registrant was required to submit and post such files). YES  NO

Indicate by check mark 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.

Indicate by check mark whether the Registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definition of "large accelerated filer", "accelerated filer", and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer  Accelerated filer

Non-accelerated filer  (Do not check if a small reporting company) Small reporting company

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

The registrant was not a public company as of the last business day of its most recently completed second fiscal quarter and, therefore, cannot calculate the aggregate market value of its voting and non-voting common equity held by non-affiliates as of such date.

The number of shares of Registrant's Common Stock outstanding as of February 28, 2017 was 20,173,740.

DOCUMENTS INCORPORATED BY REFERENCE

None.

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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 ANB020 for patients with severe allergic and atopic diseases and ANB019 for patients with GPP and 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 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 ANB020 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 initial public offering;
- 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 of our proprietary product candidates, and for certain programs, establish partnerships with leading biopharmaceutical companies where we retain certain development and commercialization rights.

Our most advanced wholly-owned antibody programs, ANB020 and ANB019, neutralize therapeutic targets that are genetically associated with severe inflammatory disorders in humans. ANB020 inhibits the activity of the interleukin-33, or IL-33, cytokine for the treatment of moderate-to-severe adult atopic dermatitis, severe adult peanut allergy and severe adult eosinophilic asthma. ANB019 inhibits the interleukin-36 receptor, or IL-36R, for the treatment of rare inflammatory diseases including generalized pustular psoriasis, or GPP, and palmo-plantar pustular psoriasis, or PPP. The current status of our clinical development activities for ANB020 and ANB019 is outlined in the chart and bullet points below under “Our Product Candidates”. Our wholly-owned pipeline includes novel checkpoint receptor agonist antibodies that we believe are applicable for treatment of certain autoimmune diseases where immune checkpoint receptors are insufficiently activated, and have demonstrated efficacy in an animal model of graft-versus-host disease.

In addition to our wholly-owned antibody programs, multiple AnaptysBio-developed antibody programs have been advanced under our collaborations to preclinical and clinical milestones. Our collaborations include an immuno-oncology-focused collaboration with TESARO and an inflammation-focused collaboration with Celgene, which are further described below under “TESARO Programs” and “Celgene Programs” respectively.

## 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:

Program	Therapeutic Indication	Development Stage & Anticipated Milestones					Commercial Rights
		Discovery	Preclinical	Phase 1	Phase 2	Phase 3	
ANB020: Anti-IL-33	Moderate-to-Severe Adult Atopic Dermatitis				Phase 2a Data H2 2017		
	Severe Adult Peanut Allergy				Phase 2a Data H2 2017		
	Severe Adult Eosinophilic Asthma				Phase 2a Data H1 2018		
ANB019: Anti-IL-36R	Generalized Pustular Psoriasis			Data H2 2017	Initiate Phase 2 2018	AnaphysBio	
	Palmoplantar Pustular Psoriasis			Initiate Phase 2 2018			
Checkpoint Agonist	Inflammation		Ongoing	Initiate 2019			
TSR-042: Anti-PD-1	Immuno-Oncology			Ongoing	Initiate registration H1 2017	TESARO	
TSR-022: Anti-TIM-3	Immuno-Oncology			Ongoing	Initiate PD-1 combo Mid-2017		
TSR-033: Anti-LAG-3	Immuno-Oncology			Initiate Q2 2017			
Anti-PD-1/TIM-3 Bispecific	Immuno-Oncology	Ongoing					
Anti-PD-1/LAG-3 Bispecific	Immuno-Oncology	Lead Candidate Identified					
Undisclosed Bispecific	Immuno-Oncology	Ongoing					
CC-90006: Anti-PD-1 Agonist	Psoriasis			Ongoing		Celgene	
Undisclosed	Inflammation		Ongoing				

Our most advanced, wholly-owned product candidates are summarized below:

- ANB020** is a potentially first-in-class antibody that inhibits the activity of IL-33, a pro-inflammatory cytokine that multiple studies have indicated is a central mediator of atopic diseases, including atopic dermatitis, food allergies and asthma. IL-33 directly mediates release of disease-associated cytokines, which recruit pro-inflammatory cells that mediate atopic disease. Because ANB020 inhibits IL-33 function, and acts upstream broadly across the key cell types and cytokines involved in atopy, we believe that its mechanism has advantages in the treatment of atopic diseases over competing agents that block only a subset of the cytokines responsible for atopic diseases. The role of IL-33 signaling in asthma has been recently genetically validated through human studies published in the medical literature. The role of IL-33 in peanut allergy is supported by translational research data, recently presented at the American Academy of Allergy, Asthma and Immunology, or AAAAI, conference in early March 2017, which concluded that IL-33-sensitive T cells are found in elevated frequency in peanut allergy patients and, upon stimulus with IL-33, are responsible for elevated secretion of effector cytokines involved in severe peanut allergy. We have completed a Phase 1 trial of ANB020 in healthy volunteers in Australia under an approved CTN. We believe the results of this Phase 1 trial demonstrate a favorable safety profile of ANB020, which was well-tolerated and for which no dose-limiting toxicities were observed, and favorable pharmacodynamic properties of ANB020, where a single dose was sufficient to suppress IL-33 function for approximately three months post-dosing as measured by an *ex vivo* pharmacodynamic assay. We have disclosed detailed data from this Phase 1 trial at the 2017 American Academy of Dermatology, or AAD and the AAAAI conferences in early March 2017. We have cleared an Investigational New Drug application, or IND, with the U.S. Food and Drug Administration, or FDA, and a Clinical Trial Authorisation, or CTA, with the U.K. Medicines and Healthcare Products Regulatory Agency, or MHRA, to initiate Phase 2a trials of ANB020 in patients

with severe adult peanut allergy and moderate-to-severe adult atopic dermatitis, respectively, each of which are currently enrolling patients. We anticipate top-line data from these trials to be announced in the second half of 2017. In addition, we plan to submit a regulatory filing to seek regulatory clearance during the first half of 2017 to initiate a Phase 2a trial in patients with severe adult eosinophilic asthma. We anticipate top-line data from this trial to be announced during the first half of 2018. Based on our analysis of publicly available data sources and interviews with physicians and key opinion leaders in the field of atopic dermatitis, we estimate approximately 1.4 million adults are affected by atopic dermatitis, of which approximately 280,000 are diagnosed with a moderate-to-severe form of this disease, of which 98,000 are believed to be suitable for treatment with systemic biological therapies in the United States. Peanut allergy is the most common cause of food-induced allergy in the United States. Based on our analysis of publicly available data sources and interviews with physicians and key opinion leaders in the food allergy field, we estimate approximately 1.7 million adults are affected by peanut allergy, of which approximately 600,000 are treated by allergists and approximately 400,000 are at risk for severe reactions and therefore we believe are suitable for treatment with systemic biological therapies in the United States. We estimate, based on our analysis of publicly available data sources and interviews with physicians and key opinion leaders focused on asthma, that asthma affects approximately 19.0 million individuals, of which approximately 1.1 million have severe disease that cannot be controlled by standard-of-care therapy.

- **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 that, based on our analysis of publicly available data sources and interviews with physicians and key opinion leaders in the field, we estimate affects approximately 3,000 patients in the United States with no approved therapies. Studies have shown that GPP can be associated in some patients with mutations, that lead to abnormally high signaling through the IL-36R, which we believe can be addressed by treatment with ANB019 irrespective of whether a GPP patient has a mutated IL-36 signaling pathway. PPP is a non-fatal form of pustular psoriasis that we estimate affects approximately 150,000 patients in the United States alone. PPP is believed to be caused by increased levels of IL-36 cytokines, resulting in inflammatory pustules on the hands and feet of patients that cause significant inability to stand, walk or do manual work, which we believe can be addressed by treatment with ANB019. We believe ANB019 is the most advanced therapeutic antibody targeting IL-36R in development. We have cleared an Australian CTN for ANB019 and plan to initiate Phase 1 trials in Australia in the first half of 2017, and anticipate announcing top-line data from this trial during the second half of 2017. We subsequently plan to seek regulatory clearance to initiate Phase 2 studies of ANB019 in GPP and PPP patients during 2018 and plan to seek FDA Orphan Drug Designation for the treatment of GPP and PPP.
- **Checkpoint receptor agonist** antibodies are being developed by AnaptysBio to multiple different immune checkpoint receptors 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 have discovered certain checkpoint receptor agonist antibodies that have demonstrated efficacy in a rodent model of graft-versus-host disease. We anticipate that, subsequent to regulatory clearance, one of our wholly-owned checkpoint receptor antibodies will initiate human testing during 2019.

## The Advantages of Our SHM Platform

Our approach to developing novel therapeutic antibody product candidates is based upon somatic hypermutation, or SHM, a critical, endogenous process that generates the essential antibody diversity required to develop a natural immune response to pathogens. Our proprietary antibody generation platform, called SHM is designed to replicate the natural process of SHM *in vitro*. Competing antibody discovery technologies include mouse immunization methodologies, microbial antibody display and human B-cell screening. We believe our SHM platform overcomes several key limitations associated with these competing technologies and has the following competitive advantages:

- **Diversity against difficult targets.** By applying SHM without the constraints of an *in vivo* environment we are able to generate an unprecedented diversity of antibodies. This enables us to develop antibodies against human targets that we believe have not otherwise been accessible to other 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 subsequently advance preclinical manufacturing and toxicology studies to the filing of an IND or foreign equivalent, typically in approximately 2.5 years. We believe this timeline is significantly shorter than conventional antibody discovery approaches based upon mouse immunization and microbial display systems.
- **Manufacturability.** By using mammalian cell display to generate our therapeutic antibodies, we believe our platform mitigates risks associated with antibody expression, formulation and stability during the antibody generation process.
- **Bispecific antibodies.** A bispecific antibody is a single therapeutic molecule designed to bind two different targets. Bispecific antibodies have the advantage of combining two therapeutic mechanisms with the goal of increasing therapeutic efficacy, in comparison to monospecific antibodies that bind either of the targets individually. We believe our competitors' bispecific strategies generally rely on proteins with non-natural formats, resulting in unpredictable pharmacokinetics and manufacturing properties. Our strategy is to develop bispecific antibodies that are composed of two different heavy chains with a common shared light chain that resemble the natural antibody structure and exhibit the desired functional activity to each target. Utilizing our proprietary SHM platform, we are able to generate a large diversity of heavy and light chain varieties against each therapeutic target, and then co-mature a common light chain in the context of two different heavy chains, which permits us to identify bispecific antibodies with sufficient potency against each of the two targets that we believe will provide greater therapeutic benefit.

## 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.

- Advancing our wholly-owned lead product candidates to clinical milestones, such as our ANB020 and ANB019 programs.
- Continuing to expand our proprietary pipeline by generating new product candidates using our technology platform, such as our preclinical checkpoint receptor agonist programs.

- Identifying emerging opportunities in key therapeutic areas.
- Retaining rights to strategic products in key commercial markets.

## Milestones

The following chart describes milestones anticipated during 2017 and 2018.

Anticipated 2017-2018 Milestones			
Program	Milestone	Anticipated Timing	
AnaptysBio	Phase 1 Trial Detailed Data at Medical Conferences	Q1 2017	
	Atopic Dermatitis Phase 2a Trial Top-Line Data	H2 2017	
	Peanut Allergy Phase 2a Trial Top-Line Data	H2 2017	
	Eosinophilic Asthma Phase 2a Trial Top-Line Data	H1 2018	
	Phase 1 Trial Top-Line Data	H2 2017	
	ANB019 (anti-IL-36R)	GPP Phase 2 Trial Initiation	2018
		PPP Phase 2 Trial Initiation	2018
Checkpoint Receptor Agonist	Phase 1 Trial Initiation	2019	
TSR-042 (anti-PD-1)	Initiate Registration Trial	H1 2017	
TESARO Partnership	TSR-022 (anti-TIM-3)	Initiate PD-1 Combo Trial	Mid-2017
	TSR-033 (anti-LAG-3)	Phase 1 Trial Initiation	Q2 2017

## Our Collaborations

We have established collaborations with pharmaceutical and biotechnology companies. Multiple antibodies, generated by us prior to or during a strategic collaboration, are currently being advanced through development by our collaborators. Our collaborations with TESARO and Celgene are described below:

## TESARO Programs

Under our immuno-oncology collaboration with TESARO, we have granted exclusive rights to TESARO to develop and commercialize antibodies generated using our SHM platform consisting of the following antibody product candidates:

- *Anti-PD-1 Monospecific Antagonist Antibody (TSR-042)*: Phase 1 clinical trial dosing initiated in the first quarter of 2016 subsequent to the acceptance of a U.S. FDA IND, finalize registration strategy and initiate a registration program in H1 2017;
- *Anti-TIM-3 Monospecific Antagonist Antibody (TSR-022)*: Phase 1 clinical trial dosing initiated in the third quarter of 2016 subsequent to the acceptance of a U.S. FDA IND, expect initiation of an anti-PD-1 combination trial in mid-2017;
- *Anti-LAG-3 Monospecific Antagonist Antibody (TSR-033)*: currently in preclinical development, expect the initiation of a Phase 1 trial in Q2 2017;
- *Anti-PD-1/TIM-3 Bispecific Antagonist Antibody*: currently in lead selection process;
- *Anti-PD-1/LAG-3 Bispecific Antagonist Antibody*: lead candidate identified; and
- *Undisclosed Bispecific Antagonist Antibody*: currently in lead selection process.

## Celgene Programs

Under our collaboration with Celgene, we developed 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 collaboration. We successfully delivered antibodies against three targets. Celgene is currently advancing two anti-inflammatory antibody programs, and has initiated a Phase 1 trial for one of these two antibodies known as CC-90006, a PD-1 agonist antibody, which is indicated for psoriasis.

## Our Wholly-Owned Product Pipeline

Our most advanced, wholly-owned pipeline programs, ANB020 and ANB019, are described below:

### ANB020: Anti-IL-33 Antibody

ANB020 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 ANB020 is the most advanced antibody therapeutic candidate in development targeting the IL-33 cytokine. We have completed a Phase 1 trial of ANB020 in healthy volunteers in Australia under an approved CTN, and are currently enrolling a Phase 2a clinical trial of ANB020 in severe peanut allergy patients under an approved US IND and a Phase 2a clinical trial of ANB020 in moderate-to-severe atopic dermatitis under an approved UK CTA.

### 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 ANB020 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.

The role of IL-33 in peanut allergy is supported by translational research data, generated under our scientific collaboration with the Benaroya Research Institute at Virginia Mason (BRI), which was presented at the AAAAI's 2017 Annual Meeting on March 4th. This study, assessed the biology of a distinct subset of T cells, called TH2A cells, which are found in elevated frequency in peanut allergic patients when compared to non-allergic individuals. TH2A cells isolated from peanut allergy patients demonstrated increased sensitivity to IL-33 signaling as a result of elevated expression of the IL-33 receptor. Data showed that, upon stimulus with IL-33, TH2A cells express significantly greater levels of effector cytokines IL-4, IL-5, and IL-13, which are believed to be associated with severe peanut allergy. The research concluded that IL-33 is a key checkpoint of allergic responses, and blocking IL-33 has the potential to reduce expression of the effector cytokines involved in severe peanut allergy. These findings provide further scientific support for the development of AnaptysBio's proprietary anti-IL-33 antibody, known as ANB020, for the treatment of severe adult peanut allergy.

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. This supports the hypothesis that an anti-IL-33 antibody, such as ANB020, has the potential to benefit asthma 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 and (ii) soluble ST2 inhibits IL-33 function, therefore blocking ST2, and likely leading to the release of additional IL-33, thereby exacerbating atopic disease.

### **ANB020 Description**

ANB020, 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. Our preclinical studies have provided evidence of ANB020's favorable potency and functional activity in human and cynomolgus monkey *in vitro* assays. The high potency and functional activity of ANB020 for human and cynomolgus monkey IL-33 was measured using standard *in vitro* assays: equilibrium dissociation constant, or  $K_D$ , and half-maximal inhibitory concentration values, or  $IC_{50}$ . ANB020 demonstrated highly potent  $K_D$  values of approximately 1 pM and 37 pM for human and cynomolgus monkey IL-33, respectively. ANB020 inhibits secretion of IL-5 from primary basophils purified from peripheral blood of healthy human subjects with an  $IC_{50}$  of approximately 1.5 nM, which is approximately 15-fold greater than that of the soluble ST2 antagonist, as shown in Figure 3 below. Lower  $K_D$  and  $IC_{50}$  values indicate higher potency and functional activity, respectively.

Using peripheral blood mononuclear cells, or PBMC, ANB020 inhibited human and cynomolgus monkey interferon-gamma release with an  $IC_{50}$  of approximately 1.1 nM and approximately 20.4 nM, respectively. We have developed a whole blood version of the PBMC assay, which we are utilizing in our Phase 1 trial to understand the pharmacodynamic activity of ANB020 in clinical trials.

Our preclinical development has also demonstrated that ANB020 has favorable manufacturability, pharmacokinetics and toxicology to support development. Studies have demonstrated desirable manufacturing properties for ANB020, 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. ANB020 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 GLPs for ANB020. In addition, we have conducted manufacturing under good manufacturing practice to produce ANB020 in quantities for initial clinical use.

## Clinical Development Plan

We have completed a Phase 1 trial of ANB020 in healthy volunteers in Australia under an approved CTN. Our Phase 1 trial assessed, in single ascending doses, or SAD, and multiple ascending doses, or MAD, safety, tolerability and pharmacokinetic characteristics of ANB020. 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 ANB020 ranging between 10 mg and 750 mg, or four multiple doses of ANB020 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 ANB020, 51 subjects (80%) experienced at least one treatment-emergent adverse events (AE) however the occurrence of AEs was similar between ANB020 (38 of 48; 79%) versus placebo (13 of 16, 81%) dosed individuals, and the most common AEs were upper respiratory tract infection (ANB020 48% vs. placebo 50%) and headache (ANB020 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 ANB020 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 ANB020, 24 subjects (75%) experienced an AE, however there was no difference in the percentage of AEs observed amongst subjects dosed with ANB020 (18 of 24, 75%) versus placebo (6 of 8, 75%), and the most common AEs were upper respiratory tract infections (ANB020 21% versus placebo 38%) and headache (ANB020 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 ANB020 in the SAD portion of the Phase 1 study using a whole blood *ex-vivo* assay upon stimulation with IL-33/IL-12, where ANB020 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 ANB020 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 ANB020 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 ANB020 dosed subjects in the SAD cohorts and 2 of 24 ANB020 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 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 ANB020 can, at certain dose levels, extend to three months subsequent to a single administration. We have disclosed detailed data from this Phase 1 trial at the AAD and AAAAI conferences in early March 2017.

We have a cleared U.S. IND and U.K. CTA to initiate Phase 2a trials for ANB020 in patients with severe adult peanut allergy and moderate-to-severe adult atopic dermatitis, respectively, each of which are currently enrolling patients. We anticipate announcing top-line data from both of these trials during the second half of 2017. In addition, we plan to submit a regulatory filing to during the first half of 2017, the approval of which is anticipated to permit initiation of a Phase 2a trial in patients with severe adult eosinophilic asthma, and we anticipate announcing top-line data from the trial during the first half of 2018. Our planned Phase 2a trial in the U.K. in moderate-to-severe atopic dermatitis patients will assess the efficacy and safety of ANB020, as measured by mechanistic inflammatory cells and cytokines within lesions and clinical disease remission, among 12 moderate-to-severe adult atopic dermatitis patients treated with a single dose of ANB020. Our planned Phase 2a trial in severe adult peanut allergy in the United States will assess the efficacy and safety of ANB020, as measured by oral food challenge, among 20 severe adult peanut allergy patients treated with either a single dose of ANB020 or placebo. Our planned Phase 2a trial in severe adult eosinophilic asthma is intended to assess the efficacy and safety of ANB020 among 20 severe adult eosinophilic asthma patients treated with one or more doses of ANB020. Each of the aforementioned clinical trials are subject to regulatory review by the respective regulatory authority applicable to the jurisdiction of the trial.

Upon demonstrating initial efficacy in Phase 2a trials, we intend to conduct subsequent Phase 2 trials and Phase 3 registration trials for ANB020 in one or more of the aforementioned clinical indications. These later-stage trials may be conducted through collaboration with a leading pharmaceutical company with strong commercial infrastructure in respiratory and allergic therapeutic areas.

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 from the description in the figure below.

### **ANB020 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 ANB020 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 ANB020 program initially on three indications: severe adult eosinophilic asthma, severe adult peanut allergy and moderate-to-severe adult atopic dermatitis.

*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. 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 will initially focus on the treatment of severe asthma that, based on our analysis, includes 1.1 million adult patients whose disease is not sufficiently controlled through standard-of-care therapy. We have conducted primary market studies that estimate approximately 45% of these patients are candidates for biologic therapies, such as ANB020.

Existing biologic therapies include Xolair, which is approved for the treatment of moderate to severe persistent allergic asthma patients whose asthma symptoms are not controlled by ICS. Xolair’s approved labeling carries a black box warning about the risk of anaphylaxis, a severe, potentially fatal, allergic reaction, and Nucala, which the FDA recently approved for the add-on maintenance treatment in patients aged 12 years or older with severe eosinophilic asthma. Other emerging therapies currently in development, such as lebrikizumab, benralizumab, tralokinumab, anrukinzumab, dupilumab, AMG 317 and CNTO 7160, have yet to be approved by the FDA for treatment of asthma, while the FDA’s Pulmonary-Allergy Drugs Advisory Committee recommended that the FDA approve reslizumab in adult patients aged 18 years and older for the treatment of inadequately controlled asthma in patients with elevated eosinophils, despite an inhaled corticosteroids treatment regimen. Xolair is a difficult drug to prescribe due to complex dosing algorithms, frequent administration and risk of anaphylaxis, and we expect the indications for Nucala, reslizumab and lebrikizumab will be limited to asthma patients defined by biomarkers. We believe that ANB020 may have therapeutic benefit across a broad range of ICS-refractory severe adult eosinophilic asthma patients, and plan to utilize biomarkers during development to differentiate ANB020 relative to competitors.

*Peanut Allergy.* Peanuts are the most common cause of food-induced allergy in the United States. We estimate, based on our analysis of publicly available data sources and interviews with physicians and key opinion leaders in the field, that approximately 1.7 million adults in the United States have allergic responses to peanut. We estimate approximately 600,000 are treated by allergists and approximately 400,000 are at risk for severe reactions and therefore we believe are suitable for treatment with systemic biological therapies.

Existing therapies have failed to prevent the occurrence of severe reactions due to accidental peanut exposure, which often results in systemic anaphylaxis and can lead to death. Immunotherapy approaches, such as oral or transdermal desensitization, currently being developed for this indication require patients to be dosed with increasing quantities of peanut antigens over time. If patients are able to overcome the toxicities of this allergen- based approach, therapeutic benefit, on an allergen-specific basis, may be observed after 12 to 24 months of oral or

skin patch based delivery of peanut allergens. The long-term safety and efficacy of immunotherapy is still uncertain, and these desensitization treatments have not yet been approved by the FDA.

ANB020 has the potential to rapidly suppress severe adult peanut allergy through its cytokine targeting mechanism, which is allergen non-specific, allowing patients with multiple allergic responses to benefit from a single therapy, and avoids tolerability issues by acting without allergen dosing. If approved, we anticipate that ANB020 could become the standard-of-care for the treatment of severe adult peanut allergy patients.

*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 ANB020 will suppress the production of the aforementioned downstream cytokines and lead to therapeutic benefit in moderate to severe adult atopic dermatitis.

Current therapies for atopic dermatitis are generally focused on the topical use of non-biologic small molecules. Dupilumab is currently in development for the treatment of atopic dermatitis, and has shown some benefit in disease remission, but requires the administration of a significantly large antibody dose (300 mg) every week or every other week, which we believe may not be convenient for atopic dermatitis patients.

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. Existing therapies include topical steroids and related therapies, however such approaches have not demonstrated significant benefit for moderate-to-severe patients. We estimate that 98,000 atopic dermatitis patients would be eligible for treatment with a systemic biologic therapy such as ANB020.

## **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 believe ANB019 is the most advanced antibody targeting the IL-36R in development.

We have cleared an Australian CTN for ANB019 and plan to initiate a Phase 1 trial in Australia in the first half of 2017. We anticipate announcing top-line data from this trial in the second half of 2017.

### **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.

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 K<sub>D</sub> and IC<sub>50</sub> values. ANB019 has demonstrated potent K<sub>D</sub> values of approximately 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. As shown in Figure 7 below, functional potency of ANB019 is at least 100-fold greater than IL-36RA in human systems, which is measured as the IC<sub>50</sub> 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<sub>D</sub> and IC<sub>50</sub> values indicate higher potency and functional activity, respectively. Similar IC<sub>50</sub> 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 cleared an Australian CTN for ANB019 and plan to commence a Phase 1 clinical trial in the first half of 2017. We anticipate announcing top-line data from this trial during the second half of 2017. This Phase 1 clinical trial will test single and multiple ascending doses of ANB019 in healthy volunteers, while also utilizing *ex vivo* assays to determine ANB019's pharmacodynamic activity range. Following completion of this initial Phase 1 trial, we plan to submit a U.S. IND and/or a U.K. CTA to support further clinical testing of ANB019 in patients.

Our initial patient testing of ANB019 will focus primarily on GPP and PPP patients. We currently plan to conduct GPP efficacy testing of ANB019 in the United States and/or the United Kingdom using a Phase 2 clinical trial expected to be initiated in 2018 that enrolls GPP patients irrespective of mutation status. We believe a small trial, potentially with fewer than 100 patients, may be sufficient to demonstrate substantial evidence of efficacy and safety of ANB019 in GPP. We intend to obtain input from FDA on clinical trial design before conducting a pivotal clinical trial in patients with GPP.

We also intend to develop ANB019 for PPP. We anticipate initiating a Phase 2 trial for PPP within the United States and/or United Kingdom during 2018, followed by one or more Phase 3 pivotal registration trials. If we use a diagnostic test to select patients for inclusion in our registration program, such as a genetic test for IL-36RA

mutations, the FDA may require that the companion diagnostic be approved or cleared for use at the time the product receives marketing approval.

Human studies have shown that IL-36 cytokines are highly upregulated in psoriasis vulgaris, in conjunction with some upregulation of other inflammatory cytokines such as TNF-alpha, IL-17A, IL-6 and IL-12. Therefore, we may, as part of our initial clinical testing of ANB019, conduct a proof-of-mechanism clinical trial with psoriasis vulgaris patients who are not currently on any biological therapies. In addition, we may also consider clinical development of ANB019 for patients with psoriasis vulgaris that have failed treatment with the current standard of care, including Stelara (ustekinumab) and Cosentyx (secukinumab).

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 from the description in the figure below.

### **ANB019 Market Opportunity**

IL-36R cytokine dysfunction is implicated in multiple inflammatory disorders including GPP, PPP, and potentially in severe, refractory cases of psoriasis vulgaris.

*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 upcoming 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 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.

*Palmo-plantar Pustular Psoriasis.* 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.

*Refractory Psoriasis Vulgaris.* Refractory psoriasis vulgaris is another potential market opportunity for the development of ANB019. While the approved biologics that target these three cytokine pathways, including Stelara (ustekinumab) and Cosentyx (secukinumab), are effective for the majority of psoriasis vulgaris patients, a subset of the population is refractory to approved biologics. For purposes of developing an estimate, we have defined the refractory population as the subset of the patient population that does not have at least a 75% response to the leading approved therapy, which is Cosentyx. Based on this definition and our analysis publicly- available information and literature, we estimate that approximately 5% of the patient population, representing approximately 375,000 patients, is refractory to the leading approved therapy for psoriasis vulgaris. We hypothesize that IL-36 cytokine function is the key inflammatory driver in such refractory patients, and therefore these patients may benefit from ANB019.

## Checkpoint Receptor Agonist Programs

Our strategy includes the discovery and development of therapeutic antibodies targeting emerging opportunities in inflammation. Checkpoint receptor agonist antibodies are being developed by AnaptysBio, to multiple different immune checkpoint receptors, 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. Certain checkpoint receptor agonist antibodies developed by AnaptysBio have demonstrated efficacy in a rodent model of graft-versus-host disease. We anticipate that, subsequent to regulatory clearance, one of our checkpoint receptor antibodies will initiate human testing during 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.

Since the first therapeutic antibody was approved by the FDA in 1986, the pharmaceutical industry has sought opportunities to leverage antibodies as therapeutic agents to treat human disease. Global sales of therapeutic antibodies have reached over \$40 billion annually and are predicted to remain a fast-growing segment of the therapeutic market.

### 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. Our 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 our

immune system to expand the limited diversity encoded within our genomes to the billions of antibody specificities required to defend ourselves 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 such as IL-33 and TIM-3.

Each evolving antibody is expressed within the SHM-active mammalian cell to concurrently (i) display the evolved antibody on the cell surface to permit cell sorting selection for potency properties while (ii) 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.
- **Bispecific antibodies.** A bispecific antibody is a single therapeutic molecule designed to bind two different targets. Bispecific antibodies have the advantage of combining two therapeutic mechanisms with the goal of increasing therapeutic efficacy, in comparison to monospecific antibodies that bind either of the targets individually. We believe our competitors' bispecific strategies generally rely on proteins with non-natural formats, resulting in unpredictable pharmacokinetics and manufacturing properties. Our strategy is to develop bispecific antibodies that are composed of two different heavy chains with a common shared light chain that resemble the natural antibody structure and exhibit the desired functional activity to each target. Utilizing our proprietary SHM platform, we are able to generate a large diversity of heavy and light chain varieties against each therapeutic target, and then co-mature a common light chain in the context of two different heavy chains, which permits us to identify bispecific antibodies with sufficient potency against each of the two targets that we believe will provide greater therapeutic benefit.

## 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. Specifically, we 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 three bispecific antibody product candidates targeting PD-1/TIM-3, PD-1/LAG-3 and an undisclosed target. 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 is 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 products to each of the four targets, 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.

## **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 to the clinic.

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.

## **In-Licensing Agreements License Agreement with MRC**

In 2006, we entered into an exclusive worldwide license agreement with the Medical Research Council, or MRC, 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. Under the terms of the agreement, or the MRC Agreement, we obtained an exclusive, worldwide, sublicensable 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 MRC an annual fee of \$55,000. Additionally, for each product developed and commercialized under the MRC Agreement, we are obligated to pay MRC 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 MRC 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 MRC Agreement will expire upon expiration of all royalty payment obligations under the MRC Agreement. Either party may terminate the MRC 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 MRC Agreement upon 60 days' notice to MRC.

## **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. Additionally, for each product developed and commercialized under the Millipore Agreement, we are obligated to pay Millipore up to an additional \$75,000 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 ANB020 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 45.0% 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 do not have any employees with experience advancing product candidates through the Australian regulatory review process. However, we have engaged Australian consultants with expertise in the regulatory requirements and clinical development of therapeutic products in Australia, and we plan to work with established manufacturing and clinical development support contractors located in Australia, who are also 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 MRC and patents licensed from Kyoto University, consisted of 38 issued patents and 43 pending patent applications as of December 31, 2016.

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:

#### **ANB020**

As of December 31, 2016, we owned 15 patent applications in various countries directed to the antibody sequence of ANB020 and its variants, epitopes, methods of use and related matters. We intend to prosecute the

pending applications and pursue patent issuance and protection in key commercial markets where significant product sales may occur. Patents that may issue from these pending applications would provide protection until January 2037.

## **ANB019**

As of December 31, 2016, we owned one international patent application, filed under the PCT, which is directed to the antibody sequence of ANB019 and its variants, epitopes, methods of use and related matters. We intend to prosecute the pending international application, and pursue patent issuance and protection in key commercial markets where significant product sales may occur. Patents that may issue from the expected international application 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 2028.

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 PTA under certain circumstances to compensate for delays in obtaining the patent from the 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 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 ANB020, including major pharmaceutical companies.

For asthma, our competitors include omalizumab (Xolair; Roche), which has received FDA approval and functions by inhibiting the binding between free IgE and FcεRI; antibodies that bind IL-5 and inhibit its interaction with the IL-5 receptor such as mepolizumab (Glaxosmithkline), which the FDA recently approved for the add-on maintenance treatment in patients aged 12 years or older with severe eosinophilic asthma, and reslizumab (Teva), which the FDA's Pulmonary-Allergy Drugs Advisory Committee recommended for approval in adult patients aged 18 years and older for the treatment of inadequately controlled asthma in patients with elevated eosinophils, despite an inhaled corticosteroids treatment regimen; antibodies, such as benralizumab (AstraZeneca) that bind the IL-5 receptor; antibodies that bind to IL-13 such as lebrikizumab (Roche), tralokinumab (AstraZeneca) and anrukinzumab (Pfizer) which are in clinical testing; antibodies that bind the IL-4 receptor alpha chain such as dupilumab (Regeneron, Sanofi) and AMG 317 (Amgen) each in clinical testing; and an ST2-binding antibody which Roche has in-licensed from Amgen (previously known as AMG 282) and plans to advance into Phase 2 clinical trials. Regeneron has recently announced an IL-33 related program (REGN 3500) in a Phase I clinical trial and is indicated for asthma and chronic obstructive pulmonary disease.

For peanut allergy, our competitors include DBV Technologies, which is developing transdermal products for tolerization of food allergies, while Aimmune Therapeutics is developing oral products for peanut allergy desensitization.

For atopic dermatitis, our competitors include dupilumab (Regeneron, Sanofi), which has recently been filed for approval by the FDA, crisaborole (Anacor, Pfizer) which has recently been filed for approval by the FDA and VTP-38543 (VitaE) which is currently in a Phase 2 trial.

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) which binds IL-1 beta and 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 Biologics License Application, or 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 GCP, an international standard meant to protect the rights and health of patients and to define the roles of clinical trial sponsors, administrators, and monitors; as well as (iii) under protocols detailing the objectives of the trial, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated. Each protocol involving testing on U.S. patients and subsequent protocol amendments must be submitted to 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 FDA files the BLA; most applications for priority review biologics are reviewed within six months of the date the FDA files the BLA. 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 current good manufacturing practice, or 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 REMS to help ensure that the benefits of the biologic outweigh the potential risks. REMS can include medication guides, communication plans for healthcare professionals, and elements to assure safe use, or ETASU. ETASU can include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring, and the use of patient registries. The requirement for a REMS can materially affect the potential market and profitability of the 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, 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 United States Patent and Trademark Office must determine that approval of the drug covered by the patent for which a patent extension is being sought is likely. Interim patent extensions are not available for a drug 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 to 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. 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 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. healthcare 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 healthcare 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 healthcare 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 healthcare 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 healthcare benefit program, including private third-party payors, willfully obstructing a criminal investigation of a healthcare 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 healthcare benefits, items or services. Like the Anti-Kickback Statute, the ACA amended the intent standard for certain healthcare 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 healthcare 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 healthcare 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 healthcare 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 healthcare 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.

### Healthcare reform

In March 2010, President Obama enacted the ACA, which has the potential to substantially change healthcare financing and delivery by both governmental and private insurers, and significantly impact the pharmaceutical and biotechnology industry.

Among the ACA provisions of importance to the pharmaceutical and biotechnology industries, in addition to those otherwise described above, are the following:

- an annual, nondeductible fee on any entity that manufactures or imports certain specified branded prescription drugs and biologic agents apportioned among these entities according to their market share in some government healthcare programs that began in 2011;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program, retroactive to January 1, 2010, to 23.1% and 13% of the average manufacturer price for most branded and generic drugs, respectively and capped the total rebate amount for innovator drugs at 100% of the Average Manufacturer Price, or AMP;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturers' outpatient drugs to be covered under Medicare Part D;
- extension of manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals beginning in 2014 and by adding new mandatory eligibility categories for individuals with income at or below 133% of the federal poverty level, thereby potentially increasing manufacturers' Medicaid rebate liability;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research;
- expansion of healthcare fraud and abuse laws, including the False Claims Act and the Anti-Kickback Statute, new government investigative powers, and enhanced penalties for noncompliance;
- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted, or injected;
- requirements to report certain financial arrangements with physicians and teaching hospitals; and
- a requirement to annually report certain information regarding drug samples that manufacturers and distributors provide to physicians.

We anticipate that the ACA will result in additional downward pressure on coverage and the price that we receive for any approved product, and could seriously harm our business. Any reduction in reimbursement from Medicare and other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our products. Such reforms could have an adverse effect on

anticipated revenues from product candidates that we may successfully develop and for which we may obtain regulatory approval and may affect our overall financial condition and ability to develop product candidates. In addition, it is possible that there will be further legislation or regulation that could harm our business, financial condition and results of operations.

For example, in August 2011, the President signed into law the Budget Control Act of 2011, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals in spending reductions. The Joint Select Committee on Deficit Reduction did not achieve a targeted deficit reduction of at least \$1.2 trillion for fiscal years 2012 through 2021, triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went into effect beginning on April 1, 2013 and will stay in effect through 2025 unless additional Congressional action is taken. Additionally, in January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, reduced Medicare payments to several providers, including hospitals and imaging centers. These new laws may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on customers for our drugs, if approved, and, accordingly, our financial operations.

### **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, state and federal laws regarding environmental protection and hazardous substances, including the Occupational Safety and Health Act, the Resource Conservancy and Recovery Act and the Toxic Substances Control Act, affect our business. 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 clinical trial authorisation must be submitted to each country's national health authority and an independent ethics committee, much like the FDA and IRB, respectively. Once the clinical trial authorisation 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.

### **Other regulations**

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. We may incur significant costs to comply with such laws and regulations now or in the future.

### **Employees**

As of December 31, 2016, we had 49 full-time employees. Of these employees, 41 were primarily engaged in research and development activities and 14 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, 2016, 2015 and 2014 and our total assets as of December 31, 2016 and 2015, is included in our Consolidated Financial Statements in Item 8 of this Annual Report.

### **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.anaptybio.com](http://www.anaptybio.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](http://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. You may also read and copy, at SEC prescribed rates, any document we file with the SEC at the SEC's Public Reference Room located at 100 F Street, N.E., Washington D.C. 20549. You can call the SEC at 1-800-SEC-0330 to obtain information on the operation of the Public Reference Room.

## 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. 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 two lead wholly-owned product candidates, ANB019 and ANB020, 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.

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 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 currently have only limited data regarding the safety profile of our wholly-owned product candidates when dosed in humans. We have recently conducted our Phase 1 clinical trial for ANB020 in healthy humans, and have only recently initiated patient studies with ANB020, and have not yet initiated clinical studies with ANB019. 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. It is not uncommon to observe results in human clinical trials that are unexpected based on preclinical testing, and many product candidates fail in clinical trials despite promising preclinical results. 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. In the single-ascending dose segment of our Phase 1 clinical trial of ANB020, the most common adverse events were upper respiratory tract infection and headache, and we observed one case of severe neutropenia in one individual, which was acute and not persistent, and was considered not to be drug-related. All safety information generated under the single-ascending dose segment of our Phase 1 clinical trial was included in the US IND and UK CTA submissions which have been subsequent cleared. No adverse events were determined to be drug related. Subjects in our ongoing and planned clinical trials may in the future suffer significant adverse events or other side effects not observed in our preclinical studies or in our ongoing Phase 1 clinical trial. 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. 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 obtains 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 ANB020 in the United States and United Kingdom, respectively, and a CTN for ANB019 in Australia, 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 TGA 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, we will not be permitted to market our product candidates in the United States until we receive approval of a Biologics License Application, or BLA, from the FDA, and will not be permitted to market 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 our CTN for ANB020 in Australia, obtaining clearance for our IND for a Phase 2a clinical trial of ANB020 in severe adult peanut allergy in the United States, obtaining clearance for our CTA for a Phase 2a clinical trial of ANB020 in moderate-to-severe adult atopic dermatitis in the United Kingdom and obtaining clearance for our CTN for ANB019 in Australia, 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, although we believe a small pivotal trial, potentially with fewer than 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. In addition, with regard to ANB020, although we intend for our investigators for our Phase 2a study to enroll only patients with severe adult peanut allergy, the protocol does not preclude enrollment of patients with non-severe adult peanut allergy. It is possible that our investigator could enroll patients with non-severe peanut allergy, which could provide us with less information than anticipated with regard to ANB020's effect on severe peanut allergy.

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 ten 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 our 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 our 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 and expand our technology platform to build a 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, obtaining manufacturing supply capability, 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 ANB020 and have no prior 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 two lead product candidates, ANB019 and ANB020, and other product candidates with and without 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 an IND or 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 asthma, our competitors include omalizumab (Xolair; Roche) which has received FDA approval and functions by inhibiting the binding between free IgE and FcεRI; antibodies that bind IL-5 and inhibit its interaction with the IL-5 receptor such as mepolizumab (Nucala; Glaxosmithkline), which the FDA recently approved for the add-on maintenance treatment in patients aged 12 years or older with severe eosinophilic asthma, and reslizumab (Teva), which the FDA's Pulmonary-Allergy Drugs Advisory Committee recommended for approval in adult patients aged 18 years and older for the treatment of inadequately controlled asthma in patients with elevated eosinophils, despite an inhaled corticosteroids treatment regimen; antibodies such as benralizumab (AstraZeneca) that bind the IL-5 receptor; antibodies that bind to IL-13 such as lebrikizumab (Roche), tralokinumab (AstraZeneca) and anrukinzumab (Pfizer), which are in clinical testing; antibodies that bind the IL-4 receptor alpha chain, such as dupilumab (Regeneron, Sanofi) and AMG 317 (Amgen) each in clinical testing, an ST2-binding antibody which Roche has in-licensed from Amgen (previously known as AMG 282) and plans to advance into Phase 2 clinical trials, and CNTO 7160, which is another ST2-binding antibody that GSK in-licensed from Janssen. Regeneron has recently announced an IL-33 related program (REGN 3500) in a Phase 1 clinical trial and is indicated for asthma and chronic obstructive pulmonary disease. For peanut allergy, our competitors include DBV Technologies, which is developing transdermal products for tolerization of food allergies, while Aimmune Therapeutics is developing oral products for peanut allergy desensitization. For atopic dermatitis, our competitors include dupilumab (Regeneron, Sanofi), which has recently been filed for approval by the FDA, crisaborole (Anacor, Pfizer), which has recently been filed for approval by the FDA, and VTP-38543 (Vitae), which is currently in a Phase 2 trial. 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) which binds IL-1 beta and 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 biologics license application, or BLA. To date, only a handful of biosimilar products have been approved under the BPCIA. However, 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, healthcare 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, healthcare 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, healthcare 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 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 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 manufacturer, we will need to transfer to another manufacturer and complete the manufacturing validation process, which can be lengthy. If we are able to adequately validate and scale-up the manufacturing process for our product candidates with a contract manufacturer, we will still need to negotiate with such contract manufacturer an agreement for commercial supply and it is not certain we will be able to come to agreement on terms acceptable to us.

### **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 and none of our product candidates have progressed to clinical development. To date, our revenue has been primarily derived from our research collaboration and license agreements with third parties, including TESARO, Inc. and TESARO Development, Ltd., or collectively, TESARO, and Celgene Corporation, or Celgene, 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. Our collaboration revenue was \$15.8 million and our net income was \$3.5 million for the year ended December 31, 2014 and our collaboration revenue was \$17.6 million and our net loss was \$(5.4) million for the year ended December 31, 2015. For the year ended December 31, 2016, our collaboration revenue was \$16.7 million and our net loss was \$(4.3) million. As of December 31, 2016, we had an accumulated deficit of \$54.9 million.

We have financed our operations primarily through private placements of our preferred stock, our initial public offering of common stock in January 2017 and the issuance of debt. We have devoted substantially all of our efforts to research and development. We have not initiated clinical development of any 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 or our collaborators' ability to:

- continue our 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;
- 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 ANB020, 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 preclinical development stages for our most advanced product candidates. 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 initiate 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 and cash equivalents and funding we expect to receive under existing collaboration agreements will fund our projected operating expenses and capital requirements through at least the next 24 months. 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 commence 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 future 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 any 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 any 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 utilize 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, prosecution, defense and enforcement 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 cost and timing of selecting, auditing and potentially validating a manufacturing site 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 a lack of available capital means that we cannot expand our operations or otherwise capitalize on our business opportunities, 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. 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 increase our capabilities to successfully commercialize our product candidates. In particular, the loss of one or more of our executive officers could be detrimental to us if we cannot recruit suitable replacements in a timely manner. 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, including our Chief Financial Officer, who joined us in January 2017, 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.

#### **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 significant 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 ANB020 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 45.0% of qualified expenditures. If we lose our ability to operate AnaptysBio Pty in Australia, or if we are ineligible or unable to receive the research and development tax credit, or the Australian government significantly reduces or eliminates the tax credit, our business and results of operation would be adversely affected.

**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, the development or commercialization of our product candidates 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 current good manufacturing practices, or cGMP, regulations and guidelines for the manufacturing of biologics used in clinical trials and, if approved, marketed products. To date, neither we nor our contract manufacturers has manufactured or attempted to manufacture cGMP batches of our 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 any product candidates to patients in planned clinical trials and products to patients, once approved, would be jeopardized. Any delay or interruption in the supply of clinical trial supplies could delay the completion of planned clinical trials, increase the costs associated with maintaining clinical trial programs and, depending upon the period of delay, require us to commence new clinical trials at additional expense or terminate clinical trials completely. Any adverse developments affecting clinical or commercial manufacturing of our product candidates or products may result in shipment delays, inventory shortages, lot failures, product

withdrawals or recalls, or other interruptions in the supply of our product candidates or products. We may also have to take inventory write-offs and incur other charges and expenses for product candidates or products that fail to meet specifications, undertake costly remediation efforts or seek more costly manufacturing alternatives. Accordingly, failures or difficulties faced at any level of our supply chain could adversely affect our business and delay or impede the development and commercialization of any of our product candidates or products and could have an adverse effect on our business, prospects, financial condition and results of operations.

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

Despite the implementation of security measures, any of the internal computer systems belonging to us, our collaborators or our third-party service providers are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failure. Any system failure, accident or security breach that causes interruptions in our own, in collaborators' or in third-party service vendors' operations could result in a material disruption of our drug discovery and development programs. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our or our collaborators' regulatory approval efforts and significantly increase our costs in order to recover or reproduce the lost data. To the extent that any disruption or security breach results in a loss or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we may incur liability as a result, our drug discovery programs and competitive position may be adversely affected and the further development of our product candidates may be delayed. Furthermore, we may incur additional costs to remedy the damages caused by these disruptions or security breaches.

**Our operations 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 facility is located in a seismically active region, which has also historically been subject to 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 event, we could lose all our antibody sequences, which would have an adverse effect on our ability to perform our obligations under our collaborations and discover new targets.

**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 other biotechnology companies to develop several of our product candidates, and such collaborations currently represent a significant portion of our product pipeline. In addition, we have entered into other collaborations pursuant to which we have provided access to our technology platform to our collaborators to enable the optimization of their own product candidates. We have 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 are advancing multiple antibodies generated through our collaboration to 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. Other than TESARO, our operational obligations under each of our collaborations has ended.

We are unable to predict the success of our collaborations. Our collaborators have discretion in determining and directing the efforts and resources, including the ability to discontinue all efforts and resources, they apply to the development and, if approval is obtained, commercialization and marketing of the product candidates covered by such collaborations. As a result, our collaborators may elect to de-prioritize our programs, change their strategic

focus or pursue alternative technologies in a manner that results in reduced, delayed or no revenue to us. Our collaborators may have other marketed products and product candidates under collaboration with other companies, including some of our competitors, and their corporate objectives may not be consistent with our best interests. Our collaborators may also be unsuccessful in developing or commercializing our products. If our collaborations are unsuccessful, our business, financial condition, results of operations and prospects could be adversely affected. In addition, any dispute or litigation proceedings we may have with our collaborators in the future could delay development programs, create uncertainty as to ownership of intellectual property rights, distract management from other business activities and generate substantial expense.

**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 a development collaboration 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. 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, or any future 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, or CROs, clinical data management organizations, or CMOs, and consultants to design, conduct, supervise and monitor preclinical studies of our product candidates and will do the same for any clinical trials. Because we rely on third parties and do not have the ability to conduct preclinical studies or clinical trials independently, we have less control over the timing, quality and other aspects of 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 preclinical studies or clinical trials, resulting in the preclinical studies or clinical trials being delayed or unsuccessful.

If we cannot contract with acceptable third parties on commercially reasonable terms, or at all, or if these third parties do not carry out their contractual duties, satisfy legal and regulatory requirements for the conduct of preclinical studies or clinical trials or meet expected deadlines, our clinical development programs could be delayed and otherwise adversely affected. In all events, we 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.

### **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 healthcare 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 have conducted, or plan to conduct, our initial clinical trials for ANB020 and ANB019 outside of the United States. However, the FDA and other foreign equivalents may not accept data from such trials, in which case our development plans will be delayed, which could materially harm our business.**

We have conducted our initial clinical trial for ANB020 in Australia and plan to conduct our initial clinical trial for ANB019 in Australia. We believe that clinical data generated in Australia will be accepted by the FDA and its foreign equivalents outside of Australia, and therefore may enable us to commence Phase 2 and possibly registration clinical trials in the United States or the United Kingdom following submission of an IND or CTA, without the need for us to repeat our Phase 1 trials in the United States or the United Kingdom. While we have received clearance from the FDA and MHRA to begin Phase 2 clinical trials for ANB020, there can be no assurance the FDA, MHRA or other foreign equivalents will accept data from the clinical trials we plan to conduct in Australia for ANB019. If the FDA, MHRA or other foreign equivalents do not accept any such data, we would likely be required to conduct additional Phase 1 clinical trials, which would be costly and time consuming, and delay aspects of our development plan, which could harm our business.

Although the FDA, MHRA and other foreign equivalents may accept data from clinical trials conducted entirely outside the United States and not under an IND, acceptance of such study data is generally subject to certain conditions. For example, the FDA requires the clinical trial to have been conducted in accordance with GCPs and the FDA must be able to validate the data from the clinical trial through an onsite inspection if it deems such inspection necessary. In addition, when studies are conducted only at sites outside of the United States, the FDA generally does not provide advance comment on the clinical protocols for the studies, and therefore there is an additional potential risk that the FDA could determine that the study design or protocol for a non-U.S. clinical trial was inadequate, which would likely require us to conduct additional clinical trials.

Conducting clinical trials outside the United States also exposes us to additional risks, including risks associated with the following:

- additional foreign regulatory requirements;
- foreign exchange fluctuations;
- compliance with foreign manufacturing, customs, shipment and storage requirements;
- cultural differences in medical practice and clinical research; and
- diminished protection of intellectual property in some countries.

In addition, in June 2016, the United Kingdom held a referendum and voted in favor of leaving the European Union. This has created political and economic uncertainty, particularly in the United Kingdom and the European Union, and could cause disruptions to, and create uncertainty surrounding, our planned clinical trial in the United Kingdom, including affecting our relationships with our existing and prospective customers, partners and employees, and could have a material impact on the regulatory regime applicable to our planned clinical trial in the United Kingdom.

**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 European Union. 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 applied for 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 healthcare 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 to 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 challenging the price, 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 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 such as our product candidates. In many countries, particularly the countries of the European Union, 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 healthcare 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 healthcare, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare 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 healthcare market.

In addition to CMS and private payors, professional organizations such as the American Medical Association, or AMA, 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, including for 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.**

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and/or affect our ability to profitably sell any product candidates for which we obtain marketing approval.

For example, in March 2010, former President Barack Obama signed into law the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or collectively the ACA, a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add transparency requirements for the healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms.

Among the provisions of the ACA of importance to our potential product candidates are the following:

- an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program;
- expansion of healthcare fraud and abuse laws, including the False Claims Act and the Anti-Kickback Statute, new government investigative powers, and enhanced penalties for noncompliance;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for a manufacturer's outpatient drugs to be covered under Medicare Part D;
- extension of manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted, or injected;
- expansion of eligibility criteria for Medicaid programs;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- requirements to report certain financial arrangements with physicians and teaching hospitals;
- a requirement to annually report certain information regarding drug samples that manufacturers and distributors provide to physicians; and
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

**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, and has stated that he will ask Congress to replace the current legislation with new legislation. There is uncertainty with respect to 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 healthcare items and services covered by plans that were authorized by the ACA. However, we cannot predict the ultimate content, timing or effect of any healthcare reform legislation or the impact of potential legislation on us. In addition, other legislative changes have been proposed and adopted 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 2025 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 healthcare 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 healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product. 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 healthcare 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 healthcare 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.**

Healthcare 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 healthcare 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 healthcare 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 healthcare 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 healthcare benefit program or making false statements relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and 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 made publicly available on a searchable website in September 2014 and will be 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 healthcare 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 healthcare providers or marketing expenditures. State and foreign laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

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

**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, selfdealing 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.

Recent 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 recently 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 on March 16, 2013. Accordingly, 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 in the United States or other jurisdictions. 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. 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;
- 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 healthcare 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 initial public offering and may not use them effectively.**

Our management has broad discretion in the application of the net proceeds from our initial public offering, 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 initial public offering in ways that ultimately increase the value of your investment. If we do not invest or apply the net proceeds from our initial public offering 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 may be 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 are an emerging growth company, and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies will make our common stock less attractive to investors.**

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012, or JOBS Act. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as amended, or the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and exemptions from the requirements of holding nonbinding advisory stockholder votes on executive compensation and stockholder approval of any golden parachute payments not previously approved. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

We will remain an emerging growth company until the earlier of (i) the last day of the fiscal year (a) following the fifth anniversary of the closing of our initial public offering, (b) in which we have total annual gross revenue of at least \$1 billion or (c) in which we are deemed to be a large accelerated filer, which requires the market value of our common stock that is held by non-affiliates to exceed \$700 million as of the prior June 30th, and (ii) the date on which we have issued more than \$1 billion in non-convertible debt during the prior three-year period.

Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, are subject to the same new or revised accounting standards as other public companies that are not emerging growth companies. As a result, changes in rules of U.S. generally accepted accounting principles or their interpretation, the adoption of new guidance or the application of existing guidance to changes in our business could significantly affect our financial position and results of operations.

**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 may 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 the sufficient coverage. We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers.

In addition, as a public company we incur additional costs and obligations in order to comply with SEC rules that implement Section 404 of the Sarbanes-Oxley Act. Under these rules, beginning with our annual report for the year ending December 31, 2017, we will be required to make a formal assessment of the effectiveness of our internal control over financial reporting, and once we cease to be an emerging growth company, we will be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with Section 404 within the prescribed period, we will be engaging in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of our internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are designed and operating effectively, and implement a continuous reporting and improvement process for internal control over financial reporting.

**Sales of a substantial number of shares of our common stock in the public market could cause our stock price to fall.**

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. Of the 20,173,740 shares of our common stock outstanding as of February 28, 2017, 14,423,740 shares are currently subject to restrictions on transfer under 180-day lock-up arrangements with either the underwriters for our initial public offering or under agreements entered into between us and the holders of those shares. These restrictions are due to expire July 24, 2017, resulting in these shares becoming eligible for public sale on July 25, 2017 if they are registered under the Securities Act of 1933, as amended, which we refer to as the Securities Act, or if they qualify for an exemption from registration under the Securities Act, including under Rules 144 or 701. Moreover, holders of an aggregate of 14,631,100 shares of our common stock and shares underlying certain warrants will have rights, subject to certain conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. 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 and the lock-up agreements described above. 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.

**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. 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 target animal studies

and 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. In October 2016, we extended the analysis period of the study through December 31, 2015, noting no ownership changes during fiscal 2015. 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.

**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.

We believe that our facilities are adequate to meet our needs for the foreseeable future.

**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.

#### Price Range of Common Stock

Our common stock has been listed on the NASDAQ Global Select market under the symbol "ANAB" since January 26, 2017. Prior to that date, there was no public trading market for our common stock. As a result, we have not set forth quarterly information with respect to the high and low sale prices for our common stock for the two most recent fiscal years.

#### Holder

As of February 28, 2017, we had approximately 84 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 Silicon Valley bank.

#### Recent Sale of Unregistered Securities

From January 1, 2016 through December 31, 2016, we sold and issued the following unregistered securities, which share numbers have been adjusted, as appropriate, to reflect the 7-to-1 reverse stock split which became effective on January 13, 2017:

- (1) We granted options to our officers and employees to purchase 330,622 shares of common stock under our Amended and Restated 2006 Equity Incentive Plan with per share exercise prices ranging from \$5.95 to \$11.20. In the same year, we issued 23,199 shares of common stock to our employees upon exercise of options at prices ranging from \$0.91 to \$6.93 for an aggregate purchase price of less than \$0.1 million.
- (2) In December 2016, the Registrant issued warrants to accredited investors to purchase an aggregate of 82,416 shares of the Registrant's Series C convertible preferred stock. The preferred stock warrants have a per share exercise price of \$4.55.

The offers, sales and issuances of the securities described in paragraph (1) above were deemed to be exempt from registration under the Securities Act under Rule 701 promulgated under the Securities Act as offers and sale of securities pursuant to certain compensatory benefit plans and contracts relating to compensation in compliance with Rule 701.

The offers, sales, and issuances of the securities described in paragraph (2) above were deemed to be exempt from registration under the Securities Act in reliance on Section 4(a)(2) of the Securities Act. The recipients of securities in each of these transactions acquired the securities for investment only and not with a view to or for sale in connection with any distribution thereof and appropriate legends were affixed to the securities issued in these transactions. Each of the recipients of securities in these transactions was an accredited or sophisticated person and had adequate access, through employment, business or other relationships, to information about us.

## Use of Proceeds from Registered Securities

On January 25, 2017, our Registration Statement on Form S-1 (File No. 333-206849) relating to the IPO of our common stock was declared effective by the SEC. Pursuant to such Registration Statement, we sold an aggregate of 5,750,000 shares of our common stock at a price of \$15.00 per share. Credit Suisse Securities (USA) LLC, Stifel, Nicolaus & Company, Incorporated, JMP Securities LLC and Wedbush Securities Inc. acted as underwriters. On January 31, 2017, we closed the sale of such shares, resulting in aggregate cash proceeds to us of approximately \$80.2 million, net of underwriting discounts and commissions.

Because the closing of our IPO occurred on January 31, 2017, as of December 31, 2016, we had not yet received the net proceeds from the sale of shares of common stock in our IPO and, therefore, had used none of the proceeds as of December 31, 2016. There has been no material change in the expected use of the net proceeds from our IPO, as described in our final prospectus filed with the SEC on January 26, 2017 pursuant to Rule 424(b) under the Securities Act of 1933, as amended.

## 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.

We have derived the following selected consolidated statement of operations data for the years ended December 31, 2016, 2015 and 2014 and the selected consolidated balance sheet data as of December 31, 2016 and 2015 from our audited consolidated financial statements included elsewhere 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 consolidated financial statements and the related notes included in this Annual Report on Form 10-K.

(in thousands)	Year Ended December 31,		
	2016	2015	2014
Collaboration revenue	\$ 16,684	\$ 17,571	\$ 15,838
Income (loss) from operations	\$ (3,025)	\$ (3,322)	\$ 4,870
Net income (loss)	\$ (4,259)	\$ (5,405)	\$ 3,532
Net income (loss) attributed to common stockholders	\$ (4,259)	\$ (5,405)	\$ 232
Net income (loss) per common share: Basic and diluted	\$ (1.62)	\$ (2.12)	\$ 0.09

(in thousands)	December 31, 2016	December 31, 2015
Total assets	\$ 62,180	\$ 56,280
Notes payable, net of current portion	13,809	4,903
Deferred rent	154	115
Preferred stock warrant liabilities	3,241	1,549
Commitments and contingencies		
Series B convertible preferred stock, \$0.001 par value, 3,963 shares authorized, issued and outstanding at December 31, 2016 and 2015; aggregate liquidation preference at December 31, 2016 of \$24,991	28,220	28,220
Series C convertible preferred stock, \$0.001 par value, 1,887 shares authorized, 1,593 shares issued and outstanding at December 31, 2016 and 2015; aggregate liquidation preference at December 31, 2016 of \$7,246	6,452	6,452
Series C-1 convertible preferred stock, \$0.001 par value, 474 shares authorized, issued and outstanding at December 31, 2016 and 2015, respectively; aggregate liquidation preference at December 31, 2016 of \$6,470	2,156	2,156
Series D convertible preferred stock, \$0.001 par value, 5,491 shares authorized, issued and outstanding at December 31, 2016 and 2015, respectively; aggregate liquidation preference at December 31, 2016 of \$40,767	40,688	40,688
Stockholders' deficit:		
Common stock, \$0.001 par value, 17,214 shares authorized, 2,651 shares and 2,630 shares issued and outstanding at December 31, 2016 and 2015, respectively	3	3
Additional paid in capital	16,672	15,482
Accumulated deficit	(54,923)	(50,664)
Total stockholders' deficit	(38,248)	(35,179)
Total liabilities, convertible preferred stock and stockholders' deficit	\$ 62,180	\$ 56,280

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

*The following discussion contains management's discussion and analysis of our financial condition and results of operations and should be read together with the historical consolidated financial statements and the notes thereto included in Part II, Item 8 "Financial Statements and Supplementary Data." This discussion contains forward-looking statements that reflect our plans, estimates and beliefs and involve numerous risks and uncertainties, including but not limited to those described in the "Risk Factors" section of this Annual Report. Actual results may differ materially from those contained in any forward-looking statements. You should carefully read "Special Note Regarding Forward-Looking Statements" and Part I, Item 1A, "Risk Factors."*

### 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 of our proprietary product candidates, and for certain programs, establish partnerships with leading biopharmaceutical companies where we retain certain development and commercialization rights.

Our most advanced wholly-owned antibody programs, ANB020 and ANB019, neutralize therapeutic targets that are genetically associated with severe inflammatory disorders in humans. ANB020 inhibits the activity of the interleukin-33, or IL-33, cytokine for the treatment of moderate-to-severe adult atopic dermatitis, severe adult peanut allergy and severe adult eosinophilic asthma. ANB019 inhibits the interleukin-36 receptor, or IL-36R, for the treatment of rare inflammatory diseases including generalized pustular psoriasis, or GPP, and palmo-plantar pustular psoriasis, or PPP. The current status of our clinical development activities for ANB020 and ANB019 is outlined in the chart and bullet points above under "Our Product Candidates" in Part 1 - Item 1. We have cleared a CTN for ANB019 and plan to commence a Phase 1 clinical trial in the first half of 2017, and anticipate announcing top-line data from this trial during the second half of 2017. We subsequently plan to seek regulatory clearance to initiate Phase 2 studies of ANB019 in GPP and PPP patients during 2018. In addition to ANB020 and ANB019, our wholly-owned pipeline includes novel checkpoint receptor agonist antibodies that we believe are applicable for treatment of certain autoimmune diseases where immune checkpoint receptors are insufficiently activated, and which have demonstrated efficacy in an animal model of graft-versus-host disease.

In addition to our wholly-owned antibody programs, multiple AnaptysBio-developed antibody programs have been advanced under our collaborations to preclinical and clinical milestones. Our collaborations include an immuno-oncology-focused collaboration with TESARO and an inflammation-focused collaboration with Celgene, which are further described above under "TESARO Programs" and "Celgene Programs" respectively in Part 1 - Item 1.

We intend to continue generating additional therapeutic antibodies against emerging biological targets across various disease applications, including immuno-oncology, inflammation and other unmet medical needs. In general, our strategy is to advance our pipeline programs to key inflection points, and leverage partnerships with pharmaceutical and biotechnology companies where appropriate.

We have generated multiple antibodies by using our SHM platform certain of which are currently being advanced by our partners to key preclinical, clinical and commercial milestones, which we anticipate will generate additional cash receipts for us. To the extent that these product candidates are commercialized, we will also be entitled to royalty payments upon commercial sales of the associated products.

As of December 31, 2016, we had an accumulated deficit of \$54.9 million primarily as a result of losses incurred since our inception in 2005. Although we reported net income of \$3.5 million during the year ended December 31, 2014, 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.

## 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. Through December 31, 2016, we have received \$65.4 million 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 are being recognized over the same period that our research and development services, for which we are reimbursed, are performed, which was extended through December 31, 2016 by amendment of the agreement in February 2016. From inception of the agreement through December 31, 2016, we have recognized \$44.3 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.

In June 2015, TESARO initiated *in vivo* toxicology studies using GLPs for an AnaptysBio-generated anti-PD-1 antagonist antibody (TSR-042) resulting in us receiving a \$1.0 million milestone in July 2015. In October 2015, TESARO initiated *in vivo* toxicology studies using GLPs for an AnaptysBio-generated anti-TIM-3 antagonist antibody (TSR-022) resulting in us receiving a \$1.0 million milestone in November 2015. In January 2016, TESARO received clearance of their IND from the FDA for an AnaptysBio-generated anti-PD-1 antagonist antibody (TSR-042) resulting in us receiving a \$4.0 million milestone payment in February 2016. In June 2016, TESARO received clearance of their IND from the FDA for an AnaptysBio-generated anti-TIM-3 antagonist antibody (TSR-022) resulting in us receiving a \$4.0 million milestone payment in June 2016. In September 2016, TESARO initiated *in vivo* toxicology studies using GLPs for an AnaptysBio-generated anti-LAG-3 antagonist antibody (TSR-033) resulting in us receiving a \$1.0 million milestone in September 2016.

#### ***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, 2016, we have recognized \$10.0 million in total revenue from Celgene.

In June 2016, Celgene successfully completed an *in vivo* toxicology study using GLPs for an AnaptysBio-generated antibody resulting in us receiving a \$0.5 million milestone payment in June 2016. In December 2016, Celgene cleared a U.S. IND with the FDA and initiated a Phase 1 trial for one of the two programs being advanced by Celgene, resulting in us earning an additional \$1.0 million Phase 1 trial initiation milestone payment, which was received in January 2017.

### **Other Collaborative Agreements**

We are party to other collaboration agreements for which we recognized \$3.7 million in collaboration revenue during the year ended December 31, 2014. We completed our obligations under these agreements in 2014 and did not recognize any additional revenue from them subsequent to the year ended December 31, 2014.

### **Research and Development**

Research and development expenses consist of costs associated with our research and development activities, including drug discovery efforts and preclinical development of our programs. 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 clinical manufacturers;
- 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 sublicense fees.

We expense research and development costs as incurred. We account for advance payments for goods and services that will be used in future research and development activities as expenses 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 on several inflammation and immuno-oncology 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 Contract Manufacturing Organizations, or 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 are conducting initial clinical trials for ANB020 and plan to conduct initial clinical trials for ANB019 in Australia to rapidly enter into first-in-human studies and benefit from research and development-related financial incentives related to the development of ANB020 and ANB019. Taking into account any financial incentives, we expect our research and development expenses to be higher for the foreseeable future as we advance our product candidates into clinical development.

### **General and Administrative**

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, including intellectual property-related legal services.

## **Interest Expense**

Interest expense consists of stated interest 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 is from the valuation of our outstanding warrants to purchase shares of our preferred stock, which is 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 have converted into warrants to purchase shares of common stock, the preferred stock warrant liabilities have been reclassified to additional paid-in capital and periodic fair value adjustments will no longer be recorded.

## **Net Operating Loss and Research and Development Tax Credit Carryforwards**

From our inception through December 31, 2013, we accumulated net operating losses, or NOLs. We generated taxable income in the United States for the years ended December 31, 2016, 2015 and 2014 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 2016, 2015 and 2014, we 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, 2016, we had federal and state NOL carryforwards of \$35.7 million and \$46.0 million, respectively. The federal and state NOLs will begin to expire in 2028 and 2017, respectively, unless previously utilized. At December 31, 2016, we had federal and California research tax credit carryforwards of \$2.2 million and \$1.9 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, 2016, noting no ownership changes during fiscal 2015 or 2016. Limitations on our ability to use NOL carryforwards and research and development tax credits to offset future taxable income could require us to pay U.S. federal income tax earlier than would be required if such limitations were not in effect. Similar rules and limitations may apply for state income tax purposes.

## **Critical Accounting Policies and Use of Estimates**

Our management's discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles, 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. The effects of material revisions in estimates, if any, will be reflected in the financial statements prospectively from the date of change in estimates.

While our significant accounting policies are described in more detail in the notes to our financial statements appearing elsewhere in this prospectus, 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 requires that four basic criteria be met before revenue can be recognized: (i) persuasive evidence that an arrangement exists; (ii) delivery has occurred and title and the risks and rewards of ownership have been transferred to the client or services have been rendered; (iii) the price is fixed or determinable; and (iv) collectability is reasonably assured.

*Multiple-Element Revenue Arrangements.* We evaluate deliverables in a multiple-element arrangement to determine whether each deliverable represents a separate unit of accounting. A deliverable constitutes a separate unit of accounting when it has standalone value to the customer. If the delivered element does not have standalone value without one of the undelivered elements in the arrangement, we combine such elements and account for them as a single unit of accounting. We allocate the consideration to each unit of accounting at the inception of the arrangement based on the relative selling price.

We recognize consideration allocated to an individual element when all other revenue recognition criteria are met for that element. Our multiple-element revenue arrangements may include the following:

- **License Arrangements.** The deliverables under our collaboration and license agreements generally include exclusive or nonexclusive licenses to one or more products generated using our technologies. As the delivered licenses have not historically had standalone value apart from the undelivered elements, these have been recognized as revenue as a combined unit of accounting. Accordingly, we recognize revenue from nonrefundable upfront fees in the same manner as the undelivered item or items, which is generally the period over which we provide research and developments services.
- **Research and Development Services.** The deliverables under our collaboration and license arrangements may include research and development services we perform on behalf of or with our collaborators. As the provision of research and development services is an integral part of our operations and we may be principally responsible for the performance of these services under the agreements, we recognize revenue on a gross basis for research and development services as we perform those services. Additionally, we recognize research related funding under collaboration research and development efforts as revenue as we perform or deliver the related services in accordance with contract terms.

*Milestone Revenue.* Our collaboration and license agreements generally include contingent contractual payments related to achievement of specific research, development and regulatory milestones and sales-based milestones that are dependent upon the performance of the licensor or collaborator. A milestone is defined as an event (i) that can only be achieved based in whole or in part on either the entity's performance or on the occurrence of a specific outcome resulting from the entity's performance, (ii) for which there is substantive uncertainty at the date the arrangement is entered into that the event will be achieved and (iii) that would result in additional payments being due to us. Contingent consideration for which payment is either contingent solely upon the passage of time or the result of a counterparty's performance is not considered substantive.

We recognize consideration that is contingent upon the achievement of a milestone in its entirety as revenue in the period in which the milestone is achieved only if the milestone is substantive in its entirety. A milestone is considered substantive when it meets all of the following criteria:

- The consideration is commensurate with either the entity's performance to achieve the milestone or the enhancement of the value of the delivered item(s) as a result of a specific outcome resulting from the entity's performance to achieve the milestone;
- The consideration relates solely to past performance; and
- The consideration is reasonable relative to all of the deliverables and payment terms within the arrangement.

Milestones that are not considered substantive are generally recognized in the same manner as the undelivered item(s), which is generally the period over which we provide research and development services.

## 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 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.

## Stock-Based Compensation

We expense the fair value of stock awards to employees, net of estimated forfeitures, adjusted to reflect actual forfeitures, over the requisite service period, which is typically the vesting period. We estimate the fair value of options granted to employees at the date of grant using the Black-Scholes option-pricing model that requires management to apply judgment and make estimates, including:

- *fair value of the underlying common shares*, as approved by our board of directors, which was determined using the option-pricing method, or OPM, in periods through December 31, 2014, and the probability-weighted expected return method, or PWERM, beginning March 31, 2015;
- *risk-free interest rate*, which is based on observed interest rates appropriate for the expected term of the stock option grants, historically U.S. Treasury constant maturities;
- *expected volatility*, which is calculated based on reported volatility data for a representative peer group of publicly traded biotechnology companies for which historical information is available. Because we were privately held as of the date of these financial statements, we do not have relevant historical data to support our expected volatility;
- *expected dividend yield*, which is zero as we have never paid cash dividends and do not expect to pay any cash dividends in the foreseeable future; and
- *expected term*, which we calculate using 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, as we have insufficient historical information regarding our stock options to provide a basis for an estimate.

We have computed the fair value of stock options at the date of grant using the following weighted average assumptions:

	Year Ended December 31,		
	2016	2015	2014
Risk-free interest rate	1.4%	1.4%	2.0%
Expected volatility	70.5%	71.2%	66.8%
Expected dividend yield	—%	—%	—%
Expected term (in years)	6.25	6.1	6.1
Weighted average grant date fair value per share	\$ 4.35	\$ 4.48	\$ 1.05

There were 330,622, 1,040,093 and 285,228 stock options granted during the years ended December 31, 2016, 2015 and 2014, respectively. From January 31, 2017 to March 3, 2017, we granted 928,191 stock options.

Stock-based compensation expense related to unvested stock option grants not yet recognized as of December 31, 2016 was \$2.9 million and the weighted average period over which these grants are expected to vest is 2.6 years. We expect to continue to grant stock options in the future, and to the extent we do, our actual stock-based compensation expense recognized in future periods will likely increase.

### Preferred Stock Warrant Liabilities

We account for warrants for shares of preferred stock with conversion features that provide for adjustments in the warrant price as derivative liabilities in the accompanying consolidated balance sheets at their fair value on the date of issuance. The derivative liabilities are revalued at each balance sheet date until such instruments, so long as they remain exercisable for shares of preferred stock, are exercised or expire, with changes in the fair value between reporting periods recorded as other income or expense.

We use the Black-Scholes option pricing model to estimate the fair value of the preferred stock warrant liabilities. Inputs we used in the Black-Scholes option pricing model to determine estimated fair value include the estimated fair value of the underlying convertible preferred stock at the valuation measurement date, the remaining contractual term of the warrants, risk-free interest rates, expected dividends and the expected volatility of the price of the underlying convertible preferred stock.

### Recent Accounting Pronouncements

In May 2014, the FASB issued 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 in FASB ASC 605, *Revenue Recognition*, 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. ASU 2014-09 becomes effective for our annual reporting period beginning January 1, 2018, including interim periods within that reporting period, with adoption permitted as early as January 1, 2017. Entities have the option of using either a full retrospective or a modified retrospective approach for the adoption of the new standard. We will transition this standard using the modified retrospective approach for our annual reporting period beginning January 1, 2018. While we are continuing to assess all potential impacts of the standard, we currently believe the most significant impact relates to our accounting for variable consideration including revenues related to contingent “milestone” based payments. 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,

given the nature of potential milestones owed to us, and the inherent risk involved in developing drugs, we believe that the majority of potential milestones will not be recognizable as of the standard adoption date.

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 becomes effective for our annual reporting period beginning January 1, 2018, including interim periods within that reporting period; early adoption is permitted. We are currently assessing the impact that this standard will have on our consolidated financial statements.

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842)*, which requires that lessees recognize a right-of-use asset and a related lease liability arising from leases on the balance sheet. ASU 2016-02 becomes effective for our annual reporting period beginning January 1, 2019, including interim periods thereafter; early adoption is permitted. We are currently assessing the impact that this standard will have on our consolidated financial statements.

In March 2016, the FASB issued ASU 2016-09, *Compensation—Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting*, which is intended to simplify the accounting for share-based payments including forfeiture rates, expected option terms, intrinsic value, income taxes as they relate to awards, and cash flow presentation. ASU 2016-09 becomes effective for our annual reporting period beginning January 1, 2017, including interim periods thereafter; early adoption is permitted. Upon adoption in January 2017, we will recognize approximately \$30,000 as a cumulative effect decrease to our accumulated deficit as a result of a change in accounting policy from calculating an estimated forfeiture rate at grant date to recording actual forfeitures as they occur. We do not anticipate any other adjustments related to adoption of this standard.

In November 2016, the FASB issued ASU 2016-18, *Statement of Cash Flows (Topic 230): Restricted Cash*, which requires companies to include cash and cash equivalents that have restrictions on withdrawal or use in total cash and cash equivalents on the statement of cash flows. ASU 2016-18 becomes effective for our annual reporting period beginning January 1, 2018, including interim periods thereafter; early adoption is permitted, including adoption in an interim period. We anticipate adopting this guidance for the year beginning January 1, 2017 and will adjust our consolidated statement of cash flows to include \$60,000 in restricted cash in the beginning and ending cash balance upon adopting this guidance.

## Results of Operations

### Comparison of the Years Ended December 31, 2016 and 2015

#### Collaboration Revenue

Collaboration revenue was \$16.7 million and \$17.6 million during the years ended December 31, 2016 and 2015, respectively. A comparison of revenue by collaborator is as follows:

(in thousands)	Year Ended December 31,		Increase (Decrease)
	2016	2015	
TESARO-amortization of upfront payments	\$ 2,634	\$ 9,386	\$ (6,752)
TESARO-funding of research and development	3,242	6,480	(3,238)
TESARO-milestones	9,308	1,705	7,603
Celgene-milestone	1,500	—	1,500
Total	<u>\$ 16,684</u>	<u>\$ 17,571</u>	<u>\$ (887)</u>

During the first and fourth quarter of 2014 we received \$17.0 million and \$2.0 million, respectively, in upfront fees under our collaboration and exclusive license agreement with TESARO. For the years ended December 31, 2016 and 2015, we recognized the amortized portion of these upfront fees in the amounts of \$2.6 million and

\$9.4 million, respectively. Originally, the upfront fees were to be recognized ratably through March 2016, however, in December 2015, we determined that the research and development services would be extended through December 31, 2016, so the upfront fees were recognized ratably through December 31, 2016. We also recognized revenue of \$3.2 million and \$6.5 million during the years ended December 31, 2016 and 2015, respectively, for research and development services performed under the agreement.

In June 2015, TESARO initiated *in vivo* toxicology studies using GLPs for an AnaptysBio-generated anti-PD-1 antagonist antibody (TSR-042) resulting in us earning a \$1.0 million milestone. We recognized revenue of \$0.1 million and \$0.9 million during the years ended December 31, 2016 and 2015, respectively. The \$1.0 million milestone payment was received in July 2015.

In January 2016, TESARO received clearance of their IND from the FDA for an AnaptysBio-generated anti-PD-1 antagonist antibody (TSR-042) resulting in us earning a \$4.0 million milestone payment. We recognized the \$4.0 million milestone payment as revenue during the year ended December 31, 2016. The \$4.0 million milestone payment was received in February 2016.

In May 2016, TESARO received clearance of their IND from the FDA for an AnaptysBio-generated anti-TIM-3 antagonist antibody (TSR-022) resulting in us earning a \$4.0 million milestone payment. We recognized the \$4.0 million milestone payment as revenue during the year ended December 31, 2016. The \$4.0 million milestone payment was received in June 2016.

In June 2016, Celgene successfully completed an *in vivo* toxicology study using GLPs for an AnaptysBio-generated antibody resulting in us earning a \$0.5 million milestone payment in June 2016. We recognized the \$0.5 million milestone payment as revenue during the year ended December 31, 2016. The \$0.5 million milestone payment was received in June 2016.

In September 2016, we achieved a \$1.0 million milestone upon initiation of *in vivo* toxicology studies using GLPs for an AnaptysBio-generated anti-LAG-3 antagonist antibody (TSR-033) being advanced by TESARO, for which we recognized revenue of \$1.0 million through December 31, 2016. The \$1.0 million milestone payment was received in September 2016.

In December 2016, Celgene cleared a U.S. IND with the FDA and initiated a Phase 1 trial, resulting in us earning a \$1.0 million milestone payment. We recognized the \$1.0 million milestone payment as revenue during the year ended December 31, 2016. The \$1.0 million milestone payment was received in January 2017.

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**

Research and development expenses were \$15.4 million and \$17.3 million during the years ended December 31, 2016 and 2015, respectively, for a decrease of \$1.9 million. The decrease was due primarily to the recognition of the tax incentive, which reduced our expenses by \$7.2 million during the year ended December 31, 2016 upon our determination that the tax incentive was collectible. No tax incentive was recorded during the year ended December 31, 2015. The decrease was offset by a \$2.1 million increase in outside service for preclinical expenses, a \$2.0 million increase in clinical expenses, as well as a \$1.2 million increase in salaries and related expenses including recruiting and relocation expense, resulting primarily from an increase in research and development personnel.

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**

General and administrative expenses were \$4.3 million and \$3.6 million during the years ended December 31, 2016 and 2015, respectively, for an increase of \$0.7 million. The increase was due primarily to a \$0.6 million increase in salaries and related expenses, including stock compensation, for senior level positions hired in mid-2015, and a \$0.2 million increase in legal expenses.

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 \$0.5 million during the year ended December 31, 2016 and represents effective interest of 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. Interest expense was \$0.5 million during the year ended December 31, 2015 and primarily represents effective interest of 9.25% on our outstanding Term A Loans, which had an outstanding principal balance of \$5.0 million as of December 31, 2015.

## **Change in Fair Value of Liabilities for Preferred Stock Warrants**

The change in fair value of the liabilities for stock warrants resulted in expense of \$0.8 million and \$1.3 million during the years ended December 31, 2016 and 2015, respectively, due to changes in the valuation of our Series C convertible preferred stock which impacts the estimated fair value of the warrants.

## **Other Income (Expense)**

Other income (expense) 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. Other income (expense) was \$(0.2) million during the year ended December 31, 2015 and primarily consisted of a foreign exchange loss of \$(0.2) million related to our Australian subsidiary, which was established in March 2015.

## **Provision for Income Taxes**

We recorded a provision for income taxes of \$0.1 million during the year ended December 31, 2015 related to alternative minimum taxes, which we were not subject to during the year ended December 31, 2016.

## Comparison of the Years Ended December 31, 2015 and 2014

### Collaboration Revenue

Collaboration revenue was \$17.6 million and \$15.8 million during the years ended December 31, 2015 and 2014, respectively. A comparison of revenue by collaborator is as follows:

(in thousands)	Year Ended December 31,		Increase (Decrease)
	2015	2014	
TESARO-amortization of upfront payments	\$ 9,386	\$ 6,980	\$ 2,406
TESARO-funding of research and development	6,480	4,568	1,912
TESARO-milestone	1,705	—	1,705
Momenta	—	3,100	(3,100)
Celgene Corporation	—	592	(592)
Other	—	598	(598)
Total	\$ 17,571	\$ 15,838	\$ 1,733

During the first and fourth quarter of 2014 we received \$17.0 million and \$2.0 million, respectively, in upfront fees under our collaboration and exclusive license agreement with TESARO. For the years ended December 31, 2015 and 2014, we recognized the amortized portion of these upfront fees in the amounts of \$9.4 million and \$7.0 million, respectively. Originally, the upfront fees were to be recognized ratably through March 2016, however, in December 2015, we determined that the research and development services would be extended through December 31, 2016, so the upfront fees will continue to be recognized ratably through December 31, 2016. We also recognized revenue of \$6.5 million and \$4.6 million during the years ended December 31, 2015 and 2014, respectively, for research and development services performed under the agreement. We recognized revenue of \$1.7 million during the year ended December 31, 2015, for the achievement of two \$1.0 million milestones upon initiation of *in vivo* toxicology studies, under the principles of good laboratory practice, using the AnaptysBio-generated anti-PD-1 antagonist antibody (TSR-042) and the AnaptysBio-generated anti-TIM-3 antagonist antibody (TSR-022), each being advanced by TESARO. The remaining unrecognized milestone payments of \$0.3 million at December 31, 2015 were recognized ratably through December 2016.

In September 2014, we successfully completed our collaboration with Momenta for which we earned a success fee. During the year ended December 31, 2014, we recognized revenue from Momenta of \$3.1 million, which relates to a \$2.0 million success fee and \$1.1 million in amortization of the upfront fee.

The final deliverable under our 2011 antibody generation agreement with Celgene was completed in 2014. During the year ended December 31, 2014, we recognized revenue of \$0.6 million, which relates to \$0.5 million for a success fee and \$92,000 for research and development services performed under this agreement.

We are a party to other collaboration agreements for which in the year ended December 31, 2014 we recognized \$0.6 million in collaboration revenue. We completed our obligations under these agreements in 2014 and do not anticipate any additional revenue from them beyond 2014, and we did not recognize any additional revenue from them during the year ended December 31, 2015.

### Research and Development

Research and development expenses were \$17.3 million and \$8.6 million during the years ended December 31, 2015 and 2014, respectively, for an increase of \$8.7 million. The increase is due primarily to a \$6.6 million increase in outside services for preclinical trial work performed primarily in Australia, as well as a \$1.7 million increase in salaries and related expenses resulting primarily from an increase in research and development personnel.

### General and Administrative

General and administrative expenses were \$3.6 million and \$2.4 million during the years ended December 31, 2015 and 2014, respectively, for an increase of \$1.2 million. The increase is due primarily to a \$0.7 million increase

in salaries and related expenses for new senior level positions, and a \$0.4 million increase in audit and tax fees for additional quarterly and annual services required in preparation for our initial public offering.

### **Interest Expense**

Interest expense was \$0.5 million and \$1.3 million during the years ended December 31, 2015 and 2014, respectively, for a decrease of \$0.8 million. The interest expense for the year ended December 31, 2015 represents effective interest of 9.25% on our outstanding Term A Loans, which had an outstanding principal balance of \$5.0 million as of December 31, 2015. The interest expense for the year ended December 31, 2014 represents stated interest of 10.0% on our convertible promissory notes principal of \$2.0 million, as well as the write-off of the remaining discount on our convertible promissory notes upon conversion of the notes into shares of Series C-1 preferred stock.

### **Change in Fair Value of Liabilities for Preferred Stock Warrants**

The change in fair value of the liabilities for stock warrants resulted in an expense of \$1.3 million and \$59,000 during the years ended December 31, 2015 and 2014, respectively, due to an increase in the valuation of our Series C convertible preferred stock which had the effect of increasing the estimated fair value of the warrants.

### **Other Income (Expense)**

Other income (expense) was (\$0.2) million during the year ended December 31, 2015 and primarily consisted of a foreign exchange loss of (\$0.2) million related to our Australian subsidiary, which was established in March 2015.

### **Provision for Income Taxes**

We recorded a provision for income taxes of \$0.1 million during the year ended December 31, 2015 related to alternative minimum taxes, which we were not subject to during the year ended December 31, 2014.

### **Liquidity and Capital Resources**

From our inception through December 31, 2016, we have received an aggregate of \$169.5 million to fund our operations which included \$85.0 million from the sale of equity securities, \$65.4 million from our collaboration agreements and \$19.1 million from venture debt. As of December 31, 2016, we had \$51.2 million in cash and cash equivalents.

In addition to our existing cash and cash equivalents, 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 Loan Agreement and our rights to payments under our collaboration agreements are our only committed external source of funds.

In January 2017 we closed our initial public offering for net proceeds of approximately \$80.2 million. 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. As of January 31, 2017, including the proceeds from our initial public offering, we had \$130.2 million in cash and cash equivalents.

Under the Loan Agreement, we may borrow up to \$15.0 million in three separate draws of \$5.0 million each. In January 2016, we amended the Loan and Security Agreement, as amended, or the "LSA 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 LSA 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. As of December 31, 2016, the Term Loans are due in 13 monthly interest-only payments through January 2018, followed by 24 equal monthly principal and interest payments beginning February 1, 2018, with final maturity in January 2020. Each Loan bears interest equal to the greater of 3-month U.S. LIBOR plus 6.37% or 7.3%. The rate was 7.3% as of December 31, 2016. In conjunction with the December 30, 2016 draw, we issued 82,416 Series C Preferred warrants to the lenders with an exercise price of \$4.55 that expire December 30, 2026.

### **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 believe our use of CROs and CMOs provides us with flexibility in managing our spending and limits our cost commitments at any point in time.

Cash and cash equivalents totaled \$51.2 million as of December 31, 2016, compared to \$51.7 million as of December 31, 2015. As of January 31, 2017, cash and cash equivalents totaled \$130.2 million and reflects net proceeds of \$80.2 million received from our initial public offering, which closed on January 31, 2017. We expect that our existing cash and cash equivalents, and projected revenue under our existing collaborations, will fund our anticipated operations through 2018. 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.

### **Operating Activities**

Net cash used in operating activities during the year ended December 31, 2016 of \$9.0 million was primarily due to our net loss of \$(4.3) million, adjusted for changes in working capital of \$(7.0) million and addbacks for non-cash expenses of \$2.3 million which includes stock-based compensation and warrant liability fair value adjustments. Net cash used in operating activities during the year ended December 31, 2015 of \$9.7 million was primarily due to our net loss of \$(5.4) million, adjusted for changes in working capital of \$(6.5) million and addbacks for non-cash expenses of \$2.3 million which includes stock-based compensation and warrant liability fair value adjustments. Net cash provided by operating activities during the year ended December 31, 2014 of \$14.6 million was primarily due to our net income of \$3.5 million, adjusted for changes in working capital of \$9.3 million and addbacks for non-cash expenses of \$1.8 million which includes stock-based compensation and warrant liability fair value adjustments.

### **Investing Activities**

Cash used in investing activities during the years ended December 31, 2016, 2015 and 2014 was primarily due to our purchases of property and equipment. As of this time, we plan to focus on our growth strategies and do not plan on using a significant amount of our cash resources in investing activities.

### **Financing Activities**

The cash provided by financing activities during the year ended December 31, 2016 of \$8.6 million was primarily related to the \$10.0 million in debt drawn on December 30, 2016, offset by \$0.3 million in payments made for the cost of issuance and \$1.1 million in payments related to deferred offering costs. Cash provided by financing activities during the year ended December 31, 2015 of \$39.4 million was primarily related to the issuance of Series D Convertible Preferred Stock for net proceeds of \$40.7 million in July 2015 offset by \$1.4 million in payments related to deferred offering costs. The cash provided by financing activities during the year ended December 31, 2014 was \$4.9 million and was related to the \$5.0 million in debt drawn on December 24, 2014, offset by \$0.1 million in payments made for the cost of issuance.

## Contractual Obligations

The following table summarizes our contractual obligations as of December 31, 2016:

(in thousands)	Total <sup>(1)</sup>	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 <sup>(2)</sup>	\$ 18,016	\$ 1,017	\$ 15,620	\$ 1,379	\$ —
Operating lease obligation <sup>(3)</sup>	2,642	532	1,119	991	—
Total	<u>\$ 20,658</u>	<u>\$ 1,549</u>	<u>\$ 16,739</u>	<u>\$ 2,370</u>	<u>\$ —</u>

- (1) Future minimum annual obligations for license payments under all collaborative in-license agreements at December 31, 2016 were \$0.3 million in fiscal 2017 and \$0.2 million 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) In December 2016, we amended the Loan Agreement to allow for the Term B Loans and Term C Loans to be drawn on December 30, 2016, delay principal repayments of all term loans until February 1, 2018 and amend the interest rate for each loan as described in "Liquidity and Capital Resources" above.
- (3) Operating lease obligation includes future rent payments under an office lease, which was amended in October 2015, and expires on August 31, 2021.

We enter into contracts in the normal course of business with clinical trial sites and clinical supply manufacturing organizations and with vendors for preclinical studies, research supplies and other services and products for operating purposes. These contracts generally provide for termination after a notice period, 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.

We are exposed to market risks in the ordinary course of our business. These risks primarily include interest rate sensitivities and foreign currency risk.

### Interest Rate Risk

Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of U.S. interest rates. Due to the short-term duration of our investment portfolio and the low-risk profile of our investments, we would not expect our operating results or cash flows to be affected to any significant degree by the effect of a sudden change in market interest rates on our investment portfolio.

Through December 29, 2016, our debt obligations bore interest at fixed rates, and therefore have no exposure to changes in interest rates. As of December 30, 2016, our debt obligations 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 a maturity date of January 2020. The rate was 7.3% as of December 31, 2016. If interest rates had been 10% higher/lower and all other variables were held constant, operating income would decrease/increase by \$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 \$0.1 million during the year ended December 31, 2016. 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, 2016 from a low of 0.686% to a high of 0.780% with a net impact of \$0.1 million to the consolidated statement of operations.

We have not hedged exposures denominated in foreign currencies, but may do so in the future.

ANAPTYSBIO, INC.  
ANNUAL REPORT ON FORM 10-K  
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**Report of Independent Registered Public Accounting Firm**

The Board of Directors and Stockholders  
AnaptysBio, Inc.:

We have audited the accompanying consolidated balance sheets of AnaptysBio, Inc. and subsidiary as of December 31, 2016 and 2015, and the related consolidated statements of operations, convertible preferred stock and stockholders' deficit, and cash flows for each of the years in the three-year period ended December 31, 2016. 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 conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of AnaptysBio, Inc. and subsidiary as of December 31, 2016 and 2015, and the results of their operations and their cash flows for each of the years in the three-year period ended December 31, 2016, in conformity with U.S. generally accepted accounting principles.

/s/ KPMG LLP

San Diego, California  
March 8, 2017

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

	December 31, 2016	December 31, 2015
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 51,232	\$ 51,684
Receivable from collaborative partners	1,225	1,226
Australian tax incentive receivable	4,118	—
Prepaid expenses and other current assets	1,633	554
Total current assets	58,208	53,464
Property and equipment, net	471	551
Restricted cash	60	60
Deferred financing costs	3,441	2,205
Total assets	<u>\$ 62,180</u>	<u>\$ 56,280</u>
<b>LIABILITIES, CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT</b>		
Current liabilities:		
Accounts payable	\$ 2,278	\$ 1,521
Accrued expenses	3,429	2,753
Deferred revenue	—	2,942
Income taxes payable	—	139
Other current liabilities	1	21
Total current liabilities	5,708	7,376
Notes payable, net of current portion	13,809	4,903
Deferred rent	154	115
Preferred stock warrant liabilities	3,241	1,549
Commitments and contingencies		
Series B convertible preferred stock, \$0.001 par value, 3,963 shares authorized, issued and outstanding at December 31, 2016 and 2015; aggregate liquidation preference at December 31, 2016 of \$24,991	28,220	28,220
Series C convertible preferred stock, \$0.001 par value, 1,887 shares authorized, 1,593 shares issued and outstanding at December 31, 2016 and 2015; aggregate liquidation preference at December 31, 2016 of \$7,246	6,452	6,452
Series C-1 convertible preferred stock, \$0.001 par value, 474 shares authorized, issued and outstanding at December 31, 2016 and 2015, respectively; aggregate liquidation preference at December 31, 2016 of \$6,470	2,156	2,156
Series D convertible preferred stock, \$0.001 par value, 5,491 shares authorized, issued and outstanding at December 31, 2016 and 2015, respectively; aggregate liquidation preference at December 31, 2016 of \$40,767	40,688	40,688
Stockholders' deficit:		
Common stock, \$0.001 par value, 17,214 shares authorized, 2,651 shares and 2,630 shares issued and outstanding at December 31, 2016 and 2015, respectively	3	3
Additional paid in capital	16,672	15,482
Accumulated deficit	(54,923)	(50,664)
Total stockholders' deficit	(38,248)	(35,179)
Total liabilities, convertible preferred stock and stockholders' deficit	<u>\$ 62,180</u>	<u>\$ 56,280</u>

See accompanying notes to consolidated financial statements.

**ANAPTYSBIO, INC.**  
**CONSOLIDATED STATEMENTS OF OPERATIONS**  
(in thousands, except per share data)

	Year Ended December 31,		
	2016	2015	2014
Collaboration revenue	\$ 16,684	\$ 17,571	\$ 15,838
Operating expenses:			
Research and development	15,419	17,304	8,614
General and administrative	4,290	3,589	2,354
Total operating expenses	19,709	20,893	10,968
Income (loss) from operations	(3,025)	(3,322)	4,870
Other expense, net			
Interest expense	(458)	(460)	(11)
Interest expense, related parties	—	—	(1,270)
Change in fair value of liability for preferred stock warrants	(756)	(1,277)	(59)
Other income (expense), net	(20)	(207)	2
Total other expense, net	(1,234)	(1,944)	(1,338)
Income (loss) before income taxes	(4,259)	(5,266)	3,532
Provision for income taxes	—	(139)	—
Net income (loss)	(4,259)	(5,405)	3,532
Net income attributed to participating securities	—	—	(3,300)
Net income (loss) attributed to common stockholders	\$ (4,259)	\$ (5,405)	\$ 232
Net income (loss) per common share:			
Basic and diluted	\$ (1.62)	\$ (2.12)	\$ 0.09
Weighted-average number of shares outstanding:			
Basic and diluted	2,637	2,551	2,481

See accompanying notes to consolidated financial statements.

**ANAPTYSBIO, INC.**  
**CONSOLIDATED STATEMENTS OF CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' 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 Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount			
<b>Balance, January 1, 2014</b>	3,963	\$28,220	1,593	\$6,452	—	\$ —	—	\$ —	2,481	\$ 2	\$ 14,262	\$ (48,791)	\$ (34,527)
Conversion of promissory notes payable to related parties into shares of Series C-1 Preferred Stock	—	—	—	—	474	2,156	—	—	—	—	—	—	—
Stock-based compensation	—	—	—	—	—	—	—	—	—	—	160	—	160
Net income	—	—	—	—	—	—	—	—	—	—	—	3,532	3,532
<b>Balance, December 31, 2014</b>	3,963	28,220	1,593	6,452	474	2,156	—	—	2,481	2	14,422	(45,259)	(30,835)
Issuance of Series D Preferred Stock	—	—	—	—	—	—	5,491	40,688	—	—	—	—	—
Reclassification of warrants	—	—	—	—	—	—	—	—	—	—	297	—	297
Shares issued under employee stock plans	—	—	—	—	—	—	—	—	149	1	159	—	160
Stock-based compensation	—	—	—	—	—	—	—	—	—	—	604	—	604
Net loss	—	—	—	—	—	—	—	—	—	—	—	(5,405)	(5,405)
<b>Balance, December 31, 2015</b>	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)
<b>Balance, December 31, 2016</b>	<u>3,963</u>	<u>\$28,220</u>	<u>1,593</u>	<u>\$6,452</u>	<u>474</u>	<u>\$2,156</u>	<u>5,491</u>	<u>\$40,688</u>	<u>2,651</u>	<u>\$ 3</u>	<u>\$ 16,672</u>	<u>\$ (54,923)</u>	<u>\$ (38,248)</u>

See accompanying notes to consolidated financial statements.

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

	Year Ended December 31,		
	2016	2015	2014
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>			
Net income (loss)	\$ (4,259)	\$ (5,405)	\$ 3,532
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	233	274	308
Stock-based compensation	1,160	604	160
Change in fair value of liability for preferred stock warrants	756	1,277	59
Noncash interest expense	105	110	1,273
Loss on disposal of property and equipment	1	3	3
Changes in operating assets and liabilities:			
Receivable from collaborative partners	1	229	(1,455)
Restricted cash	—	25	25
Australian tax incentive receivable	(4,118)	—	—
Prepaid expenses and other assets	(1,079)	204	(514)
Accounts payable and other liabilities	1,251	1,949	482
Income taxes payable	(139)	139	—
Deferred revenue	(2,942)	(9,078)	10,730
Net cash provided by (used in) operating activities	(9,030)	(9,669)	14,603
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>			
Proceeds from sale of property and equipment	—	—	5
Purchases of property and equipment	(50)	(238)	(145)
Net cash used in investing activities	(50)	(238)	(140)
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>			
Proceeds from issuance of common stock	31	160	—
Payments for repurchase of common stock	(1)	—	—
Proceeds from the issuance of preferred stock, net of issuance costs	—	40,688	—
Payments for deferred offering costs	(1,147)	(1,445)	—
Proceeds from debt	10,000	—	5,000
Payments for debt issuance costs	(255)	—	(85)
Net cash provided by financing activities	8,628	39,403	4,915
Net increase (decrease) in cash and cash equivalents	(452)	29,496	19,378
Cash and cash equivalents, beginning of period	51,684	22,188	2,810
Cash and cash equivalents, end of period	\$ 51,232	\$ 51,684	\$ 22,188
<b>SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION</b>			
Interest paid	\$ 354	\$ 326	\$ 8
Noncash investing and financing activities:			
Fair value of warrants issued with debt	\$ 936	\$ —	\$ —
Amounts accrued for property and equipment	\$ 104	\$ 11	\$ —
Amounts accrued for deferred financing costs	\$ 849	\$ 760	\$ —
Reclassification of warrants to equity	\$ —	\$ 297	\$ —
Conversion of convertible promissory notes payable to related parties into shares of Series C-1 Preferred Stock	\$ —	\$ —	\$ 2,156

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 our collaborative research and development arrangements.

Since our inception, we have devoted our primary effort to raising capital and research and development activities, and at December 31, 2016, have an accumulated deficit of \$54.9 million. Through December 31, 2016, all of our financial support has been provided primarily from the sale of our common and preferred stock, proceeds from the issuance of convertible debt and funds received under our collaborative research and development agreements. Going forward, as we continue our expansion, we may seek additional financing and/or strategic investments. However, there can be no assurance that any additional financing or strategic investments will be available to us on acceptable terms, if at all. If events or circumstances occur such that we do not obtain additional funding, we will most likely be required to reduce our plans and/or certain discretionary spending, which could have a material adverse effect on our ability to achieve our intended business objectives. The accompanying consolidated financial statements do not include any adjustments that might be necessary if we are unable to continue as a going concern.

## 2. Summary of Significant Accounting Policies

### *Basis of Presentation*

The accompanying consolidated financial statements include the Company and its wholly-owned Australian subsidiary, which was established in March 2015. All intercompany accounts and transactions have been eliminated in consolidation. We operate in one reportable segment in the United States of America and our functional and reporting currency is the U.S. dollar. The accompanying consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America (“U.S. GAAP”).

During fiscal 2016, we revised our consolidated statements of cash flows for fiscal 2014 to reflect the gross proceeds from debt within net cash flows provided by financing activities, rather than disclosing this amount net of costs to issue. For fiscal 2014, \$85,000 of issuance costs were reclassified out of proceeds from debt on the consolidated statements of cash flows to conform to the current period presentation.

### *Use of Estimates*

The preparation of the 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.

### *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, 2016 and 2015, respectively, which we used to secure a letter of credit provided as security for our operating lease for our facility.

### ***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 shorter of the lease term or the estimated useful life of the asset. 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, 2016, 2015, or 2014.

### ***Deferred Offering Costs***

Deferred offering costs represent legal, accounting and other direct costs related to our IPO. As of December 31, 2016, we have incurred an aggregate of \$3.4 million in direct costs related to our anticipated public offering of common stock. These costs were deferred and recorded as a long-term asset at December 31, 2016.

### ***Leases, Deferred Rent and Operating Lease Incentives***

Our corporate headquarters lease is classified as an operating lease. 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 requires that four basic criteria be met before revenue can be recognized: (i) persuasive evidence that an arrangement exists; (ii) delivery has occurred and title and the risks and rewards of ownership have been transferred to the client or services have been rendered; (iii) the price is fixed or determinable; and (iv) collectability is reasonably assured.

*Multiple-Element Revenue Arrangements.* We evaluate deliverables in a multiple-element arrangement to determine whether each deliverable represents a separate unit of accounting. A deliverable constitutes a separate unit of accounting when it has standalone value to the customer. If the delivered element does not have standalone value without one of the undelivered elements in the arrangement, we combine such elements and account for them as a single unit of accounting. We allocate the consideration to each unit of accounting at the inception of the arrangement based on the relative selling price.

We recognize consideration allocated to an individual element when all other revenue recognition criteria are met for that element. Our multiple-element revenue arrangements may include the following:

- **License arrangements.** The deliverables under our collaboration and license agreements generally include exclusive or nonexclusive licenses to one or more products generated using our technologies. As the delivered licenses have not historically had standalone value apart from the undelivered elements, these have been recognized as revenue as a combined unit of accounting. Accordingly, we recognize revenue from nonrefundable upfront fees in the same manner as the undelivered item(s), which is generally the period over which we provide research and development services.
- **Research and Development Services.** The deliverables under our collaboration and license arrangements include research and development services we perform on behalf of or with our collaborators. As the provision of research and development services is an integral part of our operations and we may be principally responsible for the performance of these services under the agreements, we recognize revenue on a gross basis for research and development services as we perform those services. Additionally, we recognize research related funding under collaboration research and development efforts as revenue as we perform or deliver the related services in accordance with contract terms.

*Milestone Revenue.* Our collaboration and license agreements generally include contingent contractual payments related to achievement of specific research, development and regulatory milestones and sales-based milestones that are dependent upon the performance of the licensee or collaborator.

We recognize any payment that is contingent upon the achievement of a substantive milestone entirely in the period in which the milestone is achieved. A milestone is defined as an event that can only be achieved based in whole or in part either on our performance, or the performance of our collaborators, or the occurrence of a specific outcome resulting from our past performance for which there is a substantive uncertainty at the date the arrangement is entered into that the event will be achieved.

### ***Research and Development***

Costs associated with research and development activities are expensed as incurred. Research and development costs primarily include salaries and personnel-related costs, supplies and materials, contract manufacturing, in-licensing fees, outside services, and an allocation of information technology, fringe benefits, and facility overhead costs.

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. Royalties incurred on fees received under our sublicensing arrangements are expensed in the period in which we recognize the related collaborative revenue.

### ***Australian Research and Development Tax Incentive***

We are eligible under the Australian Research and Development Tax Incentive Program (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 estimate forfeitures at the time of grant and revise those estimates in subsequent periods if actual forfeitures differ from those estimates. We use historical data to estimate pre-vesting option forfeitures and record stock-based compensation expense only for those awards that are expected to vest.

Options granted to individual service providers who are not employees or directors are accounted for at estimated fair values using the Black-Scholes option pricing model and are subject to periodic remeasurement over the period during which the services are rendered.

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***

We account 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 are revalued at each balance sheet date until such instruments are exercised or expire, with changes in the fair value between reporting periods recorded as other income or expense in the consolidated statement of operations.

#### ***Fair Value of Financial Instruments***

Our financial instruments consist principally of cash, cash equivalents, restricted cash, receivables from collaborative partners, accounts payable, notes payable and preferred stock warrant liabilities.

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—Includes other inputs that are directly or indirectly observable in the marketplace.

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

#### ***Concentration of Credit Risk***

Our policy is to place our cash and cash equivalents with high quality financial institutions in order to limit our credit risk exposure, and, at times, balances may exceed federally insured limits. To date, we have not experienced any credit losses associated with these financial instruments.

#### ***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 United States dollar (“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 and totaled \$(0.1) million and \$(0.2) million during the years ended December 31, 2016 and 2015.

### **Net Income (Loss) Per Common Share**

Basic net loss per common share is computed by dividing net loss attributed to common stockholders by the weighted-average number of common shares outstanding during the period. All participating securities are excluded from basic weighted-average common shares outstanding. Diluted net loss per share attributed to common stockholders is computed by dividing net loss attributed to common stockholders by the weighted-average number of common equivalent shares outstanding for the period. Diluted net loss per share attributed to common stockholders includes any dilutive effect from outstanding stock options and warrants using the treasury stock method. Computations for basic and diluted net loss per common share are presented on the consolidated statements of operations.

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):

(in thousands)	Year Ended December 31,		
	2016	2015	2014
Convertible preferred stock	11,521	8,581	—
Options to purchase common stock	1,969	1,511	1,079
Warrants to purchase preferred stock	295	294	263
Warrants to purchase common stock	117	117	117
Total	13,902	10,503	1,459

### **Accounting Pronouncements Recently Adopted**

In August 2014, the FASB issued ASU 2014-15, *Disclosure of Uncertainties about an Entity’s Ability to Continue as a Going Concern*. This ASU introduces an explicit requirement for management to assess if there is substantial doubt about an entity’s ability to continue as a going concern, and to provide related footnote disclosures in certain circumstances. In connection with each annual and interim period, management must assess if there is substantial doubt about an entity’s ability to continue as a going concern within one year after the issuance date. Disclosures are required if conditions give rise to substantial doubt. ASU 2014-15 is effective for all entities in the first annual period ending after December 15, 2016. Upon adoption, there was no effect to our consolidated financial statements.

In August 2016, the FASB issued ASU 2016-15, *Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments*, which addresses eight specific cash flows issues for which it provides specific guidance on treatment within the cash flow statement, with the intent of reducing diversity in practice. As permitted by this ASU, we elected to early adopt the standard beginning with our quarterly reporting period ended December 31, 2016, with retrospective application of the amended guidance. Upon adoption, there was no effect to our consolidated financial statements.

### **Recent Accounting Pronouncements**

In May 2014, the Financial Accounting Standards Board (the “FASB”) issued Accounting Standards 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 becomes effective for our annual reporting period beginning January 1, 2018, including interim periods within that reporting period; adoption is permitted as early as January 1, 2017. Entities have the option of using either a full retrospective or a modified retrospective approach for the adoption of the new standard. We will transition this standard using the modified retrospective approach for our annual reporting period beginning January 1, 2018. While we are continuing to assess all potential impacts of the standard, we currently believe the most significant impact relates to our accounting for variable consideration including revenues related to contingent “milestone” based payments. 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, given the nature of potential milestones owed to us, and the inherent risk involved in developing drugs, we believe that the majority of potential milestones will not be recognizable as of the standard adoption date.

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 becomes effective for our annual reporting period beginning January 1, 2018, including interim periods within that reporting period; early adoption is permitted. We are currently assessing the impact that this standard will have on our consolidated financial statements.

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842)*, which requires that lessees recognize a right-of-use asset and a related lease liability arising from leases on the balance sheet. ASU 2016-02 becomes effective for our annual reporting period beginning January 1, 2019, including interim periods thereafter; early adoption is permitted. We are currently reviewing all contracts outstanding and are assessing the impact that this standard will have on our consolidated financial statements.

In March 2016, the FASB issued ASU 2016-09, *Compensation—Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting*. Under the new guidance, additional paid-in capital pools will be eliminated and entities will be required to recognize the income tax effects of share-based awards in the income statement when share-based awards vest or are settled. ASU 2016-09 also changes the classification of excess tax benefits on the statement of cash flows. It also will allow an employer to repurchase more of an employee's shares than it can currently for tax withholding purposes without triggering liability accounting and to make a policy election to either account for forfeitures as they occur or to continue the current practice of estimating forfeitures at the time of grant. ASU 2016-09 becomes effective for our annual reporting period beginning January 1, 2017, including interim periods thereafter; early adoption is permitted. Upon adoption of this standard in January 2017, we will recognize a cumulative decrease of approximately \$30,000 to our accumulated deficit as a result of a change in accounting policy.

as we transition from calculating an estimated forfeiture rate at grant date to recording actual forfeitures as they occur. We do not anticipate any other adjustments related to adoption of this standard.

In November 2016, the FASB issued ASU 2016-18, *Statement of Cash Flows (Topic 230): Restricted Cash*, which requires companies to include cash and cash equivalents that have restrictions on withdrawal or use in total cash and cash equivalents on the statement of cash flows. ASU 2016-18 becomes effective for our annual reporting period beginning January 1, 2018, including interim periods thereafter; early adoption is permitted, including adoption in an interim period. We anticipate adopting this guidance for the year beginning January 1, 2017 and will adjust our consolidated statement of cash flows to include \$60,000 in restricted cash in the beginning and ending cash balance upon adopting this guidance.

### 3. Balance Sheet Accounts and Supplemental Disclosures

#### *Property and Equipment*

Property and equipment consist of the following:

(in thousands)	December 31, 2016	December 31, 2015
Laboratory equipment	\$ 3,383	\$ 3,243
Office furniture and equipment	535	553
Leasehold improvements	351	338
	4,269	4,134
Less: accumulated depreciation and amortization	(3,798)	(3,583)
Total property and equipment, net	<u>\$ 471</u>	<u>\$ 551</u>

#### *Accrued Expenses*

Accrued expenses consist of the following:

(in thousands)	December 31, 2016	December 31, 2015
Accrued compensation and related expenses	\$ 973	\$ 772
Accrued professional fees	296	566
Accrued research and contract manufacturing expenses	2,084	1,319
Other	76	96
Total accrued expenses	<u>\$ 3,429</u>	<u>\$ 2,753</u>

### 4. Collaborative Research and Development Agreements

#### *TESARO Collaboration*

In March 2014, we entered into a Collaboration and Exclusive License Agreement (TESARO Agreement) with TESARO, Inc. and TESARO Development, Inc. (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 an 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 later of the 12th anniversary of the first commercial sale of the product or the expiration of the last to expire of any patent. 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.

During the year ended December 31, 2015, we achieved two \$1.0 million milestones upon initiation of *in vivo* toxicology studies, using good laboratory practices (GLPs), for an AnaptysBio-generated anti-PD-1 antagonist antibody (TSR-042) and an AnaptysBio-generated anti-TIM-3 antagonist antibody (TSR-022), each being advanced by TESARO, for which we recognized revenue of \$1.7 million. The remaining unrecognized milestone payment of \$0.3 million at December 31, 2015 was recognized ratably through December 2016.

In January 2016, TESARO received clearance of their IND from the FDA for an AnaptysBio-generated anti-PD-1 antagonist antibody (TSR-042) resulting in us earning a \$4.0 million milestone payment. We recognized the \$4.0 million milestone payment as revenue during the year ended December 31, 2016. The \$4.0 million milestone payment was received in February 2016.

In May 2016, TESARO received clearance of their IND from the FDA for an AnaptysBio-generated anti-TIM-3 antagonist antibody (TSR-022) resulting in us earning a \$4.0 million milestone payment. We recognized the \$4.0 million milestone payment as revenue during the year ended December 31, 2016. The \$4.0 million milestone payment was received in June 2016.

In September 2016, we achieved a \$1.0 million milestone upon initiation of *in vivo* toxicology studies, using GLPs, for an AnaptysBio-generated anti-LAG-3 antagonist antibody (TSR-033), being advanced by TESARO, for which we recognized revenue \$1.0 million during the year ended December 31, 2016. The \$1.0 million milestone payment was received in September 2016.

Revenue from future contingent milestone payments will be recognized if and when such payments become due, subject to satisfaction of all of the criteria necessary to recognize revenue at that time.

Revenue recognized under this agreement aggregated \$15.2 million during the year ended December 31, 2016, which includes \$2.6 million for the amortization of the upfront fee, \$9.3 million related to five milestones earned and \$3.2 million in funding for research and development services of which \$0.2 million was a receivable at December 31, 2016. Revenue recognized under this agreement aggregated \$17.6 million during the year ended December 31, 2015, which primarily includes \$9.4 million for the amortization of the upfront fee, \$6.5 million in funding for research and development services and \$1.7 million for milestones earned. Revenue recognized under this agreement aggregated \$11.5 million during the year ended December 31, 2014, which includes \$7.0 million for the amortization of the upfront fee and \$4.5 million in funding for research and development services.

#### ***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 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.

In June 2016, Celgene successfully completed an *in vivo* toxicology study using good laboratory practices for an AnaptysBio-generated antibody resulting in us earning a \$0.5 million milestone payment in June 2016, which we recognized in full as revenue in June 2016. The \$0.5 million milestone payment was received in June 2016.

In December 2016, Celgene initiated a Phase 1 trial for an AnaptysBio-generated antibody resulting in us earning a \$1.0 million milestone payment in December 2016, which we recognized in full as revenue in December 2016. The \$1.0 million milestone was a receivable as of December 31, 2016.

No revenue was recognized under this agreement during fiscal 2015. Revenue recognized under this agreement aggregated \$0.6 million during the year ended December 31, 2014, which includes \$0.5 million in success fees and \$92,000 in funding for research and development costs.

#### **Other Collaborative Agreements**

We are party to other collaboration agreements for which we recognized \$3.7 million in collaboration revenue during the year ended December 31, 2014. We completed our obligations under these agreements in 2014 and did not recognize any additional revenue from them subsequent to the year ended December 31, 2014.

### **5. Notes Payable and Convertible Promissory Notes**

#### **Notes Payable**

On December 24, 2014, we entered into a Loan and Security Agreement (the "LSA 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 and each bear a fixed rate of interest of 6.97%. The Term B Loans for an aggregate of \$5.0 million were available for draw through December 31, 2015, contingent upon our first multi-dose PK/toxicology studies on at least two development programs and the Term C Loans for an aggregate of \$5.0 million were available for draw through December 31, 2016, contingent upon receiving FDA approval on IND submission on at least two development programs.

The costs incurred to issue the Term A Loans of \$85,000 were deferred and are included in the discount to the carrying value of the Term A Loans in the accompanying balance sheet. The Term A Loans also include a final payment fee of \$0.3 million due at the earlier of prepayment or the maturity date of the Term A 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.

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, which are subject to change under anti-dilution provisions. The warrants are exercisable at any time through December 2024. 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 LSA Agreement was amended (the "LSA Amendment") to combine Term B Loans and Term C Loans for a total of \$10.0 million available for draw 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. If the Term B Loans and

Term C Loans were issued, they would bear interest at the greater of 6.95% or the 3-month LIBOR plus 6.72%, with principal payments beginning February 1, 2017 and with final maturity in January 2019.

In December 2016, we further amended the LSA 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. As of December 31, 2016, the Term Loans are due in 13 monthly interest-only payments through January 2018, followed by 24 equal monthly principal and interest payments beginning February 1, 2018, with final maturity in January 2020. Each Loan bears interest equal to the greater of 3-month U.S. LIBOR plus 6.37% or 7.3%. The rate was 7.3% as of December 31, 2016.

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, which are subject to change under anti-dilution provisions. The warrants are exercisable at any time through December 2026. 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 of December 31, 2016, the carrying amount of the Term Loans were \$13.8 million, which is net of discounts of \$1.2 million, and are classified as noncurrent liabilities at December 31, 2016. The effective interest rate on the Term Loans at December 31, 2016 was 11.70%. As of December 31, 2016, future principal maturities of the Term Loans were \$6.9 million, \$7.5 million and \$0.6 million in 2018, 2019 and 2020, respectively.

The Term Loans are secured by a first priority interest in most of our assets, excluding intellectual property. At December 31, 2016, we were in compliance with the covenants contained in the Loan and Security Agreement.

#### ***Convertible Promissory Notes Payable to Related Parties***

In August 2013, pursuant to a Purchase Agreement, we issued convertible promissory notes to existing investors aggregating \$2.0 million. The notes, which bear interest at 10% per annum, were unsecured and subordinated to all current and future indebtedness and were convertible at any time at the option of the holders into shares of Series C-1 Preferred Stock at a conversion price of \$4.55 per share.

Authoritative accounting guidance requires that a portion of the note proceeds be allocated to additional paid-in capital for the intrinsic value, if any, of the conversion option (the "beneficial conversion feature") based upon the difference between the fair value of the underlying preferred stock at the date of issuance of the notes and the effective conversion price embedded in the notes. The resulting discount on the notes is amortized over the term of the related notes to the stated date of redemption. At August 30, 2013, the date of issuance of the notes, the intrinsic value of the conversion option exceeded the net proceeds of the notes, and therefore the resulting discount attributed to the notes was limited to \$2.0 million.

In April 2014, the principal and accrued interest on the notes, which aggregated \$2.2 million, were converted into 476,190 shares of Series C-1 Preferred Stock. The unamortized discount of \$0.4 million at the date of conversion was recognized as interest expense. Total interest expense resulting from the amortization and write-off of the discount totaled \$1.2 million during the year ended December 31, 2014.

## 6. Fair Value Measurements

### 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:

(in thousands)	Fair Value Measurements at End of Period Using:			
	Fair Value	Quoted Market Prices for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
<b>At December 31, 2016</b>				
Money market funds(1)	\$ 31,955	\$ 31,955	\$ —	\$ —
Mutual funds(2)	17,620	17,620	—	—
Preferred stock warrant liabilities	3,241	—	—	3,241
<b>At December 31, 2015</b>				
Money market funds(1)	\$ 6,755	\$ 6,755	\$ —	\$ —
Mutual funds(1)	44,077	44,077	—	—
U.S. treasury security(2)	65	65	—	—
Preferred stock warrant liabilities	1,549	—	—	1,549

(1) Included in cash and cash equivalents, and restricted cash in the accompanying consolidated balance sheets.

(2) Included in cash and cash equivalents in the accompanying consolidated balance sheets.

*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. The fair values of investments in money market funds, mutual funds and U.S. treasury securities were determined using Level 1 inputs.

*Warrant Liabilities.* Our preferred stock warrants are accounted for as derivative liabilities and measured at fair value on a recurring basis as they contain features that are either not afforded equity classification or embody risks that are not clearly and closely related to host contracts. We estimate fair values of these derivatives utilizing the Black-Scholes option-pricing model, which requires Level 3 inputs.

Estimating fair values of derivative financial instruments, including Level 3 instruments, require the use of significant and subjective inputs that may, and are likely to, change over the duration of the instrument with related changes in internal and external market factors, including changes in the estimated fair value of our equity securities.

The following weighted-average assumptions were employed in estimating the value of the liabilities for Series C preferred stock warrants using the Black-Scholes option-pricing model:

	December 31, 2016		December 31, 2015	
Fair value of preferred stock	\$	12.67	\$	9.10
Exercise price	\$	4.55	\$	4.55
Risk-free interest rate		1.5%		1.32%
Volatility		88.6%		81.0%
Dividend Yield		—%		—%
Contractual term (in years)		3.8		2.8
Weighted-average measurement date fair value per share	\$	9.65	\$	6.09

A 10% increase in the fair values of preferred stock at December 31, 2016 and 2015 would each result in increases in the estimated fair values of the preferred stock warrant liabilities of \$0.4 million and \$0.2 million, respectively.

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,	
	2016	2015
<b>Preferred Stock Warrant Liabilities:</b>		
Beginning balance	\$ (1,549)	\$ (569)
Issuance of Series C Preferred Stock warrants	(936)	—
Unrealized net losses included in other expense, net	(756)	(1,277)
Reclassification of warrant liabilities to equity	—	297
Ending balance	<u>\$ (3,241)</u>	<u>\$ (1,549)</u>

In July 2015, the Company reclassified 41,208 Series C Preferred Stock warrants from Preferred stock warrant liabilities to Additional paid in capital on the consolidated balance sheets, at fair value on the date of transfer. The reclassification occurred upon the expiration of a feature within the warrant contract that had previously precluded equity classification. As a result, these warrants are no longer remeasured at fair value on a recurring basis at December 31, 2015.

#### **Fair Value of Other Financial Instruments**

The fair value of our financial instruments estimated as of December 31, 2016 and 2015 are presented below:

	December 31, 2016		December 31, 2015	
	Carrying Amount	Fair Value	Carrying Amount	Fair Value
Notes Payable	\$ 13,809	\$ 15,531	\$ 4,903	\$ 5,201

The carrying amounts of certain of our financial instruments, including cash and cash equivalents, receivable from collaborative partner, Australian tax incentive receivable, accounts payable, and accrued expenses approximate fair value due to their short-term nature. The carrying amount of our long-term debt as of December 31, 2016 approximates fair value due to the timing of the debt draw down in relation to the balance sheet 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:

*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.

## **7. Stockholders' Equity**

### **Issuance of Series D Convertible Preferred Stock**

On July 13, 2015, we issued and sold 5,490,973 shares of Series D Convertible Preferred Stock at \$7.42 per share for net proceeds of \$40.7 million.

### **Preferred Stock**

The convertible preferred stock has been classified as temporary equity in the accompanying consolidated balance sheets as the shares include provisions allowing the holder to cause redemption of the shares upon certain change in control events that are outside of our control. We have elected not to adjust the carrying values of the convertible preferred stock to the respective liquidation preferences of such shares as we are uncertain whether or when an event would occur that would obligate us to pay the liquidation preference to the holders of such shares, as

discussed below. Adjustments to increase the carrying values to the respective liquidation preferences will be made if and when it becomes probable that an event would occur obligating us to pay such amounts.

The Series B, B-1, and B-2 Preferred Stock (collectively, the “Series B Preferred Stock”) generally have consistent rights and preferences discussed below, except that the conversion price of the Series B-2 Preferred Stock shall not be subject to adjustment in the event that we issue additional equity securities at a purchase price less than the Series B-2 conversion price.

**Dividend Rights.** The holders of the Series Preferred Stock are entitled to receive noncumulative dividends at a rate of 8% of the respective Series issue price per annum. The Series D Preferred Stock dividends are payable in preference and in priority to any Series C-1 Preferred Stock. The Series C-1 Preferred Stock dividends are payable in preference and in priority to any Series C Preferred Stock. The Series C Preferred Stock dividends are payable in preference and in priority to any Series B Preferred Stock. The Series B and Series A Preferred Stock dividends are payable in preference and in priority to any dividends on common stock.

The preferred stock dividends are payable when, as and if declared by our board of directors. As of December 31, 2015, the board of directors has not declared any dividends.

**Voting Rights.** The holders of Series Preferred Stock are entitled to one vote for each share of common stock into which such Series Preferred Stock could then be converted; and with respect to such vote, such holder shall have full voting rights and powers equal to the voting rights and powers of the holders of common stock, except that the holders of the Series B Preferred shares, voting as a separate class, are entitled to elect two members of the board of directors, the holders of the Series A Preferred and common stock shares, each voting as a separate class, are each entitled to elect one member of the board of directors, and the holders of the Preferred and common shares, voting as a single class, are entitled to elect all remaining members of the board of the directors.

**Liquidation Rights.** Upon liquidation, dissolution or winding up of the Company, the holders of Preferred Stock are entitled to receive distributions to be paid out of the assets of the Company, before any distributions are made to the holders of common stock. The holders of the Series D are entitled to receive liquidation preference at one (1) times the original issue price of \$7.42 per share plus all declared and unpaid dividends. Liquidation payments to the holders of Series D Preferred Stock have priority and are made in preference to any payments to the holders of Series C-1 Preferred Stock. The holders of the Series C-1 are entitled to receive liquidation preference at three (3) times the original issue price of \$4.55 per share plus all declared and unpaid dividends. Liquidation payments to the holders of Series C-1 Preferred Stock have priority and are made in preference to any payments to the holders of Series C Preferred Stock. The holders of the Series C Preferred Stock are entitled to receive liquidation preferences at the rate of \$4.55 per share plus all declared and unpaid dividends. Liquidation payments to the holders of Series C Preferred Stock have priority and are made in preference to any payments to the holders of Series B Preferred Stock. The holders of the Series B and Series B-1 Preferred Stock are entitled to receive liquidation preferences at the rate of \$6.30 per share plus all declared and unpaid dividends and the holders of Series A and Series B-2 Preferred Stock are entitled to receive liquidation preferences at the rate of \$7.00 per share plus all declared and unpaid dividends. Liquidation payments to the holders of Series B and Series A Preferred Stock have priority and are made in preference to any payments to the holders of common stock.

**Conversion Rights.** The shares of Series A Preferred Stock are convertible into shares of common stock at a conversion price of \$6.30 per share and the shares of Series B, C, C-1 and D Preferred Stock are convertible into an equal number of shares of common stock. The shares of Series Preferred Stock are convertible at any time, at the option of the holder, subject to certain antidilutive adjustments. Each share of Series Preferred Stock is automatically converted into common stock (i) upon the affirmative election of the holders of at least a majority of the outstanding shares of the Series Preferred Stock, voting together as a single class on an as if converted basis, or (ii) immediately upon the closing of a firmly underwritten public offering pursuant to an effective registration statement under the Securities Act of 1933, as amended, in which the gross cash proceeds to the Company (before underwriting discounts, commissions and fees) are at least \$50.0 million.

### Common Stock

We have authorized 17,214,285 shares of common stock, of which 2,651,286 shares were issued and outstanding at December 31, 2016. Common stock reserved for future issuance upon the exercise, issuance or conversion of the respective equity instruments at December 31, 2016 are as follows:

<i>(in thousands)</i>	
Convertible preferred stock	11,520,698
Issued and Outstanding:	
Stock options	1,879,428
Warrants for shares of convertible preferred stock and common stock	494,678
Shares reserved for future award grants	478,078
Total	<u>14,372,882</u>

### Repurchase of Common Stock

Certain stock option grants under our 2006 Equity Incentive Plan (the "Plan") are 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.

### 8. Equity Incentive Plan

Our 2006 Equity Incentive Plan (the "Plan") provides for the grant of incentive stock options, nonstatutory stock options, stock appreciation rights, and rights to purchase restricted stock to our employees, nonemployee directors and consultants. Recipients of incentive stock options shall be eligible to purchase shares of our common stock at an exercise price equal to no less than the estimated fair market value of such stock on the date of grant. The maximum term of options granted under the Plan is ten years. As of December 31, 2016, awards for up to 2,357,506 shares of common stock are reserved for issuance under the Plan, of which 1,879,428 are reserved for issuance upon exercise of granted and outstanding options and 478,078 shares are available for future grants.

#### Stock Options

Stock options granted to employees and nonemployees generally vest over a four-year period and 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, 2016 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, 2016	2,050,196	\$ 3.99		
Granted	330,622	\$ 6.77		
Exercises	(23,199)	\$ 1.34		
Forfeitures and cancellations	(478,191)	\$ 4.68		
Outstanding and exercisable at December 31, 2016	<u>1,879,428</u>	\$ 4.34	7.30	\$ 12,895.6
Options vested or expected to vest at December 31, 2016	1,781,801	\$ 4.24	7.23	\$ 12,393.0

Total cash received from the exercise of stock options was approximately \$31,000 during the year ended December 31, 2016.

All stock option grants under the Plan provide for exercise of the stock option prior to vesting. Shares of common stock issued upon exercise of unvested options are subject to repurchase by us at the respective original exercise price until vested. Consideration received for the exercise of unvested stock options is recorded as a liability and reclassified into equity as the related award vests.

### 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,		
	2016	2015	2014
Risk-free interest rate	1.4%	1.4%	2.0%
Expected volatility	70.5%	71.2%	66.8%
Expected dividend yield	—%	—%	—%
Expected term (in years)	6.25	6.1	6.1
Weighted average grant date fair value per share	\$ 4.35	\$ 4.48	\$ 1.05

We determine the appropriate, risk free interest rate, expected term for employee stock based awards, contractual term for nonemployee stock based awards, and volatility assumptions. The weighted-average expected option term for employee stock based awards reflects the application of the simplified method, which defines the life as the average of the contractual term of the options and the weighted average vesting period for all option tranches. The weighted average expected term for nonemployee 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 share based payment awards. The assumed dividend yield is based on our expectation of not paying dividends in the foreseeable future.

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

(in thousands)	Year Ended December 31,		
	2016	2015	2014
Research and development	\$ 420	\$ 282	\$ 87
General and administrative	740	322	73
Total	\$ 1,160	\$ 604	\$ 160

At December 31, 2016, there was \$2.9 million of unrecognized compensation cost related to unvested stock option awards, which is expected to be recognized over a remaining weighted average vesting period of 2.6 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 45% refundable tax incentive for qualified research and development activities. For the year ended December 31, 2016, \$7.2 million was recorded as a reduction to research and development expenses in the consolidated statements of operations, of which \$3.0 million related to fiscal 2015. We received the \$3.0 million in cash during the year ended December 31, 2016. In September 2016, we determined that we would meet the eligibility criteria for fiscal 2016, and have therefore recorded a reduction to research and development expense of \$4.2 million equal to 45% of our eligible expenditures for the year ended December 31, 2016, as collectability was considered reasonably assured.

## 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, 2016, 2015 or 2014.

## 11. Commitments and Contingencies

### *Operating Leases*

We lease our facility under a non-cancellable operating lease for which we exercised our option to renew for an additional five-year period in fiscal 2015. The lease now expires in August 2021.

Rent expense was \$0.5 million during the year ended December 31, 2016 and \$0.4 million during the years ended December 31, 2015 and 2014. At December 31, 2016, deferred rent aggregated \$0.2 million, which is included in noncurrent liabilities in the accompanying consolidated balance sheets. At December 31, 2016, the future minimum annual obligations under non-cancellable operating lease commitments are as follows:

Years Ending December 31, (in thousands)		
2017	\$	532
2018		550
2019		569
2020		590
2021		401
Thereafter		—
Total minimum payments required	\$	2,642

### *License Agreements*

We have entered into collaborative license agreements that provide us with rights to use certain know-how, technology and patent rights maintained by the licensors in our research and development efforts. Terms of the license agreements may require us to make upfront payments, milestone payments upon the achievement of certain product research and development objectives and royalty payments on fees received under our sublicensing arrangements and/or future sales, if any, of commercial products resulting from the collaboration.

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 17 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 during the year ended December 31, 2016 and \$0.2 million during the years ended December 31, 2015 and 2014, respectively. Total cash paid under these agreements was \$0.2 million during each of the years ended December 31, 2016, 2015 and 2014.

Future minimum annual cash obligations under all such license agreements were \$0.3 million in aggregate during 2017, and \$0.2 million in aggregate 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.

### *Letter of Credit*

At December 31, 2016 and 2015, 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 a defendant in any lawsuit.

## 12. Income Taxes

The components of income/(loss) before income tax provision (benefit) consist of the following:

(in thousands)	Year Ended December 31,		
	2016	2015	2014
U.S.	\$ (632)	\$ 1,719	\$ 3,532
Foreign	(3,627)	(6,985)	-
Balance at the end of the year	<u>\$ (4,259)</u>	<u>\$ (5,266)</u>	<u>\$ 3,532</u>

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

(in thousands)	December 31,	
	2016	2015
Deferred Tax Assets:		
Net operating loss carryforwards	\$ 15,300	\$ 16,251
Research and development credits	3,086	2,272
Deferred revenue	—	1,137
Other, net	1,017	585
Total deferred tax assets	<u>19,403</u>	<u>20,245</u>
Deferred Tax Liabilities:		
Fixed assets	(108)	(155)
Total deferred tax liabilities	<u>(108)</u>	<u>(155)</u>
Net deferred tax assets	19,295	20,090
Less: valuation allowance	(19,295)	(20,090)
Deferred tax assets, net of valuation allowance	<u>\$ —</u>	<u>\$ —</u>

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, 2016, we had federal and state net operating loss carryforwards (“NOL”) of \$35.7 million and \$46.0 million, respectively. The federal and state NOLs will begin to expire in 2028 and 2017, respectively, unless previously utilized. At December 31, 2016 we had federal and California research tax credit carryforwards of \$2.2 million and \$1.9 million, respectively. The federal research tax credit carryforward will begin to expire in 2026 and the California state credits carryforward indefinitely.

The above 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, and similar state provisions if we experience one or more ownership changes which would limit the amount of NOL and tax credit carryforwards that can be utilized to offset future taxable income and tax, respectively. In general, an ownership change as defined by Section 382 and 383, results from transactions increasing ownership of certain stockholders or public groups in the stock of the corporation by more than 50 percentage points over a three-year period. In September 2015, we completed a Section 382 analysis through December 31, 2014 and determined that there was an ownership change in 2007 that may limit the utilization of approximately \$5.3 million and \$5.4 million in federal and state NOLs, respectively, and \$0.2 million in both federal and state research tax credits. We extended the analysis period of the study through December 31, 2016, noting no ownership changes during fiscal 2015 or 2016. Our use of federal NOL carryforwards could be limited further by the provisions of Section 382 of the U.S. Internal Revenue Code of 1986, as amended, depending upon the timing and amount of additional equity securities that we have issued or will issue. State NOL carryforwards may be similarly limited. If eliminated, the related asset would be removed from the

deferred tax asset schedule with a corresponding reduction in the valuation allowance. Due to the existence of the valuation allowance, limitations created by future ownership changes, if any, will not impact our effective tax rate.

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

(in thousands)	Year Ended December 31,		
	2016	2015	2014
Expected income tax expense (benefit) at federal statutory tax rate	\$ (1,448)	\$ (1,790)	\$ 1,201
State income taxes, net of federal benefit	(174)	(206)	223
Permanent items	175	154	75
Change in fair value of preferred stock warrant liabilities	257	434	20
Research & Development expenditure	789	—	—
Return to provision adjustment	1,957	2	—
Rate differential	52	279	—
Research credits	(814)	13	(314)
Other	—	—	30
Change in the valuation allowance	(794)	1,253	(1,235)
Income tax expense	\$ -	\$ 139	\$ -

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, 2016 and 2015, we had no unrecognized tax benefits that if recognized and realized, would affect the effective tax rate due to the valuation allowance against deferred tax assets. The following table summarizes the activity related to our unrecognized tax benefits:

(in thousands)	Year Ended December 31,	
	2016	2015
Balance at the beginning of the year	\$ 252	\$ 289
Decrease related to prior year tax positions	97	(54)
Increase related to current year tax positions	60	17
Balance at the end of the year	\$ 409	\$ 252

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, 2016, 2015 and 2014, 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, 2016 and 2015 (*unaudited, in thousands, except for per share data*):

	Quarter				Year Ended December 31, 2016
	First	Second	Third	Fourth	
2016					
Operating income (loss)	\$ (1,139)	\$ 2,363	\$ (1,075)	\$ (3,174)	\$ (3,025)
Net income (loss)	\$ (888)	\$ 2,322	\$ (1,115)	\$ (4,578)	\$ (4,259)
Per common share:					
Income (loss) per share, basic	\$ (0.34)	\$ 0.07	\$ (0.42)	\$ (1.73)	\$ (1.62)
Income (loss) per share, diluted	\$ (0.34)	\$ 0.05	\$ (0.42)	\$ (1.73)	\$ (1.62)
2015					
					Year Ended December 31, 2015
Operating income (loss)	\$ 351	\$ 613	\$ (694)	\$ (3,592)	\$ (3,322)
Net loss	\$ (376)	\$ (55)	\$ (1,462)	\$ (3,512)	\$ (5,405)
Per common share:					
Loss per share, basic	\$ (0.15)	\$ (0.02)	\$ (0.57)	\$ (1.34)	\$ (2.12)
Loss per share, diluted	\$ (0.15)	\$ (0.02)	\$ (0.57)	\$ (1.34)	\$ (2.12)

### 14. Subsequent Events

#### *2006 Equity Incentive Plan*

From January 1, 2017 to March 8, 2017, we granted 928,191 stock options. The shares vest over four years from the vesting commencement date.

#### *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.

#### *Common and Preferred Stock*

On January 13, 2017, we amended our Certificate of Incorporation to increase the number of authorized shares of common stock to 60,000,000 with a par value of \$0.001 per share and decrease the number of authorized shares of preferred stock to 11,520,698 with a par value of \$0.001 per share.

#### *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 up the execution and delivery of the underwriting agreement for our initial public offering on January 26, 2017. 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 employees, officers, directors or consultants of the Company. A total of 1,955,506 shares of common stock are initially reserved for issuance under the 2017 plan. In addition, the number 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.

### ***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 up the execution and delivery of the underwriting agreement for our initial public offering on January 26, 2017. A total of 218,000 shares of common stock are initially reserved for issuance under the ESPP. 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.

### ***Initial Public Offering and Related Transactions***

On January 31, 2017, we completed an initial public offering (IPO) selling 5,750,000 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 494,678 shares of convertible preferred stock into warrants to purchase 494,678 shares of common stock and the resultant reclassification of the warrant liability to additional paid-in capital.

### ***Warrant Exercises***

Through March 8, 2017, warrants for the purchase of 234,857 shares of common stock were exercised, of which 117,235 were exercised through cashless exercise. As a result, we issued 199,295 shares of common stock, net.

**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, 2016, 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, 2016, the design and operation of our disclosure controls and procedures were effective at a reasonable assurance level.

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.

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

This annual report does not include a report of management's assessment regarding internal control over financial reporting or an attestation report of our registered public accounting firm due to a transition period established by rules of the SEC for newly public companies.

**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, 2016 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting, other than as described above.

**Item 9B. Other Information.**

None.

**PART III**

**Item 10. Directors, Executive Officers and Corporate Governance.**

**Executive Officers and Directors**

The following table provides information regarding our executive officers and directors as of December 31, 2016:

Name	Age	Position
<b>Executive Officers:</b>		
Hamza Suria, M.B.A.	40	President, Chief Executive Officer and Director
Marco Londei, M.D.	60	Chief Medical Officer
Matthew Moyle, Ph.D.	55	Chief Scientific Officer
Dominic G. Piscitelli, M.B.A., C.P.A.	42	Chief Financial Officer
<b>Non-Employee Directors:</b>		
Carol G. Gallagher, Pharm.D.(1)(2)(3)	52	Director
Nicholas B. Lydon, Ph.D., FRS(2)	59	Director
Hollings Renton, M.B.A.(3)(4)	70	Director
John P. Schmid, M.B.A.(1)	53	Director
James A. Schoeneck(1)(2)	59	Director
James N. Topper, M.D., Ph.D.(3)(5)	54	Director

- (1) Member of the Audit Committee.
- (2) Member of the Compensation Committee.
- (3) Member of the Nominating and Corporate Governance Committee.
- (4) Lead Independent Director.
- (5) Chairman of the Board of Directors.

**Executive Officers**

*Hamza Suria, M.B.A.*, has served as our President and Chief Executive Officer and a member of our board of directors since July 2011. From January 2009 to June 2011 Mr. Suria served as Vice President of Corporate Development. Before joining our company in December 2008, Mr. Suria worked at Maxygen, Inc., a biopharmaceutical company, where he was responsible for partnering and alliance management of next-generation protein therapeutics in oncology supportive care, hematology and autoimmunity, including partnerships with healthcare and pharmaceutical companies, such as Roche, Sanofi S.A., Bayer Corporation and Astellas Pharma. Mr. Suria received his M.S. in immunology from the University of Western Ontario, his Executive M.B.A. from the Richard Ivey School of Business of the University of Western Ontario and his B.S. in biochemistry from Kalamazoo College.

We believe that Mr. Suria's thorough knowledge of our company and technology, and his scientific and business experience, provide him with the qualifications and skills to serve on our board of directors.

*Marco Londei, M.D.* has served as our Chief Medical Officer since October 2016. Prior to that, Dr. Londei served as our Chief Development Officer since October 2014. Before joining our company, Dr. Londei worked as Therapeutic Area Head Immunosciences, at Bristol-Myers Squibb, a biopharmaceutical company, from November 2012 to September 2014. Before starting at Bristol-Myers Squibb, Dr. Londei served as Global Head Translational Medicine of the Autoimmunity, Transplantation & Inflammation Department at Novartis AG and Translational Science Officer at the Genomics Institute of the Novartis Research Foundation from October 2005 to October 2012. Dr. Londei was Professor at the Kennedy Institute of Rheumatology, Imperial College School of Medicine, London, from July 1999 to July 2003 and then Professor and head of the gastroenterology unit at University College London, Medical School UK, from July 2003 through September 2007. Dr. Londei received his M.D. from Università di Bologna.

*Matthew Moyle, Ph.D.* commenced serving as our Chief Scientific Officer in May 2016. Dr. Moyle has more than 25 years of industry experience in drug discovery and development of biologics. Before joining us, from

October 2010 to August 2015, Dr. Moyle served as Vice President of Biotherapeutics at Boehringer Ingelheim GmbH, a German pharmaceutical company, where he chaired Boehringer Ingelheim's International Biologics Council. Prior to that, Dr. Moyle held positions as Senior Vice President of Research and Development and Chief Scientific Officer at Theraclone Sciences, Inc., a private biotechnology company, from May 2007 to October 2010, and as Vice President of Research and Corporate Officer at Tanox, Inc., a public biotechnology company that was acquired in 2006 by Genentech, Inc., from January 2001 to August 2005, where his research organizations designed and developed several monoclonal antibody therapeutic candidates, including three that are currently in mid- to late-stage clinical trials and clinical development at leading pharmaceutical companies. Before Tanox, Dr. Moyle served in various positions at Amgen Inc. from 1995 to 2001, including heading a research department with responsibility for building and running the company's high-throughput expression-profiling facility. Before that, Dr. Moyle was a Group Leader at Corvas, International, Inc., from 1991 to 1995, where he co-discovered two novel natural product biologics that subsequently advanced to pivotal clinical trials. Dr. Moyle was a postdoctoral scientist at Genentech Inc. from 1989 to 1991, where he was part of the company's first program in small molecule therapeutics. Dr. Moyle earned a Ph.D. and B.Sc. in Biochemistry at the University of Toronto.

*Dominic G. Piscitelli, M.B.A., C.P.A.*, commenced serving as our Chief Financial Officer in January 2017. Mr. Piscitelli has more than 15 years of experience in the pharmaceutical and biopharmaceutical industries, and more than 20 years of experience in finance. Before joining us, from September 2012 to January 2017, Mr. Piscitelli served as the Vice President of Finance at Medivation, Inc., a biopharmaceutical company. Prior to that, from January 2011 to September 2012, Mr. Piscitelli served as the Senior Director of Global Finance at Astellas Pharma US, Inc., a pharmaceutical company. From September 2001 to January 2011, Mr. Piscitelli held positions at OSI Pharmaceuticals, Inc., a biotechnology company that was acquired by Astellas Pharma US, Inc. in June 2010, serving as the Vice President of Treasury and Management Finance from 2009 to 2011, and previously as Senior Director, Oncology Finance & Treasury, Director, Commercial Finance and Associate Director/Assistant Controller, SEC Reporting. Mr. Piscitelli earned both his B.A. in Business Administration and his M.B.A. from Hofstra University.

### **Non-Employee Directors**

*Carol G. Gallagher, Pharm.D.* has served as a member of our board of directors since October 2011. Dr. Gallagher has been a partner at New Enterprise Associates, a venture-capital firm, since October 2014. She has served as a director at Atara Biotherapeutics, Inc., a public biopharmaceutical company, since February 2013 and she became lead director in October 2014. She has also served as a director at Atterocor, Inc. since October 2012, as chairperson of the board of directors of eFFECTOR Therapeutics, Inc. from October 2012 to 2014 and as a director of Aragon Pharmaceuticals, Inc. from February 2012 to July 2013. Dr. Gallagher was a venture partner with Frazier Healthcare, a venture-capital firm, from November 2013 to July 2014. Dr. Gallagher served as the President and Chief Executive Officer of Calistoga Pharmaceuticals, a biopharmaceutical company, from September 2008 to April 2011, when the company was acquired by Gilead Sciences. From 2007 to 2008, Dr. Gallagher was the President and Chief Executive Officer of Metastatix, Inc., a biopharmaceutical company. Dr. Gallagher currently serves as a member of the board of directors of Cleave Biosciences, a private biopharmaceutical company. Dr. Gallagher attended Vanderbilt University and received her B.S. and Pharm.D. degrees from the University of Kentucky.

We believe that Dr. Gallagher's extensive experience in the life sciences industry and as a chief executive officer provide her with the qualifications and skills to serve on our board of directors.

*Nicholas B. Lydon, Ph.D., FRS* is a co-founder of our company and has served on our board of directors since our company was founded in November 2005. Dr. Lydon also co-founded and has served on the board of directors of BluePrint Medicines Inc. since April 2011. Since 2011, Dr. Lydon has served as Managing Member at Staurus Pharma, LLC, a biotechnology company. Dr. Lydon is also the founder of Granite Biopharma LLC, a consulting company, and has served as sole member of Granite Biopharma since 2003. Dr. Lydon also previously served as Vice President, Small Molecule Drug Discovery at Amgen Inc. from 2000 to 2002. Prior to joining Amgen, he was the Chief Executive Officer and founder of Kinetix Pharmaceuticals, Inc., a biotechnology company focused on the discovery and development of selective protein kinase inhibitors, from 1997 to 2000. Kinetix Pharmaceuticals was acquired by Amgen in 2000. Prior to joining Kinetix, Dr. Lydon worked at CIBA-GEIGY, AG (Novartis) in Basel, Switzerland from 1985 to 1997, where he was responsible for the protein kinase inhibitor program, including the discovery and preclinical development of Imatinib (Gleevec). Dr. Lydon began his pharmaceutical career at

Schering-Plough Corporation from 1982 to 1985 where his research involved studies on recombinant interferons. Dr. Lydon has been awarded the Lasker~DeBakey Clinical Medical Research Award and the Japan Prize for his work on Imatinib. Other awards include the Warren Alpert Foundation Prize, the AACR Bruce F. Cain Memorial Award and the Charles F. Kettering Prize from the General Motors Cancer Research Foundation. Dr. Lydon earned his B.S. in Biochemistry and Zoology from the University of Leeds, England, and received his Ph.D. in Biochemistry from the Medical Sciences Institute, University of Dundee, Scotland.

We believe that Dr. Lydon's extensive industry experience and significant knowledge of scientific matters provide him with the qualifications and skills to serve on our board of directors.

*Hollings Renton, M.B.A.* has served as a member of our board of directors since June 2015. Mr. Renton previously served as the Chief Executive Officer and President of Onyx Pharmaceuticals, Inc. from 1993 to 2008 and as the chairperson of the board of directors from 2000 to 2008. Before joining Onyx Pharmaceuticals, Mr. Renton served as the President and Chief Operating Officer of Chiron Corporation, a pharmaceutical company, from 1991 to 1993, following its acquisition of Cetus Corporation. Before joining Onyx Pharmaceuticals, Mr. Renton served as the President of Cetus Corporation from 1990 to 1991, as Chief Operating Officer from 1987 to 1990, and as Chief Financial Officer from 1983 to 1987. Mr. Renton currently serves as chairperson of the board of directors of Portola Pharmaceuticals, Inc. He previously served on the boards of directors of Cepheid, Inc., Kythera Biopharmaceuticals, Inc., Rigel Pharmaceuticals, Inc., Affymax Inc., Sangstat Medical Corporation, Special Olympics Northern California and the Biotechnology Industry Organization. Mr. Renton received his M.B.A. from the University of Michigan and his B.S. in Mathematics from Colorado State University.

We believe that Mr. Renton's extensive industry experience and board memberships provide him with the qualifications and skills to serve on our board of directors.

*John P. Schmid, M.B.A.* has served as a member of our board of directors since June 2015. Mr. Schmid served as Chief Financial Officer of Auspex Pharmaceuticals, Inc. from September 2013 to June 2015. Before joining Auspex Pharmaceuticals, Mr. Schmid co-founded Trius Therapeutics, Inc., a publicly traded biopharmaceutical company, where he served as the Chief Financial Officer from June 2004 until its merger with Cubist Pharmaceuticals, Inc., in September 2013. Before he joined Trius Therapeutics, Inc., Mr. Schmid served as the Chief Financial Officer at GeneFormatics, Inc., a private biotechnology company, from 1998 to 2003, and at Endonetics, Inc., a private medical device company, from 1995 to 1998. Mr. Schmid currently serves as a member of the board of directors of Neos Therapeutics, Inc., a pharmaceutical company, and as the chairman of the board of directors of Speak, Inc., a speakers bureau, which he helped found in 1989. Mr. Schmid received his M.B.A. from the University of San Diego and his B.A. from Wesleyan University.

We believe that Mr. Schmid's extensive industry experience and executive positions at multiple biopharmaceutical companies qualify him to serve on our board of directors.

*James A. Schoeneck* has served as a member of our board of directors since November 2015. Mr. Schoeneck has served as the President and Chief Executive Officer of Depomed, Inc. since April 2011 and as a director of Depomed since December 2007. Before joining Depomed, Mr. Schoeneck served as Chief Executive Officer of BrainCells Inc., a private biopharmaceutical company in San Diego, from September 2005 to April 2011. Mr. Schoeneck has served as a director of FibroGen, Inc., a public biopharmaceutical company since June 2010. Mr. Schoeneck received his B.S. in Education from Jacksonville State University.

We believe that Mr. Schoeneck's extensive industry and leadership experience provide him with the qualifications and skills to serve on our board of directors.

*James N. Topper, M.D., Ph.D.* has served as a member of our board of directors since November 2007. Dr. Topper has been a partner with Frazier Healthcare since August 2003, serving as General Partner since 2005.

Before joining Frazier Healthcare, Dr. Topper served as head of the Cardiovascular Research and Development Division of Millennium Pharmaceuticals, Inc. and ran Millennium San Francisco (formerly COR Therapeutics, Inc.) from 2002 until 2003. Before the merger of COR and Millennium in 2002, Dr. Topper served as

the Vice President of Biology at COR from August 1999 to February 2002. Dr. Topper has served as a director at ProNai Therapeutics, Inc., a public drug development company, since April 2014. Dr. Topper has served on numerous boards of directors, including Amicus Therapeutics, Inc. and Portola Pharmaceuticals, Inc. Dr. Topper received his M.D. and Ph.D. in biophysics from Stanford University and his B.S. in biology from the University of Michigan.

We believe that Dr. Topper's experience overseeing Frazier Healthcare investments in biotechnology, senior-management experience in our industry, significant knowledge of medical and scientific matters affecting our business, and understanding of our industry provide him with the qualifications and skills to serve on our board of directors.

Our board of directors has undertaken a review of the independence of each director and considered whether each director has a material relationship with us that could compromise his ability to exercise independent judgment in carrying out his responsibilities. As a result of this review, our board of directors determined that all of our directors, except for Mr. Suria, are "independent directors" as defined under the applicable rules and regulations of the Securities and Exchange Commission, or SEC, and the listing requirements and rules of Nasdaq.

#### **Election of Officers**

Our executive officers are appointed by, and serve at the discretion of, our board of directors. There are no family relationships among any of our directors or executive officers.

#### **Code of Business Conduct and Ethics**

Our board of directors has adopted a code of business conduct and ethics that applies to all of our employees, officers and directors, including our Chief Executive Officer and other executive and senior officers. The full text of our code of conduct is posted on the investor relations section of our website. The reference to our website address in this report does not include or incorporate by reference the information on our website into this report. We intend to disclose future amendments to certain provisions of our code of conduct, or waivers of these provisions, on our website or in public filings.

#### **Audit Committee**

Our audit committee is comprised of Dr. Gallagher, Mr. Schoeneck and Mr. Schmid, with Mr. Schmid as the chairman of our audit committee. The composition of our audit committee meets the requirements for independence under the current Nasdaq and SEC rules and regulations. In addition, our board of directors has determined that Mr. Schmid is an "audit committee financial expert" as defined in Item 407(d)(5)(ii) of Regulation S-K promulgated under the Securities Act. This designation does not impose on him any duties, obligations or liabilities that are greater than are generally imposed on members of our audit committee and our board of directors. Our audit committee is directly responsible for, among other things:

- selecting a firm to serve as the independent registered public accounting firm to audit our financial statements;
- ensuring the independence of the independent registered public accounting firm;
- discussing the scope and results of the audit with the independent registered public accounting firm, and reviewing, with management and that firm, our interim and year-end operating results;
- establishing procedures for employees to anonymously submit concerns about questionable accounting or audit matters;
- considering the adequacy of our internal controls;
- reviewing material related party transactions or those that require disclosure; and
- approving or, as permitted, pre-approving all audit and non-audit services to be performed by the independent registered public accounting firm.

## Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Exchange Act requires our directors, executive officers and beneficial owners of more than 10% of our common stock to file reports of holdings and transactions in our common stock and our other securities with the Securities Exchange Commission. Our directors, executive officers and beneficial owners of more than 10% of our common stock did not become subject to such Section 16(a) reporting requirements until January 25, 2017, after the completion of our fiscal year ended December 31, 2016.

### Item 11. Executive Compensation.

The following tables and accompanying narrative disclosure set forth information about the compensation provided to our executive officers during the years ended December 31, 2015 and 2016. These executive officers, who include our principal executive officer and the two most highly-compensated executive officers (other than our principal executive officer) serving as executive officers as of December 31, 2016, were:

- Hamza Suria, President, Chief Executive Officer and Director;
- Matthew Moyle, Chief Scientific Officer; and
- Marco Londei, Chief Medical Officer.

We refer to these individuals in this section as our “named executive officers.”

#### Summary Compensation Table

The following table presents summary information regarding the total compensation for services rendered in all capacities that was awarded to and earned by our named executive officers during the years ended December 31, 2015 and 2016.

	Fiscal Year	Salary	Bonus(1)	Option Awards(2)	All Other Compensation	Total
Hamza Suria, M.B.A. <i>President and Chief Executive Officer</i>	2016	\$ 425,000	\$ 153,000	\$ —	\$ 600 (4)	\$ 578,600
	2015	\$ 382,083	\$ 97,431	\$ 1,170,840	\$ 540 (4)	\$ 1,650,894
Matthew Moyle, Ph.D. <i>Chief Scientific Officer</i>	2016	\$ 181,250 (3)	\$ 44,405	\$ 614,546	\$ 37,726 (5)	\$ 877,928
Marco Londei, M.D. <i>Chief Medical Officer</i>	2016	\$ 380,000	\$ 92,340	\$ —	\$ 11,944 (6)	\$ 484,284
	2015	\$ 363,333	\$ 81,094	\$ 406,049	\$ 42,042 (7)	\$ 892,518

(1) The amounts reported in this column represent bonuses awarded at the discretion of our board of directors.

(2) The amounts reported in this column represent the aggregate grant-date fair value of the awards granted under our Amended and Restated 2006 Equity Incentive Plan to our named executive officers during the years ended December 31, 2015 and 2016, as computed in accordance with FASB ASC Topic 718. The assumptions used in calculating the grant date fair value of the awards reported in the Stock Option Awards column are set forth in Note 8 to our consolidated financial statements. Note that the amounts reported in this column reflect the aggregate accounting cost for these awards, and do not necessarily correspond to the actual economic value that may be received by the named executive officers from the awards.

(3) Reflects Dr. Moyle’s salary from the commencement of his employment on May 16, 2016, through December 31, 2016.

(4) Reflects group term life insurance premiums paid by us on behalf of Mr. Suria.

(5) Reflects reimbursements paid to, or on behalf of, Dr. Moyle during the year ended December 31, 2016, consisting of \$36,221 for temporary housing and moving expenses and \$1,505 for group term life insurance premiums paid by us on behalf of Dr. Moyle.

(6) Reflects reimbursements paid to, or on behalf of Dr. Londei during the year ended December 31, 2016, consisting of \$7,984 for moving expenses and \$3,960 for group term life insurance premiums paid by us on behalf of Dr. Londei.

- (7) Reflects reimbursements paid to, or on behalf of, Dr. Londei during the year ended December 31, 2015, consisting of \$39,462 for temporary housing and moving expenses, including tax gross-up with respect to temporary housing payments, and \$2,580 for group term life insurance premiums paid by us on behalf of Dr. Londei.

## **Employment Agreements**

The initial terms and conditions of employment of each of Mr. Suria and Drs. Londei and Moyle were set forth in written employment agreements. Each of these arrangements was approved by our board of directors. We believed these employment agreements were necessary to induce these individuals to forego other employment opportunities or leave their current employer for the uncertainty of a demanding position in a new and unfamiliar organization.

### **Mr. Suria's Employment Agreement**

Pursuant to an employment agreement effective as of January 1, 2012 and amended October 9, 2012 and September 16, 2014, or collectively the Suria Employment Agreement, Mr. Suria serves as our President and Chief Executive Officer. The Suria Employment Agreement sets forth the principal terms and conditions of his employment, including his initial annual base salary of \$285,000 and an annual target cash bonus opportunity of 25% of his base salary, subject to pro rata adjustment for any partial years worked, which bonus is earned based on our achievement of specified milestones and performance objectives, as well as Mr. Suria's performance relative to one or more performance objectives established by Mr. Suria, our compensation committee and our board of directors, the achievement of which is evaluated by us. On August 14, 2015, our board of directors increased Mr. Suria's annual base salary to \$420,000, effective as of August 1, 2015. The Suria Employment Agreement provided for the grant of a time-based stock option to purchase up to 214,239 shares of our common stock under our Amended and Restated 2006 Equity Incentive Plan. The Suria Employment Agreement also provided for the grant of a performance-based stock option to purchase up to 97,721 shares of our common stock under our Amended and Restated 2006 Equity Incentive Plan, all of which would vest immediately in the event of a change of control or qualified initial public offering. These options were granted with an exercise price equal to the fair value of our common stock on the date of grant and vest over four years as described in "—Outstanding Equity Awards at Fiscal Year-End Table" below. Mr. Suria's employment is at will and may be terminated at any time, with or without cause. However, pursuant to the terms of the Suria Employment Agreement, Mr. Suria will be entitled to severance benefits upon a qualifying termination of employment as described in "—Potential Payments upon IPO, Termination or Change in Control" below.

### **Dr. Londei's Employment Agreement**

Pursuant to an employment agreement effective as of October 20, 2014, or the Londei Employment Agreement, Dr. Londei serves as our Chief Medical Officer. The Londei Employment Agreement sets forth the principal terms and conditions of his employment, including his initial annual base salary of \$350,000 and an annual target cash bonus opportunity of 25% of his base salary, which bonus is earned based on our achievement of specified milestones and performance objectives, as well as Dr. Londei's performance relative to one or more performance objectives established by Dr. Londei, our compensation committee and our board of directors, the achievement of which is evaluated by us. On August 14, 2015, our board of directors increased Mr. Londei's annual base salary to \$375,000, effective as of August 1, 2015. Likewise, the Londei Employment Agreement provides for additional discretionary performance-based bonuses. The Londei Employment Agreement provides for the grant of a time-based stock option to purchase 160,965 shares of our common stock under our Amended and Restated 2006 Equity Incentive Plan. This option was granted with an exercise price equal to the fair value of our common stock on the date of grant and vests over four years as described in "—Outstanding Equity Awards at Fiscal Year-End Table" below. Dr. Londei's employment is at will and may be terminated at any time, with or without cause. However, pursuant to the terms of the Londei Employment Agreement, Dr. Londei will be entitled to severance benefits upon a qualifying termination of employment as described in "—Potential Payments upon IPO, Termination or Change in Control" below.

## Dr. Moyle's Employment Agreement

Pursuant to an employment agreement effective as of March 22, 2016, or the Moyle Employment Agreement, Dr. Moyle serves as our Chief Scientific Officer. The Moyle Employment Agreement sets forth the principal terms and conditions of his employment, including his initial annual base salary of \$290,000 and an annual discretionary cash bonus of up to 30% of his base salary, which bonus is earned based on achievement of certain performance goals established by our Chief Executive Officer, the final determination of which for any given year is made by our Chief Executive Officer and board of directors in their sole and absolute discretion. The Moyle Employment Agreement provides for reimbursement of actual and reasonable costs that Dr. Moyle may incur to relocate his household from Connecticut to the San Diego area no later than May 2017, up to \$135,000 in the aggregate, and the Moyle Employment Agreement provides further that, in the interim, Dr. Moyle shall be reimbursed for actual and reasonable costs incurred by Dr. Moyle for him to spend at least three weeks per month in the San Diego area, up to a maximum of an additional \$40,000 in the aggregate. The Moyle Employment Agreement provides for the grant, as soon as practicable following the effective date of the Moyle Employment Agreement, of a time-based stock option to purchase up to 169,417 shares of our common stock under our Amended and Restated 2006 Equity Incentive Plan. This option was granted with an exercise price equal to the fair market value of our common stock on the date of grant and vests over four years, with 1/4 of the underlying shares vesting on the first calendar anniversary of the effective date of the Moyle Employment Agreement and, thereafter, an additional 1/48 of the underlying shares vesting on the same day of each succeeding calendar month. Dr. Moyle's employment is at-will and may be terminated at any time, with or without cause. However, pursuant to the terms of the Moyle Employment Agreement, Dr. Moyle will be entitled to severance benefits upon a qualifying termination of employment as described in "—Potential Payments upon IPO, Termination or Change in Control" below.

## Outstanding Equity Awards at Fiscal Year-End Table

The following table presents, for each of the named executive officers, information regarding outstanding stock options held as of December 31, 2016.

Name	Grant Date(1)	Option Awards			
		Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price (\$)	Option Expiration Date
Hamza Suria, M.B.A.(2)	Dec. 9, 2008	22,428	—	\$ 2.59	Dec. 8, 2018
	Feb. 10, 2010	1,428	—	\$ 2.24	Feb. 9, 2020
	Feb. 24, 2011	6,208	—	\$ 1.61	Feb. 23, 2021
	Dec. 9, 2011	140,948	—	\$ 1.12	Dec. 8, 2021
	Feb. 1, 2012	97,721	—	\$ 1.12	Jan. 31, 2022
	Feb. 1, 2012	73,291	—	\$ 1.12	Jan. 31, 2022
	Dec. 17, 2012	19,425	—	\$ 0.91	Dec. 16, 2022
	Sep. 16, 2014	51,840	—	\$ 0.70	Sep. 15, 2024
Matthew Moyle, Ph.D.(3)	Aug. 14, 2015	88,641	177,287	\$ 6.93	Aug. 13, 2025
	July 22, 2016	—	169,417	\$ 5.95	July 21, 2026
Marco Londei, M.D.(4)	Oct. 28, 2014	160,965	—	\$ 0.70	Oct. 27, 2024
	Aug. 14, 2015	30,740	61,483	\$ 6.93	Aug. 13, 2025

- (1) All stock-option awards have been granted under our Amended and Restated 2006 Equity Incentive Plan. Except where otherwise noted, the underlying shares of each option vest over four years, with 1/4 of the underlying shares vesting on the first calendar anniversary of the grant date and, thereafter, 1/48 of the underlying shares vest on the same day of each succeeding calendar month, subject to the optionee's employment through each applicable vesting date, such that 100% of the underlying shares will have vested on the fourth calendar anniversary of the grant date. See "—2006 Equity Incentive Plan" below for a description of the plan.
- (2) These options are early-exercisable, except for the options granted on August 14, 2015. The options vested as to their underlying shares as follows:  
 (i) the shares underlying the options granted on December 9,

2008, February 10, 2010, February 24, 2011, and December 9, 2011 and December 17, 2012, and 73,291 shares underlying the options granted on February 1, 2012, have fully vested; (ii) of the 97,721 shares underlying an option granted on February 1, 2012, all vested upon our initial public offering; (iii) of the 51,840 shares underlying the option granted on September 16, 2014, 1/4 vested on September 16, 2015, and thereafter 1/48 vest on the sixteenth day of each succeeding calendar month, starting October 16 2015; and (iv) of the 265,928 shares underlying the option granted on August 14, 2015, 1/4 vested on August 13, 2016, and 1/48 vest on the thirteenth day of each succeeding calendar month, starting September 13, 2016, provided that if Mr. Suria is terminated without Cause or resigns for Good Reason (as each is defined in his employment agreement) in connection with a Change in Control (as defined in the Amended and Restated 2006 Equity Incentive Plan), then all of the shares underlying the option shall vest at that time.

- (3) These options are not early-exercisable. The options vest as to their underlying shares as follows: (i) of the 169,417 shares underlying the option granted on July 22, 2016, 1/4 vest on May 16, 2017, and 1/48 vest on the 16th day of each succeeding calendar month, starting June 16, 2017, provided that if Mr. Moyle is terminated without Cause or resigns for Good Reason (as each is defined in his employment agreement) in connection with a Change in Control (as defined in the Amended and Restated 2006 Equity Incentive Plan), then all of the shares underlying the options shall vest at that time.
- (4) These options are early-exercisable, except for the options granted on August 14, 2015. The options vest as to their underlying shares as follows: (i) of the 160,965 shares underlying the option granted on October 28, 2014, 1/4 of the shares vested on October 24, 2015, and thereafter, 1/48 vest on the 24th day of each succeeding calendar month, starting November 24, 2015, provided that if Dr. Londei is terminated without Cause or resigns for Good Reason (as each is defined in his employment agreement) in connection with a Change in Control (as defined in the Amended and Restated 2006 Equity Incentive Plan), then all of the shares underlying the option shall vest at that time; and (ii) of the 92,223 shares underlying the option granted on August 14, 2015, 1/4 vested on August 13, 2016, and 1/48 vest on the thirteenth day of each succeeding calendar month, starting September 13, 2016, provided that if Mr. Londei is terminated without Cause or resigns for Good Reason (as each is defined in his employment agreement) in connection with a Change in Control (as defined in the Amended and Restated 2006 Equity Incentive Plan), then all of the shares underlying the option shall vest at that time.

## **Potential Payments upon Termination or Change in Control**

### **Termination**

Pursuant to the Suria Employment Agreement, the Londei Employment Agreement and the Moyle Employment Agreement, in the event that Mr. Suria, Dr. Londei or Dr. Moyle is terminated without “cause” or resigns for “good reason” (each as defined in the applicable employment agreement), provided that each delivers a signed settlement and general release in favor of us and satisfies all conditions to make such release effective, (i) each will receive continued severance payments for 12 months, nine months and nine months, respectively and (ii) and if each elects continuation coverage under the Consolidated Omnibus Budget Reconciliation Act of 1985, or COBRA, we will pay directly to the insurance provider of our group health plans, the monthly premium for such continuation coverage for each officer and his family, for 12 months, nine months and nine months, respectively, or such earlier date on which coverage with a new employer is obtained.

### **Change in Control**

Pursuant to the Suria Employment Agreement and certain of his outstanding stock option agreements, if we experience a change in control and Mr. Suria is terminated without “cause” or resigns for “good reason” (each as defined in the employment agreement) upon the occurrence of, or within 13 months following, such change in control, and provided that Mr. Suria delivers a signed settlement and general release in favor of us and satisfies all conditions to make such release effective, (i) Mr. Suria will receive the continued severance payments and COBRA premiums described above for 12 months and (ii) certain of his currently outstanding stock options will vest in full as described in more detail in “—Outstanding Equity Awards at Fiscal Year-End Table” above. In addition, Mr. Suria’s option granted on February 1, 2012, will vest in full upon a change in control, subject to Mr. Suria’s employment on such date.

Pursuant to the Londei Employment Agreement, if we experience a change in control and Dr. Londei is terminated without “cause” or resigns for “good reason” (each as defined in the employment agreement or applicable option agreement) upon the occurrence of, or within 13 months following, such change in control, and provided that Dr. Londei delivers a signed settlement and general release in favor of us and satisfies all conditions to make such release effective, (i) Dr. Londei will receive the severance payments and COBRA premiums described above for nine months and (ii) each of his currently outstanding stock options will vest in full.

Pursuant to the Moyle Employment Agreement, if we experience a change in control and Dr. Moyle is terminated without “cause” or resigns for “good reason” (each as defined in the employment agreement or applicable option agreement) upon the occurrence of, or within 13 months following, such change in control, and provided that Dr. Moyle has permanently relocated his household to the San Diego area prior to such termination or resignation and delivers a signed settlement and general release in favor of us and satisfies all conditions to make such release effective (i) Dr. Moyle will receive the severance payments and COBRA premiums described above for nine months and (ii) the stock option granted to him pursuant to his employment agreement will vest in full.

Each employment agreement contains a “better after-tax” provision, which provides that if any of the payments to Mr. Suria, Dr. Londei, or Dr. Moyle respectively, constitutes a parachute payment under Section 280G of the Code, the payments will either be (i) reduced or (ii) provided in full to the executive, whichever results in the executive receiving the greater amount after taking into consideration the payment of all taxes, including the excise tax under Section 4999 of the Code, in each case based upon the highest marginal rate for the applicable tax.

### Executive Benefits

Our named executive officers are eligible to participate in our employee benefit plans on the same basis as our other employees, including our health and welfare plans.

### Non-Employee Director Compensation

The following table presents the total compensation earned or paid in the year ended December 31, 2016 for each member of our board of directors, except for our President and Chief Executive Officer, Mr. Suria, who receives no additional compensation for his service as a director. Other than as described below, none of our non-employee directors are expected to receive any fees or reimbursement of any expenses (other than customary expenses in connection with the attendance of meetings of our board of directors) or any equity or non-equity awards in the year ended December 31, 2016.

Name	Fees Earned or Paid in Cash(1)(\$)	Total(2)(\$)
Carol G. Gallagher, Pharm.D.	\$ 50,000	\$ 50,000
Nicholas B. Lydon, Ph.D., FRS	\$ 50,000	\$ 50,000
Hollings Renton, M.B.A.	\$ 50,000	\$ 50,000
John P. Schmid, M.B.A.	\$ 40,000	\$ 40,000
James A. Schoeneck	\$ 52,500	\$ 52,500

- (1) Dr. Gallagher, Dr. Lydon and Mr. Renton were each paid a \$50,000 annual retainer fee in connection with their service on our board of directors. Mr. Schmid was paid an annual retainer fee of \$35,000 and \$5,000 in connection with his service on our board of directors and audit committee, respectively. Mr. Schoeneck was paid an annual retainer fee of \$40,000, \$7,500 and \$5,000 in connection with his service on our board of directors, audit committee and compensation committee, respectively.

- (2) The following table sets forth the expected aggregate number of shares of our common stock subject to outstanding stock options held by our non-employee directors as of December 31, 2016:

<b>Director Name</b>	<b>Number of Shares Underlying Stock Options Held as of December 31, 2016</b>
Carol G. Gallagher, Pharm.D.	97,722
Nicholas B. Lydon, Ph.D., FRS	31,012
Hollings Renton, M.B.A.	51,156
John P. Schmid, M.B.A.	42,337
James A. Schoeneck	42,337

In September 2015, our board of directors approved a non-employee director compensation policy, which took effect following the completion of our initial public offering. Pursuant to this policy, each of our non-employee directors receives an annual retainer of \$40,000. Additionally, the Company's lead independent director, currently Mr. Renton, receives an additional annual payment of \$20,000; the chairperson of our board of directors receives an additional annual payment of \$15,000 when a lead independent director is also serving and \$30,000 when no lead independent director is serving; the chairpersons of our audit, compensation and nominating and corporate governance committees receive an additional annual payment of \$15,000, \$10,000 and \$7,500, respectively; and the members of our audit, compensation and nominating and corporate governance committees receive an additional annual payment of \$7,500, \$5,000 and \$3,750, respectively.

Each of our non-employee directors receives an annual option to purchase 14,258 shares of common stock, which vests in a single installment 12 months after the grant date, subject to the applicable director's continuous service through such date. Additionally, each new non-employee director will receive upon election to our board of directors, an option to purchase 28,571 shares of common stock, which will vest in 36 equal monthly installments after the grant date, subject to the director's continuous service through such date. The exercise price of such grants will be the fair market value of our common stock as of the grant date.

#### **Compensation Committee Interlocks and Insider Participation**

None of our executive officers has served as a member of our board of directors, or as a member of our compensation or similar committee, of any entity that has one or more executive officers who served on our board of directors or compensation committee during the year ended December 31, 2016. Prior to establishing the compensation committee, our full board of directors made decisions relating to the compensation of our officers. For a description of transactions between us and members of our compensation committee and affiliates of such members, please see "Certain Relationships and Related Party Transactions, and Director Independence."

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

The following table sets forth certain information with respect to the beneficial ownership of our common stock as of January 31, 2017 for:

- each of our directors;
- each of our named executive officers;
- all of our current directors and executive officers as a group; and
- each person, or group of affiliated persons, who beneficially owned more than 5% of our common stock.

The column entitled "Percentage of Shares Beneficially Owned" is based on a total of 20,006,202 shares of our common stock outstanding as of January 31, 2017.

We have determined beneficial ownership in accordance with the rules of the SEC, and the information is not necessarily indicative of beneficial ownership for any other purpose. Except as indicated by the footnotes below, we believe, based on information furnished to us, that the persons and entities named in the table below have sole voting and sole investment power with respect to all shares of common stock that they beneficially owned, subject to applicable community property laws. Unless otherwise indicated, the address of each of the individuals and entities named below is c/o AnaptysBio, Inc. at 10421 Pacific Center Court, Suite 200, San Diego, CA 92121.

Name of Beneficial Owner	Shares Beneficially Owned	Percentage of Shares Beneficially Owned
<b>5% Stockholders:</b>		
Entities affiliated with Frazier Healthcare <sup>(1)</sup>	3,688,447	18.3
Novo A/S <sup>(2)</sup>	3,033,504	15.2
Avalon Ventures VII, L.P. <sup>(3)</sup>	2,154,415	10.7
Entities affiliated with Biotechnology Value Fund, L.P. <sup>(4)</sup>	1,904,600	9.5
Alloy Ventures 2005, L.P. <sup>(5)</sup>	1,282,485	6.4
HBM Healthcare Investments (Cayman) Ltd. <sup>(6)</sup>	1,092,835	5.5
<b>Directors and Named Executive Officers:</b>		
Hamza Suria <sup>(7)</sup>	523,549	2.6
Marco Londei, M.D. <sup>(8)</sup>	199,489	1.0
Matthew Moyle Ph.D.	—	—
Carol G. Gallagher, Pharm.D. <sup>(9)</sup>	162,018	*
Nicholas B. Lydon, Ph.D., FRS <sup>(10)</sup>	335,118	1.7
Hollings Renton <sup>(11)</sup>	51,156	*
John Schmid <sup>(12)</sup>	42,337	*
James A. Schoeneck <sup>(13)</sup>	42,337	*
James N. Topper, M.D., Ph.D. <sup>(1)</sup>	3,688,447	18.3
All executive officers and directors as a group (ten persons) <sup>(14)</sup>	5,044,451	23.9

\* Represents beneficial ownership of less than one percent.

- (1) Consists of (a) 2,228,377 shares of common stock held directly by Frazier Healthcare V, L.P., (b) 1,045,031 shares of common stock held directly by Frazier Healthcare VII, L.P., (c) 297,804 shares of common stock held directly by Frazier Healthcare VII-A, L.P. and (d) 117,235 shares of common stock issuable upon the exercise of a warrant held directly by Frazier Healthcare V, L.P. The general partner of Frazier Healthcare V, L.P. is FHM V, L.P., a Delaware limited partnership. The general partner of FHM V, L.P. is FHM V, LLC, a Delaware limited liability company. The general partner of Frazier Healthcare VII, L.P. and Frazier Healthcare VII-A, L.P. is FHM VII, L.P., a Delaware limited partnership. The general partner of FHM VII, L.P. is FHM VII, LLC, a Delaware limited liability company. Dr. Topper, a member of our Board of Directors, Alan Frazier, Nader Naini, Nathan Every and Patrick Heron are members of FHM V, LLC and FHM VII, LLC and may be deemed to share voting and investment power with respect to the shares held by FHM V, LLC and FHM VII, LLC. The address of Frazier Healthcare is 601 Union, Two Union Square, Suite 3200, Seattle WA 98101.
- (2) Consists of 3,033,504 shares of common stock held directly by Novo A/S. The board of directors of Novo A/S, which is currently comprised of Sten Scheibye, Göran Ando, Jeppe Christiansen, Steen Riisgaard and Per Wold-Olsen, has shared voting and investment power with respect to these shares and may exercise such control only with the support of a majority of the board. As such, no individual member of the board is deemed to hold any beneficiary ownership in these shares. The address of Novo A/S is Tuborg Havnevej 19, 2900 Hellerup, Denmark.
- (3) Consists of (a) 2,036,932 shares of common stock held directly by Avalon Ventures VII, L.P. and (b) 117,483 shares of common stock issuable upon the exercise of a warrant held directly by Avalon Ventures VII, L.P. The general partner of Avalon Ventures II, L.P. is Avalon Ventures VII GP, LLC. The managing members of Avalon Ventures VII GP, LLC are Kevin J. Kinsella and Stephen L. Tomlin.
- (4) Consists of (a) 907,116 shares of common stock held directly by Biotechnology Value Fund, L.P., (b) 551,019 shares of common stock held directly by Biotechnology Value Fund II, L.P., (c) 74,064 shares of common stock

held directly by Biotechnology Value Trading Fund OS, L.P., (d) 135,000 shares of common stock held directly by Investment 10, L.L.C., (e) 237,401 shares of common stock held directly by MSI BVF SPV, L.L.C. The address of Biotechnology Value Fund, L.P. is 1 Sansome Street, 30<sup>th</sup> Floor, San Francisco, CA 94104.

- (5) Consists of 1,282,485 shares of common stock held directly by Alloy Ventures 2005, L.P. The general partner of Alloy Ventures 2005, L.P. is Alloy Ventures 2005, LLC. The managing members of Alloy Ventures 2005, LLC are Craig Taylor, Doug Kelly John Shoch, Dan Rubin and Tony Di Bona.
- (6) Represents 1,092,835 shares of common stock held directly by HBM Healthcare Investments (Cayman) Ltd. The board of directors of HBM Healthcare Investments (Cayman) Ltd. has sole vesting and investment power with respect to the shares. The board of directors of HBM Healthcare Investments (Cayman) Ltd. is comprised of Jean-Mar Lesieur, Richard Coles, Sophia Harris, Dr. Andrea Wicki, Paul Woodhouse and John Urquhart, none of whom has individual voting or investment power with respect to the shares.
- (7) Consists of (a) 4,998 shares of common stock held directly by Mr. Suria and (b) 518,551 shares of common stock issuable to Mr. Suria upon the exercise of stock options that are exercisable within 60 days of January 31, 2017, of which 19,440 shares were unvested but were early exercisable, as of 60 days after January 31, 2017.
- (8) Consists of (a) 2,020 shares of common stock held directly by Dr. Londei and (b) 197,469 shares of common stock issuable to Dr. Londei upon the exercise of stock options that are exercisable within 60 days of January 31, 2017, of which 63,715 shares were unvested but were early exercisable, as of 60 days after January 31, 2017.
- (9) Consists of (a) 64,296 shares of common stock held directly by Dr. Gallagher and (b) 97,722 shares of common stock issuable to Dr. Gallagher upon the exercise of stock options that are exercisable within 60 days of January 31, 2017.
- (10) Consists of (a) 287,623 shares of common stock held directly by Dr. Lydon, (b) 16,483 shares of common stock issuable upon the exercise of a warrant held directly by Dr. Lydon and (c) 31,012 shares of common stock issuable to Dr. Lydon upon the exercise of stock options that are exercisable within 60 days of January 31, 2017, of which 6,402 shares were unvested but were early exercisable, as of 60 days after January 31, 2017.
- (11) Represents 51,156 shares of common stock issuable to Mr. Renton upon the exercise of stock options that are exercisable within 60 days of January 31, 2017, of which 21,599 shares were unvested but were early exercisable, as of 60 days after January 31, 2017.
- (12) Represents 42,337 shares of common stock issuable to Mr. Schmid upon the exercise of stock options that are exercisable within 60 days of January 31, 2017, of which 20,507 shares were unvested but were early exercisable, as of 60 days after January 31, 2017.
- (13) Represents 42,337 shares of common stock issuable to Mr. Schoeneck upon the exercise of stock options that are exercisable within 60 days of January 31, 2017, of which 23,521 shares were unvested but were early exercisable, as of 60 days after January 31, 2017.
- (14) Includes shares beneficially owned by our executive officers and directors. Consists of (a) 3,930,149 shares of common stock, (b) 133,718 shares of common stock issuable upon the exercise of warrants and (c) 980,584 shares of common stock issuable upon the exercise of stock options that are exercisable within 60 days of January 31, 2017, of which 155,184 shares were unvested but early exercisable, as of 60 days after January 31, 2017.

The above table does not include Dominic G. Piscitelli, who commenced his employment with us as our Chief Financial Officer in January 2017. In connection with his employment, Mr. Piscitelli was granted an option to purchase 170,241 shares of our common stock, none of which are exercisable within 60 days of December 31, 2016.

**Equity Compensation Plan Information** The following table contains information about our equity compensation plans as of December 31, 2016. As of December 31, 2016, we had one equity compensation plan, our Amended and Restated 2006 Equity Incentive Plan, which was approved by our stockholders.

Plan Category	Number of Securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders	1,879,428	\$ 4.34	478,078
Equity compensation plans not approved by security holders	-	-	-
<b>Total</b>	<b>1,879,428</b>	<b>\$ 4.34</b>	<b>478,078</b>

In connection with our initial public offering, our board of directors and stockholders approved two new equity compensation plans, the 2017 Equity Incentive Plan and the 2017 Employee Stock Purchase Plan. The 2017 Equity Incentive Plan became effective on January 24, 2017, and the 2017 Employee Stock Purchase Plan became effective January 25, 2017. The table above does not include any amounts issuable under either the 2017 Equity Incentive Plan or the 2015 Employee Stock Purchase Plan.

We have ceased issuing awards under our Amended and Restated 2006 Equity Incentive Plan as of the effective date of our 2017 Equity Incentive Plan. The remaining shares available for issuance under the Amended and Restated 2006 Equity Plan have been rolled over into the 2017 Equity Incentive Plan. Our 2017 Equity Incentive Plan became effective on January 24, 2017. As a result, we will no longer grant any additional options under the Amended and Restated 2006 Equity Incentive Plan. However, any outstanding options granted under the Amended and Restated 2006 Equity Incentive Plan will remain outstanding, subject to the terms of our Amended and Restated 2006 Equity Incentive Plan and stock option agreements, until such outstanding options are exercised or until they terminate or expire by their terms.

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

We describe below transactions and series of similar transactions since January 1, 2016 to which we were a party or will be a party, in which:

- the amounts involved exceeded or will exceed \$120,000; and
- any of our directors, executive officers or beneficial holders of more than 5% of any class of our capital stock, or any member of the immediate family of the foregoing persons, had or will have a direct or indirect material interest.

Other than as described below, there have not been, nor are there any currently proposed, transactions or series of similar transactions to which we have been or will be a party other than compensation arrangements, which are described where required under “Executive Compensation.”

## Participation in Initial Public Offering

Certain of our existing stockholders and their affiliated entities, including stockholders affiliated with certain of our directors, purchased an aggregate of 1,946,666 shares of our common stock in our initial public offering at the initial public offering price. The following table summarizes common stock purchased by members of our board of directors and entities who held more than 5% of our outstanding capital stock at the time of the purchase:

<u>Name</u>	<u>Number of Purchased Shares</u>	<u>Aggregate Purchase Price</u>
Entities affiliated with Biotechnology Value Fund (1)	850,000	\$ 12,750,000
Entities affiliated with Frazier Healthcare (2)	400,000	\$ 6,000,000
Novo A/S	50,000	\$ 750,000
Nicholas B. Lydon, Ph.D., FRS	16,666	\$ 249,990
Total	1,316,666	\$ 19,749,990

(1) Consists of 414,373 shares purchased by Biotechnology Value Fund, L.P., 269,019 shares purchased by Biotechnology Value Fund II, L.P., 74,064 shares purchased by Biotechnology Value Trading Fund OS, L.P. and 92,544 shares purchased by MSI BVF SPV LLC.

(2) Consists of 311,291 shares purchased by Frazier Healthcare VII, L.P and 88,709 shares purchased by Frazier Healthcare VII-A, L.P.

## Amended and Restated Investors' Rights Agreement

We have entered into an amended and restated investors' rights agreement with certain holders of our convertible preferred stock, including entities with which certain of our directors are affiliated. These stockholders are entitled to rights with respect to the registration of their shares following our initial public offering under the Securities Act.

## Indemnification Agreements

We have entered into indemnification agreements with each of our directors and executive officers. The indemnification agreements, our restated certificate of incorporation and our restated bylaws require us to indemnify our directors to the fullest extent not prohibited by Delaware law. Subject to certain limitations, our restated bylaws also require us to advance expenses incurred by our directors and officers.

## Policies and Procedures for Related Party Transactions

We adopted a written related person transactions policy that our executive officers, directors, nominees for election as a director, beneficial owners of more than 5% of our common stock, and any members of the immediate family of and any entity affiliated with any of the foregoing persons, are not permitted to enter into a material related person transaction with us without the review and approval of our audit committee, or a committee composed solely of independent directors in the event it is inappropriate for our audit committee to review such transaction due to a conflict of interest. The policy provides that any request for us to enter into a transaction with an executive officer, director, nominee for election as a director, beneficial owner of more than 5% of our common stock or with any of their immediate family members or affiliates in which the amount involved exceeds \$120,000 will be presented to our audit committee for review, consideration and approval. In approving or rejecting any such proposal, our audit committee will consider the relevant facts and circumstances available and deemed relevant to the audit committee, including, but not limited to, whether the transaction is on terms no less favorable than terms generally available to an unaffiliated third party under the same or similar circumstances and the extent of the related person's interest in the transaction.

## Independence of Board of Directors and its Committees

Under the rules of the Nasdaq Stock Market, or Nasdaq, independent directors must comprise a majority of a listed company's board of directors within a specified period of the closing of our initial public offering. In addition,

the rules of Nasdaq require that, subject to specified exceptions, each member of a listed company’s audit, compensation and nominating and corporate governance committees be independent. Under the rules of Nasdaq, a director will only qualify as an “independent director” if, in the opinion of that company’s board of directors, that person does not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director.

Audit committee members must also satisfy the independence criteria set forth in Rule 10A-3 under the Securities Exchange Act of 1934, as amended. In order to be considered independent for purposes of Rule 10A-3, a member of an audit committee of a listed company may not, other than in his or her capacity as a member of the audit committee, the board of directors or any other board committee: (1) accept, directly or indirectly, any consulting, advisory or other compensatory fee from the listed company or any of its subsidiaries; or (2) be an affiliated person of the listed company or any of its subsidiaries. We currently satisfy the audit committee independence requirements of Rule 10A-3. Additionally, compensation committee members must not have a relationship with us that is material to the director’s ability to be independent from management in connection with the duties of a compensation committee member.

Our board of directors has undertaken a review of the independence of each director and considered whether each director has a material relationship with us that could compromise his ability to exercise independent judgment in carrying out his responsibilities. As a result of this review, our board of directors determined that all of our directors, except for Mr. Suria, are “independent directors” as defined under the applicable rules and regulations of the Securities and Exchange Commission, or SEC, and the listing requirements and rules of Nasdaq.

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

The following table summarizes the fees of KPMG LLP, our independent registered public accounting firm, billed us for each of the last two fiscal years.

<u>Fees Billed to AnaptysBio</u>	<u>Fiscal Year 2016</u>	<u>Fiscal Year 2015</u>
	(in thousands)	
Audit fees(1)	\$ 523	\$ 697
Audit-related fees	\$ —	\$ —
Tax fees(2)	\$ 31	\$ 48
All other fees	\$ —	\$ —
<b>Total fees</b>	<b>\$ 554</b>	<b>\$ 745</b>

- (1) “*Audit fees*” include fees for professional services provided by KPMG LLP in connection with the audit of our consolidated financial statements, review of our quarterly consolidated financial statements, and related services that are typically provided in connection with registration statements, including the registration statement for our initial public offering.
- (2) “*Tax fees*” include fees for tax compliance and advice. Tax advice fees encompass a variety of permissible services, including technical tax advice related to federal and state income tax matters; assistance with sales tax; and assistance with tax audits.

**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

See the Exhibit Index immediately following the signature page of this Annual Report on Form 10-K.

**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: March 8, 2017

### 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.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ Hamza Suria</u> Hamza Suria	President, Chief Executive Officer and Director (Principal Executive Officer)	March 8, 2017
<u>/s/ Dominic G. Piscitelli</u> Dominic G. Piscitelli	Chief Financial Officer (Principal Accounting and Financial Officer)	March 8, 2017
<u>/s/ Carol G. Gallagher</u> Carol G. Gallagher, Pharm.D.	Director	March 8, 2017
<u>/s/ Nicholas B. Lydon</u> Nicholas B. Lydon, Ph.D., FRS	Director	March 8, 2017
<u>/s/ Hollings Renton</u> Hollings Renton	Director	March 8, 2017
<u>/s/ John Schmid</u> John Schmid	Director	March 8, 2017
<u>/s/ James A. Schoeneck</u> James A. Schoeneck	Director	March 8, 2017
<u>/s/ James N. Topper</u> James N. Topper, M.D., Ph.D.	Director	March 8, 2017

**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.	S-1	333-206849	3.2	September 9, 2015	
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.	S-1	333-206849	10.5	September 9, 2015	
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.	S-1	333-206849	10.7	September 9, 2015	
10.8	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	
10.9	Antibody Generation Agreement, dated December 22, 2011, by and between the Registrant and Celgene Corporation, as modified.	S-1	333-206849	10.9	December 28, 2016	
10.10+	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	10.1	May 10, 2016	

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Exhibit Number	Description of Document	Incorporated by reference			Filing Date	Filed Herewith
		Form	File No.	Exhibit		
10.11+	License Agreement, dated August 30, 2006, by and between the Registrant and Medical Research Council, as amended.	S-1	333-206849	10.11	September 9, 2015	
10.12+	Non-Exclusive Research and Commercial License Agreement, dated May 15, 2009, by and between the Registrant and Millipore Corporation.	S-1	333-206849	10.12	September 9, 2015	
10.13	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	
21.1	Subsidiaries of the Registrant.					X
23.1	Consent of KPMG LLP, an independent registered public accounting firm.	S-1	333-206849	23.1	January 17, 2017	
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

\* 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

SUBSIDIARIES OF THE REGISTRANT

Name of Subsidiary  
AnaptysBio Pty Ltd

Jurisdiction of Incorporation or Organization  
Australia

**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)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 8, 2017

/s/ Hamza Suria  
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Hamza Suria  
*Chief Executive Officer*  
(Principal Executive Officer)

**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)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 8, 2017

/s/ Dominic G. Piscitelli

Dominic G. Piscitelli

Chief Financial Officer

(Principal Financial Officer)

**CERTIFICATION PURSUANT TO  
18 U.S.C. SECTION 1350  
AS ADOPTED PURSUANT TO SECTION 906  
OF THE SARBANES-OXLEY ACT OF 2002**

I, Hamza Suria, Chief Executive Officer of AnaptyBio, 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, 2016 (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: March 8, 2017

/s/ Hamza Suria  
Hamza Suria  
*Chief Executive Officer*  
(Principal Executive Officer)

**CERTIFICATION PURSUANT TO  
18 U.S.C. SECTION 1350  
AS ADOPTED PURSUANT TO SECTION 906  
OF THE SARBANES-OXLEY ACT OF 2002**

I, 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, 2016 (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: March 8, 2017

*/s/ Dominic G. Piscitelli*

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Dominic G. Piscitelli

*Chief Financial Officer*

(Principal Financial Officer)