

Kindred Biosciences, Inc.  
Form 10-K  
March 06, 2019  
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, 2018

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: 001-36225

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

---

Delaware  
(State or other jurisdiction of  
incorporation or organization)

46-1160142  
(I.R.S. Employer  
Identification Number)

1555 Bayshore Highway, Suite 200  
Burlingame, California 94010  
(Address of principal executive offices)  
(650) 701-7901  
Registrant's telephone number:

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

Title of each class	Name of each exchange on which registered
Common Stock, \$0.0001 par value	The NASDAQ Stock Market LLC
Preferred Stock Purchase Rights	The NASDAQ Stock Market LLC

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

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

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes  No

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports) and, (2) has been subject to such filing requirements for the past 90 days.

Yes  No

---

Edgar Filing: Kindred Biosciences, Inc. - Form 10-K

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit such files).

Yes  No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K 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, a smaller reporting company, or emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act. (Check one):

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

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act).

Yes  No

As of June 30, 2018 (the last business day of the registrant's most recently completed second fiscal quarter), the aggregate market value of the common stock of the registrant held by non-affiliates of the registrant was approximately \$269.0 million.

The outstanding number of shares of the registrant's common stock as of February 28, 2019 was 38,855,154.

Certain portions of the registrant's Proxy Statement for the 2019 annual meeting of stockholders, to be filed with the Securities and Exchange Commission pursuant to Regulation 14A not later than 120 days after the close of the registrant's fiscal year, are incorporated by reference into Part III of this Form 10-K.

## TABLE OF CONTENTS

	Page
<u>PART I.</u>	<u>1</u>
<u>ITEM 1. BUSINESS</u>	<u>1</u>
<u>ITEM 1A. RISK FACTORS</u>	<u>20</u>
<u>ITEM 1B. UNRESOLVED STAFF COMMENTS</u>	<u>45</u>
<u>ITEM 2. PROPERTIES</u>	<u>45</u>
<u>ITEM 3. LEGAL PROCEEDINGS</u>	<u>45</u>
<u>ITEM 4. MINE SAFETY DISCLOSURES</u>	<u>45</u>
 <u>PART II.</u>	 <u>46</u>
<u>ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES</u>	<u>46</u>
<u>ITEM 6. SELECTED FINANCIAL DATA</u>	<u>48</u>
<u>ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS</u>	<u>50</u>
<u>ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK</u>	<u>64</u>
<u>ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA</u>	<u>64</u>
<u>ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE</u>	<u>64</u>
<u>ITEM 9A. CONTROLS AND PROCEDURES</u>	<u>65</u>
<u>ITEM 9B. OTHER INFORMATION</u>	<u>66</u>
 <u>PART III</u>	 <u>66</u>
<u>ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE</u>	<u>66</u>
<u>ITEM 11. EXECUTIVE COMPENSATION</u>	<u>66</u>
<u>ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS</u>	<u>66</u>
<u>ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE</u>	<u>66</u>
<u>ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES</u>	<u>66</u>
 <u>PART IV</u>	 <u>67</u>
<u>ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES</u>	<u>67</u>
<u>ITEM 16. FORM 10-K SUMMARY</u>	<u>71</u>
 <u>INDEX TO FINANCIAL STATEMENTS</u>	 <u>F- 1</u>

Table of Contents

**CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS**

This Annual Report on Form 10-K contains forward-looking statements within the meaning of the U.S. Private Securities Litigation Reform Act of 1995. All statements contained in this Annual Report that do not relate to matters of historical fact should be considered forward-looking statements, including, but not limited to, statements regarding our expectations about the trials, regulatory approval, manufacturing, distribution and commercialization of our current and future products and product candidates, and statements regarding our anticipated revenues, expenses, margins, profits and use of cash. These forward-looking statements are based on our current expectations. These statements are not promises or guarantees, but involve known and unknown risks, uncertainties and other important factors that may cause our actual results to be materially different from any future results expressed or implied by the forward-looking statements. These risks include, but are not limited to, the following: our limited operating history and expectations of losses for the foreseeable future; the absence of significant revenue from our products and product candidates for the foreseeable future; our potential inability to obtain any necessary additional financing; our substantial dependence on the success of our lead products and product candidates, which may not be successfully commercialized even if they are approved for marketing; the effect of competition; our potential inability to obtain regulatory approval for our existing or future product candidates; our dependence on third parties to conduct some of our development activities; our dependence upon third-party manufacturers for supplies of our products and product candidates; uncertainties regarding the outcomes of trials regarding our product candidates; our potential failure to attract and retain senior management and key scientific personnel; uncertainty about our ability to develop a satisfactory sales organization; our significant costs of operating as a public company; our potential inability to obtain and maintain patent protection and other intellectual property protection for our products and product candidates; potential claims by third parties alleging our infringement of their patents and other intellectual property rights; our potential failure to comply with regulatory requirements, which are subject to change on an ongoing basis; the potential volatility of our stock price; and the significant control over our business by our principal stockholders and management.

For a further description of these risks and other risks that we face, please see the risk factors described in Item 1A of this Annual Report under the caption “Risk Factors” and any subsequent updates that may be contained in our Quarterly Reports on Form 10-Q and other documents we file with the Securities and Exchange Commission (the “SEC”). As a result of these risks, actual results may differ materially from those indicated by the forward-looking statements made in this Annual Report. Forward-looking statements contained in this Annual Report speak only as of the date of this Annual Report, and we undertake no obligation to update or revise these statements except as may be required by law.

---

Table of Contents

PART I.

ITEM 1. BUSINESS.

Overview

We are a commercial-stage biopharmaceutical company focused on saving and improving the lives of pets. Our mission is to bring to our pets the same kinds of safe and effective medicines that our human family members enjoy. Our core strategy is to identify compounds and targets that have already demonstrated safety and efficacy in humans and to develop therapeutics based on these validated compounds and targets for pets, primarily dogs, cats and horses. We believe that this approach will lead to shorter development times and higher approval rates than pursuing new, non-validated compounds and targets. Our current portfolio includes one approved product and over 20 product candidates in development, consisting of both small molecules and biologics.

We were incorporated in Delaware in September 2012. The address of our principal executive offices is 1555 Bayshore Highway, Suite 200, Burlingame, CA 94010. Unless the context requires otherwise, references to “KindredBio,” “the Company,” “we,” “us” or “our” in this Annual Report on Form 10-K for the fiscal year ended December 31, 2018 (the “2018 Annual Report”) refer to Kindred Biosciences, Inc., a Delaware corporation, and its subsidiaries.

Product Highlight

Mirataz® (mirtazapine transdermal ointment), our transdermal drug for the management of weight loss in cats, was approved by the Food and Drug Administration (the “FDA”) in May 2018. Mirtazapine, the active ingredient in Mirataz, is an  $\alpha_2$ -adrenergic receptor antagonist nor-adrenergic and serotonergic antidepressant drug. Mirtazapine is known to be a potent antagonist of 5-HT<sub>2</sub> and 5-HT<sub>3</sub> serotonin receptors in the central nervous system (“CNS”), and a potent inhibitor of histamine H<sub>1</sub> receptors. Because mirtazapine blocks 5-HT<sub>2</sub> and 5-HT<sub>3</sub> receptors, only 5-HT<sub>1A</sub>- mediated serotonergic transmission is enhanced. Inhibition of 5-HT<sub>2</sub> receptors may account for the orexigenic effects of mirtazapine, resulting in weight gain in cats experience unintended weight loss. Mirataz, classified as a weight gain drug by the FDA, became commercially available to U.S. veterinarians on July 9, 2018.

Mirataz is the first and only FDA approved transdermal medication specifically developed for the management of weight loss in cats. Unintended weight loss is a serious unmet medical need in cats, and may be caused by multiple factors, including chronic illness, like chronic kidney disease, or behavioral issues, such as stress. If untreated, it may lead to hepatic failure, which can be a life-threatening condition.

Weight loss in cats represents a leading cause of visits to the veterinarian for cats and a veterinarian will see on average 7 or more cats per week with this condition. Our research estimates that as many as 9,000,000 cats each year are diagnosed with unintended weight loss caused by varying underlying conditions, such as chronic kidney disease, cancer or diabetes, with approximately 3,000,000 cats being treated for unintended weight loss each year. Mirataz, which is formulated with our proprietary Accusorb™ technology, is applied topically to the cat’s inner ear (pinna) once a day, providing a more attractive application route compared to oral administration. 74% of veterinarians report that ease of administering medication is a primary factor in selecting medication for feline

## Table of Contents

weight loss. The product is classified as a weight gain drug and can be used in cats with various underlying diseases associated with unintended weight loss.

### Clinical Data

The pivotal field study, KB105, was a multicenter, randomized, double-blind, placebo-controlled pivotal field study that enrolled 230 cats to assess the effectiveness of Mirataz in managing weight loss in cats. The primary endpoint was percentage change in body weight from Day 1 to Week 2. At Week 2, the mean percent increase in body weight from Day 1 was 3.94% in the KIND-010 group (n=83), versus 0.41% in the placebo group (n=94) ( $p < 0.0001$ ). In the target animal safety study, Mirataz was generally well-tolerated and no significant safety concerns were identified. At the proposed label dose, topical administration of mirtazapine ointment was associated with mild, reversible skin changes at the site of dose application (ear).

### Commercialization and Distribution

Mirataz is marketed through our commercial team in conjunction with third-party national and regional distributors, who in turn warehouse, ship, and sell Mirataz to companion animal veterinarians. Our commercial team promotes our product through direct field contact with veterinarians and their staff. We generally grant our third-party distributors, which comprise more than 800 sales representatives, the right to promote our product in a territory for a specified period of time.

We currently sell and distribute Mirataz in the United States through the wholesale channel. Our combined sales to four large distributors, namely MWI, Henry Schein (now Covetrus), Patterson and Midwest, each accounted for more than 10% of total revenues for the year ended December 31, 2018. On a combined basis, these distributors accounted for approximately 91% of our product sales in 2018, with regional and home delivery partners making up the remainder. Mirataz was included in the two largest U.S. corporately owned veterinary groups of pet hospitals (VCA and Banfield Pet Hospital) within six months of launch. The commercial team comes from the top veterinary companies and has on average more than 15 years of experience with over 10 launches per team member.

As of December 31, 2018, we recorded \$2.0 million in Mirataz net product revenues. In the third quarter of 2018 (the first partial quarter of launch), net product sales were \$0.6 million. This result represented initial stocking orders to distribution and subsequent move-out from distribution to clinics to satisfy orders. We took a judicious approach to distribution's initial stocking orders, preferring smaller initial orders and faster reorders that accurately reflect underlying customer demand, rather than large initial stocking orders that could take time to work through and result in an uneven launch profile.

Mirataz had strong uptake in the fourth quarter (the second quarter of launch), with net product revenues more than doubling quarter-over-quarter to \$1.3 million. Approximately 33% of the approximate 25,000 veterinary clinics in the U.S. purchased Mirataz in the second half of 2018, which is consistent with our stated goal. During this same period, approximately 56% of veterinary clinics placed re-orders. Customer feedback to date has been uniformly positive.

As of the date of the filing of this 2018 Annual Report, we continue to see subsequent move-out of Mirataz from distribution into the clinics at an increased rate from what we saw in the first few months of the launch as the sales, distribution, and marketing team's efforts reach veterinary customers. Having achieved strong uptake to date,

## Table of Contents

our focus is on driving re-orders and further increasing re-order size. As veterinarians have gained experience and are becoming familiar with the product and its potential uses, our average order sizes have increased quarter over quarter. Throughout the year 2019, we expect continued revenue growth.

In December 2017, the EMA accepted our Mirataz submission for review. We responded to the EMA's list of questions and expect that Mirataz will be approved by the EMA in 2019. Regulatory approval is subject to the typical risks inherent in such a process.

### Product Candidates

#### Zimeta™ (dipyron injection) (Zimeta IV)

The FDA has approved the safety and effectiveness technical sections for Zimeta IV for the control of pyrexia (fever) in horses. The FDA has indicated it does not have any additional questions or requests from us regarding the Chemistry, Manufacturing and Controls ("CMC") technical section. We have filed a New Animal Drug Application (NADA) for Zimeta IV with the FDA. Pending a positive inspection of the contract manufacturer of the active pharmaceutical ingredient ("API") dipyron, FDA approval of Zimeta IV is expected in mid-May 2019. Regulatory approval is subject to the typical risks inherent in such a process. Preparations for the commercial launch remain on track.

#### Zimeta (dipyron oral gel) (Zimeta Oral)

The pivotal field effectiveness study for Zimeta Oral has been completed with positive results. The target animal safety study is also complete, and Zimeta Oral was found to be well-tolerated. We have transferred the product to the commercial manufacturer and are in discussions with the FDA and EMA regarding the data required to show bioequivalence to the previously manufactured product. Zimeta Oral, which is a proprietary oral gel, is expected to expand use of the drug and build upon the success of Zimeta IV.

#### KIND-016

In October 2018, we announced positive topline results from our pilot effectiveness study of KIND-016, a fully caninized, high-affinity monoclonal antibody targeting interleukin-31 (IL-31), for the treatment of atopic dermatitis in dogs. Atopic dermatitis is the leading reason owners take their dog to the veterinarian, and the current market size is almost \$600 million annually and growing rapidly. In addition, we announced that the U.S. Patent and Trademark Office has issued a patent (Patent No. 10,093,731) for KindredBio's anti-IL31 antibody.

The study was a randomized, blinded, placebo-controlled, pilot laboratory study that enrolled 32 dogs to assess the effectiveness of KIND-016 at three doses. A single dose of KIND-016 was administered on day 0 and itching was induced at weeks 1, 2, 3, 4, 6, and 8 with an injection of canine IL-31.

KindredBio's IL-31 antibody resulted in statistically significant reductions in pruritus ( $p < 0.0001$  to  $p < 0.05$ ) across all dose groups and was sustained for 6 to 8 weeks, with a clear dose response. The reduction in the itching score was as high as 86.1%. Based on a preliminary review of the safety data, the drug appears to be well tolerated. We are also currently conducting a pilot field effectiveness study for our IL-31 antibody.

#### KIND-014

In May 2018, we announced positive results from our pilot field effectiveness study of KIND-014 for the treatment of gastric ulcers in horses. This study was a randomized, single-blind, placebo-controlled, dose-ranging study that enrolled 53 horses (40 horses in three KIND-014 groups with different doses and dosing schedules, 13 horses in the placebo group). The objective was to determine the effective dose of KIND-014 for the treatment of gastric ulcers in horses. At Week 3, the gastric ulcer resolution (gastric ulcer score=0) rates in all three KIND-014 groups were statistically significantly higher than the placebo group ( $p$ -values  $< 0.05$ ). We have selected a formulation for development and anticipate moving into a pivotal field study in 2019.

#### epoCat™ (KIND-510a)





## Table of Contents

In January 2019, we announced positive topline results from our pilot field effectiveness study of epoCat (KIND-510a), a long-acting feline recombinant erythropoietin that is being developed for the management of anemia in cats.

Anemia is a common condition that is estimated to afflict millions of older cats. It is often associated with chronic kidney disease, because kidneys produce erythropoietin and chronic kidney disease leads to decreased levels of endogenous erythropoietin. Chronic kidney disease affects approximately half of older cats, making it a leading cause of feline mortality. Human erythropoietins, which are multi-billion-dollar products in the human market, are immunogenic in cats.

epoCat is a recombinant feline erythropoietin that has been engineered by KindredBio to have a prolonged half-life. Erythropoietin is an endogenous protein that regulates and stimulates production of red blood cells.

In the study, which enrolled 23 cats with anemia, epoCat rapidly increased mean hematocrit (a measure of red blood cell count), with statistically significant improvement seen as early as Week 1 ( $p < 0.0001$ ). The effect was sustained, with continued statistically significant improvement at Weeks 2, 3, 4, 5, and 6 ( $p < 0.0001$  at each visit). Compared to baseline, the mean peak improvement in hematocrit was 55.4%.

In addition, 95.5% of the 22 evaluable patients achieved treatment success over the 6-week treatment period, defined prospectively as either a 30% increase in hematocrit value over baseline or the hematocrit value reaching normal range. Furthermore, cats treated with epoCat demonstrated statistically significant improvements over baseline ( $p < 0.01$  to  $p < 0.05$ ) across all three health-related quality of life (QoL) domains, Vitality, Comfort, and Emotional Wellbeing, as measured by a validated QoL instrument. Based on a preliminary review of the safety data, the drug appears to be well tolerated. We plan to commence a pivotal study this year and are currently in discussions with the FDA regarding study design. The FDA has agreed to accept hematocrit as the primary endpoint for the pivotal study.

### KIND-011

The pilot field effectiveness study of our anti-TNF monoclonal antibody targeting sick or septic foals has been completed with positive results. We are now in discussions with the FDA regarding the pivotal study design. Sepsis in foals can cause up to 50% mortality and is an important unmet medical need. There is currently no FDA-approved therapy. We intend to continue field studies during the 2020 foaling season, following discussion with the FDA regarding the development plan.

### KIND-509

The pilot field efficacy study for our anti-TNF antibody for canine inflammatory bowel disease (IBD) has been initiated and is currently enrolling. IBD is a chronic disease of the gastrointestinal tract and can affect dogs at any age, but is more common in middle-aged and older dogs.

In addition, we have multiple other product candidates, including several biologics, in various stages of development, with the potential to launch one or more products annually.

### Market Overview

We believe there are significant unmet medical needs for pets, and that the pet therapeutics segment of the animal health industry is likely to grow substantially as new therapeutics are identified, developed and marketed specifically for pets. We plan to commercialize our feline, equine and canine products in the United States through a direct sales

force complemented by selected distributor relationships, and in the European Union (the “EU”) through distributors and other third parties.

Relative to human drug development, the development of pet therapeutics is generally faster and less expensive, since it requires fewer clinical studies involving fewer subjects and can be conducted directly in the target species. For example, studies that are typically required for approval of human drugs such as QTC studies,

4

---

## Table of Contents

which detect cardiac irregularities, elderly patient studies, renal impairment studies, hepatic impairment studies or costly, long-term genotoxicity studies are not required for pet therapeutics. Based on our progress since inception in September 2012, we believe we can develop small molecule pet therapeutics from the Investigational New Animal Drug (the “INAD”) filing with the FDA to marketing approval in three to five years at an average cost of approximately \$5 million per product candidate. The lower cost associated with the development of pet therapeutics permits us to pursue multiple product candidates simultaneously and avoid the binary outcome associated with the development of a single lead therapy by some human biotechnology companies. Because we typically develop drugs that have successfully been developed for humans, the active ingredients in many of our small molecule product candidates also have established Chemistry, Manufacturing and Controls, which are important gating factors in the regulatory approval process. As a result, we usually do not need to invest in an active pharmaceutical ingredient, process development to comply with good manufacturing practices (“GMP”), standards for our small molecule product candidates, and we can often advance our programs more rapidly than if we were pursuing new chemical entities.

Our biologics program, from INAD to marketing approval, is expected to take four to six years at an average cost of approximately \$8 million per product candidate.

We estimate that the total U.S. market for veterinary care was approximately \$72.1 billion in 2018, an increase of 67% from 2008. In 2016, 68% of households owned a pet, which translates to an estimated 89.7 million dogs and 94.2 million cats currently living in the United States. We believe there are many unmet or underserved medical needs and that the pet therapeutics portion of the market can grow significantly as new, safe and effective therapeutics are identified, developed and marketed. We expect continued market growth as new pet therapeutics are developed and owners grow more familiar with the treatment of pets with such therapeutics.

We are also targeting the equine market because we have promising products for the equine sector and because we believe that it shares many similarities with the orphan human market. There are fewer horses than dogs or cats, but the willingness to pay is substantially higher. In addition, the cost of building a commercial infrastructure is much less for the equine market. We believe that a dozen or fewer sales representatives are sufficient to launch and support an equine product nationally.

## Management Team

Our management team’s extensive experience in both human and animal drug development has enabled us to quickly establish our product pipeline and should continue to enable us to promptly obtain Protocol Concurrences from the FDA for our product candidates and to conduct the clinical trials. Our management team also has extensive experience in biologics, including in the development of antibodies such as Lucentis, Tysabri, Xolair, and Rituxan.

Richard Chin, M.D., our Chief Executive Officer, was previously Head of Clinical Research for the Biotherapeutics Unit at Genentech, Inc., where he oversaw Phase I through Phase IV clinical programs for all products except oncology. Denise Bevers, our President and Chief Operating Officer, has over 20 years of experience in clinical operations and medical affairs. She previously held leadership positions at Elan Pharmaceuticals, Scripps Clinic and Research Foundation, Quintiles, and SkyePharma. Wendy Wee, our Chief Financial Officer, has over 30 years of experience and most recently was Vice President of Finance and Principal Accounting Officer at Telik, Inc. Hangjun Zhan, Ph.D., our Chief Scientific Officer, is a well-established protein biochemist and biophysicist with over 20 years of drug discovery experience in the biotechnology industry.

## Product Pipeline

Our current product pipeline consists of small molecules and biologics for a range of indications in dogs, cats and horses, with near-term focus on equine small molecule products and canine and feline biologics products.

The US Department of Agriculture's (the "USDA") Center for Veterinary Biologics and the FDA's Center for Veterinary Medicine have a memorandum of understanding under which animal products are to be regulated by the USDA as biologics, if they are intended for use to diagnose, cure, mitigate, treat, or prevent disease in animals and they work primarily through an immune process, or by the FDA as drugs, if they are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of animal disease if the primary mechanism of action is not

Table of Contents

immunological or is undefined. Although we believe that most of our current animal biologics will be regulated by the USDA based on their mechanisms of action, certain of our animal biologics will be regulated by the FDA instead of the USDA.

We are currently pursuing over 20 indications with various small molecule and biologics product candidates. The following table illustrates some of the product candidates that we are developing.

Product Selection and Development

We utilize a rigorous screening and review process to identify compounds and targets that have demonstrated safety and efficacy in humans. Where possible, we try to identify compounds that have already demonstrated efficacy in the target companion animal species and address unmet medical needs in veterinary medicine. In some cases, we identify a chemical or functional equivalent of a validated human drug that addresses the same biological target or pathway. We review these compounds and targets with a view to differentiating them from existing treatments, including human products used extra-label in animals, based on ease of administration, method of delivery, dosing regimen, and other similar factors. Previously approved drugs that are found to have an idiosyncratic side effect in humans fit well with our target criteria, since such drugs are often no longer available for human use and could potentially be well suited for companion animals. We then develop these compounds for dogs, cats or horses for regulatory approval in the United States and the EU.

For our small molecule product candidates, we customize the dosage, formulation, flavor and other characteristics of the product candidate before initiating pivotal clinical trials. In some cases, we reformulate the drug to have a longer half-life or into a form that is easier to administer for certain species. Pet therapeutics that are palatable to animals can command premium prices and significant market share, as evidenced by the still-dominant position of Rimadyl compared to generics. Usually, the active ingredients in our small molecule product candidates are already available as a GMP-quality API. We target small molecule product candidates for which the active ingredient has not been previously approved for use in animals. If we are the first to gain approval for the use of such an active ingredient in animals, our small molecule product will enjoy five years of marketing exclusivity in the United States and ten years in the EU for the approved indication. Where appropriate, we also will seek patents and trademarks to provide added intellectual property protection in addition to the five or ten-year marketing

## Table of Contents

exclusivity. In addition, we plan to introduce improved formulations, combination products and other product improvements in order to extend the lifecycle of our products.

Biologic therapies are typically derived from living organisms. A biologic can be defined as a large complex molecule (nucleic acid and protein platforms) produced from or extracted from a biological or living system. They are made by genetically engineering living cells, and a high level of precision is required in the manufacturing process to produce a consistent biologic product each time. A biologic product can be a monoclonal antibody, a vaccine, a tissue, or various proteins such as cytokines, enzymes, fusion proteins, whole cells, and viral and non-viral gene therapies. Our biologic product candidates are usually based on therapies and targets for which products have been successfully commercialized for humans. Human antibody therapies are expensive and are often ineffective in other species since they are usually immunogenic or recognized as foreign bodies and rejected by the immune systems of dogs, cats, horses, and other animals. We identify or create biologics, including antibodies, that are fully or mostly canine, feline, or equine. We are developing a long-acting feline recombinant erythropoietin. We are also developing antibodies that target canine IL-31, IL-4/IL-13, IL-17a, TNF, CD-20, IgE, and other validated targets. We generally intend to seek composition-of-matter and other patents for these new biologics.

KIND-Bodies, a unique biologics scaffold with certain advantages over traditional monoclonal antibodies, including bispecific binding, is also under development.

We have an in-house laboratory capable of protein engineering, cell line development, analytics, and other activities necessary for advancing a world-class biologics pipeline. We believe that we have one of the best biologics teams in the pharmaceutical industry, drawn from some of the top biotechnology companies.

We have constructed a state-of-the-art manufacturing plant in Burlingame, California for our initial biologic product candidates, which we believe is one of the first GMP biologics plants for veterinary products. We started GMP manufacturing in January 2018 and believe that the plant will position us as a leader in the veterinary biologics field, and potentially afford us an advantage in cost of goods for our products. We acquired a second manufacturing plant in August 2017 in Elwood, Kansas and construction to support our initial production lines is expected to be completed by mid-2019. The Elwood facility includes approximately 180,000 square feet with clean rooms, utility, equipment, and related quality documentation suitable for small molecule and biologics manufacturing.

Our small molecule product candidates, if approved, may eventually face generic competition in the United States and in the EU. In the United States, a generic animal drug may be approved pursuant to an Abbreviated New Animal Drug Application ("ANADA"). Instead of demonstrating the drug's safety and effectiveness in the target species as required in a NADA, a generic applicant must only show that the proposed generic product is the same as, and bioequivalent to, the approved brand name product. However, if our product candidates are the first approved by the FDA or the EMA as applicable for use in animals, they will be eligible for five years of regulatory exclusivity in the United States and ten years in the EU. There is no comparable pathway for approval of a generic veterinary biologic regulated by the USDA.

### Business Strategy

Key elements of our business strategy are as follows:

Focus on the long-term success of Mirataz

Having achieved strong uptake to date, our focus is on driving re-orders and further increasing re-order size. As veterinarians have gained trial experience and are becoming familiar with the product and the potential uses, our average order sizes have increased quarter over quarter.

Obtain FDA approval for Zimeta IV and EMA approval for Mirataz and launch products in the second half of 2019

In November 2015, we announced positive topline results from a pivotal trial of Zimeta (dipyron injection), also known as KIND-012, for the control of pyrexia (fever) in horses. The FDA has approved the safety

7

---

## Table of Contents

and effectiveness technical sections for Zimeta IV and has indicated it does not have any additional questions or requests from us regarding the CMC technical section. We have filed a NADA for Zimeta IV with the FDA. Pending a positive inspection of the contract manufacturer of the API, dipyrone, FDA approval of Zimeta IV is expected in mid-2019. Regulatory approval is subject to the typical risks inherent in such a process. Preparations for the commercial launch remain on track.

The EMA has accepted our European marketing authorization application for the review of Mirataz with the official acceptance date of December 21, 2017. We responded to the EMA's list of questions or LOQ and expect that Mirataz will be approved by the EMA in 2019. Regulatory approval is subject to the typical risks inherent in such a process.

Continue to focus on the development of our pipeline

We expect to initiate pivotal field studies for epoCat, IL-31 antibody and KIND-014 in 2019. We are currently developing KIND-015 for the management of clinical signs associated with equine metabolic syndrome and anti-TNF in septic foals. In addition to early stage pilot efficacy studies of IL-4/IL-13 antibodies for atopic dermatitis in dogs and KIND-509 for inflammatory bowel disease in dogs, we are also developing multiple other products, including interleukin antibodies and canine checkpoint inhibitors. In all, we have over 20 programs for various indications for dogs, cats, and horses.

Continue to focus on cost-effective research and development execution

In order to execute our studies rapidly and efficiently, we have built an experienced team drawn from both the veterinary and human pharmaceutical industries. We rely primarily on our own personnel or independent contractors, rather than on contract research organizations ("CROs"), for many business-critical tasks, including protocol designs, regulatory interactions, statistics, data management and clinical operations. By doing so, we believe we can maintain higher quality, achieve lower costs and seek regulatory approval more quickly. Since our inception in September 2012, we have been able to quickly and efficiently build and advance our pipeline.

Leverage our antibody and biologics experience

Members of our team have extensive experience developing biologics such as antibodies. We are leveraging their expertise to identify and develop antibody-based therapies for pets based on approved human therapies, and to identify appropriate manufacturing technologies for these product candidates.

Leverage our current product pipeline in additional animal species

We intend to develop our product candidates primarily for approval in one or more indications in dogs, cats and horses. We believe the market for horse therapeutics may be particularly attractive, as it can be targeted by a limited sales force and has potentially less price sensitivity than therapeutic treatments for dogs and cats, because horse owners are willing to spend more on treatments for these more expensive companion animals. As an example, a one-month supply of omeprazole for a horse can cost over a thousand dollars. We may consider the development of our current or future product candidates for additional species in the future, but our pipeline currently is focused on dogs, cats and horses only.

Expand our pipeline with additional product candidates

We actively seek to identify small molecule and biologic therapeutics, or in some cases therapeutic targets, that have demonstrated safety and efficacy in humans, focusing on small molecules that are already marketed for humans or biologics for which there are no animal counterparts. These therapeutics typically have been tested in animals such as



dogs as part of standard toxicology studies in human clinical development. We have identified over 30 additional product candidates in the pre-INAD stage that we may potentially pursue. We will seek to protect our product candidates through a combination of regulatory exclusivity periods in the United States and in the EU, patents, know-how and other customary means.

## Table of Contents

Commercialize our equine products with our own direct sales force in the United States and with distributors in other regions

In conjunction with FDA approval of one or more of our lead equine product candidates, we intend to utilize a direct sales organization, complimented by select distributor relationships, to market our products directly to veterinarians in the United States. For our equine products, we believe we can accomplish this with a sales force of 4 to 12 sales representatives and reach most of the prescribing equine veterinarians in the United States. We also intend to establish collaborations with distributors to commercialize any of our products that may be approved by the EMA.

Commercialize our canine and feline products with our own direct sales force in the United States and with distributors in other regions

We currently utilize a direct sales organization, complimented by select distributor relationships, to market our first approved product directly to veterinarians in the United States. With Mirataz's FDA approval, we established a 37-person direct sales force, (equivalent to a sales force with 25 field territories also supported by Inside Sales, Strategic Account Sales and Sales Management) supplemented by sales support from our distributors. We intend to grow our direct sales force incrementally if and as additional product candidates are approved for marketing or as our current products can support, and to utilize national and regional distributors to augment our sales force.

## Pet Therapeutics Market

### Overview

U.S. consumers spent an estimated \$72.1 billion on their pets in 2018, according to the American Pet Products Association ("APPA") an increase of 67% from 2008. The veterinary care segment has been among the fastest growing segments of the overall U.S. pet market. This segment accounted for an estimated \$18.3 billion spent on veterinary care in 2018, an increase of 65% from 2008.

We believe several factors will contribute to an increase in spending on pet therapeutics. Pets are generally living longer, with the average lifespan for dogs increasing by nearly a year to 12 years and 13.1 years for cats between 2012 and 2016 according to a study by Banfield Pet Hospitals. As a result, pets are increasingly exhibiting many of the same diseases associated with aging in humans such as cardiovascular disease, arthritis, and diabetes. For example, the incidence of diabetes in dogs has increased by 79.7% since 2006, while in felines, the prevalence of diabetes in cats has increased 18.1% over the same timeframe. The incidence of osteoarthritis in dogs has increased by 82% since 2006 according to the same study. As it is with human health, obesity is a growing concern for pets. The Association for Pet Obesity Prevention estimates that in 2017, 56% of dogs and 60% of cats are overweight or obese, which translates to 50.2 million dogs and 65.5 million cats. According to a 2016 study, in the past 10 years Banfield Pet Hospitals witnessed a 169 percent increase in overweight cats and a 158 percent increase in overweight dogs. Banfield further reports that obesity in cats and dogs has been linked to more than 20 ailments. Not surprisingly then, Banfield's records indicate dog owners spend 17% more on healthcare costs and nearly 25% more on medications versus owners of healthy-weight dogs. In addition, pet ownership numbers may increase as more people become aware of the myriad health benefits of pet ownership. According to the Human Animal Bond Research Institute, studies show that some of the benefits of having a dog include helping to lower your blood pressure, decrease your risk of heart disease, and preventing allergies in children.

Among pet owners, there is growing familiarity in treating these pet diseases with medications. According to the APPA, approximately 77% of U.S. dog owners treated their dogs with medications in 2015, an increase of over 50% from the level reported in 2004. In a 2010 poll by the Associated Press, 35% of pet owners are willing to spend \$2,000 to treat their pet for a serious medical condition. More recently, a 2017 Harris Poll by the American Institute of

Certified Public Accountants indicated that 76% of the U.S. adults (1,004, of which 526 identified as pet owners) surveyed would make financial sacrifices for their pets to pay for an emergency expense such as medical care. Additionally, 79% said they would stop eating at restaurants and 67% would give up a vacation to pay for pet-related expenses if they were in a difficult financial situation. Respondents also indicated that they would cancel cable and TV streaming services (61%), sacrifice contributions to their retirement account (37%), cancel a cell

## Table of Contents

phone plan (35%), or forego paying a credit card bill (27%) to pay for their pet's expenses. We expect pet owners to spend more on their pets' health and welfare as new therapeutics are developed specifically for pets, particularly as 95% of pet owners considered their pet to be a member of their family, according to a 2015 survey by the Harris Poll of Harris Interactive.

### Pet Therapeutics Market Dynamics

The respective businesses of developing and commercializing therapeutics for pets and for humans share a number of characteristics, including the need to demonstrate safety and efficacy in clinical trials, obtain FDA or other regulatory approval for marketing, manufacture the therapeutics in facilities compliant with GMP requirements and market the therapeutics only for their intended indication based on claims permitted in the product label, and not for other uses, which is referred to as extra-label use.

Despite their similarities, there are a number of important differences between the pet therapeutics and human therapeutics businesses, including:

Faster, less expensive and more predictable development. The development of pet therapeutics requires fewer clinical studies in fewer subject animals than the development of human therapeutics and, unlike human therapeutics, is conducted directly in the target animals. We believe our strategy of selecting compounds and targets with demonstrated efficacy and safety in humans enhances the predictability of results and probability of success of our pivotal trials relative to compounds and targets that have not been previously validated.

Role and incentives for veterinary practices. In the United States, veterinarians generally serve the dual role of doctor and pharmacist, and pet owners typically purchase medicines directly from their veterinarians. Therapeutics specifically developed for pets enable veterinarians to provide potentially superior treatment options, while also increasing revenue from the sale of these therapeutics.

Primarily private-pay nature of veterinary market. Pet owners in the United States generally pay for pet therapeutics out-of-pocket, and 10% of dog owners and 5% of cat owners have health insurance for their pets. As a result, pet owners must make decisions primarily on their veterinarians' advice regarding available treatment options, rather than on the treatment options' eligibility for reimbursement by insurance companies or government payers. We believe this results in less pricing pressure than in human healthcare, although the limited adoption of insurance may also reduce pet owners' ability to pay for therapeutics recommended by their veterinarians.

Less generic competition and strong brand loyalty. There is less generic competition in the pet therapeutics industry than in the human healthcare industry. Approximately 14% of veterinary drugs face generic competition, and the percentage of generic prescriptions in the veterinary space is only 7% as compared to approximately 81% for human drugs. For example, Rimadyl, the leading U.S. pet NSAID, lost regulatory exclusivity in 2001, but its sales continued to grow since generic competition was introduced in 2005. We believe that stronger brand loyalty and lack of mandatory generic drug substitution, as in human pharmaceuticals, partially explains the low penetration of generics in veterinary medicine.

### Unmet Medical Needs in the Pet Therapeutics Market

Despite the growing market for pet therapeutics, there are relatively few treatment options approved for use in pets as compared to human therapeutic treatments. As a result, veterinarians often must resort to prescribing products approved for use in humans but not approved, formulated or even formally studied in pets. Veterinarians must then rely upon trial and error or untested rules of thumb to assess the proper dosage needed to be effective in the particular species without undue risk of side effects. The veterinarian must also find a way to administer the human product in animals and determine the appropriate dose to treat the disease in the species, which are important and potentially overlooked practical considerations in the treatment of pets.

Even in disease categories with approved pet therapeutics, significant unmet medical needs remain. For example, the NSAID class of products, commonly prescribed for pain, have potentially serious side effects in dogs

## Table of Contents

that limit their long-term use and may require ongoing monitoring by veterinarians. The treatment of pain in cats is further complicated as a result of their differing biology, which makes NSAIDs toxic.

Animal health companies have been relatively slow to develop new therapeutics for pets and have tended to focus primarily on the larger market for the treatment of livestock and other farm animals. In 2018 in the United States, for every 19 NDAs approved for human therapeutics, one NADA was approved for animal therapeutics. Human pharmaceutical companies received FDA approval for 59 novel drugs (non-generic), while pet therapeutic companies received only three novel FDA drug approvals. In the EU, human pharmaceutical companies received EMA approval for 42 novel drugs in 2018, compared to only 3 novel drug approvals for pet therapeutic companies.

We believe that therapeutics specifically developed for pets can extend and improve pets' quality of life, help veterinarians achieve improved medical outcomes and make the process of administering therapeutics to pets much more convenient. Advances in human medicines have created new therapeutics for managing chronic diseases associated with aging, such as osteoarthritis, cancer, diabetes and cardiovascular diseases. Pets often suffer from the same disease as humans, including diabetes, arthritis, cancer, Alzheimer's disease (canine cognitive dysfunction), lupus, Crohn's disease, Lou Gehrig's disease (degenerative myelopathy) and others. In most cases, the biologies of the diseases in pets are very similar to those in humans. Because of the similarity of the diseases, many human drugs, when formulated properly and administered in proper doses, are effective in pets. However, most human drugs are neither formulated nor approved for animals.

### Products in Development

#### Zimeta (dipyrone injection)

##### Overview

Zimeta IV, also known as KIND-012, is a pyrazolone anti-inflammatory drug, with a mechanism of action unlike traditional NSAIDs. The active ingredient in Zimeta, dipyrone, is widely used both for horses and humans as an antipyretic outside of the United States. It is also considered to be an anti-spasmodic that can be used in horses without masking the surgical signs of colic.

In humans, the active ingredient in Zimeta can, in very rare cases, cause bone marrow suppression. In some countries, it is still available as prescription or over the counter medication, while in other countries, it has been withdrawn from market. However, the side effects are not seen in horses, and the product is widely used outside the U.S. by many equine veterinarians.

We are developing Zimeta for the control of pyrexia (fever) in horses. The FDA has approved the safety and effectiveness technical sections for Zimeta IV and has indicated it does not have any additional questions or requests from us regarding the CMC technical section. We have filed a NADA for Zimeta IV with the FDA. Pending a positive inspection of the contract manufacturer of the API dipyrone, FDA approval of Zimeta IV is expected in mid-2019. Regulatory approval is subject to the typical risks inherent in such a process. Preparations for the commercial launch remain on track.

The active ingredient in Zimeta IV is available as GMP-grade material from two suppliers, and we believe our current manufacturer or other suppliers will be able to provide sufficient quantities for commercialization. In addition, we executed a commercial manufacturing agreement with Corden Pharma SPA for the manufacture of Zimeta IV. The agreement provides for production to supply KindredBio's initial launch and future commercial campaigns upon regulatory approval, with capabilities to meet excess demand.

Clinical Data

The pivotal field study was a multicenter, randomized, blinded, placebo-controlled pivotal study that enrolled 138 horses to assess the effectiveness of Zimeta IV. The primary endpoint was improvement (a 2°F or greater decrease in temperature from baseline) or resolution of fever (a return to normothermia ( $\leq 101.0^{\circ}\text{F}$ )) at hour 6 following treatment. The success rate was approximately 75% in the KIND-012 group vs. approximately 20% in the placebo group ( $p < 0.0001$ ).

## Table of Contents

We have also completed the pivotal field effectiveness study of Zimeta™ Oral (dipyron oral gel) for the treatment of fever in horses and announced positive topline results in December 2017. This study was a multicenter, randomized, blinded, placebo-controlled pivotal study that enrolled 139 horses to assess the effectiveness of Zimeta Oral. The primary endpoint was improvement or resolution of fever 6 hours after treatment. The success rate was approximately 78% in the Zimeta Oral group vs. approximately 18% in the placebo group ( $p = 0.0026$ ). The target animal safety study is also complete, and Zimeta Oral was found to be well-tolerated. We have transferred the product to the commercial manufacturer and are in discussions with the FDA and EMA regarding the data required to show bioequivalence to the previously manufactured product. Zimeta Oral, which is a proprietary oral gel, is expected to expand use of the drug and build upon the success of Zimeta IV.

## Other Product Candidates

epoCat, or KIND-510a, is a long-acting feline recombinant erythropoietin that is being developed for the management of anemia in cats. Anemia is a common condition that is estimated to afflict millions of older cats. It is often associated with chronic kidney disease, because kidneys produce erythropoietin and chronic kidney disease leads to decreased levels of endogenous erythropoietin. Chronic kidney disease affects approximately half of older cats, making it a leading cause of feline mortality. Human erythropoietins, which are multi-billion-dollar products in the human market, are immunogenic in cats.

epoCat is a recombinant feline erythropoietin that has been engineered by KindredBio to have a prolonged half-life. Erythropoietin is an endogenous protein that regulates and stimulates production of red blood cells.

In January 2019, we reported positive topline results from the pilot field effectiveness study of our enhanced version of epoCat. In the study, which enrolled 23 cats with anemia secondary to chronic kidney disease, epoCat rapidly increased mean hematocrit, with statistically significant improvement as early as Week 1 ( $p < 0.0001$ ). The effect was sustained, with continued statistically significant improvement at Weeks 2, 3, 4, 5, and 6 ( $p < 0.0001$  at each visit). Compared to baseline, the mean of peak percent improvement in hematocrit by Week 6 was 55.4%.

Canine atopic dermatitis (“CAD”) is an immune-mediated inflammatory skin condition in dogs and is the leading reason owners take their dog to the veterinarian. Atopic dermatitis is a large market, with the leading two products on the market selling close to \$600 million per year.

In October 2018, we announced positive topline results from our pilot effectiveness study of KIND-016, a fully caninized, high-affinity monoclonal antibody targeting interleukin-31 (IL-31), for the treatment of atopic dermatitis in dogs.

The study was a randomized, blinded, placebo-controlled, pilot laboratory study that enrolled 32 dogs to assess the effectiveness of KIND-016 at three doses. A single dose of KIND-016 was administered on day 0 and itching was induced at weeks 1, 2, 3, 4, 6, and 8 with an injection of canine IL-31.

KindredBio's IL-31 antibody resulted in statistically significant reductions in pruritus ( $p < 0.0001$  to  $p < 0.05$ ) across all dose groups and was sustained for 6 to 8 weeks, with a clear dose response. The reduction in the itching score was as high as 86.1%. Based on a preliminary review of the safety data, the drug appears to be well tolerated.

We are also currently conducting a pilot field effectiveness study for our IL-31 antibody. We continue to expect pilot efficacy results for our canine anti-IL-4/IL-13 SINK molecule in 2019 and are advancing other programs for atopic dermatitis. We are pursuing a multi-pronged approach toward atopic dermatitis, with a portfolio of promising biologics.

In addition, we announced that the U.S. Patent and Trademark Office has issued a patent (Patent No. 10,093,731) for KindredBio's anti-IL31 antibody.



KIND-011 is an anti-Tumor Necrosis Factor (“anti-TNF”) treatment for newborn foals. Sick newborn foals, defined as sepsis score  $\geq 11$  or positive blood culture, are challenging and difficult to treat and result in approximately 50% mortality. We have completed a pilot field study in sick or septic foals to assess safety and efficacy of anti-TNF monoclonal antibody, with positive results. By Kaplan-Meier analysis, the difference in

12

---

## Table of Contents

survival between the control and placebo groups was statistically significant ( $p=0.0293$ ). We intend to continue field studies during the 2020 foaling season. There is currently no FDA-approved therapy and we are now in discussions with the FDA regarding the pivotal study design for KIND-011.

KIND-509 is an antibody that targets the canine TNF. The pilot field efficacy study for our anti-TNF antibody for canine inflammatory bowel disease (IBD) has been initiated and is currently enrolling. The group of gastrointestinal diseases known as IBD results in the inflammation of the intestines and chronic symptoms related to gastrointestinal system, in particular diarrhea, chronic intermittent vomiting and weight loss. IBD can affect dogs at any age but is more common in middle-aged and older dogs.

Our other promising biologic product candidates in our pipeline with key focus areas of atopic dermatitis and cancer include: KIND-502, an IgE antibody that targets the canine counterpart of the human target for Xolair, for allergic and immune-mediated diseases; KIND-0888, an antibody that targets CD20; and several antibodies that target cytokines involved in atopic dermatitis.

In addition to biologics, we have the following small molecule programs:

KIND-014 is a small molecule product candidate we are developing for treatment of equine gastric ulcers in horses. In May 2018, we announced positive results from the pilot field effectiveness study of KIND-014 for the treatment of gastric ulcers in horses. The study was a randomized, single-blind, placebo-controlled, dose-ranging study that enrolled 53 horses (40 horses in three KIND-014 groups with different doses and dosing schedules, 13 horses in the placebo group). The objective was to determine the effective dose of KIND-014 for the treatment of gastric ulcers in horses. At Week 3, the gastric ulcer resolution (gastric ulcer score=0) rates in all three KIND-014 groups were statistically significantly higher than the placebo group ( $p$ -values  $< 0.05$ ). We have selected a formulation for development and anticipate moving into a pivotal field study in 2019.

Equine gastric ulcer syndrome (EGUS) is a common condition in horses which encompasses primary and secondary erosive and ulcerative diseases of both the squamous and glandular parts of the stomach. It affects approximately half of all horses. A variety of clinical signs are associated with EGUS, including poor appetite, poor condition, colic, and behavioral issues.

KIND-015 is a small molecule product we are developing for the management of clinical signs associated with equine metabolic syndrome (“EMS”). EMS is an endocrinopathy affecting horses and ponies. It is of primary concern due to its link to obesity, insulin resistance, and subsequent laminitis which is a painful and debilitating disease of the digital laminae (the tissue inter-connection between the coffin bone and hoof wall). Often by the time clinical signs are recognized, crippling body changes such as sinking and rotation of the coffin bone have occurred. KIND-015 delays absorption of glucose from the gastrointestinal tract, increases insulin sensitivity (enhancing peripheral tissue sensitivity to insulin) and glucose uptake into cells, and inhibits synthesis of glucose by the liver. We have initiated a pilot field effectiveness study.

## Product Launches and Commercialization

Our executive management team has extensive experience with product launches. Richard Chin, M.D., our Chief Executive Officer, and Denise Bevers, our President and Chief Operating Officer, have each been involved in the launch of numerous products in humans, including such drugs as Tysabri and Xolair. Other members of the KindredBio team have experience with multiple product launches for companion animals.

If our equine product candidates are approved by the FDA, we intend to establish a direct sales organization to market our products directly to veterinarians in the United States. For our equine products, we believe we can do this with a

sales force of 4 to 12 sales representatives and reach most of the prescribing equine veterinarians in the United States. We also intend to establish collaborations with distributors to commercialize any of our products that may be approved with the EMA.

Our direct sales force sells products directly to veterinarians, who typically mark up the pet therapeutics they prescribe for pet owners. According to industry sources, approximately one-third of pet veterinary practice revenue comes from prescription drug sales, vaccinations and non-prescription medicines. We believe veterinarians

## Table of Contents

are self-motivated to prescribe innovative therapeutics that are safe, effective, and supported by reliable clinical data and regulatory approval in order to improve the health of pets, while also generating additional revenue.

Animal health companies commonly use wholesale veterinary distributors to inventory, sell, bill and ship products to independent veterinarians. We estimate that the top three national distributors are responsible for fulfillment of over 70% of U.S. pet sales by veterinarians. Each of these distributor organizations has a sales team of approximately 281 field sales representatives, 147 telesales representatives and a dozen distribution centers geographically placed throughout the United States. We intend to grow our direct sales force incrementally if and as our product candidates are approved for marketing, and to utilize national and regional distributors to augment our sales force.

### Manufacturing

We have no internal manufacturing capabilities for small molecule drug products. To ensure dependable and high-quality supply of the API in our toxicology studies and pivotal trials, we rely on GMP-compliant contract manufacturers for small molecules rather than devote capital and resources toward developing or acquiring our own manufacturing facilities. Our selection process for small molecule products takes into account the availability of established and cost-effective GMP manufacturing before proceeding to an IND filing. We believe that contract manufacturers can manufacture these supplies more cheaply than we could on our own.

We have a sufficient supply of formulated drugs for Mirataz and expect to have a sufficient supply for our potential launch of Zimeta. We also have identified multiple potential contract manufacturers to provide commercial supplies of future formulated drug product candidates if they are approved for marketing. We have or intend to secure contract manufacturers with established track records of quality product supply and significant experience with regulatory requirements of the FDA and the EMA.

For biologics, we have established our own GMP manufacturing capabilities in Burlingame, California and proceeded to GMP manufacturing in January 2018. In August 2017, we acquired a manufacturing facility in Elwood, Kansas and expect to complete construction to support initial production lines in mid-2019. The Elwood facility includes approximately 180,000 square feet with clean rooms, utility, equipment, and related quality documentation suitable for biologics and small molecule manufacturing. The USDA regulates the manufacture of pet biologics under standards that are less stringent than those for human biologics, which may reduce the cost of goods of our biologic product candidates relative to human biologics.

While we and our contract manufacturers have historically been able to obtain supplies of the API for development of our small molecule product candidates, neither we nor our contract manufacturers have long-term supply agreements with the API manufacturers. We also have no agreements for commercial-scale supply of the API or manufacture of any of our product candidates. As a result, we and our contract manufacturers may be unable to procure API in a timely manner on commercially reasonable terms, or at all.

### Competition

While there are fewer competitors in the pet therapeutics industry than in the human pharmaceutical industry, the development and commercialization of new animal health medicines is highly competitive, and we expect considerable competition from major pharmaceutical, biotechnology and specialty animal health medicines companies.

Our potential competitors include large animal health companies, which currently derive the majority of their revenue from livestock medications. For example, in 2018 livestock accounted for 54%, and pets 45%, of sales for Zoetis, a large company focused on animal health. Within the pet therapeutics market, vaccines and parasiticides are currently the greatest sources of revenue.

Large animal health companies include Merck Animal Health, the animal health division of Merck & Co., Inc.; Bayer Animal Health, the animal health division of Bayer AG; Boehringer Ingelheim Animal Health, the animal health division of Boehringer Ingelheim GmbH; Elanco Animal Health Incorporated; and Zoetis, Inc. We will also compete against several animal health companies in Europe, such as the Virbac Group, Ceva Animal

## Table of Contents

Health and Dechra Pharmaceuticals PLC. We are also aware of smaller companies that are developing products for use in the pet therapeutics market, including Aratana Therapeutics, Inc.

At the product level, we will face competition for Mirataz from Entyce, if used off-label or eventually approved for cats, for Zimeta from Banamine and Butazolidin even though they are not approved for control of fever in horses, for KIND-014 from GastroGard and UlcerGard and potentially from additional products in development. In addition, we may face competition from various products including additional products in development. Our products may also face competition from generic medicines and products approved for use in humans that are used extra-label for pets. Some of our other products also may face competition from their human generic equivalents in countries where such equivalents are available.

Many of our competitors and potential competitors have substantially more financial, technical and human resources than we do. Many also have far more experience than we have in the development, manufacture, regulation and worldwide commercialization of animal health medicines, including pet therapeutics. In addition, these and other potential competing products may benefit from greater brand recognition and brand loyalty than any that our product candidates may achieve. Accordingly, there is no assurance that we and our products can compete effectively.

## Intellectual Property

We intend to rely primarily upon a combination of regulatory exclusivity, patents, trade secret protection, proprietary know-how, license agreements, and confidentiality agreements to protect our product formulations, biologics, processes, therapeutic methods and other technologies, and to operate without infringing on the proprietary rights of other parties, both in the United States and in other countries. We currently have numerous provisional, nonprovisional, and international patent applications pending, and two issued patents, for our IL-31 antibody compositions-of-matter and corresponding methods of use. Because our first approved product and our other small molecule product candidates are based on generic human drugs, there is little, if any, composition-of-matter patent protection available for the API in such product candidates. Where feasible, however, we are pursuing the broadest intellectual property protection possible for our small molecule products, such as patent protection of enhanced formulations of our products and associated methods of use, both in the United States and abroad. For example, we are developing slow release oral formulations or transdermal formulations of some of our products. We also intend to develop combination therapies and slow release parenteral formulations of some of our products. In addition, we have filed patent applications on many of our biologic products. However, even intellectual property protection, if available to us, may not afford us with complete protection against competitors. See “Risk Factors-Risks Related to Intellectual Property.”

We depend upon the skills, knowledge and experience of our management personnel, as well as that of our other employees, advisors, consultants and contractors, none of which are patentable. To help protect our know-how, and any inventions for which patents may be difficult to obtain or enforce, we require all of our employees, consultants, advisors and other contractors to enter into customary confidentiality and inventions agreements that prohibit the disclosure of confidential information and, where applicable, require disclosure and assignment to us of the ideas, developments, discoveries and inventions important to our business.

## Regulatory

The development, approval and sale of animal health products are governed by the laws and regulations of each country in which we intend to sell our products. To comply with these regulatory requirements, we have established processes and resources to provide oversight of the development and launch of our products and their maintenance in the market.

United States

15

---

## Table of Contents

Three federal regulatory agencies regulate the health aspects of animal health products in the United States: the FDA; the USDA; and the Environmental Protection Agency (the “EPA”). In addition, the Drug Enforcement Administration (the “DEA”) regulates animal therapeutics that are classified as controlled substances.

The FDA Center for Veterinary Medicine (the “CVM”), regulates animal pharmaceuticals under the Federal Food, Drug and Cosmetic Act. The USDA Center for Veterinary Biologics (the “CVB”), regulates veterinary vaccines and certain biologics pursuant to the Virus, Serum, Toxin Act. The EPA Office of Pesticide Programs (the “OPP”) regulates veterinary pesticides under the Federal Insecticide, Fungicide and Rodenticide Act. Many topical products used for treatment of flea and tick infestations are regulated by the EPA.

All of our current product candidates are animal pharmaceuticals or biologics regulated by the CVM or the CVB, respectively. Manufacturers of animal health pharmaceuticals and biologics, including us, must show their products to be safe, effective and produced by a consistent method of manufacture. We are also required to conduct post-approval monitoring of products and to submit reports of product quality defects, adverse events or unexpected results, and are subject to regulatory inspection from time to time. In addition, for our controlled substance product candidates, we are required to comply with the Controlled Substances Act (the “CSA”) and related state laws regarding manufacturing, labeling, packaging, testing, dispensing, production and procurement quotas, recordkeeping, reporting, handling, shipment and disposal.

### Requirements for Approval of Veterinary Pharmaceuticals for Pets

As a condition to regulatory approval for the sale of animal products, regulatory agencies worldwide generally require that a product to be used for pets be demonstrated to:

- be safe for the intended use in the intended species;
- have substantial evidence of effectiveness for the intended use;
- have a defined manufacturing process that ensures the product can be made with high quality consistency; and
- be safe for humans handling the product and for the environment.

**Safety.** To determine that a new veterinary drug is safe for use, most regulatory authorities will require us to provide data from a safety study generated in laboratory cats, dogs, and horses tested at doses higher than the intended label dose, over a period of time determined by the intended length of dosing of the product. In the case of the FDA, the design and review of the safety study and the study protocol can be completed prior to initiation of the study to help assure that the data generated will meet FDA requirements. These studies are conducted under rigorous quality control, including GLP, to assure integrity of the data. They are designed to clearly define a safety margin, identify any potential safety concerns, and establish a safe dose for the product. In addition, safety data from pivotal field studies conducted under GCP standards are evaluated to assure that the product will be safe in the target population. Furthermore, because safety and effectiveness studies must conform to VICH guidelines, which are established under an international program aimed at harmonizing technical requirements for veterinary product registration, they can be utilized by regulatory bodies in the European Union, Japan, Canada, New Zealand and Australia.

**Effectiveness.** Early pilot studies may be conducted in laboratory cats, dogs, or horses to establish effectiveness and the dose range for each product. Data on how well the drug is absorbed when dosed by different routes of administration and the relationship of the dose to the effectiveness are studied. When an effective dose is established, a study protocol to test the product in real world conditions is developed prior to beginning the study. In the case of the FDA, the pivotal effectiveness field study protocol can be submitted for review and concurrence prior to study initiation, to help assure that the data generated will meet requirements.

The pivotal field effectiveness study must be conducted with the formulation of the product that is intended to be commercialized, and is a multi-site, randomized, controlled study, generally with a placebo control. To reduce bias in the study, individuals doing the assessment are not told whether the subject is in the group receiving the treatment



being tested or the placebo group. In both the United States and the European Union, the number of

16

---

## Table of Contents

subjects enrolled in pivotal field effectiveness studies is required to be approximately 100 to 150 animal subjects treated with the test product and a comparable number of subjects in the control group that receive the placebo. In many cases, a pivotal field study may be designed with clinical sites in both the European Union and the United States, and this single study may satisfy regulatory requirements in both jurisdictions.

Chemistry, Manufacturing and Controls ("CMC"). To assure that the product can be manufactured consistently, regulatory agencies will require us to provide documentation of the process by which the API is made and the controls applicable to that process that assure the API and the formulation of the final commercial product meet certain criteria, including quality, purity and stability. After a product is approved, we will be required to communicate with the regulatory bodies any changes in the procedures or manufacturing site. Both API and commercial formulations are required to be manufactured at facilities that practice pharmaceutical GMP.

Environmental and Human Safety. We will not be required under United States law to provide an environmental impact statement for products currently in development if the products are given at the home of the pet's owner or in a veterinary hospital. If products might result in some type of environmental exposure or release, the environmental impact must be assessed. For approval in the EU, a risk assessment for potential human exposure will be required.

Labeling, All Other Information, and Freedom of Information Summary. We also will be required to submit the intended label for the product, and also any information regarding additional research that has been conducted with the drug, to the CVM and other regulatory bodies for review. We will draft, and submit for regulatory review, the Freedom of Information Summary for use in the United States. This summary outlines the studies and provides substantial information that the FDA uses to assess the drug's safety and effectiveness and then publishes on its website.

### Regulatory Process at the FDA

To begin the development process for products in the United States, we must file an Investigational New Animal Drug ("INAD") submission with the FDA. We will then usually hold a pre-development meeting with the FDA to reach a general agreement on the plans for providing the data necessary to fulfill requirements for an NADA. During development, we will usually submit pivotal protocols to the FDA for review and concurrence prior to conducting the required studies. We will gather and submit data on manufacturing, safety and effectiveness to the FDA for review, and this review will be conducted according to timelines specified in the Animal Drug User Fee Act. These are called technical sections, which collectively form the basis of the NADA. Once all data have been submitted and reviewed for each technical section - safety, effectiveness and CMC - the FDA will issue us a technical section complete letter as each section review is completed, and when the three letters have been issued, we will compile a draft of the Freedom of Information Summary, the proposed labeling, and all other relevant information, and submit these for FDA review. An administrative NADA is a NADA that is submitted after all of the technical sections that fulfill the requirements for the approval of the new animal drug have been reviewed by the CVM and the CVM has issued a technical section complete letter for each of those technical sections. Although this process is not required and submission of a non-administrative NADA is also acceptable, we plan to take advantage of the administrative NADA process to obtain a more timely, phased review. Because the CVM has already reviewed the individual technical sections before the administrative NADA is filed, the CVM is committed under its user fee agreements to reviewing and acting on 90% of administrative NADAs within 60 days after submission. The CVM user fee goal is to review and act on 90% of non-administrative NADAs within 180 days after submission. After approval, we will be required to collect reports of adverse events and submit them on a regular basis to the FDA.

### Regulatory Process at the USDA

To begin the development process for veterinary biologics products in the United States, we typically file an Application for United States Veterinary Biological Product License with the USDA. For the biologics products that we develop, we may then meet with the USDA to reach a general agreement on the plans for providing the data necessary to fulfill requirements for an approval. During development, we gather and submit data on manufacturing, purity and potency to the USDA for review. Once all data have been submitted and reviewed, the USDA will issue its decision. Unlike the FDA, there are no timelines specified by law for the USDA's review.



## Table of Contents

In some cases, it may be unclear whether our product candidates meet the definition of a biological product subject to regulation by the USDA or a drug subject to regulation by the FDA. The USDA's Center for Veterinary Biologics and the FDA's Center for Veterinary Medicine have a memorandum of understanding concerning their joint responsibilities for resolving jurisdictional issues over products of this nature. Under the memorandum of understanding, animal products are to be regulated by the USDA as biologics if they are intended for use to diagnose, cure, mitigate, treat, or prevent disease in animals and they work primarily through an immune process, or by the FDA as drugs, if they are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of animal disease if the primary mechanism of action is not immunological or is undefined.

### Regulatory Process at the EMA

The EMA is responsible for coordinating scientific evaluation of applications for marketing approval for pet therapeutics in the EU. Its veterinary review section is distinct from the review section for human drugs. To perform these evaluations the EMA established a specific scientific committee, the Committee for Medicinal Products for Veterinary Use ("CVMP"). The CVMP considers applications submitted by companies for the marketing approval of individual pet therapeutics and evaluates whether or not the medicines meet the necessary quality, safety and efficacy requirements. Assessments conducted by the CVMP are based on scientific criteria and are intended to ensure that pet therapeutics reaching the marketplace have a positive benefit-risk balance in the pet population for which they are intended. Based on the CVMP's recommendation, a centralized marketing authorization is granted by the EMA, which allows the product to be marketed in any of the EU states, Norway, Lichtenstein and Iceland. The CVMP is also responsible for various post-authorization and maintenance activities, including the assessment of modifications or extensions to an existing marketing authorization.

To obtain authorization from the EMA, we must submit a marketing authorization application called a dossier. The dossier is the EMA's equivalent of the FDA's NADA and includes data from studies showing the quality, safety and efficacy of the product. The CVMP reviews and evaluates the dossier. For any dossier, a rapporteur and co-rapporteur are appointed from the members of the CVMP. Their role is to lead the scientific evaluation and prepare the assessment report. The rapporteur can utilize experts to assist it in performing its assessment. The report is critiqued by the co-rapporteur and other members of the CVMP before the CVMP makes its determination. The final opinion of the CVMP is generally given within 210 days of the submission of a dossier, but the EMA makes the final decision on the approval of products. In general, the requirements for regulatory approval of an animal health product in the EU are similar to those in the United States, requiring demonstrated evidence of purity, safety, efficacy and consistency of manufacturing processes.

Alternatively, product approval applications may be submitted directly to the regulatory authority in each country rather than by centralized approval by the EMA.

### Regulatory Processes at the DEA

The DEA regulates controlled substances as Schedule I, II, III, IV or V substances. Schedule I substances by definition have no established medicinal use and may not be marketed or sold in the United States. An animal drug may be listed as Schedule II, III, IV or V, with Schedule II substances considered to present the highest risk of abuse and Schedule V substances the lowest relative risk of abuse among such substances. Certain of our product candidates are likely to be scheduled as controlled substances under the CSA. Consequently, their manufacture, shipment, storage, sale and use will be subject to a high degree of regulation.

Annual registration is required for any facility that manufactures, distributes, dispenses, imports or exports any controlled substance. The registration is specific to the particular location, activity and controlled substance schedule. For example, separate registrations are needed for import and manufacturing, and each registration will specify which schedules of controlled substances are authorized.

The DEA typically inspects a facility to review its security measures prior to issuing a registration. Security requirements vary by controlled substance schedule, with the most stringent requirements applying to Schedule I and Schedule II substances. Required security measures include background checks on employees and physical control of inventory through measures such as cages, surveillance cameras and inventory reconciliations. Records must be maintained for the handling of all controlled substances, and periodic reports must be made to the DEA, for



## Table of Contents

example, distribution reports for Schedule II controlled substances, Schedule III substances that are narcotics, and other designated substances. Reports must also be made for thefts or losses of any controlled substance, and to obtain authorization to destroy any controlled substance. In addition, special authorization and notification requirements apply to imports and exports.

In addition, a DEA quota system controls and limits the availability and production of controlled substances in Schedule I or II. Distributions of any Schedule I or II controlled substance must also be accompanied by special order forms, with copies provided to the DEA. The DEA may adjust aggregate production quotas and individual production and procurement quotas from time to time during the year, although the DEA has substantial discretion in whether or not to make such adjustments.

### Other Regulatory Considerations

Regulatory rules relating to human food safety, food additives, or drug residues in food will not apply to the products we currently are developing because our products are not intended for use in food animals or food production animals, with the exception of horses, which qualify as food animals in Europe and Canada.

Advertising and promotion of animal health products is controlled by regulations in the United States and other countries. These rules generally restrict advertising and promotion to those claims and uses that have been reviewed and authorized by the applicable agency. We will conduct a review of advertising and promotional material for compliance with local and regional requirements in the markets where we sell pet therapeutics.

Our small molecule product candidates, if approved, may eventually face generic competition in the United States and in the EU. In the United States, a generic animal drug may be approved pursuant to an Abbreviated New Animal Drug Application ("ANADA"). Instead of demonstrating the drug's safety and effectiveness in the target species as required in a NADA, a generic applicant must only show that the proposed generic product is the same as, and bioequivalent to, the approved brand name product. However, if our product candidates are the first approved by the FDA or the EMA as applicable for use in animals, they will be eligible for five years of regulatory exclusivity in the United States and ten years in the EU. There is no comparable pathway for approval of a generic veterinary biologic regulated by the USDA.

### Employees

As of December 31, 2018, we had 146 employees, including 33 employees with D.V.M., M.D. or Ph.D. degrees. Of our employees, 49, including Dr. Chin and Ms. Bevers are engaged in one or more aspects of our research and development activities. Dr. Chin and Ms. Bevers also are engaged in corporate and administrative activities. None of our employees are represented by labor unions or covered by collective bargaining agreements.

### Available Information

We file annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, proxy statements and other documents with the Securities and Exchange Commission (the "SEC"). All of our filings with the SEC (including documents that we "furnish" with the SEC rather than "file" with the SEC) are available on the SEC's website at [www.sec.gov](http://www.sec.gov). Our filings with the SEC are also available free of charge on our website at [www.kindredbio.com](http://www.kindredbio.com) as soon as reasonably practicable after each document is electronically filed with or furnished to the SEC. The information contained in, or accessible through, our website is not a part of this Annual Report on Form 10-K and is not incorporated by reference into any other filings that we make with the SEC.

Table of Contents

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 contained in or incorporated by reference into our other public filings with the Securities and Exchange Commission, 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. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations.

Risks Related to Our Business

We have a limited operating history, are not profitable and may never become profitable.

We are a commercial stage biopharmaceutical company. Since our formation in September 2012 and until June 2018, our operations were limited to the identification of product candidates and research and development of our product candidates, including our lead product candidates, Mirataz and Zimeta. It was only in July 2018 that Mirataz became commercially available. As a result, we have limited historical operations upon which to evaluate our business and prospects, we have demonstrated an ability to obtain marketing approval for only one of our product candidates and have not yet successfully overcome the risks and uncertainties frequently encountered by companies in emerging fields such as the pet therapeutics industry. We have only generated revenue on one product for two quarters to-date and will continue to incur significant research and development and other expenses. As of December 31, 2018, we had an accumulated deficit of \$161.7 million. For the foreseeable future, we expect to continue to incur losses, which will increase significantly from historical levels as we expand our product development activities, seek regulatory approvals for our product candidates and begin to commercialize them if they are approved by the Center for Veterinary Medicine branch of the FDA, the USDA or the EMA. Even if we succeed in developing and commercializing one or more product candidates, we expect to continue to incur losses for the foreseeable future, and we may never become profitable. If we fail to achieve or maintain profitability, it would adversely affect the value of our common stock.

We may need to raise additional capital to achieve our goals.

Although Mirataz became commercially available in July 2018, it will take approximately four to five years to achieve peak sales. In addition, we are dependent on the FDA's inspection of the API manufacturer of our second product candidate, Zimeta. Regulatory approval for Zimeta is subject to the typical risks inherent in such a process. Our other small molecule product candidates will require from three to five years of further development at a cost of an average of approximately \$5 million per product candidate, and our biologics candidates will require four to six years of further development at an average cost of approximately \$8 million per product candidate before we expect to be able to apply for marketing approval in the United States. We also are actively involved in identifying additional human therapeutics for development and commercialization as pet therapeutics and will continue to expend substantial resources for the foreseeable future to develop our current product candidates and any other product candidates we may develop or acquire. These expenditures will include: costs of identifying additional potential product candidates; costs associated with drug formulation; costs associated with conducting pilot, pivotal, and toxicology studies; costs associated with completing other research and development activities; costs associated with payments to technology licensors and maintaining other intellectual property; costs of obtaining regulatory approvals; costs associated with establishing commercial manufacturing and supply capabilities; and costs associated with marketing and selling any of our products approved for sale. We also may incur unanticipated costs. Because the outcome of our development activities and commercialization efforts is inherently uncertain, the actual amounts necessary to successfully complete the development and commercialization of our current or future product candidates may be greater or less than we anticipate.

Table of Contents

We believe we have sufficient cash and cash equivalents to fund our operating plan for at least another 24 months. However, we may seek additional funds through public or private equity or debt financings or other sources such as strategic collaborations. Additionally, we do not expect our existing cash and cash equivalents to be sufficient to complete the development of all of our current product candidates, or of any additional product candidates that we may identify, and we may need to raise additional capital to fund these activities. Even if we believe we have sufficient funds on hand for our current or planned future business and operations, we may seek from time to time to raise additional capital based upon favorable market conditions or strategic considerations such as potential acquisitions.

Our future capital requirements depend on many factors, including, but not limited to:

- the scope, progress, results and costs of researching and developing our current or future product candidates;
- the timing of, and the costs involved in, obtaining regulatory approvals for any of our current or future product candidates;
- the number and characteristics of the product candidates we pursue;
- the cost of manufacturing our current and future product candidates and any products we successfully commercialize;
- the cost of commercialization activities for approved products and for any of our current or future product candidates that are approved for sale, including marketing, sales and distribution costs;
- the expenses needed to attract and retain skilled personnel;
- the costs associated with being a public company;
- our ability to establish and maintain strategic collaborations, licensing or other arrangements and the financial terms of such agreements; and
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing current and future patents, including litigation costs and the outcome of any such litigation.

Additional funds may not be available when we need them on terms that are acceptable to us, or at all. If adequate funds are not available to us on a timely basis, we may be required to delay, limit, reduce or terminate one or more of our product development programs or any future commercialization efforts.

We are substantially dependent on the success of Mirataz as well as product candidates in our pipeline and cannot be certain that any of our product candidates will be approved for marketing or successfully commercialized even if approved.

Although we have one product on the market, our current efforts are, and a substantial portion of our efforts over the foreseeable future will be, primarily focused on the long-term commercial success of Mirataz, FDA approval of our second lead product candidate, Zimeta, and on the progress of other product candidates that are in our pipeline. We discontinued our previous lead product candidates, SentiKind and CereKin, as a result of not meeting their primary endpoints. We also re-assessed our atopic dermatitis program and the atopic dermatitis market and decided to discontinue our AtoKin study in order to redirect our resources toward other programs in our portfolio. Accordingly, our near-term prospects, including our ability to generate material product revenue, obtain any new financing if needed to fund our business and operations, or enter into potential strategic transactions, will depend heavily on the successful development and commercialization of Mirataz and one or more of our lead product candidates, which in turn will depend on a number of factors, including the following:



Table of Contents

the successful completion of the pivotal trials and toxicology studies of one or more of our current product candidates, which may take significantly longer than we currently anticipate and will depend, in part, upon the satisfactory performance of third-party contractors;

our ability to demonstrate to the satisfaction of the FDA, the USDA and the EMA the safety and efficacy of our product candidates and to obtain regulatory approvals;

the ability of us or our third-party manufacturers to manufacture supplies of Mirataz to meet the market demand and of any of our product candidates and to develop, validate and maintain commercially viable manufacturing processes that are compliant with GMP and to manufacture them at an acceptable cost as well as the ability to sell them at an acceptable price with reasonable margins;

our ability to successfully launch commercial sales of our current product candidates, assuming marketing approval is obtained, whether alone or in collaboration with others;

the effectiveness of our commercialization efforts, including the effectiveness of marketing, sales and distribution strategy and operations, whether performed solely by us or in conjunction with third-party national and regional distributors.

the availability, perceived advantages, relative cost, relative safety and relative efficacy of Mirataz and our product candidates compared to alternative and competing treatments;

the acceptance of Mirataz and our product candidates as safe and effective by veterinarians, pet owners and the animal health community;

the prevalence and severity of adverse side effects and our ability to maintain a continued acceptable safety profile of a product following approval;

our ability to obtain supplemental indications for Mirataz and our product candidates;

any product liability claim or lawsuit we may be involved in from time to time with regards to Mirataz and our product candidates;

our ability to achieve and maintain compliance with all regulatory requirements applicable to our business; and

our ability to obtain and enforce our intellectual property rights and obtain marketing exclusivity for Mirataz and our product candidates, and avoid or prevail in any third-party patent interference, patent infringement claims or administrative patent proceedings initiated by third parties or the U.S. Patent and Trademark Office, or USPTO.

Many of these factors are beyond our control. Accordingly, we cannot assure you that we will be successful in commercializing Mirataz or developing current product candidates. If we are unsuccessful in marketing Mirataz or are significantly delayed in developing and commercializing Zimeta or any of our other current or future product candidates, our business and prospects will be materially adversely affected, and you may lose all or a portion of the value of your investment in our common stock.

Most of our current and future small molecule product candidates are or will be based on generic human drugs, and other companies may develop substantially similar products that may compete with our products.

Most of the small molecule product candidates we are currently developing or expect to develop are based on generic human drugs. We do not engage in early-stage research or discovery with respect to our small molecule product

candidates, but focus primarily on product candidates whose active pharmaceutical

Table of Contents

ingredient has been successfully commercialized or demonstrated to be safe and/or effective in human trials, which we sometimes refer to as validated. Our small molecule product candidates may face competition from their human generic equivalents in countries where such equivalents are available and used in unapproved animal indications, which is known as extra-label use.

In cases where there is a human generic available there is no assurance that the eventual prices of our products will be lower than or competitive with the prices of human generic equivalents used extra-label, or that a palatable, easy-to-administer formulation such as the chewable, beef-flavored formulation that we utilize will be sufficient to differentiate them from their human equivalents. Human generics available outside the United States cannot be imported into the United States for use in animals, except on a case-by-case basis where the FDA determines it is medically necessary.

In most cases, we target small molecule product candidates for which the active ingredients have not been previously approved for use in animals. If we are the first to gain approval for the use of such active ingredients in animals, our small molecule products will enjoy five years of marketing exclusivity in the United States and ten years in the EU for the approved indication. We also plan to differentiate our products where possible with specific formulations, including flavors, methods of administration, and other strategies, but we cannot assure you that we will be able to prevent competitors from developing substantially similar products and bringing those products to market earlier than we can. In addition, while we expect to have composition of matter patent applications for most of our biologic product candidates, those applications may not ultimately result in granted patents. Although there are no generic regulatory approval pathways for animal biologics in the United States and European Economic Area ("EEA"), our competitors may develop similar biologics that do not infringe any patents we may obtain. For example, competitors may develop different antibodies that bind to the same target as our antibodies. Thus, our competitors may be able to develop and market competing products if they are willing and able to conduct the full set of required studies, file a NADA with the FDA, or Application for United States Veterinary Biological Product License with the USDA, which is also called a Product License Application ("PLA"), and obtain marketing approval. If such competing products achieve regulatory approval and commercialization prior to our product candidates, or if our intellectual property protection and efforts to obtain regulatory exclusivity fail to provide us with exclusive marketing rights for some of our products, then our business and prospects could be materially adversely affected.

If our product candidates are approved, they may face significant competition and may be unable to compete effectively.

The development and commercialization of pet therapeutics is highly competitive and our success will depend on our ability to compete effectively with other products in the market. With respect to both Mirataz and any of our product candidates that are approved, we expect to compete with animal health divisions of major pharmaceutical and biotechnology companies such as Merck Animal Health, Elanco, Bayer Animal Health, and Boehringer Ingelheim Animal Health, as well as specialty animal health medicines companies such as Zoetis, Virbac Group, Ceva Animal Health and Dechra Pharmaceuticals. Additionally, we are aware of several early-stage companies that are developing products for use in the pet therapeutics market, including Aratana Therapeutics Inc. and Jaguar Health, Inc. We also expect to compete with academic institutions, governmental agencies and private organizations that are conducting research in the field of animal health medicines.

If approved, Zimeta will face competition from existing products approved for treatment of horses such as Banamine. Mirtazapine, the active ingredient in Mirataz, is widely used today in human generic and compounded formulations. Many of our product candidates also will face competition from various products approved for use in humans that are used extra-label in animals, and Mirataz and all of our product candidates will face potential competition from new products in development. These and other potential competing products may benefit from greater brand recognition and brand loyalty than our product candidates may achieve.

Table of Contents

Many of our competitors and potential competitors have substantially more financial, technical and human resources than we do. Many also have far more experience than we have in the development, manufacture, regulation and worldwide commercialization of animal health medicines, including pet therapeutics.

For these reasons, there is no assurance that we and any of our approved products can compete effectively.

The development of our biologic product candidates is dependent upon relatively novel technologies and uncertain regulatory pathways.

We have developed and plan to continue to develop biologics, including animal antibodies, for pets. Identification, optimization, and manufacture of therapeutic animal biologics is a relatively new field in which unanticipated difficulties or challenges could arise, and we expect the discovery, development, manufacturing and sale of biologic products to be a long, expensive and uncertain process. While many biologics have been approved for use in humans, apart from vaccines, relatively few recombinant proteins or antibodies have been approved for use in animals. There are unique risks and uncertainties with biologics, the development, manufacturing, and sale of which are subject to regulations that are often more complex and extensive than the regulations applicable to other small molecule products. We may be unable to identify biologics suitable for development or to achieve the potency and stability required for use in pets. In particular, canine, feline, and equine antibodies represent new types of product candidates that may be difficult to develop successfully.

In some cases, it may be unclear whether our product candidates meet the definition of a biological product subject to regulation by the USDA or a drug subject to regulation by the FDA. The USDA's Center for Veterinary Biologics and the FDA's Center for Veterinary Medicine have a memorandum of understanding concerning their joint responsibilities for resolving jurisdictional issues over products of this nature. Under the memorandum of understanding, animal products are to be regulated by the USDA as biologics, if they are intended for use to diagnose, cure, mitigate, treat, or prevent disease in animals and they work primarily through an immune process, or by the FDA as drugs, if they are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of animal disease if the primary mechanism of action is not immunological or is undefined.

Although we believe that most of our current animal biologics will be regulated by the USDA based on their mechanisms of action, the USDA and the FDA may not agree with our assessment, or disputes may arise between the USDA and the FDA over regulatory jurisdiction for one or more of such biologics. If so, the development of our biologics may be delayed while any such disputes are adjudicated by the agencies. Furthermore, if the agencies were to determine that one or more of our animal biologics will be regulated by the FDA instead of the USDA, the time and cost of developing such biologics may be longer and more expensive than we currently anticipate, and we may determine to discontinue development of such biologics. It is also possible that the USDA's regulatory standards for novel biologics may be more difficult to satisfy than we anticipate. The current trend indicates that the FDA is attempting to exert jurisdiction over more biologics.

We believe that some veterinarians prefer to see further efficacy data before making a new biologic product prescribing decision. Accordingly, we may also find it necessary to conduct additional studies of our biologic product candidates in order to achieve commercial success.

The results of earlier studies may not be predictive of the results of our pivotal trials, and we may be unable to obtain regulatory approval for our existing or future product candidates under applicable regulatory requirements. The denial or delay of any regulatory approval would prevent or delay our commercialization efforts and adversely affect our potential to generate material product revenue and our financial condition and results of operations.

The research, testing, manufacturing, labeling, approval, sale, marketing and distribution of pet therapeutics are subject to extensive regulation. We are usually not permitted to market our products in the

Table of Contents

United States until we receive approval of an NADA from the FDA or a PLA from the USDA, or in the EU or in other EEA countries until we receive marketing approval from the EMA. To gain approval to market a pet therapeutic for a particular species, we must provide the FDA, the USDA and the EMA, as applicable, with efficacy data from pivotal trials that adequately demonstrate that our product candidates are safe and effective in the target species (e.g., dogs, cats or horses) for the intended indications. In addition, we must provide manufacturing data. For the FDA and EMA, we must provide data from toxicology studies, also called target animal safety studies, and in some cases environmental impact data. We are conducting the pivotal trial of our compounds internally without significant outsourcing, but we rely on contract research organizations ("CROs") and other third parties to conduct our toxicology studies and for certain other development activities. The results of toxicology studies and other initial development activities, and of any previous studies in humans or animals conducted by us or third parties, may not be predictive of future results of pivotal trials or other future studies, and failure can occur at any time during the conduct of pivotal trials and other development activities by us or our CROs. Our pivotal trial may fail to show the desired safety or efficacy of our product candidates despite promising initial data or the results in previous human or animal studies conducted by others, and success of a product candidate in prior animal studies, or in the treatment of human beings, does not ensure success in subsequent studies. Clinical trials in humans and pivotal trials in animals sometimes fail to show a benefit even for drugs that are effective, because of statistical limitations in the design of the trials or other statistical anomalies. Therefore, even if our studies and other development activities are completed as planned, the results may not be sufficient to obtain regulatory approval for our product candidates.

The FDA, USDA or EMA can delay, limit or deny approval of any of our product candidates for many reasons, including:

• if the FDA, USDA or EMA disagrees with our interpretation of data from our pivotal studies or other development efforts;

• if we are unable to demonstrate to the satisfaction of the FDA, USDA or EMA that the product candidate is safe and effective for the target indication;

• if the FDA, USDA or EMA requires additional studies or changes its approval policies or regulations;

• if the FDA, USDA or EMA does not approve of the formulation, labeling or the specifications of our current and future product candidates; and

• if the FDA, USDA or EMA fails to approve the manufacturing processes of our third-party contract manufacturers.

Further, even if we receive approval of our product candidates, such approval may be for a more limited indication than we originally requested, and the FDA, USDA or EMA may not approve the labeling that we believe is necessary or desirable for the successful commercialization of our product candidates.

Any delay or failure in obtaining applicable regulatory approval for the intended indications of our product candidates would delay or prevent commercialization of such product candidates and would materially adversely impact our business and prospects.

Our Protocol Concurrences with the FDA for our pivotal studies do not guarantee marketing approval in the United States.

We may conduct pivotal trials under Protocol Concurrences with the FDA. A Protocol Concurrence in animal drug development is analogous to a Special Protocol Assessment in human drug development, and means that the FDA agrees that the design and analyses proposed in a protocol are acceptable to support regulatory approval of the product candidate with respect to effectiveness of the indication studied and will not change its view of these matters, unless public or animal health concerns arise that were not recognized at the time of protocol concurrence or we change the protocol. Even under a Protocol Concurrence, approval of a

## Table of Contents

NADA by the FDA is not guaranteed, because a final determination that the agreed-upon protocol satisfies a specific objective, such as the demonstration of efficacy, or supports an approval decision, will be based on a complete review of all the data submitted to the FDA.

Development of pet therapeutics is inherently expensive, time-consuming and uncertain, and any delay or discontinuance of our current or future pivotal trials would significantly harm our business and prospects.

Development of pet therapeutics remains an inherently lengthy, expensive and uncertain process, and there is no assurance that our development activities will be successful. We do not know whether the trials of our current or future product candidates will begin or conclude on time, and they may be delayed or discontinued for a variety of reasons, including if we are unable to:

- address any safety concerns that arise during the course of the studies;
- complete the studies due to deviations from the study protocols or the occurrence of adverse events;
- add new study sites;
- address any conflicts with new or existing laws or regulations; or
- reach agreement on acceptable terms with study sites, which can be subject to extensive negotiation and may vary significantly among different sites.

Any delays in completing our development efforts will increase our costs, delay our product candidate development and approval process and jeopardize our ability to commence product sales and generate revenue. Any of these occurrences may significantly harm our business, financial condition and prospects. In addition, factors that may cause a delay in the commencement or completion of our development efforts may also ultimately lead to the denial of regulatory approval of our product candidates which, as described above, would materially, adversely impact our business and prospects.

We currently rely on third parties to conduct some of our development activities and may rely more heavily on such third parties in the future. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may be unable to obtain regulatory approval for or commercialize our current or future product candidates as planned.

We currently plan to conduct our own pivotal trials, but we rely upon CROs to conduct our toxicology studies and for other development activities. We also may rely on CROs in the future to conduct one or more pivotal trials. These CROs are not our employees, and except for contractual duties and obligations, we have limited ability to control the amount or timing of resources that they devote to our programs or manage the risks associated with their activities on our behalf. We are responsible to regulatory authorities for ensuring that each of our studies is conducted in accordance with the development plans and trial protocols, and any failure by our CROs to do so may adversely affect our ability to obtain regulatory approvals, subject us to penalties, or harm our credibility with regulators. The FDA and foreign regulatory authorities also require us and our CROs to comply with regulations and standards, commonly referred to as good clinical practices ("GCPs"), or good laboratory practices ("GLPs"), for conducting, monitoring, recording and reporting the results of our studies to ensure that the data and results are scientifically credible and accurate.

Our agreements with CROs may allow termination by the CROs in certain circumstances with little or no advance notice to us. These agreements generally will require our CROs to reasonably cooperate with us at our expense for an orderly winding down of the CROs' services under the agreements. If the CROs conducting our studies do not comply with their contractual duties or obligations to us, or if they experience work stoppages, do not meet expected deadlines, terminate their agreements with us or need to be replaced, or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our development protocols or GCPs or for any other reason, we may need to secure new arrangements with alternative CROs, which could be difficult and costly. In such event, our studies also may need to be extended, delayed or

## Table of Contents

terminated as a result, or may need to be repeated. If any of the foregoing were to occur, regulatory approval and commercialization of our product candidates may be delayed and we may be required to expend substantial additional resources.

Even if we obtain regulatory approval of one or more of our current or future product candidates, they may never achieve market acceptance or commercial success.

If we obtain FDA, USDA or EMA approvals for one or more of our current or future product candidates, they may not achieve market acceptance among veterinarians and pet owners and may not be commercially successful. Market acceptance of any of our current or future product candidates for which we may receive approval depends on a number of factors, including:

- the indications for which our products are approved;
- the potential and perceived advantages of our product candidates over alternative treatments, including generic medicines and competing products currently prescribed by veterinarians, and products approved for use in humans that are used extra-label in animals;
- the cost of treatment in relation to alternative treatments and willingness on the part of veterinarians and pet owners to pay for our products, including other discretionary items, especially during economically challenging times;
- the prevalence and severity of any adverse side effects of our products;
- the relative convenience and ease of administration of our products;
- the effectiveness of our sales and marketing efforts; and
- the proper training and administration of our products by veterinarians and acceptance by veterinarians and pet owners of our products as safe and effective.

Any failure by our product candidates that obtain regulatory approval to achieve market acceptance or commercial success would adversely affect our financial condition and results of operations.

Pet therapeutics, like human therapeutics, are subject to unanticipated post-approval safety or efficacy concerns, which may harm our business and reputation.

The success of our commercialization efforts will depend upon the perceived safety and effectiveness of pet therapeutics, in general, and of our products, in particular. Unanticipated safety or efficacy concerns can arise with respect to approved pet therapeutics after they enter into commerce, which may result in product recalls or withdrawals or suspension of sales, as well as product liability and other claims. Because reliable detection of rare events might require exposure of millions of animals, it is not possible to rule out the risk until well after the launch of the product.

It is also possible that the occurrence of significant adverse side effects in approved human generic compounds upon which our product candidates are based could impact our products. Any safety or efficacy concerns, or recalls, withdrawals or suspensions of sales of our products or other pet therapeutics, or of their human equivalents, could harm our reputation, in particular, or pet therapeutics, generally, and materially, adversely affect our business and prospects or the potential growth of the pet therapeutics industry, regardless of whether such concerns or actions are justified.

Future federal and state legislation may result in increased exposure to product liability claims, which could result in substantial losses to us.

## Table of Contents

Under current federal and state laws, pets are generally considered to be personal property of their pet owners and, as such, pet owners' recovery for product liability claims involving their pets may be limited to the replacement value of the pets. Pet owners and their advocates, however, have filed lawsuits from time to time seeking non-economic damages such as pain and suffering and emotional distress for harm to their pets based on theories applicable to personal injuries to humans. If new legislation is passed to allow recovery for such non-economic damages, or if precedents are set allowing for such recovery, we could be exposed to increased product liability claims that could result in substantial losses to us if successful. In addition, some horses can be worth millions of dollars or more, and product liability for horses may be very high.

It is also possible that our product liability insurance will not be sufficient to cover any future product liability claims against us.

If we fail to retain current members of our senior management, or to attract and keep additional key personnel, our business and prospects could be materially adversely impacted.

Our success depends on our continued ability to attract, retain and motivate highly qualified management and scientific personnel. We are highly dependent upon our senior management, particularly Richard Chin, M.D., our Chief Executive Officer, Denise Bevers, our President and Chief Operating Officer, Wendy Wee, our Chief Financial Officer and Hangjun Zhan, Ph.D., our Chief Scientific Officer. The loss of services of any of our key personnel could adversely affect our ability to successfully develop our current or future product pipeline and commercialize our product candidates. Although we have entered into employment agreements with these key members of senior management, such agreements generally do not prohibit them from leaving our employ at any time. We currently do not maintain "key man" life insurance on any of our senior management team. The loss of Dr. Chin or other members of our current senior management could adversely affect the timing or outcomes of our current and planned studies, as well as longer-term prospects for commercializing our product candidates.

In addition, competition for qualified personnel in the animal health fields is intense, because there is a limited number of individuals who are trained or experienced in the field. We will need to hire additional personnel as we expand our product development and commercialization activities, and we may not be able to attract and retain qualified personnel on acceptable terms, or at all.

We are dependent upon third-party manufacturers for supplies of Mirataz and our current product candidates and intend to rely on third-party manufacturers for commercial quantities of any of our product candidates that may be approved.

We currently have no internal capability to manufacture Mirataz or the formulated small molecule product candidates for use in our studies or commercial supplies of any of our product candidates that may be approved and will be dependent upon third-party manufacturers for such supplies. We and our contract manufacturers have historically been able to obtain supplies of the API for development of our small molecule product candidates, but neither we nor our contract manufacturers have long-term supply agreements with the API manufacturers. We also have no agreements for commercial-scale supply of the API or manufacture of Mirataz or any of our product candidates. As a result, we and our contract manufacturers may be unable to procure API in a timely manner on commercially reasonable terms, or at all. Any delay in identifying and contracting with third-party contract manufacturers on commercially reasonable terms would have an adverse impact upon our current product development activities and current and future commercialization efforts.

The facilities used by our contract manufacturers to manufacture the drugs are subject to inspections by the FDA, USDA, and the EMA, and we depend on our contract manufacturers to comply with GMP or other applicable regulatory standards. If our contract manufacturers cannot successfully manufacture material in compliance with these strict regulatory requirements, we and they will not be able to secure or maintain regulatory approval for their manufacturing facilities. In some cases, we also are dependent on our contract manufacturers to produce supplies in conformity to our specifications and maintain quality control and quality assurance practices and not to employ disqualified personnel. If the FDA or a comparable foreign regulatory



Table of Contents

authority does not approve the manufacturing facilities of our contract manufacturers, or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which could result in delays in, or adversely affect our ability to, develop or commercialize our product candidates. We and our contract manufacturers also may be subject to penalties and sanctions from the FDA and other regulatory authorities for any violations of applicable regulatory requirements. The USDA and EMA employ different regulatory standards than the FDA, so we may require multiple manufacturing processes and facilities for the same product candidate or any approved product. The commercialization of Mirataz or any of our product candidates could be adversely affected if we are unable to secure sufficient quantities and quality of drug products in a timely manner.

The raw materials used to manufacture Mirataz and our current small molecule product candidates are generally readily available in commercial quantities from multiple suppliers, but we will be dependent upon our contract manufacturers to obtain these raw materials. If manufacturers are unable to do so as and when they are needed to supply our development and commercial needs, we will have no other means of producing Mirataz and our product candidates until they are able to do so or we or they procure alternative supplies of the API. If our third-party manufacturers suffer damage or destruction to their facilities or equipment, we may experience disruptions in supplies, or be unable to obtain supplies of Mirataz or our product candidates on a timely basis. Any inability to secure sufficient quantities and quality of the API or other raw materials in Mirataz and our products candidates would adversely impact our development activities and commercialization efforts. In some cases, contract manufacturers may be reluctant to manufacture the API in pet therapeutics, because of regulatory or other concerns. This may make it more difficult for us to identify manufacturers needed to supply sufficient quantities of Mirataz and our product candidates for development.

Biologics manufacturing is difficult and costly and may not be commercially viable.

There are no established sources of the active ingredients in our biologic product candidates, so we or our collaborators will be required to develop the manufacturing process, perform validation and in some cases establish new facilities to manufacture pet biologics. Manufacturing of pet biologics, apart from vaccines, is a relatively new field in which unanticipated difficulties or challenges could arise. Small changes in the manufacturing process can have significant impact on product quality, consistency and yield. Manufacturing biologics, especially in large quantities, is complex and may require the use of innovative technologies that we may need to develop ourselves or in conjunction with third-party collaborators. Such manufacturing requires facilities specifically designed and validated for this purpose and sophisticated quality assurance and quality control procedures. Biologics are also usually costly to manufacture, because production usually requires the use of living organisms. Factors such as these may make it more technically challenging, time-consuming and expensive than we anticipate to manufacture biologics. Animal antibodies also must be manufactured at a sufficiently low cost that they are economically viable for us and for our customers. We are building a manufacturing plant for biologics manufacturing. There may be unanticipated issues in the construction and commissioning of the plant, including cost overruns, timeline delays, and other technical or regulatory issues. In addition, if we build a manufacturing plant and it is not utilized to full capacity, it may result in increased annual costs and increase in cost of goods. There is no assurance that we will be able to manufacture biologics at an economical cost, if at all.

Once completed, the facilities used to manufacture the biologics are subject to inspections by the FDA, USDA and the EMA. If we cannot successfully manufacture material in compliance with these strict regulatory requirements, we will not be able to secure or maintain regulatory approval for the manufacturing facility. If the FDA or a comparable foreign regulatory authority does not approve the manufacturing facilities, or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which could result in delays in, or adversely affect our ability to, develop or commercialize our product candidates. We also may be subject to penalties and sanctions from the FDA and other regulatory authorities for any violations of applicable regulatory requirements. The USDA and EMA employ different regulatory standards than the FDA, so we may require multiple manufacturing processes and facilities for the same product candidate or any approved product.

## Table of Contents

We currently have a small commercial organization. If we are unable to expand sales capabilities on our own or through third parties, we may not be able to market and sell significant amounts of Mirataz or current or future product candidates, if approved, or generate significant product revenue.

We currently have a small commercial organization with a 37-person direct sales force established in the United States and we utilize distributors to commercialize our products, which is expensive and time-consuming. In jurisdictions outside of the United States we intend to utilize companies with an established commercial presence to market our products in those jurisdictions, but we may be unable to enter into such arrangements on acceptable terms, if at all. Because we have limited prior experience in the marketing, sale and distribution of pet therapeutics or other products, there are significant risks involved in building and managing a sales organization, including our ability to hire, retain and motivate qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel, and effectively oversee a geographically dispersed sales and marketing team. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of our therapeutics. If we are not successful in commercializing any of our current or future product candidates, either on our own or through one or more distributors, we may never generate significant revenue and may continue to incur significant losses, which would adversely affect our financial condition and results of operations.

If we are not successful in identifying, developing, and commercializing additional product candidates, our ability to expand our business and achieve our strategic objectives would be impaired.

A key element of our strategy is to identify, develop and commercialize a portfolio of products to serve the emerging pet therapeutics market. We expect to identify additional potential pet therapeutic product candidates from targets, molecules, and compounds discovered or developed as part of human biopharmaceutical research. If we are unable to identify human health-generated molecules and compounds to conduct research and development, our ability to develop new products could be limited. In addition, we may in the future enter into license agreements with third parties to provide us with rights to the compounds for purposes of our business. Even if we enter into these arrangements, we may not be able to maintain these relationships or establish new ones in the future on acceptable terms, or at all.

Even if we successfully identify or license potential product candidates, we may still fail to develop or commercialize a product candidate for any number of reasons, including the following:

- a product candidate may be covered by third parties' patents or other exclusive rights unknown to us;
- a product candidate may on further study be shown to have harmful side effects in pets or other characteristics that indicate it is unlikely to be effective or otherwise does not meet applicable regulatory criteria;
- a product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all;
- a product candidate may not be accepted as safe and effective by veterinarians, pet owners and the pet therapeutic community; and
- competitors may develop alternatives that render our product candidates obsolete.

Failure to identify further product candidates ultimately suitable for development and commercialization would have an adverse impact on our growth strategy and future business prospects.

Changes in distribution channels for pet therapeutics may make it more difficult or expensive to distribute our products.

Table of Contents

In the United States, pet owners typically purchase their pet therapeutics from their local veterinarians who also prescribe such therapeutics. There is a trend, however, toward increased purchases of pet therapeutics from Internet-based retailers, “big-box” retail stores and other over-the-counter distribution channels, which follows a significant shift in recent years away from the traditional veterinarian distribution channel in the sale of parasiticides and vaccines. It is also possible that pet owners may come to rely increasingly on internet-based animal health information rather than on their veterinarians. We currently expect to market our pet therapeutics directly to veterinarians, so any reduced reliance on veterinarians by pet owners could materially adversely affect our business and prospects. Pet owners also may substitute human health products for pet therapeutics if the human health products are less expensive or more readily available, which substitution also could adversely affect our business.

Legislation has been or may be proposed in the United States or abroad that would require veterinarians to provide pet owners with written prescriptions and disclosures that the pet owner has the right to fill the prescriptions through other means. If enacted, such legislation could lead to a reduction in the number of pet owners who purchase their pet therapeutics directly from veterinarians, which also could adversely affect our business.

While most of our biologic products will be delivered by injection and therefore may be insulated to a degree from competition from non-veterinary dispensing, for our small molecule products, over time, these and other competitive conditions may make us reliant upon Internet-based retailers, “big-box” retail stores or other over-the-counter distribution channels, for which we have no current or planned business relationships, to sell our pet products. Any of these events could materially adversely affect our business and prospects or require us to dramatically change our marketing and distribution strategies, which may not be feasible or successful.

Consolidation of our customers could negatively affect the pricing of our products.

Veterinarians will be our primary customers for any approved products. In recent years, there has been a trend towards the consolidation of veterinary clinics and animal hospitals. If this trend continues, these large clinics and hospitals could attempt to leverage their buying power to obtain favorable pricing from us and other pet therapeutics companies. Any resulting downward pressure on the prices of any of our approved products could have a material adverse effect on our results of operations and financial condition.

We will need to increase the size of our organization and may not successfully manage our growth.

As of February 28, 2019, we had 151 employees, and our management systems currently in place may not be adequate to support our future growth, if any. Our ability to manage our growth effectively will require us to hire, train, retain, manage and motivate additional employees and to implement and improve our operational, financial and management systems. These demands also may require the hiring of additional senior management personnel or the development of additional expertise by our senior management personnel. If we fail to expand and enhance our operational, financial and management systems in conjunction with our potential future growth, it could have a material adverse effect on our business, financial condition and results of operations.

Our research and development relies on evaluations in animals, which is controversial and may become subject to bans or additional regulations.

The evaluation of our product candidates in target animals is required to develop and commercialize our product candidates. Although our animal testing will be subject to GLP and GCP requirements, as applicable, animal testing in the human pharmaceutical industry and in other industries has been the subject of controversy and adverse publicity. Some organizations and individuals have sought to ban animal testing or encourage the adoption of additional regulations applicable to animal testing. To the extent that such bans or regulations are imposed, our research and development activities, and by extension our operating results and financial condition, could be materially adversely affected. In addition, negative publicity about animal practices by us or in our industry could harm our reputation among potential customers for our products.

Table of Contents

Mirataz and, if approved, our product candidates may be marketed in the United States only in the target animals and for the indications for which they are approved, and if we want to expand the approved animals or indications, we will need to obtain additional FDA or USDA approvals, which may not be granted.

We may market or advertise Mirataz and any of our product candidates that are approved only in the specific species and for treatment of the specific indications for which they were approved, which could limit use of the products by veterinarians and pet owners. We intend to develop, promote and commercialize one or more of our current product candidates for other animals and new treatment indications in the future, but there is no assurance whether or at what additional time and expense we will be able to do so. If we do not obtain marketing approvals for other animals or for new indications, our ability to expand our business may be adversely affected.

Use of a drug outside its cleared or approved indications in the animal context is known as extra-label use. Under the Animal Medicinal Drug Use Clarification Act of 1994 (the "AMDUCA"), veterinarians are permitted to prescribe extra-label uses of certain approved animal drugs and approved human drugs for animals under certain conditions. Thus, although veterinarians may in the future prescribe and use human-approved products or our products for extra-label uses, we may not promote our products for extra-label uses. If the FDA determines that any of our marketing activities constitute promotion of an extra-label use, it could subject us to regulatory enforcement, which could have an adverse impact on our reputation and potential liability to us.

The commercial potential of a product candidate in development is difficult to predict. The market for our product candidates, or for the pet therapeutics industry as a whole, is uncertain and may be smaller than we anticipate, which could significantly and negatively impact our revenue, results of operations and financial condition.

It is very difficult to estimate the commercial potential of any of our product candidates because of the emerging nature of our industry as a whole. The pet therapeutics market continues to evolve and it is difficult to predict the market potential for what we believe to be the unmet medical needs of pets. The market will depend on important factors such as safety and efficacy compared to other available treatments, including potential human generic therapeutic alternatives with similar efficacy profiles, changing standards of care, preferences of veterinarians, the willingness of pet owners to pay for such products, and the availability of competitive alternatives that may emerge either during the product development process or after commercial introduction. If the market potential for our product candidates is less than we anticipate due to one or more of these factors, it could negatively impact our business, financial condition and results of operations. Further, the willingness of pet owners to pay for our product candidates, if approved, may be less than we anticipate, and may be negatively affected by overall economic conditions. The current penetration of pet insurance in the United States is low, pet owners are likely to have to pay for our products, if at all, out-of-pocket, and pet owners may not be willing or able to pay for any approved products of ours.

We may acquire other businesses or form joint ventures that may be unsuccessful and could adversely dilute your ownership of our company.

As part of our business strategy, we may pursue acquisitions of other complementary assets and businesses and may also pursue strategic alliances. Our company has no experience in acquiring other assets or businesses and has limited experience in forming such alliances. We may not be able to successfully integrate any acquisitions into our existing business, and we could assume unknown or contingent liabilities or become subject to possible stockholder claims in connection with any related-party or third-party acquisitions or other transactions. We also could experience adverse effects on our reported results of operations from acquisition-related charges, amortization of acquired technology and other intangibles and impairment charges relating to write-offs of goodwill and other intangible assets from time to time following an acquisition. Integration of an acquired company requires management resources that otherwise would be available for ongoing development of our existing business. We may not realize the anticipated benefits of any acquisition, technology license or strategic alliance.

## Table of Contents

To finance future acquisitions, we may choose to issue shares of our common stock as consideration, which would dilute your ownership interest in us. Alternatively, it may be necessary for us to raise additional funds through public or private financings. Additional funds may not be available on terms that are favorable to us and, in the case of equity financings, may result in dilution to our stockholders.

### Risks Related to Intellectual Property

Our commercial success will depend, in part, on obtaining and maintaining patent protection for our products.

In so far as our business strategy is to develop successful human drugs and biologics for veterinary use, our ability to obtain a proprietary intellectual property position for our products is uncertain. We have two issued patents for our IL-31 antibody, but no issued patents Mirataz, Zimeta, or any of our other lead product candidates at this time.

However, we have filed patent applications covering various aspects of our products and product candidates, and the U.S. Patent and Trademark Office (the "USPTO") has issued a patent (Patent No. 10,093,731) for our anti IL-31 antibody. Our other patent applications may never result in the issuance of patents, and/or patents issued to us may be dominated by the patents of third parties, including, for example, patents issued to analogous human drug or biological compositions and their usages. Furthermore, even if they are unchallenged by third parties, our current or future patents, if issued, may not adequately protect our intellectual property or prevent others from designing around their claims. In order to commercialize our products and product candidates in one or more species, we could be required to enter into third party licenses or, if a license is not available on terms that we consider reasonable, we could be required to cease development or commercialization of one or more of our drug or biologic products or product candidates. Thus, if we cannot obtain ownership of issued patents covering our products and product candidates, our business and prospects would be adversely affected.

It is possible that no patents will issue to us to cover an approved product, and/ or that we will have little to no commercial protection against competing products. In such cases, we would then rely solely on other forms of exclusivity, such as regulatory exclusivity provided by the Federal Food, Drug and Cosmetic Act, if available, which may provide less protection to our competitive position.

Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of any patents that issue. On September 16, 2011, the Leahy-Smith America Invents Act (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, redefine prior art, may affect patent litigation, and switch the U.S. patent system from a "first-to-invent" system to a "first-to-file" system. Under a "first-to-file" system, assuming the other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to the patent on an invention regardless of whether another inventor had made the invention earlier. 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 patent applications and the enforcement or defense of any patents that issue, all of which could have a material adverse effect on our business and financial condition.

We may become subject to third parties' claims alleging infringement of patents and proprietary rights or priority of invention, which would be costly, time-consuming and, if successfully asserted against us, delay or prevent the development and commercialization of our current or future product candidates.

There has been substantial litigation regarding patents and other intellectual property rights in the field of therapeutics, as well as patent challenge proceedings, including interference and administrative law proceedings before the United States Patent and Trademark Office, or the USPTO, and oppositions and other

Table of Contents

comparable proceedings in foreign jurisdictions. Under U.S. patent reform laws, new procedures, including inter partes review and post-grant review, were implemented as of March 16, 2013, and the implementation of such reform laws presents uncertainty regarding the outcome of any challenges to our patents, if any. We are aware of a European patent which claims antibodies that bind to dog IL31 with certain functional characteristics, and the patent is currently opposed by multiple parties. The patent may or may not be relevant to one of our product candidates in Europe. There may be issued patents and pending patent applications with claims directed to long-acting or extended-release pharmaceutical formulations and uses of the same small molecules as in some of our small molecule product candidates, and other patents and pending patent applications with claims directed to pharmaceutical formulations and use of human biologics conceptually similar to some of our biologics product candidates. There also may be other patents already issued of which we are unaware that might be infringed by one of our current or future product candidates. Because patent applications can take many years to issue and may be confidential for eighteen months or more after filing, there may be applications now pending of which we are unaware and which may later result in issued patents that may be infringed by our current or future product candidates. There is no assurance that our current or future product candidates will not infringe these or other existing or future third-party patents. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents.

To the extent we become subject to future third-party claims against us or our collaborators, we could incur substantial expenses and, if any such claims are successful, we could be liable to pay substantial damages, including treble damages and attorney's fees if we or our collaborators are found to be willfully infringing a third-party's patents. If a patent infringement suit were brought against us or our collaborators, we or they could be forced to stop or delay research, development, manufacturing or sales of our product or product candidate that is the subject of the suit. Even if we are successful in defending such claims, infringement and other intellectual property claims can be expensive and time-consuming to litigate and divert management's attention from our business and operations. As a result of or in order to avoid potential patent infringement claims, we or our collaborators may be compelled to seek a license from a third party for which we would be required to pay license fees or royalties, or both. Moreover, these licenses may not be available on acceptable terms, or at all. Even if we or our collaborators were able to obtain such a license, the rights may be nonexclusive, which could allow our competitors access to the same intellectual property. Any of these events could harm our business and prospects.

In addition to possible infringement claims against us, we may be subject to third-party preissuance submission of prior art to the USPTO, or become involved in opposition, interference, derivation, reexamination, inter partes review, post-grant review, or other patent office proceedings or litigation in the United States or elsewhere, challenging our patent rights or the patent rights of others. We may also become involved in similar opposition proceedings in the European Patent Office or similar offices in other jurisdictions regarding our intellectual property rights with respect to our products and technology. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our current or future patent rights, if any, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights.

If our efforts to protect the proprietary nature of the intellectual property related to Mirataz or any of our current or future product candidates are not adequate, we may not be able to compete effectively in our market.

We intend to rely upon a combination of regulatory exclusivity periods, patents, trade secret protection, confidentiality agreements, and license agreements to protect the intellectual property related to Mirataz and our current product candidates and our development programs.

Composition-of-matter patents on the active pharmaceutical ingredients in pharmaceutical products, including pet therapeutics, are generally considered to be the strongest form of intellectual property protection, since such patents provide protection without regard to any particular method of use or manufacture. Because

## Table of Contents

all of our current small molecule product candidates are based on generic human drugs, and because there is little, if any, composition of matter patent protection still available for the API of such drugs, we do not seek to obtain such composition-of-matter patents for the API in our small molecule product candidates. In addition, we cannot be certain that all of the composition-of-matter claims in our patent applications for our biologics product candidates will be considered patentable by the USPTO and courts in the United States, or by the patent offices and courts in foreign countries.

Method-of-use patents protect the use of a product for the claimed method. This type of patent does not prevent a competitor from developing or marketing an identical product for an indication that is outside the scope of the issued claims. Moreover, even if competitors do not actively promote their product for our targeted indications for which we may obtain patents, veterinarians may recommend that pet owners use these products extra-label, or pet owners may do so themselves. Although extra-label use may infringe or contribute to the infringement of method-of-use patents, the practice is common and such infringement is difficult to prevent or prosecute.

If the breadth or strength of protection provided by any patent applications or patents we may own, in-license, or pursue with respect to any of our current or future product candidates is threatened, it could threaten our ability to commercialize any of our current or future product candidates. Further, if we encounter delays in our development efforts, the period of time during which we could market any of our current or future product candidates under any patent protection we obtain would be reduced.

Even where laws provide protection or we are able to obtain patents, costly and time-consuming litigation may be necessary to enforce and determine the scope of our proprietary rights, and the outcome of such litigation would be uncertain. Moreover, any actions we may bring to enforce our intellectual property against our competitors could provoke them to bring counterclaims against us, and some of our competitors have substantially greater intellectual property portfolios than we have.

We also rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable or for which we have not filed patent applications, processes for which patents are difficult to enforce and other elements of our product development processes that involve proprietary know-how, information or technology that is not covered by patents. Although we require all of our employees to assign their inventions to us, and endeavor to execute confidentiality agreements with all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information or technology, we cannot be certain that we have executed such agreements with all parties who may have helped to develop our intellectual property or had access to our proprietary information, or that our agreements will not be breached. We cannot guarantee that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. If we are unable to prevent material disclosure of the intellectual property related to our technologies to third parties, we will not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, results of operations and financial condition.

Any disclosure to or misappropriation by third parties of our confidential proprietary information could enable competitors to quickly duplicate or surpass our technological achievements, thus eroding our competitive position in our market.

We may be involved in lawsuits to protect or enforce any patents issued to us, which could be expensive, time-consuming and unsuccessful.

Competitors may infringe any patents that issue to us, or any patents that we may license. To counter infringement or unauthorized use of any patents we may obtain, we may be required to file infringement claims, which can be expensive and time-consuming to litigate. In addition, if we or one of our future collaborators were to initiate legal proceedings against a third party to enforce a patent covering our current product candidates, or one of our future products, the defendant could counterclaim that the patent is invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or





Table of Contents

unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a materially misleading statement, during prosecution. Third parties may also raise similar claims before the USPTO, even outside the context of litigation. The outcome following legal assertions of invalidity and unenforceability is unpredictable. We cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of any current or future patent protection on our current or future product candidates. Such a loss of patent protection could have a material adverse impact on our business. Litigation proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be unsuccessful, it could have an adverse effect on the price of our common stock. Finally, we may not be able to prevent, alone or with the support of our licensors, misappropriation of our trade secrets or confidential information, particularly in countries where the laws may not protect those rights as fully as in the United States. Changes in U.S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our products.

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 involves both technological and legal complexity. Therefore, obtaining and enforcing biopharmaceutical patents is costly, time-consuming and inherently uncertain. In addition, the United States has recently enacted and implemented wide-ranging patent reform legislation. The U.S. Supreme Court has ruled on several patent cases in recent years, 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 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 the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce patents that we might obtain in the future.

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

Filing, prosecuting and defending patents on product and product candidates throughout the world would be prohibitively expensive. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we may obtain patent protection, but where patent enforcement is not as strong as that in the United States. These products may compete with our products in jurisdictions where we do not have any issued or licensed patents and any future patent claims or other intellectual property rights may not be effective or sufficient to prevent them from so 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 biopharmaceuticals, which could make it difficult for us to stop the infringement of our patents, if any, or marketing of competing products in violation of our proprietary rights generally. Further, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. Proceedings to enforce our future patent rights, if

## Table of Contents

any, in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business.

We have one registered US trademark for our current product candidate KINDLET, as well as one registered trademark for KINDLET in Europe, one registered US trademark for our product candidate MIRATAZ, and one registered trademark for MIRATAZ in Norway. Additionally, nine other trademark applications pending in the US, and 48 other trademark applications pending in 14 jurisdictions (i.e., European Union, Iceland, Liechtenstein, Norway, Canada, Australia, New Zealand, China, Egypt, Japan, Morocco, United Kingdom, Saudi Arabia, and United Arab Emirates). We have no registered trademarks for our company name or for our other current product candidates in the United States or any other countries, and failure to obtain those registrations could adversely affect our business.

Seven of our US pending trademark applications have received Notices of Allowance and are awaiting their first use in commerce prior to Registration. Three European trademark applications and one New Zealand trademark application are currently being examined and currently having outstanding oppositions, four trademark applications in each of Canada, Australia, China, Egypt, Europe, Japan, Morocco, New Zealand, Saudi Arabia, and the United Arab Emirates are awaiting examination. Accordingly, while various of our pending trademark applications have been allowed but not yet registered, various other of our pending US and foreign trademark applications have neither been allowed nor registered. During trademark registration proceedings, we may receive rejections. If so, we will have an opportunity to respond, but we may be unable to overcome such rejections. In addition, USPTO and comparable agencies in many foreign jurisdictions may permit third parties to oppose pending trademark applications and to seek to cancel registered trademarks. Such opposition proceedings have been filed and are currently pending for three European trademark applications, and one New Zealand trademark application. Current and future opposition or cancellation proceedings, if any, filed against any of our trademark applications or any registered trademarks may result in cancellation of these trademarks. Moreover, any name we propose to use with our product candidates in the United States must be approved by the FDA or the USDA, regardless of whether we have registered or applied to register as a trademark. The FDA typically conducts a review of proposed product names, including an evaluation of potential for confusion with other product names. If the FDA or the USDA objects to any of our proposed proprietary product names, we may be required to expend significant additional resources in an effort to identify a suitable substitute name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA or USDA.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties.

We have received confidential and proprietary information from third parties. In addition, we employ individuals who were previously employed at other biotechnology, pharmaceutical or animal health companies. We may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise improperly used or disclosed confidential information of these third parties or our employees' former employers. Litigation may be necessary to defend against any such claims. Even if we are successful in defending against any such claims, such litigation could result in substantial cost and be a distraction to our management and employees.

### Risks Related to Government Regulation

Even after receiving regulatory approval of Mirataz and even if we receive regulatory approval for any of our current or future product candidates, we will be subject to ongoing FDA, USDA, and EMA obligations and continued regulatory review, which may result in significant additional expense. Additionally, Mirataz and any product candidates, if approved, will be subject to labeling and manufacturing requirements and could be subject to other restrictions. Failure to comply with these regulatory requirements or the occurrence of unanticipated problems with our products could result in significant penalties.

## Table of Contents

For Mirataz and for any of our current or future product candidates approved by the FDA, USDA, or EMA, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for Mirataz and every other approved product will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, establishment registration, and product listing, as well as continued compliance with GMP, GLP and GCP for any studies that we conduct post-approval. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

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

The FDA, USDA, or EMA's 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, which would adversely affect our business.

Any of our current or future approved products may cause or contribute to adverse medical events that we are required to report to regulatory authorities and, if we fail to do so, we could be subject to sanctions that would materially harm our business.

Certain regulatory authorities will require that we report certain information about adverse medical events regarding an approved product if the product may have caused or contributed to those adverse events. The timing of our obligation to report would be triggered by the date we become aware of the adverse event as well as the nature of the event. We may fail to report adverse events we become aware of within the prescribed timeframe. We may also fail to appreciate that we have become aware of a reportable adverse event, especially if it is not reported to us as an adverse event or if it is an adverse event that is unexpected or removed in time from the use of our product. If we fail to comply with our reporting obligations, the regulatory authorities could take action including criminal prosecution, seizure of our product or delay in approval or clearance of future products.

Legislative or regulatory reforms with respect to pet therapeutics may make it more difficult and costly for us to obtain regulatory clearance or approval of any of our current or future product candidates and to produce, market, and distribute our products after clearance or approval is obtained.

From time to time, legislation is drafted and introduced in the U.S. Congress or EU that could significantly change the statutory provisions governing the testing, regulatory clearance or approval, manufacture, and marketing of regulated products. In addition, FDA and USDA regulations and guidance are often revised or reinterpreted by the FDA and USDA in ways that may significantly affect our business and our products. Similar changes in laws or regulations can occur in other countries. Any new regulations or revisions or reinterpretations of existing regulations in the United States or in other countries may impose additional

## Table of Contents

costs or lengthen review times of any of our current or future product candidates. We cannot determine what effect changes in regulations, statutes, legal interpretation or policies, when and if promulgated, enacted or adopted may have on our business in the future. Such changes could, among other things, require:

- changes to manufacturing methods;
- recall, replacement, or discontinuance of certain products; and
- additional record keeping.

Each of these would likely entail substantial time and cost and could materially harm our financial results. In addition, delays in receipt of or failure to receive regulatory clearances or approvals for any future products would harm our business, financial condition, and results of operations.

Certain of our product candidates currently in development may be classified as controlled substances, the manufacture, use, sale, importation, exportation, and distribution of which are subject to additional regulation by state, federal, and foreign law enforcement and other regulatory agencies.

Certain of our product candidates may be subject to regulation as controlled substances under the federal Controlled Substances Act of 1970, or CSA, and regulations of the U.S. Drug Enforcement Administration, or DEA. The DEA regulates controlled substances as Schedule I, II, III, IV or V substances. Schedule I substances by definition have no established medicinal use and may not be marketed or sold in the United States. An animal drug product may be listed as Schedule II, III, IV or V, with Schedule II substances considered to present the highest risk of abuse and Schedule V substances the lowest relative risk of abuse among such substances.

Various states also independently regulate controlled substances. Though state-controlled substances laws often mirror federal law, because the states are separate jurisdictions, they may separately schedule drugs as well. While some states automatically schedule a drug when the DEA does so, in other states there must be rulemaking or a legislative action. State scheduling may delay commercial sale of any controlled substance drug product for which we obtain federal regulatory approval and adverse scheduling could impair the commercial attractiveness of such product. We would also be required to obtain separate state registrations in order to be able to obtain, handle and distribute controlled substances for target animal studies, and failure to meet applicable regulatory requirements could lead to enforcement and sanctions from the states in addition to those from the DEA or otherwise arising under federal law. For any of our product candidates classified as controlled substances, we and our suppliers, manufacturers, contractors, customers and distributors will be required to obtain and maintain applicable registrations from state, federal and foreign law enforcement and regulatory agencies and comply with state, federal and foreign laws and regulations regarding the manufacture, use, sale, importation, exportation and distribution of controlled substances. There is a risk that DEA regulations may limit the supply of the compounds used in pivotal trials of our product candidates, and, in the future, the ability to produce and distribute our products in the volume needed to meet commercial demand.

Regulations associated with controlled substances govern manufacturing, labeling, packaging, testing, dispensing, production and procurement quotas, recordkeeping, reporting, handling, shipment and disposal. These regulations increase the personnel needs and the expense associated with development and commercialization of product candidates containing controlled substances. The DEA and some states conduct periodic inspections of registered establishments that handle controlled substances. Failure to obtain and maintain required registrations or comply with any applicable regulations could delay or preclude us from developing and commercializing our product candidates containing controlled substances and subject us to enforcement action. The DEA may seek civil penalties, refuse to renew necessary registrations or initiate proceedings to revoke those registrations. In some circumstances, violations could lead to criminal proceedings. Because of their restrictive nature, these regulations could limit commercialization of any of our product candidates that are classified as controlled substances.

Table of Contents

Risks Related to Our Common Stock

The price of our common stock could be subject to volatility related or unrelated to our operations.

Our stock prices and the market prices for securities of biotechnology companies in general have been highly volatile, with recent significant price and volume fluctuations, and may continue to be highly volatile in the future. Since our initial public offering in December 2013, the trading price of our common stock has ranged from a low of \$2.90 to a high of \$26.99. The trading price may continue to be subject to wide fluctuations in response to various factors, some of which are beyond our control. These factors include those discussed previously in this “Risk Factors” section of this Annual Report on Form 10-K and others, such as:

- any delays in, or suspension or failure of, our current and future studies;
- announcements of regulatory approval or disapproval of any of our current or future product candidates or of regulatory actions affecting us or our industry;
- delays in the commercialization of Mirataz or our current or future product candidates;
- manufacturing and supply issues related to our development programs and commercialization of Mirataz and our current or future product candidates;
- quarterly variations in our results of operations or those of our competitors;
- changes in our earnings estimates or recommendations by securities analysts or adverse publicity regarding us or Mirataz or our product candidates;
- announcements by us or our competitors of new product candidates, significant contracts, commercial relationships, acquisitions or capital commitments;
- announcements relating to future development or license agreements including termination of such agreements;
- adverse developments with respect to our intellectual property rights or those of our principal collaborators;
- commencement of litigation involving us or our competitors;
- any major changes in our board of directors or management;
- new legislation in the United States relating to the prescription, sale, distribution or pricing of pet therapeutics;
- product liability claims, other litigation or public concern about the safety of Mirataz or our product candidates or future products;
- market conditions in the animal health industry, in general, or in the pet therapeutics sector, in particular, including performance of our competitors; and
- general economic conditions in the United States and abroad.

In addition, the stock market, in general, or the market for stocks in our industry, in particular, may experience broad market fluctuations, which may adversely affect the market price or liquidity of our common stock. Any sudden decline in the market price of our common stock could trigger securities class-action lawsuits against us. If any of our stockholders were to bring such a lawsuit against us, we could incur substantial costs defending the lawsuit and the time and attention of our management would be diverted from

Table of Contents

our business and operations. We also could be subject to damages claims if we are found to be at fault in connection with a decline in our stock price.

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

Although we have research coverage by securities and industry analysts, if coverage is not maintained, the market price for our common stock may be adversely affected. Our stock price also may decline if any analyst who covers us issues an adverse or erroneous 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 analysts' expectations. If one or more analysts cease coverage of us or fail to regularly publish reports on us, we could lose visibility in the financial markets, which could cause our stock price or trading volume to decline and possibly adversely affect our ability to engage in future financings.

Our quarterly and annual operating results may be volatile and may vary significantly from the estimates and expectations of investors and third parties, including securities or industry analysts, which could cause the market price of our common stock to decline.

It has been our practice not to provide forward-looking sales, revenue or earnings guidance and not to endorse any third party's sales, revenue or earnings estimates, including the estimates of securities or industry analysts. As a result, our actual operating results may be below the expectations of our investors and third parties, including securities or industry analysts. Investors should not rely on any estimates, research or reports published by third parties, including analysts. Furthermore, many factors could cause our revenues and operating results to vary significantly in the future, including, but not limited to, those set out in the "Risk Factors" section of this Annual Report on Form 10-K.

Accordingly, we believe that quarter-to-quarter comparisons of our operating results are not necessarily meaningful. Investors should not rely on the results of one quarter as an indication of our future performance.

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

As of December 31, 2018, our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates beneficially own in the aggregate approximately 41% of our outstanding shares of common stock, excluding shares they may acquire upon exercise of stock options or upon the vesting or restricted stock units they hold. As a result of their stock ownership, these stockholders may have the ability to influence our management and policies and will be able to significantly affect the outcome of matters requiring stockholder approval such as elections of directors, amendments of our organizational documents or approvals of any merger, sale of assets or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders.

If we fail to maintain an effective system of disclosure controls and internal control over financial reporting, our ability to produce timely and accurate financial statements or comply with applicable regulations could be impaired.

As a public company, we are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), the Sarbanes-Oxley Act of 2002, as amended (the "Sarbanes-Oxley Act"), and the listing standards of the NASDAQ Stock Market. We expect that the requirements of these rules and regulations will continue to increase our legal, accounting and financial compliance costs, make some activities more difficult, time consuming and costly, and place significant strain on our personnel, systems and resources.

The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. We are continuing to develop and refine our

Table of Contents

disclosure controls and other procedures that are designed to ensure that information required to be disclosed by us in the reports that we will file with the SEC is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms, and that information required to be disclosed in reports under the Exchange Act is accumulated and communicated to our principal executive and financial officers. We are also continuing to improve our internal control over financial reporting. In order to maintain and improve the effectiveness of our disclosure controls and procedures and internal control over financial reporting, we have expended, and anticipate that we will continue to expend, significant resources, including accounting-related costs and significant management oversight. Our current controls and any new controls that we develop may become inadequate because of changes in conditions in our business. Further, weaknesses in our disclosure controls or our internal control over financial reporting may be discovered in the future. Any failure to develop or maintain effective controls, or any difficulties encountered in their implementation or improvement, could harm our operating results or cause us to fail to meet our reporting obligations and may result in a restatement of our financial statements for prior periods. Any failure to implement and maintain effective internal control over financial reporting also could adversely affect the results of management evaluations of our internal control over financial reporting that we are required to include in our periodic reports that we file with the SEC. Ineffective disclosure controls and procedures and internal control over financial reporting could also cause investors to lose confidence in our reported financial and other information, which would likely have a negative effect on the trading price of our common stock. In addition, if we are unable to continue to meet these requirements, we may not be able to remain listed on the NASDAQ Stock Market.

Any failure to maintain effective disclosure controls and internal control over financial reporting could have a material and adverse effect on our business and operating results and cause a decline in the price of our common stock.

Because we are no longer an "emerging growth company," as defined in the JOBS Act, we must incur additional expenses and devote increased management time to compliance with additional disclosures that are applicable to companies that are not emerging growth companies.

From our initial public offering of common stock until December 31, 2018, we were an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act"). For as long as we were an emerging growth company, we were permitted to take advantage of reduced regulatory and reporting requirements that are otherwise generally applicable to public companies. These included, without limitation, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation and exemptions from the requirements of holding non-binding advisory votes on executive compensation and golden parachute payments. Because we ceased to be an emerging growth company effective as of December 31, 2018, we expect to incur additional expenses and to devote increased management time toward ensuring compliance with those requirements applicable to companies that are not emerging growth companies.

In particular, beginning with this Annual Report on Form 10-K, our independent registered public accounting firm is required to provide an annual attestation report regarding the effectiveness of our internal control over financial reporting. In connection with obtaining this annual attestation report, we may need to undertake various actions, such as implementing additional internal controls and procedures and hiring additional accounting or internal audit staff. Testing and maintaining internal control over financial reporting can divert our management's attention from other matters that are important to the operation of our business. If our independent registered public accounting firm is unable to express an opinion as to the effectiveness of our internal control over financial reporting, investors may lose confidence in the accuracy and completeness of our financial reports and the market price of our common stock could be negatively affected, and we could become subject to investigations by the SEC or other regulatory authorities or to stockholder litigation, which could have an adverse impact on the market price or our common stock and cause us to incur additional expenses.





Table of Contents

During any period in which we continue to be a "smaller reporting company," as defined in Rule 12b-2 of the Exchange Act, by reason of having annual revenues of less than \$100 million and a "public float" of less than \$700 million, we are entitled to elect to comply in our filings with the SEC with some or all of the reduced public company reporting requirements that are available to a smaller reporting company, such as reduced executive compensation disclosure in proxy statements. However, our status as a smaller reporting company will not exempt us from the requirement to provide the annual attestation report from our independent registered public accounting firm regarding the effectiveness of our internal control over financial reporting.

Provisions in our charter documents and under Delaware law could discourage a takeover that stockholders may consider favorable and may lead to entrenchment of management.

Our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that could delay or prevent changes in control or changes in our management without the consent of our board of directors.

These provisions include the following:

- a classified board of directors with three-year staggered terms, which may delay the ability of stockholders to change the membership of a majority of our board of directors;

- no cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates;

- the exclusive right of our board of directors to elect a director to fill a vacancy created by the expansion of the board of directors or the resignation, death or removal of a director, which prevents stockholders from being able to fill vacancies on our board of directors;

- the ability of our board of directors to authorize the issuance of shares of preferred stock and to determine the terms of those shares, including preferences and voting rights, without stockholder approval, which could adversely affect the rights of our common stockholders or be used to deter a possible acquisition of our company;

- the ability of our board of directors to amend our bylaws without obtaining stockholder approval;

- the required approval of the holders of at least two-thirds of the shares entitled to vote at an election of directors to adopt, amend or repeal our bylaws or repeal the provisions of our amended and restated certificate of incorporation regarding the election and removal of directors;

- a prohibition on stockholder action by written consent, which forces stockholder action to be taken at an annual or special meeting of our stockholders;

- the requirement that a special meeting of stockholders may be called only by the chairman of the board of directors, the chief executive officer, the president or the board of directors, which may delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors; and

- advance notice procedures that stockholders must comply with in order to nominate candidates to our board of directors or to propose matters to be acted upon at a stockholders' meeting, which may discourage or deter a potential acquirer from conducting a solicitation of proxies to elect the acquirer's own slate of directors or otherwise attempting to obtain control of us.

These provisions could inhibit or prevent possible transactions that some stockholders may consider attractive.

We are also subject to the anti-takeover provisions contained in Section 203 of the Delaware General Corporation Law. Under Section 203, a corporation generally may not engage in a business combination with

Table of Contents

any holder of 15% or more of its capital stock unless the holder has held the stock for three years or, among other exceptions, the board of directors has approved the transaction.

Our stockholder rights agreement could discourage a takeover that stockholders may consider favorable and may lead to an entrenchment of management.

On May 19, 2017, our board of directors approved and adopted a rights agreement with American Stock Transfer & Trust Company, LLC, as rights agent, and, on July 24, 2017, our stockholders approved the adoption of the rights agreement. The rights agreement is intended to protect our stockholders from coercive or otherwise unfair proposals to acquire control of KindredBio by significantly diluting the ownership interest of any person who acquires at least 20% of our outstanding common stock by providing all other stockholders with the right to acquire additional shares of our preferred stock or common stock at a significant discount. Although the rights agreement is intended to encourage an acquiring person to negotiate a proposed merger or other business combination with our board of directors and management, it could discourage a takeover transaction that stockholders may consider favorable and may lead to an entrenchment of management.

Our amended and restated by-laws designate the Court of Chancery of the State of Delaware as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or other employees.

Our amended and restated by-laws provide that, unless we consent in writing to an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for (1) any derivative action or proceeding brought on our behalf, (2) any action asserting a claim of breach of a fiduciary duty owed by any director, officer or other employee to us or our stockholders, (3) any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law, or (4) any action asserting a claim that is governed by the internal affairs doctrine. Any person purchasing or otherwise acquiring any interest in any shares of our capital stock shall be deemed to have notice of and to have consented to this provision of our amended and restated by-laws. This choice-of-forum provision may limit our stockholders' ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits. Alternatively, if a court were to find this provision of our amended and restated by-laws inapplicable or unenforceable with respect to one or more of the specified types of actions or proceedings, we may incur additional costs associated with resolving such matters in other jurisdictions, which could adversely affect our business and financial condition.

We do not intend to pay dividends on our common stock, and the ability of investors in our common stock to achieve a return on their investment will depend on appreciation in the market price of our common stock.

We currently intend to invest any future earnings to fund our growth and not to pay any cash dividends on our common stock. Since we do not intend to pay dividends, the ability of investors in our common stock to receive a return on their investment will depend on any appreciation in the market price of our common stock. There is no assurance that our common stock will appreciate in price.

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

Under Section 382 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an "ownership change," the corporation's ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes (such as research and development tax credits) to offset its post-change income and taxes may be limited. In general, an "ownership change" occurs if there is a cumulative change in our ownership by "5% shareholders" that exceeds 50 percentage points over a rolling three-year period. Similar rules may apply under state tax laws. If we experience one or more ownership changes as a result of future transactions in our stock, we may be limited in our ability to use our net operating loss carryforwards and other tax assets to reduce taxes owed on the net taxable income that we earn. Any such limitations on the ability to use our net operating loss carryforwards and other tax assets could potentially result in increased future tax liability to us.

Table of Contents

ITEM 1B. UNRESOLVED STAFF COMMENTS.

None.

ITEM 2. PROPERTIES.

Our corporate headquarters are located in Burlingame, California. In April 2014, we entered into new non-cancelable operating leases for 2,145 square feet of laboratory space through May 2017 and 6,900 square feet of office space through November 2017. In January, August and November 2015, we amended our original operating lease for laboratory space to expand the facility with an additional 2,431 square feet, 131 square feet and 123 square feet, respectively, of manufacturing space through May 2017. In February and October 2016, we further amended our original operating lease for laboratory space to further expand the facility with an additional 3,599 square feet and 2,326 square feet, respectively, of quality control and laboratory space through May 2017. In February 2017, we further amended our existing lease for an expansion of an additional 721 square feet of laboratory space. Commencing on June 1, 2017, the non-cancelable operating lease for the entire existing laboratory space of a total 11,476 square feet is extended for another five years through May 2022. In August 2015, we entered into a new non-cancelable operating lease for 3,126 square feet of office space in San Diego, California through September 2019. In April 2017, we renewed our headquarters office lease for 6,900 square feet of office space in Burlingame, California through November 30, 2020 and in June 2017, we amended the lease with an additional 1,190 square feet of office space through November 30, 2020. In October 2018, we entered into a sublease agreement for 5,613 square feet laboratory space next to our current laboratory facility. The sublease agreement expires on March 31, 2019. After that, the lease will continue on a month-to-month basis unless or until terminated by either party, with or without cause, by giving the other party thirty days written notice, provided that the extended term shall not extend beyond December 31, 2019.

On June 21, 2017, we entered into a purchase agreement with Strategic Veterinary Pharmaceuticals, Inc. ("SVP") for the purchase of an approximately 180,000 sq. ft. biologics plant (the "Plant") with clean rooms, utility, equipment, and related quality documentation suitable for small molecule and biologics manufacturing, that is located in Elwood, Kansas. The purchase was finalized on August 7, 2017 upon completion of the diligence period and satisfaction of the conditions of escrow. The Plant was purchased for \$3,750,000, which includes approximately eight acres of land located at 1411 Oak Street, Elwood, Kansas, all improvements located at the Plant, and all personal property and intangible property owned by SVP and located at the Plant or used in connection with the operation of the Plant.

ITEM 3. LEGAL PROCEEDINGS.

We are not currently a party to any material legal proceedings.

ITEM 4. MINE SAFETY DISCLOSURES.

Not applicable.

Table of Contents

## PART II

ITEM MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND  
5. ISSUER PURCHASES OF EQUITY SECURITIES.

## Market Information

Since December 12, 2013, our common stock has been traded on The NASDAQ Capital Market under the symbol "KIN." Prior to December 12, 2013, there was no public trading market for our common stock.

## Common Stock Information

As of February 28, 2019, there were 38,855,154 outstanding shares of our common stock outstanding held of record by approximately 23 holders.

## Dividends

We have never declared or paid any cash dividends on our capital stock. We intend to retain any future earnings and do not expect to pay any dividends in the foreseeable future. Any future determination to declare cash dividends will be made at the discretion of our board of directors, subject to applicable laws, and will depend on a number of factors, including our financial condition, results of operations, capital requirements, contractual restrictions, general business conditions and other factors that our board of directors may deem relevant.

## Equity Compensation Plan Information

The following table sets forth certain information as of December 31, 2018 regarding securities authorized for issuance under our equity compensation plans:

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted-average exercise price of outstanding options, warrants and rights	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))
	(a)	(b)	(c)
Equity compensation plans approved by stockholders:			
2012 Equity Incentive Plan (terminated)	3,041,999	\$6.80	—
2016 Equity Incentive Plan (terminated)	2,376,436	\$7.64	—
2018 Equity Incentive Plan	403,493	\$12.57	2,596,507
Equity compensation plans not approved by stockholders	—	—	—
Total	5,821,928	\$7.54	2,596,507

## Stock Performance Graph

The following line graph presentation compares cumulative total stockholder returns of Kindred Biosciences, Inc. with The NASDAQ Stock Market Index and The NASDAQ Biotechnology Index (the "Peer Index") for the period from December 12, 2013 (the date that our common stock commenced trading on the NASDAQ Capital Market) to December 31, 2018. The graph and table assume that \$100 was invested in each of our common stock, The NASDAQ Stock Market Index and the Peer Index on December 12, 2013, and that all dividends were reinvested. The returns shown are based on historical results and are not intended to suggest future

Table of Contents

performance. The graph shall not be deemed “soliciting material” or to be “filed” with the SEC for purposes of Section 18 of the Exchange Act or otherwise subject to the liabilities under that Section, and shall not be deemed to be incorporated by reference into any of our filings of under the Securities Act of 1933, as amended, or the Exchange Act.

	12/31/13	6/30/14	12/31/14	6/30/15	12/31/15	6/30/16	12/31/16	6/30/17	12/31/17	6/30/18	12/31/18
Kindred Biosciences, Inc.	100.00	166.88	66.70	61.06	30.44	31.69	38.05	76.99	84.60	95.34	98.03
NASDAQ Composite-Total Returns	100.00	106.18	114.75	121.51	122.74	119.47	133.62	153.28	173.22	189.45	168.30
NASDAQ Biotechnology Index	100.00	113.51	134.40	163.69	150.22	114.54	118.15	138.67	143.74	148.26	131.00

## Recent Sales of Securities

On December 12, 2013, our registration statement on Form S-1 (File No. 333-192242) was declared effective by the SEC for our initial public offering pursuant to which we sold an aggregate of 8,625,000 shares of our common stock at a price to the public of \$7.00 per share. On April 8, 2014, we completed a follow-on public offering of 3,450,000 shares of our common stock at a price to the public of \$18.00 per share.

We received net proceeds in the offering of approximately \$54,871,000 after deduction of underwriting discounts and commissions and offering expenses of \$5,504,000 from the initial public offering and approximately \$58,065,000 after deduction of underwriting discounts and commissions and offering expenses of \$4,035,000 from the follow-on public offering.

In June 2017, we completed the sale of 4,501,985 shares of common stock under an At Market Issuance, or ATM, Sales Agreement. Net proceeds, after deducting approximately \$1,038,000 in underwriting commissions and offering costs, were approximately \$28,962,000. In July 2017, we completed an underwritten public offering of common stock. After giving effect to the exercise of the over-allotment option by the underwriters, the total number of shares sold by us in the public offering totaled 3,314,000 shares with gross proceeds of \$24,855,000. Net proceeds, after deducting underwriting commission and offering costs, were approximately \$23,198,000.

Table of Contents

In May 2018, we entered into an ATM Sales Agreement and terminated the Sales Agreement in June 2018 after having sold 188,100 shares, representing gross proceeds of approximately \$1,903,000. Net proceeds, after deducting commission, fees and offering costs, were approximately \$1,758,000.

In June 2018, we completed a public offering of 5,326,314 shares of common stock, which included the underwriter's option to purchase additional shares, at a public offering price of \$9.50 per share for total gross proceeds of approximately \$50,600,000. Net proceeds, after deducting underwriting discounts and commissions and offering expenses were approximately \$47,422,000.

In January 2019, we completed a public offering of 4,847,250 shares of our common stock, which includes the exercise in full by the underwriters of their option to purchase 632,250 additional shares of our common stock, at a public offering price of \$9.50 per share for total gross proceeds of approximately \$46,049,000. Net proceeds, after deducting underwriting discounts and commissions and offering expenses were approximately \$43,118,000.

During the fiscal years ended December 31, 2016 and 2015, we did not sell any securities that were not registered under the Securities Act.

Repurchase of Shares

We did not repurchase any of our shares of capital stock during the fiscal years ended December 31, 2018, 2017 and 2016.

ITEM 6. SELECTED FINANCIAL DATA.

The following selected historical information has been derived from the audited consolidated financial statements of Kindred Biosciences and should be read in conjunction with "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Item 8. Financial Statements and Supplementary Data" included elsewhere in this Annual Report on Form 10-K. The Statement of Operations and Comprehensive Loss Data and the Balance Sheet Data are derived from the audited consolidated financial statements which are included in the Form 10-K. The historical results are not necessarily indicative of the results of operations to be expected in the future.

Table of Contents

(In thousands, except per share amounts)	Years ended December 31,				
	2018	2017	2016	2015	2014
Statement of Operations and Comprehensive Loss Data:					
Net product revenues	\$1,966	\$—	\$—	\$—	\$—
Operating expenses:					
Cost of product sales	324	—	—	—	—
Research and development	26,399	17,665	13,861	19,412	18,694
General and administrative	26,499	13,988	8,308	7,850	8,539
Restructuring costs	—	—	655	—	—
Total operating expenses	53,222	31,653	22,824	27,262	27,233
Loss from operations	(51,256 )	(31,653 )	(22,824 )	(27,262 )	(27,233 )
Interest and other income, net	1,566	774	325	132	94
Net loss	(49,690 )	(30,879 )	(22,499 )	(27,130 )	(27,139 )
Change in unrealized gains or losses on available-for-sale securities	20	—	19	(23 )	(27 )
Comprehensive loss	\$(49,670)	\$(30,879)	\$(22,480)	\$(27,153)	\$(27,166)
Net loss per share, basic and diluted <sup>(1)</sup>	\$(1.60 )	\$(1.23 )	\$(1.13 )	\$(1.37 )	\$(1.44 )
Weighted-average number of common shares outstanding, basic and diluted	31,001	25,084	19,873	19,773	18,782

(In thousands)	As of December 31,				
	2018	2017	2016	2015	2014
Balance Sheet Data:					
Cash and cash equivalents	\$56,302	\$34,813	\$6,687	\$19,992	\$12,969
Short-term investments	17,630	46,207	50,068	53,051	88,058
Long-term investments	—	1,499	1,052	4,590	—
Working capital	64,888	75,790	54,170	70,547	98,652
Total assets	106,482	90,822	61,576	79,619	101,920
Total liabilities	15,275	6,142	3,896	3,248	2,896
Accumulated deficit	(161,670)	(111,980)	(81,101)	(58,602 )	(31,472 )
Total stockholders' equity	91,207	84,680	57,680	76,371	99,024

(1) See Note 13 of the notes to consolidated financial statements included elsewhere in this annual report for an explanation of the method used to calculate the basic and diluted net loss per share attributable to common stockholders and the number of shares used in the computation of the per share amounts.

Table of Contents

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

Management's Discussion and Analysis of Financial Condition and Results of Operations

You should read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements and the related notes and other financial information included elsewhere in this Annual Report on Form 10-K. Some of the information contained in this discussion and analysis, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risks and uncertainties. You should review the "Risk Factors" section of this Annual Report for a discussion of important factors that could cause our actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis or elsewhere in this Annual Report.

Overview

We are a commercial-stage biopharmaceutical company focused on saving and improving the lives of pets. Our mission is to bring to our pets the same kinds of safe and effective medicines that our human family members enjoy. Our core strategy is to identify compounds and targets that have already demonstrated safety and efficacy in humans and to develop therapeutics based on these validated compounds and targets for pets, primarily dogs, cats and horses. We believe this approach will lead to shorter development times and higher approval rates than pursuing new, non-validated compounds and targets. Our current portfolio includes over 20 product candidates in development consisting of both small molecule pharmaceuticals and biologics.

On May 4, 2018, KindredBio received approval of Mirataz<sup>®</sup> (mirtazapine transdermal ointment) and on July 9, 2018, we announced the commercial availability of Mirataz to veterinarians in the United States. We have submitted all major technical sections of the New Animal Drug Application ("NADA"), to the FDA for our second product candidate, Zimeta. In addition, we have multiple other product candidates, including several biologics, in various stages of development. We believe there are significant unmet medical needs for pets, and that the pet therapeutics segment of the animal health industry is likely to grow substantially as new therapeutics are identified, developed and marketed specifically for pets.

Mirataz is the first and only transdermal medication specifically developed and FDA-approved for the management of weight loss in cats. Weight loss is a serious and potentially fatal condition that represents the leading cause of visits to the veterinarian for cats. Mirataz, which is formulated with our proprietary Accusorb<sup>™</sup> technology, is applied topically to the cat's inner ear (pinna) once a day, providing a more attractive application route compared to oral administration. The product is classified as a weight gain drug and can be used in cats with various underlying diseases associated with unintended weight loss.

Business Updates

In July 2018, Mirataz became commercially available to veterinarians in the United States through our network of national and regional distributors, home-delivery distributors, as well as through our direct sales organization. We reported \$2.0 million in net product revenues for the year ended December 31, 2018 related to Mirataz sales. In the second half of 2018, we saw strong clinic penetration as approximately 33% of the approximate 25,000 veterinary clinics in the United States have ordered Mirataz with approximately 56% of participating veterinary clinics placing re-orders in that period. We believe that clinic penetration is an early indicator that veterinarians are pleased to have the first and only transdermal ointment to manage weight loss in cats. In the near term our goal is to focus on brand awareness and convince veterinarians Mirataz is the only solution for management of feline weight loss. In the coming quarters, we expect frequency and duration of therapy to increase as veterinarians become increasingly comfortable with the use of Mirataz and the therapeutic establishes itself in clinical practice.





## Table of Contents

In December 2017, the EMA accepted our Mirataz submission for review. We responded to the EMA's list of questions and expect that Mirataz will be approved by the EMA in 2019. Regulatory approval is subject to the typical risks inherent in such a process.

The FDA has approved the safety and effectiveness technical sections for Zimeta IV for the control of pyrexia (fever) in horses and has indicated it does not have any additional questions or requests from us regarding the CMC technical section. We have filed a NADA for Zimeta IV with the FDA. Pending a positive inspection of the contract manufacturer of the API dipyrone, FDA approval of Zimeta IV is expected in mid-2019. Regulatory approval is subject to the typical risks inherent in such a process. Preparations for the commercial launch remain on track.

The pivotal field effectiveness study for Zimeta Oral has been completed with positive results. The target animal safety study is also complete, and Zimeta Oral was found to be well-tolerated. We have transferred the product to the commercial manufacturer and are in discussions with the FDA and EMA regarding the data required to show bioequivalence to the previously manufactured product. Zimeta Oral, which is a proprietary oral gel, is expected to expand use of the drug and build upon the success of Zimeta IV.

On October 30, 2018, we reported positive topline results from our pilot effectiveness study of KIND-016, a fully caninized, high-affinity monoclonal antibody targeting interleukin-31 (IL-31), for the treatment of atopic dermatitis in dogs. The study was a randomized, blinded, placebo-controlled, pilot laboratory study that enrolled 32 dogs to assess the effectiveness of KIND-016 at three doses. A single dose of KIND-016 was administered on day 0 and itching was induced at weeks 1, 2, 3, 4, 6, and 8 with an injection of canine IL-31. Our IL-31 antibody resulted in statistically significant reductions in pruritus ( $p < 0.0001$  to  $p < 0.05$ ) across all dose groups and was sustained for 6 to 8 weeks, with a clear dose response. The reduction in the itching score was as high as 86.1%. Based on a preliminary review of the safety data, the drug appears to be well tolerated. In addition, we announced that the U.S. Patent and Trademark Office has issued a patent (Patent No. 10,093,731) for KindredBio's anti-IL31 antibody.

We are also currently conducting a pilot field effectiveness study for our IL-31 antibody. We continue to expect pilot efficacy results for our canine anti-IL4/IL13 SINK molecule in 2019 and are advancing other programs for atopic dermatitis.

Atopic dermatitis is an immune-mediated inflammatory skin condition in dogs. It is the leading reason owners take their dog to the veterinarian, and the current market size is close to \$600 million annually and growing rapidly. KindredBio is pursuing a multi-pronged approach toward atopic dermatitis, with a portfolio of promising biologics.

On January 14, 2019, we reported positive topline results from the pilot field effectiveness study of our enhanced version of epoCat™ (long-acting feline recombinant erythropoietin) for the treatment of anemia in cats. Anemia is a common condition in older cats which is often associated with chronic kidney disease resulting in decreased levels of endogenous erythropoietin. epoCat is a recombinant feline erythropoietin that has been specially engineered by us with a prolonged half-life, intended to be administered once-monthly. Erythropoietin is an endogenous protein that regulates and stimulates production of red blood cells. In the study, which enrolled 23 cats with anemia secondary to chronic kidney disease, epoCat rapidly increased mean hematocrit, with statistically significant improvement as early as Week 1 ( $p < 0.0001$ ). The effect was sustained, with continued statistically significant improvement at Weeks 2, 3, 4, 5, and 6 ( $p < 0.0001$  at each visit). Compared to baseline, the mean of peak percent improvement in hematocrit by Week 6 was 55.4%.

In addition, 95.5% of the 22 evaluable patients achieved treatment success over the 6-week treatment period, defined prospectively as either a 30% increase in hematocrit value over baseline or the hematocrit value reaching normal range. Furthermore, epoCat resulted in statistically significant improvements over baseline ( $p < 0.01$  to  $p < 0.05$ ) across

all three health-related quality of life (QoL) domains, namely Vitality, Comfort, and Emotional Wellbeing, as measured by a validated QoL instrument. Based on a preliminary

## Table of Contents

review of the safety data, the drug appears to be well tolerated. We plan to commence a pivotal study this year and are currently in discussions with the FDA regarding study design. The FDA has agreed to accept hematocrit as the primary endpoint for the pivotal study.

We are also developing KIND-014 for the treatment of equine gastric ulcers in horses. In May 2018, we announced positive results from its pilot field effectiveness study of KIND-014 for the treatment of gastric ulcers in horses. This study was a randomized, single-blind, placebo-controlled, dose-ranging study that enrolled 53 horses (40 horses in three KIND-014 groups with different doses and dosing schedules, 13 horses in the placebo group). The objective was to determine the effective dose of KIND-014 for the treatment of gastric ulcers in horses. At Week 3, the gastric ulcer resolution (gastric ulcer score=0) rates in all three KIND-014 groups were statistically significantly higher than the placebo group (p-values < 0.05). We have selected a formulation for development and anticipate moving into a pivotal field study in 2019.

The pilot field effectiveness study of KIND-011, our anti-TNF monoclonal antibody, targeting sick or septic foals has been completed with positive results. We are now in discussions with the FDA regarding the pivotal study design. Sepsis in foals can cause up to 50% mortality and is an important unmet medical need. There is currently no FDA-approved therapy. We intend to continue field studies during the 2020 foaling season, following discussion with the FDA regarding the development plan.

We have initiated a pilot field effectiveness of our anti-TNF monoclonal antibody targeting inflammatory bowel disease in dogs. This study is anticipated to report data in 2019.

In addition to the product candidates discussed above, we are in the early stages of development for multiple additional indications, including interleukin antibodies and canine checkpoint inhibitors, with the potential to attain approval for one or more products annually for several years. In all, we have over 20 programs for various indications for dogs, cats, and horses. We plan to commercialize our products in the United States through a direct sales force complemented by selected distributor relationships, and in the EU through distributors and other third parties.

We have constructed a Good Manufacturing Practice, or GMP, biologics manufacturing plant in Burlingame, CA which is fully commissioned. We have proceeded to GMP manufacturing of our feline erythropoietin product candidate in January 2018. In addition, construction of our biologics manufacturing lines in our manufacturing plant in Elwood, Kansas is expected to be completed by mid-2019. The Elwood facility includes approximately 180,000 square feet with clean rooms, utility, equipment, and related quality documentation suitable for biologics and small molecule manufacturing.

We are a commercial-stage company with one product just recently approved for marketing and sale. We have incurred significant net losses since our inception. We incurred cumulative net losses of \$161.7 million through December 31, 2018. These losses have resulted principally from costs incurred in connection with investigating and developing our product candidates, research and development activities and general and administrative costs associated with our operations.

Historically, our funding has been a combination of private and public offerings, including our initial public offering in December 2013 that provided us with net proceeds of \$54.9 million and a follow-on public offering in April 2014 that provided us with net proceeds of \$58.1 million. During the six months ended June 30, 2017, we completed the sale of 4,501,985 shares of common stock under an At Market Issuance Sales Agreement, or ATM, that provided us with net proceeds of \$29.0 million, after deducting commissions and offering costs. In July 2017, we completed an underwritten public offering of 3,000,000 shares of common stock and in August 2017, we completed the closing of the exercise of the underwriter's option to purchase an additional 314,000 shares of common stock, both at an offering price of \$7.50 per share. Net proceeds, after deducting underwriting commission and offering costs, were

approximately \$23.2 million. In May 2018, we entered into an ATM, but terminated that ATM in June 2018 after having sold 188,100 shares, representing net proceeds of approximately \$1.8 million, after deducting commission, fees and offering costs. On June 22, 2018, we completed a public offering of 5,326,314 shares of common stock at a public offering price of \$9.50

## Table of Contents

per share. Net proceeds after deducting underwriting discounts and commissions and offering expenses were \$47.4 million. As of December 31, 2018, we had cash, cash equivalents and investments in available-for-sale securities of \$73.9 million.

On January 23, 2019, we completed a public offering of 4,847,250 shares of our common stock, which included the exercise in full by the underwriters of their option to purchase 632,250 additional shares of our common stock, at a public offering price of \$9.50 per share for total gross proceeds of approximately \$46 million. Net proceeds, after deducting underwriting discounts and commissions and offering expenses were approximately \$43.1 million.

For the foreseeable future, we expect to continue to incur losses, which will increase significantly from historical levels as we expand our product development activities, seek regulatory approvals for our product candidates and begin to commercialize them if they are approved by the Center for Veterinary Medicine branch, or CVM, of the FDA, the U.S. Department of Agriculture, or USDA, or the European Medicines Agency, or EMA. If we are required to further fund our operations, we expect to do so through public or private equity offerings, debt financings, corporate collaborations and licensing arrangements. We cannot assure you that such funds will be available on terms favorable to us, if at all. Arrangements with collaborators or others may require us to relinquish rights to certain of our technologies or product candidates. In addition, we may never successfully complete development of, obtain adequate patent protection for, obtain necessary regulatory approval, or achieve commercial viability for any other product candidates besides Mirataz. If we are not able to raise additional capital on terms acceptable to us, or at all, as and when needed, we may be required to curtail our operations, and we may be unable to continue as a going concern.

## Financial Overview

### Revenues

Our revenues consists of net sales of our first product, Mirataz.

### Cost of Product Revenues

Cost of product revenues consists primarily of the cost of direct materials, direct labor and overhead costs associated with manufacturing, inbound shipping and other third-party logistics costs.

### Research and Development Expense

All costs of research and development are expensed in the period incurred. Research and development costs primarily consist of contracted development costs, manufacturing costs, salaries and related expenses for personnel, stock-based compensation expense, regulatory, outside service providers, professional and consulting services, travel costs and materials used in clinical trials and research and development.

We are currently pursuing over 20 indications. We typically use our employee and infrastructure resources across multiple development programs. We track outsourced development costs by development compound but do not allocate personnel or other internal costs related to development to specific programs or development compounds as these expenses are included in personnel costs and other internal costs.

### Selling, General and Administrative Expense

Selling, general and administrative expense consists primarily of personnel costs, including salaries, related benefits and stock-based compensation for employees, consultants and directors. Selling, general and administrative expenses also include rent and other facilities costs, conference and sponsorship activities, travel costs, professional fees for legal, accounting and tax, information technology services, business development activities, costs associated with being a public company and other general and commercial business services.



## Table of Contents

### Interest and Other Income, Net

Consist of interest earned on our cash, cash equivalents and short-term investments and asset disposals.

### Income Taxes

As of December 31, 2018, we had net operating loss carryforwards for federal and state income tax purposes of \$139,843,000 and \$139,763,000, respectively, which will begin to expire in fiscal year 2032. Our management has evaluated the factors bearing upon the realizability of our deferred tax assets, which are comprised principally of net operating loss carryforwards. Our management concluded that, due to the uncertainty of realizing any tax benefits as of December 31, 2018, a valuation allowance was necessary to fully offset our deferred tax assets.

### Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States, or U.S. GAAP. The preparation of our consolidated financial statements and related disclosures requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities, and revenue, costs and expenses and related disclosures during the reporting periods. On an ongoing basis, we evaluate our estimates and judgments, including those described below. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are more fully described in Note 2 of the notes to our consolidated financial statements appearing elsewhere in this document, we believe that the estimates and assumptions involved in the following accounting policies may have the greatest potential impact on our consolidated financial statements.

### JOBS Act

On April 5, 2012, the Jumpstart Our Business Startups Act, or the JOBS Act, was signed into law. The JOBS Act contains provisions that, among other things, reduce certain reporting requirements for an "emerging growth company." As an "emerging growth company" we elected not to take advantage of the extended transition period afforded by the JOBS Act for the implementation of new or revised accounting standards, and as a result, we complied with new or revised accounting standards on the relevant dates on which adoption of such standards is required for non-emerging growth companies. Section 107 of the JOBS Act provides that our decision not to take advantage of the extended transition period is irrevocable.

We relied on other exemptions and reduced reporting requirements provided by the JOBS Act which state, among other things, that we are not required to (i) provide an auditor's attestation report on our system of internal control over financial reporting or (ii) comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the consolidated financial statements. The five-year exemption period following the completion of our initial public offering has ended and we have complied with the reporting requirements for the year ended December 31, 2018.

### Revenue Recognition

Our revenues consist of product revenues resulting from the sale of Mirataz for the management of weight loss in cats. We account for a contract with a customer when there is a legally enforceable contract



## Table of Contents

between us and our customer, the rights of the parties are identified, the contract has commercial substance, and collectability of the contract consideration is probable. Our customers could either be distributors who subsequently resell our products to third parties such as veterinarians, clinics or animal hospitals or the third parties themselves.

In accordance with ASC 606, we applied the following steps to recognize revenue for the sale of Mirataz that reflects the consideration to which we expect to be entitled to receive in exchange for the promised goods (See Note 2):

1. Identify the contract with a customer
2. Identify the performance obligations in the contract
3. Determine the transaction price
4. Allocate the transaction price to the performance obligations
5. Determine the satisfaction of performance obligation

## Product Returns

Consistent with the industry practice, we generally offer customers a limited right of return of damaged or expired product that has been purchased directly from us. Our return policy generally allows customers to receive credit for expired products within 90 days after the product's expiration date. We estimate the amount of our product revenues that may be returned by our customers and record these estimates as a reduction of product revenues in the period the related product revenues are recognized, as well as within accrued liabilities, in the consolidated balance sheets.

## Fair Value Measurements

We invest our cash in money market funds, cash deposits and debt instruments of the U.S. government agency securities. In the current market environment, the assessment of the fair value of the debt securities can be difficult and subjective. Accounting Standards Codification, or ASC, 820, "Fair Value Measurements and Disclosure" standard describes a fair value hierarchy based on three levels of inputs, of which the first two are considered observable and the last unobservable, that may be used to measure fair value which are the following:

- Quoted prices  
in active  
markets for  
Level 1 identical  
assets or  
liabilities;
- Level 2 Inputs other  
than Level 1  
that are  
observable,  
either directly  
or indirectly,  
such as quoted  
prices for  
similar assets  
or liabilities;  
quoted prices  
in markets  
that are not  
active; or  
other inputs

that are  
observable or  
can be  
corroborated  
by observable  
market data  
for  
substantially  
the full term  
of the assets  
or liabilities;  
and  
Unobservable  
inputs that are  
supported by  
little or no  
market  
activity and  
that are  
significant to  
the fair value  
of the assets  
or liabilities.

Level 3

The  
determination  
of fair value  
for Level 3  
instruments  
requires the  
most  
management  
judgment and  
subjectivity.

#### Inventories

We value inventory at the lower of cost or net realizable value. We determine the cost of inventory using the standard-cost method, which approximates actual cost based on a first-in, first-out method. We analyze our inventory levels quarterly and write down inventory subject to expire in excess of expected requirements, or that has a cost basis in excess of its expected net realizable value. These inventory related costs are recognized as cost of product revenues on the accompanying consolidated statements of operations. Currently our inventory consists of finished goods only.

#### Research and Development

As part of the process of preparing our consolidated financial statements, we are required to estimate accrued research and development expenses. Examples of estimated accrued expenses include fees paid to

## Table of Contents

vendors and clinical sites in connection with our pivotal studies, to CROs in connection with our toxicology studies, and to contract manufacturers in connection with the production of API and formulated drug.

We review new and open contracts and communicate with applicable internal and vendor personnel to identify services that have been performed on our behalf and estimate the level of service performed and the associated costs incurred for the service when we have not yet been invoiced or otherwise notified of the actual cost for accrued expenses. The majority of our service providers invoice us monthly in arrears for services performed or as milestones are achieved in relation to our contract manufacturers. We make estimates of our accrued expenses as of each balance sheet date.

We base our accrued expenses related to pivotal studies on our estimates of the services received and efforts expended pursuant to contracts with vendors, our internal resources, and payments to clinical sites based on enrollment projections. The financial terms of the vendor agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. Payments under some of these contracts depend on factors such as the successful enrollment of animals and the completion of development milestones. 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 related expense accrual accordingly on a prospective basis. If we do not identify costs that have been incurred or if we underestimate or overestimate the level of services performed or the costs of these services, our actual expenses could differ from our estimates. To date, we have not made any material adjustments to our estimates of accrued research and development expenses or the level of services performed in any reporting period presented.

### Stock-Based Compensation

We measure stock-based awards granted to employees and directors at fair value on the date of grant and recognize the corresponding compensation expense of the awards, net of estimated forfeitures, over the requisite service periods, which correspond to the vesting periods of the awards. Generally, we issue stock-based awards with only service-based vesting conditions, and record compensation expense for these awards using the straight-line method. Our intention is to grant stock-based awards with exercise prices equivalent to the fair value of our common stock as of the date of grant.

Our accounting policy for equity instruments issued to consultants and vendors in exchange for goods and services follows Financial Accounting Standards Board ("FASB") guidance. All transactions in which goods or services are the consideration received for the issuance of equity instruments are accounted for based on the fair value of the consideration received or the fair value of the equity instrument issued, whichever is more reliably measurable. The measurement date of the fair value of the equity instrument issued is the earlier of the date on which the counterparty's performance is complete or the date at which a commitment for performance is reached. Non-employee grants of stock-based compensation, except those grants to non-employee, shareholder-approved Board Members, were previously fair valued under ASC 505-50 "Equity-Based Payments to Non-employees". In Q2 2018, we adopted ASU 2018-07 "Compensation - Stock Compensation (Topic 718) - Improvements to Non-Employee Share-Based Payment Accounting and non-employee grants are now fair valued in the same manner as employee grants. The fair value of each stock-based award is estimated using the Black-Scholes option-pricing model. The expected volatility is based on the historic volatility of our own stock. The expected terms of our awards have been determined utilizing the "simplified" method, since our historical experience for option grants is not relevant to our expectations for recent grants. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. Expected dividend yield is zero, based on the fact that we have never paid cash dividends and do not expect to pay any cash dividends in the foreseeable future. See Note 9 in Notes to Consolidated Financial Statements for further information.

Table of Contents

## Results of Operations

The following table summarizes the results of our operations for the periods indicated:

(In thousands, except per share amounts)	Years Ended December 31,		
	2018	2017	2016
Net product revenues	\$1,966	\$—	\$—
Operating expenses:			
Cost of product revenues	324	—	—
Research and development	26,399	17,665	13,861
General and administrative	26,499	13,988	8,308
Restructuring costs	—	—	655
Total operating expenses	53,222	31,653	22,824
Loss from operations	(51,256 )	(31,653 )	(22,824 )
Interest and other income, net	1,566	774	325
Net loss	(49,690 )	(30,879 )	(22,499 )
Change in unrealized gains or losses on available-for-sale securities	20	—	19
Comprehensive loss	\$(49,670)	\$(30,879)	\$(22,480)
Net loss per share attributable to common stockholders, basic and diluted	\$(1.60 )	\$(1.23 )	\$(1.13 )
Weighted-average number of common shares outstanding, basic and diluted	31,001	25,084	19,873

## Revenues

We adopted ASC 606 in the first quarter of our fiscal year that began on January 1, 2018. This new standard replaced the previous revenue recognition guidance in U.S. GAAP. No prior period adjustments were needed as our first commercial shipments began in July 2018. Our revenues consist of product revenue resulting from the sale of Mirataz™ (mirtazapine transdermal ointment) for the management of weight loss in cats. We account for a contract with a customer when there is a legally enforceable contract between us and our customer, the rights of the parties are identified, the contract has commercial substance, and collectability of the contract consideration is probable. Our revenues are measured based on the consideration specified in the contract with each customer, net of product returns, discounts and allowances.

The following table presents revenues and cost of product revenues for the year ended December 31, 2018 (in thousands):

Table of Contents

	Years Ended		
	2018	2017	2016
Gross product revenues	\$2,027	\$ —	—
Less allowance for product returns	(61 )	—	—
Net product revenues	1,966	—	—
Cost of product revenues	(324 )	—	—
Gross profit	\$1,642	\$ —	—

**Concentrations of credit risk**

Our revenue was generated entirely from sales within the United States. Our product sales to four large distributors, namely MWI, Henry Schein (now Covetrus), Patterson and Midwest each accounted for more than 10% of total revenues for the year ended December 31, 2018. On a combined basis, in 2018, these distributors accounted for approximately 91% of our product sales in the United States.

**Product returns**

Our return policy generally allows customers to receive credit for expired products within 90 days after the product's expiration date. We currently estimate product return liabilities of 3% of gross revenue using probability-weighted available industry data and data provided by our distributors such as the inventories remaining in the distribution channel. Adjustments will be made in the future if actual results vary from our estimates.

**Accounts receivable and allowance for doubtful accounts**

Accounts receivable are stated at their carrying values, net of any allowances for doubtful accounts. Accounts receivable consist primarily of amounts due from distributors, for which collection is probable based on the customer's intent and ability to pay. Receivables are evaluated for collection probability on a regular basis and an allowance for doubtful accounts is recorded, if necessary. We have no allowance for doubtful accounts as of December 31, 2018 as our analysis did not uncover any collection risks.

**Research and Development Expense**

All costs of research and development are expensed in the period incurred. Research and development costs consist primarily of salaries and related expenses for personnel, stock-based compensation expense, fees paid to consultants, outside service providers, professional services, travel costs and materials used in clinical trials and research and development. We are currently pursuing multiple product candidates for over 20 indications. We typically use our employee and infrastructure resources across multiple development programs.

Research and development expense was as follows for the periods indicated:

Table of Contents

(In thousands except percentages)	Years ended December 31,			Annual percent change		
	2018	2017	2016	2018/2017	2017/2016	
Payroll and related	\$10,204	\$6,517	\$5,794	57%	12%	%
Consulting	2,360	1,669	1,204	41%	39%	%
Field trial costs, including materials	3,915	3,675	3,015	7%	22%	%
Stock-based compensation	1,746	1,650	1,464	6%	13%	%
Other	8,174	4,154	2,384	97%	74%	%
	\$26,399	\$17,665	\$13,861	49%	27%	%

During the year ended December 31, 2018, research and development expense related primarily to advancing the development of Zimeta Oral, KIND-014, KIND-016 and epoCat. We also increased our spending in biologics as we continue to advance additional potential candidates in our biologics program. In addition, we have increased the headcount of our in-house team to focus on the GMP manufacturing process for our potential biologic candidates.

Research and development expenses for the year ended December 31, 2018 increased by 49% to \$26.4 million compared with \$17.7 million for the same period in 2017. Payroll and related expenses increased by \$3.7 million due to increase in headcount as we advance our development programs and our biologics manufacturing for epoCat and KIND-016, studies including lab supplies increased by \$2.5 million. Higher regulatory and research fees, consulting, depreciation, rent as a result of expanded lab spaces and other facility costs as well as field trial costs also contributed to the increase in expenses. Outsourced research and development expense related to our Zimeta (IV and Oral), KIND-014, Mirataz and other product development programs for the year ended December 31, 2018 were \$1.4 million, \$0.7 million, \$0.3 million and \$2.0 million, respectively.

Research and development expenses for the year ended December 31, 2017 increased by 27% to \$17.7 million compared with \$13.9 million for the same period in 2016. Payroll and related expenses increased by \$0.7 million due to increase in headcount as we advance our biologics programs. Our consulting and field trial costs increased by \$0.5 million and \$0.7 million, respectively, due to the pivotal field effectiveness study of Zimeta Oral for the treatment of fever in horses. In addition, stock-based compensation expense increased by approximately \$0.2 million. Other costs have increased by \$1.8 million as we have increased our rented lab spaces and incurring higher maintenance and depreciation expenses, as well as higher biologics manufacturing and lab supplies expenses. Outsourced research and development expense related to our Zimeta (IV and Oral), KIND-014, Mirataz and other product development programs for the year ended December 31, 2017 were \$1.7 million, \$0.6 million, \$0.3 million and \$1.9 million, respectively.

We expect research and development expense to increase for the foreseeable future as we continue to further develop our biologics programs and small molecule compounds. In addition, we expect biologics manufacturing expenses to increase due to the manufacture of IL-31 and epoCat antibodies for our pivotal field studies. Due to the inherently unpredictable nature of our development, we cannot reasonably estimate or predict the nature, specific timing or estimated costs of the efforts that will be necessary to complete the development of our product candidates.

#### Selling, General and Administrative Expense

The composition of general and administrative expense was as follows for the periods indicated:

Table of Contents

(In thousands except percentages)	Years ended December 31,			Annual percent change		
	2018	2017	2016	2018/2017	2017/2016	
Payroll and related	\$9,498	\$4,391	\$2,583	116%	70%	%
Consulting, professional and legal fees	3,561	2,011	996	77%	102%	%
Stock-based compensation	4,531	3,557	2,164	27%	64%	%
Corporate and marketing expenses	4,420	2,084	1,468	112%	42%	%
Other	4,489	1,945	1,097	131%	77%	%
	\$26,499	\$13,988	\$8,308	89%	68%	%

Selling, general and administrative expenses for the year ended December 31, 2018 increased by 89% to \$26.5 million compared with \$14.0 million for the same period in 2017. The overall increase is primarily the result of KindredBio's transition from a development stage to a commercial stage company. Headcount increase was due to the expansion of our commercial organization and administrative personnel to support the company's growth. Sales and marketing expenses account for a big component of the increase due to the launch of Mirataz. Consulting, legal and professional fees as well as facilities costs increased as we became a commercial stage organization. Higher stock-based compensation expense also contributed to the increase.

General and administrative expenses for the year ended December 31, 2017 increased by 68% to \$14.0 million compared with \$8.3 million for the same period in 2016. The increase in general and administrative expense was related to increased headcount including higher marketing and corporate expenses as we have initiated pre-launch activities and build-out of a small commercial team. In addition, higher stock-based compensation expense along with higher consulting and professional fees as we build out our corporate infrastructure, also contributed to the increase in expenses.

We expect selling, general and administrative expense to increase going forward as we continue to expand our workforce, focus on the long-term success of Mirataz and the future launch of Zimeta IV.

**Restructuring Costs**

A restructuring charge of \$655,000 in the first quarter of 2016 were fully paid as of March 2016. There was no further restructuring charge after that.

**Interest and Other Income, Net**

(In thousands)	Years ended December 31,		
	2018	2017	2016
Interest and other income, net	\$1,566	\$774	\$325

The increase of approximately \$792,000 in 2018 compared to 2017 and \$449,000 in 2017 compared to 2016 was due to higher interest income from higher cash balances as a result of the completion of our ATM financings and follow-on public offerings of common stock in 2018 and 2017. Better market performance also contributed in higher interest income in 2018.

**Liquidity and Capital Resources**

We have incurred losses and negative cash flows from operations since our inception in September 2012. We incurred net losses of \$49.7 million, \$30.9 million and \$22.5 million for the years ended December 31, 2018, 2017, and 2016, respectively. These losses have resulted primarily from costs incurred in research and development activities and selling, general and administrative costs associated with our operations. As of December 31, 2018, we had an accumulated deficit of \$161.7 million.

Table of Contents

During the year ended December 31, 2013, we raised approximately \$67.0 million, net of offering costs, primarily in connection with our initial public offering and through the sale of preferred stock (subsequently converted to common stock at the time of our initial public offering). In April 2014, we completed a follow-on public offering of common stock, resulting in net proceeds of approximately \$58.1 million. In 2017, we completed the sale of common stock under an At Market Issuance Sales Agreement, or the Sales Agreement as well as an underwritten public offering, resulting in net proceeds of approximately \$29.0 million and \$23.2 million, respectively. In May 2018, we entered into another Sales Agreement, but terminated the Sales Agreement in June 2018 after having sold 188,100 shares, representing gross proceeds of approximately \$1.9 million. Net proceeds, after deducting commission, fees and offering costs, were approximately \$1.8 million. Also, in June 2018 we completed a public offering of 5,326,314 shares of common stock, which included the underwriter's option to purchase additional shares, at a public offering price of \$9.50 per share for total gross proceeds of approximately \$50.6 million. Net proceeds, after deducting underwriting discounts and commissions and offering expenses were approximately \$47.4 million. In January 2019, we completed a public offering of 4,847,250 shares of our common stock, which includes the exercise in full by the underwriters of their option to purchase 632,250 additional shares of the Company's common stock, at a public offering price of \$9.50 per share for total gross proceeds of approximately \$46.0 million. Net proceeds, after deducting underwriting discounts and commissions and offering expenses were approximately \$43.1 million. As of December 31, 2018, we had cash, cash equivalents and investments in available-for-sale securities of approximately \$73.9 million and together with the \$43.1 million raised in January 2019, we believe are sufficient to fund our planned operations for at least the next 24 months.

## Cash Flows

The following table shows a summary of our cash flows for the periods set forth below:

(In thousands)	Years ended December 31,		
	2018	2017	2016
Cash flows used in operating activities	\$(45,035)	\$(21,878)	\$(18,781)
Cash flows provided by (used in) investing activities	\$16,604	\$(2,668)	\$5,314
Cash flows provided by financing activities	\$49,920	\$52,672	\$162

## Net cash used in operating activities

During the year ended December 31, 2018, net cash used in operating activities was \$45.0 million. Our net loss of \$49.7 million included non-cash charges primarily in the form of share-based compensation of \$6.3 million, depreciation expense of \$805,000 and accretion of discounts and amortization of premiums on investments of \$179,000. The non-cash charges were partly impacted by changes in operating assets and liabilities that resulted in approximately \$2.3 million of cash used in operating activities.

During the year ended December 31, 2017, net cash used in operating activities was \$21.9 million. Our net loss of \$30.9 million included non-cash charges primarily in the form of share-based compensation of \$5.2 million, depreciation expense of \$475,000 and accretion of discounts and amortization of premiums on investments of \$162,000. The non-cash charges were partly impacted by changes in operating assets and liabilities that resulted in approximately \$3.1 million of cash provided by operating activities.

During the year ended December 31, 2016, net cash used in operating activities was \$18.8 million. Our net loss of \$22.5 million included non-cash charges primarily in the form of share-based compensation of \$3.6 million, depreciation expense of \$155,000 and accretion of discounts and amortization of premiums on investments of \$274,000. The non-cash charges were partly offset by changes in operating assets and liabilities that resulted in \$341,000 of cash used in operating activities.



## Table of Contents

### Net cash provided by (used in) investing activities

During the year ended December 31, 2018, net cash provided by investing activities was \$16.6 million, which resulted from \$30.3 million related to the proceeds of sales and maturities of investments, net of purchases of investments, offset by \$20.1 million in purchases of property and equipment, of which \$6.2 million is included in accounts payable and accrued liabilities at December 31, 2018, also positively affected by sale of equipment of \$248,000.

During the year ended December 31, 2017, net cash used in investing activities was \$2.7 million, which resulted from \$3.3 million related to the proceeds of sales and maturities of investments, net of purchases of investments, offset by \$6.2 million in purchases of property and equipment, of which \$0.3 million is included in accounts payable and accrued liabilities at December 31, 2017.

During the year ended December 31, 2016, net cash provided by investing activities was \$5.3 million, which resulted from \$6.3 million related to the maturities of investments, net of purchases of investments, partially offset by \$1.6 million in purchases of property and equipment, of which \$0.7 million is included in accounts payable and accrued liabilities at December 31, 2016.

### Net cash provided by financing activities

During the year ended December 31, 2018, net cash provided by financing activities consisted of approximately \$49.2 million in net proceeds from the sale of common stock through an ATM and follow-on public offering, and approximately \$1.0 million from the exercise of stock options and purchase of ESPP shares, offset by payment of \$247,000 related to restricted stock awards tax liability on net settlement.

During the year ended December 31, 2017, net cash provided by financing activities consisted of approximately \$52.2 million in net proceeds from the sale of common stock through an ATM and follow-on public offering, and approximately \$0.5 million from the exercise of stock options and purchase of ESPP shares.

During the year ended December 31, 2016, net cash provided by financing activities consisted of proceeds from stock option exercises and purchase of ESPP shares.

### Future Funding Requirements

We anticipate that we will continue to incur losses for the next several years due to expenses relating to:

- pivotal trials of our product candidates;
- toxicology studies for our product candidates;
- biologics manufacturing; and
- commercialization of one or more of our product candidates, if approved.

We believe our existing cash, cash equivalents and investments in available-for-sale securities will be sufficient to fund our operating plan for at least the next 24 months. However, our operating plan may change as a result of many factors currently unknown to us, and we may need to seek additional funds sooner than planned, through public or private equity or debt financings or other sources, such as strategic collaborations. Such financing may result in dilution to stockholders, imposition of debt covenants and repayment obligations or other restrictions that may affect our business. 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.

Our future capital requirements depend on many factors, including, but not limited to:

## Table of Contents

the scope, progress, results and costs of researching and developing our current or future product candidates; the timing of, and the costs involved in, obtaining regulatory approvals for any of our current or future product candidates;

the number and characteristics of the product candidates we pursue;

the cost of manufacturing our current and future product candidates and any products we successfully commercialize, including cost of building internal biologics manufacturing capacity;

the cost of commercialization activities if any of our future product candidates are approved for sale, including marketing, sales and distribution costs;

the expenses needed to attract and retain skilled personnel;

the costs associated with being a public company;

our ability to establish and maintain strategic collaborations, licensing or other arrangements and the financial terms of such agreements; and

the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing current and future patents, including litigation costs and the outcome of any such litigation.

### Contractual Obligations

We have non-cancelable operating leases for two office spaces and expanded laboratory space under which we are obligated to make minimum lease payments totaling \$2.2 million through May 2022, the timing of which is described in more detail in the notes to the consolidated financial statements. In addition, we have three operating leases for equipment under which we are obligated to make minimum lease payments totaling \$28,000 through 2020.

### Off-Balance Sheet Arrangements

Since inception, we have not engaged in the use of any off-balance sheet arrangements, such as structured finance entities, special purpose entities or variable interest entities.

### Recently Issued Accounting Pronouncements

In February 2016, Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2016-02, "Leases (Topic 842)", requiring organizations that lease assets—referred to as “lessees”—to recognize on the consolidated balance sheet the assets and liabilities for the rights and obligations created by those leases. Under the new guidance, a lessee will be required to recognize assets and liabilities for leases with lease terms of more than 12 months. The ASU on leases will take effect for public companies for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2018.

In July 2018, the FASB issued ASU No. 2018-10, "Codification Improvements to Topic 842, Leases", which affects narrow aspects of the guidance issued in ASU No. 2016-02. The amendments in this ASU related to transition do not include amendments from proposed ASU, Leases (Topic 842): Targeted Improvements, specific to a new and optional transition method to adopt the new lease requirements in ASU 2016-02. For entities that have not adopted Topic 842, the effective date and transition requirements will be the same as the effective date and transition requirements in Topic 842.

In July 2018, the FASB issued ASU No. 2018-11, "Targeted Improvements to Topic 842, Leases". The Standard provide another transition method in addition to the existing transition method by allowing entities to initially apply the new lease standard at the adoption date and recognize a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption. For entities that have not adopted Topic 842, the effective date and transition requirements will be the same as the effective date and transition requirements in Topic 842.

We adopted ASC 842 as of January 1, 2019. In preparation of adopting ASC 842, we have purchased a special lease software and also implemented additional internal controls to enable future preparation of



## Table of Contents

financial information in accordance with ASC 842. We believe the largest impact will be on the consolidated balance sheets for the accounting of facilities-related lease, which represents a majority of its operating leases it has entered into a lease. These leases will be recognized under the new lease standard as ROU (Right of Use) assets and operating lease liabilities. We will also be required to provide expanded disclosures for the leasing arrangements. As of December 31, 2018, we had \$2.2 million of undiscounted future minimum operating lease commitments that are not recognized on our consolidated balance sheets under the new standard. We are still in the process of finalizing the evaluations of the effect of ASU 842 on our financial statements and disclosures and will finalize our accounting assessment and quantitative impact of the adoption in the first quarter of 2019.

In July 2018, the FASB issued ASU No. 2018-09, "Codification Improvements", and the amendments in this ASU affect a wide variety of Topics in the Codification. It applies to all reporting entities within the scope of the affected accounting guidance. It will take effect for public companies for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2018. We have adopted the new guidance and the impact of this standard does not have a material impact on our financial statements.

In August 2018, the FASB issued ASU No. 2018-13, "Fair Value Measurement (Topic 820)", which changes to disclosure requirements for fair value measurement. The amendments of this update modify the disclosure requirements on fair value measurements about Topic 820. It applies to all reporting entities within the scope of the affected accounting guidance. It will take effect for public companies for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019. We are currently evaluating the new guidance and have not determined the impact this standard may have on our financial statements.

We do not believe there are any other recently issued standards not yet effective that will have a material impact on our consolidated financial statements when the standards become effective.

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

### Interest Rate Fluctuation Risk

The primary objective of our investment activities is to preserve capital. We do not utilize hedging contracts or similar instruments.

We are exposed to certain market risks relating primarily to (1) interest rate risk on our cash and cash equivalents, (2) market price risk on our short-term investments, and (3) risks relating to the financial viability of the institutions which hold our capital and through which we have invested our funds. We manage such risks by investing in short-term, liquid, highly-rated instruments. As of December 31, 2018, our cash equivalents, short-term and long-term investments are invested in money market funds, U.S. treasury bills, U.S. treasury bonds, U.S. government agencies, commercial paper and high-grade corporate notes. We do not believe we have any material exposure to interest rate risk due to the extremely low interest rate environment, the short duration of the securities we hold and our ability to hold our investments to maturity if necessary. Declines in interest rates would reduce investment income, but would not have a material effect on our financial condition or results of operations.

We do not currently have exposure to foreign currency risk.

## ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.

Our consolidated financial statements appear commencing on page F-1 of this Annual Report on Form 10-K, which information is incorporated herein by reference.

## ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE.



Table of Contents

None.

ITEM 9A. CONTROLS AND PROCEDURES.

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures (as defined in Exchange Act Rule 13a-15(e)) that are designed to assure that information required to be disclosed in our Exchange Act reports is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to management, including our Chief Executive Officer and our Chief Financial Officer (the "Certifying Officers"), as appropriate, to allow timely decisions regarding required disclosures.

In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide reasonable assurance only of achieving the desired control objectives, and management necessarily is required to apply its judgment in weighing the costs and benefits of possible new or different controls and procedures. Limitations are inherent in all control systems, so no evaluation of controls can provide absolute assurance that all control issues and any fraud within the company have been detected. As required by Exchange Act Rule 13a-15(b), as of the end of the period covered by this Annual Report on Form 10-K, management, under the supervision and with the participation of our Certifying Officers, evaluated the effectiveness of our disclosure controls and procedures. Based on this evaluation, the Certifying Officers have concluded that, as of the end of the period covered by this Annual Report on Form 10-K, our disclosure controls and procedures were effective at a reasonable assurance level.

Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. Internal control over financial reporting is a process designed by, or under the supervision of, our Chief Executive Officer and Chief Financial Officer and effected by our board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in Internal Control - Integrated Framework (2013) issued by the Committee of Sponsoring Organizations (COSO). Based on such evaluation, our management concluded that our internal control over financial reporting was effective at a reasonable assurance level as of December 31, 2018.

The effectiveness of our internal control over financial reporting as of December 31, 2018, has been audited by an independent registered public accounting firm, as stated in their attestation report, which is included in their annual report under "Item 8. Financial Statements and Supplementary Data" of this Annual Report.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting during the quarter ended December 31, 2018 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Table of Contents

ITEM 9B. OTHER INFORMATION

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required to be disclosed by this item will be contained in our Definitive Proxy Statement for the Annual Meeting of Stockholders to be filed with the SEC no later than April 30, 2019 and is incorporated herein by reference.

ITEM 11. EXECUTIVE  
COMPENSATION

The information required to be disclosed by this item will be contained in our Definitive Proxy Statement for the Annual Meeting of Stockholders to be filed with the SEC no later than April 30, 2019 and is incorporated herein by reference.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND  
RELATED STOCKHOLDER MATTERS

The information required to be disclosed by this item will be contained in our Definitive Proxy Statement for the Annual Meeting of Stockholders to be filed with the SEC no later than April 30, 2019 and is incorporated herein by reference.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information required to be disclosed by this item will be contained in our Definitive Proxy Statement for the Annual Meeting of Stockholders to be filed with the SEC no later than April 30, 2019 and is incorporated herein by reference.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The information required to be disclosed by this item will be contained in our Definitive Proxy Statement for the Annual Meeting of Stockholders to be filed with the SEC no later than April 30, 2019 and is incorporated herein by reference.

Table of Contents

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES.

Our financial statements and related notes thereto are listed and included in this Annual Report on Form 10-K beginning on page F-1. The following exhibits are filed with, or are incorporated by reference into, this Annual Report:

67

---



Table of Contents

EXHIBIT INDEX

Exhibit No.	Description
3.1	<u>Amended and Restated Certificate of Incorporation of Kindred Biosciences, Inc.</u> (1)
3.2	<u>Amended and Restated Bylaws of Kindred Biosciences, Inc.</u> (1)
3.3	<u>Certificate of Designations of Series A Preferred Stock of Kindred Biosciences, Inc.</u> (12)
4.1	<u>Specimen Common Stock Certificate of Kindred Biosciences, Inc.</u> (2)
4.2	<u>Rights Agreement between Kindred Biosciences, Inc. and American Stock Transfer &amp; Trust Company, LLC, as rights agent dated May 19, 2017</u> (12)
10.1	<u>Kindred Biosciences, Inc. 2012 Equity Incentive Plan</u> †(3)
10.2	<u>Form of Stock Option Agreement under 2012 Equity Incentive Plan</u> †(8)
10.3	<u>Form of Restricted Stock Agreement under 2012 Equity Incentive Plan</u> †(5)
10.4	<u>Kindred Biosciences, Inc. 2014 Employee Stock Purchase Plan</u> †(7)
10.5	<u>Kindred Biosciences, Inc. 2016 Equity Incentive Plan</u> †(10)
10.6	<u>Form of Stock Option Agreement under 2016 Equity Incentive Plan</u> †(11)
10.7	<u>Form of Restricted Stock Award Agreement under 2016 Equity Incentive Plan</u> † (16)
10.8	<u>Form of Restricted Stock Unit Award Agreement under 2016 Equity Incentive Plan</u> † (17)
10.9	<u>Employment Agreement dated September 1, 2013 between Kindred Biosciences, Inc. and Richard Chin, M.D.</u> †(3)
10.10	<u>Amendment No. 2, dated November 11, 2013, to Employment Agreement between Kindred Biosciences, Inc. and Richard Chin, M.D.</u> †(4)
10.11	<u>Employment Agreement dated June 20, 2013 between Kindred Biosciences, Inc. and Denise Bevers</u> (4)
10.12	<u>Amendment No. 1 dated November 11, 2013 to Employment Agreement between Kindred Biosciences, Inc. and Denise Bevers</u> †(4)
10.13	<u>Amendment No. 2 dated June 4, 2015 to Employment Agreement between Kindred Biosciences, Inc. and Denise Bevers</u> †(9)
10.14	<u>Amendment No. 3 dated May 19, 2017 to Employment Agreement between Kindred Biosciences, Inc. and Denise Bevers</u> †(12)
10.15	<u>Employment Agreement dated July 24, 2017 between Kindred Biosciences, Inc. and Wendy Wee</u> †(14)
10.16	<u>Form of Indemnification Agreement between Kindred Biosciences, Inc. and each of its directors and executive officers</u> †(4)
10.17	<u>Office Lease Agreement by and between Kindred Biosciences, Inc. and Oriz Corporation dated May 27, 2014</u> (6)
10.18	<u>Office Lease Addendum by and between Kindred Biosciences, Inc. and Oriz Corporation dated April 6, 2017</u> (17)

Table of Contents

Exhibit No.	Description
10.19	<u>Office Lease Second Addendum by and between Kindred Biosciences, Inc. and Ortiz Corporation dated June 27, 2017</u> (17)
10.20	<u>Commercial Manufacture and Supply Agreement by and between Kindred Biosciences, Inc. and Corden Pharma S.p.A dated June 21, 2017.</u> (13)
10.21	<u>Purchase Agreement by and between Kindred Biosciences, Inc. and Strategic Veterinary Pharmaceuticals, Inc. dated June 21, 2017.</u> (13)
10.22	<u>Commercial Manufacture and Supply Agreement by and between Kindred Biosciences, Inc. and DPT Laboratories, Ltd. dated November 6, 2017.</u> (15)
10.23	<u>Kindred Biosciences, Inc. 2018 Equity Incentive Plan</u> †(18)
10.24	<u>Amendment to Kindred Biosciences, Inc. 2014 Employee Stock Purchase Plan</u> †(19)
10.25	<u>Standard Form of Agreement Between Owner and Design-Builder dated March 29, 2018, between Kindred Biosciences, Inc. and CRB Builders, LLC</u> (20)
10.26	<u>Amended and Restated Executive Employment Agreement by and between Kindred Biosciences, Inc. and Richard Chin dated May 22, 2018</u> †(21)
10.27	<u>Amended and Restated Executive Employment Agreement by and between Kindred Biosciences, Inc. and Denise Bevers dated May 22, 2018</u> †(21)
10.28	<u>Amended and Restated Executive Employment Agreement by and between Kindred Biosciences, Inc. and Wendy Wee dated May 22, 2018</u> †(21)
10.29	<u>Amended and Restated Executive Employment Agreement by and between Kindred Biosciences, Inc. and Hangjun Zhan dated May 22, 2018</u> †(21)
10.30	<u>Form of Stock Option Grant Notice and Stock Option Agreement under 2018 Equity Incentive Plan</u> † (22)
10.31	<u>Form of Restricted Stock Award Grant Notice and Restricted Stock Award Agreement under 2018 Equity Incentive Plan</u> † (22)
10.32	<u>Form of Restricted Stock Unit Award Grant Notice and Restricted Stock Unit Award Agreement under 2018 Equity Incentive Plan</u> † (22)
10.33	<u>Strategic Supply Agreement between Kindred Biosciences, Inc. and Pall Corporation dated June 26, 2018</u> (23)
10.34	<u>Kindred Biosciences, Inc. 2016 Equity Plan Equity Awards Agreement Amendment Form</u> †(23)
10.35	<u>Kindred Biosciences, Inc. 2016 Equity Plan Option Agreement Amendment Form</u> †(23)
10.36	<u>Amendment No. 1 to Amended and Restated Executive Employment Agreement by and between Kindred Biosciences, Inc. and Denise Bevers dated October 19, 2018</u> †(24)
21.1	<u>Subsidiaries of the registrant</u>
23.1	<u>Consent of KMJ Corbin &amp; Company LLP, Independent Registered Public Accounting Firm</u>
31.1	<u>Certification of the Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002</u>
31.2	<u>Certification of the Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002</u>
32.1	<u>Certification of the Chief Executive Officer and Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002</u>
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document

Table of Contents

Exhibit No. Description

101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Labels Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

Indicates a management contract or compensatory plan or arrangement.

- (1) Previously filed on December 17, 2013 as an exhibit to Registrant's Report on Form 8-K and incorporated herein by reference.
- (2) Previously filed on December 2, 2013 as an exhibit to Registrant's Amendment No. 4 to Registration Statement on Form S-1 (File No. 333-192242) and incorporated herein by reference.
- (3) Previously filed on November 8, 2013 as an exhibit to Registrant's Registration Statement on Form S-1 (File No. 333-192242) and incorporated herein by reference.
- (4) Previously filed on November 13, 2013 as an exhibit to Registrant's Amendment No. 1 to Registration Statement on Form S-1 (File No. 333-192242) and incorporated herein by reference.
- (5) Previously filed on May 14, 2014 as an exhibit to Registrant's Quarterly Report on Form 10-Q and incorporated herein by reference.
- (6) Previously filed on August 13, 2014 as an exhibit to Registrant's Quarterly Report on Form 10-Q and incorporated herein by reference.
- (7) Previously filed on October 14, 2014 as an appendix to Registrant's Definitive Proxy Statement on Schedule 14A and incorporated herein by reference.
- (8) Previously filed on March 13, 2015 as an exhibit to Registrant's Annual Report on Form 10-K and incorporated herein by reference.
- (9) Previously filed on June 4, 2015 as an exhibit to Registrant's Report on Form 8-K and incorporated herein by reference.
- (10) Previously filed on April 8, 2016 as Appendix A to the Registrant's Definitive Proxy Statement on Schedule 14A, and incorporated herein by reference.
- (11) Previously filed on June 3, 2016 as an exhibit to Registrant's Report to Registration Statement on Form S-8 (File No. 333-211839) and incorporated herein by reference.
- (12) Previously filed on May 24, 2017 as an exhibit to Registrant's Report on Form 8-K and incorporated herein by reference.
- (13) Previously filed on June 26, 2017 as an exhibit to Registrant's Report on Form 8-K and incorporated herein by reference.
- (14) Previously filed on July 28, 2017 as an exhibit to Registrant's Report on Form 8-K and incorporated herein by reference.
- (15) Previously filed on November 7, 2017 as an exhibit to Registrant's Report on Form 8-K and incorporated herein by reference.
- (16) Previously filed on March 1, 2017 as an exhibit to Registrant's Annual Report on Form 10-K and incorporated herein by reference.
- (17) Previously filed on March 1, 2018 as an exhibit to Registrant's Annual Report on Form 10-K and incorporated herein by reference.
- (18) Previously filed on April 25, 2018 as Appendix A to the Registrant's Definitive Proxy Statement on Schedule 14A, and incorporated herein by reference.

Table of Contents

- (19) Previously filed on April 25, 2018 as Appendix B to the Registrant's Definitive Proxy Statement on Schedule 14A, and incorporated herein by reference.
- (20) Previously filed on May 8, 2018 as an exhibit to Registrant's Quarterly Report on Form 10-Q and incorporated herein by reference.
- (21) Previously filed on May 29, 2018 as an exhibit to Registrant's Report on Form 8-K and incorporated herein by reference.
- (22) Previously filed on July 24, 2018 as an exhibit to Registrant's Registration Statement on Form S 8 (File No. 333 226321) and incorporated herein by reference.
- (23) Previously filed on August 9, 2018 as an exhibit to Registrant's Quarterly Report on Form 10-Q and incorporated herein by reference.
- (24) Previously filed on November 7, 2018 as an exhibit to Registrant's Quarterly Report on Form 10-Q and incorporated herein by reference.

ITEM 16. FORM 10-K SUMMARY

None

Table of Contents

SIGNATURES

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

KINDRED BIOSCIENCES, INC.

Date: March 6, 2019 By: /s/ Wendy Wee

Wendy Wee

Chief Financial Officer and Principal Financial and Accounting Officer

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

Signature	Title	Date
/s/ Richard Chin Richard Chin, M.D.	Chief Executive Officer and Director (Principal Executive Officer)	March 6, 2019
/s/ Wendy Wee Wendy Wee	Chief Financial Officer (Principal Financial and Accounting Officer)	March 6, 2019
/s/ Denise Bevers Denise Bevers	President, Chief Operating Officer and Director	March 6, 2019
/s/ Ernest Mario Ernest Mario, Ph.D.	Director	March 6, 2019
/s/ Joseph McCracken Joseph McCracken, DVM	Director	March 6, 2019
/s/ Herbert Montgomery Herbert Montgomery	Director	March 6, 2019
/s/ Raymond Townsend Raymond Townsend, Pharm.D.	Director	March 6, 2019
/s/ Ervin Veszprémi Ervin Veszprémi	Director	March 6, 2019

Table of Contents

Index to Consolidated Financial Statements	Page
Financial Statements:	
<u>Reports of Independent Registered Public Accounting Firm</u>	<u>F- 2</u>
<u>Consolidated Balance Sheets as of December 31, 2018 and 2017</u>	<u>F- 5</u>
<u>Consolidated Statements of Operations and Comprehensive Loss for the years ended December 31, 2018, 2017 and 2016</u>	<u>F- 6</u>
<u>Consolidated Statements of Changes in Stockholders' Equity for the years ended December 31, 2018, 2017 and 2016</u>	<u>F- 7</u>
<u>Consolidated Statements of Cash Flows for the years ended December 31, 2018, 2017 and 2016</u>	<u>F- 8</u>
<u>Notes to Consolidated Financial Statements</u>	<u>F- 9</u>

F- 1

---

Table of Contents

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of Kindred Biosciences, Inc.

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Kindred Biosciences, Inc. and Subsidiary (the “Company”) as of December 31, 2018 and 2017, the related consolidated statements of operations and comprehensive loss, changes in stockholders’ equity and cash flows for each of the three years in the period ended December 31, 2018, and the related notes (collectively referred to as the “consolidated financial statements”). In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2018 and 2017, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2018, in conformity with accounting principles generally accepted in the United States of America.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (“PCAOB”), the Company’s internal control over financial reporting as of December 31, 2018, based on criteria established in Internal Control - Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (“COSO”) and our report dated March 6, 2019 expressed an unqualified opinion on the Company’s internal control over financial reporting.

Basis for Opinion

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

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ KMJ Corbin & Company LLP

We have served as the Company's auditor since 2013.

Costa Mesa, California  
March 6, 2019





Table of Contents

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of Kindred Biosciences, Inc.

Opinion on Internal Control over Financial Reporting

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

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (“PCAOB”), the consolidated balance sheets of the Company as of December 31, 2018 and 2017, the related consolidated statements of operations and comprehensive loss, changes in stockholders’ equity and cash flows for each of the three years in the period ended December 31, 2018, and the related notes (collectively referred to as the “consolidated financial statements”), and our report dated March 6, 2019 expressed an unqualified opinion on those consolidated financial statements.

Basis for Opinion

The Company’s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management’s Report on Internal Control over Financial Reporting included in Item 9A. Our responsibility is to express an opinion on the Company’s internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

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

Definition and Limitations of Internal Control Over Financial Reporting

A company’s internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with accounting principles generally accepted in the United States of America. A company’s internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with accounting principles generally accepted in the United States of America, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of

the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

F- 3

---

Table of Contents

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

/s/ KMJ Corbin & Company LLP

Costa Mesa, California

March 6, 2019

F- 4

---

Table of ContentsKindred Biosciences, Inc.  
Consolidated Balance Sheets

(In thousands, except share and per share amounts)

	December 31,	
	2018	2017
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$56,302	\$34,813
Short-term investments	17,630	46,207
Accounts receivable	903	—
Inventories	3,570	—
Prepaid expenses and other	1,664	797
Total current assets	80,069	81,817
Property and equipment, net	26,343	7,457
Long-term investments	—	1,499
Other assets	70	49
Total assets	\$106,482	\$90,822
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$3,576	\$1,439
Accrued compensation	3,436	2,688
Accrued liabilities	8,169	1,900
Total current liabilities	15,181	6,027
Long-term liability	94	115
Total liabilities	15,275	6,142
Commitments and contingencies (Note 10)		
Stockholders' equity:		
Common stock; \$0.0001 par value; 100,000,000 shares authorized; 33,948,254 shares and 28,182,563 shares issued and outstanding at December 31, 2018 and 2017, respectively	3	3
Additional paid-in capital	252,885	196,688
Accumulated other comprehensive loss	(11 )	(31 )
Accumulated deficit	(161,670 )	(111,980)
Total stockholders' equity	91,207	84,680
Total liabilities and stockholders' equity	\$106,482	\$90,822

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

Table of Contents

Kindred Biosciences, Inc.  
 Consolidated Statements of Operations and Comprehensive Loss  
 (In thousands, except per share amounts)

	Years Ended December 31,		
	2018	2017	2016
Net product revenues	\$1,966	\$—	\$—
Operating expenses:			
Cost of product revenues	324	—	—
Research and development	26,399	17,665	13,861
General and administrative	26,499	13,988	8,308
Restructuring costs	—	—	655
Total operating expenses	53,222	31,653	22,824
Loss from operations	(51,256 )	(31,653 )	(22,824 )
Interest and other income, net	1,566	774	325
Net loss	(49,690 )	(30,879 )	(22,499 )
Change in unrealized gains on available-for-sale securities	20	—	19
Comprehensive loss	\$(49,670)	\$(30,879)	\$(22,480)
Net loss per share, basic and diluted	\$(1.60 )	\$(1.23 )	\$(1.13 )
Weighted-average number of common shares outstanding, basic and diluted	31,001	25,084	19,873

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

F- 6

---

Table of Contents

Kindred Biosciences, Inc.

Consolidated Statements of Changes in Stockholders' Equity

(In thousands)

	Common Stock		Additional	Accumulated	Accumulated	Total
	Shares	Amount	Paid-In Capital	Other Comprehensive Loss	Deficit	Stockholders' Equity
Balance at December 31, 2015	19,836	\$ 2	\$ 135,021	\$ (50 )	\$ (58,602 )	\$ 76,371
Comprehensive loss						
Net loss	—	—	—	—	(22,499 )	(22,499 )
Change in unrealized gains on available-for-sale securities	—	—	—	19	—	19
Total comprehensive loss						(22,480 )
Stock-based compensation	—	—	3,627	—	—	3,627
Exercise of common stock options	40	—	23	—	—	23
Common stock issued under ESPP	40	—	139	—	—	139
Balance at December 31, 2016	19,916	2	138,810	(31 )	(81,101 )	57,680
Comprehensive loss						
Net loss	—	—	—	—	(30,879 )	(30,879 )
Change in unrealized losses on available-for-sale securities	—	—	—	—	—	—
Total comprehensive loss						(30,879 )
Restricted stock awards, unvested	250	—	—	—	—	—
Stock-based compensation	—	—	5,207	—	—	5,207
Exercise of common stock options	157	—	311	—	—	311
At-the-Market issuance of common stock, net of \$1,038 of issuance costs	4,502	1	28,961	—	—	28,962
Public offering of common stock, net of \$1,657 of offering costs	3,314	—	23,198	—	—	23,198
Common stock issued under ESPP	44	—	201	—	—	201
Balance at December 31, 2017	28,183	3	196,688	(31 )	(111,980 )	84,680
Comprehensive loss						
Net loss	—	—	—	—	(49,690 )	(49,690 )
Change in unrealized gains on available for sale securities	—	—	—	20	—	20
Total comprehensive loss						(49,670 )
Shares withheld related to net share settlement of equity awards	(27 )	—	(247 )	—	—	(247 )
Stock-based compensation	—	—	6,277	—	—	6,277
Exercise of common stock options	231	—	635	—	—	635
At-the-Market issuance of common stock, net of \$145 of issuance costs	188	—	1,758	—	—	1,758
Public offering of common stock, net of \$3,178 of offering costs	5,326	—	47,422	—	—	47,422
Common stock issued under ESPP	47	—	352	—	—	352
Balance at December 31, 2018	33,948	\$ 3	\$ 252,885	\$ (11 )	\$ (161,670 )	\$ 91,207

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



Table of Contents

Kindred Biosciences, Inc.  
 Consolidated Statements of Cash Flows  
 (In thousands)

	Years Ended December 31,		
	2018	2017	2016
<b>Cash Flows from Operating Activities</b>			
Net loss	\$(49,690)	\$(30,879)	\$(22,499)
Adjustments to reconcile net loss to net cash used in operating activities:			
Stock-based compensation expense	6,277	5,207	3,627
Depreciation and amortization expense	805	475	155
Loss on disposal of property and equipment	34	27	3
Amortization of (discount) premium on marketable securities	(179)	) 162	274
Changes in operating assets and liabilities:			
Accounts receivable	(903)	) —	—
Inventories	(3,570)	) —	—
Prepaid expenses and other	(867)	) 485	(570)
Other assets	(21)	) (3)	(16)
Accounts payable	277	1,280	(710)
Accrued liabilities and accrued compensation	2,802	1,368	955
Net cash used in operating activities	(45,035)	) (21,878)	(18,781)
<b>Cash Flows from Investing Activities</b>			
Purchases of investments	(25,100)	) (70,110)	(72,047)
Sales of investments	800	4,897	—
Maturities of investments	54,575	68,465	78,313
Purchases of property and equipment	(13,919)	) (5,920)	(952)
Proceeds from sale of property and equipment	248	—	—
Net cash provided by (used in) investing activities	16,604	(2,668)	) 5,314
<b>Cash Flows from Financing Activities</b>			
Exercise of stock options and purchase of ESPP shares	987	512	162
Payment of restricted stock awards tax liability on net settlement	(247)	) —	—
Net proceeds from sales of common stock	49,180	52,160	—
Net cash provided by financing activities	49,920	52,672	162
Net change in cash and cash equivalents	21,489	28,126	(13,305)
Cash and cash equivalents at beginning of year	34,813	6,687	19,992
Cash and cash equivalents at end of year	\$56,302	\$34,813	\$6,687
Supplemental disclosure of non-cash financing activities:			
Purchases of property and equipment included in accounts payable and accrued liabilities		\$6,205	\$266 \$670

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



Table of Contents

Kindred Biosciences, Inc

Notes to Consolidated Financial Statements

1. Organization and Description of Business

Kindred Biosciences, Inc. ("we", "us" or "our") was incorporated on September 25, 2012 (inception) in the State of Delaware. On April 25, 2016, we filed a Certificate of Incorporation with the State of Delaware for a wholly owned subsidiary, KindredBio Equine, Inc. ("Subsidiary"). The Subsidiary has one class of capital stock which is designated common stock, \$0.0001 par value per share. The authorized number of shares of common stock for the Subsidiary is 1,000.

We are a commercial-stage biopharmaceutical company focused on saving and improving the lives of pets. Our activities since inception have consisted principally of raising capital, establishing facilities, recruiting management and technical staff and performing research and development and advancing our product candidates seeking regulatory approval. Our headquarters are in Burlingame, California.

We are subject to risks common to companies in the biotechnology and pharmaceutical industries. There can be no assurance that our research and development will be successfully completed, that adequate protection for our technology will be obtained, that any products developed will obtain necessary government regulatory approval or that any approved products will be commercially viable. We operate in an environment of substantial competition from other animal health companies. In addition, we are dependent upon the services of our employees and consultants, as well as third-party contract research organizations and manufacturers.

Liquidity

We have incurred losses and negative cash flows from operations and had an accumulated deficit of \$161.7 million as of December 31, 2018. We expect to continue to incur losses and negative cash flows, which will increase significantly from historical levels as we expand our product development activities, seek regulatory approvals for our product candidates, establish a biologics manufacturing capability, and commercialize approved products. We might require additional capital until such time as we can generate operating revenues in excess of operating expenses. To date, we have been funded primarily through sales of convertible preferred stock and the sale of our common stock in our initial public offering in December 2013, in which we raised approximately \$67.0 million, net of offering costs. In April 2014, we completed a follow-on public offering of common stock, resulting in net proceeds of approximately \$58.1 million. In 2017, we completed the sale of common stock under an At Market Issuance Sales Agreement, or the Sales Agreement as well as an underwritten public offering, resulting in net proceeds of approximately \$29.0 million and \$23.2 million, respectively. In May 2018, we entered into another Sales Agreement, but terminated the Sales Agreement in June 2018 after having sold 188,100 shares, representing gross proceeds of approximately \$1.9 million. Net proceeds, after deducting commission, fees and offering costs, were approximately \$1.8 million. Also, in June 2018 we completed a public offering of 5,326,314 shares of common stock, which included the underwriters' option to purchase additional shares, at a public offering price of \$9.50 per share for total gross proceeds of approximately \$50.6 million. Net proceeds, after deducting underwriting discounts and commissions and offering expenses were approximately \$47.4 million. In January 2019, we completed a public offering of 4,847,250 shares of common stock, which includes the exercise in full by the underwriters' option to purchase 632,250 additional shares of the Company's common stock, at a public offering price of \$9.50 per share for total gross proceeds of approximately \$46.0 million. Net proceeds, after deducting underwriting discounts and commissions and offering expenses were approximately \$43.1 million. As of December 31, 2018, we believe our cash, cash equivalents and investments in available-for-sale securities of approximately \$73.9 million and together with the \$43.1 million raised in January 2019, are sufficient to fund our planned operations for at least the next 24 months.

Table of Contents

Kindred Biosciences, Inc.

Notes to Consolidated Financial Statements (continued)

If we require additional funding for operations, we may seek such funding through public or private equity or debt financings or other sources, such as corporate collaborations and licensing arrangements. We may not be able to obtain financing on acceptable terms, or at all, and we may not be able to enter into corporate collaborations or licensing arrangements. The terms of any financing may result in dilution or otherwise adversely affect the holdings or the rights of our stockholders. If we are unable to obtain funding, we could be forced to delay, reduce or eliminate our research and development programs or commercialization efforts, which could adversely affect our business prospects.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP") and include the accounts of the Company and its wholly owned Subsidiary. All intercompany accounts and transactions have been eliminated in consolidation.

Use of Estimates

The preparation of financial statements and related disclosures in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the consolidated financial statements, and the reported amounts of revenues and expenses during the reporting periods. Estimates are based historical experiences or on forecasts, including information received from third parties and other assumptions that the Company believes are reasonable under the circumstances. Estimates are periodically reviewed in light of changes in circumstances, facts and experience. Actual results could differ from those estimates.

Cash, Cash Equivalents and Investments

We consider all highly liquid investments purchased with an original maturity of three months or less at the date of acquisition to be cash equivalents. Debt securities with original maturities greater than three months and remaining maturities less than one year are classified as short-term investments. We classify all investments as available-for-sale. Available-for-sale securities are carried at estimated fair value, with accumulated unrealized gains and losses reported as a component of accumulated other comprehensive income (loss) in the accompanying consolidated balance sheets. Realized gains or losses on the sale of investments are determined on a specific identification method, and such gains and losses are reflected as a component of interest and other income, net in the accompanying consolidated statements of operations and comprehensive loss.

Marketable securities investments are evaluated periodically for impairment. We take into account general market conditions, changes in the economic environment as well as specific investment attributes, such as credit downgrade or illiquidity for each investment, the expected cash flows from the securities, our intent to sell the securities and whether or not we will be required to sell the securities before the recovery of their amortized cost, to estimate the fair value of our investments and to determine whether impairment is other than temporary. If it is determined that a decline in fair value of any investment is other than temporary, then the unrealized loss related to credit risk would be included in interest and other income, net.

Concentration of Credit Risk and of Significant Suppliers and Customers

Financial instruments that potentially subject us to concentrations of credit risk consist primarily of

Table of Contents

Kindred Biosciences, Inc.

Notes to Consolidated Financial Statements (continued)

cash, cash equivalents and investments. From time to time, we maintain cash and cash equivalent balances in excess of amounts insured by the Federal Deposit Insurance Corporation ("FDIC") and the Securities Investor Protection Corporation ("SIPC"). Primarily all of our cash, cash equivalents and investments at December 31, 2018 were in excess of amounts insured by the FDIC and SIPC. We do not believe that we are subject to unusual credit risk beyond the normal credit risk associated with commercial banking relationships.

We are dependent on third-party manufacturers to supply products for research and development activities in our programs. In particular, we rely on a small number of manufacturers to supply us with our requirements for the active pharmaceutical ingredients, or API, and formulated drugs related to some of these programs. These programs would be adversely affected by a significant interruption in the supply of API.

We are also dependent on a combination of national and regional distributors for our product sales of Mirataz. See Note 3.

Fair Value Measurements

We use the provisions of Accounting Standards Codification ("ASC") 820, "Fair Value Measurements and Disclosure", to determine the fair values of our financial and nonfinancial assets and liabilities where applicable. ASC 820 defines fair value, establishes a framework for measuring fair value in U.S. GAAP and expands disclosure about fair value measurements. The objective of fair value measurement is to determine the price that would be received to sell the asset or paid to transfer the liability (an exit price) in an orderly transaction between market participants at the measurement date. ASC 820 emphasizes that fair value is a market-based measurement, not an entity-specific measurement, and that market participant assumptions include assumptions about risk and effect of a restriction on the sale or use of an asset. To increase consistency and comparability in fair value measurement and related disclosures, ASC 820 establishes a fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value into three broad levels: (1) Level 1 inputs are quoted prices (unadjusted) in active markets for identical assets or liabilities that the reporting entity has the ability to access at the measurement date; (2) Level 2 inputs are inputs other than quoted prices included in Level 1 that are observable for the asset or liability, either directly or indirectly through corroboration with observable market data; and (3) Level 3 inputs are unobservable inputs for the asset or liability that reflect the reporting entity's own assumptions about risk and the assumptions market participants would use in pricing the asset or liability developed based on the best information available in the circumstances.

Government agency notes, corporate notes and commercial papers are recorded at their estimated fair value. Since these available-for-sale securities generally have market prices from multiple sources and it can be difficult to select the best individual price directly from the quoted prices in the active markets, we use Level 2 inputs for the valuation of these securities. Using the Level 2 inputs, a "consensus price" or a weighted average price for each of these securities can be derived from a distribution-curve-based algorithm which includes market prices obtained from a variety of industrial standard data providers (e.g. Bloomberg), security master files from large financial institutions, and other third-party sources.

The carrying amount of financial instruments, including cash, accounts payable and accrued liabilities approximate fair value due to the short maturities of these financial instruments. Financial assets, which consist of money market funds and available-for-sale securities, are measured at fair value on a recurring basis (see Note 4).

Property and Equipment

On June 21, 2017, we entered into a purchase agreement with Strategic Veterinary Pharmaceuticals, Inc. ("SVP") for the purchase of an approximately 180,000 sq. ft. biologics plant ("the Plant") with clean

Table of Contents

Kindred Biosciences, Inc.

Notes to Consolidated Financial Statements (continued)

rooms, utility, equipment, and related quality documentation suitable for small molecule and biologics manufacturing, that is located in Elwood, Kansas. The purchase was finalized on August 7, 2017 upon completion of the diligence period and satisfaction of the conditions of escrow. The Plant was purchased for \$3,750,000, which includes approximately eight acres of land located at 1411 Oak Street, Elwood, Kansas, all improvements located at the Plant, and all personal property and intangible property owned by SVP and located at the Plant or used in connection with the operation of the Plant.

Property and equipment are stated at cost less accumulated depreciation and amortization. We calculate depreciation using the straight-line method over the estimated useful lives of the assets, which range from two to five years for furniture, fixtures, lab and computer equipment and software, and fifteen to thirty-nine years for land improvements and real property. Land and assets held within construction in progress are not depreciated. Construction in progress is related to the construction or development of property and equipment that have not yet been placed in service for their intended use. Expenditures for repairs and maintenance of assets are charged to expense as incurred. We amortize leasehold improvements using the straight-line method over the estimated useful lives of the respective assets or the lease term, whichever is shorter. Upon retirement or sale, the cost and related accumulated depreciation and amortization of assets disposed of are removed from the accounts and any resulting gain or loss is included in other income/expense.

Licenses

The costs incurred for the rights to use licensed technologies in the research and development process, including licensing fees and milestone payments, are charged to research and development expense as incurred in situations where we have not identified an alternative future use for the acquired rights, and are capitalized in situations where we have identified an alternative future use. No costs associated with the use of licensed technologies have been capitalized to date.

Impairment of Long-Lived Assets

We review long-lived assets, including property and equipment, for impairment whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. Factors that we consider in deciding when to perform an impairment review include significant underperformance of the business in relation to expectations, significant negative industry or economic trends, and significant changes or planned changes in the use of the assets. If an impairment review is performed to evaluate a long-lived asset for recoverability, we compare forecasts of undiscounted cash flows expected to result from the use and eventual disposition of the long-lived asset to its carrying value. An impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of an asset are less than its carrying amount. The impairment loss would be based on the excess of the carrying value of the impaired asset over its fair value, determined based on discounted cash flows. To date, we have not recorded any impairment losses on long-lived assets.

Revenue Recognition

We adopted ASC Topic 606 ("ASC 606"), "Revenue from Contracts with Customers" in the first quarter of our fiscal year that began on January 1, 2018. This new standard replaced the previous revenue recognition guidance in U.S. GAAP. No prior period adjustments were needed as our first commercial shipments began in July 2018. Our revenue consists of product revenue resulting from the sale of Mirataz for the management of weight loss in cats. We account for a contract with a customer when there is a legally enforceable contract between us and our customer, the rights of the parties are identified, the contract has commercial substance, and collectability of the contract consideration is probable. Our customers could either be distributors who subsequently resell our products to third parties such as veterinarians, clinics or animal hospitals or the third parties themselves.



Table of Contents

Kindred Biosciences, Inc.

Notes to Consolidated Financial Statements (continued)

We use a contract manufacturer to produce Mirataz and a third-party logistics vendor to process and fulfill orders. We concluded we are the principal in our sales because we control access to services rendered by both vendors and direct their activities. We have no significant obligations to distributors to generate pull-through sales.

In accordance with ASC 606, we applied the following steps to recognize revenue for the sale of Mirataz that reflects the consideration to which we expect to be entitled to receive in exchange for the promised goods:

1. Identify the contract with a customer

A contract with a customer exists when we enter into an enforceable contract with a customer. These contracts define each party's rights, payment terms and other contractual terms and conditions of the sale. We apply judgment in determining the customer's ability and intention to pay, which is based on published credit and financial information pertaining to the customer.

2. Identify the performance obligations in the contract

Our product in a given purchase order is delivered at the same time and we do not separate an individual order into separate performance obligations. We have concluded the sale of finished goods and related shipping and handling are accounted for as a single performance obligation as there are no other promises to deliver goods beyond what is specified in each accepted customer order.

3. Determine the transaction price

The transaction price is determined based on the consideration to which we will be entitled to receive in exchange for transferring goods to the customer, typically a fixed consideration in our contractual agreements.

4. Allocate the transaction price to the performance obligations

The transaction price is allocated entirely to the performance obligation to provide pharmaceutical products. The nature of the promises/obligations under our contracts is to transfer a distinct good. Accordingly, because a single performance obligation exists, no allocation of the transaction price is necessary.

5. Determine the satisfaction of performance obligation

Revenue is recognized when control of the finished goods is transferred to the customer, net of applicable reserves for variable consideration. Control of the finished goods is transferred at a point in time, upon delivery to the customer.

Reserves for Variable Consideration

Revenues from product sales are recorded at the net sales price, which includes estimates of variable consideration for which reserves are established. Components of variable consideration include product returns, allowances and discounts. These estimates take into consideration a range of possible outcomes for the expected value (probability-weighted estimate) or relevant factors such as current contractual and statutory requirements, specific known market events and trends, industry data, and forecasted customer buying and payment patterns. Overall, these reserves reflect our best estimates of the amount of consideration to which we are entitled based on the terms of the

respective underlying contracts. The amount of variable consideration

F- 13

---

Table of Contents

Kindred Biosciences, Inc.

Notes to Consolidated Financial Statements (continued)

included in the transaction price may be constrained and is included in the net sales price only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized where the contract will not occur in a future period. Actual amounts of consideration ultimately received may differ from our estimates. If actual results in the future vary from our estimates, we will adjust these estimates, which would affect net product revenues and earnings in the period such variances become known.

Product Returns

Consistent with the industry practice, we generally offer customers a limited right of return of damaged or expired product that has been purchased directly from us. Our return policy generally allows customers to receive credit for expired products within 90 days after the product's expiration date. We estimate the amount of our product revenues that may be returned by our customers and record these estimates as a reduction of product revenues in the period the related product revenues are recognized, as well as within accrued liabilities, in the consolidated balance sheets. We currently estimate product return liabilities using probability-weighted available industry data and data provided by the our distributors such as the inventories remaining in the distribution channel. To-date, we have no returns and believe that returns of our product in future periods will be minimal. We do not record a return asset associated with the returned damaged or expired goods due to such asset is deemed to be fully impaired at the time of product return.

Sales Discounts and Allowances

We compensate our distributors for sales order management, data and distribution and other services through sales discounts and allowances. However, such services are not distinct from our sale of products to distributors and, therefore, these discounts and allowances are recorded as a reduction of product revenues in the statements of operations, as well as a reduction to accounts receivable in the consolidated balance sheets.

Practical Expedients and Exemptions

We generally expense sales commissions when incurred because the amortization period would have been one year or less. These costs are recorded within sales and marketing expenses.

Cost of Product Revenues

Cost of product revenues consists primarily of the cost of direct materials, direct labor and overhead costs associated with manufacturing, inbound shipping and other third-party logistics costs.

Inventories

We value inventory at the lower of cost or net realizable value. We determine the cost of inventory using the standard-cost method, which approximates actual cost based on a first-in, first-out method. We analyze our inventory levels quarterly and write down inventory subject to expire in excess of expected requirements, or that has a cost basis in excess of its expected net realizable value. These inventory related costs are recognized as cost of product revenues on the accompanying Consolidated Statements of Operations and Comprehensive Loss. Currently our inventory consists of finished goods only.

Research and Development Costs



All costs of research and development are expensed in the period incurred. Research and development costs primarily consist of salaries and related expenses for personnel, stock-based compensation expense, fees paid to consultants, outside service providers, professional services, travel costs and materials used in clinical trials and research and development.

F- 14

---

Table of Contents

Kindred Biosciences, Inc.

Notes to Consolidated Financial Statements (continued)

Patent Costs

All patent-related costs incurred in connection with filing patent applications are recorded in research and development expenses when incurred, as recoverability of such expenditures is uncertain.

Stock-Based Compensation

Our stock-based compensation plan (see Note 9) provides for the grant of stock options, restricted common stock, restricted stock units and stock appreciation rights. The estimated fair values of employee stock option grants are determined as of the date of grant using the Black-Scholes option pricing model. This method incorporates the fair value of our common stock at the date of each grant and various assumptions such as the risk-free interest rate, expected volatility based on historic volatility of Kindred Biosciences own stock prices, and expected dividend yield, and expected term of the options. The estimated fair values of restricted stock awards are determined based on the fair value of our common stock on the date of grant. The estimated fair values of stock-based awards, including the effect of estimated forfeitures, are expensed over the requisite service period, which is generally the awards' vesting period. We classify stock-based compensation expense in the consolidated statements of operations and comprehensive loss in the same manner in which the award recipient's payroll costs are classified.

Our accounting policy for equity instruments issued to consultants and vendors in exchange for goods and services follows Financial Accounting Standards Board ("FASB") guidance. All transactions in which goods or services are the consideration received for the issuance of equity instruments are accounted for based on the fair value of the consideration received or the fair value of the equity instrument issued, whichever is more reliably measurable. The measurement date of the fair value of the equity instrument issued is the earlier of the date on which the counterparty's performance is complete or the date at which a commitment for performance is reached. Non-employee grants of stock-based compensation, except those grants to non-employee, shareholder-approved Board Members, were previously valued under ASC 505-50 "Equity-Based Payments to Non-Employees". In Q2 2018, we adopted ASU 2018-07 "Compensation - Stock Compensation (Topic 718) - Improvements to Non-Employee Share-Based Payment Accounting" and non-employee grants are now valued in the same manner as employee grants.

Income Taxes

We account for income taxes using the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been recognized in the consolidated financial statements or in our tax returns. Deferred taxes are determined based on the difference between the financial statement and tax basis of assets and liabilities using enacted tax rates in effect in the years in which the differences are expected to reverse. Changes in deferred tax assets and liabilities are recorded in the provision for income taxes. We assess the likelihood that our deferred tax assets will be recovered from future taxable income and, to the extent we believe, based upon the weight of available evidence, that it is more likely than not that all or a portion of deferred tax assets will not be realized, a valuation allowance is established through a charge to income tax expense. Potential for recovery of deferred tax assets is evaluated by estimating the future taxable profits expected and considering prudent and feasible tax planning strategies.

We account for uncertainty in income taxes recognized in the consolidated financial statements by applying a two-step process to determine the amount of tax benefit to be recognized. First, the tax position must be evaluated to determine the likelihood that it will be sustained upon external examination by the taxing authorities. If the tax position is deemed more-likely-than-not to be sustained, the tax position is then assessed to determine the amount of benefit to recognize in the consolidated financial statements. The amount of the benefit that may be recognized is the largest amount that has a greater than 50% likelihood of being realized

Table of Contents

Kindred Biosciences, Inc.

Notes to Consolidated Financial Statements (continued)

upon ultimate settlement. The provision for income taxes includes the effects of any resulting tax reserves, or unrecognized tax benefits, that are considered appropriate as well as the related net interest and penalties.

Comprehensive Loss

Our comprehensive loss includes the change in unrealized gains or losses on available-for-sale securities. The cumulative amount of gains or losses is reflected as a separate component of stockholders' equity in the accompanying consolidated balance sheets as accumulated other comprehensive loss.

Segment Data

We manage our operations as a single segment for the purposes of assessing performance and making operating decisions. We are a veterinary biotechnology company focusing on developing therapies for pets. Our chief operating decision maker is our Chief Executive Officer. All assets are held in the United States.

Basic and Diluted Net Loss Per Common Share

Basic net loss per common share is computed by dividing net loss attributable to common stockholders for the period by the weighted average number of common shares outstanding during the period. Diluted net loss per share is computed by dividing the net loss attributable to common stockholders for the period by the weighted average number of common shares, including potential dilutive shares of common stock assuming the dilutive effect of potentially dilutive securities. For periods in which we have reported a net loss, diluted net loss per common share is the same as basic net loss per common share, since the impact of the potentially dilutive securities would be anti-dilutive to the calculation of net loss per common share (see Note 13).

Recently Issued Accounting Pronouncements

In February 2016, Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2016-02, "Leases (Topic 842)", requiring organizations that lease assets—referred to as “lessees”—to recognize on the consolidated balance sheet the assets and liabilities for the rights and obligations created by those leases. Under the new guidance, a lessee will be required to recognize assets and liabilities for leases with lease terms of more than 12 months. The ASU on leases will take effect for public companies for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2018.

In July 2018, the FASB issued ASU No. 2018-10, "Codification Improvements to Topic 842, Leases", which affects narrow aspects of the guidance issued in ASU No. 2016-02. The amendments in this ASU related to transition do not include amendments from proposed ASU, Leases (Topic 842): Targeted Improvements, specific to a new and optional transition method to adopt the new lease requirements in ASU 2016-02. For entities that have not adopted Topic 842, the effective date and transition requirements will be the same as the effective date and transition requirements in Topic 842.

In July 2018, the FASB issued ASU No. 2018-11, "Targeted Improvements to Topic 842, Leases". This update provides another transition method in addition to the existing transition method by allowing entities to initially apply the new lease standard at the adoption date and recognize a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption. For entities that have not adopted Topic 842, the effective date and transition requirements will be the same as the effective date and transition requirements in Topic 842.

We adopted ASC 842 as of January 1, 2019. In preparation of adopting ASC 842, we have purchased a special lease software and also implemented additional internal controls to enable future preparation of

Table of Contents

Kindred Biosciences, Inc.

Notes to Consolidated Financial Statements (continued)

financial information in accordance with ASC 842. We believe the largest impact will be on the consolidated balance sheets for the accounting of facilities-related leases, which represent a majority of the operating leases the Company has entered into. These leases will be recognized under the new lease standard as ROU (Right of Use) assets and operating lease liabilities. We will also be required to provide expanded disclosures for the leasing arrangements. As of December 31, 2018, we had \$2.2 million of undiscounted future minimum operating lease commitments that are not recognized on our consolidated balance sheets under the new standard. We are still in the process of finalizing the evaluations of the effect of ASU 842 on our consolidated financial statements and disclosures and will finalize our accounting assessment and quantitative impact of the adoption in the first quarter of 2019.

In July 2018, the FASB issued ASU No. 2018-09, "Codification Improvements", and the amendments in this ASU affect a wide variety of Topics in the Codification. It applies to all reporting entities within the scope of the affected accounting guidance. It will take effect for public companies for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2018. We have adopted the new guidance and the impact of this standard does not have a material impact on our consolidated financial statements.

In August 2018, the FASB issued ASU No. 2018-13, "Fair Value Measurement (Topic 820)", which changes to disclosure requirements for fair value measurement. The amendments of this update modify the disclosure requirements on fair value measurements about Topic 820. It applies to all reporting entities within the scope of the affected accounting guidance. It will take effect for public companies for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019. We are currently evaluating the new guidance and have not determined the impact this standard may have on our consolidated financial statements.

We do not believe there are any other recently issued standards not yet effective that will have a material impact on our consolidated financial statements when the standards become effective.

### 3. Revenues and Cost of Product Revenues

We adopted ASC 606 in the first quarter of our fiscal year that began on January 1, 2018. This new standard replaced the previous revenue recognition guidance in U.S. GAAP. No prior period adjustments were needed as our first commercial shipments began in July 2018. Our revenues consist of product revenues resulting from the sale of Mirataz for the management of weight loss in cats. We account for a contract with a customer when there is a legally enforceable contract between us and our customer, the rights of the parties are identified, the contract has commercial substance, and collectability of the contract consideration is probable. Our revenues are measured based on the consideration specified in the contract with each customer, net of product returns, discounts and allowances.

Table of Contents

Kindred Biosciences, Inc.

## Notes to Consolidated Financial Statements (continued)

The following table presents revenues and cost of product revenues for the year ended December 31, 2018 (there were no revenues recognized in previous years) (in thousands):

	Year Ended December 31, 2018
Gross product revenues	\$ 2,027
Less allowance for product returns	(61 )
Net product revenues	1,966
Cost of product revenues	(324 )
Gross Profit	\$ 1,642

## Concentrations of credit risk

Our revenue was generated entirely from sales within the United States. Our product sales to four large distributors, namely MWI, Henry Schein, Patterson and Midwest each accounted for more than 10% of total revenues for the year ended December 31, 2018. On a combined basis, in 2018, these distributors accounted for approximately 91% of our product sales in the United States.

## Product returns

Our return policy generally allows customers to receive credit for expired products within 90 days after the product's expiration date. We currently estimate product return liabilities of 3% of gross revenue using probability-weighted available industry data and data provided by our distributors such as the inventories remaining in the distribution channel. Adjustments will be made in the future if actual results vary from our estimates.

## Accounts receivable and allowance for doubtful accounts

Accounts receivable are stated at their carrying values, net of any allowances for doubtful accounts. Accounts receivable consist primarily of amounts due from distributors, for which collection is probable based on the customer's intent and ability to pay. Receivables are evaluated for collection probability on a regular basis and an allowance for doubtful accounts is recorded, if necessary. We have no allowance for doubtful accounts as of December 31, 2018 as our analysis did not uncover any collection risks.

## 4. Fair Value Measurements

We measure certain financial assets at fair value on a recurring basis, including cash equivalents and available-for-sale securities. The fair value of these financial assets was determined based on a three-tier fair value hierarchy as described in Note 2, which prioritizes the inputs used in measuring fair value.



Table of Contents

Kindred Biosciences, Inc.

## Notes to Consolidated Financial Statements (continued)

The following table presents information about our financial assets that are measured at fair value on a recurring basis as of December 31, 2018 and indicates the fair value hierarchy of the valuation techniques utilized to determine such fair value:

(In thousands)	Fair Value Measurements as of December 31, 2018				
	Description	Total	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Unobservable Inputs (Level 3)
Cash equivalents:					
Money market funds	\$1,276	\$ 1,276	\$ —	\$ —	—
U.S. treasury bills	500	500	—	—	—
Commercial paper	45,332	—	45,332	—	—
U.S. treasury bonds and notes	7,949	—	7,949	—	—
Short-term investments:					
Commercial paper	5,353	—	5,353	—	—
Corporate notes	12,277	—	12,277	—	—
	\$72,687	\$ 1,776	\$ 70,911	\$ —	—

The following table presents information about our financial assets that are measured at fair value on a recurring basis as of December 31, 2017 and indicates the fair value hierarchy of the valuation techniques utilized to determine such fair value:

(In thousands)	Fair Value Measurements as of December 31, 2017				
	Description	Total	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Unobservable Inputs (Level 3)
Cash equivalents:					
Money market funds	\$801	\$ 801	\$ —	\$ —	—
Commercial paper	31,977	—	31,977	—	—
Corporate notes	1,500	—	1,500	—	—
Short-term investments:					
Commercial paper	22,052	—	22,052	—	—
US government agency notes	6,746	—	6,746	—	—
U.S. treasury bonds and notes	3,482	3,482	—	—	—
Corporate notes	13,927	—	13,927	—	—
Long-term investments:					

Edgar Filing: Kindred Biosciences, Inc. - Form 10-K

Corporate notes

1,499	—	1,499	—	
\$81,984	\$ 4,283	\$ 77,701	\$	—

F- 19

---



Table of Contents

Kindred Biosciences, Inc.

## Notes to Consolidated Financial Statements (continued)

There were no other transfers of assets between Level 1, Level 2 or Level 3 of the fair value hierarchy during the years ended December 31, 2018 and 2017.

At December 31, 2018 and 2017, we did not have any financial liabilities which were measured at fair value on a recurring basis.

## 5. Investments

The following tables summarize our investments in available-for-sale securities by significant investment category reported as short-term or long-term investments as of December 31, 2018 and 2017 (in thousands):

	December 31, 2018			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Short-term investments:				
Commercial paper	\$5,353	\$ —	—\$ —	\$5,353
Corporate notes	12,288	—	(11 )	12,277
	17,641	—	(11 )	17,630
Total available-for-sale investments	\$17,641	\$ —	—\$ (11 )	\$17,630

	December 31, 2017			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Short-term investments:				
Commercial paper	\$22,052	\$ —	—\$ —	\$22,052
U.S. government agency notes	6,750	—	(4 )	6,746
U.S. treasury bonds and notes	3,483	—	(1 )	3,482
Corporate notes	13,946	—	(19 )	13,927
	46,231	—	(24 )	46,207
Long-term investments:				
Corporate notes	1,506	—	(7 )	1,499
Total available-for-sale investments	\$47,737	\$ —	—\$ (31 )	\$47,706

Table of Contents

Kindred Biosciences, Inc.

## Notes to Consolidated Financial Statements (continued)

The following table summarizes the contractual maturities of our available-for-sale securities at December 31, 2018 (in thousands):

	Amortized Fair	
	Cost	Value
Mature in less than one year	\$ 17,641	\$ 17,630
Mature in one year or more	\$ —	\$ —

## 6. Property and Equipment, Net

Property and equipment consisted of the following:

(In thousands)	As of December	
	31, 2018	2017
Computer and lab equipment	\$4,923	\$2,303
Furniture and fixtures	65	46
Leasehold improvements	930	930
Construction-in-process	21,999	4,969
Total	27,917	8,248
Less accumulated depreciation and amortization	(1,574 )	(791)
Property and equipment, net	\$26,343	\$7,457

Construction-in-process is comprised of land, land improvements, building, building improvement and equipment that have not been put into service for their intended use as of December 31, 2018. As disclosed in Note 2, the Plant was purchased for \$3,750,000, which includes approximately eight acres of land, all improvements located at the Plant, and all personal property and intangible property located at the Plant or used in connection with the operation of the Plant. We incurred approximately \$18,249,000 in building renovation and construction costs as well as additional manufacturing and lab equipment that have not been put into service, resulting in a construction-in-process balance of \$21,999,000 at December 31, 2018.

Depreciation and amortization expense was \$805,000, \$475,000 and \$155,000 for the years ended December 31, 2018, 2017 and 2016, respectively.

## 7. Accrued Liabilities

Accrued liabilities consisted of the following as of December 31, 2018 and 2017:

(In thousands)	December 31, December 31,	
	2018	2017
Accrued consulting	\$ 627	\$ 335
Accrued research and development costs	2,509	919
Accrued other	5,012	646
Deferred rent	115	115
	8,263	2,015
Less current portion	(8,169 )	(1,900 )
Long-term liability (deferred rent)	\$ 94	\$ 115

Table of Contents

Kindred Biosciences, Inc.

Notes to Consolidated Financial Statements (continued)

8. Stockholders' Equity

Preferred Stock

Our Certificate of Incorporation, as amended, authorizes us to issue 10,000,000 shares of \$0.0001 par value preferred stock. At December 31, 2018, 100,000 unissued shares of our preferred stock are designated as Series A Preferred Stock, and the remaining 9,900,000 unissued shares of our preferred stock are undesignated.

Common Stock

Our Certificate of Incorporation, as amended and restated, authorizes us to issue 100,000,000 shares of \$0.0001 par value common stock.

Each share of common stock entitles the holder to one vote on all matters submitted to a vote of our stockholders, provided, however, that, except as otherwise required by law, holders of common stock shall not be entitled to vote on any amendment to the Certificate of Incorporation that relates solely to the terms of one or more outstanding shares of preferred stock if the holders of such affected series are entitled, either separately or together with the holders of one or more other series, to vote thereon pursuant to the Certificate of Incorporation or pursuant to the Delaware General Corporation Law.

In 2016, we issued 39,501 shares of common stock upon exercise of stock options for total proceeds of \$23,000. In addition, we issued 40,429 shares of common stock to employees in connection with our employee stock purchase program for total proceeds of \$139,000.

In 2017, we issued 156,927 shares of common stock upon exercise of stock options for total proceeds of \$311,000. In addition, we issued 43,561 shares of common stock to employees in connection with our employee stock purchase program for total proceeds of \$201,000.

In 2018, we issued 231,407 shares of common stock upon exercise of stock options for total proceeds of \$635,000. In addition, we issued 46,850 shares of common stock to employees in connection with our employee stock purchase program for total proceeds of \$352,000.

As of December 31, 2018, we had 33,948,254 shares of common stock outstanding.

Stock Offerings

In January 2015, we filed a shelf registration statement on Form S-3 to offer and sell, from time to time, equity and debt securities in one or more offerings up to a total dollar amount of \$150.0 million. On December 19, 2016, we entered into an At Market Issuance Sales Agreement with FBR Capital Markets & Co., or FBR, pursuant to which we were able to issue and sell shares of our common stock having an aggregate offering price up to \$30.0 million, through FBR as our sales agent. In conjunction with the sales agreement, FBR received compensation based on an aggregate of 3% of the gross proceeds on the sale price per share of our common stock. Any sales made pursuant to the sales agreement were deemed an "at-the-market" offering and were made pursuant to the shelf registration statement on Form S-3. For the year ended December 31, 2016, we did not sell any shares through FBR under the sales agreement. During the six months ended June 30, 2017, we completed the sale of 4,501,985 shares of common stock under the Sales Agreement. Net proceeds, after deducting approximately \$906,000 in commissions and fees and approximately \$132,000 in offering costs, were approximately \$28,962,000. On July 12, 2017, we completed an underwritten public offering of 3,000,000 shares of common stock at an offering price of \$7.50 per share for total gross proceeds of \$22,500,000. On August 11, 2017, we completed the closing of the exercise of the underwriter's

option to purchase an additional 314,000 shares of common stock at the public offering price of \$7.50 per share,

F- 22

---

Table of Contents

Kindred Biosciences, Inc.

Notes to Consolidated Financial Statements (continued)

resulting in additional gross proceeds of \$2,355,000. After giving effect to the exercise of the over-allotment option, the total number of shares sold by us in the public offering increased to 3,314,000 shares and gross proceeds increased to \$24,855,000. Net proceeds, after deducting underwriting commission and offering costs, were approximately \$23,198,000.

In January 2018, we filed a new shelf registration statement on Form S-3 to offer and sell, from time to time, equity and debt securities in one or more offerings up to a total dollar amount of \$150.0 million due to the expiration of our January 2015 shelf registration. In May 2018, we entered into an At Market Issuance Sales Agreement, or the Sales Agreement, with B. Riley FBR, Inc., and Oppenheimer & Co. Inc. acting as our distribution agents, relating to the sale of up to \$50,000,000 of our common stock from time to time. We terminated the Sales Agreement in June 2018 after having sold 188,100 shares, representing gross proceeds of approximately \$1,903,000. Net proceeds, after deducting commission, fees and offering costs, were approximately \$1,758,000. On June 20, 2018, we entered into an underwriting agreement with Cantor Fitzgerald & Co., as representative of the underwriters, and on June 22, 2018 we completed a public offering of 5,326,314 shares of common stock, which included the underwriters' option to purchase additional shares, at a public offering price of \$9.50 per share for total gross proceeds of approximately \$50,600,000. Net proceeds, after deducting underwriting discounts and commissions and offering expenses were approximately \$47,422,000.

On January 18, 2019, we entered into an underwriting agreement with Barclays Capital Inc. and Stifel, Nicolaus & Company, Incorporated, as representatives of the underwriters, and on January 23, 2019, we completed a public offering of 4,847,250 shares of our common stock, which included the exercise in full by the underwriters of their option to purchase 632,250 additional shares of the Company's common stock, at a public offering price of \$9.50 per share for total gross proceeds of approximately \$46,049,000. Net proceeds, after deducting underwriting discounts and commissions and offering expenses were approximately \$43,118,000.

#### 9. Stock-Based Awards and Benefit Plan

On November 4, 2012, our board of directors adopted the Kindred Biosciences, Inc. 2012 Equity Incentive Plan (the "2012 Plan"). The 2012 Plan provided for our board of directors to grant incentive stock options or non-qualified stock options for the purchase of common stock, to issue or sell shares of restricted common stock and to grant stock appreciation rights ("SARs") to our employees, directors, consultants and advisers of the Company. Pursuant to the terms of the 2012 Plan, no options or SARs shall be granted under the 2012 Plan after 10 years from the date of adoption of the 2012 Plan. We reserved 4,000,000 shares of our common stock for issuance under the 2012 Plan. The 2012 Plan terminated in May 2016 and 3,041,999 stock option shares which had been granted prior to the plan's expiration remaining outstanding as of December 31, 2018.

In May 2016, we adopted the 2016 Equity Incentive Plan (the "2016 Plan"), and reserved 3,000,000 shares of our common stock for issuance under the 2016 Plan. The 2016 Plan was the successor to our 2012 Plan and all awards made under the 2012 Plan remained subject to the terms of that plan. Options granted under the 2016 Plan were either incentive stock options or nonstatutory stock options. The 2016 Plan also provided for the grant of stock appreciation rights, restricted stock awards, restricted stock unit awards, performance stock awards, performance cash awards and other stock awards. The exercise price of a stock option was not less than 100% of the closing price of our common stock on the date of the grant. If, at any time we granted an option, and the optionee directly or by attribution owned stock possessing more than 10% of the total combined voting power of all classes of our stock, the option price was at least 110% of the fair value and was not exercisable more than five years after the date of grant. Options generally vested over a period of one or four years from the date of grant. Options granted under the 2016 Plan expired no later than 10 years from



Table of Contents

Kindred Biosciences, Inc.

## Notes to Consolidated Financial Statements (continued)

the date of grant. As of December 31, 2018, there were 2,376,436 option shares outstanding, 187,500 restricted stock awards issued but unvested, and 315,000 restricted stock units granted but unvested, and no shares are available for future grants under the 2016 Plan since it was retired in June 2018.

In June 2018, we adopted the 2018 Equity Incentive Plan (the “2018 Plan”), and reserved 3,000,000 shares of our common stock for issuance under the 2018 Plan. The 2018 Plan is the successor to our 2016 Plan. All awards made under the 2016 and 2012 Plans shall remain subject to the terms of these plans. Options granted under the 2018 Plan may be either incentive stock options or nonstatutory stock options. The 2018 Plan also provides for the grant of stock appreciation rights, restricted stock awards, restricted stock unit awards, performance stock awards, performance cash awards and other stock awards. The exercise price of a stock option may not be less than 100% of the closing price of our common stock on the date of the grant. If, at any time we grant an incentive stock option, and the optionee directly or by attribution owns stock possessing more than 10% of the total combined voting power of all classes of our stock, the option price shall be at least 110% of the fair value and shall not be exercisable more than five years after the date of grant. Options generally vest over a period of one or four years from the date of grant. Options granted under the 2018 Plan expire no later than 10 years from the date of grant. As of December 31, 2018, there were 403,493 option shares outstanding, and 2,596,507 shares available for future grants under the 2018 Plan.

## 2014 Employee Stock Purchase Plan

In December 2014, our board of directors adopted the Kindred Biosciences, Inc. 2014 Employee Stock Purchase Plan (the “Purchase Plan”). A total of 200,000 shares of our common stock are authorized for issuance under the Purchase Plan. At the Annual Meeting of Stockholders of Kindred Biosciences, Inc. held on June 22, 2018, our stockholders approved an amendment to increase the number of shares that may be issued under the ESPP from 200,000 shares to 500,000 shares. The Purchase Plan permits eligible employees to purchase common stock at a discount through payroll deductions during defined six months consecutive offering periods beginning on December 1st. The price at which the stock is purchased is equal to the lower of 85% of the fair market value of the common stock on the first day of the offering or 85% of the fair market value of our common stock on the purchase date. A participant may purchase a maximum of 2,000 shares of common stock during each offering period, not to exceed \$25,000 worth of common stock on the offering date during each calendar year. We use the Black-Scholes option pricing model, in combination with discounted employee price, in determining the value of the Purchase Plan expense to be recognized during each offering period. The weighted-average grant date fair value per share using the Black-Scholes option pricing model was \$2.72 during the year ended December 31, 2018.

As of December 31, 2018, there were 184,392 shares of common stock issued under the Purchase Plan and 315,608 shares available for future issuance under the Purchase Plan. At December 31, 2018 and 2017, we had an outstanding liability of \$47,000 and \$27,000, respectively, which is included in accrued compensation on the consolidated balance sheets, for employee contributions to the Purchase Plan for shares pending issuance at the end of the next offering period.

## Reserved Shares

At December 31, 2018, shares of common stock reserved for future issuance inclusive of outstanding option shares are as follows:

2018 Equity Incentive Plan	2,596,507
2014 Employee Stock Purchase Plan	315,608
	2,912,115

Stock Option Plan Activity Summary

F- 24

---



Table of Contents

Kindred Biosciences, Inc.

## Notes to Consolidated Financial Statements (continued)

A summary of activity under our stock option plans is as follows:

	Shares Available For Grant	Shares Issuable Under Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (In Years)	Aggregate Intrinsic Value
Balance, December 31, 2015	726,402	3,116,185	\$7.26	8.2	\$2,908,000
2012 Plan terminated (a)	(307,107 )				
2016 Plan authorized (b)	3,000,000				
Granted	(847,683 )	847,683	\$3.48		
Exercised		(39,501 )	\$0.57		
Expired	43,818	(43,818 )	\$14.52		
Forfeited - stock options	312,220	(312,220 )	\$7.06		
Balance, December 31, 2016	2,927,650	3,568,329	\$6.36	7.5	\$4,353,000
2012 Plan true up retired shares (c)	(26,977 )				
2016 Plan issued RSA shares (d)	(250,000 )				
Granted	(1,208,200)	1,208,200	\$6.62		
Exercised		(156,927 )	\$1.98		
Expired	7,267	(7,267 )	\$14.54		
Forfeited - stock options	38,710	(38,710 )	\$6.60		
Balance, December 31, 2017	1,488,450	4,573,625	\$6.57	7.2	\$18,745,000
2012 Plan true up retired shares (e)	(56,953 )				
2016 Plan RSA forfeited on 1/23/18 (f)	26,980				
2016 Plan RSU issued on 1/22/18 (g)	(315,000 )				
2016 Plan true up retired shares (h)	(56,636 )				
2018 Incentive Plan (i)	3,000,000				
Granted	(1,607,193)	1,607,193	\$9.78		
Exercised		(242,031 )	\$3.19		
Expired	36,791	(36,791 )	\$13.05		
Forfeited - stock options	80,068	(80,068 )	\$7.40		
Balance, December 31, 2018	2,596,507	5,821,928	\$7.54	7.1	\$24,780,000
Options vested and expected to vest, December 31, 2018		5,821,928	\$7.54	7.1	\$24,780,000
		3,716,187	\$7.01	6.1	\$18,806,000

Options exercisable,  
December 31, 2018

- (a) The 2012 Equity Incentive Plan terminated in May 2016. All shares available for grant under this Plan expired.
- (b) The 2016 Equity Incentive Plan was adopted and approved by stockholders in May 2016.
- (c) True up all expired shares available for grant under the 2012 Equity Incentive Plan, which was terminated in May 2016.
- (d) Issued 250,000 RSA shares on January 23, 2017 under the 2016 Equity Incentive Plan.
- (e) True up expired shares available for grant under the 2012 Equity Incentive Plan, which was terminated in May 2016.
- (f) Vested 62,500 RSA shares on January 23, 2018. 26,980 shares were forfeited to cover tax liability.
- (g) Issued 315,000 RSU units on January 22, 2018 under the 2016 Equity Incentive Plan.
- (h) The 2016 Equity Incentive Plan terminated in June 2018. All shares available for grant under this Plan expired.
- (i) The 2018 Equity Incentive Plan was adopted and approved by stockholders in June 2018.

The aggregate intrinsic value of options is calculated as the difference between the exercise price of

F- 25

---

Table of Contents

Kindred Biosciences, Inc.

## Notes to Consolidated Financial Statements (continued)

options and the fair value of our common stock for those options that had exercise prices lower than the fair value of our common stock on December 31, 2018, 2017 and 2016.

The aggregate intrinsic value of stock options exercised during the years ended December 31, 2018, 2017 and 2016 was \$2,261,000, \$911,000 and \$117,000, respectively.

We received proceeds of \$635,000, \$311,000 and \$23,000 from the exercise of common stock options during the years ended December 31, 2018, 2017 and 2016, respectively.

The weighted-average grant date fair value of options granted during the years ended December 31, 2018, 2017 and 2016 was \$5.58, \$4.21 and \$2.45 per share, respectively.

**Restricted Stock**

On January 23, 2017, we granted 250,000 shares of restricted stock awards to four employees. Shares will vest 25% on each one year anniversary of the grant date provided that the employee is in the employment of the Company on such vesting date. The total stock-based compensation expense related to these awards is \$1,600,000. On January 22, 2018, we granted 315,000 shares of restricted stock units to four employees. Shares will vest 25% on each one year anniversary of the grant date provided that the employee is in the employment of the Company on such vesting date. The total stock-based compensation expense related to these units is \$2,756,000. As of December 31, 2018, we have an aggregate of approximately \$2,933,000 unrecognized stock-based compensation expense for restricted stock awards outstanding which is expected to be recognized over a weighted-average period of 2.8 years.

Restricted stock activity for the year ended December 31, 2018, was as follows:

Restricted Stock Award	Shares	Weighted Average Grant Date Fair Value
Unvested balance at December 31, 2017	250,000	\$6.40
Granted	—	—
Vested	(62,500)	6.40
Forfeited	—	—
Unvested balance at December 31, 2018	187,500	\$6.40

Restricted Stock Units	Shares	Weighted Average Grant Date Fair Value
Unvested balance at December 31, 2017	—	—
Granted	315,000	\$8.75
Vested	—	—
Forfeited	—	—
Unvested balance at December 31, 2018	315,000	\$8.75

**Stock-Based Compensation**

We recognize stock-based compensation expense for only the portion of awards that are expected to

Table of Contents

Kindred Biosciences, Inc.

## Notes to Consolidated Financial Statements (continued)

vest. In developing a forfeiture rate estimate, we have considered our historical experience to estimate pre-vesting forfeitures for service-based awards. The impact of a forfeiture rate adjustment will be recognized in full in the period of adjustment, and if the actual forfeiture rate is materially different from our estimate, we may be required to record adjustments to stock-based compensation expense in future periods.

The fair value of each stock option grant is estimated on the date of grant using the Black-Scholes option-pricing model. Due to insufficient company-specific historical and implied volatility information, we used to estimate the expected stock price volatility based on the historical volatility of publicly traded peer companies. During the quarter ended March 31, 2018, an analysis was completed to compare our own stock volatility to the volatility calculated using peer analysis. The conclusion was that Kindred Biosciences has enough history to provide a reliable expected volatility. As a result, we use the volatility of our own stock. The expected term of our common stock options has been determined utilizing the “simplified” method as we have insufficient historical experience for options grants overall, rendering existing historical experience irrelevant to expectations for current grants. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. Expected dividend yield is based on the fact that we have never paid cash dividends and does not expect to pay any cash dividends in the foreseeable future.

Total stock-based compensation expense, related to all of our share-based payment awards, is comprised of the following:

(In thousands)	Years Ended		
	December 31,		
	2018	2017	2016
Research and development	\$1,746	\$1,650	\$1,463
General and administrative	4,531	3,557	2,164
	\$6,277	\$5,207	\$3,627

Total stock-based compensation expense includes stock options, restricted stock awards, restricted stock units, and expense from the Purchase Plan for the years ended December 31, 2018, 2017, and 2016.

We had an aggregate of approximately \$9,093,000 of unrecognized stock-based compensation expense for unvested stock-based awards as of December 31, 2018, which is expected to be recognized over a weighted average period of 2.8 years.

## Valuation assumptions

The relevant data used to determine the fair value of stock-based awards is as follows:

Table of Contents

Kindred Biosciences, Inc.

## Notes to Consolidated Financial Statements (continued)

	Years Ended December 31,		
	2018	2017	2016
Stock options:			
Weighted average risk-free interest rate	2.62%	1.98%	1.61%
Weighted average expected term (in years)	5.9	6.0	6.3
Weighted average expected volatility	59.2%	70.4%	83.4%
Weighted average expected dividend yield	—	—	—
Fair value at grant date	\$5.58	\$4.21	\$2.45
Employee stock purchase plan:			
Weighted average risk-free interest rate	2.02%	1.04%	0.50%
Weighted average expected term (in years)	0.5	0.5	0.5
Weighted average expected volatility	43.7%	56.7%	84.4%
Weighted average expected dividend yield	—	—	—
Fair value at grant date	\$2.72	\$1.73	\$1.42
Restricted stock awards:			
Fair value at grant date	—	\$6.40	—
Restricted stock units:			
Fair value at grant date	\$8.75	—	—

## 10. Commitments and Contingencies

## Operating Leases

In April 2014, we entered into non-cancelable operating leases for 2,145 square feet of laboratory space through May 2017 and 6,900 square feet of office space through November 2017. In January, August and November 2015, we amended our original operating lease for laboratory space to expand the facility with an additional 2,431 square feet, 131 square feet and 123 square feet, respectively, of manufacturing space through May 2017. In February and October 2016, we further amended our original operating lease for laboratory space to further expand the facility with an additional 3,599 square feet and 2,326 square feet, respectively, of quality control and laboratory space through May 2017. In February 2017, we further amended our existing lease for an expansion of an additional 721 square feet of laboratory space. Commencing on June 1, 2017, the non-cancellable operating lease for the entire existing laboratory space of a total 11,476 square feet is extended for another five years through May 2022. In August 2015, we entered into a new non-cancelable operating lease for 3,126 square feet of office space in San Diego, California through September 2019. In April 2017, we renewed our headquarters office lease for 6,900 square feet of office space in Burlingame, California through November 30, 2020 and in June 2017, we amended the lease with an additional 1,190 square feet of office space through November 30, 2020. In October 2018, we entered into a sublease agreement for an additional 5,613 square feet of laboratory space next to our current laboratory facility. The sublease agreement expires on March 31, 2019. After that, the lease will continue on a month-to-month basis unless or until terminated by either party, with or without cause, by giving the other party 30 days written notice, provided that the extended term shall not extend beyond December 31, 2019.



Table of Contents

Kindred Biosciences, Inc.

## Notes to Consolidated Financial Statements (continued)

Rent expense for the years ended December 31, 2018, 2017 and 2016 was \$814,000, \$679,000 and \$522,000, respectively. As of December 31, 2018, we are obligated to make minimum lease payments under all of our operating leases as follows (in thousands):

Year ending December 31,	Lease Payments
2019	\$ 835
2020	726
2021	459
2022	194
Thereafter	—
Total	\$ 2,214

In March 2018, we entered into a standard form of agreement with CRB Builders, LLC (“CRB”) in connection with the renovation of the Plant. Pursuant to the agreement, CRB will provide pre-construction and construction services in connection with constructing and renovating the Plant to provide approximately 16,500 square feet of new production space and supporting Fill and Finish and Bio Production processes (the “Project”). The date for substantial completion of CRB’s work on the Project is anticipated to be in mid-2019, which is subject to adjustment in accordance with the terms of the agreement as the renovation progresses, or as agreed and requested by us. The agreement is subject to customary undertakings, covenants, obligations, rights and conditions.

**Purchase Commitments**

In June 2018, we entered into a Strategic Supply Agreement (the “Agreement”), with Pall Corporation (“Pall”) for purchase of equipment and consumables to be used in support of our manufacturing requirements, including, but not limited to, the Plant. Pursuant to the Agreement, we will purchase certain pharmaceutical manufacturing equipment and related services in the aggregate amount of \$3.8 million with a seven-year consumable purchase obligation in the aggregate amount of approximately \$16.5 million. The Agreement is subject to customary undertakings, covenants, obligations, rights and conditions. We have incurred \$3,286,000 in equipment purchase costs and \$588,000 in other purchase costs as of December 31, 2018.

**Indemnities and Guarantees**

We have made certain indemnities and guarantees, under which we may be required to make payments to a guaranteed or indemnified party, in relation to certain transactions. We indemnify our officers and directors to the maximum extent permitted under the laws of the State of Delaware. The duration of these indemnities and guarantees varies and, in certain cases, is indefinite. These indemnities and guarantees do not provide for any limitation of the maximum potential future payments we could be obligated to make. Historically, we have not been obligated to make any payments for these obligations and no liabilities have been recorded for these indemnities and guarantees in the accompanying consolidated balance sheets.

**Legal Matters**

In the ordinary course of business, we may face various claims brought by third parties and may, from time to time, make claims or take legal actions to assert our rights, including intellectual property disputes, contractual disputes and other commercial disputes. Any of these claims could subject us to litigation. Management believes there are currently no claims that are likely to have a material effect on our consolidated financial position and results of operations.





Table of Contents

Kindred Biosciences, Inc.

## Notes to Consolidated Financial Statements (continued)

## 11. Restructuring Plan

On January 8, 2016, our Board of Directors committed to a restructuring plan intended to better align our workforce to our revised operating needs and program development plans. On January 11, 2016, we implemented the restructuring plan that focused on streamlining our development programs and to ensure our remaining funds are sufficient to fund our planned operations through 2018. To match these priorities, we reduced our workforce by 18 positions, or approximately 31% of our workforce, resulting in a total workforce of 39 positions. As a result of the restructuring plan which has been completed, we recorded a restructuring charge of approximately \$655,000 related to severance payments which was entirely paid in the quarter ended March 31, 2016. There were no further restructuring charges since then.

## 12. Income Taxes

There is no provision for income taxes because we have historically incurred operating losses and we maintain a full valuation allowance against our net deferred tax assets.

Differences between the provision (benefit) for income taxes and income taxes at the statutory federal income tax rate are as follows:

(In thousands, except percentages)	For the years ended December 31,					
	2018		2017		2016	
Income tax expense (benefit) at statutory federal rate	\$(10,436)	21.0 %	\$(10,499)	34.0 %	\$(7,651)	34.0 %
State income tax, net of federal benefit	(3,748)	) 7.5	(1,880)	) 6.1	(1,389)	) 6.2
Permanent items	13	—	63	(0.2)	38	(0.2)
Research credits	(1,909)	) 3.8	(1,172)	) 3.8	(970)	) 4.3
Stock-based compensation	(237)	) 0.5	(122)	) 0.4	(29)	) 0.1
ASC 740-10	864	(1.7)	469	(1.5)	388	(1.7)
Change in valuation allowance	14,949	(30.1)	(128)	) 0.4	9,602	(42.6)
Tax Cuts and Jobs Act	—	—	13,092	(42.4)	—	—
Other	504	(1.0)	177	(0.6)	11	(0.1)
Provision (benefit) for income taxes	\$—	— %	\$—	— %	\$—	— %

Deferred tax assets are recognized for temporary differences that will result in deductible amounts in future periods. The components of the deferred tax assets are as follows at December 31, 2018 and 2017:

Table of Contents

Kindred Biosciences, Inc.

## Notes to Consolidated Financial Statements (continued)

(In thousands)	December 31,	
	2018	2017
Deferred tax assets:		
Net operating loss carryforwards	\$39,579	\$26,369
Research & development credits	3,589	3,044
Accrued expenses	893	753
Amortization and depreciation	(393 )	(132 )
Stock-based compensation	6,173	4,860
Other	10	12
	49,851	34,906
Valuation Allowance	(49,851 )	(34,906 )
Net current deferred tax assets	\$—	\$—

At December 31, 2018, we had net deferred tax assets of \$49,851,000. Due to uncertainties surrounding our ability to generate future taxable income to realize these assets, a full valuation allowance has been established to offset the net deferred tax asset.

Additionally, the future utilization of our net operating loss and research and development tax credits carryforwards is subject to annual limitation under Sections 382 and 383 of the Internal Revenue Code of 1986, and similar state tax provisions due to ownership change limitations that have occurred previously or that could occur in the future. These ownership changes limit the amount of the net operating loss and research and development tax credit carryforward and other deferred tax assets that can be utilized to offset future taxable income and tax, respectively. In general, an ownership change, as defined by Sections 382 and 383, results from transactions increasing ownership of certain stockholders or public groups in the stock of the corporation by more than 50 percent points over a three-year period. We believe we incurred ownership changes since April 2014, however, we have not completed an analysis yet to determine the impact of our ability to use net operating losses and research and development credits as of December 31, 2018.

At December 31, 2018, we had federal and California net operating loss carryovers of \$139,843,000 and \$139,763,000, respectively. The federal and California net loss carryforwards will begin to expire in 2032.

At December 31, 2018, we had federal and state research tax credit carryovers of approximately \$3,625,000 and \$3,617,000, respectively. The federal research and development tax credit carryforwards will begin to expire in 2033. The California research and development credit carryforwards are available indefinitely.

The impact of an uncertain income tax position on the income tax return must be recognized at the largest amount that is more likely than not to be sustained upon audit by the relevant taxing authority. An uncertain income tax position will not be recognized if it has less than a 50% likelihood of being sustained. There were no unrecognized tax benefits recorded by us as of the date of adoption. As a result of the implementation, we did not recognize an increase in the liability for unrecognized tax benefits.

A rollforward of changes in our unrecognized tax benefits is shown below.

Table of Contents

Kindred Biosciences, Inc.

## Notes to Consolidated Financial Statements (continued)

(In thousands)	December 31,		
	2018	2017	2016
Balance at beginning of year	\$2,252	\$1,698	\$1,234
Additions based on tax positions related to the current year	944	554	464
Additions for tax positions of prior years	—	—	—
Balance at end of year	\$3,196	\$2,252	\$1,698

The amount of unrecognized tax benefits that would impact the effective tax rate if recognized and realized is \$2,893,000.

Our practice is to recognize interest and/or penalties related to income tax matters as income tax expense. We had no accrual for interest or penalties on our accompanying consolidated balance sheets at December 31, 2018, 2017 and 2016, and have not recognized interest and/or penalties in our consolidated statements of operations and comprehensive loss for the years ended December 31, 2018, 2017 and 2016.

We do not anticipate a significant change to our unrecognized tax benefits during the next twelve months.

We file tax returns as prescribed by tax laws of the jurisdictions in which we operate. In the normal course of business, we are subject to examination by federal and state jurisdictions, where applicable. There are currently no pending tax examinations. Our federal and state tax returns are still open under statute from 2013 to present.

On December 22, 2017, the President of the United States signed into law the Tax Cuts and Jobs Act (the "Act"). The Act amended the Internal Revenue Code to reduce tax rates and modify policies, credits, and deductions for individuals and businesses. For businesses, the Act reduced the corporate tax rate from a maximum of 35% to a flat 21% rate. The rate reduction was effective on January 1, 2018.

As a result of the rate reduction, we have reduced the deferred tax asset balance as of December 31, 2017 by \$13.1 million.

Due to our full valuation allowance position, we have also reduced the valuation allowance by the same amount.

We have completed our evaluation of the potential impacts of IRC Section 162(m) as amended by the Act of 2017 and concluded there is no impact on our December 31, 2018 financial statements.

## 13. Net Loss Per Share

Basic and diluted net loss per share was calculated as follows for the years ended December 31, 2018, 2017 and 2016:

F- 32

Table of Contents

Kindred Biosciences, Inc.

## Notes to Consolidated Financial Statements (continued)

(In thousands, except per share amounts)

	Years Ended December 31,		
	2018	2017	2016
Basic and diluted net loss per share attributable to common stockholders:			
Numerator:			
Net loss attributable to common stockholders	\$(49,690)	\$(30,879)	\$(22,499)
Denominator:			
Weighted-average number of common shares outstanding, basic and diluted	31,001	25,084	19,873
Net loss per common share attributable to common stockholders, basic and diluted	\$(1.60 )	\$(1.23 )	\$(1.13 )

There was no difference between our net loss and the net loss attributable to common stockholders for all periods presented.

Stock options to purchase 5,821,928 shares, 4,573,625 shares and 3,568,329 shares of common stock as of December 31, 2018, 2017 and 2016, respectively, were excluded from the computation of diluted net loss per share attributable to common stockholders because their effect was anti-dilutive. 187,500 shares unvested restricted stock award as of December 31, 2018 and 250,000 shares unvested restricted stock award as of December 31, 2017 were also excluded from the computation of diluted net loss per share calculations because their effect was anti-dilutive. 315,000 units of granted but unvested restricted stock units as of December 31, 2018 were also excluded from the computation of diluted net loss per share calculations because their effect was anti-dilutive.

## 14. Employee Savings Plan

We have established an employee savings plan pursuant to Section 401(k) of the Internal Revenue Code, effective May 1, 2014. The plan allows participating employees to deposit into tax deferred investment accounts up to 90% of their salary, subject to annual limits. We make contributions to the plan in an amount equal to 50% on the first 6% for a maximum of 3% of the participant's compensation which is deferred. We contributed approximately \$292,000, \$149,000 and \$101,000 to the plan during the years ended December 31, 2018, 2017 and 2016, respectively.

## 15. Selected Quarterly Financial Information (unaudited)

The following table presents selected unaudited quarterly financial data for each of the quarters in the years ended December 31, 2018 and 2017.

Table of Contents

Kindred Biosciences, Inc.

## Notes to Consolidated Financial Statements (continued)

(In thousands, except per share amounts)	2018				2017			
	Dec. 31	Sep. 30	Jun. 30	Mar. 31	Dec. 31	Sep. 30	Jun. 30	Mar. 31
Quarter ended								
Net product revenues	\$1,326	\$640	\$—	\$—	\$—	\$—	\$—	\$—
Operating costs and expenses								
Cost of product revenues	214	110	—	—	—	—	—	—
Research and development	7,756	7,477	5,820	5,346	5,142	4,877	3,866	3,780
General and administrative	9,219	6,608	5,770	4,902	4,820	3,269	3,056	2,843
Total operating cost and expenses	17,189	14,195	11,590	10,248	9,962	8,146	6,922	6,623
Loss from operations	(15,863 )	(13,555 )	(11,590 )	(10,248 )	(9,962 )	(8,146 )	(6,922 )	(6,623 )
Interest and other income, net	422	518	349	277	232	256	155	131
Net loss	\$(15,441)	\$(13,037)	\$(11,241)	\$(9,971)	\$(9,730)	\$(7,890)	\$(6,767)	\$(6,492)
Net loss per share, basic and diluted (1)	\$(0.46 )	\$(0.39 )	\$(0.39 )	\$(0.36 )	\$(0.35 )	\$(0.29 )	\$(0.29 )	\$(0.30 )
Weighted average shares used in computing net loss per share, basic and diluted	33,708	33,601	28,619	27,986	27,915	27,400	23,409	21,516

(1) Net loss per share for each quarter is calculated as a discrete period; the sum of four quarters may not equal the calculated full year amount.

## 16. Subsequent Events

On January 18, 2019, we entered into an underwriting agreement (the "Underwriting Agreement") with Barclays Capital Inc. and Stifel, Nicolaus & Company, Incorporated, as representatives of the underwriters, and on January 23, 2019, we completed a public offering of 4,847,250 shares of common stock, which includes the exercise in full by the underwriters of their option to purchase 632,250 additional shares of our common stock, at a public offering price of \$9.50 per share for total gross proceeds of approximately \$46 million. Net proceeds, after deducting underwriting discounts and commissions and offering expenses were approximately \$43.1 million.

On February 1, 2019, we filed a Certificate of Incorporation with the State of Delaware for a wholly owned subsidiary, Centaur Biopharmaceutical Services, Inc. (the "Subsidiary"). The Subsidiary has one class of capital stock which is designated common stock, \$0.0001 par value per share. The authorized number of shares of common stock for the Subsidiary is 1,000.