Kindred Biosciences, Inc.
Form S-1/A
December 09, 2013
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As filed with the Securities and Exchange Commission on December 9, 2013

Registration No. 333-192242

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

AMENDMENT NO. 4

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. ¨

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. ¨

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. ¨

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. ¨

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

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.

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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 DECEMBER 9, 2013

PRELIMINARY PROSPECTUS

5,750,000 Shares

KINDRED BIOSCIENCES, INC.

Common Stock

$ per share

This is the initial public offering of Kindred Biosciences, Inc. We are offering 5,750,000 shares of our common stock. Prior to this offering, there has been no public market for our common stock. We estimate that the initial public offering price will be between $6.00 and $8.00 per share.

Our common stock has been approved for listing on the NASDAQ Capital Market under the symbol KIN, subject to official notice of issuance.

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.

Investing in our common stock involves a high degree of risk. See Risk Factors beginning on page 12.

	Per Share	Total

Initial public offering price	$	$
Underwriting discounts and commissions(1)	$	$
Proceeds, before expenses to us	$	$

(1) We refer you to Underwriting beginning on page 116 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 862,500 additional shares of common stock.

The underwriters expect to deliver shares of common stock to purchasers on , 2013.

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.

BMO Capital Markets **Guggenheim Securities**

Roth Capital Partners

The date of this prospectus is , 2013.

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Until , 201 (25 days after the commencement of this offering), all dealers that buy, sell or trade shares of our common stock, whether or not participating in this offering, may be required to deliver a prospectus. This delivery requirement is in addition to the obligation of dealers to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.

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.

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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 12 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, and we expect to initiate the pivotal trials for AtoKin and SentiKin by early 2014. 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 analysis proposed in a protocol, and will not later alter its perspective 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, 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.

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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.

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. Members of our management team also have 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.

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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 our product candidates currently in development, we have identified over 30 potential small molecule and biologic therapeutics that are in the pre-INAD stage. We utilize a rigorous screening and review

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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.

Pet Therapeutics Market

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. 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. 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, 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.

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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. We expect to have data from the pivotal trial in the second quarter of 2014 and, if positive, intend to submit a NADA in mid-2014, with potential marketing approval in the second half of 2015.

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 expect to initiate by early 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 are currently negotiating a Protocol Concurrence with the FDA for the pivotal trial for SentiKin for post-operative pain in dogs, and we intend to initiate the trial by early 2014. We expect to receive data from the trial in

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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.

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;

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- 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.

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	5,750,000 shares (or 6,612,500 shares if the underwriters exercise their option to purchase additional shares in full)
Common stock to be outstanding after this offering	13,297,881 shares (or 14,160,381 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 862,500 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 the research and development of our product candidates, to establish our commercial infrastructure in the United States and for general corporate and working capital purposes. See Use of Proceeds on page 38 for a more detailed description of the intended use of proceeds from this offering
Offering price	$ per share
Risk Factors	See Risk Factors beginning on page 12 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
Directed share program	At our request, the underwriters have reserved up to 5% of the shares to be offered in this offering for sale at the initial public offering price to certain of our directors, officers, existing stockholders, employees, business associates and related persons. Any directed shares not purchased will be offered by the underwriters to the general public on the same basis as all other shares offered
NASDAQ Capital Market symbol	KIN

The number of shares of our common stock to be outstanding after this offering is based on 3,012,675 shares of our common stock outstanding as of September 30, 2013 and 4,535,206 shares of our common stock that will be issued upon the automatic conversion of our outstanding shares of convertible preferred stock as of September 30, 2013, which will occur immediately upon the effectiveness of the registration statement of which this prospectus is a part. The number of shares of our common stock to be outstanding after this offering excludes:

1,165,423 shares of common stock issuable upon exercise of stock options outstanding as of September 30, 2013 at a weighted-average exercise price of $0.55 per share; and

2,827,102 shares of common stock reserved as of September 30, 2013 for future issuance under our 2012 equity incentive plan.

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

the filing of our amended and restated certificate of incorporation and the adoption of our amended and restated bylaws, which will be in effect as of the closing of this offering;

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the automatic conversion of all outstanding shares of our convertible preferred stock into shares of our common stock on a one-for-one basis immediately upon the effectiveness of the registration statement of which this prospectus is a part;

no exercise of the outstanding options, 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.

Our board of directors has indicated its intention to grant options to purchase an aggregate of 45,000 shares of our common stock to certain of our directors and employees concurrent with the pricing of this offering with an exercise price equal to the initial public offering price.

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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 ended on the dates indicated. We have derived the statement of operations and comprehensive loss data for the period from September 25, 2012 (inception) through December 31, 2012 from our audited financial statements included elsewhere in this prospectus. The statement of operations and comprehensive loss data for the nine months ended September 30, 2013 and for the cumulative period from September 25, 2012 (inception) through September 30, 2013 and the balance sheet data as of September 30, 2013 have been derived from our unaudited financial statements appearing elsewhere in this prospectus. This unaudited interim financial information has been prepared on the same basis as our audited financial statements and, in our opinion, reflects all adjustments, consisting only of normal and recurring adjustments, which we consider necessary for a fair presentation of our financial position as of September 30, 2013. 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 and the results for the nine months ended September 30, 2013 should not be considered indicative of results expected for the full fiscal year 2013. The results of operations for the period from September 25, 2012 (inception) through September 30, 2012 are not presented as they were insignificant.

	For The Period From September 25, 2012 (Inception) Through December 31, 2012	Nine Months Ended September 30, 2013 (unaudited)	Cumulative Period From September 25, 2012 (Inception) Through September 30, 2013 (unaudited)
Statement of Operations and Comprehensive Loss Data:			
Operating expenses:			
Research and development	$ 74,772	$ 1,394,547	$ 1,469,319
General and administrative	44,864	437,737	482,601
Total operating expenses	119,636	1,832,284	1,951,920
Loss from operations	(119,636)	(1,832,284)	(1,951,920)
Other income (expense):			
Interest income	25	2,662	2,687
Interest expense		(48)	(48)
Total other income, net	25	2,614	2,639
Net loss and comprehensive loss	$ (119,611)	$ (1,829,670)	$ (1,949,281)
Net loss per share attributable to common stockholders, basic and diluted[(1)]	$ (0.06)	$ (0.61)	

Weighted-average common shares outstanding, basic and diluted[(1)]	2,112,520	3,001,286
Pro forma net loss per share attributable to common stockholders, basic and diluted (unaudited)[(1)]	$ (0.04)	$ (0.39)
Weighted-average shares used in computing pro forma net loss per share attributable to common stockholders, basic and diluted (unaudited)[(1)]	2,718,082	4,713,320

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	As of September 30, 2013		
	Actual	Pro Forma[2]	Pro Forma as Adjusted[2][3]
Balance Sheet Data:			
Cash and cash equivalents	$ 10,991,682	$ 10,991,682	$ 47,372,270
Total assets	11,364,946	11,364,946	47,745,534
Total current liabilities	806,682	806,682	806,682
Convertible preferred stock	12,083,952		
Deficit accumulated during the development stage	(1,949,281)	(1,949,281)	(1,949,281)
Total stockholders equity	(1,525,688)	10,558,264	46,938,852
Total liabilities, convertible preferred stock and stockholders equity	11,364,946	11,364,946	47,745,534

(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 historical and pro forma 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) The pro forma balance sheet gives effect to the automatic conversion of all of our outstanding shares of convertible preferred stock as of September 30, 2013 into an aggregate of 4,535,206 shares of common stock immediately upon the effectiveness of the registration statement of which this prospectus is a part.

(3) The pro forma as adjusted balance sheet gives further effect to the issuance and sale of 5,750,000 shares of common stock in this offering at the assumed initial public offering price of $7.00 per share, the midpoint of the range set forth on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. Each $1.00 increase (decrease) in the assumed initial public offering price of $7.00 per share would increase (decrease) the pro forma as adjusted amount of each of cash and cash equivalents, total assets, total stockholders equity and total liabilities, convertible preferred stock and stockholders equity by approximately $5.3 million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, each increase (decrease) of 1.0 million shares in the number of shares offered by us at the assumed initial public offering price would increase (decrease) each of cash and cash equivalents, total assets, total stockholders equity and total liabilities, convertible preferred stock and stockholders equity by approximately $6.5 million. The pro forma information discussed above is illustrative only and will be adjusted based on the actual initial public offering price and other terms of our initial public offering determined at pricing.

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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 no meaningful 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 nine months ended September 30, 2013 was $1,829,670 and for the period from September 25, 2012 (inception) through December 31, 2012 was $119,611. As of September 30, 2013, we had a deficit accumulated during the development stage of $1,949,281. 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 candidate in a pivotal trial, also known as a field efficacy trial, is CereKin. We expect to initiate the pivotal trials for AtoKin and SentiKin by early 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

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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 the net proceeds from this offering, together with our existing cash, will be sufficient to fund our operating plan through the anticipated approval and launch of one or more of our lead product candidates. However, we may experience unexpected events that require us to seek additional funds sooner than planned through public or private equity or debt financings or other sources such as strategic collaborations. Additionally, we do not expect the proceeds from this offering 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. We have no current agreements or arrangements with respect to any such financings or collaborations, and any such financings or collaborations may result in 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. Even if we believe we have sufficient funds on hand for our current or planned future business and operations, we may seek from time to time to raise additional capital based upon favorable market conditions or strategic considerations such as potential acquisitions.

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

- the scope, progress, results and costs of researching and developing our current or future product candidates;
- the timing of, and the costs involved in, obtaining regulatory approvals for any of our current or future product candidates;
- the number and characteristics of the product candidates we pursue;
- the cost of manufacturing our current and future product candidates and any products we successfully commercialize;
- the cost of commercialization activities 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, in which we initiated the pivotal trial in August 2013 under a Protocol Concurrence with the FDA, and AtoKin and SentiKin, in which we expect to initiate pivotal trials by early 2014 under separate Protocol Concurrences. Accordingly, our near-term prospects, including our ability to generate material product revenue, obtain any new

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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;
- 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.

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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 Therapeutics, which recently completed its initial public offering. 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.

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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.

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 for our planned pivotal trials of AtoKin for the treatment of atopic dermatitis in dogs. A Protocol

Concurrence means that the FDA fundamentally agrees with the design, execution, and analyses proposed in a protocol, and is a commitment that the FDA 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. 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.

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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
- 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.

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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. Subject to possible appeal of the EMA s decision by affected parties, 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.

We currently have no product liability insurance, but intend to obtain it as we get closer to the commercialization of our product candidates. We cannot assure you that we will be able to do so on affordable terms, or at all. It also is possible that any product liability insurance we obtain 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.

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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, 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.

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.

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

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

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

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

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

We currently have only six full-time employees and three part-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.

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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. 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.

Risks Related to Intellectual Property

We currently do not own any issued patents, and there can be no assurance that our patent strategy will be effective to enhance marketing exclusivity.

We currently do not own any issued patents, and we cannot assure you that patents based on our patent applications will ever be issued. The strength of patents in the field of pet therapeutics involves complex legal and scientific questions and can be uncertain. Our patent applications may fail to result in issued patents in the United States or in other countries. Even if patents do successfully issue, third parties may challenge their validity, enforceability or scope, which may result in such patents being narrowed, invalidated or held unenforceable. Furthermore, even if they are unchallenged, our patents, if issued, may not adequately protect our intellectual property or prevent others from designing around their claims. If we cannot obtain ownership of issued patents covering our product candidates, our business and prospects would be adversely affected.

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-

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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 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.

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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 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.

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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.

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.

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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 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

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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.

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;

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recall, replacement, or discontinuance of certain products; and

additional record keeping.

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

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

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

Various states also independently regulate controlled substances. Though state controlled substances laws often mirror federal law, because the states are separate jurisdictions, they may separately schedule drugs as well. While some states automatically schedule a drug when the DEA does so, in other states there must be rulemaking or a legislative action. State scheduling may delay commercial sale of any controlled substance drug product for which we obtain federal regulatory approval and adverse scheduling could impair the commercial attractiveness of such product. We would also be required to obtain separate state registrations in order to be able to obtain, handle and distribute controlled substances for target animal studies, and failure to meet applicable regulatory requirements could lead to enforcement and sanctions from the states in addition to those from the DEA or otherwise arising under federal law.

For any of our product candidates classified as controlled substances, we and our suppliers, manufacturers, contractors, customers and distributors will be required to obtain and maintain applicable registrations from state, federal and foreign law enforcement and regulatory agencies and comply with state, federal and foreign laws and regulations regarding the manufacture, use, sale, importation, exportation and distribution of controlled substances. There is a risk that DEA regulations may limit the supply of the compounds used in pivotal trials of our product candidates, and, in the future, the ability to produce and distribute our products in the volume needed to meet commercial demand.

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

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Risks Related to this Offering and Our Common Stock

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

If a market for our common stock develops following this offering, the trading price of our common stock could 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;
- announcements by us or our competitors of new product candidates, significant contracts, commercial relationships, acquisitions or capital commitments;
- announcements relating to future development or license agreements including termination of such agreements;
- adverse developments with respect to our intellectual property rights or those of our principal collaborators;
- commencement of litigation involving us or our competitors;
- any major changes in our board of directors or management;

new legislation in the United States relating to the prescription, sale, distribution or pricing of pet therapeutics;

product liability claims, other litigation or public concern about the safety of 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.

No active market for our common stock exists or may develop, and you may not be able to resell your common stock at or above the initial public offering price.

Prior to this offering, there has been no public market for shares of our common stock. We and the representatives of the underwriters determined the initial public offering price of our common stock by arm s-length negotiations, and the initial public offering price does not necessarily reflect the price at which investors in

the market will be willing to buy and sell our shares following this offering. If no active trading market for our common stock develops or is sustained following this offering, you may be unable to sell your shares when you wish to sell them or at a price that you consider attractive or satisfactory. The lack of an active market may also adversely affect our ability to raise capital by selling securities in the future, or impair our ability to in-license or acquire other product candidates, businesses or technologies using our shares as consideration.

Purchasers in this offering will experience immediate and substantial dilution in the book value of their investment.

The initial public offering price of our common stock is substantially higher than the pro forma net tangible book value per share of our common stock before giving effect to this offering. Accordingly, if you purchase our common stock in this offering, you will incur immediate dilution of approximately $3.47 per share, representing the difference between the assumed initial public offering price of $7.00 per share and our pro forma as adjusted net tangible book value per share as of September 30, 2013. In addition, following this offering, and assuming the sale by us of 5,750,000 shares of our common stock in this offering at the assumed initial public offering price of $7.00 per share, purchasers in this offering will have contributed approximately 76.9% of the total gross consideration paid by stockholders to us to purchase shares of our common stock through September 30, 2013, but will own only approximately 43.2% of the shares of common stock outstanding immediately after this offering. Furthermore, if the underwriters exercise their option to purchase additional shares of our common stock or our outstanding stock options are exercised, you will experience further dilution. For a further description of the dilution that you will experience immediately after this offering, see the section in this prospectus entitled Dilution.

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.

We do not currently have research coverage by securities and industry analysts, and if no significant coverage is initiated or maintained following this offering, 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.

Upon the closing of this offering, based on shares outstanding as of November 11, 2013, our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates will beneficially own in the aggregate approximately 35.1% of our outstanding shares of common stock. 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 discussed in this prospectus, the trading price of our common stock could decline. Based upon the number of shares

outstanding as of September 30, 2013, upon the closing of this offering, we will have outstanding a total of 13,297,881 shares of common stock, assuming the conversion of all outstanding shares of our convertible preferred stock into 4,535,206 shares of our common stock. Of these shares, approximately 5,750,000 shares, plus any shares sold upon exercise of the underwriters option to purchase additional shares of our common stock, will be freely tradable in the public market immediately following this offering.

The lock-up agreements pertaining to this offering will expire 180 days from the date of this prospectus. After the lock-up agreements expire, up to an additional 7,547,881 shares of common stock will be eligible for sale in the public market, 3,720,506 of which 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 will have broad discretion to use the net proceeds of this offering, and may use them in ways that do not enhance our operating results or the market price of our common stock.

Our management will have broad discretion regarding the use of proceeds of this offering, and we could spend the net proceeds in ways our stockholders may not agree with or that do not yield a favorable return, if at all. We intend to use the net proceeds of this offering for the research and development of our product candidates, manufacturing, marketing, distribution and commercialization of any approved products and other general corporate and working capital purposes. We may also use a portion of the net proceeds to acquire additional product candidates or complementary assets or businesses; however, we currently have no agreements or commitments to complete any such transaction. Our use of these proceeds may differ substantially from our current plans. If we do not invest or apply the proceeds of this offering in ways that improve our operating results or our prospects, our stock price could decline.

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 this 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 will be 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 this offering and in preparation and audit of our financial statements included in this prospectus, 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 have identified relate 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 recent hiring of a Chief Financial Officer and additional employees and accounting consultants, these steps may not remedy the material

weaknesses. Our management and independent registered public accounting firm did not perform an evaluation

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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. Going forward, as a public company, absent an available exemption, our management will be 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 we and 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. We cannot be certain as to when we will be able to implement the requirements of Section 404 of the Sarbanes-Oxley Act. If we fail to implement the requirements of Section 404 in a timely manner, 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 that will be in effect upon the closing of this offering will contain provisions that could delay or prevent changes in control or changes in our management without the consent of our board of directors. We expect 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;
- 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.

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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 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 your ability to achieve a return on your investment will depend on appreciation in the market price of our common stock.

As described in the section entitled Dividend Policy in this prospectus, we currently intend to invest our future earnings, if any, to fund our growth and not to pay any cash dividends on our common stock. Since we do not intend to pay dividends, your ability to receive a return on your investment will depend on any future appreciation in the market price of our common stock. There is no assurance that our common stock will appreciate in price.

As a newly public company, we will incur significant additional costs, and our management will be required to devote substantial management time and attention to our public reporting obligations.

As a privately-held company, we have not been required to comply with public reporting, corporate governance and financial accounting practices and policies required of a publicly-traded company. As a publicly-traded company, we will incur significant additional legal, accounting and other expenses compared to historical levels. In addition, new and changing laws, regulations and standards relating to corporate governance and public disclosure, including the Dodd-Frank Wall Street Reform and Consumer Protection Act and the rules and regulations thereunder, as well as under the Sarbanes-Oxley Act, the JOBS Act and the rules and regulations of the U.S. Securities and Exchange Commission, or SEC, and The NASDAQ Stock Market, may result in an increase in our costs and the time that our board of directors and management must devote to our compliance with these rules and regulations. We expect these rules and regulations to substantially increase our legal and financial compliance costs and to divert management time and attention from our product development and other business activities.

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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.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements. All statements other than statements of historical facts contained in this prospectus, including statements regarding our future results of operations and financial position, business strategy, prospective products, product approvals, research and development costs, timing and likelihood of success, plans and objectives of management for future operations, and future results of current and anticipated products are forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements.

In some cases, you can identify forward-looking statements by terms such as may, will, should, expect, plan, a anticipate, could, intend, target, project, contemplate, believe, estimate, predict, potential or con of these terms or other similar expressions. The forward-looking statements in this prospectus are only predictions. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. These forward-looking statements speak only as of the date of this prospectus and are subject to a number of risks, uncertainties and assumptions described under the sections in this prospectus entitled Risk Factors and Management s Discussion and Analysis of Financial Condition and Results of Operations and elsewhere in this prospectus. Forward-looking statements are subject to inherent risks and uncertainties, some of which cannot be predicted or quantified and some of which are beyond our control. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. Moreover, we operate in a dynamic industry and economy. New risk factors and uncertainties may emerge from time to time, and it is not possible for management to predict all risk factors and uncertainties that we may face. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise.

INDUSTRY DATA

Unless otherwise indicated, information contained in this prospectus concerning our industry and the markets in which we operate, including our general expectations and market position, market opportunity and market share, is based on information from our own management estimates and research, as well as from industry and general publications and research, surveys and studies conducted by third parties. Management estimates are derived from publicly available information, our knowledge of our industry and assumptions based on such information and knowledge, which we believe to be reasonable. In addition, assumptions and estimates of our and our industry s future performance are necessarily subject to a high degree of uncertainty and risk due to a variety of factors, including those described in Risk Factors. These and other factors could cause our future performance to differ materially from our assumptions and estimates. See Special Note Regarding Forward-Looking Statements.

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USE OF PROCEEDS

We estimate that the net proceeds to us from the sale of the common stock that we are offering will be approximately $36.4 million (or $42.0 million if the underwriters exercise their option to purchase additional shares in full), assuming an initial public offering price of $7.00 per share, the midpoint of the range set forth on the cover page of this prospectus, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. Each $1.00 increase (decrease) in the assumed initial public offering price of $7.00 per share would increase (decrease) the net proceeds to us from this offering by approximately $5.3 million, assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. We may also increase or decrease the number of shares we are offering. Each increase (decrease) of 1.0 million in the number of shares offered by us at the assumed initial public offering price would increase (decrease) the net proceeds to us from this offering, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us, by approximately $6.5 million.

We intend to use the net proceeds of this offering for the research and development of our product candidates, to establish our commercial infrastructure within the United States and for other general corporate and working capital purposes. More specifically, we expect to use:

- approximately $3 million to $5 million each to complete the clinical development of:
  - CereKin for the treatment of osteoarthritis pain in dogs;
  - AtoKin for the treatment of atopic dermatitis in dogs; and
  - SentiKin for the treatment of post-operative pain in dogs; and
- the balance, together with our existing cash and cash equivalents, to establish our commercial infrastructure within the United States once one or more of our product candidates obtains marketing approval and for other general corporate and working capital purposes.

We may also use a portion of the net proceeds to acquire additional product candidates or complementary assets or businesses; however, we currently have no agreements or commitments to complete any such transaction.

Pending use of the proceeds as described above, we intend to invest the net proceeds of this offering in short-term, interest-bearing, investment-grade securities or certificates of deposit.

Our management will have broad discretion regarding the use of proceeds of this offering, and investors will be relying on the judgment of our management regarding the application of the proceeds from this offering. We may change the use of these proceeds from those described above as a result of various factors such as competitive developments, the results of our early clinical development and commercialization efforts, acquisition and investment opportunities and other factors.

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DIVIDEND POLICY

We have never declared or paid any cash dividends on our capital stock. We intend to retain future earnings, if any, to finance the operation and expansion of our business and do not anticipate paying any cash dividends in the foreseeable future. Any future determination related to dividend policy will be made at the discretion of our board of directors after considering our financial condition, results of operations, capital requirements, business prospects and other factors the board of directors deems relevant, and subject to the restrictions contained in our current or future financing instruments.

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CAPITALIZATION

The following table sets forth our cash and cash equivalents and capitalization as of September 30, 2013 as follows:

- on an actual basis;
- on a pro forma basis to reflect the automatic conversion of all shares of our convertible preferred stock outstanding as of September 30, 2013 into 4,535,206 shares of common stock immediately upon the effectiveness of the registration statement of which this prospectus is a part; and
- on a pro forma as adjusted basis to give further effect to our issuance and sale of 5,750,000 shares of common stock in this offering at an assumed initial public offering price of $7.00 per share, the midpoint of the range set forth on the cover page of this prospectus, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The pro forma and pro forma as adjusted information below is illustrative only, and our capitalization following the closing of this offering will be adjusted based on the actual initial public offering price and other terms of this offering determined at pricing. You should read this information in conjunction with our financial statements and the related notes appearing at the end of this prospectus and the section in this prospectus entitled Management s Discussion and Analysis of Financial Condition and Results of Operations and other financial information contained in this prospectus.

	As of September 30, 2013		
	Actual	Pro Forma	Pro Forma As Adjusted[1]
Cash and cash equivalents	$ 10,991,682	$ 10,991,682	$ 47,372,270
Convertible preferred stock (Series AA, A-1 and A-1A), par value $0.0001 per share; 5,015,000 shares authorized, 4,535,206 shares issued and outstanding, actual; no shares issued and outstanding, pro forma and pro forma as adjusted	$ 12,083,952	$	$
Common stock, par value $0.0001 per share; 50,000,000 shares authorized, 3,012,675 shares issued and outstanding, actual; 7,547,881 shares issued and outstanding, pro forma; 13,297,881 shares issued and outstanding, pro forma as adjusted	301	755	1,330
Preferred stock, par value $0.0001 per share; 9,985,000 shares authorized, no shares issued and outstanding, actual and pro forma; 10,000,000 shares authorized, no shares issued and outstanding pro forma as adjusted			
Additional paid-in capital	423,292	12,506,790	48,886,803
Deficit accumulated during the development stage	(1,949,281)	(1,949,281)	(1,949,281)

Total stockholders equity (deficit)	(1,525,688)	10,558,264	46,938,852
Total capitalization	$ 10,558,264	$ 10,558,264	$ 46,938,852

(1) Each $1.00 increase (decrease) in the assumed initial public offering price of $7.00 per share, the midpoint of the range set forth on the cover page of this prospectus, would increase (decrease) the pro forma as adjusted amount of each of cash and cash equivalents, total stockholders equity (deficit) and total capitalization by approximately $5.3 million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same. Similarly, each increase (decrease) of 1.0 million shares in the number of shares offered by us at the assumed initial public offering price per share would increase (decrease) the pro forma as adjusted amount of each of cash and cash equivalents, total stockholders equity (deficit) and total capitalization by approximately $6.5 million after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

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The table above does not reflect:

- 1,165,423 shares of common stock issuable upon exercise of stock options outstanding as of September 30, 2013 at a weighted-average exercise price of $0.55 per share; and

- 2,827,102 shares of common stock reserved as of September 30, 2013 for future issuance under our 2012 equity incentive plan.

Our board of directors has indicated its intention to grant options to purchase an aggregate of 45,000 shares of our common stock to certain of our directors and employees concurrent with the pricing of this offering with an exercise price equal to the initial public offering price.

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DILUTION

If you invest in our common stock in this offering, your ownership interest will be immediately diluted to the extent of the difference between the initial public offering price per share and the pro forma as adjusted net tangible book value per share of our common stock after this offering.

As of September 30, 2013, we had a historical net tangible book value (deficit) of $(1.5) million, or $(0.51) per share of common stock. Our historical net tangible book value (deficit) per share represents total tangible assets less total liabilities and convertible preferred stock divided by the number of shares of common stock outstanding at September 30, 2013.

Our pro forma net tangible book value as of September 30, 2013 was $10.6 million, or $1.40 per share of our common stock, after giving effect to the automatic conversion of all outstanding shares of our convertible preferred stock into 4,535,206 shares of common stock immediately upon the effectiveness of the registration statement of which this prospectus is a part.

After giving further effect to the sale of 5,750,000 shares of common stock in this offering at an assumed initial public offering price of $7.00 per share, the midpoint of the range set forth on the cover page of this prospectus, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value as of September 30, 2013 would have been approximately $46.9 million, or approximately $3.53 per share. This amount represents an immediate increase in pro forma net tangible book value of $2.13 per share to our existing stockholders and an immediate dilution in pro forma net tangible book value of approximately $3.47 per share to new investors purchasing shares of common stock in this offering.

Dilution per share to new investors is determined by subtracting pro forma as adjusted net tangible book value per share after this offering from the initial public offering price per share paid by new investors. The following table illustrates this dilution:

Assumed initial public offering price per share		$ 7.00
Historical net tangible book value (deficit) per share as of September 30, 2013	$ (0.51)	
Increase per share attributable to the conversion of our convertible preferred stock	1.91	
Pro forma net tangible book value per share as of September 30, 2013	1.40	
Increase in pro forma net tangible book value per share attributable to this offering	2.13	
Pro forma as adjusted net tangible book value per share after this offering		3.53
Dilution per share to new investors		$ 3.47

Each $1.00 increase (decrease) in the assumed initial public offering price of $7.00 per share, the midpoint of the range set forth on the cover page of this prospectus, would increase (decrease) the pro forma as adjusted net tangible book value per share after this offering by approximately $0.40, and dilution in pro forma net tangible book value per share to new investors by approximately $0.60, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the estimated underwriting discounts and commissions and the estimated offering expenses payable by us. Each increase of 1.0 million shares in the number of

shares offered by us would increase our pro forma as adjusted net tangible book value per share after this offering by approximately $0.21 per share and decrease the dilution to investors participating in this offering by approximately $0.21 per share, assuming that the assumed initial public offering price remains the same, and after deducting the estimated underwriting discounts and commissions and the estimated offering expenses payable by us. Each decrease of 1.0 million shares in the number of shares offered by us would decrease our pro forma as adjusted net tangible book value per share after this offering by

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approximately $0.24 per share and increase the dilution to investors participating in this offering by approximately $0.24 per share, assuming that the assumed initial public offering price remains the same, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

If the underwriters exercise their option to purchase additional shares of our common stock in full in this offering, the pro forma as adjusted net tangible book value after the offering would be $3.71 per share, the increase in pro forma as adjusted net tangible book value per share to existing stockholders would be $2.31 per share and the dilution per share to new investors would be $3.29 per share, in each case assuming an initial public offering price of $7.00 per share.

The following table summarizes on the pro forma as adjusted basis described above, as of September 30, 2013, the differences between the number of shares purchased from us, the total consideration paid to us in cash and the average price per share that existing stockholders and new investors in this offering paid. The calculation below is based on the assumed initial public offering price of $7.00 per share, the midpoint of the range set forth on the cover page of this prospectus, before deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

	Shares Purchased		Total Consideration		Average Price Per Share
	Number	Percent	Amount	Percent	
Existing stockholders	7,547,881	56.8%	$ 12,099,794	23.1%	$ 1.60
New investors	5,750,000	43.2%	$ 40,250,000	76.9%	$ 7.00
Total	13,297,881	100%	$ 52,349,794	100%	$ 3.94

The foregoing tables and calculations exclude:

- 1,165,423 shares of common stock issuable upon exercise of stock options outstanding as of September 30, 2013 at a weighted-average exercise price of $0.55 per share; and
- 2,827,102 shares of common stock reserved for issuance as of September 30, 2013 under our 2012 equity incentive plan.

Our board of directors has indicated its intention to grant options to purchase an aggregate of 45,000 shares of our common stock to certain of our directors and employees concurrent with the pricing of this offering with an exercise price equal to the initial public offering price.

To the extent any of these outstanding options is exercised, there will be further dilution to new investors. If all of such outstanding options had been exercised as of September 30, 2013, the pro forma as adjusted net tangible book value per share after this offering would be $3.29, and total dilution per share to new investors would be $3.71.

If the underwriters exercise their option to purchase additional shares of our common stock in full:

the percentage of shares of common stock held by existing stockholders will decrease to approximately 53.3% of the total number of shares of our common stock outstanding after this offering; and

the number of shares held by new investors will increase to 6,612,500, or approximately 46.7% of the total number of shares of our common stock outstanding after this offering.

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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 prospectus and in the section of this prospectus 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 and the balance sheet data as of December 31, 2012 from our audited financial statements appearing elsewhere in this prospectus. The statement of operations and comprehensive loss data for the nine months ended September 30, 2013 and for the cumulative period from September 25, 2012 (inception) through September 30, 2013 and the balance sheet data as of September 30, 2013 have been derived from our unaudited financial statements appearing elsewhere in this prospectus. The unaudited interim financial information has been prepared on the same basis as our audited financial statements and, in our opinion, reflects all adjustments, consisting only of normal and recurring adjustments, that we consider necessary for a fair presentation of our financial position as of September 30, 2013 and operating results for the period ended September 30, 2013. The historical results are not necessarily indicative of the results to be expected for any future periods and the results for the nine months ended September 30, 2013 should not be considered indicative of results expected for the full fiscal year 2013. The results of operations for the period from September 25, 2012 (inception) through September 30, 2012 are not presented as they were insignificant.

	For The Period From September 25, 2012 (Inception) Through December 31, 2012	Nine Months Ended September 30, 2013 (unaudited)	Cumulative Period From September 25, 2012 (Inception) Through September 30, 2013 (unaudited)
Statement of Operations and Comprehensive Loss Data:			
Operating expenses:			
Research and development	$ 74,772	$ 1,394,547	$ 1,469,319
General and administrative	44,864	437,737	482,601
Total operating expenses	119,636	1,832,284	1,951,920
Loss from operations	(119,636)	(1,832,284)	(1,951,920)
Other income (expense):			
Interest income	25	2,662	2,687
Interest expense		(48)	(48)
Total other income, net	25	2,614	2,639
Net loss and comprehensive loss	$ (119,611)	$ (1,829,670)	$ (1,949,281)

Net loss per share attributable to common stockholders, basic and diluted[1]	$ (0.06)	$ (0.61)
Weighted-average common shares outstanding, basic and diluted[1]	2,112,520	3,001,286
Pro forma net loss per share attributable to common stockholders, basic and diluted (unaudited)[1]	$ (0.04)	$ (0.39)
Weighted-average shares used in computing pro forma net loss per share attributable to common stockholders, basic and diluted (unaudited)[1]	2,718,082	4,713,320

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	As of December 31, 2012	As of September 30, 2013 (unaudited)
Balance Sheet Data:		
Cash and cash equivalents	$ 937,516	$ 10,991,682
Total assets	938,020	11,364,946
Total liabilities	70,281	806,682
Convertible preferred stock	987,050	12,083,952
Deficit accumulated during the development stage	(119,611)	(1,949,281)
Total liabilities, convertible preferred stock and stockholders equity (deficit)	938,020	11,364,946

(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 historical and pro forma 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.

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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 prospectus. Some of the information contained in this discussion and analysis or set forth elsewhere in this prospectus, 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 prospectus 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 expect to initiate the pivotal trials for AtoKin and SentiKin by early 2014. 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, 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.

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 $1,829,670 for the nine months ended September 30, 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 September 30, 2013, we had a deficit accumulated during the development stage of $1,949,281 and cash and cash equivalents of $10,991,682.

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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

Research and development expense is expensed as incurred and consists primarily of wages, stock-based compensation and employee benefits for all employees engaged in scientific research and development functions, and other operational costs related to our research and development activities, including costs of studies, contract manufacturers and API service providers, regulatory, professional and consulting fees, and travel costs.

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.

Income Taxes

As of December 31, 2012, we had net operating loss carryforwards for federal and state income tax purposes of $89,511 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, 2012, a valuation allowance was necessary to fully offset our deferred tax assets.

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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 prospectus, 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.

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

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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:

	Period from September 25, 2012 (inception) through December 31, 2012	Nine Months Ended September 30, 2013
Risk-free interest rate	0.62% - 0.72%	0.62% - 2.75%
Expected term (in years)	10.0	5.0-10.0
Expected volatility	(2,474)	(6)

Total revenues	89,572	77,795	11,777	15
Costs and expenses and other (income):				
Cost of product revenues	26,766	19,159	7,607	40
Cost of laboratory services	26,295	22,209	4,086	18
Research and development	9,220	8,637	583	7
Selling, general, and administrative	41,314	33,272	8,042	24
Provision for uncollectible accounts receivable	5,189	3,716	1,473	40
Legal expenses	4,195	5,588	(1,393)	(25)
Interest income	(581)	(3,696)	3,115	(84)
Other loss (income)	(74)	(171)	97	(57)
Foreign currency loss (gain)	725	(27)	752	
Total costs and expenses net	113,049	88,687	24,362	27
Loss before income taxes	(23,477)	(10,892)	12,585	116
(Provision) benefit for income taxes	(87)	239	326	
Net loss	$ (23,564)	$ (10,653)	$ 12,911	121

Fiscal 2009 compared to Fiscal 2008

Consolidated Results:

The 2009 period and the 2008 period refer to the fiscal years ended July 31, 2009 and 2008, respectively. The 2009 period includes the full year results of Biomol which was acquired on May 8, 2008 and the results of Assay Designs from March 12, 2009, the date of acquisition, to July 31, 2009.

Product revenues during the 2009 period were $40.6 million compared to $28.1 million in the 2008 period, an increase of $12.5 million or 45%. Acquisition growth represented $12.1 million or a 43% increase over product revenues in the 2008 period, primarily from Biomol and Assay Designs, $1.4 million or 5% was from organic growth, offset by $1.0 million or 4% negative effect from foreign currency.

Royalty and license fee income during the 2009 period was $9.4 million compared to $7.6 million in the 2008 period, an increase of $1.7 million or 23%. Royalties are primarily earned from net sales of Qiagen products subject to a license and from a License Agreement with Abbott. During the 2009 period, the Company recognized royalties of approximately $6.7 million from

Qiagen, an increase of approximately $1.2 million over the 2008 period, and royalties and license fees under the Abbott License Agreement of approximately $2.7 million, an increase of $0.5 million over the 2008 period. There are no direct expenses relating to royalty and license fee income.

Clinical laboratory revenues during the 2009 period were $39.6 million compared to $42.1 million in the 2008 period, a decrease of $2.5 million or 6%. Revenues were adversely affected by contractual adjustments of $2.3 million. These immaterial adjustments related to computational errors that affected the calculated expected reimbursement rate in fiscal 2008, 2007 and 2006 and for periods prior to August 1, 2005 for the majority of payers and credits issued which were not accrued for timely. The reduced service volume was partially impacted by reduced billings on our legacy billing system in fiscal 2009, including the investigation of and rebilling of denials during the period, as a result of the realignment of certain billing personnel to implement our new comprehensive billing and accounts receivable system. This new system was effective for all laboratory services performed after August 1, 2008. We believe that the new billing and accounts receivable system enhances our billing and collection process.

The cost of product revenues during the 2009 period was $26.8 million compared to $19.2 million in the 2008 period, an increase of $7.6 million or 40%. The increase is principally due to the inclusion of Biomol and Assay Designs cost of product revenues of approximately $7.4 million in the 2009 period, which includes the impact of an inventory fair value adjustment of $2.2 million related to sales of inventory acquired from Biomol and Assay Designs.

The cost of clinical laboratory services during the 2009 period was $26.3 million as compared to $22.2 million in the prior period, an increase of $4.1 million or 18%. The Company incurred increased costs primarily relating to reagent and supplies costs of $1.1 million, laboratory personnel costs of $1.8 million, and outside testing labs of $0.7 million, and other related lab costs of $0.5 million. Laboratory personnel costs increases resulted from additional headcounts in phlebotomists to expand patient collection sites and other personnel to manage expanded internal operations.

Research and development expenses were approximately $9.2 million during the 2009 period compared to $8.6 million in the 2008 period an increase of $0.6 million or 7%. Research and development costs increased $2.4 million at the Life Sciences segment, principally related to the inclusion of Biomol and Assay Designs, offset by a decrease at the Therapeutic segment of $1.8 million due to a decrease in clinical trial activities.

Selling, general and administrative expenses were approximately $41.3 million during the 2009 period as compared to $33.3 million in the 2008 period, an increase of $8.0 million or 24%. Life Sciences selling, general and administrative costs increased by $5.2 million over the 2008 period, which principally related to the inclusion of Biomol and Assays Designs. The increase in the Company s other segments selling, general and administrative expenses of approximately $2.9 million was primarily due to payroll and related personnel costs approximating $0.5 million, consulting and professional fees of $1.2 million, other overhead costs of $1.0 million and information technology costs of $0.3 million.

The provision for uncollectible accounts receivable, primarily relating to the Clinical Labs segment, was $5.2 million for the 2009 period as compared to $3.7 million in the 2008 period. The increase in the 2009 period of $1.5 million or 40% was attributed to 1) increased provisions for the Clinical Labs legacy billing system, which was replaced in August 2008, due to reduced collection efforts relating to the legacy billing system, 2) the correction of the immaterial $0.6 million error in the allowance for doubtful accounts determined relating to 2008, and 3) increased provisions required based on changes in payer mix. Outstanding receivables, which are fully reserved, will remain on the legacy system until the earlier of: all invoices are collected, all collection efforts are exhausted, or all invoices are written off in accordance with our critical accounting policy.

Legal expense was $4.2 million during the 2009 period compared to $5.6 million in the 2008 period, a decrease of $1.4 million or 25%, primarily due to a decrease in patent litigation activity in the current period of $2.6 million offset by increases in the Life Science segment of $0.2 million for realignment of existing and establishment of new global operating units and increases in other legal costs of $1.0 million.

Interest income decreased by $3.1 million or 84% to $0.6 million during the 2009 period compared to $3.7 million during the 2008 period. Interest income decreased during the 2009 period due to the decline in interest rates in response to monetary policy actions taken by the U.S. Federal Reserve and lower invested balances. The Company earns interest by investing primarily in short term and liquid U.S. government instruments and money market accounts.

Other income was $0.1 million during the 2009 period versus $0.2 million in the year ago period.

The loss on foreign currency was $0.7 million during the 2009 period. During the 2009 period, the Company s Life Sciences segment incurred a non-cash foreign currency loss of approximately $0.7 million on an intercompany term loan denominated in pounds sterling due to the strengthening of the US dollar as at July 31, 2009 versus July 31, 2008.

The Company s effective income tax rate (provision) benefit for the 2009 period was (0.4%), compared to 2.2% during the 2008 period. The tax provision for both periods was based on state and local taxes and book to tax differences for inventory acquired from Biomol and differed from the expected net operating loss carry forward benefit at the U.S. federal statutory rate of 34% primarily due to the inability to recognize such benefit. The carry forward benefit cannot be recognized because of uncertainties relating to future taxable income, in terms of both its timing and its sufficiency.

Segment Results

The Life Sciences segment s income before taxes was approximately $1.7 million for the 2009 period and $3.4 million for the 2008 period. Revenues from product shipments increased by $12.5 million primarily due to the inclusion of products sales of $12.1 million from Biomol and Assay Designs in the 2009 period. Royalty and license fee income increased $1.7 million primarily from the existing Qiagen and Abbott licensing and royalty agreements.

The segment s gross margin of $23.2 million increased $6.6 over the prior year period, after being negatively impacted by a $2.2 million fair value adjustment attributed to the sale of inventory acquired from Biomol and Assay Designs. Segment operating expenses, including selling, general and administrative and legal of $14.9 million and research and development of $5.9 million, increased by approximately $7.5 million during the 2009 period primarily due to the inclusion of Biomol and Assay Designs expenses of $7.5 million. The 2009 expenses include amortization of intangibles of $1.2 million, $0.4 million in legal costs to establish new and realign existing global entities, and marketing costs of $0.2 million relating to the integration of our brands. The segment experienced a non-cash foreign currency loss of $0.7 million resulting from an intercompany loan denominated in pounds sterling. In aggregate, the inventory fair value adjustment, amortization of intangibles, the one-time legal and marketing costs and the non-cash foreign currency loss, negatively impacted the segment operating results by $4.7 million.

The Clinical Labs segment s loss before taxes was $7.3 million for the 2009 period as compared to income before taxes of $2.0 million in the 2008 period. The 2009 results were negatively impacted by lower service volume of $2.5 million partially due to a charge of $2.3 million relating to contractual adjustments discussed above, The decrease in the 2009 period s gross margin of $6.6 million was due to the decreased service revenues, change in fiscal 2009 payer mix and increased cost of laboratory services. Selling, general and administrative increased approximately $1.1 million primarily due to increases in office support salaries and operational costs to maintain the facility. The provision for uncollectible accounts increased by $1.5 million primarily due to an increased provision related to the legacy billing system and the correction of the previously noted immaterial error $0.6 million in the allowance for doubtful accounts related to fiscal 2008. The segment earned interest in the 2009 period of $0.1 million and $0.2 million in the 2008 period.

The Therapeutics segment s loss before income taxes was approximately $3.4 million for the 2009 period as compared to a loss of $5.1 million for the 2008 period. The decrease in the loss of $1.7 million was primarily due to a decrease in clinical trial activities of $1.8 million offset by a non-recurring government grant of $0.1 million which was recognized in the 2008 period.

The Other segment s loss before taxes for the 2009 period was approximately $14.6 million compared to $11.3 million in the 2008 period, an increase of $3.3 million. Selling, general, and administrative and legal increased by $0.3 million as the result of a $1.6 million decrease in legal expenses due to decreased patent litigation activity, partially offset by increases in professional and consulting fees of $1.2 million, and payroll and related costs of $0.7 million. The decrease in interest income of $2.9 million due to the decline in interest rates in response to monetary policy actions taken by the U.S. Federal Reserve and lower levels of cash available for investment.

Results of Operations

Comparative Financial Data for the Fiscal Years Ended July 31,
(in 000 s)

	2008	2007	Increase (Decrease)	% Change
Revenues:				
Product revenues	$ 28,087	$ 6,658	$ 21,429	322
Royalty and license fee income	7,630	5,820	1,810	31
Clinical laboratory services	42,078	40,430	1,648	4
Total revenues	77,795	52,908	24,887	47
Costs and expenses and other (income):				
Cost of product revenues	19,159	5,034	14,125	281
Cost of laboratory services	22,209	19,151	3,058	16
Research and development	8,637	9,393	(756)	(8)
Selling, general, and administrative	33,272	25,348	7,924	31
Provision for uncollectible accounts receivable	3,716	4,653	(937)	(20)
Legal expenses	5,588	10,295	(4,707)	(46)
Interest income	(3,696)	(5,092)	1,396	(27)
Other loss (income)	(171)	(2,699)	2,528	(94)
Foreign currency (gain)	(27)		(27)	
Total costs and expenses net	88,687	66,083	22,604	34
Loss before income taxes	(10,892)	(13,175)	2,283	17
Benefit (provision) for income taxes	239	(85)	324	
Net loss	$ (10,653)	$ (13,260)	$ 2,607	20

Fiscal 2008 Compared to Fiscal 2007

Consolidated Results

The 2008 period and the 2007 period refer to the fiscal years ended July 31, 2008 and 2007, respectively. The 2008 period includes the full year results of Axxora which was acquired on May 31, 2007 and the results of Biomol from May 8, 2008, the date of acquisition, to July 31, 2008.

Product revenues during the 2008 period were $28.1 million compared to $6.7 million in the year ago period, an increase of $21.4 million or 322%. The 2008 period increase is primarily due to the contribution of product revenues from the Axxora and Biomol acquisitions.

Royalty and license fee income during the 2008 period was $7.6 million compared to $5.8 million in the 2007 period, an increase of $1.8 million or 31%. Royalties are earned from the reported net sales of Qiagen products subject to a license and from a License Agreement with Abbott which was entered into in the third quarter of fiscal 2007. During the 2008 period, the Company recognized royalties of approximately $5.5 million from Qiagen, an increase of approximately $0.7 million over the prior year ago period, and royalties and license fees under the Abbott License Agreement of approximately $2.1 million, an increase of approximately $1.1 million over the year ago period. There are no expenses relating to royalty and license fee income.

Clinical laboratory revenues during the 2008 period were $42.1 million compared to $40.4 million in the 2007 period, an increase of $1.7 million or 4%. The Company experienced an increase in service revenues during the 2008 period primarily due to an expansion of an insurance provider agreement with United Healthcare which occurred in January 2007, which was partially offset by an increase in the contractual adjustment, which reduced gross billings by 81.8% as compared to 79.0% in the 2007 period. The increase in the contractual adjustment is due to continued competitive pricing throughout the industry which has

negatively impacted reimbursement rates for tests and an increase in revenue mix from lower paying insurance providers.

The cost of product revenues during the 2008 period was $19.1 million compared to $5.0 million in the 2007 period, an increase of $14.1 million. The increase is primarily due to the full year impact of Axxora s and the partial period of Biomol s cost of product revenues of approximately $13.0 million and $1.6 million, respectively for the 2008 period, which includes the impact of an inventory fair value adjustment of $2.0 million related to sales of inventory acquired from Axxora and Biomol offset by decreases at Enzo Life Sciences - New York.

The cost of clinical laboratory services during the 2008 period was $22.2 million as compared to $19.2 million in the prior period, an increase of $3.0 million or 16%. Due to the increased volume of patients serviced and tests performed, the Company incurred increased costs primarily relating to reagent costs of $1.4 million, laboratory personnel costs of $1.1 million, outside reference lab costs of $0.1 million, and other related laboratory costs of $0.2 million.

Research and development expenses were approximately $8.6 million during the 2008 period, compared to $9.4 million in the 2007 period, a decrease of $0.8 million or 8%. The decrease was due to a decrease of $0.9 million relating to the timing of clinical trial and related activities at the Therapeutics segment, a decrease of $0.3 million in research supplies and related costs at Enzo Life Sciences - New York, offset by the increase in research and development incurred by Axxora and Biomol of $0.4 million.

Selling, general and administrative expenses were approximately $33.3 million during the 2008 period as compared to $25.3 million in the 2007 period, an increase of $8.0 million or 31%. Included in the 2008 period is approximately $6.8 million of selling, general and administrative expenses increases related to the full year of Axxora and Biomol expenses from the date of acquisition. The increase in the other Companies operations of approximately $1.5 million was primarily due to payroll and payroll related costs of $1.8 million and professional fees of $0.3 million offset by a decrease in information technology costs of $0.3 million and a decrease in insurance costs of $0.3 million.

The provision for uncollectible accounts receivable, primarily relating to the clinical laboratory segment was $3.7 million for the 2008 period as compared to $4.7 million in the 2007 period, the decrease of $0.9 million or 20% was due to improved billing and collections procedures.

Legal expense was $5.6 million during the 2008 period compared to $10.3 million in the 2007 period, a decrease of $4.7 million or 46%, due to a decrease in patent litigation activity in the current period.

Interest income was $3.7 million during the 2008 period as compared to $5.1 million during the 2007 period. The Company earns interest by investing primarily in short term and liquid investments, including money market accounts, commercial paper and US government instruments. The Company had higher average invested balances during the 2007 period due to the net proceeds from registered direct offerings of common stock in December 2006 and February 2007 offset by uses of cash for operations and the acquisition of Axxora in May 2007. The 2008 period s invested cash was reduced by the use of $15.0 million of cash to purchase Biomol in May 2008 and by the use of cash to fund operations. Further, interest income decreased during the 2008 period because the rates declined in response to monetary policy actions taken by the U.S. Federal Reserve.

The Company earned other income of $0.2 million during the 2008 period versus $2.7 million in the 2007 period. During the 2007 period, the Company recognized a $2.0 million gain on a patent litigation settlement and a $0.7 million payment from a former distributor under an expired distribution agreement which is presently subject to a lawsuit in which the Company is plaintiff.

The Company s effective tax rate benefit (provision) for the 2008 period was 2.2%, compared to (1.0%) during the 2007 period. The tax benefit for the 2008 period was based on state and local taxes, book to tax differences for inventory acquired from Axxora, and taxes and interest incurred from a local tax audit and differed from the expected net operating loss carry forward benefit at the U.S. federal statutory rate of 34% primarily due to the inability to recognize such benefit. The carry forward benefit cannot be recognized because of uncertainties relating to future taxable income, in terms of both its timing and its sufficiency.

The tax provision for the 2007 period was based on state and local taxes, and differed from the expected net operating loss benefit at the U.S. federal statutory rate of 34% primarily due the inability to recognize such benefit. The carry forward benefit cannot be recognized because of uncertainties relating to future taxable income, in terms of both its timing and its sufficiency, which would enable the Company to realize the federal carry forward benefit.

Segment Results

The Life Sciences segment s income before taxes was approximately $3.4 million for the 2008 period as compared to $4.0 million in the 2007 period. The decrease is partially due to the recognition in the 2007 period of the Company s $2.0 million patent litigation settlement with Sigma Aldrich and a $0.7 million payment from a former distributor under an expired distribution agreement which is presently subject to a lawsuit in which the Company is plaintiff. Product revenues increased by $21.4 million in the 2008 period due to the contribution of products revenues from Axxora for the full year in 2008 as compared to the two months in 2007 and the Biomol acquisition from the date of acquisition. Royalty and license fee income increased $1.8 million from the existing Qiagen agreement and the Abbott License Agreement entered into in the third quarter of fiscal 2007. The segment s gross margin of $16.6 million was negatively impacted by $2.0 million representing the fair value adjustment attributed to the sale of inventory acquired from Axxora and Biomol. The remaining fair value adjustment attributed to inventory acquired from Biomol of $1.4 million will negatively impact gross margins through May 2009. Segment operating expenses, including selling, general and administrative and research and development, increased by approximately $7.1 million during the 2008 period primarily due to the inclusion of Axxora s and Biomol s expenses.

The Clinical Laboratory segment s income before taxes was $2.0 million for the 2008 period as compared to $3.3 million in the 2007 period. The 2008 period was positively impacted by an increase in laboratory service revenues of $1.6 million or 4%, due to the expansion of an insurance provider agreement effective January 2007. The gross profit was negatively impacted by an increase in the cost of laboratory services of $3.0 million as compared to the 2007 period. In the 2008 period the selling, general and administrative costs increased by approximately $0.9 million due primarily due to increases in sales commissions of $0.3 million and payroll and payroll related costs of $0.6 million, attributable to the increase in service revenues. The provision for uncollectible accounts receivables decreased by $1.0 million due to improved billing and collection procedures. The segment also earned interest in the 2008 period of $0.2 million on its cash generated by operations.

The Therapeutics segment s loss before income taxes was approximately $5.0 million for the 2008 period as compared to a loss of $6.0 million for the 2007 period. The decrease in the loss of $1.0 million was primarily due to decreases in clinical trial activities, consulting, payroll and payroll related costs of $0.9 million, and the recognition of $0.1 million from a government grant, included in other income in the consolidated financial statements.

The Other segment s loss before taxes for the 2008 period was approximately $11.3 million, a decrease of $3.1 million as compared to $14.4 million in the 2007 period. The Other segment s 2008 period loss reflects a decrease in legal expenses of $4.9 million due to a decrease in patent litigation activity in the current period compared to the 2007 period, partially offset by an increase in general and administrative expenses of $0.2 million, and a decrease in interest income of $1.5 million due to lower levels of cash available for investment and declining interest rates.

Liquidity and Capital Resources

At July 31, 2009, our cash and cash equivalents were $6.9 million and short-term investments of $43.3 million, or $50.2 million in aggregate as compared to $78.3 at July 31, 2008. Short-term investments are in U.S. Government instruments. We had working capital of $60.5 million at July 31, 2009 compared to $92.4 million at July 31, 2008. In 2009, the decrease of $ 31.9 million was primarily due to the use of cash for acquisitions of approximately $14.5 million, cash used in operations of $11.5 million and $2.7 million used for capital expenditures.

Net cash used in operating activities for the year ended July 31, 2009 was approximately $11.5 million as compared to net cash used in operating activities of $8.6 million for the year ended July 31, 2008. The increase in net cash used in operating activities in fiscal 2009 of $2.9 million was due to the net change in operating assets and liabilities, primarily due to changes in accounts receivable, accounts payable, accrued liabilities and deferred revenue, as compared to the prior year and the impact of non cash items offset by the $12.9 million increase in the net loss.

In fiscal 2009, net cash used in investing activities was approximately $60.2 million as compared to the fiscal 2008 net cash used of $18.8 million. Fiscal 2009 uses were primarily due to: net purchases of short-term investment of $43.3 million, acquisitions of $14.5 million, of which $13.0 million related to the acquisition of Assay Designs, Inc., inclusive of acquisition costs, and an additional purchase price of $1.5 million relating to the Biomol earn-out and capital expenditures of approximately $2.7 million.

In fiscal 2009, net cash provided by financing activities was approximately $0.4 million as compared to $0.5 million in fiscal 2008, arising in both years from the proceeds from the exercise of stock options.

We believe that our current cash and cash equivalents are sufficient for our foreseeable liquidity and capital resource needs over the next 12 months, although there can be no assurance that future events will not alter such view.

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The Company investment policy limits investments to short-term, low risk and highly liquid instruments, including money market accounts and funds, commercial paper and US government instruments.

Effect of New Accounting Pronouncements

In June 2009, the FASB issued SFAS No. 168, The FASB Accounting Standards Codification and the Hierarchy of Generally Accepted Accounting Principles a replacement of FASB Statement No. 162. SFAS No. 168 establishes the FASB Accounting Standards Codification as the source of authoritative accounting principles and the framework for selecting the principles used in the preparation of financial statements of nongovernmental entities that are presented in conformity with generally accepted accounting principles in the United States. SFAS No. 162 is effective for the Company s interim reporting period ending on October 31, 2009. The Company does not anticipate the adoption of SFAS No. 168 will have a material impact on its financial position, results of operations or cash flows.

In May 2009, the FASB issued SFAS No. 165, Subsequent Events (SFAS 165). SFAS 165 is intended to establish general standards of accounting for and disclosure of events that occur after the balance sheet date but before financial statements are issued or are available to be issued. In particular, SFAS 165 sets forth the period after the balance sheet date during which management of a reporting entity should evaluate events or transactions that may occur for potential recognition or disclosure in the financial statements; the circumstances under which an entity should recognize events or transactions occurring after the balance sheet date in its financial statements; and the disclosures that an entity should make about events or transactions that occurred after the balance sheet date. SFAS 165 is effective for interim or annual financial periods ending after June 15, 2009. During the three months ended July 31, 2009, the Company adopted SFAS SFAS 165. In response to SFAS 165, management has evaluated subsequent events through October 14, 2009, which is the date that the Company s financial statements were filed.

In April 2009, the FASB issued FSP SFAS No. 141(R)-1 Accounting for Assets Acquired and Liabilities Assumed in a Business Combination That Arise from Contingencies, FSP SFAS No. 141(R)-1 will amend the provisions related to the initial recognition and measurement, subsequent measurement and disclosure of assets and liabilities arising from contingencies in a business combination under SFAS No. 141(R), Business Combinations. The FSP will carry forward the requirements in SFAS No. 141, Business Combinations, for acquired contingencies, thereby requiring that such contingencies be recognized at fair value on the acquisition date if fair value can be reasonably estimated during the allocation period. Otherwise, entities would typically account for the acquired contingencies in accordance with SFAS No. 5, Accounting for Contingencies. The FSP will have the same effective date as SFAS No. 141(R), and will therefore be effective for the Company s business combinations for which the acquisition date is on or after August 1, 2009. The Company is currently evaluating the impact of the implementation of FSP SFAS No. 141(R)-1 on its consolidated financial position, results of operations and cash flows.

In April 2009, the FASB issued FSP SFAS No. 107-1 and APB 28-1, Interim Disclosures about Fair Value of Financial Instruments . FSP SFAS No. 107-1 and APB 28-1 enhances consistency in financial reporting by increasing the frequency of fair value disclosures. The FSP relates to fair value disclosures for any financial instruments that are not currently reflected on a company s balance sheet at fair value. Prior to the effective date of this FSP, fair values for these assets and liabilities have only been disclosed once a year. The FSP will now require these disclosures on a quarterly basis, providing qualitative and quantitative information about fair value estimates for all those financial instruments not measured on the balance sheet at fair value. The disclosure requirement under this FSP is effective for the Company s interim reporting period ending on October 31, 2009.

In April 2008, the FASB issued FSP FAS 142-3, Determination of the Useful Life of Intangible Assets (FSP FAS 142-3). FSP FAS 142-3 amends the factors that should be considered in developing renewal or extension assumptions used to determine the useful life of a recognized intangible asset under FASB Statement No.142, Goodwill and Other Intangible Assets. FSP FAS 142-3 also requires expanded disclosure related to the determination of intangible asset useful lives. FSP FAS 142-3 is effective for financial statements issued for fiscal years beginning after December 15, 2008, and interim periods within those fiscal years. The Company is currently evaluating the impact that the adoption of FSP FAS 142-3 will have on its consolidated results of operation, cash flows or financial condition.

In December 2007, the FASB issued Statement No. 141 (revised 2007), Business Combinations (SFAS No. 141R). SFAS No. 141R establishes principles and requirements for how the acquirer in a business combination recognizes and measures in its financial statements the identifiable assets acquired, the liabilities assumed, any controlling interest in the business and the goodwill acquired.

SFAS No. 141R further requires that: 1) contingent consideration arrangements will be fair valued at the acquisition date and included on that basis in the purchase price consideration, 2) acquisition-related costs will be expensed as incurred rather than capitalized as part of the purchase price, 3) reversal of valuation allowances created in purchase accounting will be recorded through the income tax provision, 4) in order to accrue for a restructuring plan in purchase accounting, the requirements of SFAS No. 146, Accounting for Costs Associated with Exit or Disposal Activities , would have to be met at the acquisition date. SFAS No. 141R also establishes disclosure requirements that will require disclosure of the nature and financial effects of the business combination. SFAS No. 141R will impact business combinations for the Company that may be completed on or after August 1, 2009. The Company cannot anticipate whether the adoption of SFAS No. 141R will have a material impact on its results of operations and financial condition as the impact is solely dependent on the terms of any business combination entered into by the Company on or after August 1, 2009.

Contractual Obligations

The Company has entered into various real estate and equipment operating leases and has employment agreements with certain executive officers. The real estate lease for the Company s Farmingdale Clinical Lab and Research facility is with a related party. See Item 2, Properties, and Note 15 to the Consolidated Financial Statements for a further description of these various leases.

The following is a summary of future payments under the Company s contractual obligations as of July 31, 2009:

Payments Due by Period

In 000 s	Total	Less than 1 year	1-3 years	4-5 years	Over 5 years
Real estate and equipment leases	$ 20,316	$ 4,410	$ 7,195	$ 4,565	$ 4,146
Employment agreements	3,159	1,948	1,211		
Total contractual cash obligations	$ 23,475	$ 6,358	$ 8,406	$ 4,565	$ 4,146

Management is not aware of any material claims, disputes or settled matters concerning third-party reimbursements that would have a material effect on our financial statements.

The Company does not have any off-balance sheet arrangements as such term is defined in Item 303(a) (4) of Regulation S-K.

Critical Accounting Policies

General

The Company s discussion and analysis of its financial condition and results of operations are based upon Enzo Biochem, Inc. consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires the Company to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses; these estimates and judgments also affect related disclosure of contingent assets and liabilities. On an on-going basis, we evaluate our estimates, including those related to contractual expense, allowance for uncollectible accounts, inventory, intangible assets and income taxes. The Company bases its estimates on experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

Product revenues

Revenues from product sales are recognized when the products are shipped and title transfers, the sales price is fixed or determinable and collectibility is reasonably assured.

Royalties

Royalty revenues are recorded in the period earned. Royalties received in advance of being earned are recorded as deferred revenues.

License fees and multiple element arrangements

When evaluating multiple element arrangements, the Company considers whether the components of the arrangement represent separate units of accounting as defined in Emerging Issues Task Force (EITF) Issue No. 00-21, Revenue Arrangements with Multiple Deliverables (EITF 00-21). Application of this standard requires subjective determinations and requires management to make judgments about the fair value of the individual elements and whether such elements are separable from the other aspects of the contractual relationship.

Revenues - Clinical laboratory services

Revenues from the clinical laboratory are recognized upon completion of the testing process for a specific patient and reported to the ordering physician. These revenues and the associated accounts receivable are based on gross amounts billed or billable for services rendered, net of a contractual adjustment, which is the difference between amounts billed to payers and the expected approved reimbursable settlements from such payers.

The following table represents the clinical laboratory segment s net revenues and percentages by revenue category:

	Year ended July 31 2009		Year ended July 31 2008		Year ended July 31 2007	
Revenue category	**(In 000 s)**	**(in %)**	**(In 000 s)**	**(in %)**	**(In 000 s)**	**(in %)**
Medicare	$ 9,138	23	$ 9,078	22	$ 8,478	21
Third-party payers	20,073	51	24,768	59	25,060	62
Patient self-pay	6,056	15	3,582	8	2,952	7
HMO s	4,337	11	4,650	11	3,940	10
Total	$ 39,604	100%	$ 42,078	100%	$ 40,430	100%

The Company provides services to certain patients covered by various third-party payers, including the Federal Medicare program. Laws and regulations governing Medicare are complex and subject to interpretation for which action for noncompliance includes fines, penalties and exclusion from the Medicare programs. The Company believes that it is in compliance with all applicable laws and regulations and is not aware of any pending or threatened investigations involving allegations of potential wrongdoing.

Other than the Medicare program, one provider whose programs are included in the Third-party payer and Health Maintenance Organizations (HMO s) categories represented 25%, 26%, and 20% of the Clinical Labs services net revenues for the fiscal years ended July 31, 2009, 2008 and 2007 respectively.

Contractual Adjustment

The Company s estimate of contractual adjustment is based on significant assumptions and judgments, such as its interpretation of payer reimbursement policies, and bears the risk of change. The estimation process is based on the experience of amounts approved as reimbursable and ultimately settled by payers, versus the corresponding gross amount billed to the respective payers. The contractual adjustment is an estimate that reduces gross revenue, based on gross billing rates, to amounts expected to be approved and reimbursed. Gross billings are based on a standard fee schedule we set for all third party payers, including Medicare, health maintenance organizations (HMO s) and managed care. The Company adjusts the contractual adjustment estimate quarterly, based on its evaluation of current and historical settlement experience with payers, industry reimbursement trends, and other relevant factors. The other relevant factors that affect our contractual adjustment include the monthly and quarterly review of: 1) current gross billings and receivables and reimbursement by payer, 2) current changes in third party arrangements. 3) the growth of in-network provider arrangements and managed care plans specific to our Company.

Our clinical laboratory business is primarily dependent upon reimbursement from third-party payers, such as Medicare (which principally serves patients 65 and older) and insurers. We are subject to variances in reimbursement rates among different third-party payers, as well as constant changes of reimbursement rates. Changes that decrease reimbursement rates or coverage would negatively impact our revenues. The number of individuals covered under managed care contracts or other similar arrangements has grown over the past several years and may continue to grow in the future. In addition, Medicare and other government healthcare programs continue to shift to managed care. These trends will continue to reduce our revenues per test.

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During the years ended July 31, 2009, 2008 and 2007, the contractual adjustment percentages, determined using current and historical reimbursement statistics, were 80.8%, 81.8% and 79.0%, respectively, of gross billings. The Company believes a decline in reimbursement rates or a shift to managed care, or similar arrangements may be offset by the positive impact of an increase in the number of tests we perform. However, there can be no assurance that we can increase the number of tests we perform or that if we do increase the number of tests we perform, that we can maintain that higher number of tests performed, or that an increase in the number of tests we perform would result in increased revenue.

The Company estimates (by using a sensitivity analysis) that each 1% point change in the contractual adjustment percentage could result in a change in clinical laboratory services revenues of approximately $2,040,000 and $2,316,000, for the years ended July 31, 2009 and 2008, respectively, and a change in the net accounts receivable of approximately $287,000 and $301,000 as of July 31, 2009 and 2008, respectively.

Our clinical laboratory financial billing system records gross billings using a standard fee schedule for all payers and does not record contractual adjustment by payer at the time of billing. Therefore, we are unable to quantify the effect of contractual adjustment recorded during the current period that relate to revenue recorded in a previous period. However, we can reasonably estimate our contractual adjustment to revenue on a timely basis based on our quarterly review process, which includes:

- an analysis of industry reimbursement trends;
- an evaluation of third-party reimbursement rates changes and changes in reimbursement arrangements with third-party payers;
- a rolling monthly analysis of current and historical claim settlement and reimbursement experience with payers;
- an analysis of current gross billings and receivables by payer.

Accounts Receivable and Allowance for Doubtful Accounts

Accounts receivable are reported at realizable value, net of allowances for doubtful accounts, which is estimated and recorded in the period of the related revenue.

The following is a table of the Company s net accounts receivable by segment. The Clinical Labs segment s net receivables are detailed by billing category and as a percent to its total net receivables. As of July 31, 2009 and 2008, approximately 40% and 58%, respectively, of the Company s net accounts receivable relates to its Clinical Labs business, which operates in the New York Metropolitan and New Jersey areas. The Life Sciences segment s accounts receivable, of which $2.1 million or 28% and $3.3 million or 51% represents foreign receivables as of July 31, 2009 and 2008 respectively, includes royalty receivables of $2.5 and $2.1 million, as of July 31, 2009 and 2008, respectively, of which approximately $1.9 million and $1.5 million, respectively is from Qiagen Corporation.

Net accounts receivable

	As of July 31, 2009		As of July 31, 2008	
Billing category	**(In 000 s)**	**(in %)**	**(In 000 s)**	**(in %)**
Clinical Labs				
Medicare	$ 1,113	22	$ 1,600	18
Third party payers	2,003	40	4,610	52
Patient self-pay	1,635	32	2,144	24
HMO s	303	6	537	6
Total clinical labs	5,054	100%	8,891	100%
Total life sciences	7,426		6,457	
Total accounts receivable	$ 12,480		$ 15,348	

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Changes in the Company s allowance for doubtful accounts are as follows:

In 000 s	July 31, 2009	July 31, 2008
Beginning balance	$ 886	$ 1,404
Provision for doubtful accounts	5,189	3,716
Write-offs, net	(1,289)	(4,234)
Ending balance	$ 4,786	$ 886

For the Clinical Labs segment, the allowance for doubtful accounts represents amounts that the Company does not expect to collect after the Company has exhausted its collection procedures. The Company estimates its allowance for doubtful accounts in the period the related services are billed and adjusts the estimate in future accounting periods as necessary. It bases the estimate for the allowance on the evaluation of historical collection experience, the aging profile of accounts receivable, the historical doubtful account write-off percentages, payer mix, and other relevant factors.

The allowance for doubtful accounts includes the balances, after receipt of the approved settlements from third party payers for the insufficient diagnosis information received from the ordering physician, which result in denials of payment and the uncollectible portion of receivables from self payers, including deductibles and copayments, which are subject to credit risk and patients ability to pay. During the years ended July 31, 2009 and 2008, the Company determined an allowance for doubtful accounts less than 210 days and wrote off 100% of accounts receivable over 210 days, as it assumed those accounts are uncollectible, except for certain fully reserved balances, principally related to Medicare. These accounts have not been written off because the payer s filing date deadline has not occurred or the collection process has not been exhausted. The Company s collection experience on Medicare receivables beyond 210 days has been insignificant. The Company adjusts the historical collection analysis for recoveries, if any, on an ongoing basis.

The Company s ability to collect outstanding receivables from third party payers is critical to its operating performance and cash flows. The primary collection risk lies with uninsured patients or patients for whom primary insurance has paid but a patient portion remains outstanding. The Company also assesses the current state of its billing functions in order to identify any known collection or reimbursement issues in order to assess the impact, if any, on the allowance estimates, which involves judgment. The Company believes that the collectibility of its receivables is directly linked to the quality of its billing processes, most notably, those related to obtaining the correct information in order to bill effectively for the services provided. Should circumstances change (e.g. shift in payer mix, decline in economic conditions or deterioration in aging of receivables), our estimates of net realizable value of receivables could be reduced by a material amount.

During the period ended 2009 versus 2008, our bad debt expense and related allowance for doubtful accounts increased by $1.5 million, as a result of the impact of 1) increased provisions for the Clinical Labs legacy billing system, which was replaced in August 2008, due to reduced collection efforts relating to the legacy billing system, 2) the correction of the aforementioned $0.6 million immaterial error in the allowance for doubtful accounts relating to fiscal 2008, and 3.) increased provisions required based on changes in payer mix. The Company is presently managing two systems until the legacy system collection efforts are deemed completed.

Billing for laboratory services is complicated because of many factors, especially: the differences between our standard gross fee schedule for all payers and the reimbursement rates of the various payers we deal with, disparity of coverage and information requirements among the various payers, and disputes with payers as to which party is responsible for reimbursement.

The following table indicates the Clinical Labs aged gross receivables by payer group (in thousands), which is prior to adjustment to gross receivables for: 1) contractual adjustment, 2) fully reserved balances not yet written off, and 3) other revenue adjustments. The amounts as of July 31, 2009 are from the Company s new billing system and the amounts as of July 31, 2008 are from the Company s legacy billing system. The fully reserved amount as of July 31, 2009 is for billing from the new system only. As of July 31, 2009, all uncollected receivables from the legacy billing system have been fully reserved.

As of July 31, 2009	Total Amount	%	Medicare Amount	%	Third Party Payers Amount	%	Self-pay Amount	%	HMO s Amount	%
1-30 days	$ 19,251	70%	$ 3,193	61%	$ 9,695	73%	$ 2,882	51%	$ 3,481	99%
31-60 days	4,508	17%	894	16%	1,957	15%	1,635	29%	22	1%
61-90 days	1,783	6%	256	5%	680	5%	836	15%	11	%
91-120 days	1,039	4%	249	5%	483	4%	280	5%	7	%
121-150 days	335	1%	134	3%	202	2%		%	4	%
Greater than 150 days*	621	2%	536	10%	100	1%		%		%
Totals	$ 27,537	100%	$ 5,262	100%	$ 13,117	100%	$ 5,633	100%	$ 3,525	100%

As of July 31, 2008	Total Amount	%	Medicare Amount	%	Third Party Payers Amount	%	Self-pay Amount	%	HMO s Amount	%
1-30 days	$ 15,879	56%	$ 3,278	44%	$ 7,019	62%	$ 1,654	29%	$ 3,928	94%
31-60 days	4,038	14%	725	10%	2,196	19%	960	17%	157	4%
61-90 days	1,836	6%	468	6%	636	6%	682	12%	50	1%
91-120 days	1,460	5%	291	4%	534	5%	614	11%	21	1%
121-150 days	1,074	4%	192	3%	548	5%	323	5%	11	0%
Greater than 150 days**	4,300	15%	2,412	33%	380	3%	1,506	26%	2	0%
Totals	$ 28,587	100%	$ 7,366	100%	$ 11,313	100%	$ 5,739	100%	$ 4,169	100%

** Total includes $340 fully reserved over 210 days as of July 31, 2009.

** Total includes $2,796 fully reserved over 210 days as of July 31, 2008.

Income Taxes

The Company accounts for income taxes under the liability method of accounting for income taxes. Under the liability method, deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. The liability method requires that any tax benefits recognized for net operating loss carry forwards and other items be reduced by a valuation allowance where it is not more likely than not the benefits will be realized in the foreseeable future.

Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. Under the liability method, the effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date.

On August 1, 2007, the Company adopted Financial Accounting Standards Board (FASB) Interpretation No. 48, Accounting for Uncertainty in Income Taxes - an interpretation of FASB Statement No. 109 (FIN 48). FIN 48 prescribes a more-likely-than-not threshold for the recognition and derecognition of tax positions, provides guidance on the accounting for interest and penalties relating to tax positions and requires that the cumulative effect of applying the provisions of FIN 48 be reported as an adjustment to the opening balance of retained earnings or other appropriate components of equity or net assets in the statement of financial position. The Company did not have any significant unrecognized tax positions and there was no material effect on our financial condition or results of operations as a result of implementing FIN 48.

Inventory

The Company values inventory at the lower of cost (first-in, first-out) or market. Work-in-process and finished goods inventories consist of material, labor, and manufacturing overhead. On a quarterly basis, we review inventory quantities on hand and analyze the provision for excess and obsolete inventory based on our estimate of sales forecasts based on sales history and anticipated future demand. Our estimate of future product demand may not be accurate and we may understate or overstate the provision for excess and obsolete inventory. Accordingly, unanticipated changes in demand could have a significant impact on the value of our inventory and results of operations. At July 31, 2009 and 2008, our reserve for excess and obsolete inventory was $1,005,000 and $637,000 respectively.

Goodwill and Indefinite-Lived Intangibles

Goodwill, representing the cost of acquired businesses in excess of the fair value of net assets acquired, and indefinite-lived intangibles are not amortized, but are evaluated annually for impairment. The Company performs its annual impairment test as of the first day of its fiscal fourth quarter or if indicators of potential impairment exist. Goodwill is considered impaired if the carrying amount of the reporting unit exceeds its estimated fair value. In assessing the recoverability of goodwill, the Company reviews both quantitative as well as qualitative factors to support its assumptions with regard to fair value. The fair value of a reporting unit, which is based on geographic region, is estimated using both a discounted cash flow model and a weighted average multiple of earnings before interest and taxes from comparable companies. To date, there have been no impairment charges recorded. As of May 1, 2009, one of the Company□s reporting unit□s fair value exceeded its carrying value by 10%. This reporting unit□s goodwill was $5.3 million at the date of our annual impairment test. In determining fair value, the Company makes certain judgments, including the identification of reporting units and the selection of comparable companies. If these estimates or their related assumptions change in the future as a result of changes in strategy and/or market conditions, the Company may be required to record an impairment charge.

Intangible Assets

Intangible assets (exclusive of patents), arose primarily from acquisitions and primarily consist of customer relationships, trademarks, licenses, employment and non-compete agreements, and website and database content. Finite-lived intangible assets are amortized according to their estimated useful lives, which range from 4 to 15 years. The Company has capitalized certain legal costs directly incurred in pursuing patent applications as patent costs. When such applications result in an issued patent, the related costs are amortized over a ten year period or the life of the patent, whichever is shorter, using the straight-line method. The Company reviews its issued patents and pending patent applications, and if it determines to abandon a patent application or that an issued patent no longer has economic value, the unamortized balance in deferred patent costs relating to that patent is immediately expensed.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

We are exposed to market risk from changes in foreign currency exchange rates resulting from the recent acquisitions with foreign locations (See Item 1A. Risk Factors and Note 2 in the notes to consolidated financial statements) and, to a much lesser extent, interest rates on investments in short-term instruments, that could impact our results of operations and financial position. We do not currently engage in any hedging or market risk management tools.

Foreign Currency Exchange Rate Risk

The financial reporting of our non-U.S. subsidiaries is denominated in currencies other than the U.S. dollar. Since the functional currency of our non-U.S. subsidiaries is the local currency, foreign currency translation adjustments are accumulated as a component of accumulated other comprehensive income in stockholders equity. Assuming a hypothetical aggregate change of 10% in the exchange rates of foreign currencies against the U.S. dollar at July 31, 2009, our assets and liabilities would increase or decrease by $2.0 million and $0.5 million, respectively, and our net sales and net earnings would increase or decrease by $1.6 million and $0.1 million, respectively, on an annual basis.

We also maintain intercompany balances and loans receivable with subsidiaries with different local currencies. These amounts are at risk of foreign exchange losses if exchange rates fluctuate. Assuming a hypothetical aggregate change of 10% in the exchange rates of foreign currencies against the U.S. dollar at July 31, 2009, our pre-tax earnings would be favorably or unfavorably impacted by approximately $0.5 million on an annual basis.

Interest Rate Risk

Our excess cash is invested in highly liquid short term US government instruments and money market funds with high credit ratings. Changes in interest rates may affect the investment income we earn on cash and cash equivalents and therefore affect our cash flows and results of operations. As of July 31, 2009, we were exposed to interest rate change market risk with respect to our short-term investments in US Government instruments of $43.3 million. The short-term investments bear interest rates ranging from 0% to 0.5%. Each 100 basis point (or 1%) fluctuation in interest rates will increase or decrease interest income on the short-term investments by approximately $0.5 million on an annual basis.

As of July 31, 2009, we did not maintain any fixed or variable interest rate financing.

Item 8. Financial Statements and Supplementary Data

The response to this item is submitted in a separate section of this report. See Item 15(a) (1) and (2)

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

Not applicable.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

As required by Rule 13a-15(e) of the Securities Exchange Act of 1934, as amended (the Exchange Act), we conducted an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures as of July 31, 2009. This evaluation was carried out under the supervision and with participation of our Chief Executive Officer and Chief Financial Officer. There are inherent limitations to the effectiveness of any system of disclosure controls and procedures. Therefore, effective disclosure controls and procedures can only provide reasonable assurance of achieving their control objectives.

Based upon our evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures are effective at that reasonable assurance level as of July 31, 2009, and that information required to be disclosed in the reports that we file under the Exchange Act is recorded, processed, summarized and reported in a timely manner and is accumulated and communicated to management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

Changes in Internal Control over Financial Reporting

There was no change in our internal control over financial reporting during the fourth quarter ended July 31, 2009 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Management s Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rules 13a-15(f) under the Exchange Act.

Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles and includes those policies and procedures that:

pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of our assets;

provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of management and our directors; and

provide reasonable assurance regarding prevention and timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on our financial statements.

Internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems that are determined to be effective provide only reasonable assurance with respect to financial statement preparation and presentation. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Management assessed the effectiveness of our internal control over financial reporting based on criteria for effective internal control over financial reporting described in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

Management s evaluation did not include assessing the effectiveness of internal controls over financial reporting at Assay Designs Inc, (ADI), which was acquired March 12, 2009, and whose financial statements reflect total assets and net revenues of 10.1% and 4.5% respectively, of the consolidated financial statements as of and for the year ended July 31, 2009. Management has opted to exclude ADI from its assessment based upon the SEC s comments in Management s Report on Internal Control Over Financial Reporting and Certification of Disclosure in Exchange Act Periodic Reports, Frequently Asked Questions (FAQ) (revised October 6, 2004) . The response to FAQ No. 3 states that the SEC would not object to management referring in the report to a discussion in the registrant s Form 10-K or 10-KSB regarding the scope of the assessment and to such disclosure noting that management excluded the acquired business from management s report on internal control over financial reporting .

Based on its assessment, management concluded that we maintained effective internal control over financial reporting as of July 31, 2009. Ernst & Young LLP, our independent registered public accounting firm, has issued an attestation report on our internal control over financial reporting as of July 31, 2009. This report, in which Ernst & Young LLP has expressed an unqualified opinion, appears in this Item 9A.

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders of Enzo Biochem, Inc.

We have audited Enzo Biochem, Inc. s (the Company) internal control over financial reporting as of July 31, 2009, based on criteria established in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). Enzo Biochem, Inc. s management is responsible for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management s Annual Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company s internal control over financial reporting based on our audit.

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

A company s internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company s internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company s assets that could have a material effect on the financial statements.

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

As indicated in the accompanying Management s Annual Report on Internal Control over Financial Reporting, management s assessment of and conclusion on the effectiveness of internal control over financial reporting did not include the internal controls of Assay Designs, Inc. which is included in the 2009 consolidated financial statements of Enzo Biochem, Inc., and constituted 10.1% and 10.2% of total and net assets, respectively, as of July 31, 2009 and $4,100,000 and ($1,200,000) of revenues and net loss, respectively, for the year then ended. Our audit of internal control over financial reporting of Enzo Biochem, Inc. also did not include an evaluation of the internal control over financial reporting of Assay Designs, Inc.

In our opinion, Enzo Biochem, Inc. maintained, in all material respects, effective internal control over financial reporting as of July 31, 2009 based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of Enzo Biochem, Inc. as of July 31, 2009 and 2008 and the related consolidated statements of operations, stockholders equity and comprehensive income (loss) and cash flows for each of the three years in the period ended July 31, 2009 of Enzo Biochem, Inc. and our report dated October 14, 2009 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Melville, New York
October 14, 2009

Item 9B. Other Information

None

PART III

Item 10. Directors, Executive Officers and Corporate Governance

The information required under this item will be set forth in the Company s proxy statement to be filed with the Securities and Exchange Commission on or before November 27, 2009 and is incorporated herein by reference.

Item 11. Executive Compensation

The information required under this item will be set forth in the Company s proxy statement to be filed with the Securities and Exchange Commission on or before November 27, 2009 and is incorporated herein by reference.

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

The information required under this item will be set forth in the Company s proxy statement to be filed with the Securities and Exchange Commission on or before November 27, 2009 and is incorporated herein by reference.

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

The information required under this item will be set forth in the Company s proxy statement to be filed with the Securities and Exchange Commission on or before November 27, 2009 and is incorporated herein by reference.

Item 14. Principal Accountant Fees and Services

The information required under this item will be set forth in the Company s proxy statement expected to be filed with the Securities and Exchange Commission on or before November 27, 2009 and is incorporated herein by reference.

PART IV

Item 15. Exhibits, Financial Statement Schedules

(a) (1) Consolidated Financial Statements
Consolidated Balance Sheets - July 31, 2009 and 2008
Consolidated Statements of Operations- Years ended July 31, 2009, 2008 and 2007
Consolidated Statements of Stockholders Equity and Comprehensive Income (Loss) - Years ended July 31, 2009,
2008 and 2007
Consolidated Statements of Cash Flows - Years ended July 31, 2009, 2008 and 2007
Notes to Consolidated Financial Statements.

(2) Financial Statement Schedule
Schedule II - Valuation and Qualifying Accounts

All other schedules have been omitted because the required information is included in the consolidated financial statements or the notes thereto or because they are not required.

(3) Exhibits

The following documents are filed as Exhibits to this Annual Report on Form 10-K:

Exhibit No.	Description
3(a)	Certificate of Incorporation, as amended March 17, 1980. (1)
3(b)	June 16, 1981 Certificate of Amendment of the Certificate of Incorporation. (2)
3(c)	Certificate of Amendment to the Certificate of Incorporation. (3)
3(d)	Amended and restated Bylaws. (14)
10 (c)	Employment Agreements with Elazar Rabbani. (5)
10(d)	Employment Agreement with Shahram Rabbani. (5)
10(e)	Employment Agreement with Barry Weiner. (5)
10(f)	1994 Stock Option Plan. (6)
10(g)	1999 Stock Option Plan. (7)
10 (h)	Amendment to Elazar Rabbani s employment agreement. (8)
10 (i)	Amendment to Shahram Rabbani s employment agreement. (8)
10 (j)	Amendment to Barry Weiner s employment agreement. (8)
10 (k)	2005 Equity Compensation Incentive Plan (10)
10 (l)	Lease agreement with Pari Management (11)
10 (m)	Settlement and Release Agreement between the Company and Sigma Aldrich (12)
10 (n)	Stock Purchase Agreement By and Among Enzo Life Sciences, Inc., Axxora Life Sciences Inc., and the Stock holders, Option holders and Warrant holders (13)
10 (o)	Stock Asset Purchase Agreement By and Among Buyer Parties and Seller Parties (14)
10 (p)	Asset Purchase Agreement By and Among Enzo Life Sciences, Acquisition, Inc. and Assay Designs, Inc. (15).
14 (a)	Code of Ethics (10)
21	Subsidiaries of the registrant: Enzo Clinical Labs, Inc., a New York corporation. Enzo Life Sciences, Inc., a New York corporation. Enzo Therapeutics, Inc., a New York corporation. Enzo Realty, LLC, a New York Corporation
23	Consent of Independent Registered Public Accounting Firm filed herewith.
31 (a)	Certification of CEO Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 filed herewith.
31 (b)	Certification of CFO Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 filed herewith.
32 (a)	Certification of CEO Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 filed herewith.

32 (b)	Certification of CFO Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 filed herewith.

Notes to exhibits

(1)	The exhibits were filed as exhibits to the Company s Registration Statement on Form S-18 (File No. 2-67359) and are incorporated herein by reference.
(2)	This exhibit was filed as an exhibit to the Company s Form 10-K for the year ended July 31, 1981 and is incorporated herein by reference.
(3)	This exhibit was filed with the Company s Annual Report on Form 10-K for the year ended July31, 1989 and is incorporated herein by reference.
(5)	This exhibit was filed with the Company s Annual Report on Form 10-K for the year ended July31, 1994 and is incorporated herein by reference.
(6)	This exhibit was filed with the Company s Annual Report on Form 10-K for the year ended July31, 1995 and is incorporated herein by reference.
(7)	This exhibit was filed with the Company s Registration Statement on Form S-8 (333-87153) and is incorporated herein by reference.
(8)	This exhibit was filed with the Company s Annual Report on Form 10-K for the year ended July31, 2000 and is incorporated herein by reference.
(9)	This exhibit was filed with the Company s Annual Report on Form 10-K for the year ended July31, 2004 and is incorporated herein by reference.
(10)	This exhibit was filed as an exhibit to the Company s Proxy Statement of Schedule 14A filed on January 19, 2005 and is incorporated herein by reference.
(11)	This exhibit was filed with the Company s Annual Report on Form 10-K for the year ended July31, 2006 and is incorporated herein by reference.
(12)	This exhibit was filed with the Company s Current Report on Form 8-K on September 21, 2006 and is incorporated herein by reference.
(13)	This exhibit was filed with the Company s Current Report on Form 8-K May 30, 2007 and is incorporated herein by reference.
(14)	This exhibit was filed with the Company s Current Report on Form 8-K May 8, 2008 and is incorporated herein by reference.
(15)	This exhibit was filed with the Company s Current Report on Form 8-K March 13, 2009 and is incorporated herein by reference.
(b)	See Item 15(a) (3), above.
(c)	See Item 15(a) (2), above.

SIGNATURES

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

ENZO BIOCHEM, INC.

Date: October 14, 2009 By: /s/ Elazar Rabbani Ph.D.

Chairman of the Board

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

By: /s/ Elazar Rabbani Ph.D. October 14, 2009

Elazar Rabbani,
Chairman of Board of Directors
(Principal Executive Officer)

By: /s/ Barry W. Weiner October 14, 2009

Barry W. Weiner,
President, Chief Financial Officer, Principal Accounting Officer and
Director

Shahram K. Rabbani,
Secretary, Treasurer and Director

By: /s/ Irwin Gerson October 14, 2009

Irwin Gerson, Director

By: /s/ Stephen B. H. Kent Ph.D. October 14, 2009

Stephen B. H. Kent, Director

By: /s/ Bernard L. Kasten MD October 14, 2009

Bernard Kasten, Director

By: /s/ Melvin F. Lazar October 14, 2009

Melvin F. Lazar, Director

FORM 10-K, ITEM 15(a) (1) and (2)
ENZO BIOCHEM, INC.

LIST OF CONSOLIDATED FINANCIAL STATEMENTS AND FINANCIAL STATEMENT SCHEDULE

The following consolidated financial statements and financial statement schedule of Enzo Biochem, Inc. are included in Item 15(a):

All other schedules for which provision is made in the applicable accounting regulation of the Securities and Exchange Commission are not required under the related instructions or are inapplicable, and therefore have been omitted.

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders of Enzo Biochem, Inc.

We have audited the accompanying consolidated balance sheets of Enzo Biochem, Inc. (the Company) as of July 31, 2009 and 2008, and the related consolidated statements of operations, stockholders equity and comprehensive income (loss), and cash flows for each of the three years in the period ended July 31, 2009. Our audits also included the financial statement schedule listed in the Index at Item 15(a). These financial statements and schedule are the responsibility of the Company s management. Our responsibility is to express an opinion on these financial statements and schedule based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Enzo Biochem, Inc. at July 31, 2009 and 2008, and the consolidated results of their operations and their cash flows for each of the three years in the period ended July 31, 2009, in conformity with U.S. generally accepted accounting principles. Also, in our opinion, the related financial statement schedule, when considered in relation to the basic financial statements taken as a whole, present fairly in all material respects the information set forth therein.

As discussed in Note 9 to the consolidated financial statements, effective August 1, 2007, the Company adopted the provisions of Financial Accounting Standards Board Interpretation No. 48, Accounting for Uncertainty in Income Taxes.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), Enzo Biochem Inc. s internal control over financial reporting as of July 31, 2009, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated October 14, 2009 expressed an unqualified opinion.

/s/ Ernst & Young LLP

Melville, New York
October 14, 2009

ENZO BIOCHEM, INC.
CONSOLIDATED BALANCE SHEETS
(in thousands, except share and per share data)

	July 31, 2009	July 31, 2008
ASSETS		
Current assets:		
Cash and cash equivalents	$ 6,929	$ 78,322
Short term investments	43,306	
Accounts receivable, net of allowance for doubtful accounts of $4,786 in 2009 and $886 in 2008	12,480	15,348
Inventories	9,264	9,514
Prepaid expenses	2,482	2,496
Total current assets	74,461	105,680
Property, plant, and equipment, net	11,323	9,053
Goodwill	24,896	21,321
Intangible assets, net	22,009	17,656
Other	439	812
Total assets	$ 133,128	$ 154,522
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable trade	$ 4,242	$ 4,299
Accrued liabilities	8,426	7,370
Other current liabilities	1,062	1,161
Deferred taxes	213	458
Total current liabilities	13,943	13,288
Deferred revenue	38	512
Deferred taxes	2,366	2,433
Commitments and contingencies		
Stockholders equity:		
Preferred Stock, $.01 par value; authorized 25,000,000 shares; no shares issued or outstanding		
Common Stock, $.01 par value; authorized 75,000,000 shares; shares issued: 38,589,880 at July 31, 2009 and 38,007,581 at July 31, 2008	386	380
Additional paid-in capital	306,280	303,811
Less treasury stock at cost: 735,554 shares at July 31, 2009 and 777,719 shares at July 31, 2008	(10,440)	(11,331)
Accumulated deficit	(179,721)	(156,157)
Accumulated other comprehensive income	276	1,586
Total stockholders equity	116,781	138,289
Total liabilities and stockholders equity	$ 133,128	$ 154,522

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

ENZO BIOCHEM, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except per share data)

	Years ended July 31,		
	2009	**2008**	**2007**
Revenues:			
Product revenues	$ 40,592	$ 28,087	$ 6,658
Royalty and license fee income	9,376	7,630	5,820
Clinical laboratory services	39,604	42,078	40,430
	89,572	77,795	52,908
Costs and expenses and other (income):			
Cost of product revenues	26,766	19,159	5,034
Cost of clinical laboratory services	26,295	22,209	19,151
Research and development expense	9,220	8,637	9,393
Selling, general, and administrative expense	41,314	33,272	25,348
Provision for uncollectible accounts receivable	5,189	3,716	4,653
Legal expense	4,195	5,588	10,295
Interest income	(581)	(3,696)	(5,092)
Other income	(74)	(171)	(2,699)
Foreign exchange loss (gain)	725	(27)	
	113,049	88,687	66,083
Loss before income taxes	(23,477)	(10,892)	(13,175)
(Provision) benefit for income taxes	(87)	239	(85)
Net loss	($ 23,564)	($ 10,653)	($ 13,260)
Net loss per common share:			
Basic	($ 0.63)	($ 0.29)	($ 0.38)
Diluted	($ 0.63)	($ 0.29)	($ 0.38)
Weighted average common shares outstanding:			
Basic	37,511	36,883	35,017
Diluted	37,511	36,883	35,017

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

ENZO BIOCHEM, INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY
AND COMPREHENSIVE INCOME (LOSS)
Years ended July 31, 2009, 2008, and 2007
(In thousands, except share data)

	Common Stock Shares	*Treasury Stock Shares*	Common Stock Amount	Additional Paid-in Capital	Treasury Stock Amount	Accumulated Deficit	Accumulated Other Comprehensive (Loss) Income	Total Stockholders Equity	Comprehensive income (loss)
Balance at July 31, 2006	*32,844,200*	*569,700*	$ 328	$ 236,002	$ (8,499)	$ (132,244)	$	$ 95,587	
Net (loss) for the year ended July 31, 2007						(13,260)		(13,260)	$ (13,260)
Net proceeds from issuance of common stock	*4,285,715*		43	56,954				56,997	
Purchase of treasury stock		*26,756*			(416)			(416)	
Exercise of stock options	*95,525*		1	915				916	
Issuance of stock for employee 401(k) plan match	*29,370*			421				421	
Vesting of restricted stock	*25,913*								
Stock based compensation charges				1,477				1,477	
Stock based compensation for consulting services				130				130	
Foreign currency translation adjustments							42	42	42
Comprehensive (loss)									$ (13,218)
Balance at July 31, 2007	*37,280,723*	*596,456*	372	295,899	(8,915)	(145,504)	42	141,894	
Net (loss) for the year ended July 31, 2008						(10,653)		(10,653)	$ (10,653)
Purchase of treasury stock		*181,263*			(2,416)			(2,416)	
Exercise of stock options	*267,345*		3	2,881				2,884	
Vesting of restricted stock	*70,963*		1					1	
Stock based compensation charges				1,566				1,566	
Issuance of stock for employee 401(k) plan match	36,550			481				481	
Issuance of stock for acquisition	352,000		4	2,996				3,000	
Common stock issuance costs adjustment				(12)				(12)	

Foreign currency translation adjustments							1,544	1,544	1,544
Comprehensive (loss)									$ (9,109)
Balance at July 31, 2008	*38,007,581*	*777,719*	380	303,811	(11,331)	(156,157)	1,586	138,289	
Net (loss) for the year ended July 31, 2009						(23,564)		(23,564)	$ (23,564)
Purchase of treasury stock		*99,985*			(1,126)			(1,126)	
Exercise of stock options	*251,162*		3	1,471				1,474	
Vesting of restricted stock	*128,941*		1					1	
Stock based compensation charges				1,435				1,435	
Issuance of treasury stock for employee 401(k) plan match		*(142,150)*		(1,435)	2,017			582	
Issuance of stock for acquisition earn out	202,196		2	998				1,000	
Foreign currency translation adjustments							(1,310)	(1,310)	(1,310)
Comprehensive (loss)									$ (24,874)
Balance at July 31, 2009	*38,589,880*	*735,554*	$ 386	$ 306,280	$ (10,440)	$ (179,721)	$ 276	$ 116,781	

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

ENZO BIOCHEM, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)

	Years ended July 31,		
	2009	**2008**	**2007**
Cash flows from operating activities:			
Net loss	($ 23,564)	($ 10,653)	($ 13,260)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization of property, plant and equipment	2,185	1,488	1,038
Amortization of intangible assets	1,277	658	151
Provision for uncollectible accounts receivable	5,189	3,716	4,653
Write-off and/or reserve for obsolete inventory	378	283	360
Deferred income tax (benefit) provision		(644)	(178)
Share based compensation charges	1,435	1,566	1,477
Issuance of common stock for 401(k) employer match	582	481	421
Deferred revenue recognized	(475)	(426)	
Gain on termination of officers life insurance policies		(313)	
Options issued to consultants			130
Foreign exchange loss on intercompany loan	697		
Other			10
Changes in operating assets and liabilities:			
Accounts receivable	(1,409)	(2,837)	(6,086)
Inventories	2,269	1,012	533
Prepaid expenses	208	(574)	31
Recoverable and prepaid income taxes			1,931
Accounts payable trade	(571)	(1,060)	429
Accrued liabilities	528	(1,066)	2,892
Other current liabilities	(206)	(195)	74
Deferred revenue			1,628
Adjustments	12,087	2,089	9,494
Net cash used in operating activities	(11,477)	(8,564)	(3,766)
Cash flows from investing activities:			
Capital expenditures	(2,709)	(3,231)	(1,448)
Proceeds from termination of officers life insurance		1,085	
Maturities of short term investments	318,650		
Purchases of short term investments	(361,956)		
(Increase) decrease in cash surrender values			(75)
Decrease (increase) in security deposits and other	384	(491)	(14)
Acquisitions, net of cash acquired	(14,541)	(16,144)	(16,888)
Net cash used in investing activities	(60,172)	(18,781)	(18,425)
Cash flows from financing activities:			
Net proceeds from issuance of common stock			56,997
Proceeds from the exercise of stock options	348	470	500
Issuance costs from issuance of common stock		(12)	

Net cash provided by financing activities	348	458	57,497
Effect of exchange rate changes on cash and cash equivalents	(92)	60	(11)
(Decrease) increase in cash and cash equivalents	(71,393)	(26,827)	35,295
Cash and cash equivalents - beginning of year	78,322	105,149	69,854
Cash and cash equivalents - end of year	$ 6,929	$ 78,322	$ 105,149

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

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Note 1 - Summary of significant accounting policies

Nature of business

Enzo Biochem, Inc. (the Company) is engaged in research, development, manufacturing and marketing of diagnostic and research products based on genetic engineering, biotechnology and molecular biology. These products are designed for the diagnosis of and/or screening for infectious diseases, cancers, genetic defects and other medically pertinent diagnostic information and are distributed in the United States and internationally. The Company is conducting research and development activities in the development of therapeutic products based on the Company s technology platform of genetic modulation and immune modulation. The Company also operates a clinical laboratory that offers and provides diagnostic medical testing services to the health care community in the New York Metropolitan and New Jersey areas. The Company operates in three segments (see Note 17).

On March 12, 2009, Enzo Life Sciences, Inc. and Enzo Life Sciences Acquisition, Inc., a newly formed wholly owned subsidiary of Enzo Life Sciences, Inc. (Acquisition Sub), entered into an asset purchase agreement (Purchase Agreement) dated as of March 12, 2009 with Assay Designs, Inc. (Assay Designs). Assay Designs, a privately owned company with annual sales of approximately $11 million, was engaged in researching, developing, manufacturing, distributing, marketing and selling specialty immunological and biochemical protein detection kits, assays, reagents, antibodies, recombinant proteins and related products and providing related services for use in the biotechnology, pharmaceutical and life sciences research industries (Business). Under the terms of the Purchase Agreement, Acquisition Sub purchased from Assay Designs substantially all of its assets, including trade accounts receivable, inventory, fixed assets, and intellectual property, used in or related to the Business and assumed certain of Assay Designs liabilities, including trade accounts payable, capital lease obligations and certain other current liabilities. The Assay Design Acquisition strengthens the Company s position as a global provider of life sciences reagents by broadening our product offerings and manufacturing capabilities (see Note 2).

On May 8, 2008, Enzo Life Sciences, Inc. (Enzo Life Sciences), a wholly-owned subsidiary of the Company, acquired substantially all assets and certain liabilities of Biomol International L.P. (Biomol LP) and the issued and outstanding capital stock of Affiniti, Limited, a wholly owned subsidiary of Biomol L.P., referred to as Biomol . Biomol is a developer, manufacturer and distributor of reagents for the research and biochemical industries and is based in the U.S. and its wholly-owned subsidiary is located in Exeter, United Kingdom. Biomol utilizes third-party distributors located in other major markets throughout the world. As a result of this transaction, Enzo Life Sciences has expanded its product offerings, both through internal manufacturing and distribution, and increases its geographic distribution (see Note 2).

Effective May 31, 2007, Enzo Life Sciences completed the acquisition of all of the issued and outstanding capital stock of Axxora Life Sciences, Inc. (Axxora). Axxora is a developer, manufacturer and distributor of reagents for the research and biochemical industries and is based in the U.S. with wholly-owned subsidiaries in the U.S., Switzerland, Germany and the United Kingdom. Axxora utilizes third-party distributors located in other major markets throughout the world. Axxora s electronic marketplace enables customers to purchase research reagents from internationally recognized manufacturers covering all areas of the life sciences research reagents field. As a result of this transaction, Enzo Life Sciences has expanded its product offerings both through internal manufacturing and distribution and increases its geographic distribution (see Note 2).

Principles of consolidation

The accompanying consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States (U.S. GAAP) and include the accounts of the Company and its wholly-owned subsidiaries, Enzo Clinical Labs, Inc., Enzo Life Sciences, Inc., Enzo Therapeutics, Inc. and Enzo Realty LLC (Realty). All intercompany transactions and balances have been eliminated. The results of operations for companies acquired are included in the consolidated financial statements from the effective date of the acquisition.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amount of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and amounts of income and expenses during the reporting period. Actual results could differ from those estimates.

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Foreign Currency Translation

In accordance with Statement of Financial Accounting Standards (SFAS) No. 52, Foreign Currency Translation (SFAS No. 52), the Company has determined that the functional currency for its foreign subsidiaries is the local currency. Assets and liabilities denominated in foreign currencies are translated at current exchange rates and profit and loss accounts are translated at weighted average exchange rates. Resulting translation gains and losses are included as a separate component of stockholders equity as accumulated other comprehensive income or loss.

Cash and cash equivalents

Cash and cash equivalents include highly liquid US Government instruments with maturities of three months or less at the time acquired by the Company and money market funds.

Concentration of credit risk

Financial instruments that potentially subject the Company to concentrations of credit risk primarily consist of cash and cash equivalents, accounts receivable, accounts payable and accrued liabilities. The Company s cash equivalents are invested in diverse financial instruments with high credit ratings. The Company believes the fair value of the aforementioned financial instruments approximates the current value due to the immediate or short-term nature of these items.

Concentration of credit risk with respect to the Company s life sciences segment is mitigated by the diversity of the Company s clients and their dispersion across many different geographic regions. To reduce risk, the Company routinely assesses the financial strength of these customers and, consequently, believes that its accounts receivable credit exposure with respect to these customers is limited.

The Company believes that the concentration of credit risk with respect to the Clinical Labs accounts receivable is mitigated by the diversity of its numerous third party payers and individual patient accounts and is limited to certain large payers that insure individuals that utilize the Clinical labs services. To reduce risk, the Company routinely assesses the financial strength of these payers and, consequently, believes that its accounts receivable credit risk exposure, with respect to these payers, is limited. While the Company also has receivables due from the Federal Medicare program, the Company does not believe that these receivables represent a credit risk since the Medicare program is funded by the federal government and payment is primarily dependent on our submitting the appropriate documentation.

Revenue Recognition

Product revenues

Revenues from product sales are recognized when the products are shipped and title transfers, the sales price is fixed or determinable and collectibility is reasonably assured.

Royalties

Royalty revenues are recorded in the period earned. Royalties received in advance of being earned are recorded as deferred revenues in the accompanying balance sheet.

License Fees and Multiple Element Arrangements

When evaluating multiple element arrangements, the Company considers whether the components of the arrangement represent separate units of accounting as defined in Emerging Issues Task Force (EITF) Issue No. 00-21, *Revenue Arrangements with Multiple Deliverables* (EITF 00-21). Application of this standard requires subjective determinations and requires management to make judgments about the fair value of the individual elements and whether such elements are separable from the other aspects of the contractual relationship.

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Clinical laboratory services

Revenues from the clinical laboratory are recognized upon completion of the testing process for a specific patient and reported to the ordering physician. These revenues and the associated accounts receivable are based on gross amounts billed or billable for services rendered, net of a contractual adjustment, which is the difference between amounts billed to payers and the expected approved reimbursable settlements from such payers.

The following are tables of the Clinical Lab segment s net revenues and revenue percentages by revenue category:

	Years ended July 31					
	2009		2008		2007	
Revenue category	**(In 000 s)**	**(in %)**	**(In 000 s)**	**(in %)**	**(In 000 s)**	**(in %)**
Medicare	$ 9,138	23	$ 9,078	22	$ 8,478	21
Third-party payers	20,073	51	24,768	59	25,060	62
Patient self-pay	6,056	15	3,582	8	2,952	7
HMO s	4,337	11	4,650	11	3,940	10
Total	$ 39,604	100%	$ 42,078	100%	$ 40,430	100%

The Company provides services to certain patients covered by various third-party payers, including the Federal Medicare program. Laws and regulations governing Medicare are complex and subject to interpretation for which action for noncompliance includes fines, penalties and exclusion from the Medicare programs. The Company believes that it is in compliance with all applicable laws and regulations and is not aware of any pending or threatened investigations involving allegations of potential wrongdoing.

Other than the Medicare program, United Healthcare of New York whose programs are included in the Third-party payers and Health Maintenance Organizations (HMO s) categories, represents 25%, 26% and 20% of the Clinical labs segment net revenue for the fiscal year ended July 31, 2009, 2008 and 2007 respectively.

Contractual Adjustment

The Company s estimate of contractual adjustment is based on significant assumptions and judgments, such as its interpretation of payer reimbursement policies, and bears the risk of change. The estimation process is based on the experience of amounts approved as reimbursable and ultimately settled by payers, versus the corresponding gross amount billed to the respective payers. The contractual adjustment is an estimate that reduces gross revenue, based on gross billing rates, to amounts expected to be approved and reimbursed. Gross billings are based on a standard fee schedule the Company sets for all third-party payers, including Medicare, HMO s and managed care providers. The Company adjusts the contractual adjustment estimate quarterly, based on its evaluation of current and historical settlement experience with payers, industry reimbursement trends, and other relevant factors which include the monthly and quarterly review of: 1) current gross billings and receivables and reimbursement by payer, 2) current changes in third party arrangements and 3) the growth of in-network provider arrangements and managed care plans specific to our Company.

During the years ended July 31, 2009, 2008 and 2007, the contractual adjustment percentages, determined using current and historical reimbursement statistics, were 80.8%, 81.8% and 79.0%, respectively, of gross billings.

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Accounts Receivable and Allowance for Doubtful Accounts

Accounts receivable are reported at realizable value, net of allowances for doubtful accounts, which is estimated and recorded in the period of the related revenue.

For the Clinical Labs segment, the allowance for doubtful accounts represents amounts that the Company does not expect to collect after the Company has exhausted its collection procedures. The Company estimates its allowance for doubtful accounts in the period the related services are billed and adjusts the estimate in future accounting periods as necessary. It bases the estimate for the allowance on the evaluation of historical collection experience, the aging profile of accounts receivable, payer mix and other relevant factors.

During the years ended July 31, 2009 and 2008, the Company determined an allowance for doubtful accounts for customers whose accounts receivable have been outstanding less than 210 days and wrote off 100% of accounts receivable over 210 days, as it determined based on historical trends that those accounts were uncollectible, except for certain fully reserved balances, principally related to Medicare. These accounts have not been written off because the payer s filing date deadline has not occurred or the collection process has not been exhausted. The Company adjusts the historical collection analysis for recoveries, if any, on an ongoing basis.

The Company s ability to collect outstanding receivables from third-party payers is critical to its operating performance and cash flows. The primary collection risk lies with uninsured patients or patients for whom primary insurance has paid but a patient portion remains outstanding. The Company also assesses the current state of its billing functions in order to identify any known collection issues and to assess the impact, if any, on the allowance estimates which involves judgment. The Company believes that the collectibility of its receivables is directly linked to the quality of its billing processes, most notably, those related to obtaining the correct information in order to bill effectively for the services provided. Should circumstances change (e.g. shift in payer mix, decline in economic conditions or deterioration in aging of receivables), our estimates of net realizable value of receivables could be reduced by a material amount.

The Clinical Labs segment s net receivables are detailed by billing category and as a percent to its total net receivables. At July 31, 2009 and 2008, approximately 40% and 58%, respectively, of the Company s net accounts receivable relates to its Clinical Labs business, which operates in the New York Metropolitan and New Jersey areas.

The Life Sciences segment s accounts receivable includes royalties receivable of $2.5 million and $2.1 million, as of July 31, 2009 and 2008, respectively, of which approximately $1.9 million and $1.5 million, respectively is from Qiagen Corporation (see Note 13).

The following is a table of the Company s net accounts receivable by segment.

Net accounts receivable **Billing category**	**As of July 31, 2009**		**As of July 31, 2008**	
Clinical Labs	**(In 000 s)**	**(in %)**	**(In 000 s)**	**(in %)**
Medicare	$ 1,113	22	$ 1,600	18
Third party payers	2,003	40	4,610	52
Patient self-pay	1,635	32	2,144	24
HMO s	303	6	537	6
Total Clinical Labs	5,054	100%	8,891	100%
Total Life Sciences	7,426		6,457	
Total accounts receivable	$ 12,480		$ 15,348	

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Changes in the Company s allowance for doubtful accounts are as follows:

In 000 s	July 31, 2009	July 31, 2008
Beginning balance	$ 886	$ 1,404
Provision for doubtful accounts	5,189	3,716
Write-offs	(1,289)	(4,234)
Ending balance	$ 4,786	$ 886

Inventories

Inventories are stated at the lower of cost (first-in, first-out) or market. Appropriate consideration is given to obsolescence and other factors in evaluating net realizable value. Work-in-process and finished goods inventories consist of material, labor and manufacturing overhead acquired inventories are recorded at fair value.

Property, plant and equipment

Property, plant and equipment is stated at cost, and depreciated on the straight-line basis over the estimated useful lives of the various asset classes as follows: building and building improvements 15-30 years and laboratory machinery and equipment and office furniture and computer equipment - ranges from 3-10 years. Leasehold improvements are amortized over the term of the related leases or estimated useful lives of the assets, whichever is shorter.

Impairment of Long-Lived Assets

The Company reviews the recoverability of the carrying value of long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be fully recoverable. Should indicators of impairment exist, the carrying values of the assets are evaluated in relation to the operating performance and future undiscounted cash flows of the underlying business. The net book value of an asset is adjusted to fair value if its expected future undiscounted cash flow is less than its book value. No indicators of impairment were identified during the years ended July 31, 2009, 2008 or 2007.

Goodwill and Indefinite-Lived Intangibles

Goodwill, representing the cost of acquired businesses in excess of the fair value of net assets acquired, and indefinite-lived intangibles are not amortized, but are evaluated annually for impairment. The Company performs its annual impairment test as of the first day of its fiscal fourth quarter or if indicators of potential impairment exist. Goodwill is considered impaired if the carrying amount of the reporting unit exceeds its estimated fair value. In assessing the recoverability of goodwill, the Company reviews both quantitative as well as qualitative factors to support its assumptions with regard to fair value. The fair value of a reporting unit, which is based on geographic region, is estimated using both a discounted cash flow model and a weighted average multiple of earnings before interest and taxes from comparable companies. In determining fair value, the Company makes certain judgments, including the identification of reporting units and the selection of comparable companies. If these estimates or their related assumptions change in the future as a result of changes in strategy and/or market conditions, the Company may be required to record an impairment charge. To date, there has been no impairment charges recorded.

Intangible Assets

Intangible assets (exclusive of patents), arose primarily from acquisitions (See Note 2), and primarily consist of customer relationships, trademarks, licenses, employment and non-compete agreements, and website and database content. Finite-lived intangible assets are amortized according to their estimated useful lives, which range from 4 to 15 years.

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The Company has capitalized certain legal costs directly incurred in pursuing patent applications as patent costs. When such applications result in an issued patent, the related costs are amortized over a ten year period or the life of the patent, whichever is shorter, using the straight-line method. The Company reviews its issued patents and pending patent applications, and if it determines to abandon a patent application or that an issued patent no longer has economic value, the unamortized balance in deferred patent costs relating to that patent is immediately expensed.

Comprehensive income (loss)

SFAS No. 130, Reporting Comprehensive Income (SFAS 130), requires reporting and displaying of comprehensive income (loss) and its components. In accordance with SFAS 130, the Accumulated Other Comprehensive Income (Loss), which is comprised of foreign currency translation adjustments, is disclosed as a separate component of stockholders equity. Comprehensive loss consists of net loss and foreign currency translation adjustments. Foreign currency translation adjustments included in comprehensive loss were not tax effected as investments in international affiliates are deemed to be permanent.

Shipping and Handling Costs

Shipping and handling costs associated with the distribution of finished goods to customers are recorded in cost of goods sold.

Research and Development

Research and development costs are charged to expense as incurred.

Advertising

All costs associated with advertising are expensed as incurred. Advertising expense, included in Selling, general and administrative expense, approximated $634,000, $113,000 and $12,000 for the years ended July 31, 2009, 2008 and 2007, respectively.

Income Taxes

The Company accounts for income taxes under the liability method of accounting for income taxes. Under the liability method, deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. The liability method requires that any tax benefits recognized for net operating loss carryforwards and other items be reduced by a valuation allowance when it is more likely than not that the benefits may not be realized. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. Under the liability method, the effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date.

It is the Company s policy to provide for uncertain tax positions and the related interest and penalties based upon management s assessment of whether a tax benefit is more likely than not to be sustained upon examination by tax authorities. At July 31, 2009, the Company believes it has appropriately accounted for any unrecognized tax benefits. To the extent the Company prevails in matters for which a liability for an unrecognized tax benefit is established or is required to pay amounts in excess of the liability, the Company s effective tax rate in a given financial statement period may be affected.

Segment Reporting

The Company follows SFAS No. 131, Disclosures About Segments of an Enterprise and Related Information (SFAS 131) which establishes standards for reporting information on operating segments in interim and annual financial statements. An enterprise is required to separately report information about each operating segment that engages in business activities from which the segment may earn revenues and incur expenses, whose separate operating results are regularly reviewed by the chief operating decision maker regarding allocation of resources and performance assessment and which exceed specific quantitative thresholds related to revenue and profit or loss. The Company s operating activities are reported in three segments (see Note 17).

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Net income (loss) per share

The Company applies SFAS No. 128, Earnings per Share (SFAS 128). SFAS 128 establishes standards for computing and presenting earnings per share. Basic net income (loss) per share represents net income (loss) divided by the weighted average number of common shares outstanding during the period. The dilutive effect of potential common shares, consisting of outstanding stock options and unvested restricted stock, is determined using the treasury stock method in accordance with SFAS 128. Diluted weighted average shares outstanding for fiscal 2009, 2008 and 2007 do not include the potential common shares from stock options and unvested restricted stock because to do so would have been antidilutive. Accordingly, basic and diluted net loss per share is the same in fiscal 2009, 2008 and 2007. The number of potential common shares (in the money options) and unvested restricted stock excluded from the calculation of diluted earnings per share during the years ended July 31, 2009, 2008, and 2007 was 105,000, 240,000, and 619,000, respectively.

For the years ended July 31, 2009, 2008 and 2007, the effect of approximately 1,191,000, 1,734,000 and 873,000 respectively, of outstanding out of the money options to purchase common shares were excluded from the calculation of diluted net loss per share because their effect would be anti-dilutive.

The following table sets forth the computation of basic and diluted net loss per share pursuant to SFAS 128 for the years ended July 31:

In 000 s	**2009**	**2008**	**2007**
Numerator:			
Net loss	$ (23,564)	$ (10,653)	$ (13,260)
Denominator:			
Weighted-average common shares outstanding- Basic	37,511	36,883	35,017
Add: effect of dilutive stock options and restricted stock			
Weighted-average common shares outstanding - Diluted	37,511	36,883	35,017
Net loss per share			
Basic	$ (0.63)	$ (0.29)	$ (0.38)
Diluted	$ (0.63)	$ (0.29)	$ (0.38)

Share-Based Compensation

The Company records compensation expense associated with stock options and restricted stock in accordance with SFAS No. 123(R), Share-Based Payment. The Company adopted the modified prospective application method provided for under SFAS 123(R) and consequently did not retroactively adjust results from prior periods. Under this transition method, compensation cost associated with stock options and awards recognized in the fiscal years ended July 31, 2009, 2008 and 2007, includes: (a) compensation cost of all stock-based payments granted prior to, but not yet vested as of July 31, 2005 (based on grant-date fair value estimated in accordance with the original provisions of SFAS No. 123(R), and (b) compensation cost for all stock-based payments granted on or after August 1, 2005 (based on the grant-date fair value estimated in accordance with the new provision of SFAS No. 123(R)).

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For the years ended July 31, 2009, 2008 and 2007, share-based compensation expense relating to the fair value of restricted shares and restricted stock units vested during the years ended July 31, 2009, 2008 and 2007 was approximately $1,415,000, $1,316,000, and $649,000, respectively (see Note 11). No excess tax benefits were recognized for the year ended July 31, 2009, 2008 and 2007.

The following table sets forth the amount of expense related to share-based payment arrangements included in specific line items in the accompanying Statement of operations for the years ended July 31:

In 000 s	2009	2008	2007
Cost of products	$ 8	$ 14	$ 10
Research and development	13	97	162
Selling, general and administrative	1,414	1,455	1,305
	$ 1,435	$ 1,566	$ 1,477

As of July 31, 2009, there was $1.7 million of total unrecognized compensation cost related to nonvested share-based payment arrangements granted under the Company s stock option and restricted stock plans, which will be recognized over a weighted average remaining life of approximately 1.75 years.

Effect of new accounting pronouncements

In June 2009, the FASB issued SFAS No. 168, The FASB Accounting Standards Codification and the Hierarchy of Generally Accepted Accounting Principles a replacement of FASB Statement No. 162 . SFAS No. 168 establishes the FASB Accounting Standards Codification as the source of authoritative accounting principles and the framework for selecting the principles used in the preparation of financial statements of nongovernmental entities that are presented in conformity with generally accepted accounting principles in the United States. SFAS No. 162 is effective for the Company s interim reporting period ending on October 31, 2009. The Company does not anticipate the adoption of SFAS No. 168 will have a material impact on its financial position, results of operations or cash flows.

In May 2009, the FASB issued SFAS No. 165, Subsequent Events (SFAS 165). SFAS 165 is intended to establish general standards of accounting for and disclosure of events that occur after the balance sheet date but before financial statements are issued or are available to be issued. In particular, SFAS 165 sets forth the period after the balance sheet date during which management of a reporting entity should evaluate events or transactions that may occur for potential recognition or disclosure in the financial statements; the circumstances under which an entity should recognize events or transactions occurring after the balance sheet date in its financial statements; and the disclosures that an entity should make about events or transactions that occurred after the balance sheet date. SFAS 165 is effective for interim or annual financial periods ending after June 15, 2009. During the three months ended July 31, 2009, the Company adopted SFAS SFAS 165. In response to SFAS 165, management has evaluated subsequent events through October 14, 2009, which is the date that the Company s financial statements were filed.

In April 2009, the FASB issued FSP SFAS No. 141(R)-1 Accounting for Assets Acquired and Liabilities Assumed in a Business Combination That Arise from Contingencies . FSP SFAS No. 141(R)-1 will amend the provisions related to the initial recognition and measurement, subsequent measurement and disclosure of assets and liabilities arising from contingencies in a business combination under SFAS No. 141(R), Business Combinations . The FSP will carry forward the requirements in SFAS No. 141, Business Combinations, for acquired contingencies, thereby requiring that such contingencies be recognized at fair value on the acquisition date if fair value can be reasonably estimated during the allocation period. Otherwise, entities would typically account for the acquired contingencies in accordance with SFAS No. 5, Accounting for Contingencies. The FSP will have the same effective date as SFAS No. 141(R), and will therefore be effective for the Company s business combinations for which the acquisition date is on or after August 1, 2009. The Company is currently evaluating the impact of the implementation of FSP SFAS No. 141(R)-1 on its consolidated financial position, results of operations and cash flows.

In April 2009, the FASB issued FSP SFAS No. 107-1 and APB 28-1, Interim Disclosures about Fair Value of Financial Instruments. FSP SFAS No. 107-1 and APB 28-1 enhances consistency in financial reporting by increasing the frequency of fair value disclosures. The FSP relates to fair value disclosures for any financial instruments that are not currently reflected on a company s balance sheet at fair value. Prior to the effective date of this FSP, fair values for these assets and liabilities have only been

disclosed once a year.

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The FSP will now require these disclosures on a quarterly basis, providing qualitative and quantitative information about fair value estimates for all those financial instruments not measured on the balance sheet at fair value. The disclosure requirement under this FSP is effective for the Company s interim reporting period ending on October 31, 2009.

In April 2008, the FASB issued FSP FAS 142-3, Determination of the Useful Life of Intangible Assets (FSP FAS 142-3). FSP FAS 142-3 amends the factors that should be considered in developing renewal or extension assumptions used to determine the useful life of a recognized intangible asset under FASB Statement No.142, Goodwill and Other Intangible Assets. FSP FAS 142-3 also requires expanded disclosure related to the determination of intangible asset useful lives. FSP FAS 142-3 is effective for financial statements issued for fiscal years beginning after December 15, 2008, and interim periods within those fiscal years. The Company is currently evaluating the impact that the adoption of FSP FAS 142-3 will have on its consolidated results of operation, cash flows or financial condition.

In December 2007, the FASB issued Statement No. 141 (revised 2007), Business Combinations (SFAS No. 141R). SFAS No. 141R establishes principles and requirements for how the acquirer in a business combination recognizes and measures in its financial statements the identifiable assets acquired, the liabilities assumed, any controlling interest in the business and the goodwill acquired. SFAS No. 141R further requires that: 1) contingent consideration arrangements will be fair valued at the acquisition date and included on that basis in the purchase price consideration, 2) acquisition-related costs will be expensed as incurred rather than capitalized as part of the purchase price, 3) reversal of valuation allowances created in purchase accounting will be recorded through the income tax provision, 4) in order to accrue for a restructuring plan in purchase accounting, the requirements of SFAS No. 146, Accounting for Costs Associated with Exit or Disposal Activities , would have to be met at the acquisition date. SFAS No. 141R also establishes disclosure requirements that will require disclosure of the nature and financial effects of the business combination. SFAS No. 141R will impact business combinations for the Company that may be completed on or after August 1, 2009. The Company cannot anticipate whether the adoption of SFAS No. 141R will have a material impact on its results of operations and financial condition as the impact is solely dependent on the terms of any business combination entered into by the Company on or after August 1, 2009.

Reclassifications

Certain amounts in prior years have been reclassified to conform to current year presentation. In Fiscal 2009, the Company reclassified certain payroll taxes and employee benefits included in selling, general and administrative expense to cost of sales. The payroll taxes and benefits reclassed were approximately $1,146,000 and $952,000 for the years ended July 31, 2008 and 2007, respectively.

NOTE 2 - Acquisitions Assay Designs, Inc.

On March 12, 2009, Enzo Life Sciences, Inc. and Enzo Life Sciences Acquisition, Inc., a newly formed wholly owned subsidiary of Enzo Life Sciences, Inc. (Acquisition Sub), entered into an asset purchase agreement (Purchase Agreement) dated as of March 12, 2009 with Assay Designs, Inc. (Assay Designs). Assay Designs, a privately owned company with annual sales of approximately $11 million, was engaged in researching, developing, manufacturing, distributing, marketing and selling specialty immunological and biochemical protein detection kits, assays, reagents, antibodies, recombinant proteins and related products and providing related services for use in the biotechnology, pharmaceutical and life sciences research industries (Business). Under the terms of the Purchase Agreement, Acquisition Sub purchased from Assay Designs substantially all of its assets, including trade accounts receivable, inventory, fixed assets, and intellectual property, used in or related to the Business and assumed certain of Assay Designs liabilities, including trade accounts payable, capital lease obligations and certain other current liabilities.

The execution of the Purchase Agreement and the closing of the transaction occurred simultaneously on March 12, 2009. The purchase price consisted of $12,228,000 in cash, exclusive of acquisition costs of approximately $540,000, and was subject to an upward or downward post-closing purchase price adjustment based on Assay Designs working capital as of the closing date and $328,000 representing estimated costs to consolidate an acquired facility and involuntary termination of certain employees, of which $184,000 is outstanding and included in accrued liabilities in the accompanying balance sheet at July 31, 2009. At the closing, $100,000 was held in escrow to secure the payment of any downward post-closing purchase price adjustment and $750,000 was held in escrow for 12 months to secure the payment of any indemnification obligations of Assay Designs under the Purchase Agreement. Subsequent to the acquisition date, the Company paid $270,000 in additional purchase price in connection with the working capital adjustment and released the $100,000 escrow amount.

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The Company expects the cost of the acquisition to be increased when the integration plan to consolidate a facility and the involuntary termination of certain employees is finalized. The Assay Design Acquisition strengthens the Company s position as a global provider of life sciences reagents by broadening our product offerings and manufacturing capabilities.

The acquisition was funded with the Company s cash. Effective March 12, 2009, Assay Designs became a wholly-owned subsidiary of Enzo Life Sciences. The consolidated financial statements include the results of operations for Assay Designs from the date of acquisition.

The following table presents the preliminary estimated fair values of the assets acquired and liabilities assumed (in thousands) as of the date of acquisition:

Current assets	$ 4,235
Property and equipment	1,747
Other assets	11
Intangible assets	6,360
Goodwill	1,803
Total assets acquired	14,156
Less:	
Current liabilities	1,115
Total liabilities assumed	1,115
Net assets acquired	$ 13,041

The preliminary purchase price allocation is based on management s estimate of acquired tangible and intangible assets and will be adjusted based on the final valuation to be completed within one year from the acquisition date. The excess of the total purchase price over the fair value of the net assets acquired, including the estimated fair value of the identifiable intangible assets, has been allocated to goodwill.

Biomol International, L.P.

On May 8, 2008, Enzo Life Sciences, Inc. acquired substantially all of the U.S. based assets and certain liabilities of Biomol International, LP (Biomol LP) through a newly formed US subsidiary Biomol International, Inc. and all of the stock of Biomol s wholly-owned United Kingdom subsidiary, Affinity Limited, through Axxora UK, a wholly-owned subsidiary of Enzo Life Sciences, collectively referred to as Biomol for approximately $18.1 million in cash and stock, subject to adjustment, exclusive of acquisition costs of approximately $800,000 and two contingent earn-out payments accounted for as additional purchase consideration if and when the contingencies are resolved beyond a reasonable doubt. At closing, the purchase price was satisfied as follows: $12.9 million in cash was paid to Biomol LP, issuance of 352,000 shares of Enzo common stock, at fair market value, to Biomol LP, $1.5 million in cash was paid to an escrow agent for the one-year period following the closing to satisfy any indemnification obligations of the sellers under the Agreement and $550,000 was paid to an escrow agent, for the 60 day period following the closing to satisfy any specified purchase price adjustments. The $550,000 was released by the escrow agent in August 2008. The earn-outs of $2.5 million on each of the next two anniversaries of the acquisition date will be based on attaining certain revenue and EBITDA targets, as defined. Biomol was a privately owned, closely held global manufacturer and marketer of specialty life sciences research products. Effective May 8, 2008, Biomol became a wholly-owned subsidiary of Enzo Life Sciences. The acquisition was financed with the Company s cash and cash equivalents and Enzo common stock. The consolidated financial statements include the results of operations for Biomol from the date of acquisition. Effective February 2, 2009, the names of Biomol International, Inc. and Affinity Limited were changed to Enzo Life Sciences International, Inc. and Enzo Life Sciences (UK) Ltd., respectively.

In June 2009, the conditions for the first annual earn-out of $2.5 million were met and the Company recorded $2.5 million of additional goodwill. The Company issued 202,196 shares of Enzo common stock at fair value and paid $1.5 million in cash to satisfy the $2.5 million earn-out liability.

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The following table presents the fair values of the assets acquired and liabilities assumed (in thousands):

Current assets	$ 5,167
Property and equipment	939
Other assets	18
Intangible assets	7,660
Goodwill	9,226
Total assets acquired	23,010
Less:	
Current liabilities	1,100
Deferred tax liabilities	609
Total liabilities assumed	1,709
Net assets acquired	$ 21,301

The purchase price allocation is based on a valuation of acquired tangible and intangible assets based on the final valuation completed in fiscal 2009. The Company determined the estimated fair value of the identifiable intangible assets based on various factors including: cost, discounted cash flow and relief from royalty approaches in determining the purchase price allocation. The excess of the total purchase price over the fair value of the net assets acquired, including the estimated fair value of the identifiable intangible assets, has been allocated to goodwill.

Axxora Life Sciences, Inc.

On May 29, 2007, Enzo Life Sciences entered into a Stock Purchase Agreement (the Agreement), by and among Enzo Life Sciences, Axxora and the stockholders, option holders and warrant holders of Axxora who own all of the issued and outstanding capital stock, options and warrants, respectively, of Axxora (collectively, the Security holders). Pursuant to the Agreement, Enzo Life Sciences purchased all of the issued and outstanding capital stock of Axxora from the Security holders for an aggregate purchase price of $16,322,000, exclusive of acquisition costs of $1,023,000, $475,000 previously advanced to Axxora to repay outstanding debt, and acquired cash of $881,000, which is included in current assets below. Effective May 31, 2007, Axxora became a wholly-owned subsidiary of Enzo Life Sciences. The acquisition was financed with the Company s cash and cash equivalents. The consolidated financial statements presented herein include the results of operations for Axxora from the date of acquisition.

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The following table presents the fair values of the assets acquired and liabilities assumed (in thousands):

Current assets	$ 9,033
Property and equipment	360
Other assets	82
Intangible assets	8,220
Goodwill	6,470
Total assets acquired	24,165
Less:	
Current liabilities	3,919
Deferred tax liabilities	2,426
Total liabilities assumed	6,345
Net assets acquired	$ 17,820

The purchase price allocation is based on a valuation of acquired intangible assets based on the final valuation completed in fiscal 2008. The Company determined the fair value of the identifiable intangible assets based on various factors including: cost, discounted cash flow and relief from royalty approaches in determining the purchase price allocation. The excess of the total purchase price over the fair value of the net assets acquired, including the estimated fair value of the identifiable intangible assets, has been allocated to goodwill.

On March 7, 2008, Axxora acquired 100% of the outstanding stock of a distributor of life science products in Belgium for a total consideration of approximately $229,000 in cash, net of cash acquired, including transaction costs. Liabilities assumed aggregated $369,000. Prior to the acquisition, the acquired company was a distributor of Enzo Life Science s products as well as other unrelated manufacturers. The Company recorded goodwill of $232,000 and intangibles for customer relationships of $174,000 related to this acquisition. The consolidated financial statements presented herein include the results of operations for the acquired company from the date of acquisition. For financial reporting purposes, useful lives for the acquisitions have been assigned as follows:

Customer relationships	8 -15 years
Trademarks	Indefinite
Other intangibles	4-5 years

The following unaudited pro forma financial information presents the combined results of operations of the Company and acquisitions completed in 2009 and 2008 as if the acquisitions had occurred as of August 1, 2007. The pro forma financial information reflects appropriate adjustments for amortization of intangible assets and interest expense. The pro forma financial information presented is not necessarily indicative of either the actual consolidated operating results had the acquisition been completed at the beginning of each period or future operating results of the consolidated entities.

	Year Ended July 31,	
	2009	**2008**
Net revenues	$ 96,227	$ 97,737
Net loss	$ (24,098)	$ (10,381)
Net loss per common share:		

Basic and diluted	$ (0.64)	$ (0.28)

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Note 3- Supplemental disclosure for statement of cash flows

In the years ended July 31, 2009, 2008, and 2007, net income taxes (refunded to) or paid by the Company approximated $220,000, $233,000, and $(1,670,000) respectively.

In fiscal 2009, certain officers of the Company exercised 206,576 stock options in a non-cash transaction. The officers surrendered 99,985 shares of previously acquired common stock to exercise the stock options. The Company recorded approximately $1.1 million, the market value of the surrendered shares, as treasury stock.

In fiscal 2008, certain officers and directors of the Company exercised 220,158 stock options in non-cash transactions. The officers surrendered 181,263 shares of previously owned shares of the Company s common stock to exercise the stock options. The Company recorded approximately $2.4 million, the market value of the surrendered shares, as treasury stock.

In fiscal 2007, certain officers of the Company exercised 43,112 stock options in non-cash transactions. The officers surrendered 26,756 shares of previously owned shares of the Company s common stock to exercise the stock options. The Company recorded approximately $0.4 million, the market value of the surrendered shares, as treasury stock.

Note 4 Short term investments

At July 31, 2009 the Company s short-term investments, whose fair value approximates cost, are in U.S. Government Treasury bills, which are purchased at discounts with remaining maturities of under ninety days.

Effective August 1, 2008, the Company adopted SFAS No. 157, Fair Value Measurements (SFAS 157), for assets and liabilities measured at fair value on a recurring basis. SFAS 157 establishes a common definition for fair value to be applied to existing GAAP that require the use of fair value measurements, establishes a framework for measuring fair value and expands disclosure about such fair value measurements. The adoption of SFAS 157 did not have an impact on the Company s financial position or operating results, but did expand certain disclosures.

SFAS 157 defines fair value as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. Additionally, SFAS 157 requires the use of valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs. These inputs are prioritized below:

Level 1: Observable inputs such as quoted market prices in active markets for identical assets or liabilities.

Level 2: Observable market-based inputs or unobservable inputs that are corroborated by market data.

Level 3: Unobservable inputs for which there is little or no market data, which require the use of the reporting entity s own assumptions.

At July 31, 2009, the Company s short-term investments are classified as Level 1 assets. The Company had no short term investments or marketable securities at July 31, 2008.

Note 5 Accumulated Other Comprehensive Income (Loss)

The following is a summary of accumulated other comprehensive loss, relating to the effect of foreign currency translation:

In 000 s	**Accumulated income (loss) before tax**	**Tax (expense) or benefit**	**Accumulated income (loss) net of tax**
Balance - July 31, 2006			

Fiscal 2007 gain on foreign currency translation	$ 42	$ 42
Balance - July 31, 2007	42	42
Fiscal 2008 gain on foreign currency translation	1,544	1,544
Balance July 31, 2008	1,586	1,586
Fiscal 2009 loss on foreign currency translation	(1,310)	(1,310)
Balance July 31, 2009	$ 276	$ 276

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Note 6 - Inventories

At July 31, 2009 and 2008 inventories, net of reserves of $1,005,000 and $637,000, respectively, consist of:

In 000 s	2009	2008
Raw materials	$ 1,228	$ 341
Work in process	1,072	899
Finished products	6,964	8,274
	$ 9,264	$ 9,514

Note 7 Property, plant, and equipment

At July 31, 2009 and 2008 property, plant, and equipment consist of:

In 000 s	2009	2008
Building and building improvements	$ 4,219	$ 4,199
Laboratory machinery and equipment	6,553	4,002
Office furniture and computer equipment	11,330	8,617
Leasehold improvements	4,430	4,281
	26,532	21,099
Accumulated depreciation and amortization	(15,921)	(12,758)
	10,611	8,341
Land and land improvements	712	712
	$ 11,323	$ 9,053

Note 8 Goodwill and intangible assets

The Company s change in the net carrying amount of goodwill by business segment is as follows (in thousands):

	Enzo Life Sciences	Enzo Clinical Labs	Total
August 1, 2007	$ 6,224	$ 7,452	$ 13,676
Acquisitions see Note 2	7,137		7,137
Foreign currency translation	508		508
July 31, 2008	13,869	7,452	21,321
Acquisition see Note 2	4,303		4,303
Other Adjustments	(148)		(148)
Foreign currency translation	(580)		(580)

July 31, 2009	$ 17,444	$ 7,452	$ 24,896

Intangible assets, all of which are included in the Life Science segment, consist of the following (in thousands):

	July 31, 2009			July 31, 2008		
	Gross	Accumulated Amortization	Net	Gross	Accumulated Amortization	Net
Finite-lived intangible assets:						
Patents	$ 11,027	$ (10,030)	$ 997	$ 11,027	$ (9,929)	$ 1,098
Customer relationships	12,125	(1,190)	10,935	8,314	(392)	7,922
Non-compete and employment agreements	469	(280)	189	481	(126)	355
Website and acquired content	1,005	(303)	702	984	(117)	867
Licensed technology and other	588	(83)	505	737	(29)	708
Indefinitely-lived intangible assets:						
Trademarks	8,681		8,681	6,706		6,706
Total	$ 33,895	$ (11,886)	$ 22,009	$ 28,249	$ (10,593)	$ 17,656

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Estimated amortization expense related to these finite-lived intangible assets for the five succeeding fiscal years ending July 31 is as follows (in thousands):

2010	$ 1,520
2011	1,421
2012	1,337
2013	1,292
2014	1,211

At July 31, 2009, the weighted average useful lives of amortizable intangible assets were approximately 10 years.

Amortization expense for the years ended July 31, 2009, 2008, and 2007 was $1,277,000, $658,000, and $151,000, respectively.

Note 9 - Income taxes

The Company accounts for income taxes under the provisions of SFAS 109. The (provision) benefit for income taxes is as follows:

Fiscal year ended July 31, (in 000 s)	**2009**	**2008**	**2007**
Current (provision) benefit:			
Federal	$	$	$
State and local	(75)	(320)	(261)
Foreign	(12)	(85)	(2)
Deferred benefit (provision)		644	178
(Provision) benefit for income taxes	$ (87)	$ 239	$ (85)

Deferred tax assets and liabilities arise from temporary differences between the tax basis of assets and liabilities and their reported amounts in the financial statements. The components of deferred tax assets (liabilities) as of July 31, 2009 and 2008 are as follows:

In 000 s	**July 31, 2009**	**July 31, 2008**
Deferred tax assets:		
Federal tax carryforward losses	$ 16,507	$ 10,693
Provision for uncollectible accounts receivable	1,763	309
State and local tax carry forward losses	2,080	1,478
Accrued royalties	279	456
Stock compensation	794	505
Depreciation	152	46
Research and development and other tax credit carryforwards	618	530
Realized and unrealized losses on marketable securities	138	138
Inventory	261	
Other, net	251	236
Gross deferred tax assets	22,843	14,391
Deferred tax liabilities:		
Deferred patent costs	(235)	(252)
Inventory		(265)
Intangibles	(2,730)	(3,039)

Prepaid expenses	(657)	(686)
Other, net	(84)	(75)
Gross deferred tax liabilities	(3,706)	(4,317)
Net deferred tax assets (liabilities) before valuation allowance	19,137	10,074
Less: valuation allowance	(21,716)	(12,965)
Net deferred tax assets (liabilities)	$ (2,579)	$ (2,891)

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At July 31, 2009, the Company had net deferred tax liabilities of approximately $2.6 million which consists primarily of identifiable intangible assets and cumulative tax deductions in excess of book expenses recognized by foreign subsidiaries (see Note 2).

Deferred tax liabilities are included in the consolidated balance sheets as follows:

In 000 s	July 31, 2009	July 31, 2008
Deferred taxes:		
Current	$ 213	$ 458
Non-current	2,366	2,433
	$ 2,579	$ 2,891

Pursuant to SFAS 109, the Company recorded a valuation allowance during the year ended July 31, 2009 and 2008 equal to domestic and certain foreign net deferred tax assets. The Company believes that the valuation allowance is necessary as it is not more likely than not that the deferred tax assets will be realized in the foreseeable future based on positive and negative evidence available at this time. This conclusion was reached because of uncertainties relating to future taxable income, in terms of both its timing and its sufficiency, which would enable the Company to realize the deferred tax assets.

As of July 31, 2009, the Company had U.S. federal net operating loss carryforwards of approximately $45.8 million. The U.S. federal tax loss carryforwards, if not fully utilized, expire between 2011 and 2029. Utilization is dependent on generating sufficient taxable income prior to expiration of the tax loss carryforwards. As of July 31, 2009, the Company has state and local tax loss carryforwards of approximately $56.8 million.

As a result of the acquisition described in Note 2 Axxora Acquisition, approximately $1.4 million of the Company s U.S. federal net operating loss carryforwards are subject to an annual limitation under Internal Revenue Code Section 382 due to the ownership change. However, management does not believe that such a change would have a significant impact on the Company s ability to utilize its tax loss carryforwards.

The components of loss before income taxes consisted of the following for the years ended July 31:

In 000 s	2009	2008	2007
United States operations	$ (21,221)	$ (9,605)	$ (12,595)
International operations	(2,256)	(1,287)	(580)
Loss before taxes	$ (23,477)	$ (10,892)	$ (13,175)

The benefit (provision) for income taxes were at rates different from U.S. federal statutory rates for the following reasons:

Year ended July 31,	2009	2008	2007
Federal statutory rate	34%	34%	34%
Expenses not deductible for income tax return purposes	(0.4)%	(1.1%)	(3.0%)
State income taxes, net of (benefit) of federal tax deduction	2.5%	1.4%	(1.0%)
Change in valuation allowance	(37.8)%	(32.9%)	(30.0%)
Other	1.3%	0.8%	(1.0%)

(0.4)%	2.2%	(1.0%)

U.S. federal income taxes have not been provided on the undistributed earnings of approximately $238,000 at July 31, 2009 of the Company s foreign subsidiaries, because the determination of the amount of unrecognized US income tax liability with respect to such earnings is not practicable.

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The Company adopted the provisions of FIN 48 on August 1, 2007. The cumulative effect of adopting FIN 48 did not have a material impact on the Company s financial position or results of operations. A reconciliation of the beginning and ending amount of unrecognized tax benefits is as follows:

In 000 s

Balance at August 1, 2008	$ 291
Additions for tax positions related to prior years	
Additions for tax positions related to current year	
Reductions for lapse of statute of limitations	(157)
Tax audit settlements	(24)
Balance at July 31, 2009	$ 110

Approximately $97,000 of the FIN 48 liability at July 31, 2009, which relates to the Axxora acquisition described in Note 2, can be completely reduced within the next two months with the lapse of the statute of limitations. The amount, if recognized, would not affect the Company s effective tax rate.

Interest and penalties related to income tax liabilities are included in income tax expense. During the fiscal year ended July 31, 2009, the Company recognized a net decrease of approximately $2,000. The Company has accrued approximately $24,000 for the payment of interest and penalties as of July 31, 2009 and had accrued approximately $64,000 as of July 31, 2008.

The Company files income tax returns in the U.S. Federal jurisdiction, various U.S. state jurisdictions and several foreign jurisdictions. With few exceptions, the years that remain subject to examination are fiscal July 31, 2006 through fiscal 2008.

Note 10 Accrued Liabilities and Other Current Liabilities

At July 31, 2009 and 2008, accrued liabilities consist of:

In 000 s	**2009**	**2008**
Legal	$ 1,095	$ 1,702
Payroll, benefits, and commissions	2,737	1,989
Research and development	656	1,200
Professional fees	1,752	584
Outside reference lab testing	65	46
Other	2,121	1,849
	$ 8,426	$ 7,370

At July 31, 2009 and 2008, other current liabilities consist of:

In 000 s	**2009**	**2008**
Deferred revenue	$ 850	$ 1,089
Other	212	72
	$ 1,062	$ 1,161

Note 11 Stockholders equity

Common stock offerings

In June 2009, the Company issued 202,196 shares of common stock at a fair value of $1.0 million in connection with the Biomol earn-out of $2.5 million (see Note 2).

During fiscal 2007, the Company entered into two Placement Agent Agreements with Lazard Capital Markets LLC, as exclusive placement agent, relating to registered direct offerings (Offerings) of shares of the Company s common stock. In December 2006, the Company entered into a definitive Subscription Agreement with various institutional investors relating to the sale of an aggregate of 3,285,715 shares of common stock for a purchase price of $14.00 per share.

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Net proceeds from the Offering aggregating $42.9 million, net of placement fees and financing costs of $3.1 million, were credited to common stock and additional paid-in capital. In February 2007, the Company entered into the second definitive Subscription Agreement with an investor for the sale of an aggregate of 1,000,000 shares of common stock for a purchase price of $15.00 per share. Net proceeds from this Offering aggregated $14.1 million, net of placement fees and financing costs of $0.9 million, and were credited to common stock and additional paid in capital. The Company filed prospectus supplements with the SEC relating to the Offerings under a Registration Statement filed and supplement thereto.

Treasury stock

In fiscal 2009, certain officers of the Company exercised 206,576 stock options in a non-cash transaction. The officers surrendered 99,985 shares of previously acquired common stock to exercise the stock options. The Company recorded approximately $1.1 million, the market value of the surrendered shares, as treasury stock.

In fiscal 2009, the Company issued 142,150 shares from treasury stock for its employees 401(k) matched contributions obligation. The Company recorded approximately $2.0 million, the average acquisition cost of the shares, as a reduction of treasury stock (see Note 3).

In fiscal 2008, certain officers and a director of the Company exercised 220,158 stock options in a non-cash transaction. The officers and director surrendered 181,263 previously owned shares of the Company s common stock to exercise the stock options. The Company recorded approximately $2.4 million, the market value of surrendered shares, as treasury stock.

In fiscal 2007, certain officers of the Company exercised 43,112 stock options in a non-cash transaction. The officers surrendered 26,756 shares of previously owned shares of the Company s common stock to exercise the stock options. The Company recorded approximately $0.4 million, the market value of the surrendered shares, as treasury stock.

Incentive stock option plans

The Company has incentive stock option plans (the 1994 Plan and 1999 Plan) and an incentive stock option and restricted stock award plan (the 2005 Plan), collectively the Plans , under which the Company may grant options for up to 1,336,745 common shares under the 1994 plan, options for up to 2,312,356 common shares under the 1999 Plan and options and restricted stock awards for up to 1,000,000 common shares under the 2005 Plan. No additional options may be granted under the 1994 or 1999 Plans. The exercise price of options granted under such plans is equal to or greater than fair market value of the common stock on the date of grant. The options granted pursuant to the plans may be either incentive stock options or non statutory options. Stock options generally become exercisable at 25% per year after one year and expire ten years after the date of grant. The 2005 Plan provides for the issuance of restricted stock and restricted stock unit awards which generally vest over a two to four year period.

As of July 31, 2009, there were approximately 401,000 shares available for grant under the Company s 2005 Plan.

A summary of the information pursuant to the Company s stock option plans for the years ended July 31, 2009, 2008, and 2007 is as follows:

	2009		2008		2007	
	Options	Weighted - Average Exercise Price	Options	Weighted - Average Exercise Price	Options	Weighted - Average Exercise Price
Outstanding at beginning of year	2,275,415	$ 13.13	2,700,457	$ 13.32	2,877,727	$ 13.20
Granted		$		$	27,761	$ 17.06
Exercised	(251,162)	$ 5.87	(267,345)	$ 10.80	(95,525)	$ 9.60
Cancelled	(832,734)	$ 13.87	(157,697)	$ 20.42	(109,506)	$ 14.36

Outstanding at end of year	1,191,519	$	14.41	2,275,415	$	13.13	2,700,457	$ 13.32
Exercisable at end of year	1,191,519	$	14.41	2,250,483	$	13.12	2,670,680	$ 13.32
Weighted average fair value of options granted during year		$						$ 4.42

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The aggregate intrinsic value of stock options exercised during the years ended July 31, 2009, 2008 and 2007, including the non-cash transactions (see Note 3) was $1.4 million, $0.7 million and $0.7 million, respectively. There is no aggregate intrinsic value of options both outstanding and exercisable at July 31, 2009.

The following table summarizes information for stock options outstanding at July 31, 2009:

	Options outstanding and exercisable		
Range of Exercise prices	Shares	Weighted-Average Remaining Contractual Life in years	Weighted-Average Exercise Price
$8.33-12.25	621,083	2.7	11.89
$12.93-19.02	544,388	4.6	16.95
$20.20-24.84	26,048	2.2	21.54
	1,191,519		

During the year ended July 31, 2007, the Company granted 27,761 options under a two year consulting arrangement with a former employee with an exercise price of $17.06 which were fully vested at the inception of the arrangement. The assumptions used to fair value this option grant as of May 2, 2007 were as follows: risk free interest rate of 4.65%, expected term of 2 years, expected volatility of 40%, and no dividend yield. The fair value of the options of approximately $123,000 was recognized as an expense and included in selling, general and administrative expense in the accompanying statement of operations for the year ended July 31, 2007.

Restricted Stock Awards

During fiscal 2009, 2008 and 2007, the compensation committee of the Company s board of directors approved grants of 291,801, 160,140 and 97,700 of restricted stock and restricted stock unit awards (the Awards), respectively, under the 2005 Plan to the Company s directors, certain officers and employees. The Awards vest upon the recipient s continued employment or director service ratably over either two, three or four years. Share-based compensation expense is recorded over the vesting period on a straight-line basis. The Awards will be forfeited if the recipient ceases to be employed by or serve as a director of the Company, as defined in the Award grants. The Awards settle in shares of the Company s common stock on a one-for-one basis. As of July 31, 2009, 377,400 shares were unvested.

A summary of the information pursuant to the Company s Restricted Stock Awards for the years ended July 31, 2009, 2008 and 2007 is as follows:

	2009		2008		2007	
	Awards	Weighted - Average Award Price	Awards	Weighted - Average Award Price	Awards	Weighted - Average Award Price
Outstanding at beginning of year	220,240	$ 12.34	141,062	$ 14.15	77,450	12.21
Awarded	291,801	$ 4.05	160,140	$ 11.42	97,700	$ 15.16
Vested	(128,941)	$ 12.11	(70,962)	$ 13.55	(25,913)	12.34
Forfeited	(5,700)	$ 10.18	(10,000)	$ 14.73	(8,175)	$ 13.60
Outstanding at end of year	377,400	$ 6.05	220,240	$ 12.34	141,062	$ 14.15

Weighted average market value of awards granted during year	$ 4.05	$ 11.42	$ 15.16

Note 12 - Employee benefit plan

The Company has a qualified Salary Reduction Profit Sharing Plan (the Plan) for eligible U.S. employees under Section 401(k) of the Internal Revenue Code. The Plan provides for voluntary employee contributions through salary reduction and voluntary employer contributions at the discretion of the Company. For the years ended July 31, 2009, 2008, and 2007, the Company authorized employer matched contributions of 50% of the employees contribution up to 10% of the employees compensation, payable in Enzo Biochem, Inc. common stock. The 401 (k) employer matched contributions expense was approximately 582,000, 481,000, and 421,800, in fiscal years 2009, 2008, and 2007, respectively.

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The Company s Swiss operations provide a pension plan under the Swiss government s social security system for Swiss employees. Employees are required to contribute based on a formula and the Company s Swiss operations make contributions of at least 50% of the employee contribution. During the years ended July 31, 2009 and 2008 and the two months ended July 31, 2007, the period after the acquisition of Axxora Life Sciences, Inc., the employer contributions related to the Swiss benefit pension plan was approximately $399,000, $325,000, and $58,000, respectively.

Pension expense at the other international operations was approximately $36,000 and $3,000 for the years ended July 31, 2009 and 2008, respectively

Note 13 Royalty and other income

In fiscal 2007, The Company as plaintiff and Sigma Aldrich (Sigma) entered into a Settlement Agreement and Release (the Settlement Agreement). Pursuant to the Settlement Agreement, the Company s litigation with Sigma was dismissed and the Company recognized a $2 million gain on patent litigation settlement which is included in Other income in the accompanying statement of operations for the year ended July 31, 2007 (see Note 16).

In fiscal 2007, the Company received a payment of approximately $699,000 from Perkin Elmer Inc. (Perkin Elmer) for amounts due under a Distribution Agreement (the Distribution Agreement) which terminated December 31, 2004. The Distribution Agreement is presently subject to a lawsuit for breach of contract, patent infringement, unfair competition under state law, unfair competition under federal law, tortuous interference with business relations, and fraud in the inducement of contract (See Note 16). Perkin Elmer advised in a letter to the Company that the payment was owed under the Distribution Agreement and was delayed because of changes to their accounting system and personnel changes and that it was always their intent to comply with the Distribution Agreement. The Company advised Perkin Elmer that the payment did not represent all amounts owed under the Distribution Agreement. Accordingly, the payment is included in Other income in the accompanying statement of operations for the year ended July 31, 2007.

In fiscal 2005, the Company as plaintiff finalized and executed a settlement and license agreement with Digene Corporation to settle a patent litigation lawsuit (the Agreement). Under the terms of the Agreement, the Company received an initial payment of $16.0 million, would earn in the first annual period (October 1, 2004 to September 30, 2005) a minimum royalty payment of $2.5 million, and receive a minimum royalty of $3.5 million in each of the next four annual periods. Digene Corporation was acquired by QIAGEN. The license agreement with the Company was assigned to QIAGEN Gaithersburg Inc. (Qiagen). In addition, the Agreement provides for the Company to receive quarterly running royalties on the net sales of Qiagen products subject to the license until the expiration of the patent on April 24, 2018. These quarterly running royalties are fully creditable against the minimum royalty payments due in the first five years of the Agreement. The balance, if any, of the minimum royalty payment is recognized in the final quarter of the applicable annual royalty period. During the years ended July 31, 2009, 2008 and 2007, the Company recorded royalty income under the Agreement of approximately $6.7 million, $5.5 million, and $4.7 million, respectively, which is included in the Life Sciences segment.

Note 14 - Licensing and Supply Agreement:

On April 27, 2007 (the Effective Date) Enzo Life Sciences, Inc. (Life Sciences) and Abbott Molecular Inc. (Abbott) entered into a 5 year agreement covering the supply of certain of Enzo Life Sciences products to Abbott for use in their product line. The parties also entered into a limited non-exclusive royalty bearing cross-licensing agreement (Licensing Agreement) for various patents. The Licensing Agreement requires each party to pay royalties, as defined through the lives of the related covered patents. In connection with a component of the License Agreement, Abbott paid a one-time fee of $1.5 million relating to a fully paid-up license and sublicense, as defined. The one-time fee will be recognized as revenue over the longest expected patent life. At July 31, 2009, the Company s balance sheet includes current and non-current deferred revenue of approximately $0.4 and $0.1 million, respectively, relating to the one-time fee. During the years ended July 31, 2009, 2008 and 2007, the Company recorded approximately $2.7 million, $2.1 million and $1.0 million in royalties and license fee income under the Licensing Agreement.

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Note 15 Commitments

Leases

The Company leases equipment, office and laboratory space under several non-cancelable operating leases that expire between March 2010 and March 2017. Certain leases include renewal options and rent escalation clauses. An entity owned by certain executive officers/directors of the Company owns the building that the Company leases as its main facility for laboratory operations and certain research operations. In March 2005, the Company amended and extended the lease for another 12 years. In addition to the minimum annual rentals of space, the lease is subject to annual increases, based on the consumer price index. Annual increases are limited to 3% per year. Rent expense, inclusive of real estate taxes, approximated $1,424,000, $1,395,000, and $1,376,000 during fiscal years 2009, 2008, and 2007.

Total rent expense incurred by the Company during fiscal 2009, 2008 and 2007 was approximately $3,818,000, $2,885,000, and $2,510,000, respectively. Minimum future annual rentals under non-cancelable operating leases as of July 31, 2009, are as follows:

Years ended July 31,	In 000 s
2010	$ 4,410
2011	4,090
2012	3,105
2013	2,623
2014	1,942
Thereafter	4,146
	$ 20,316

Employment Agreements

The Company has employment agreements with certain officers that are cancelable at any time but provide for severance pay in the event an officer is terminated by the Company without cause, as defined in the agreements. Unless cancelled earlier, the contracts expire through May 2010. Aggregate minimum compensation commitments, exclusive of any severance provisions, for the years ending July 31, 2010 and 2011 are $1,948,000 and $1,211,000 respectively.

Note 16 Contingences

In October 2002, the Company filed suit in the United States District Court of the Southern District of New York against Amersham plc, Amersham Biosciences, Perkin Elmer, Inc., Perkin Elmer Life Sciences, Inc., Sigma-Aldrich Corporation, Sigma Chemical Company, Inc., Molecular Probes, Inc. and Orchid Biosciences, Inc. In January 2003, the Company amended its complaint to include defendants Sigma Aldrich Co. and Sigma Aldrich, Inc. The counts set forth in the suit are for breach of contract; patent infringement; unfair competition under state law; unfair competition under federal law; tortious interference with business relations; and fraud in the inducement of contract. The complaint alleges that these counts arise out of the defendants breach of distributorship agreements with the Company concerning labeled nucleotide products and technology, and the defendants infringement of patents covering the same. In April, 2003, the court directed that individual complaints be filed separately against each defendant. The defendants have answered the individual complaints and asserted a variety of affirmative defenses and counterclaims.

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Fact discovery is ongoing. The court issued a claim construction opinion on July 10, 2006. The Company and Sigma Aldrich (Sigma) entered into a Settlement Agreement and Release effective September 15, 2006 (the Agreement). Pursuant to the Agreement, the Company s litigation with Sigma was dismissed and the Company recognized $2 million on settlement in the quarter ending October 31, 2006. On January 3, 2007, the remaining defendants moved for summary judgment on all counts in the individual complaints. During a two-day hearing held on July 17 through July 18, 2007, the defendants subsequently withdrew the invalidity portion of their summary judgment motions. The court has yet to rule on the pending summary judgment motions. There can be no assurance that the Company will be successful with the remaining outstanding litigation. However, even if the Company is not successful, management does not believe that there will be a significant adverse monetary impact to the Company. The Company has not recorded revenue under these distribution agreements in fiscal 2009, 2008 and 2007. The Company recorded other income from Perkin Elmer in fiscal 2007 (See Note 13).

On October 28, 2003, the Company and Enzo Life Sciences, Inc., filed suit in the United States District Court of the Eastern District of New York against Affymetrix, Inc (Affymetrix). The Complaint alleges that Affymetrix improperly transferred or distributed substantial business assets of the Company to third parties, including portions of the Company s proprietary technology, reagent systems, detection reagents and other intellectual property. The Complaint also charges that Affymetrix failed to account for certain shortfalls in sales of the Company s products, and that Affymetrix improperly induced collaborators and customers to use the Company s products in unauthorized fields or otherwise in violation of the agreement. The Complaint seeks full compensation from Affymetrix to the Company for its substantial damages, in addition to injunctive and declaratory relief to prohibit, among other things, Affymetrix s unauthorized use, development, manufacture, sale, distribution and transfer of the Company s products, technology, and/or intellectual property, as well as to prohibit Affymetrix from inducing collaborators, joint venture partners, customers and other third parties to use the Company s products in violation of the terms of the agreement and the Company s rights. Subsequent to the filing of the Complaint against Affymetrix, Inc. referenced above, on or about November 10, 2003, Affymetrix, Inc. filed its own Complaint against the Company and its subsidiary, Enzo Life Sciences, Inc., in the United States District Court for the Southern District of New York, seeking among other things, declaratory relief that Affymetrix, Inc., has not breached the parties agreement, that it has not infringed certain of Enzo s Patents, and that certain of Enzo s patents are invalid. The Affymetrix Complaint also seeks damages for alleged breach of the parties agreement, unfair competition, and tortuous interference, as well as certain injunction relief to prevent alleged unfair competition and tortuous interference. The Company does not believe that the Affymetrix Complaint has any merit and intends to defend vigorously. Affymetrix also moved to transfer venue of Enzo s action to the Southern District of New York, where other actions commenced by Enzo were pending as well as Affymetrix s subsequently filed action. On January 30, 2004, Affymetrix s motion to transfer was granted. Accordingly, the Enzo and Affymetrix actions are now both pending in the Southern District of New York. Initial pleadings have been completed and discovery has commenced. The Court issued a Markman (claim construction) opinion on July 10, 2006. The Company has not recorded any revenue from Affymetrix during the fiscal years ended July 31, 2009, 2008 or 2007.

On June 2, 2004, Roche Diagnostic GmbH and Roche Molecular Systems, Inc. (collectively Roche) filed suit in the U.S. District Court of the Southern District of New York against Enzo Biochem, Inc. and Enzo Life Sciences, Inc. (collectively Enzo). The Complaint was filed after Enzo rejected Roche s latest cash offer to settle Enzo s claims for, *inter alia*, alleged breach of contract and misappropriation of Enzo s assets. The Complaint seeks declaratory judgment (i) of patent invalidity with respect to Enzo s 4,994,373 patent (the 373 patent), (ii) of no breach by Roche of its 1994 Distribution and Supply Agreement with Enzo (the 1994 Agreement), (iii) that non-payment by Roche to Enzo for certain sales of Roche products does not constitute a breach of the 1994 Agreement, and (iv) that Enzo s claims of ownership to proprietary inventions, technology and products developed by Roche are without basis. In addition, the suit claims tortious interference and unfair competition. The Company does not believe that the Complaint has merit and intends to vigorously respond to such action with appropriate affirmative defenses and counterclaims. Enzo filed an Answer and Counterclaims on November 3, 2004 alleging multiple breaches of the 1994 Agreement and related infringement of Enzo s 373 patent. Discovery has commenced. The Court issued a Markman opinion on July 10, 2006. The Company did not record any revenue from Roche during the fiscal years ended July 31, 2009, 2008 or 2007. The Roche agreement remains in force to date.

On June 7, 2004, the Company and Enzo Life Sciences, Inc., filed suit in the United States District Court for the District of Connecticut against Applera Corporation and its wholly-owned subsidiary Tropix, Inc. The complaint alleges infringement of six patents (relating to DNA sequencing systems, labeled nucleotide products, and other technology).

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Yale University is the owner of four of the patents and the Company is the exclusive licensee. These four patents are commonly referred to as the Ward patents. Accordingly, Yale is also a plaintiff in the lawsuit. Yale and Enzo are aligned in protecting the validity and enforceability of the patents. Enzo Life Sciences is the owner of the remaining two patents. The complaint seeks permanent injunction and damages (including treble damages for willful infringement). Defendants answered the complaint on July 29, 2004. The answer pleads affirmative defenses of invalidity, estoppels and laches and asserts counterclaims of non-infringement and invalidity. A Markman hearing was held on May 25, 2006 and the district court issued a ruling on October 12, 2006. On August 17, 2007, the Company voluntarily dismissed the infringement claims for one of the patents in suit without prejudice. Defendants similarly dismissed their defenses and counterclaims as to that patent. On the same date, the Company conceded a judgment of non-infringement for another of the patents in suit based on the district court s claim construction, reserving the right to appeal their construction. The defendants filed motions for summary judgment for invalidity, laches and non-infringement of the Ward patents on March 5, 2007. The Company and other plaintiff filed a motion for summary judgment on infringement of the Ward patents on March 5, 2007. On August 20, 2007, the district court heard oral arguments on the motions for summary judgment. On September 6, 2007, the court granted defendants motion for summary judgment of invalidity of three of the remaining Ward patents and entered judgment to that effect. The Company and other plaintiff filed a notice of appeal to the United States Court of Appeals for the Federal Circuit on September 7, 2007. On January 30, 2008, the Court of Appeals for the Federal Circuit granted the Company s alternative motion to dismiss its appeal and remand to the Connecticut Court for further proceedings incident to an entry of a final, appealable judgment. The Company requested the Connecticut Court to dispose of all outstanding issues (including the Company s claim under the fourth Ward patent and certain counterclaims of Applera s) and enter final judgment. The Connecticut Court granted this request. The Company subsequently filed an Appeal on April 7, 2009. Briefing is completed and the matter has not yet been set for submission or argument. The Company and other plaintiff intend to vigorously argue this appeal; however, the outcome of the appeal cannot be anticipated at this time. If the appeal is granted, there can be no assurance that the Company will be successful in this litigation. Even if the Company is not successful, management does not believe that there will be a significant adverse monetary impact on the Company.

In January 2006, the Company was named along with certain of its officers and directors among others, in several complaints titled Francis Scott Hunt, et al. v. Enzo Biochem Inc., et al., Index No. 06-CV-00170 (SAS) and Ken Roberts v. Enzo Biochem, Inc. et al., Index No. 06-CV-00213 (SAS), and Paul Lewicki v. Enzo Biochem Inc., et al., Index No. 06-CV-06347 (SAS) based only upon a claim for common law fraud. These three consolidated actions were all filed in the United States District Court for the Southern District of New York (the Court). The actions seek damages in excess of $8 million and are all based on allegations of a fraudulent scheme to pump and dump Enzo securities as was initially set forth in a previous action (filed by the same attorney) which was dismissed by the Eastern District of Virginia and such dismissal was thereafter affirmed by the Fourth Circuit Court of Appeals and is now final since the U.S. Supreme Court denied a petition for certiorari. The Company and the other defendants likewise moved to dismiss all of the Complaints in these actions and that motion was granted by the Court. As a result, some of the Plaintiffs were no longer able to pursue their claims or choose not to pursue them further. Other Plaintiffs amended their Complaints and the Company and the other defendants moved once again to dismiss those Amended Complaints. The Court granted in part and denied in part those motions. The remaining Plaintiffs then conducted discovery, and following the completion of discovery, the Company and other defendants moved for summary judgment dismissal of the Amended Complaints. The Court recently granted the defendants motion and dismissed all the Amended Complaints. Several of the Plaintiffs then filed a notice of appeal to the Second Circuit Court of Appeals. The Company believes that the latest complaints in these actions have no merit and that the appeals also lacks merit. The Company will continue to defend these actions vigorously.

Shahram K. Rabbani (Mr. Rabbani), the Secretary and Treasurer and a member of the board of directors of the Company and the former President of Enzo Clinical Labs, Inc., in connection with the termination of his employment, submitted on April 30, 2009 a demand for arbitration and related statement of claim to the American Arbitration Association. The statement of claim names the Company, Dr. Elazar Rabbani, the Chairman of the Board and Chief Executive Officer of the Company, and Barry W. Weiner, the President and Chief Financial Officer and a member of the board of directors of the Company, as respondents and alleges, among other things, claims relating to the termination of Mr. Rabbani s employment as President of Clinical Labs. The statement of claim purports to allege claims for breach of contract against the Company, unlawful retaliation under the Sarbanes-Oxley s whistleblower statute (the Claims) against the Company, Dr. Rabbani and Mr. Weiner, and tortious interference with contract against Dr. Rabbani and Mr. Weiner. Mr. Rabbani seeks damages of no less than $10 million including attorneys fees, costs, and punitive damages. The Company believes the Claims are without merit and intends to defend vigorously against them.

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Subsequent to April 30, 2009, the Company conducted a review, as directed by a special committee of the Board of Directors, relating to the aforementioned Claims pertaining to Enzo Clinical Labs. The review concluded that the purported Claims were unsubstantiated.

On September 18, 2009, Mr. Rabbani amended his statement of claim to add a claim for defamation against the Company and a claim against the Company, Dr. Rabbani and Mr. Weiner seeking a declaratory judgment. The Company also believes these additional claims are without merit and intends to defend vigorously against them

The Company is party to other claims, legal actions and complaints that arise in the ordinary course of business. The Company believes that any liability that may ultimately result from the resolution of these matters will not, individually or in the aggregate, have a material adverse effect on its financial position or results of operations.

Note 17 Segment reporting

The Company has three reportable segments: Life Sciences, Therapeutics and Clinical Labs. The Company s Life Sciences segment develops, manufactures, and markets products to research and pharmaceutical customers. The Company s Therapeutic segment conducts research and development activities for therapeutic drug candidates. The Clinical Labs segment provides diagnostic services to the health care community. The Company evaluates segment performance based on segment income (loss) before taxes. Costs excluded from segment income (loss) before taxes and reported as Other consist of corporate general and administrative costs which are not allocable to the three reportable segments.

Management of the Company assesses assets on a consolidated basis only and therefore, assets by reportable segment have not been included in the reportable segments below. The accounting policies of the reportable segments are the same as those described in the summary of significant accounting policies.

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The following financial information (in thousands) represents the operating results of the reportable segments of the Company:

Year ended July 31, 2009

Revenues:	Life Sciences	Therapeutics	Clinical Labs	Other	Consolidated
Product revenues	$ 40,592				$ 40,592
Royalty income and license fee income	9,376				9,376
Clinical laboratory services			$ 39,604		39,604
	49,968		39,604		89,572
Cost and expenses and other (income):					
Cost of product revenues	26,766				26,766
Cost of clinical laboratory services			26,295		26,295
Research and development	5,855	$ 3,365			9,220
Provision for uncollectible accounts			5,189		5,189
Selling, general and administrative and legal	14,938		15,498	$ 15,073	45,509
Interest income			(57)	(524)	(581)
Other income	(25)		(49)		(74)
Foreign exchange loss (gain)	725				725
Income (loss) before income taxes	$ 1,709	$ (3,365)	$ (7,272)	$ (14,549)	$ (23,477)
Depreciation and amortization included above	$ 2,350	$ 50	$ 946	$ 116	$ 3,462
Share - based compensation included in					
Cost of products			$ 8		$ 8
Research and development	$ 13				13
Selling, general and administrative and legal	128	$ 119	135	$ 1,032	1,414
Total	$ 141	$ 119	$ 143	$ 1,032	$ 1,435
Capital expenditures	$ 1,334	$ 78	1,253	$ 44	$ 2,709

Year ended July 31, 2008

Revenues:	Life Sciences	Therapeutics	Clinical Labs	Other	Consolidated
Product revenues	$ 28,087				$ 28,087
Royalty and license fee income	7,630				7,630
Clinical laboratory services			$ 42,078		42,078
	35,717		42,078		77,795
Cost and expenses and other (income):					
Cost of product revenues	19,159				19,159
Cost of clinical laboratory services			22,209		22,209

Research and development	3,473	$ 5,164			8,637
Provision for uncollectible accounts			3,716		3,716
Selling, general and administrative and legal	9,779		14,349	$ 14,732	38,860
Interest income			(239)	(3,457)	(3,696)
Other income	(71)	(100)			(171)
Foreign exchange loss (gain)	(27)				(27)
Income (loss) before income taxes	$ 3,404	$ (5,064)	$ 2,043	$ (11,275)	$ (10,892)
Depreciation and amortization included above	$ 1,138	$ 35	$ 853	$ 120	$ 2,146
Share - based compensation included in					
Cost of products	$ 8		$ 6		$ 14
Research and development	34	$ 63			97
Selling, general and administrative and legal	129		247	$ 1,079	1,455
Total	$ 171	$ 63	$ 253	$ 1,079	$ 1,566
Capital expenditures	$ 2,308	$ 63	$ 797	$ 63	$ 3,231

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Year ended July 31, 2007

Revenues:	**Life Sciences**	**Therapeutics**	**Clinical Labs**	**Other**	**Consolidated**
Product revenues	$ 6,658				$ 6,658
Royalty and license fee income	5,820				5,820
Clinical laboratory services			$ 40,430		40,430
	12,478		40,430		52,908
Cost and expenses and other (income):					
Cost of product revenues	5,034				5,034
Cost of clinical laboratory services			19,151		19,151
Research and development	3,349	$ 6,044			9,393
Provision for uncollectible accounts			4,653		4,653
Selling, general and administrative and legal	2,772		13,451	$ 19,420	35,643
Interest income			(99)	(4,993)	(5,092)
Other income	(2,699)				(2,699)
Income (loss) before income taxes	$ 4,022	$ (6,044)	$ 3,274	$ (14,427)	$ (13,175)
Depreciation and amortization included above	$ 288	$ 16	$ 838	$ 47	$ 1,189
Share - based compensation included in					
Cost of products	$ 10				$ 10
Research and development	51	$ 111			162
Selling, general and administrative and legal	66		$ 358	$ 881	1,305
Total	$ 127	$ 111	$ 358	$ 881	$ 1,477
Capital expenditures	$ 106	$ 82	$ 698	$ 562	$ 1,448

Geographic financial information is as follows (in thousands):

Net sales to unaffiliated customers:	**2009**	**2008**	**2007**
United States	$ 75,936	$ 62,243	$ 50,051
Switzerland	6,487	9,142	945
United Kingdom	2,517	2,127	272
Other international countries	4,632	4,283	1,640
Total	$ 89,572	$ 77,795	$ 52,908

Long-lived assets at July 31,	**2009**	**2008**	**2007**
United States	$ 45,896	$ 34,202	$ 21,438
Switzerland	7,075	7,437	6,652

United Kingdom	3,334	4,193	
Other international countries	1,923	2,198	1,545
Total	$ 58,228	$ 48,030	$ 29,635

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The Company s reportable segments are determined based on the services they perform, the products they sell, and the royalties and license fee income they earn, not on the geographic area in which they operate. The Company s Clinical Labs segment operates 100% in the United States with all revenue derived from that country. The Life Sciences segment earns product revenue both in the United States and foreign countries and royalty and license fee income in the United States. The following is a summary of the Life Sciences segment revenues attributable to customers located in the United States and foreign countries:

In 000 s	2009	2008	2007
United States	$ 36,332	$ 20,165	$ 9,621
Foreign countries	13,636	15,552	2,857
	$ 49,968	$ 35,717	$ 12,478

Note 18 Summary of Selected Quarterly Financial Data (unaudited)

The following table contains statement of operations information for each quarter of the years ended July 31, 2009 and 2008. The Company believes that the following information reflects all normal recurring adjustments necessary for a fair presentation of the information for the periods presented. The operating results for any quarter are not necessarily indicative of results for any future period.

Unaudited quarterly financial data (in thousands, except per share amounts) for fiscal 2009 and 2008 is summarized as follows:

	Quarter Ended			
Fiscal 2009	October 31, 2008	January 31, 2009	April 30, 2009	July 31, 2009
Total revenues	$ 21,065	$ 20,916	$ 23,061	$ 24,530
Gross profit	8,168	8,007	9,706	10,630
Loss before income taxes	(6,233)	(7,567)	(4,226)	(5,451)
Net loss	(6,372)	(7,673)	(4,242)	(5,277)
Basic loss per common share	$ (0.18)	$ (0.20)	$ (0.11)	$ (0.14)
Diluted loss per common share	$ (0.18)	$ (0.20)	$ (0.11)	$ (0.14)

	Quarter Ended			
Fiscal 2008	October 31, 2007	January 31, 2008	April 30, 2008	July 31, 2008
Total revenues	$ 19,447	$ 18,224	$ 18,948	$ 21,176
Gross profit	9,632	8,795	9,082	8,918
Loss before income taxes	(1,347)	(4,013)	(1,940)	(3,592)
Net loss	(1,232)	(4,055)	(2,107)	(3,259)
Basic loss per common share	$ (0.03)	$ (0.11)	$ (0.06)	$ (0.09)
Diluted loss per common share	$ (0.03)	$ (0.11)	$ (0.06)	$ (0.09)

ENZO BIOCHEM, INC
SCHEDULE II
VALUATION AND QUALIFYING ACCOUNTS
Years ended July 31, 2009, 2008 and 2007
(in thousands)

Year ended July 31,	Description	Balance at Beginning of period	Charged (credited) to costs and expenses	Charged to other accounts	Deductions	Balance at end of period
2009	Allowance for doubtful accounts receivable	886	5,189		1,289 (1)	4,786
2008	Allowance for doubtful accounts receivable	1,404	3,716		4,234 (1)	886
2007	Allowance for doubtful accounts receivable	1,033	4,653		4,282 (1)	1,404
2009	Deferred tax valuation allowance	12,965	8,751			21,716
2008	Deferred tax valuation allowance	9,385	3,580			12,965
2007	Deferred tax valuation allowance	4,856	5,220		691 (2)	9,385
2009	Reserve for obsolete inventory	637	378		10	1,005
2008	Reserve for obsolete inventory	379	283		25 (3)	637
2007	Reserve for obsolete inventory	238	337		196 (3)	379

(1) Write-off of uncollectible accounts receivable.

(2) Utilization of deferred tax assets

(3) Write-off of obsolete inventory