Kindred Biosciences, Inc.
Form 10-K
March 06, 2019
UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

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FORM 10-K

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

For the fiscal year ended December 31, 2018

o 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	46-1160142
(State or other jurisdiction of incorporation or organization)	(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 o No þ
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 o No þ
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 þ No o

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 þ No o
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. þ
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 o	Accelerated filer þ	Non-accelerated filer o	Smaller reporting company þ
			Emerging growth company o

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. o

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

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.

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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.

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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 a an a2-adrenergic receptor antagonist nor-adrenergic and serotonergic antidepressant drug. Mirtazapine is known to be a potent antagonist of 5-HT2 and 5-HT3 serotonin receptors in the central nervous system ("CNS"), and a potent inhibitor of histamine H1 receptors. Because mirtazapine blocks 5-HT2 and 5-HT3 receptors, only 5-HT1A- mediated serotonergic transmission is enhanced. Inhibition of 5-HT2 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

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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,

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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™ (dipyrone 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") dipyrone, 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 (dipyrone 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)

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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,

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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

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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

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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 (dipyrone injection), also known as KIND-012, for the control of pyrexia (fever) in horses. The FDA has approved the safety

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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.

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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 Miratazʼs 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

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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' ad