Kindred Biosciences, Inc.
Form 10-K
March 14, 2014
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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, 2013

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)

1499 Bayshore Highway, Suite 226
Burlingame, California 94010
(Address of principal executive offices)
(650) 701-7901
Registrant's telephone number:

Securities registered under Section 12(b) of the Act: Common Stock, $0.0001 par value.

Securities registered under 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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes þ No o

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Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405 of this chapter) 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, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer o	Accelerated filer o	Non-accelerated filer þ (Do not check if a smaller reporting company)	Smaller reporting company 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
The registrant completed the initial public offering of its common stock on December 12, 2013. Accordingly, there was no public market for the registrant's common stock as of June 30, 2013, the last business day of the registrant's most recently completed second fiscal quarter.

The outstanding number of shares of common stock as of March 10, 2014 was 16,227,120.
Documents incorporated by reference: Certain portions of the registrant's Proxy Statement for the 2014 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 under Part III of this Form 10-K.

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING INFORMATION

This annual report contains forward-looking statements. All statements that address operating performance, events or developments that we expect or anticipate will occur in the future are forward-looking statements. The forward-looking statements are contained principally in the sections entitled “Business,” “Risk Factors,” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations.” In some cases, you can identify forward-looking statements by terms such as “may,” “will,” “should,” “could,” “would,” “expects,” “plans,” “anticipat “believes,” “estimates,” “projects,” “predicts,” “potential” and similar expressions intended to identify forward-looking statements.

These forward-looking statements are based on management’s beliefs and assumptions and on information currently available to management. Management believes that these forward-looking statements are reasonable as and when made. However, readers should not place undue reliance on any such forward-looking statements because such statements speak only as of the date when made. We do not undertake any obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law. In addition, forward-looking statements are subject to certain risks and uncertainties that could cause actual results, events and developments to differ materially from our historical experience and our present expectations or projections. These risks and uncertainties include, but are not limited to, those described in the sections entitled “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and elsewhere in this annual report and those described from time to time in our future reports which we will file with the Securities and Exchange Commission. You should read this annual report and the documents that we have filed as exhibits to this annual report completely.

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PART I.

ITEM 1. BUSINESS.

Overview

We are a development 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. We have three product candidates that are in, or will shortly enter, pivotal field efficacy trials, or pivotal trials, and expect approval of one or more of these product candidates in 2015. In addition, we have seven 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.

Our lead product candidates are CereKin for the treatment of osteoarthritis pain and inflammation in dogs, AtoKin for the treatment of atopic dermatitis in dogs and SentiKin for the treatment of post-operative pain in dogs. All of these product candidates, if approved, would be first-in-class drugs in the pet therapeutic market.

In August 2013, we initiated the pivotal trial for CereKin, in February 2014, we initiated the pivotal trial for AtoKin, and we expect to initiate the pivotal trial for SentiKin by April 2014. Assuming positive results from these trials, we intend to submit New Animal Drug Applications, or NADAs, for marketing approval of CereKin, AtoKin and SentiKin in the United States starting in 2014, and anticipate potential marketing approvals and product launches in the second half of 2015. If approved in the United States, we may make similar regulatory filings for these products with the European Medicines Agency, or EMA, for marketing approval in the European Union, or EU.

We are currently developing product candidates for ten additional indications, with the potential to launch two or more products annually for several years starting in the second half of 2015. 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. Because we seek to identify product candidates that are not protected by third-party patents, we typically do not need to obtain licenses or make any upfront, milestone or royalty payments in connection with our product candidates.

Relative to human drug development, the development of pet therapeutics is generally faster, more predictable 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, 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 pet therapeutics from the Investigational New Animal Drug, or INAD, filing with the FDA to marketing approval in three to five years at a cost of approximately $3 million to $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, or CMC, which are important gating factors in the regulatory approval process. As a result, we usually do not need to invest in active pharmaceutical ingredient, or API, process development to comply with good manufacturing practices, or 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.

We estimate that the total U.S. market for veterinary care was approximately $13.7 billion in 2012, an increase of 48% from 2006. 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,

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developed and marketed. As an example, the market for therapeutics treating osteoarthritis for dogs has grown from less than $10 million to over $450 million since 1997, driven by the introduction of non-steroidal anti-inflammatory drugs, or NSAIDs, such as Rimadyl approved for animals. We expect continued market growth as new pet therapeutics are developed and owners grow more familiar with the treatment of pets with such therapeutics. This continues a trend reported by the American Pet Products Association, or APPA, which found approximately 78% of U.S. dog owners treated their dogs with medications in 2010, as compared to 50% in 1998.

Our management team's extensive experience in both human and animal drug development has enabled us to quickly establish our product pipeline, obtain Protocol Concurrences from the FDA for CereKin and AtoKin and commence the pivotal trial of CereKin. 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 co-founder and 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. Kevin Schultz, D.V.M., Ph.D., our Chief Scientific Officer, was one of the founding team members of Merial Limited, a leading veterinary medicine company, and served as Merial's Chief Scientific Officer, where he oversaw development of numerous animal therapeutics and vaccines, as well as Frontline Plus, one of the best-selling pet therapeutic products in history. Stephen Sundlof, D.V.M., Ph.D., our Senior Vice President of Regulatory Affairs, was the Director of the FDA's Center for Veterinary Medicine, or CVM, from 1994 to 2008, where he oversaw all veterinary products regulated by the FDA. Denise Bevers, our co-founder and Chief Operating Officer, has over 20 years of experience in clinical operations and medical affairs.

Product Pipeline

Our current product pipeline consists of small molecules and biologics for a range of indications in dogs, cats and horses. Small molecules are generally chemical compounds administered orally and biologics are generally proteins and vaccines administered by injection. In December 2012, we filed INADs for CereKin for osteoarthritis in dogs and for AtoKin for atopic dermatitis in dogs. We filed INADs for SentiKin for post-operative pain in dogs and for KIND-006 for gastrointestinal disease in cats in March 2013, and in June 2013, we filed an INAD for KIND-007 for cancer and immune diseases in dogs. Although there is no equivalent of an INAD for biologic products, we have requested that the USDA assign a reviewer for several of our biologic product candidates to begin the USDA review process.

The USDA's 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 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, it is possible that the agencies may determine that one or more of our animal biologics will be regulated by the FDA instead of the USDA.

The following table illustrates ten product candidates that we are developing for 13 indications. References in the table to "PLA" mean an Application for United States Veterinary Biological Product License with the USDA, also called a Product License Agreement.

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In addition to our product candidates currently in development, we have identified over 30 potential small molecule and biologic therapeutics that are in the pre-INAD stage, including molecules targeting cancer metabolism, checkpoint inhibitors, and feline erythropoetin.

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 that 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. We also try to identify product candidates that are free from any intellectual property rights of others, including drugs or dosage forms that are not marketed in the United States, or marketed only in a few countries, to minimize the potential for competition from human generics. For example, 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. As our product candidates are generally not protected by third-party patents, we typically do not need to obtain a license or make any upfront, milestone or royalty payments in connection with our product candidates.

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, such as our chewable,

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beef-flavored formulation for dogs. Pet therapeutics that are palatable to animals can command premium price and significant market share, as evidenced by the still-dominant position of Rimadyl compared to generic carprofen. 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 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-year or ten-year marketing exclusivity. In addition, we plan to introduce improved formulations, combination products and other product improvements in order to extend the lifecycle of our products.

Our biologic product candidates are 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. As an example, we have created new biologics for dogs that target the canine counterparts of the human targets of Enbrel and Orencia. We are currently undertaking the development of manufacturing processes for our initial biologic product candidates. We generally intend to seek composition-of-matter patents and other patents for these new chemical entities. Our biologic products, if approved, will not face generic competition or such generic competition may be significantly delayed, because there is presently no biosimilar pathway for veterinary biologics in the United States or in the EU. Our management team has extensive experience in human antibody therapies and in the development of biologics products, including Lucentis, Tysabri, and Xolair.

Business Strategy

Key elements of our business strategy are as follows:

Advance CereKin, AtoKin, SentiKin and our other product candidates through development and regulatory approval

We have initiated enrollment in the pivotal trial of CereKin and AtoKin, and intend to initiate the pivotal trial for SentiKin by April 2014. The trials are being, or will be, conducted in parallel with the required toxicology, or target animal safety, studies and CMC activities. If these trials and other development activities are successful, we expect to submit NADAs for CereKin in mid-2014, and for AtoKin and SentiKin in late 2014, with potential marketing approvals for the first of these products starting in mid 2014. If approved in the United States, we will consider making similar regulatory filings for these products with the EMA.

In addition to CereKin, AtoKin and SentiKin, we are developing product candidates for ten additional indications in dogs and cats. We intend to advance these products into pivotal trials, which, if successful, and completed on time as currently planned, would enable us to launch two or more approved products annually for several years beginning in the second half of 2015.

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, or 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, among other things:

- identify 10 product candidates that we are developing for 13 indications;
- obtain Protocol Concurrences with the FDA for two of our lead product candidates;
- commence pivotal trial enrollment for CereKin; and
- create new biologics for dogs that target the canine counterpart targets of Enbrel and Orencia.

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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. For example, we are initially developing CereKin for the treatment of osteoarthritis pain in dogs, but have also filed an INAD and conducted a pharmacokinetic study for its use in horses. We are also developing SentiKin for post-operative pain in 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 several 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, and that are free from intellectual property rights of others in the United States. 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.

Commercialize our 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 product candidates, if approved, we intend to establish a direct sales organization eventually numbering approximately 50 sales representatives to market our products directly to veterinarians in the United States. We believe such a sales force will be sufficient to reach the top quartile of the highest prescribing veterinary clinics in the United States. By adding complementary distributor relationships, we believe we can expand our commercial reach to a majority of all 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.

Pet Therapeutics Market

Overview

U.S. consumers spent an estimated $53 billion on their pets in 2012, according to the American Pet Products Association, or APPA, an increase of 38% from 2006. This figure includes approximately $3.5 billion spent on flea and tick treatments, $1.5 billion spent on knee-joint surgeries in dogs and $370 million spent on pet Halloween costumes.

The veterinary care segment has been among the fastest growing segments of the overall U.S. pet market. This segment accounted for an estimated $13.7 billion in 2012, an increase of 48% from 2006. In 2011, approximately $4.3 billion was spent on parasiticides and vaccines and approximately $2.4 billion was spent on pet therapeutics, our target segment. With approximately 83 million dogs and 96 million cats in the United States, this represents average annual spending on pet therapeutics of less than $14 per pet. This compares to approximately $1,700 that veterinarians estimate their clients would be willing to pay before refusing or stopping treatment for their pets, according to a 2012 DVM Newsmagazine State of the Profession survey.

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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 half a year to 11 years between 2002 and 2012 according to a study by Banfield Pet Hospital. As a result, pets are increasingly exhibiting many of the same diseases associated with aging in humans. The incidence of osteoarthritis in dogs, for example, has increased by 38% since 2007 according to the same study. Among pet owners, there is growing familiarity in treating these pet diseases with medications. According to the APPA, approximately 78% of U.S. dog owners treated their dogs with medications in 2010, as compared to 50% in 1998. In a 2010 poll by Associated Press, 35% of pet owners are willing to spend $2,000 to treat their pet for a serious medical condition. We expect pet owners to spend more on their pets' health and welfare as new therapeutics are developed specifically for pets, particularly as 91% of pet owners considered their pet to be a member of their family, according to a 2011 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 less than 5% of pet owners currently purchase pet insurance. 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

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human product in animals and determine the amount actually dosed, 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 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. On average, only approximately 11 NADAs were filed annually for animal therapeutics, compared to an average of approximately 123 NDAs filed annually for human therapeutics, over the five-year periods ended June 30, 2012 and December 31, 2011, respectively. In 2012, human pharmaceutical companies received FDA approval for 39 new drugs, while pet therapeutics companies received FDA approval for only 11 new drugs, six of which were for use in dogs or cats. In the EU, human pharmaceutical companies received EMA approval for 52 drugs in 2012, compared to only three approvals for pet therapeutics companies.

We believe that therapeutics specifically developed for pets can extend and improve the quality of the lives of pets, 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

CereKin

Overview

CereKin is an oral, chewable, beef-flavored formulation of diacerein, an interleukin-1 beta, or IL-1, inhibitor that we are developing for osteoarthritis pain and inflammation in dogs. We initiated the pivotal trial for CereKin in August 2013 under a Protocol Concurrence with the FDA. We expect to have data from the pivotal trial in mid 2014 and, if positive, intend to submit NADA starting in mid-2014, with potential marketing approval in the second half of 2015. If approved, CereKin would be a first-in-class drug for the veterinary market.

The active ingredient in CereKin has been the subject of multiple studies in humans, has been used by millions of human patients over twenty years, and has been demonstrated to be effective for the treatment of osteoarthritis pain and inflammation. Human drugs containing the active ingredient in CereKin are marketed extensively outside the United States for treatment of osteoarthritis and are generally considered to be safe, except for certain gastrointestinal side effects and rare idiosyncratic skin and liver side effects in humans that occur at a rate of one in a million or less, for which the active ingredient is undergoing review in the EU. These side effects appear to be less frequent or absent in dogs.

We have also conducted a pharmacokinetic study of CereKin in horses, and plan to develop it for osteoarthritis pain in horses. We have an INAD for this indication and expect to initiate the pivotal trial in 2014.

The active ingredient in CereKin is available as GMP-grade material from several suppliers, and we believe our current manufacturer or other suppliers will be able to provide sufficient quantities of the API for potential commercialization.

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Canine Osteoarthritis Market Opportunity

Canine osteoarthritis is a chronic, progressive degenerative joint disease and the most common inflammatory joint disease in dogs. The prevalence of osteoarthritis increases with age, usually occurring in dogs aged nine years or older, but it can occur even in young animals. According to industry sources, the number of pets diagnosed with osteoarthritis has increased significantly over the past five years and an estimated 20% of dogs over the age of one are diagnosed with osteoarthritis. Osteoarthritis is manifested clinically by lameness and pain, immobility, restriction of motion, decreased weight-bearing and swollen joints. Other changes include joint instability, narrowing of joint space, erosion and ulceration of the cartilage of the joint and detrimental remodeling of bone and joint surfaces.

NSAIDs such as carprofen, which is marketed under the brand name Rimadyl, are the most common treatment for canine osteoarthritis. Rimadyl was the first product approved for the control of pain and inflammation associated with canine osteoarthritis and its introduction created a product category around a previously unmet medical need. Corticosteroids are also used to treat canine osteoarthritis extra-label, but safety considerations restrict their long-term application.

The NSAID segment has been one of the fastest growing categories in pet therapeutics since 2005, with four additional NSAID approvals and the approval of the first of five generic carprofen products. According to surveys conducted in 2013 by Brakke Consulting, the U.S. dog and cat pain market was approximately $247 million in 2012. Veterinarians recommended NSAID therapy for 83% of the dogs they treated with osteoarthritis, and believed approximately 60% received treatment. Rimadyl remains the leading prescription treatment with 2012 U.S. sales of $90 million and nearly 40% market share, with generic carprofen sales limited to approximately $20 million in that year.

While NSAID side effects in most dogs are generally mild, some dogs have a sensitivity that results in hepatic and/or gastrointestinal toxicity and, in extreme cases, death. As a result, NSAID label language contains bolded warnings and specifies that baseline blood tests should be conducted, and pets should be periodically monitored using blood tests to check for any toxic effects. Given the associated side effects and required monitoring with blood tests that are associated with NSAID therapy, up to approximately 50% of dogs remain untreated or cannot be treated chronically. Non-steroidal anti-inflammatory drugs, or NSAIDs, are the only approved treatment for canine osteoarthritis, other than steroids and one vitamin-mineral based drug.

Our Solution - CereKin

We are developing CereKin for the management of pain and inflammation associated with osteoarthritis, initially for dogs. The active ingredient in CereKin has demonstrated efficacy in treating osteoarthritis in both humans and dogs. We believe that, if approved, CereKin will not require blood monitoring tests and may be used alone or in combination with NSAIDs. In humans, the active ingredient in CereKin has demonstrated added effectiveness when combined with NSAIDs versus NSAIDs alone. Based on data from a study published in 1999 in Arthritis & Rheumatism, we expect CereKin may have disease-modifying effects, mediated by direct protection of bone tissue in dogs and may protect against NSAID-induced GI tract problems.

Diacerein, the active ingredient in CereKin, is an oral IL-1 inhibitor with potential disease-modifying effects that has been shown to be an effective osteoarthritis therapeutic in humans. The active ingredient is approved in multiple countries in the EU and other foreign jurisdictions for the treatment of osteoarthritis in humans. Its efficacy has been demonstrated in multiple, randomized, controlled human trials in patients with knee or hip osteoarthritis, and has been used for decades in millions of human patients. Diacerein is not associated with the serious adverse events caused by NSAIDs, such as gastrointestinal bleeding or renal failure. In humans, diacerein is associated with certain gastrointestinal side effects, such as diarrhea, and rare idiosyncratic skin and liver side effects. Based on a recommendation from the EMA’s Pharmacovigilance Risk Assessment Committee, the EMA is currently considering the suspension of human drugs containing diacerein until convincing evidence of a positive risk-benefit balance is provided in a specific human population. We believe these side effects are less frequent or absent in dogs, and that the risk-benefit balance in dogs is more favorable than in humans due to the relative lack of approved treatment options for dogs. However, because reliable detection of rare events would require exposure of

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millions or tens of millions of dogs, it is not possible to rule out the risk of such events until well after the launch of the product.

CereKin works through a different mechanism than corticosteroids or NSAIDs. Preclinical studies have demonstrated that the active ingredient in CereKin downregulates the production and activity of IL-1, an important signaling molecule that activates inflammation in a variety of tissues. IL-1 is a well-validated target. Human antibodies and other biologics against IL-1 such as anakinra, gevokizumab, and rilonacept, have shown activity in a number of diseases, including rheumatoid arthritis, gout and uveitis. However, unlike these biologics, CereKin can be administered orally. In addition, by inhibiting IL-1, CereKin downregulates a number of other cytokines, including tumor necrosis factor, or TNF, a cytokine that plays a key role in many inflammatory diseases such as arthritis.

Clinical Data

The active ingredient in CereKin has demonstrated pain-reducing and disease-modifying effects in humans and animals, including dogs, sheep, and mice.

In multiple randomized, placebo-controlled studies in humans, the active ingredient in CereKin significantly reduced osteoarthritis pain and improved function compared with placebo. For example, in a study of 168 patients published in Arthritis & Rheumatism in 2007, the active ingredient in CereKin demonstrated up to a 70% response rate compared to 40% for placebo following a three-month dosing interval. For the purpose of determining the response rate, a response was considered to have occurred if the patient experienced a specified reduction in pain in combination with a specified change in the Western Ontario and McMaster Universities Osteoarthritis Index, or WOMAC, a validated osteoarthritis scale.

Response Rates in Human Osteoarthritis Patients with the
Active Ingredient in CereKin and Placebo

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In several studies in laboratory dogs, the active ingredient in CereKin has demonstrated an ability to effectively treat osteoarthritis, and in many cases to delay bone damage caused by the disease. In the above-mentioned 1999 study, a randomized, placebo-controlled study was conducted in adult dogs in a model of osteoarthritis of the knee. Dogs treated with the active ingredient in CereKin exhibited a statistically significant lower SFA score, a validated measure of osteoarthritis severity with higher numbers representing greater severity, than dogs treated with placebo, as shown in the following table:

SFA Scores in Dogs Treated with the Active Ingredient in CereKin and Placebo

	Week 16	Week 32
Diacerein	0.6	3.4
Placebo	1.3	6.3
	p=0.04	p=0.05

p-value <0.05 indicates statistical significance on a 95% or higher confidence level

Multiple other studies in dogs have demonstrated similar beneficial effects, as well as safety and tolerability, in the treatment of canine arthritis. For example, the rate of diarrhea reported in humans treated with diacerein is approximately 40%, as published in a Cochrane Review in 2009. However, none of the ten dogs in a study published in Arthritis and Rheumatism by Smith in 1999, nor any of the seven dogs in a study published in Osteoarthritis and Cartilage by Brandt in 1997, experienced diarrhea, though some loose stools were noted, despite being treated chronically at doses between 30 mg/kg to 40 mg/kg a day, substantially higher than the human dose of approximately 1 mg/kg a day. Liver toxicity in dogs has not been observed, and given the idiosyncratic nature of the side effect in humans, we do not expect this side effect to cross the species boundary.

In rodent models, including a model of spontaneous arthritis, for example as published by Tamura in Osteoarthritis and Cartilage in 1999, and Gadotti in Pharmacology, Biochemistry, and Behavior in 2012, the active ingredient in CereKin has been effective in preventing bone destruction and reducing joint lesions associated with osteoarthritis when dosed over time.

Pivotal Trial for CereKin

In August 2013, we initiated enrollment in the pivotal trial of CereKin in dogs for the treatment of osteoarthritis pain and inflammation under a Protocol Concurrence with the FDA. The pivotal trial is a multi-center, randomized double-blind, placebo-controlled study of both safety and efficacy of CereKin. We intend to enroll at least 300 dogs aged one year or older, and test two oral doses of CereKin, 5 mg/kg twice daily and 20 mg/kg twice daily, versus placebo, for eight weeks.

The primary endpoint of the pivotal trial is the change in Canine Brief Pain Inventory, or CBPI, at eight weeks. The CBPI is a validated pain scoring system consisting of ten questions asked of dog owners to evaluate the severity of their dog's pain and how much the pain interferes with the dog's normal behavior. For each question, scores can range from zero to ten, with ten being the most severe. Each dog will be scored on day one and at two-week intervals for eight weeks, with the endpoint measuring the change from day one to week eight. Secondary endpoints will include the change in score on the investigator's Dog Osteoarthritis Scoring Sheet, or DOSS, and CBPI trends over the course of the study, and severity of individual signs of osteoarthritis from the DOSS. DOSS is a six-question investigator scoring system with scores ranging from zero to four, with four being the most severe.

AtoKin

Overview

AtoKin is a high-dose, oral, chewable, beef-flavored formulation of fexofenadine that we are developing for atopic dermatitis in dogs. The active ingredient in AtoKin is a potent and selective antihistamine that is approved for allergic diseases in humans. Published data indicate that the active ingredient is as effective as steroids in treating canine atopic dermatitis. We have been granted a Protocol Concurrence by the FDA for the pivotal trial of AtoKin,

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and have initiated the pivotal study in February 2014. We expect to receive data from the trial in late 2014 and, if positive, we intend to submit a NADA in late 2014, with potential marketing approval in late 2015.

The active ingredient in AtoKin is available as GMP-grade material from several suppliers, and we believe our current manufacturer or other suppliers will be able to provide sufficient quantities for our pivotal trial and potential commercialization.

Canine Atopic Dermatitis Market Opportunity

Atopic dermatitis is a common, potentially chronic, allergic skin disease that affects up to 10% of all dogs. It is the second most common allergic skin condition in dogs, surpassed only by flea allergies. Dogs with atopic dermatitis often suffer from pruritus, or severe itching, hair loss, tearing of the skin from deep scratching, frequent licking of their paws and excessive tear production. Secondary skin problems are also common, including skin infections. The condition can be highly uncomfortable or even debilitating, and in extreme cases, euthanasia is necessary to avoid undue suffering.

The mainstay therapy for pruritus is oral corticosteroids and oral cyclosporine. A recently approved product, Apoquel, a Janus kinase inhibitor, is also available for treating atopic dermatitis. While these drugs are effective, they have significant side effects that can prevent their long-term use. They all suppress the dog’s immune system, and can lead to serious side effects including infections. Corticosteroids also can cause osteoporosis, endocrine problems and cataracts in dogs and tend to cause dogs to eat, drink and urinate frequently, which is typically considered undesirable by pet owners. Because atopic dermatitis in dogs is often a chronic condition, these safety and side effect issues create a significant unmet medical need for a safe and effective long-term treatment.

Our Solution - AtoKin

AtoKin is an oral, chewable, beef-flavored formulation of fexofenadine. The active ingredient in AtoKin has been shown to be as effective as a steroid in the treatment of atopic dermatitis in a placebo-controlled study in dogs.

The active ingredient in AtoKin has an excellent track record of safety in animals and humans. Because it is not an immunosuppressive drug, AtoKin may be utilized both as a first-line therapy and also as a long-term maintenance therapy for chronic atopic dermatitis in dogs without increased risk of infections or other safety concerns associated with currently available therapeutics. In addition, the active ingredient in AtoKin has not been associated with the excessive eating, drinking, and urinating in animals that steroids can cause.

Clinical Data

The active ingredient in AtoKin is widely used to treat allergies in humans and is marketed under the brand name Allegra in the United States. The drug has been used by veterinarians extra-label in dogs and cats for the treatment of allergies, typically at the same low dose used for humans of approximately 2-4 mg/kg/day. Reported results at this lower dosage have been mixed.

In a study published in 2009 in Slovenian Veterinary Research, the efficacy of a high-dose of the active ingredient in AtoKin was compared with methylpredisolone, a corticosteroid considered to be the standard of care for atopic dermatitis in dogs. Thirty dogs suffering from atopic dermatitis were randomized, with one group receiving the drug orally at 18 mg/kg/day and the other group receiving methylprednisolone at 0.5 mg/kg daily for five days then every other day for six weeks.

Dogs were analyzed in the initial baseline visit, at week three and at week six using the canine atopic dermatitis extent and severity index, or CADESI, which evaluates the severity of three parameters in dogs at various pre-determined body areas: erythema, or reddening of the skin; lichenification, or thickening and hardening of the skin; and excoriation, or abrasion and wearing of the skin. In addition, dog owners were asked to evaluate the degree of pruritus in their dogs using a visual analog scale from 0-100, with 0 being no pruritus and 100 being intense/incessant pruritus.

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Both the active ingredient in AtoKin and methylprednisolone resulted in statistically significant reductions in CADESI scores from baseline to the second visit at week three. Statistically significant reductions in the CADESI score were also maintained in both groups at the final visit at week six of the study as illustrated in the following table, and in addition, a statistically significant difference in favor of fexofenadine versus methylprednisolone was found at week 6 as measured by CADESI (p=0.012):
Average CADESI Score
Fexofenadine versus Methylprednisolone

Evaluation of pruritus in both groups showed a similar trend over time, with a reduced itching in both groups. At the final evaluation at week six, both the fexofenadine and methylprednisolone groups had significantly reduced pruritus from baseline as illustrated in the table below:
Average Pruritus Visual Analog Score (0-100)
Fexofenadine versus Methylprednisolone

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Pivotal Trial for AtoKin

We have obtained a Protocol Concurrence from the FDA for the pivotal trial to study the safety and efficacy of AtoKin in dogs for the treatment of atopic dermatitis. The pivotal trial is a multi-center, randomized double-blind, placebo-controlled study. We intend to enroll at least 200 dogs one year of age or older with atopic dermatitis. We will test 20 mg/kg oral doses of AtoKin once daily in addition to placebo.

The co-primary endpoints of the pivotal trial are based on the Canine Atopic Dermatitis Lesion Index, or CADLI, and Pruritus Visual Analog Score, or PVAS. The CADLI score is a validated composite index of six clinical symptoms associated with canine atopic dermatitis evaluated in five specified body regions. At each specified body region, each parameter is scored by the investigator from zero to five, with a score of zero defined as no lesion and a score of five defined as a severe/extensive lesions. PVAS is scored by the pet owner using a zero-to-ten analog scale, with a score of zero representing no pruritus/chewing and a score of ten equating to incessant and intense pruritus/chewing.

SentiKin

Overview

We intend to develop SentiKin initially as a therapeutic to manage post-operative pain in dogs, cats and horses. SentiKin is an oral, non-NSAID, non-opioid analgesic formulation of flupirtine. The active ingredient in SentiKin is approved for the treatment of pain in humans in multiple countries outside the United States and has demonstrated potency comparable to tramadol. It has also demonstrated efficacy in treating pain in dogs. Due to a rare side effect affecting the liver that is seen only with long-term use, the EMA recently determined that the risk-benefit profile of flupirtine justified its use in humans for short-term indications only. We are developing flupirtine for post-operative pain, which is a short-term indication.

We are currently negotiating a Protocol Concurrence with the FDA for the pivotal trial for SentiKin for post-operative pain in dogs, and intend to initiate the trial by April 2014. We expect to receive data from the trial in late 2014 and, if positive, we intend to submit a NADA in late 2014, with potential marketing approval in late 2015. We are also developing SentiKin for post-operative pain in horses. In the future, we intend to develop SentiKin for post-operative pain in cats, as well as for seizures in both dogs and cats.

The active ingredient in SentiKin is available as GMP-grade material from several suppliers, and we believe our current manufacturer or other suppliers will be able to provide sufficient quantities for our planned pivotal trial and potential commercialization.

Canine Post-Operative Pain Market Opportunity

Approximately 50% of dog surgeries each year are spays and neuters. Other common surgeries include cancer surgery, declawing, cruciate repairs and bone fracture repairs. There is no established protocol for the use of pain medications following these surgeries, and pain management practices have traditionally been based on the veterinarian’s views on the level of pain associated with a specific surgical procedure and the perceived pain tolerance of the dogs. As pet owners have increasingly requested medications for their pets’ post-operative pain, veterinarians have made recent advances in treating pain in pets.

Some drugs used for post-operative pain in dogs have been approved by the FDA, while others are used extra-label. The only systemic drugs approved for treatment of post-operative pain in dogs are NSAIDs, fentanyl, and pentazocine. The most commonly used post-operative pain medication in dogs is the NSAID Rimadyl, which has been approved by the FDA for this use. As previously described in our discussion regarding CereKin for post-operative pain in dogs, NSAIDs have demonstrated serious side effects that result in prescribed ongoing monitoring of dog health during their use. For example, some dogs have a sensitivity that results in kidney toxicity and, in extreme cases, death. Consequently, we believe there is an unmet medical need for a drug for post-operative use that is effective in dogs, but also safer on the liver, gastrointestinal system and kidneys. We believe that development of a potent non-narcotic analgesic addresses an important unmet medical need and may lead to a new standard of care in pain control.

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In surgeries associated with the most severe post-operative pain, fentanyl is commonly used. Fentanyl is a controlled narcotic drug, and pets are often kept in the hospital while receiving fentanyl. The majority of fentanyl is dispensed as fentanyl patches, although such use in pets has not been approved. In 2012, Nexcyon received FDA approval for a transdermal fentanyl solution in dogs, but its use in this format has not been widely accepted by veterinarians. Fentanyl is associated with significant sedation and respiratory depression, which are undesirable analgesic effects. It also has potential for diversion and abuse by owners. Pentazocine, also a controlled narcotic drug, is not widely used in dogs and has potential for sedation, respiratory depression and abuse. We believe that there are unmet needs in pets receiving painful surgeries, especially if effective and extended pain relief could be achieved with a non-narcotic medicine.

Our Solution - SentiKin

We believe that, if approved, SentiKin will provide pain relief that is superior to NSAIDs and comparable to some opioids, without the potential for opioid addiction or the risk of possible diversion and abuse by pet owners.

The active ingredient in SentiKin is a centrally acting non-opioid, non-NSAID, and non-steroidal analgesic that has been approved for use in humans. Its mechanism of action is believed to be via selective opening of the potassium channel in cells that makes neurons less susceptible to activation. The active ingredient in SentiKin has been used in humans for various pain management indications, including post-operative pain, trauma, dental extractions, painful muscle spasms, cancer pain, degenerative joint disease, migraine headaches and dysmenorrhea. It has been used by millions of human patients in many countries. Due to a rare side effect affecting the liver, the EMA recently determined that the risk-benefit profile of flupirtine justified its use only for short-term indications. While we believe these side effects are idiosyncratic and specific to humans, we cannot assure you that these same side effects will not occur in dogs. Because detection of these rare side effects would require testing of millions of dogs, we will not be able to rule out this risk until well after commercial launch of the product.

Clinical Data

In multiple animal studies, including one in dogs, the active ingredient in SentiKin has been demonstrated to have potent analgesic effects, or pain relief.

At least eight trials have been conducted in humans to evaluate the efficacy of the active ingredient in SentiKin. In most of these studies that compared these products, pain relief was as good as or better than diclofenac (a NSAID) or tramadol (an opioid analgesic). In another study, orthopedic surgery patients received either pentazocine (an opioid analgesic) or flupirtine and 80% to 95% of flupirtine treated patients experienced satisfaction to treatment as compared to 67% to 79% of patients receiving pentazocine.

In a dog study of the tooth pulp stimulation to induce pain, the active ingredient in SentiKin demonstrated effectiveness in reducing the effect of the stimulation.

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In one study of 209 patients with lower back pain, published in Current Medical Research and Opinion in 2008, the active ingredient of SentiKin was shown to have efficacy similar to tramadol in controlling pain in patients following five to seven days of dosing.

Other Product Candidates

In addition to small molecules, we have a pipeline of several promising biologics. Our current biologic product candidates include: KIND-502, a new biologic that targets the canine counterpart of the human target for Xolair, for allergic and immune-mediated diseases; KIND-506, a new biologic that targets the canine counterpart of the human target for Enbrel, for inflammatory and autoimmune diseases; KIND-507, a new biologic that targets the canine counterpart of the human target for Orencia, for immune-mediated diseases; KIND-504, a cancer vaccine, in which the active ingredient has demonstrated efficacy in certain types of cancers in humans and in dogs, several checkpoint inhibitors, feline erythropoetin, and KIND-501, an antiangiogenic biologic for cancer in dogs.

Members of our management have extensive experience with biologics, including antibodies such as Lucentis, Tysabri, Xolair and Rituxan. Antibody discovery technologies perform differently in different targets, and some technologies that work well for one target do not work for other targets. For this reason, we are pursuing multiple strategies for generation of dog, cat and horse antibodies. For example, we have internal expertise, outside consultants and service providers that enable us to convert antibodies such as mouse and rabbit antibodies into dog (caninize), cat (felinize), and horse (equinize) forms. Because rabbit antibodies usually have much higher affinity than mouse antibodies, we anticipate that smaller quantities of our antibodies may be sufficient to produce clinical efficacy, which we believe would reduce our cost of goods compared to other more traditionally caninized, felinized, and equinized antibodies.

In addition, we are pursuing strategies to produce 100% dog, cat and horse antibodies, which do not have any mouse or other exogenous amino acids. We believe the fully canine, feline, and equine antibodies may be less immunogenic than antibodies that have been caninized, felinized or equinized via more traditional methods, since those typically are composed of 10% or greater mouse amino acids.

Some of our other small molecule product candidates include: KIND-007, an inhibitor of Bruton’s tyrosine kinase, an enzyme important in certain lymphomas and immune-mediated human diseases; and KIND-006, a promotility agent for gastrointestinal diseases in cats.

We also have identified over 30 additional pre-INAD product candidates, including small molecules and biologics, for potential future development.

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Product Launches and Commercialization

Our executive management team has extensive experience with product launches. Richard Chin, M.D., and Denise Bevers, our co-founders and Chief Executive Officer and Chief Operating Officer, respectively, have each been involved in the launch of numerous products in humans, including such drugs as Tysabri and Xolair. Kevin Schulz, D.V.M., Ph.D., our Chief Scientific Officer, has been involved in the launch of over 20 products for animals, including such products as Frontline Plus and Previcox.

If our product candidates are approved by the FDA, we intend to launch and commercialize our products in the United States with a direct sales force eventually numbering approximately 50 sales representatives, which we believe will be sufficient to reach the top quartile of the highest prescribing veterinary clinics. We also intend to selectively utilize distributors, which we believe will enable us to expand our commercial reach to a majority of all veterinarians in the United States. Since even large veterinary pharmaceutical companies have sales forces of only approximately 50 to 200 sales representatives, we believe we can compete effectively with a combination of our own direct sales force and complementary distributors.

Our direct sales force will sell 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 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 approximately 70% of U.S. pet sales by veterinarians. Each of these distributor organizations has a sales team of approximately 275 field sales representatives, 175 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. 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 INAD 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 to conduct our pivotal trials of CereKin and AtoKin, as well as our currently planned toxicology studies. We also have identified multiple contract manufacturers to provide commercial supplies of the formulated drug product candidates if they are approved for marketing. We 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 intend to collaborate with established manufacturers for U.S. Department of Agriculture, or USDA, regulated biologics products, as well as other third parties who have novel manufacturing technologies that can potentially achieve substantial reductions in our cost of goods. 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 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.

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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 2012 livestock accounted for 65%, and pets 35%, 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.; Merial, the animal health division of Sanofi S.A.; Elanco, the animal health division of Eli Lilly and Company; Bayer Animal Health, the animal health division of Bayer AG; Novartis Animal Health, the animal health division of Novartis AG; Boehringer Ingelheim Animal Health, the animal health division of Boehringer Ingelheim GmbH; and Zoetis, Inc. We will also compete against several animal health companies in Europe, such as the Virbac Group, Ceva Animal Health and Dechra Pharmaceuticals PLC. We are also aware of several smaller early stage 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 CereKin and SentiKin (for pain) from Rimadyl, Deramaxx, Previcox, Equioxx and Metacam, as well as potentially from additional products in development. We will face competition for AtoKin and KIND-502 from Atopica, Apoquel, and steroids, as well as potentially from additional products in development. For our other products, we may face competition from various products including additional products in development. Our products will also face competition from generic medicines and products approved for use in humans that are used extra-label for pets. For example, AtoKin, our second product candidate, will face competition from fexofenadine, a human generic available in the United States. 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, proprietary know-how, and confidentiality agreements to protect our product formulations, processes, methods and other technologies and to preserve any trade secrets and operate without infringing on the proprietary rights of other parties, both in the United States and in other countries. We currently have no issued patents and have only provisional patent applications. Because most of our current product candidates, including all of our current 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 intend to pursue the broadest intellectual property protection possible for our current compounds and any future compounds and any proprietary technology through enhanced formulations of our products, both in the United States and abroad. For example, we are developing slow release oral formulations of some of our products, and we intend to develop combination therapies and slow release parenteral formulations of some of our 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

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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

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, or the EPA. In addition, the Drug Enforcement Administration, or DEA, regulates animal therapeutics that are classified as controlled substances.

The FDA Center for Veterinary Medicine, or CVM, regulates animal pharmaceuticals under the Federal Food, Drug and Cosmetic Act. The USDA Center for Veterinary Biologics, or CVB, regulates veterinary vaccines and certain biologics pursuant to the Virus, Serum, Toxin Act. The EPA Office of Pesticide Programs, or 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 will also be required to conduct post-approval monitoring of products and to submit reports of product quality defects, adverse events or unexpected results, and be subject to regulatory inspection from time to time. In addition, for our controlled substance product candidates, we will be required to comply with the Controlled Substances Act, or 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 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 ensure that 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 and dogs 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.

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Effectiveness . Early pilot studies may be conducted in laboratory cats or dogs 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 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, or 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, or 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 we refer to as NADA in this annual report. 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 CVM and 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 CVM has already reviewed the individual technical sections before the administrative NADA is filed, 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.

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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 for the USDA for review. Once all data has 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.

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 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

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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 made to the DEA, for 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 the 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, or 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, 2013, we had twelve employees, including six employees with D.V.M., M.D. or Ph.D. degrees. Of our employees, eight 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, as is Mr. Galliker. None of our employees are represented by labor unions or covered by collective bargaining agreements.

Corporate Information

We were incorporated on September 25, 2012 by our co-founder, Richard Chin, M.D., our President and Chief Executive Officer. Our principal executive offices are located at 1499 Bayshore Highway, Suite 226, Burlingame, California 94010, and our telephone number is (650) 701-7901. We also maintain a mailing address at 58 West Portal Avenue, #105, San Francisco, California 94127. Our website address is www.kindredbio.com. The information contained in, or accessible through, our website should not be considered a part of this annual report.

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ITEM 1A. RISK FACTORS

Risks Related to Our Business

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

We are a development stage biopharmaceutical company. Since our formation in September 2012, our operations have been limited to the identification of product candidates and research and development of our lead product candidates, primarily CereKin, AtoKin and SentiKin. As a result, we have limited historical operations upon which to evaluate our business and prospects and have not yet demonstrated an ability to obtain marketing approval for any of our product candidates or successfully overcome the risks and uncertainties frequently encountered by companies in emerging fields such as the pet therapeutics industry. We also have not generated any revenue to date, and continue to incur significant research and development and other expenses. Our net loss and comprehensive loss for the fiscal year ended December 31, 2013 was $4,213,368 and for the period from September 25, 2012 (inception) through December 31, 2013 was $4,332,979. As of December 31, 2013, we had a deficit accumulated during the development stage of $4,332,979. 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 U.S. Food and Drug Administration, or FDA, the U.S. Department of Agriculture, or USDA, or the European Medicines Agency, or 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 will have no material product revenue for the foreseeable future, and we may need to raise additional capital to achieve our goals.

Until, and unless, we receive approval from the FDA, USDA or EMA, as applicable, for one or more of our product candidates, we cannot market or sell our products in the United States or in the European Union, or EU, and will have no material product revenue. Currently, our only product candidates in a pivotal trial, also known as a field efficacy trial, are CereKin and AtoKin. We expect to initiate the pivotal trials for SentiKin by April 2014. Our other current product candidates will require from three to five years of further development at a cost of approximately $3 million to $5 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.

We believe we have sufficient cash and cash equivalents to fund our operating plan through the anticipated approval and launch of one or more of our lead product candidates. 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

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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 if any of our current or 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 possible patent claims, 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 our current lead product candidates, and cannot be certain that any of them will be approved for marketing or successfully commercialized even if approved.

We have no product approved for sale in any jurisdiction. Our current efforts are, and a substantial portion of our efforts over the foreseeable future will be, primarily focused on our lead product candidates, CereKin, AtoKin and SentiKin. 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 one or more of our lead candidates, which in turn will depend on a number of factors, including the following:

- 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 our third-party manufacturers to manufacture supplies of any of our product candidates and to develop, validate and maintain viable commercial manufacturing processes that are compliant with Good Manufacturing Practices, or GMP;

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- 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 availability, perceived advantages, relative cost, relative safety and relative efficacy of our products compared to alternative and competing treatments;
- the acceptance of our product candidates as safe and effective by veterinarians, pet owners and the animal health community;
- 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 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 developing or commercializing one or more of our lead product candidates. If we are unsuccessful or are significantly delayed in developing and commercializing CereKin, AtoKin, SentiKin 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 ingredient, or API, has been successfully commercialized or demonstrated to be safe or effective in human trials, which we sometimes refer to as validated. There is little, if any, third-party patent protection of the active ingredient in most of our current small molecule product candidates, and this means that 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.

While in most cases we select product candidates that are not available as a human generic in the United States, 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.

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, new patents 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 patents on most of our biologic product candidates, we may not ultimately be able to obtain such patents. Although there are no generic regulatory approval pathways for animal biologics in the United States and European Economic Area, or EEA, our competitors may develop biologics that bind to the same target, but do not infringe any patents we may obtain. Thus, our competitors may be able to develop and market

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competing products if they are willing and able to conduct the full set of required studies, file a New Animal Drug Application, or NADA, with the FDA, or Application for United States Veterinary Biological Product License with the USDA, also called a Product License Application, or 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 depends on our ability to compete effectively with other products in the market. If our product candidates are approved, we expect to compete with animal health divisions of major pharmaceutical and biotechnology companies such as Merck Animal Health, Merial, Elanco, Bayer Animal Health, Novartis and Boehringer Ingelheim Animal Health, as well as specialty animal health medicines companies such as Zoetis and, in Europe, 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. 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, CereKin and SentiKin will face competition from existing products approved for pain in dogs such as Rimadyl, Deramaxx, Previcox and Metacam. Similarly, AtoKin will face competition from existing products such as Atopica and Apoquel and from steroids, and SentiKin will compete against other pain drugs such as Recuvyra. 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 all of our products 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.

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. We also expect to compete with academic institutions, governmental agencies and private organizations that are conducting research in the field of animal health medicines.

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

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

We plan 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

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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.

Because the regulatory standards for pet biologics are often less stringent than for small molecule animal drugs, we believe that some veterinarians prefer to see further efficacy data before making a new biologic product purchasing 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 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 CereKin internally without significant outsourcing, and plan to also conduct the pivotal trials in AtoKin and SentiKin the same way, but we rely on contract research organizations, or 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 trials 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:

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- 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 have Protocol Concurrences with the FDA for the pivotal trial of CereKin for the treatment of osteoarthritis in dogs and for our planned pivotal trial of AtoKin for the treatment of atopic dermatitis in dogs. 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 an 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 our current or planned pivotal trials of CereKin, AtoKin and SentiKin, or of our other 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

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- 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, including our current and planned pivotal trials of CereKin, AtoKin and SentiKin, 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, or GCPs, or good laboratory practices, or 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 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;

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- 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. 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. Diacerein, the active ingredient in CereKin, has been associated with gastrointestinal side effects and rare skin and liver side effects that occur at a rate of one in a million or less in humans, for which diacerein is undergoing a safety and efficacy review by the EMA. Because reliable detection of such rare events would require exposure of millions or tens of millions of dogs, it is not possible to rule out the risk until well after the launch of the product. The EMA's Pharmacovigilance Risk Assessment Committee has recommended to the Coordination Group for Mutual Recognition and Decentralised Procedures—Human, or CMDh, that diacerein be suspended from marketing for humans because of these side effects, until convincing evidence of a positive benefit-risk balance in a specific human patient population is provided. The recommendation has been appealed by manufacturers of diacerein. Subject to the appeal, the CMDh will undertake its own assessment of the drug, followed possibly by review by the European Commission.

The active ingredient in SentiKin, has been associated with rare idiosyncratic liver adverse reactions. The EMA has conducted a review of the drug and has determined that the risk-benefit profile in humans justifies its use in short-term indications, but not in long-term indications. We intend to develop SentiKin for short-term treatment of post-operative pain, but we may be not able to rule out a potential liver adverse effect until well after the launch of the drug. 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.

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

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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 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 President and Chief Executive Officer, Kevin Schultz, D.V.M., Ph.D., our Head of Research and Development and Chief Scientific Officer, Denise Bevers, our Chief Operating Officer, Stephen Galliker, our Chief Financial Officer, and Stephen Sundlof, D.V.M., Ph.D., our Senior Vice President of Regulatory Affairs. 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 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 the formulated product candidates for use in our studies or commercial supplies of any of our product candidates that may be approved, and will be entirely 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 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 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 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. 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 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,

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so we may require multiple manufacturing processes and facilities for the same product candidate or any approved product.

The commercialization of 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 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 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 product candidates on a timely basis. Any inability to secure sufficient quantities and quality of the API or other raw materials in 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 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. There is no assurance that we will be able to manufacture biologics at an economical cost, if at all.

If we are unable to establish sales capabilities on our own or through third parties, we may not be able to market and sell our current or future product candidates, if approved, and generate product revenue.

We currently have no sales, marketing or distribution capabilities. If our current or future product candidates receive regulatory approval, we expect to establish a direct sales organization in the United States and to utilize distributors to commercialize our products, which will be 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. We have no prior experience in the marketing, sale and distribution of pet therapeutics or other products, and there are significant risks involved in building and managing a sales organization, including our potential inability 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 and entry into adequate arrangements with distributors would adversely impact the commercialization of our product candidates. 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.

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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. Ideally, we try to identify product candidates that are free from any intellectual property rights of others. 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 yield product candidates for development and commercialization for many reasons, including the following:

- product candidates we develop 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.

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.

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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 December 31, 2013, we had twelve full-time employees, and our management systems currently in place are not likely to 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.

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.

If our product candidates are approved by regulatory authorities, we may market or advertise them 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, or 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.

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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 may pursue strategic alliances. Our company has no experience in acquiring other assets or businesses companies 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.

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 do not have any issued patents for our lead product candidates at this time. However, we have filed patent applications covering various aspects of our drug and biological candidates in animals. Our 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 patents, if issued, may not adequately protect our intellectual property or prevent others from designing around their claims. In order to

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commercialize our drug and biological 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 product candidates, our business and prospects would be adversely affected.

It is possible that no patents will issue to us to cover our approved products, 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, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted, 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 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 future patents, if any. We are aware of several 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 the product candidate

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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, 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. If third parties have prepared and filed patent applications in the United States that also claim technology to which we have rights, we may have to participate in interference proceedings in the USPTO to determine the priority of invention. 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 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 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 our current product candidates and our development programs.

Composition-of-matter patents on the active 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. We do not have composition-of-matter patents for the active ingredient in our small molecule product candidates, and there is little, if any, such composition-of-matter patent protection available. Moreover, we cannot be certain that the claims in our patent applications covering composition-of-matter of 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 specified 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 patented method. 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 future 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

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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 future patents issued to us, which could be expensive, time-consuming and unsuccessful.

Competitors may infringe any patents that may 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 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 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.

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

We have no registered trademarks for our company name or for our current product candidates in the United States or any other countries, and failure to obtain those registrations could adversely affect our business.

Although we have filed a trademark application for our company name and for our CereKin and AtoKin product candidates in the United States, our applications have not been granted and the corresponding marks have not been registered in the United States. We have not filed for these or other trademarks in any other countries. 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. If opposition or cancellation proceedings are filed against any of our trademark applications or any registered trademarks, our trademarks may not survive such proceedings. 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

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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 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, 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.

If the FDA, USDA, or EMA approves any of our current or future product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for the 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.

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If approved, any of our current or future 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.

If we are successful in commercializing any of our current or future product candidates, at least certain regulatory authorities will require that we report certain information about adverse medical events if those products 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 products. If we fail to comply with our reporting obligations, the regulatory authorities could take action including criminal prosecution, seizure of our products 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 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

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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.

Risks Related to Our Common Stock

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

Since our initial public offering in December 2013, the trading price of our common stock has ranged from a low of $8.75 to a high of $26.89. 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 prospectus 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 our current or future product candidates;
- manufacturing and supply issues related to our development programs and commercialization of 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 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;

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- 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 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 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 an 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 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 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, 2013 our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates beneficially own in the aggregate approximately 43.7% of our outstanding shares of common stock, excluding shares they may acquire upon exercise of stock options 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.

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

If our existing stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market after the expiration or termination of the lock-up and other legal restrictions on resale as a result of our initial public offering, the trading price of our common stock could decline. The lock-

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up agreements pertaining to our initial public offering will expire 180 days from December 12, 2013. Based on stock ownership as of March 10, 2014, after the lock-up agreements expire, approximately 16,227,120 shares of common stock will be eligible for sale in the public market, of which approximately 3,766,006 shares are held by directors, executive officers and other affiliates and will be subject to vesting schedules or volume limitations under Rule 144 under the Securities Act. The representatives of the underwriters may, in their sole, joint discretion, permit our officers, directors and other stockholders who are subject to lock-up agreements to sell shares even prior to the expiration of the lock-up agreements. In addition, shares of common stock that are subject to outstanding options under our 2012 equity incentive plan will become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules, the lock-up agreements and Rule 144 and Rule 701 under the Securities Act. The sale or possible sale of these additional shares may adversely affect the trading price of our common stock.

We have identified material weaknesses in our internal control over financial reporting. If we fail to remedy these material weaknesses or otherwise achieve and maintain effective internal control over financial reporting, we may not be able to accurately report our operating results or prevent fraud and, as a result, our business could be harmed and current and potential stockholders could lose confidence in us, which could cause our stock price to fall.

Prior to our recent initial public offering, we were not subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, or the Exchange Act, and had limited accounting personnel and other resources with which to address our internal controls and procedures. As a public reporting company, we are required, among other obligations, to maintain effective internal control over financial reporting suitable to prepare our publicly reported financial statements in a timely and accurate manner. In connection with our initial public offering, we identified two material weaknesses in our internal control over financial reporting. A material weakness is defined as a control deficiency, or combination of control deficiencies, that adversely affects an entity's ability to initiate, authorize, record, process or report financial data reliably in accordance with accounting principles generally accepted in the United States, or GAAP, such that there is more than a remote likelihood that a material misstatement of the entity's financial statements will not be prevented or detected by the entity's internal control over financial reporting. The material weaknesses we identified related to our accounting for complex equity transactions and our lack of segregation of duties within the accounting function due to a limited number of personnel. Although we have implemented steps aimed at addressing these material weaknesses, including the hiring of a Chief Financial Officer and additional employees and accounting consultants, these steps may not remedy the material weaknesses. Our independent registered public accounting firm did not perform an evaluation of our internal control over financial reporting during any period in accordance with the provisions of the Sarbanes-Oxley Act of 2002, or Sarbanes-Oxley Act. In connection with the preparation of our audited financial statements contained in this annual report, going forward, our management is required to comply with Section 404(a) of the Sarbanes-Oxley Act in the course of preparing our financial statements; however, so long as we remain an emerging growth company, we will not be required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act. Had our independent registered public accounting firm performed an evaluation of our internal control over financial reporting in accordance with the provisions of the Sarbanes-Oxley Act, additional control deficiencies amounting to material weaknesses may have been identified. If we fail to comply with the requirements of Section 404, we might be subject to sanctions or investigation by regulatory agencies such as the SEC. In addition, failure to comply with Section 404 or the report by us of a material weakness may cause investors to lose confidence in our financial statements, and the trading price of our common stock may decline. If we fail to remedy any material weakness, our financial statements may be inaccurate, our access to the capital markets may be restricted and the trading price of our ordinary shares may suffer.

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 to 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;

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- 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 alter 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 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 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 (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim of breach of a fiduciary duty owed by any director, officer or other employee to us or our stockholders, (iii) any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law, or (iv) 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

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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.

We are an "emerging growth company" and we cannot be certain if the reduced disclosure requirements applicable to "emerging growth companies" will make our common stock less attractive to investors.

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, and we may take advantage of certain exemptions and relief from various reporting requirements that are applicable to other public companies that are not "emerging growth companies." In particular, while we are an "emerging growth company" (i) we will not be required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act, (ii) we will be exempt from any rules that may be adopted by the Public Company Accounting Oversight Board requiring mandatory audit firm rotations or a supplement to the auditor's report on financial statements, (iii) we will be subject to reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and (iv) we will not be required to hold nonbinding advisory votes on executive compensation or stockholder approval of any golden parachute payments not previously approved. In addition, the JOBS Act provides that an emerging growth company can delay its adoption of any new or revised accounting standards, but we have irrevocably elected not to avail ourselves of this exemption and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies. We may remain an "emerging growth company" until as late as December 31, 2018 (the fiscal year-end following the fifth anniversary of the completion of this initial public offering), though we may cease to be an "emerging growth company" earlier under certain circumstances, including (i) if the market value of our common stock that is held by non-affiliates exceeds $700 million as of any June 30, in which case we would cease to be an "emerging growth company" as of the following December 31, or (ii) if our gross revenue exceeds $1 billion in any fiscal year.

The exact implications of the JOBS Act are still subject to interpretations and guidance by the SEC and other regulatory agencies, and we cannot assure you that we will be able to take advantage of all of the benefits of the JOBS Act. In addition, investors may find our common stock less attractive if we rely on the exemptions and relief granted by the JOBS Act. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may decline and/or become more volatile.

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 our initial public offering or 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.

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ITEM 1B. UNRESOLVED STAFF COMMENTS.
Not Applicable.

ITEM 2. PROPERTIES.
Our corporate headquarters are located in Burlingame, California, where we lease and occupy approximately 600 square feet of office space pursuant to a month-to-month lease.

ITEM 3. LEGAL PROCEEDINGS.
We are not currently a party to any material legal proceedings.

ITEM 4. MINE SAFETY DISCLOSURES.
Not applicable.

PART II

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

Market Information
Since December 12, 2013, our common stock has been traded on The NASDAQ Capital Market under the symbol "KIN." The following table sets forth the high and low sale prices for our common stock for the periods indicated as reported on The NASDAQ Capital Market:

	High	Low
Fiscal Year 2013:		
Fourth Quarter (from December 12, 2013)	$14.06	$8.75

Common Stock Information
As of March 10, 2014, there were outstanding 16,227,120 shares of the our common stock outstanding held of record by approximately 80 holders.

Dividends
We currently intend to retain any future earnings to finance our operations and expansion of our business and not to pay any cash dividends on our common stock.

Equity Compensation Plan
The following table sets forth certain information as of December 31, 2013, 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	1,375,914	$1.33	2,579,661
	—	—	—

Equity compensation plans not approved by stockholders			
Total	1,375,914	$1.33	2,579,661

Comparison of Cumulative Total Returns

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 three-month period from December 12, 2013 to February 28, 2014. 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 performance.

	12/12/2013	12/31/2013	1/31/2014	2/28/2014
Kindred Biosciences, Inc.	100.00	93.47	129.96	188.79
NASDAQ Composite-Total Returns	100.00	104.52	102.76	108.05
NASDAQ Biotechnology Index	100.00	105.15	113.99	122.74

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Recent Sales of Unregistered Securities

During the fiscal year ended December 31, 2013, we sold the following unregistered securities:

Sales of Convertible Preferred Stock

In June 2013, we issued 5,000 shares of Series A-1 convertible preferred stock valued at $15,850 on the date of issuance for partial payment of Series A-1 offering costs.

Between June and August 2013, we issued and sold to investors an aggregate of 1,850,204 shares of our Series A-1 convertible preferred stock at a purchase price of $3.17 per share, or a total of $5,865,147. In August 2013, we issued and sold to investors an aggregate of 1,650,396 shares of our Series A-1A convertible preferred stock at a purchase price of $3.17 per share, or a total of $5,231,755.

In August 2013, we issued 5,000 shares and 24,606 shares of Series A-1 and Series A-1A convertible preferred stock, respectively, valued at $3.17 per share, or a total of $93,850, as payment for legal fees and a finder's fee relating to our convertible preferred stock offerings.

On November 11, 2013, the Company issued 15,000 shares of the Series AA convertible preferred stock to TroyGould PC, our outside counsel, in settlement of accrued Series AA Preferred Stock offering costs of $12,950 and accrued Series A-1 Preferred Stock offering costs of $2,050.

Option and Common Stock Issuances

On August 29, 2013, we issued 5,200 shares of restricted common stock valued for this purpose at a price of $2.27 per share to a consultant for services rendered.

On September 7, 2013, the we issued 7,475 shares of common stock upon exercise of stock options by a consultant at a price of $0.32 per share for total proceeds of $2,392.

On October 7, 2013, we issued 8,000 shares of common stock upon exercise of stock options by a consultant at a price $0.32 per share for total proceeds of $2,560.

On November 3, 2013, we issued 18,750 shares of common stock upon exercise of stock options by an employee at a price $0.32 per share for total proceeds of $6,000.

On December 11, 2013, we granted 5,000 shares of restricted common stock valued for this purpose at a price of $7.00 per share to a consultant for services rendered.

The securities described above were issued to investors in reliance upon the exemption from the registration requirements of the Securities Act, as set forth in Section 4(2) under the Securities Act and Regulation D promulgated thereunder relating to transactions by an issuer not involving any public offering. All purchasers of shares of convertible preferred stock described above represented to us in connection with their purchase that they were accredited investors and were acquiring the shares for their own account for investment purposes only and not with a view to, or for sale in connection with, any distribution thereof. The purchasers received written disclosures that the securities had not been registered under the Securities Act and that any resale must be made pursuant to a registration statement or an available exemption from such registration.

From our inception on September 25, 2012 through December 31, 2013, we awarded or granted to certain of our employees, directors and outside consultants in connection with services provided to us by such parties stock options to purchase an aggregate of 1,410,139 shares of our common stock with exercise prices of $0.32 per share, $0.36 per share, $0.90 per share, $1.37 per share, $3.83 per share or $7.00 per share.

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The stock options described above were issued pursuant to written compensatory plans or arrangements with our employees and directors, in reliance on the exemption from the registration requirements of the Securities Act provided by Rule 701 promulgated under the Securities Act or the exemption set forth in Section 4(2) under the Securities Act and Regulation D promulgated thereunder relating to transactions by an issuer not involving any public offering. All recipients either received adequate information about us or had access, through their employment or other relationship with us, to such information.

Use of Proceeds

On December 12, 2013, our registration statement on Form S-1 (File No. 333-192242) was declared effective by the Securities and Exchange Commission (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.

We received net proceeds in the offering of approximately $54,871,471 after deduction of underwriting commissions and offering expenses of $5,503,529.

There has been no material change in the planned use of proceeds from our initial public offering as described in our final prospectus filed with the SEC on December 12, 2013 pursuant to Rule 424(b). BMO Capital Markets Corp. and Guggenheim Securities, LLC acted as managing underwriters of the offering.

Repurchase of Shares

We did not repurchase any of our shares of common stock during the fiscal year ended December 31, 2013.

ITEM 6. SELECTED FINANCIAL DATA.

You should read the following selected financial data in conjunction with our financial statements and the related notes thereto appearing elsewhere in this annual report and in the section of this annual report entitled “Management’s Discussion and Analysis of Financial Condition and Results of Operations.”

We have derived the statements of operations and comprehensive loss data for the period from September 25, 2012 (inception) through December 31, 2012, the year ended December 31, 2013, and the cumulative period from September 25, 2012 (inception) through December 31, 2013, and the balance sheet data as of December 31, 2012 and 2013 from our audited financial statements appearing elsewhere in this report. The historical results are not necessarily indicative of the results to be expected for any future periods.

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	For The Period From September 25, 2012 (Inception) Through December 31, 2012	Year Ended December 31, 2013	Cumulative Period From September 25, 2012 (Inception) Through December 31, 2013
Statement of Operations and Comprehensive Loss Data:			
Operating expenses:			
Research and development	$74,772	$3,140,606	$3,215,378
General and administrative	44,864	1,078,687	1,123,551
Total operating expenses	119,636	4,219,293	4,338,929
Loss from operations	(119,636)	(4,219,293)	(4,338,929)
Other income (expense):			
Interest income	25	5,981	6,006
Interest expense	—	(56)	(56)
Total other income, net	25	5,925	5,950
Net loss and comprehensive loss	$(119,611)	$(4,213,368)	$(4,332,979)
Net loss per share attributable to common stockholders, basic and diluted[1]	$(0.06)	$(1.13)	
Weighted-average common shares outstanding, basic and diluted[1]	2,112,520	3,731,929	

	As of December 31, 2012	As of December 31, 2013
Balance Sheet Data:		
Cash and cash equivalents	$937,516	$65,328,787
Total assets	938,020	65,488,070
Total liabilities	70,281	2,209,596
Convertible preferred stock	987,050	—
Deficit accumulated during the development stage	(119,611)	(4,332,979)
Total stockholders' equity (deficit)	(119,311)	63,278,474

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(1) See Note 11 of the notes to 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.

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF 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 financial statements and the related notes and other financial information included elsewhere in this document. Some of the information contained in this discussion and analysis or set forth elsewhere in this document, 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 document 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.

Overview

We are a development 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. We have three product candidates that are in, or will shortly enter, pivotal field efficacy trials, or pivotal trials, and expect approval of one or more of these product candidates in 2015. In addition, we have seven 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.

Our lead product candidates are CereKin for the treatment of osteoarthritis pain and inflammation in dogs, AtoKin for the treatment of atopic dermatitis in dogs and SentiKin for the treatment of post-operative pain in dogs. All of these product candidates, if approved, would be first-in-class drugs in the pet therapeutic market.

In August 2013, we initiated the pivotal trial for CereKin, and we initiated the pivotal trial for AtoKin in early 2014 and expect to initiate the pivotal trial for SentiKin by April of this year. We have received from the U.S. Food and Drug Administration, or FDA, Protocol Concurrences for CereKin and AtoKin, and expect to receive a similar Protocol Concurrence for SentiKin. A Protocol Concurrence in animal drug development is analogous to a Special Protocol Assessment in human drug development, and means that the FDA fundamentally agrees with the design, execution and analyses proposed in a protocol, and will not later alter its perspectives on these issues unless public or animal health concerns appear that were not recognized at the time of protocol assessment. Assuming positive results from these trials, we intend to submit new animal drug applications technical section, or NADAs, for marketing approval of CereKin, AtoKin, and SentiKin in the United States starting in 2014, and anticipate potential marketing approvals and product launches in the second half of 2015. If approved in the United States, we will potentially make similar regulatory filings for these products with the European Medicines Agency, or EMA.

We are currently developing product candidates for ten additional indications, with the potential to launch two or more products annually for several years starting in the second half of 2015. 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.

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We are a development-stage company with no products approved for marketing and sale, and we have not generated any revenue. We have incurred significant net losses since our inception. We incurred net losses of $119,611 for the period from September 25, 2012 (inception) through December 31, 2012 and $4,213,368 for the year ended December 31, 2013. 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. As of December 31, 2013, we had a deficit accumulated during the development stage of $4,332,979 and cash and cash equivalents of $65,328,787.

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 U.S. Food and Drug Administration, or 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 product candidate. 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.

Revenue

We do not have any products approved for sale, have not generated any revenue from product sales since our inception and do not expect to generate any material revenue from the sale of products in the near future. If our development efforts result in clinical success and regulatory approval or collaboration agreements with third parties for any of our product candidates, we may generate revenue from those product candidates.

Operating Expenses

The majority of our operating expenses to date have been for the research and development activities related to our lead product candidates.

Research and Development Expense

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.

We are currently pursuing ten product candidates for 13 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.

General and Administrative Expense

General and administrative expense consists primarily of personnel costs, including salaries, related benefits and stock-based compensation for employees, consultants and directors. General and administrative expenses also include rent and other facilities costs and professional and consulting fees for legal, accounting, tax services and other general business services.

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Income Taxes

As of December 31, 2013, we had net operating loss carryforwards for federal and state income tax purposes of $1,202,135 and $1,202,935, 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, 2013, 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 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 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 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 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 are electing 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 will comply 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.

In addition, we are in the process of evaluating the benefits of relying on the other exemptions and reduced reporting requirements provided by the JOBS Act. Subject to certain conditions set forth in the JOBS Act, if as an "emerging growth company" we choose to rely on such exemptions, we may not be required to, among other things, (i) provide an auditor's attestation report on our system of internal controls over financial reporting pursuant to Section 404, and (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 financial statements (auditor discussion and analysis). These exemptions will apply for a period of five years following the completion of our initial public offering or until we no longer meet the requirements of being an "emerging growth company," whichever is earlier.

Research and Development

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

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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.

We account for all stock-based awards issued to non-employees based on the fair value of the award on each measurement date. Stock-based awards granted to non-employees are subject to revaluation at each reporting date over their vesting terms or until approved by our board of directors and settled. As a result, the charge to operations for non-employee awards with vesting conditions or awards which have not been approved and settled is affected each reporting period by changes in the fair value of our common stock.

The fair value of each stock-based award is estimated using the Black-Scholes option-pricing model. At the time of our historical option grants, we were a private company and lacked company-specific historical and implied stock price volatility information. Therefore, we estimated our expected stock price volatility based on the historical volatility of our publicly-traded peer companies and expect to continue to do so until such time as we have adequate historical data regarding the volatility of our common stock price. 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. The assumptions we used to determine the fair value of stock-based compensation in each period were as follows:

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	For the Period September 25, 2012 (Inception) Through December 31, 2012	For the Year Ended December 31, 2013
Risk-free interest rate	0.62% - 0.72%	0.61% -3.04%
Expected term (in years)	10.0	5.0 - 10.0
Expected volatility	90%	80%-90%
Expected dividend yield	—	—

The fair value of our common stock underlying stock-based awards has historically been determined by our board of directors, with assistance from management, based upon information available at the time of grant. The intention has been that all awards granted are exercisable at a price per share not less than the per share fair value of our common stock underlying those awards on the date of grant. Given the absence of a public trading market for our common stock, and in accordance with the American Institute of Certified Public Accountants Practice Aid, Valuation of Privately-Held-Company Equity Securities Issued as Compensation, our board of directors has exercised reasonable judgment and considered numerous objective and subjective factors to determine the best estimate of the fair value of our common stock at each grant date. These factors included:

- contemporaneous or retrospective third-party valuations of our company and our securities;
- historical operating and financial performance;
- our stage of development and the material risks related to our business and industry;
- current business conditions and projections;
- risks inherent to the development of our products;
- the progress of our research and development programs, including the status of clinical studies for our products;
- achievement of enterprise milestones;
- our financial condition, including cash on hand;
- our need for future financing to fund our research and development efforts and the commercialization of our product candidates;
- the composition of, and changes to, our management team and board of directors;
- the rights and preferences of our Series AA, Series A-1 and Series A-1A convertible preferred stock relative to our common stock;
- the lack of marketability of our common stock;
- an analysis of mergers and acquisitions, initial public offerings and the market performance of similar companies in the animal health and biotechnology industry sectors;
- the likelihood of achieving a discrete liquidity event, such as a sale or merger, or initial public offering, given prevailing market conditions; and

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- external market and economic conditions and other trends and conditions affecting the pharmaceutical, animal health and biotechnology industry sectors.

The following table summarizes stock options granted from our inception through December 31, 2013:

	Number of Common Shares Subject to Options Granted	Per Share Exercise Price of Options	Reassessed Fair Value of Common Stock[1]	Intrinsic Value of Common Share at Grant Date
February 4, 2013	176,525	$ 0.32	$0.32	—
February 4, 2013	400,000	$ 0.36	$0.32	—
May 9, 2013	154,793	$ 0.32	$0.32	—
August 29, 2013	156,488	$ 0.90 (2)	$2.27	$1.37
August 29, 2013	256,092	$ 1.37 (3)	$2.27	$0.90
September 12, 2013	29,000	$ 1.37	$2.27	$0.90
November 11, 2013	183,241	$ 3.83	$3.83	—
December 11, 2013	54,000	$ 7.00	$7.00	—

(1) In connection with the preparation of our financial statements for the period from September 25, 2012 (inception) through December 31, 2012 and for the year ended December 31, 2013 and in preparing for our 2013 initial public offering, we reexamined the valuations of our common stock as of each grant date in 2013 due to the acceleration of the timeframe to a potential liquidity event. In connection with our reexamination, we obtained a retrospective independent third-party valuation of our common stock to assist our board of directors in its reassessment.

(2) Reflects options granted to non-employee consultants.

(3) Reflects options granted to directors, officers and other employees at an exercise price of $0.90 per share based on an internal valuation performed by our board of directors. In preparation for the initial filing of the registration statement relating to our initial public offering, we undertook a reassessment of our board of directors' initial valuation, which resulted in a fair value determination of $1.37 per share. Given the grants had only recently been made, with the consent of each employee or director, we adjusted the exercise price of their options to $1.37 per share. The exercise price of options issued to consultants (i.e., those not subject to the provisions of Section 409A of the Internal Revenue Code) was not adjusted.

The following discussion describes our board of directors' analysis of the fair value of our common stock as of each grant date.

Stock-based Awards Granted on February 4, 2013 and May 9, 2013

On February 4, 2013 and May 9, 2013, our board of directors granted options to purchase 576,525 and 154,793 shares, respectively, of our common stock. These grants included an option to purchase 400,000 shares of our common stock granted to our President and Chief Executive Officer at an exercise price of $0.36 per share, which reflected 110% of the board of director's estimated fair value of our common stock. The remaining options were granted with an exercise price of $0.32 per share. In establishing this exercise price for the February 4, 2013 grants, our board of directors performed an internal valuation of the fair value of our common stock as of that date. In performing this valuation, our board of directors considered various

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traditional valuation techniques. After considering the current stage of our development and other factors including the fact that they were valuing a non-marketable common stock interest in a closely-held company, our board of directors determined that the Backsolve Method and the Asset Approach were likely to provide a reasonable indication of fair value.

The Backsolve Method derives the implied value for one type of equity security from a contemporaneous transaction involving another equity security. The February 4, 2013 valuation was based on the issuance price of the Series AA convertible preferred stock that we sold to investors in November 2012. Given that the sale of the Series AA convertible preferred stock had occurred within close proximity to the February 4, 2013 internal valuation and involved third-party investors, our board of directors believed it was reasonable to use that transaction in establishing the enterprise value of our company. Our board of directors also considered the Asset Approach for determining enterprise value. The Asset Approach considers the book value of equity, plus intangible value created through research and development efforts, as an indication of value. No intangible value was attributed to research and development efforts given our early stage of development and the fact that we had not yet initiated clinical trials or other significant development efforts and did not own any patents. Weightings of 60 % and 40% were applied to the Backsolve Method and the Asset Approach, respectively, to determine our implied enterprise value.

Our board of directors then used the option pricing method, or OPM, to allocate the resulting enterprise value among our respective classes of capital stock to determine the fair value of our common stock. The OPM treats common stock and preferred stock as call options on the total equity value of a company, with exercise prices based on the value thresholds at which the allocation among the various holders of a company's securities changes. Under this method, the common stock has value only if the funds available for distribution to the stockholders exceed the value of the liquidation preference at the time of a liquidity event such as a merger, sale or initial public offering, or IPO, assuming the enterprise has funds available to make a liquidation preference meaningful and collectible by the holders of preferred stock. The common stock is modeled as a call option on the underlying equity value at a predetermined exercise price. In the model, the exercise price is based on a comparison with the total equity value, rather than, as in the case of a regular call option, a comparison with a per share stock price. The OPM uses the Black-Scholes option-pricing model to price the call option. This model defines the securities' fair values as functions of the current fair value of a company and uses assumptions such as the anticipated timing of a potential liquidity event and the estimated volatility of the equity securities.

For purposes of the February 4, 2013 internal valuation, we allocated value to the respective classes of stock using the OPM assuming a weighted expected term to liquidity of five years based on then-current plans and estimates of our board of directors and management regarding a liquidity event, which assumed a high probability of failure. The volatility assumption was based on an analysis of guideline public companies' historical equity volatility for a period of five years, which is commensurate with the term assumption. The guideline public companies used for comparison were selected by us based on the similarity of their industry, market capitalization and stage of development as compared to us. Based on this analysis, we utilized, a volatility assumption of 90%. The risk-free rate was estimated as the five-year U.S. Treasury yield. Since we are a private company and our common stock is illiquid, we applied a discount for lack of marketability of 33% to the common stock value. Based on these factors, our board of directors concluded that our common stock had a fair value of $0.32 per share as of February 4, 2013.

In connection with the May 9, 2013 grant of options, our board of directors reexamined its February 4, 2013 internal valuation. The board of directors noted that, although we had continued to make progress on the development of our potential product candidates, we had achieved no significant milestones since the February 4, 2013 internal valuation. Our board of directors also acknowledged the continued risk inherent in development of our product candidates, our expected need for additional financing and our financial position, including our limited available cash. Based on this analysis, our board of directors determined that no change had occurred in the fair value of our common stock since the February 4, 2013 internal valuation and that the estimated fair value of our common stock also was $0.32 per share as of May 9, 2013.

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Stock-based Awards Granted on August 29, 2013 and September 12, 2013

On August 29, 2013 and September 12, 2013, our board of directors granted options to purchase an aggregate of 412,580 and 29,000 shares, respectively, of our common stock initially with an exercise price of $0.90 per share. In establishing this exercise price for the August 29, 2013 option grants, our board of directors performed an internal valuation of the fair value of our common stock as of that date. Based on this internal valuation, our board of directors determined that the estimated fair value of our common stock as of August 29, 2013 was $0.90 per share. Given the close proximity to the August 29, 2013 grant date and that no significant changes had occurred in the business since that date, our board of directors determined that the estimated fair value of our common stock as of September 12, 2013 also was $0.90 per share.

Subsequent to the completion of our internal valuation of the fair value of our common stock as of August 29, 2013 and the grant of the August 29, 2013 and September 12, 2013 stock options, our board of directors reconsidered the factors previously used to estimate the fair value of $0.90 per share and determined that a revised valuation should be conducted. In performing this revised valuation certain assumptions used in the initial valuation were changed including revising the volatility assumption from 44% to 70%. To assist in this revision of the August 29, 2013 valuation, our board of directors considered a third-party valuation in determining the value of our common stock as of that date.

In performing the August 29, 2013 revised valuation, the third party valuation considered various traditional valuation techniques and determined that the Backsolve Method was the most appropriate method to provide a reasonable indication of the implied enterprise value of our company. For purposes of the Backsolve Method, our board of directors relied on the issuance price of the Series A-1 and Series A-1A convertible preferred stock that we sold to investors in June through August 2013 at a price of $3.17 per share. Given that the Series A-1 and Series A-1A financings included third-party investors, and given the proximity of the financings to the August 29, 2013 internal valuation, our board of directors believed it was reasonable to use the Series A-1 and Series A-1A financing transactions in establishing the enterprise value of our company.

For purposes of the August 29, 2013 revised valuation, we allocated value among our respective classes of stock using the OPM assuming a time to liquidity of one year based on then-current plans and estimates of our board of directors and management regarding a liquidity event. The decrease in the time to liquidity from five years in the February 4, 2013 valuation to the one year assumption used in our August 29, 2013 valuation was due to several factors that had changed during this timeframe. These factors included better than anticipated progress in our stage of development, improving capital markets, and consideration by our board of directors of accelerating the timeframe for a proposed initial public offering. As a result our board of directors concluded that it was appropriate to use an estimate of a time to liquidity of one year for purposes of the August 29, 2013 revised valuation.

The volatility assumption was based on an analysis of guideline public companies' historical equity volatility for a period of one year, which is commensurate with the term assumption. We selected the guideline public companies based on the similarity of their industry, business model, product offerings and stage of development as compared to us. Based on this analysis, we utilized a volatility assumption of 70%. The risk-free rate was estimated as the one-year U.S. Treasury yield. A discount for lack of marketability of 21% was then applied to the common stock value as we are a private company and our common stock is illiquid.

Based on this analysis, our board of directors determined that the reassessed estimated fair value of our common stock as of August 29, 2013 was $1.37 per share. Given the close proximity to the August 29, 2013 grant date and that no significant changes had occurred in the business since that date, our board of directors determined that the reassessed estimated fair value of our common stock was $1.37 per share as of September 12, 2013.

In connection with the completion of the reassessed valuation the board of directors, with the consent of the affected option holders, approved an increase in the exercise price from $0.90 per share to $1.37 per

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share for all employee and directors options granted to the option holders on August 29, 2013 and September 12, 2013. The exercise price of options issued to non- employee outside consultants was not adjusted.

Stock-based Awards Granted on November 11, 2013

On November 11, 2013, our board of directors granted options to purchase an aggregate of 183,241 shares of our common stock with an exercise price of $3.83 per share. To assist in establishing the exercise price of these grants, our board of directors considered a third-party valuation of our common stock as of October 21, 2013. Between October 21, 2013 and November 11, 2013, our board of directors noted that we continued to operate our business in the ordinary course, and no events occurred that would cause the fair value of our common stock to increase between these dates. In performing the October 21, 2013 valuation, the third-party valuation considered various traditional valuation techniques. After considering the current stage of our development and other factors, including the fact that they were valuing a non-marketable common stock interest in a closely-held company, the third party valuation determined that the probability-weighted expected return method, or PWERM, was the most appropriate method to provide a reasonable indication of fair value. Under the PWERM, the value of our various equity securities are estimated based upon an analysis of future values for the enterprise assuming various future outcomes.

Shares are valued based on the probability-weighted present value of expected future investment returns, considering each of the possible future outcomes regarding our company, as well as the rights of each class of stock. The future outcomes considered typically include an initial public offering, a sale or merger of our company, any dissolution and our remaining as a private company. The future value of the common stock under each outcome is discounted back to the valuation date at an appropriate risk-adjusted discount rate and probability weighted to arrive at an indication of value for our preferred stock and our common stock. A discount for lack of marketability, to account for the illiquidity of our common stock, is applied to the indicated common stock value to determine the fair value of our common stock.

Four types of future event scenarios were considered: an IPO in the near term, a sale or merger of our company in the later term, an IPO in the later term, and a bankruptcy of our company. As of October 21, 2013, management and our board of directors determined that the probability for the IPO in the near term was 60%, the later term sale or merger scenario was 10%, the IPO in the later term was 20% and bankruptcy was 10%. The enterprise value was estimated using the guideline public company method and guideline transaction method under the market approach for the IPO and sale or merger scenarios. For the bankruptcy scenario, a net asset value approach was used.

The multiples of market value of total invested capital or MVIC to cash, book value of invested capital, research and development expenses, and return on investment were selected to be the most appropriate to determine the fair value of our company in the early term IPO scenario. The multiples of MVIC to the projected revenues were considered for the later term IPO scenario as we expect to commercialize our products and start generating revenues. Additionally, the MVIC of the selected comparable companies was considered. The selected multiples were adjusted to reflect the perceived growth and risk of our company relative to those of the guideline companies. The future value was then discounted back to the valuation date based on the appropriate risk adjusted discount rate.

For the later term sale or merger scenario, we utilized the guideline transaction method, which considers pricing multiples from acquisitions of guideline companies. The recent acquisitions of entities in our industry or similar industries were estimated to generate comparable revenue at the time of sale or merger in the later term. The multiples of MVIC to the projected revenues then were applied. The level of MVIC was also considered. The selected multiples were then adjusted to reflect the perceived growth and risk of our company relative to those of the acquisition transactions. The future value was then discounted back to the valuation date based on the appropriate risk adjusted discount rate.

Due to early stage of our company, there is a low probability of successful commercialization of our product candidates and of our becoming profitable. Thus, a probability to the orderly liquidation scenario was

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incorporated. We believe that our cash and cash equivalents balance as of December 31, 2013 is sufficient to fund our planned operations for a least the next 12 months, so an end-date of 2015 was selected as the expected term for the bankruptcy scenario. A company's orderly liquidation value is the net amount received if its assets are sold and its liabilities retired. Our intellectual property was considered our primary asset at the point of bankruptcy. The fair value of our intellectual property under the bankruptcy scenario was estimated based on the projected research and development expenses and discounted to present value as of the valuation date.

To derive the value of our common stock for each scenario, the proceeds to the common stockholders were calculated based on the respective preferences and priorities of our preferred and common stock. In our common stock valuations as of October 21, 2013, we applied risk adjusted discount rates of 20% for each of the near-term IPO, later term sale or merger, and later term IPO scenarios. This discount rate was applied for the October 21, 2013 valuation due to the higher likelihood of an early liquidity event, achieved milestones, and lower risk of our business compared to the August 29, 2013 retrospective valuation (see below). A lower discount rate of 16.5% was applied for the bankruptcy risk scenario due to lower volatility associated with the projected expenses that were used to estimate the liquidation value of the asset under a bankruptcy scenario. In assessing the appropriate discount rate for various scenarios, we examined the definitions associated with various stages of development and liquidity event and compared these definitions to the current state of our business.

We utilized the Black-Scholes option pricing model to determine the value of a theoretical put option based on the preliminary value indications, because our common stock lacks liquidity until a liquidity event occurs. The volatility assumption was based on an analysis of guideline public companies' historical equity volatility for a period commensurate with the assumed term used for each of the scenarios. Based on the selected guideline public companies and remaining terms, a volatility of 80% was selected for each of the early term IPO, later term sale or merger, and later IPO scenarios. As of October 21, 2013, discounts for lack of marketability of 12.5%, 28.5%, and 28.5% were applied to the near term IPO, later term sale or merger, and later term IPO scenarios, respectively.

Based on this analysis and a consideration of events and other factors that had occurred between the October 21, 2013 common stock valuation date and the November 11, 2013 grant date, our board of directors determined that the estimated fair value of our common stock as of October 21, 2013 was $3.83 per share.

Stock-based Awards Granted on December 11, 2013

On December 11, 2013, our board of directors granted options to purchase an aggregate of 54,000 shares of our common stock with an exercise price of $7.00 per share. Our board of directors determined that the estimated fair value of our common stock as of December 11, 2013 was $7.00 per share based on the initial public offering price in our 2013 initial public offering.

Retrospective Valuations of Common Stock

In connection with the preparation of our financial statements for the period from September 25, 2012 (inception) through December 31, 2012 and for the year ended December 31, 2013, and in preparing for our 2013 initial public offering, we determined that retrospective valuations of our common stock as of each of our option grant dates were appropriate due to the acceleration of the timeframe to a potential liquidity event. In connection with that reexamination, we obtained retrospective third-party valuations of our common stock to assist our board of directors in its reassessment.

February 4, 2013 and May 9, 2013

In connection with our reexamination, we engaged in a retrospective valuation of the fair value of our common stock for financial reporting purposes as of February 4, 2013 and May 9, 2013. To assist in its reassessment, our board of directors obtained a retrospective third-party valuation of our common stock. In performing this valuation, the third-party valuation considered various traditional valuation techniques. After considering the current stage of our development and other factors, including the fact that they were valuing a

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non-marketable common stock interest in a closely-held company, the third party valuation determined that the Backsolve Method and the Asset Approach were likely to provide a reasonable indication of fair value. The February 9, 2013 retrospective valuation was based on the price of the Series AA convertible preferred stock that we sold to investors in November 2012. The Asset Approach considered the total invested capital to date in the company. A weighting of 50% was applied to both the Backsolve Method and the Asset Approach to determine the implied enterprise value of our company.

The value was allocated to the respective classes of stock using the OPM assuming a weighted expected term to liquidity of two years based on then-current plans and estimates of the board of directors and management regarding a liquidity event. The volatility assumption was based on an analysis of guideline public companies' historical equity volatility for a period of two years, which is commensurate with the term assumption. The guideline public companies used for comparison were selected based on the similarity of their industry, business model, product offerings and stage of development as compared to us. Based on this analysis we utilized, a volatility assumption of 70%. The risk-free rate was estimated as the then-average yield of U.S. Treasury notes commensurate with the estimated time to liquidity of two years. A discount for lack of marketability of 29% was then applied to the common stock value as we are a private company and our common stock is illiquid. Based on this analysis, our board of directors concluded that the fair value of our common stock as of February 4, 2013 was $0.22 per share.

Our board of directors considered the results of the third-party valuation, which was lower than the previously estimated fair value of $0.32 per share of common stock derived from the board of directors' February 4, 2013 internal valuation. As a result, our board determined that no change to the fair value of our common stock was necessary for financial reporting purposes for the February 4, 2013 and May 9, 2013 option grants. Our board of directors also considered the factors that contributed to the different fair values in each valuation, the most significant of which was the assumption related to the time to a liquidity event of five years in the February 4, 2013 internal valuation and two years in the retrospective valuation.

August 29, 2013 and September 12, 2013

In connection with the preparation of our financial statements, our board of directors obtained a retrospective third-party valuation of our common stock as of August 29, 2013. The third-party valuation considered various traditional valuation techniques. After considering the current stage of our development and the closely-held nature of our company, the third party determined that the PWERM was the most appropriate method to provide a reasonable indication of fair value.

As of August 29, 2013, four types of future event scenarios were considered: an IPO in the near term; a sale or merger in the later term; an IPO in the later term; and a bankruptcy. As of August 29, 2013, management and our board of directors determined that the probability for the IPO in the near term was 30%, for the later term sale or merger scenario 25%, the IPO in the later term 25% and 20% for a bankruptcy.

The enterprise value of our company was estimated using the guideline public company method and guideline transaction method under the market approach for the IPO and sale or merger scenarios. The net asset value approach was used for the bankruptcy scenario.

The IPO scenario is based on the guideline company method. Appropriate guideline companies, were considered to be publicly traded biotechnology companies that were in the early development stage. The pool of potential guideline companies was then narrowed based on the companies' business descriptions, markets served, stages of growth, business model, pipeline of drugs, profitability and revenue. The multiples of MVIC to cash, book value of invested capital, research and development expenses, and return on investment were concluded to be the most applicable to determine the fair value of our company under the early term IPO scenario. The multiples of MVIC to the projected revenues were considered for the later term IPO scenario as we expect to commercialize our products and begin to generate revenue. The value of invested capital of the selected guideline public companies was also considered. The selected multiples were adjusted to reflect the perceived growth and risk of our company relative to those of the guideline public companies. The future value

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was then present valued to the valuation date based on the appropriate risk adjusted discount rate. For the later term sale or merger scenario the Guideline Transaction Method was applied to consider pricing multiples from acquisitions of guideline companies. Recent acquisitions of entities in the same or similar industries to our company were estimated to generate comparable revenue at the time of sale or merger in the later term. The multiples of MVIC to the projected revenues were applied. The level of MVIC was also considered. The selected multiples were then adjusted to reflect the perceived growth and risk of the Company relative to those of the guideline transactions. The future value was then present valued to the valuation date based on the appropriate risk adjusted discount rate.

Due to the early stage of our company, there is a low probability of successful commercialization of our product candidates and of becoming profitable, so a probability to the orderly liquidation scenario was incorporated. A company's orderly liquidation value is the net amount received if its assets are sold and its liabilities retired. Our primary asset would be our intellectual property, the fair value of which was estimated based on the projected research and development expenses prior to bankruptcy, and discounted to present value as of the valuation date.

To derive the value of our common stock for each scenario, the proceeds to the common stock holders were calculated based on the preferences and priorities of our preferred and common stock. For purposes of the August 29, 2013 valuation, a risk adjusted discount rate of 35% were applied to each of the near-term IPO, later term sale or merger, and later term IPO scenarios. A lower discount rate of 16.5% was applied for the bankruptcy risk scenario due to a lower volatility associated with the projected expenses used to estimate the liquidation value of our assets under a bankruptcy scenario. In assessing the appropriate discount rate for various scenarios, we examined the definitions associated with various stages of development and liquidity event and compared these definitions to the current state of our business.

We utilized the Black-Scholes Option Pricing Model to determine the value of a theoretical put option based on the preliminary value indications, because our common stock lacks liquidity until a liquidity event occurs. The volatility assumption was based on an analysis of the guideline public companies' historical equity volatility for a period commensurate with the assumed term used for each of the scenarios.

Based on the selected guideline companies and the remaining terms to each event, we selected volatilities of 85% for the early term IPO and 80% for each of the later term sale or merger and later term IPO scenarios. Discounts for lack of marketability of 15%, 29.5%, and 29.5% were applied to the near term IPO, later term sale or merger, and later term IPO scenarios, respectively.

Based on this analysis, our board of directors determined that the estimated fair value of our common stock as of August 29, 2013 was $2.27 per share. Given, for financial accounting purposes, the close proximity to the August 29, 2013 grant date and our board of directors' conclusion that no significant changes had occurred in our business since that date, our board of directors determined that the estimated fair value of our common stock was $2.27 per share as of September 12, 2013 for financial accounting purposes.

Results of Operations

Our results of operations from September 25, 2012 (inception) through December 31, 2012, for the year ended December 31, 2013 and for the cumulative period from September 25, 2012 (inception) through December 31, 2013 are as follows:

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	For The Period From September 25, 2012 (Inception) Through December 31, 2012	Year Ended December 31, 2013	Cumulative Period From September 25, 2012 (Inception) Through December 31, 2013
Operating expenses:			
Research and development	$74,772	$3,140,606	$3,215,378
General and administrative	44,864	1,078,687	1,123,551
Total operating expenses	119,636	4,219,293	4,338,929
Loss from operations	(119,636)	(4,219,293)	(4,338,929)
Total other income, net	25	5,925	5,950
Net loss and comprehensive loss	$(119,611)	$(4,213,368)	$(4,332,979)
Net loss per share attributable to common stockholders, basic and diluted	$(0.06)	$(1.13)	
Weighted-average common shares outstanding, basic and diluted	2,112,520	3,731,929	

Revenue

We did not generate any revenue during the period from September 25, 2012 (inception) through December 31, 2012 or for the year ended December 31, 2013.

Research and Development Expense

Research and development expense for the period from September 25, 2012 (inception) through December 31, 2012 was $74,772. Research and development expense for the year ended December 31, 2013 was $3,140,606. The composition of these expenses was as follows:

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	For the Period from September 25, 2012 (Inception) Through December 31, 2012	Year Ended December 31, 2013
Payroll and related	$51,417	$950,606
Consulting	12,963	1,005,767
Clinical trial costs	4,427	1,058,095
Other	5,965	126,138
	$74,772	$3,140,606

Payroll and related costs, as well as consulting costs, for the period ended December 31, 2012 were primarily attributable to recruiting and building our research and development team. During this period, we relied extensively on consultants as we began to build our internal research and development team. There were no outsourced research and development expenses for the period from September 25, 2012 (inception) to December 31, 2012 related to our CereKin, AtoKin or SentiKin product development programs. During this period, we also filed three INADs, including the INADs for CereKin and AtoKin. Included in research and development expense for the period ended December 31, 2012 was $11,340 of stock-based compensation expense.

During the year ended December 31, 2013, research and development expenses primarily related to advancing the development of our lead product candidates. During this period we developed the protocols for CereKin and AtoKin, received Protocol Concurrences from the FDA for both compounds and increased our staffing to support the planning for initiation of the pivotal trials of CereKin and AtoKin. Included in research and development expenses for the year ended December 31, 2013 was $826,499 of stock-based compensation expense. Outsourced research and development expenses related to our CereKin, AtoKin and SentiKin product development programs for the year ended December 31, 2013 were $1,264,336, $192,000 and $22,545, respectively.

We expect research and development expense to increase significantly for the foreseeable future as we continue to increase our headcount, commence pivotal studies and further develop our compounds. 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.

General and Administrative Expense

General and administrative expense for the period from September 25, 2012 (inception) through December 31, 2012 was $44,864. General and administrative expense for the year ended December 31, 2013 was $1,078,687. The composition of general and administrative expense was as follows:

	For the Period from September 25, 2012 (Inception) Through December 31, 2012	Year Ended December 31, 2013
Payroll and related	$36,406	$537,967
Consulting and legal fees	351	277,594
Regulatory fees	—	87,700
Other	8,107	175,426
	$44,864	$1,078,687

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For the period ended December 31, 2012, general and administrative expense related primarily to our corporate formation and initial financing activities.

For the year ended December 31, 2013, general and administrative expense related primarily to additional financing activities, salaries, rent and other facilities costs, professional and consulting fees for legal, accounting and tax services and other general business services. We expect general and administrative expense to increase significantly as we begin operating as a public company and continue to build our corporate infrastructure. Included in general and administrative expense for the year ended December 31, 2013 was $95,282 of stock-based compensation expense.

Liquidity and Capital Resources

We have incurred losses and negative cash flows from operations and have not generated any revenue since our inception in September 2012 through December 31, 2013. As of December 31, 2013, we had a deficit accumulated during the development stage of $4,332,979. During the year ended December 31, 2013, the Company raised a total of $65,979,246, net of transaction expenses 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). These transactions, net of operating expenses, result in the Company having a cash and cash equivalents balance at December 31, 2013 of $65,328,787. We believe that our cash and cash equivalents balance as of December 31, 2013 is 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:

	For the Period from September 25, 2012 (Inception) Through December 31, 2012	Year Ended December 31, 2013
Cash flows used in operating activities	$(62,784)	$(1,573,152)
Cash flows used in investing activities	$—	$(14,823)
Cash flows provided by financing activities	$1,000,300	$65,979,246

Net cash used in operating activities

During the period from September 25, 2012 (inception) through December 31, 2012, net cash used in operating activities was $62,784. Net cash used in operating activities primarily resulted from our net loss of $119,611, partially offset by non-cash, stock-based compensation of $11,340 and changes in operating assets and liabilities of $45,487.

During the year ended December 31, 2013, net