Kindred Biosciences, Inc.
Form S-1/A
March 31, 2014

As filed with the Securities and Exchange Commission on March 31 , 2014 Registration No. 333-194660
UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

AMENDMENT NO. 1
TO
FORM S-1
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

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

Delaware	2834	46-1160142
(State or other jurisdiction of incorporation or organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification No.)

1499 Bayshore Highway, Suite 226
Burlingame, California 94010
(650) 701-7901
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Richard Chin, M.D.
President and Chief Executive Officer
Kindred Biosciences, Inc.
1499 Bayshore Highway, Suite 226
Burlingame, California 94010
(650) 701-7901
(Name, address, including zip code, and telephone number, including area code, of agent for service)
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Approximate date of commencement of proposed sale to the public: As soon as practicable after this Registration Statement is declared effective.
If any of the securities being registered on this form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box. o

If this form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

If this form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

If this form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

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.

Large accelerated filer	o	Accelerated filer	o
Non-accelerated filer	x (Do not check if a smaller reporting company)	Smaller reporting company	o

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the Registration Statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

The information in this preliminary prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state or other jurisdiction where the offer or sale is not permitted.

SUBJECT TO COMPLETION DATED MARCH 31 , 2014

PRELIMINARY PROSPECTUS

$50,000,000

Kindred Biosciences, Inc.

Common Stock

We are offering shares of our common stock.

Our common stock is listed on The NASDAQ Capital Market under the symbol “KIN.” On March 28, 2014, the last reported sale price of our common stock on The NASDAQ Capital Market was $18.91.

Investing in our common stock involves a high degree of risk. See “Risk Factors” beginning on page 10.

We are an “emerging growth company” as defined by the Jumpstart Our Business Startups Act of 2012 and, as such, we have elected to comply with certain reduced public company reporting requirements for this prospectus and future filings.

	Per Share	Total
Public offering price	$	$
Underwriting discounts and commissions(1)	$	$
Proceeds, before expenses to us	$	$

(1) We refer you to “Underwriting” beginning on page 103 of this prospectus for additional information regarding underwriter compensation.

We have granted the underwriters a 30-day option to purchase a total of up to additional shares of common stock.

The underwriters expect to deliver shares of common stock to purchasers on , 2014.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

Leerink Partners BMO Capital Markets Guggenheim Securities

The date of this prospectus is , 2014.

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We have not, and the underwriters have not, authorized anyone to provide any information or to make any representations other than those contained in this prospectus or in any free writing prospectus prepared by or on behalf of us or to which we have referred you. We take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. This prospectus is an offer to sell only the shares offered hereby, but only under the circumstances and in the jurisdictions where it is lawful to do so. The information contained in this prospectus or in any applicable free writing prospectus is current only as of its date, regardless of its time of delivery or any sale of shares of our common stock. Our business, financial condition, results of operations and prospects may have changed since that date.

For investors outside the United States: We have not, and the underwriters have not, done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. Persons outside the United States who come into possession of this prospectus must inform themselves, and observe any restrictions relating to, the offering of the shares of common stock and the distribution of this prospectus outside the United States.

Kindred Biosciences, Kindred Bio, CereKin, AtoKin, SentiKin and "Best Medicines for Our Best Friends" are six of our trademarks that are used in this prospectus. This prospectus also includes trademarks, tradenames and service marks that are the property of other organizations. Solely for convenience, trademarks and tradenames referred to in this prospectus appear without the ® and ™ symbols, but those references are not intended to indicate that we will not assert, to the fullest extent under applicable law, our rights or that the applicable owner will not assert its rights, to these trademarks and tradenames.

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PROSPECTUS SUMMARY

This summary highlights information contained elsewhere in this prospectus. This summary does not contain all of the information you should consider before investing in our common stock. You should read this entire prospectus carefully, especially the section in this prospectus entitled "Risk Factors" beginning on page 10 and our financial statements and the related notes thereto appearing at the end of this prospectus, before making an investment decision. As used in this prospectus, references to "we," "us," "our," "our company" and "Kindred" refer to Kindred Biosciences, Inc. References to "product candidates," "drugs," and "compounds" refer to both small molecules and biologics.

Overview

Our Company

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 initiated the pivotal trial for SentiKin in March 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 some human biotechnology companies' development of a single lead therapy. The active ingredients in many of our small molecule product candidates also have established chemistry, manufacturing and controls, or CMC, which can be important gating factors in the regulatory approval process. As a result, we usually do not need to invest further in active pharmaceutical ingredient, or API, process development to comply with good manufacturing practices, or GMP, standards for our small molecule product candidates.

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Product Pipeline

Our current product pipeline consists of small molecules and biologics in various stages of development 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. 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 Application for United States Veterinary Biological Product License with the USDA, also called a Product License Agreement.

In addition to the products candidates in the above chart, we have several projects that are entering the pipeline, including immune checkpoint inhibitors and feline erythropoietin. We utilize a rigorous screening and review process to identify compounds and targets that have demonstrated safety and efficacy in humans and would address unmet medical needs in veterinary medicine if formulated for use in pets.

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Pet Therapeutics Market

U.S. consumers spent an estimated $55.5 billion on their pets in 2013, according to the American Pet Products Association, or APPA, an increase of 44% from 2006. The veterinary care segment has been among the fastest growing segments of the overall U.S. pet market. This segment accounted for an estimated $14.2 billion in 2013, an increase of 54% 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. We believe several factors, including the increased longevity of pets and willingness of pet owners to treat their pets with medications, will contribute to continued growth in the spending on pet therapeutics.

Despite the growing market for pet products, generally, there are relatively few therapeutic treatment options approved for use in pets as compared to humans. As a result, veterinarians often 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 for the human product to be effective in the particular species without undue risk of side effects. The veterinarian also must find a way to administer the human product in animals and determine the amount actually dosed, which are important considerations in treating pets with human drugs. 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.

Although there are many similarities between the businesses of developing and commercializing therapeutics for pets and for humans, there also are a number of important differences, including:

- Faster, less expensive and more predictable development. The development of pet therapeutics requires fewer clinical studies in fewer subject animals than human therapeutics and, unlike human drug development, can be 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 regarding available treatment options primarily on the advice of their veterinarians, rather than on the treatment options' eligibility for reimbursement by insurance companies or government payers. We believe this results in less pricing pressure compared to 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 therapeutics 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. We believe that stronger brand loyalty and lack of mandatory generic drug substitution, as is the case for human pharmaceuticals, partially explains the low penetration of generics in veterinary medicine.

Lead Product Candidates

CereKin

CereKin is an oral, chewable, beef-flavored formulation of diacerein, an interleukin-1 beta inhibitor that we are developing for osteoarthritis pain and inflammation in dogs. Human drugs containing the active ingredient in CereKin are marketed extensively outside the United States for the treatment of osteoarthritis and are generally considered to be safe, except for certain gastrointestinal side effects and rare indiosyncratic skin and liver side effects in humans, for which the drug is undergoing review in the EU. These side effects appear to be less frequent or absent in dogs. Several published studies have shown that the active ingredient is effective in treating canine arthritis. We initiated the pivotal trial for CereKin in August 2013 under a Protocol Concurrence with the FDA. A Protocol Concurrence in animal drug development is analogous to a Special

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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. We expect to have data from the pivotal trial in the second quarter of 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.

Canine osteoarthritis is a chronic, progressive, degenerative joint disease, diagnosed in an estimated 20% of dogs over the age of one. Non-steroidal anti-inflammatory drugs, or NSAIDs, are the only approved treatment for canine osteoarthritis (other than steroids and a vitamin-mineral based drug), but some dogs have a sensitivity to NSAIDs that results in renal, hepatic or gastrointestinal, or GI, toxicity and, in extreme cases, death. As a result, dogs that are prescribed NSAIDs must often be monitored with baseline and periodic blood tests, and up to approximately 50% of dogs remain untreated or cannot be treated in chronic cases. If approved, we believe CereKin will be effective in the treatment of canine osteoarthritis pain and inflammation, without the need for blood monitoring tests. In humans, the active ingredient in CereKin has demonstrated added effectiveness when combined with NSAIDs versus NSAIDs alone. Based on published data, we expect CereKin may have disease-modifying effects in dogs and also may protect against NSAID-induced GI tract problems.

AtoKin

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, which we initiated 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.

Atopic dermatitis is a common, potentially chronic, allergic skin disease that affects up to 10% of all dogs. 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. While currently approved drugs such as corticosteroids and oral cyclosporine are effective, they all suppress the dog's immune system, potentially leading to serious infections. Corticosteroids also have other side effects, including osteoporosis, endocrine problems, cataracts and frequent urination. We believe that, if approved, AtoKin could be effective as both a first-line therapy and as a long-term maintenance therapy for chronic atopic dermatitis in dogs, with a safety profile superior to currently approved therapeutics.

SentiKin

SentiKin is an oral, non-NSAID, non-opioid analgesic, formulation of flupirtine that we are developing for management of post-operative pain in dogs, cats and horses. 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. Published studies suggest that the active ingredient is effective in treating canine pain. We initiated the pivotal study for SentiKin in March 2014. We have discussed the design of the pivotal study with the FDA, and based on those discussions, we have submitted the protocol for a Protocol Concurrence which we expect to receive in mid-April. 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.

There is no standard of care for the use of pain medications following dog surgeries, and the only systemic drugs approved for treatment of post-operative pain in dogs are NSAIDs, fentanyl and pentazocine. NSAIDs are generally less effective than opioids in controlling pain and have other well-documented side effects described above in our discussion regarding CereKin. Fentanyl is a controlled narcotic drug, and pets are often kept in the hospital while receiving fentanyl. Pentazocine is a controlled narcotic drug, not widely used in dogs. We believe that, if approved, SentiKin may provide post-operative 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.

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Business Strategy

Our mission is to bring to pets the same kinds of safe and effective medicines that our human family members enjoy. Key elements of our business strategy are as follows:

- advance CereKin, AtoKin, SentiKin and our other product candidates through development and continue to focus on execution of cost-effective research and development;
- leverage our antibody and biologics experience;
- leverage our current product pipeline in additional animal species;
- expand our pipeline with additional product candidates; and
- commercialize our products with our own direct sales force in the United States and with distributors in other regions.

Risks Related to Our Business

Our ability to successfully implement our business strategy is subject to numerous risks, as more fully described in the section entitled “Risk Factors” immediately following this prospectus summary. These risks include, among others:

- we have a limited operating history, are not profitable and may never become profitable;
- we will have no material product revenue for the foreseeable future, and we may need to raise additional capital to achieve our goals;
- 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;
- 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;
- 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;
- 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;
- even if we obtain regulatory approval for our current or future product candidates, they may never achieve market acceptance or commercial success;
- we do not own any issued patents covering our product candidates;
- 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; and
- 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.

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 prospectus.

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Implications of Being an Emerging Growth Company

As a company with less than $1.0 billion in revenue during our last fiscal year, we qualify as an "emerging growth company" as defined in the Jumpstart Our Business Startups Act, or JOBS Act, enacted in April 2012. An "emerging growth company" may take advantage of reduced reporting requirements that are otherwise applicable to public companies. These reduced reporting requirements include:

- not being required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act of 2002, as amended, or the Sarbanes-Oxley Act;
- reduced disclosure obligations regarding executive compensation in this prospectus and in our future periodic reports, proxy statements and registration statements; and
- not being required to hold a nonbinding advisory vote on executive compensation or to seek stockholder approval of any golden parachute payments not previously approved.

We may take advantage of these reduced reporting obligations until the last day of our fiscal year following the fifth anniversary of the date of the first sale of our common equity securities pursuant to an effective registration statement under the Securities Act of 1933, as amended, or the Securities Act, which fifth anniversary will occur in 2018. However, if certain events occur prior to the end of such five-year period, including if we become a "large accelerated filer," our annual gross revenue exceeds $1.0 billion or we issue more than $1.0 billion of non-convertible debt in any three-year period, we will cease to be an emerging growth company.

We have elected to take advantage of certain of the reduced disclosure obligations regarding executive compensation in this prospectus and may elect to take advantage of other reduced reporting requirements in future filings with the Securities and Exchange Commission, or the SEC. As a result, the information that we provide to our stockholders may be different than the information you might receive from other public reporting companies in which you hold equity interests.

The JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. 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.

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THE OFFERING

Common stock offered by us	2,644,104 shares (or 3,040,720 shares if the underwriters exercise their option to purchase additional shares in full)
Common stock to be outstanding after this offering	18,871,224 shares (or 19,267,840 shares if the underwriters exercise their option to purchase additional shares in full)
Option to purchase additional shares	We have granted the underwriters a 30-day option to purchase up to 396,616 additional shares of our common stock to cover over-allotments, if any
Use of proceeds	We intend to use the net proceeds of this offering for potential strategic acquisitions of complementary assets or businesses, to accelerate and expand our pipeline, and for general corporate and working capital purposes. See “Use of Proceeds” on page 32 for a more detailed description of the intended use of proceeds from this offering
Risk factors	See “Risk Factors” beginning on page 10 and other information included in this prospectus for a discussion of factors that you should consider carefully before deciding to invest in our common stock
NASDAQ Capital Market symbol	“KIN”

The number of shares of our common stock to be outstanding after this offering is based on 16,227,120 shares of our common stock outstanding as of March 31, 2014. The number of shares of our common stock to be outstanding after this offering excludes:

- 2,127,627 shares of common stock issuable upon exercise of stock options outstanding as of March 31, 2014 at a weighted-average exercise price of $6.58 per share;
- 5,000 shares of common stock issuable upon vesting of an award of restricted common stock outstanding as of March 31, 2014; and
- 1,815,448 shares of common stock reserved as of March 31, 2014 for future issuance under our 2012 Equity Incentive Plan.

Unless otherwise indicated, the information in this prospectus assumes the following:

- assumes a base offering of 2,644,104 shares, based on a $50,000,000 offering at an assumed per share price of $18.91 per share (the last reported price of our common stock on The NASDAQ Capital Market on March 28, 2014);
- no exercise of the outstanding stock options and vesting of outstanding restricted stock, and no issuance or award of shares of our common stock reserved for issuance, under our 2012 Equity Incentive Plan as described above; and
- no exercise by the underwriters of their option to purchase additional shares of our common stock.

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SUMMARY SELECTED FINANCIAL DATA

The following tables set forth a summary of our selected historical financial data as of and for the periods indicated. We have derived the summary selected financial data (except the pro forma balance sheet data as of December 31, 2013) from our audited financial statements included elsewhere in this prospectus. You should read this data together with our financial statements and related notes appearing elsewhere in this prospectus and the sections in this prospectus entitled “Selected Financial Data” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations.” The historical results are not necessarily indicative of the results to be expected for any future periods.

	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	

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		As of December 31, 2013	
	As of December 31, 2012	Actual	Pro Forma (2)(3)(4)
Balance Sheet Data:			
Cash and cash equivalents	$937,516	$65,328,787	$112,018,787
Total assets	938,020	65,488,070	112,178,070
Total liabilities	70,281	2,209,596	2,209,596
Convertible preferred stock	987,050	—	—
Deficit accumulated during the development stage	(119,611)	(4,332,979)	(4,332,979)
Total stockholders' equity (deficit)	$(119,311)	$63,278,474	$109,968,474

(1) See Note 11 of the notes to financial statements included elsewhere in this prospectus 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.

(2) Pro Forma to give effect to the assumed sale of 2,644,104 shares of our common stock in this offering at an assumed public offering price of $18.91 per share (the last reported price of our common stock on The NASDAQ Capital Market on March 28, 2014), after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

(3) A $1.00 increase (decrease) in the assumed public offering price of $18.91 per share (the last reported price of our common stock on The NASDAQ Capital Market on March 28, 2014), would increase (decrease) the pro forma amount of each of cash and cash equivalents, total assets, and total stockholders' equity by approximately $2.5 million, assuming that the number of shares offered by us remains the same and after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

(4) Each increase (decrease) of 100,000 shares in the number of shares offered by us would increase (decrease) the pro forma amount of cash and cash equivalents, total stockholders’ equity and total capitalization by approximately $1.8 million, assuming that the assumed public offering price remains the same, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

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RISK FACTORS

Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below, as well as the other information in this prospectus, including our financial statements and the related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations," before deciding whether to invest in our common stock. The occurrence of any of the events or developments described below could harm our financial condition, results of operations, business and prospects. In such an event, the market price of our common stock could decline, and you may lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may have similar adverse effects on us.

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 pivotal trials, also known as a field efficacy trials, are CereKin, AtoKin and SentiKin. 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 our existing cash and cash equivalents, together with the net proceeds of this offering, will be sufficient to fund our operating plan through the anticipated approval and commercial launch of one or more of our lead product candidates.

Even if we believe we have sufficient funds on hand for our current or planned future business and operations, we may seek from time to time to raise additional capital based upon favorable market conditions or strategic considerations such as availability of potential acquisitions. We have no current agreements or arrangements with respect to any financings, and any

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such financings may result in further dilution to our stockholders, the imposition of debt covenants and repayment obligations or other restrictions that may adversely affect our business or the value of our common stock.

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, and are focused primarily on the development of our lead product candidates, CereKin, AtoKin and SentiKin. Accordingly, our near-term prospects, including our ability to generate material product revenue, 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;
- 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;

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- 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 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

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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 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.

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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:

- 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 the pivotal trial of AtoKin for the treatment of atopic dermatitis in dogs, and are currently negotiating with the FDA a Protocol Concurrence for the pivotal trial of SentiKin for post-operative pain 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

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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 the pivotal trials of CereKin and AtoKin or the planned pivotal trial of SentiKin, or of our other current or future product candidates, will conclude or begin on time, and they may be delayed or discontinued for a variety of reasons, including if we are unable to:

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

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

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

We currently plan to conduct our own pivotal trials, including our current 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.

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

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

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

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

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

The success of our commercialization efforts will depend upon the perceived safety and effectiveness of pet therapeutics, in general, and of our products, in particular. Unanticipated safety or efficacy concerns can arise with respect to approved pet therapeutics after they enter into commerce, which may result in product recalls or withdrawals or suspension of sales, as well as product liability and other claims. 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.

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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 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.

Although we maintain product liability insurance, it is possible that our 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, Stephen Sundlof, D.V.M., Ph.D., our Senior Vice President of Regulatory Affairs, and Blake Hawley, D.V.M., our Chief Commercial Officer. The loss of services of any of our key personnel could adversely affect our ability to successfully develop our current or future product pipeline and commercialize our product candidates. Although we have entered into employment agreements with these key members of senior management, such agreements generally do not prohibit them from leaving our employ at any time. We currently maintain "key man" life insurance on Dr. Chin, but 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

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different regulatory standards than the FDA, so we may require multiple manufacturing processes and facilities for the same product candidate or any approved product.

The commercialization of 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, 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.

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

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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.

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.