HESKA CORP
Form 10-K
March 31, 2014

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

(Mark One)

x ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2013

OR

o TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from _____ to _____

Commission file number: 0-22427

HESKA CORPORATION
(Exact name of registrant as specified in its charter)

Delaware	77-0192527
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)
3760 Rocky Mountain Avenue Loveland, Colorado	80538
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: (970) 493-7272

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

Public Common Stock, $.01 par value	The Nasdaq Stock Market LLC
(Title of Class)	(Name of Each Exchange on Which Registered)

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

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

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No o

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of the registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

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

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

The aggregate market value of voting common stock held by non-affiliates of the Registrant was approximately $36,561,525 as of June 28, 2013 based upon the closing price on the Nasdaq Capital Market reported for such date. This calculation does not reflect a determination that certain persons are affiliates of the Registrant for any other purpose.

6,044,568 shares of the Registrant's Public Common Stock, $.01 par value, were outstanding at March 28, 2014.

DOCUMENTS INCORPORATED BY REFERENCE

Items 10, 11, 12, 13 and 14 of Part III incorporate by reference information from the Registrant's Proxy Statement to be filed with the Securities and Exchange Commission in connection with the solicitation of proxies for the Registrant's 2014 Annual Meeting of Stockholders.

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HESKA, ALLERCEPT, E-SCREEN, HEMATRUE, SOLO STEP, THYROMED, VET/OX and VITALPATH are registered trademarks and CBC-DIFF, ELEMENT DC, G2 DIGITAL and VET/IV are trademarks of Heska Corporation. TRI-HEART is a registered trademark of Intervet Inc., d/b/a Merck Animal Health, formerly known as Schering-Plough Animal Health Corporation ("Merck Animal Health"), in the United States and is a registered trademark of Heska Corporation in other countries. DRI-CHEM is a registered trademark of FUJIFILM Corporation. This Form 10-K also refers to trademarks and trade names of other organizations

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Statement Regarding Forward Looking Statements

This Form 10-K contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). For this purpose, any statements contained herein that are not statements of current or historical fact may be deemed to be forward-looking statements. Without limiting the foregoing, words such as "anticipates," "expects," "intends," "plans," "believes," "seeks," "estimates," variations of such words and similar expressions are intended to identify such forward-looking statements. These statements are not guarantees of future performance and are subject to certain risks, uncertainties and assumptions that are difficult to predict. Therefore, actual results could differ materially from those expressed or forecasted in any such forward-looking statements as a result of certain factors, including those set forth in "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations," "Business" and elsewhere in this Form 10-K. Readers are cautioned not to place undue reliance on these forward-looking statements.

Although we believe that expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance or achievements. We expressly disclaim any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in our expectations with regard thereto or any change in events, conditions or circumstances on which any such statement is based. These forward-looking statements apply only as of the date of this Form 10-K or for statements incorporated by reference from our 2014 definitive proxy statement on Schedule 14A, as of the date of the Schedule 14A.

Internet Site

Our Internet address is www.heska.com. Because we believe it provides useful information in a cost-effective manner to interested investors, via a link on our website our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act are publicly available free of charge and we believe are available as soon as reasonably practical after we electronically file such material with, or furnish it to, the Securities Exchange Commission (the "SEC"). Information contained on our website is not a part of this annual report on Form 10-K.

PART I

Item 1. Business.

We develop, manufacture, market, sell and support veterinary products. Our core focus is on the canine and feline companion animal health markets where we strive to provide high value products.

Our business is composed of two reportable segments, Core Companion Animal Health and Other Vaccines, Pharmaceuticals and Products. The Core Companion Animal Health segment ("CCA") includes, primarily for canine and feline use, blood testing instruments and supplies, digital imaging products, software and services, and single use products and services such as heartworm diagnostic tests, heartworm preventive products, allergy immunotherapy products and allergy testing. These products are sold directly to veterinarians by us as well as through distribution relationships. The Other Vaccines, Pharmaceuticals and Products segment ("OVP") includes private label vaccine and pharmaceutical production, primarily for cattle but also for other animals including small mammals. All OVP products are sold by third parties under third party labels. Please refer to Note 10 of our audited consolidated financial statements filed herewith for financial information about each of our segments.

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Our principal executive offices are located at 3760 Rocky Mountain Avenue, Loveland, Colorado 80538, our telephone number is (970) 493-7272 and our internet address is www.heska.com. We originally incorporated in California in 1988, and we subsequently incorporated in Delaware in 1997.

Background

We were founded as Paravax, Inc. in 1988 and conducted research on vaccines to prevent infections by parasites. We changed our name to Heska Corporation in 1995, completed our initial public offering in 1997 and continued to be a research and development-focused company, devoting substantial resources to the research and development of innovative products for the companion animal health market. In 2001 and 2002, we took steps to lower our expense base, largely in internal research and development. We subsequently continued to concentrate our efforts on operating improvements, such as enhancing the effectiveness of our sales and marketing efforts and pursuing cost efficiencies, as well as seeking new product opportunities with third parties. We acquired a 54.6% interest in Cuattro Veterinary USA, LLC in February 2013, which marked our entry into the digital imaging market. In June 2013, we sold certain non-core assets useful for the production of both bovine and feline vaccines to Elanco Animal Health ("Elanco"), a division of Eli Lilly and Company.

Core Companion Animal Health Segment

We presently sell a variety of companion animal health products and services, among the most significant of which are the following:

Veterinary Blood Testing and Other Non-Imaging Instruments

We offer a line of veterinary blood testing and other instruments, some of which are described below. We also market and sell consumable supplies for these instruments. Our line of veterinary instruments includes the following:

Blood Chemistry. The Element DCTM Veterinary Chemistry Analyzer (the "Element DC") was launched in October 2012. The Element DC is an easy-to-use, robust system that uses dry slide technology for blood chemistry and electrolyte analysis and has the ability to run 22 tests at a time with a single blood sample. Test slides are available as both pre-packaged panels as well as individual slides. The Element DC is faster and has an enhanced user interface compared to the instrument it replaced, the DRI-CHEM 4000 Veterinary Chemistry Analyzer (the "DRI-CHEM 4000"). The DRI-CHEM 7000 Veterinary Chemistry Analyzer (the "DRI-CHEM 7000") is a complementary chemistry offering, co-branded with FUJIFILM Corporation ("FUJIFILM"), with higher throughput, multiple patient staging and a "STAT" feature which provides emergency sample flexibility in critical cases. The Element DC, DRI-CHEM 7000 and DRI-CHEM 4000 all utilize the same test slides. We are supplied with the Element DC, the DRI-CHEM 7000 and affiliated test slides and supplies under a contractual agreement with FUJIFILM.

Hematology. The HEMATRUE Veterinary Hematology Analyzer is an easy-to-use blood analyzer that measures such key parameters as white blood cell count, red blood cell count, platelet count and hemoglobin levels in animals. In addition, we continue to service and support our previous hematology instrument, the HESKA CBC-DIFF Veterinary Hematology System. We are supplied new instruments and affiliated reagents and supplies of these products under a contractual agreement with Boule Medical AB ("Boule").

Blood Gases and Electrolytes. The Element POC™ Blood Gas & Electrolyte Analyzer ("EPOC") is a handheld, wireless analyzer which delivers rapid blood gas, electrolyte, metabolite, and basic blood chemistry testing. EPOC features test cards with room temperature storage which can offer results with less than 100 µL of sample as well as WiFi and Bluetooth connectivity. We began to ship EPOC units to customers in October 2013. EPOC and affiliated consumables and supplies are supplied to us under contractual agreement with BBI Animal Health Limited, a unit of Alere Inc. In addition, we continue to service and support our previous blood gas and electrolyte instrument for which we are supplied affiliated consumables and supplies under a contractual agreement with Roche Diagnostics Corporation ("Roche").

IV Pumps. The VET/IV 2.2 infusion pump is a compact, affordable IV pump that allows veterinarians to easily provide regulated infusion of fluids, drugs or nutritional products for their patients.

Veterinary Imaging Instruments and Services

On February 24, 2013, we acquired a 54.6% interest in Cuattro Veterinary USA, LLC, which was subsequently renamed Heska Imaging US, LLC ("Heska Imaging") and operates only in the United States. This transaction marked our entry into the veterinary imaging area. Heska Imaging's offerings in this area include:

Digital Radiography Solutions. Our digital radiography solutions are marketed and sold under the "Cuattro" brand name. We sell hardware including digital radiography detectors, acquisition workstation equipment, positioning aides such as tunnels and tables, viewing computers and other accessories along with embedded software and support, data hosting and other services. The CloudDRTM solution combines flat panel digital radiography with web-based image storage. The CloudbankTM archive is an automatic, secure, web-based image storage solution designed to interface with the software we sell. ViewCloudTM is a PACS (Picture Archival and Communications System) for Cloudbank for web or local viewing, reporting, planning and email sharing of studies on internet devices, including personal computers, Mac desktop and portable systems, tablet devices, iPadTM devices and smartphones. SupportCloudTM is a support package including call center voice and remote diagnostics, recovery and other services, such as the provision of warranty-related loaner units, to support CloudDR, Cloudbank and ViewCloud.

We also sell mobile digital radiography products, primarily for equine use. The Uno 4TM is a full powered, seamlessly integrated, portable digital radiography generator with an embedded detector and touchscreen computer based upon a patented design of Cuattro, LLC. The Slate 4TM Wireless features a 16 bit detector for use with an existing generator and which communicates wirelessly with a mobile, case-based direct sunlight readable display, including multi-touch software and the ability to natively link to Digital Imaging and Communication in Medicine, or DICOM, servers of all types as well as Cloudbank. Slate 4 TM comes in a 19" model and a 12" model, both of which are handheld, touchscreen, tablets with embedded wireless communication, battery-powered and line-powered capabilities, and image acquisition and communication functions.

Cuattro, LLC provides us with the hardware, software and support, data hosting and other services for our digital radiography solutions under exclusive contractual arrangements in the United States.

Ultrasound Systems. Our ultrasound products, including affiliated probes and peripherals, are provided to us under an exclusive agreement with Esaote USA ("Esaote"). We sell several different ultrasound products with varying features and corresponding price points, all under Esaote's trade names or logos. These offerings include the MyLab 30 Gold Vet, a compact, portable, high performance model offering optional products for use with abdominal, cardiac and small parts applications. The ultrasound

products we sell generally seamlessly integrate with our Cloudbank and ViewCloud offerings discussed above for image storing and viewing.

Point-of-Care Heartworm Diagnostic Tests

Heartworm infections of dogs and cats are caused by the parasite Dirofilaria immitis. This parasitic worm is transmitted in larval form to dogs and cats through the bite of an infected mosquito. Larvae develop into adult worms that live in the pulmonary arteries and heart of the host, where they can cause serious cardiovascular, pulmonary, liver and kidney disease. Our canine and feline heartworm diagnostic tests use monoclonal antibodies or a recombinant heartworm antigen, respectively, to detect heartworm antigens or antibodies circulating in the blood of an infected animal.

We currently market and sell heartworm diagnostic tests for both dogs and cats. SOLO STEP CH for dogs and SOLO STEP FH for cats are available in point-of-care, single use formats that can be used by veterinarians on site. We also offer SOLO STEP CH Batch Test Strips, a rapid and simple point-of-care antigen detection test for dogs that allows veterinarians in larger practices to run multiple samples at the same time. We obtain SOLO STEP CH, SOLO STEP FH and SOLO STEP Batch Test Strips under a contractual agreement with Quidel Corporation ("Quidel").

Heartworm Preventive Products

We have an agreement with Merck Animal Health, a unit of Merck & Co., Inc., granting Merck Animal Health the exclusive distribution and marketing rights for our canine heartworm prevention product, TRI-HEART Plus Chewable Tablets, ultimately sold to or through veterinarians in the United States and Canada. TRI-HEART Plus Chewable Tablets (ivermectin/pyrantel) are indicated for use as a monthly preventive treatment of canine heartworm infection and for treatment and control of ascarid and hookworm infections. We manufacture TRI-HEART Plus Chewable Tablets at our Des Moines, Iowa production facility.

Allergy Products and Services

Allergy is common in companion animals, and it has been estimated to affect approximately 10% to 15% of dogs. Clinical symptoms of allergy are variable, but are often manifested as persistent and serious skin disease in dogs and cats. Clinical management of allergic disease is problematic, as there are a large number of allergens that may give rise to these conditions. Although skin testing is often regarded as the most accurate diagnostic procedure, such tests can be painful, subjective and inconvenient. The effectiveness of the immunotherapy that is prescribed to treat allergic disease is inherently limited by inaccuracies in the diagnostic process.

Our ALLERCEPT Definitive Allergen Panels provide the most accurate determination of which we are aware of the specific allergens to which an animal, such as a dog, cat or horse, is reacting. The panels use a highly specific recombinant version of the natural IgE receptor to test the serum of potentially allergic animals for IgE directed against a panel of known allergens. A typical test panel consists primarily of various pollen, grass, mold, insect and mite allergens. The test results serve as the basis for prescription ALLERCEPT Therapy Shots and ALLERCEPT Therapy Drops. We operate veterinary laboratories in Loveland, Colorado and Fribourg, Switzerland which both offer blood testing using our ALLERCEPT Definitive Allergen Panels.

We sell kits to conduct blood testing using our ALLERCEPT Definitive Allergen Panels to third-party veterinary diagnostic laboratories outside of the United States. We also sell products to screen for the presence of allergen-specific IgE to these customers – we sell kits to conduct preliminary blood testing using products based on our ALLERCEPT Definitive Allergen Panels as well as a similar test requiring less

technical sophistication, our E-SCREEN Test. Animals testing positive for allergen-specific IgE using these screening tests are candidates for further evaluation using our ALLERCEPT Definitive Allergen Panels.

Veterinarians who use our ALLERCEPT Definitive Allergen Panels often purchase our ALLERCEPT Therapy Shots for those animals with positive test results. These prescription immunotherapy treatment sets are formulated specifically for each allergic animal and contain only the allergens to which the animal has significant levels of IgE antibodies. The prescription formulations are administered in a series of injections, with doses increasing over several months, to ameliorate the allergic condition of the animal. Immunotherapy is generally continued for an extended time. Immunotherapy delivered by injection is referred to as subcutaneous immunotherapy. We offer canine, feline and equine subcutaneous immunotherapy treatment products. In February 2012, we announced we had licensed intellectual property for a proprietary, sublingual (administered under the tongue) therapy treatment for pets suffering with allergies – now known as ALLERCEPT Therapy Drops. We believe our ALLERCEPT Therapy Drops offer a convenient alternative to subcutaneous injection, thereby enhancing the likelihood of pet owner compliance.

Other Core Companion Animal Health Single Use Products. We also sell other products in our Core Companion Animal Health segment. For example, we sell E.R.D. Reagent Packs used to detect microalbuminuria, the most sensitive indicator of renal damage, to VCA Antech, Inc. for use in its veterinary diagnostic laboratories.

Other Vaccines, Pharmaceuticals and Products Segment

We developed a line of bovine vaccines that are licensed by the United States Department of Agriculture ("USDA"). Historically, the largest distributor of these vaccines was Agri Laboratories, Ltd. ("AgriLabs"), who sold these vaccines primarily under the Titanium® and MasterGuard® brands. In November 2013, AgriLabs assigned the long-term agreement with us related to these vaccines to, and the agreement was assumed by, Eli Lilly and Company ("Eli Lilly") acting through Elanco.

We manufacture biological and pharmaceutical products for a number of other animal health companies. We manufacture products for animals other than cattle including horses and small mammals. Our offerings range from providing complete turnkey services which include research, licensing, production, labeling and packaging of products to providing any one of these services as needed by our customers as well as validation support and distribution services.

Marketing, Sales and Customer Support

We estimate that there are approximately 53,000 veterinarians in the United States whose practices are devoted principally to small animal medicine. These veterinarians practice in approximately 24,000 clinics in the United States. In 2013, our products were sold to approximately 13,000 such clinics in the United States. Veterinarians may obtain our products directly from us or indirectly through others. All our Core Companion Animal Health products ultimately are sold primarily to or through veterinarians. In many cases, veterinarians will markup their costs to the end user. The acceptance of our products by veterinarians is critical to our success.

We currently market our Core Companion Animal Health products in the United States to veterinarians through an outside field organization, a telephone sales force, independent third-party distributors, as well as through trade shows and print advertising and through other distribution relationships, such as Merck Animal Health in the case of our heartworm preventive. Our outside field organization currently consists of 36 individuals in various parts of the United States. Our inside sales force consists of 18 persons.

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We have a staff dedicated to customer and product support in our Core Companion Animal Health segment including veterinarians, technical support specialists and service technicians. Individuals from our product development group may also be used as a resource in responding to certain product inquiries.

Internationally, we market our Core Companion Animal Health products to veterinarians primarily through third-party veterinary diagnostic laboratories, independent third-party distributors and Novartis Agro K.K., Tokyo ("Novartis Japan"). These entities typically provide customer support. Novartis Japan exclusively markets and distributes SOLO STEP CH in Japan.

All OVP products are marketed and sold by third parties under third-party labels.

We grant third parties rights to our intellectual property as well as our products, with our compensation often taking the form of royalties and/or milestone payments.

Manufacturing

The majority of our revenue is from proprietary products manufactured by third parties. Third parties manufacture our veterinary instruments, including affiliated consumables and supplies, as well as other products including key components of our heartworm point-of-care diagnostic tests. Our chemistry instruments and affiliated supplies are manufactured under contract with FUJIFILM. Our hematology instruments and affiliated supplies are manufactured under contract with Boule. Our digital radiography products are supplied under contract with Cuattro, LLC, which typically buys its hardware products and components from third parties. Our ultrasound products are supplied under a contract with Esaote USA. Key components of our heartworm point-of-care diagnostic tests are manufactured under a contract with Quidel. We manufacture and supply Quidel with certain critical raw materials and perform the final packaging operations for these products. Our facility in Des Moines, Iowa is a USDA, Food and Drug Administration ("FDA"), and Drug Enforcement Agency ("DEA") licensed biological and pharmaceutical manufacturing facility. This facility currently has the capacity to manufacture more than 50 million doses of vaccine each year. We expect that we will, for the foreseeable future, manufacture most or all of our pharmaceutical and biological products at this facility, as well as most or all of our recombinant proteins and other proprietary reagents for our diagnostic tests. We currently manufacture our canine heartworm prevention product, our allergy treatment products and all our OVP segment products at this facility. Our OVP segment's customers purchase products in both finished and bulk format, and we perform all phases of manufacturing, including growth of the active bacterial and viral agents, sterile filling, lyophilization and packaging at this facility. We manufacture our various allergy diagnostic products at our Des Moines facility, our Loveland facility and our Fribourg facility. We believe the raw materials for products we manufacture are available from more than one source.

Product Development

We are committed to providing innovative products to address health needs of companion animals. We may obtain such products from external sources, external collaboration or internal research and development.

We are committed to identifying external product opportunities and creating business and technical collaborations that lead to high value veterinary products. We believe that our active participation in scientific networks and our reputation for investing in research enhances our ability to acquire external product opportunities. We have collaborated, and intend to continue to do so, with a number of companies and universities. Examples of such collaborations include:

- Quidel for the development of SOLO STEP CH Cassettes, SOLO STEP CH Batch Test Strips and SOLO STEP FH Cassettes;

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Boule for the development of veterinary applications for the HEMATRUE Veterinary Hematology Analyzer and associated reagents; and

FUJIFILM for the development of veterinary applications for the Element DC Veterinary Chemistry Analyzer and associated slides and supplies.

Internal research and development is managed on a case-by-case basis. We employ individuals with microbiology, immunology, genetics, biochemistry, molecular biology, parasitology as well as veterinary expertise and will form multidisciplinary product-associated teams as appropriate. We incurred expenses of $1.7 million, $1.0 million and $1.5 million in the years ended December 31, 2011, 2012 and 2013, respectively, in support of our research and development activities.

Intellectual Property

We believe that patents, trademarks, copyrights and other proprietary rights are important to our business. We also rely upon trade secrets, know-how, continuing technological innovations and licensing opportunities to develop and maintain our competitive position. The proprietary technologies of our OVP segment are primarily protected through trade secret protection of, for example, our manufacturing processes in this area.

We actively seek patent protection both in the United States and abroad. Our issued and pending patent portfolios primarily relate to heartworm control, flea control, allergy, infectious disease vaccines, diagnostic and detection tests, immunomodulators, instrumentation, nutrition, pain control and vaccine delivery technologies. As of December 31, 2013, we owned, co-owned or had rights to 185 issued U.S. patents expiring at various dates from January 2014 to May 2028 and had no pending U.S. patent applications. Applications corresponding to pending U.S. applications have been or will be filed in other countries. Our corresponding foreign patent portfolio as of December 31, 2013 included 141 issued patents and 4 pending applications in various foreign countries expiring at various dates from January 2014 to March 2026.

We also have obtained exclusive and non-exclusive licenses for numerous other patents held by academic institutions and for profit companies.

Seasonality

In 2013, our fourth quarter results were significantly stronger than those for any other quarter. We expect this trend to continue in the future, primarily as this is our understanding of the historical results at Heska Imaging and other digital imaging businesses.

Government Regulation

Although the majority of our revenue is from the sale of unregulated items, many of our products or products that we may develop are, or may be, subject to extensive regulation by governmental authorities in the United States, including the USDA and the FDA, and by similar agencies in other countries. These regulations govern, among other things, the development, testing, manufacturing, labeling, storage, pre-market approval, advertising, promotion, sale and distribution of our products. Satisfaction of these requirements can take several years to achieve and the time needed to satisfy them may vary substantially, based on the type, complexity and novelty of the product. Any product that we develop must receive all relevant regulatory approval or clearances, if required, before it may be marketed in a particular country. The following summarizes the major U.S. government agencies that regulate animal health products:

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USDA. Vaccines and certain single use, point-of-care diagnostics are considered veterinary biologics and are therefore regulated by the Center for Veterinary Biologics, or CVB, of the USDA. Industry data indicate that it takes approximately four years and in excess of $1.0 million to license a conventional vaccine for animals from basic research through licensing. In contrast to vaccines, single use, point-of-care diagnostics can typically be licensed by the USDA in about two years, at considerably less cost. However, vaccines or diagnostics that use innovative materials, such as those resulting from recombinant DNA technology, usually require additional time to license. The USDA licensing process involves the submission of several data packages. These packages include information on how the product will be manufactured, information on the efficacy and safety of the product in laboratory and target animal studies and information on performance of the product in field conditions.

FDA. Pharmaceutical products, which typically include synthetic compounds, are approved and monitored by the Center for Veterinary Medicine of the FDA. Industry data indicate that developing a new drug for animals requires approximately 4 to 6 years from the initiation of a regulatory process to market introduction and costs approximately $4 to $6 million. Of this time, approximately three years is spent in animal studies and the regulatory review process. However, unlike human drugs, neither preclinical studies nor a sequential phase system of studies are required. Rather, for animal drugs, studies for safety and efficacy may be conducted immediately in the species for which the drug is intended. Thus, there is no required phased evaluation of drug performance, and the Center for Veterinary Medicine will review data at appropriate times in the drug development process. In addition, the time and cost for developing companion animal drugs may be significantly less than for drugs for livestock animals, which are estimated to be approximately 10 to 12 years from the initiation of a regulatory process to market introduction and may have costs of approximately $10 to $12 million.

EPA. Products that are applied topically to animals or to premises to control external parasites are regulated by the Environmental Protection Agency, or EPA.

After we have received regulatory licensing or approval for our products, numerous regulatory requirements typically apply. Among the conditions for certain regulatory approvals is the requirement that our manufacturing facilities or those of our third-party manufacturers conform to current Good Manufacturing Practices or other manufacturing regulations, which include requirements relating to quality control and quality assurance as well as maintenance of records and documentation. The USDA, FDA and foreign regulatory authorities strictly enforce manufacturing regulatory requirements through periodic inspections and/or reports.

A number of our animal health products are not regulated. For example, certain products such as our ALLERCEPT panels are not regulated by either the USDA or FDA. Similarly, none of our veterinary instruments requires regulatory approval to be marketed and sold in the United States.

We have pursued regulatory approval outside the United States based on market demographics of foreign countries. For marketing outside the United States, we are subject to foreign regulatory requirements governing regulatory licensing and approval for many of our products. Licensing and approval by comparable regulatory authorities of foreign countries must be obtained before we can market products in those countries. Product licensing approval processes and requirements vary from country to country and the time required for such approvals may differ substantially from that required in the United States. We cannot be certain that approval of any of our products in one country will result in approvals in any other country. To date, we or our distributors have sought regulatory approval for certain of our products in Canada, which is governed by the Canadian Center for Veterinary Biologics, or CCVB; in Japan, which is governed by the Japanese Ministry of Agriculture, Forestry and Fisheries, or MAFF; in Australia, which is governed by the Australian Department of Agriculture, Fisheries and Forestry, or ADAFF; in South Africa, which is governed

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by the Republic of South Africa Department of Agriculture, or RSADA; and in certain other countries requiring such approval.Core Companion Animal Health products previously discussed which have received regulatory approval in the United States and/or elsewhere are summarized below.

Products	Country	Regulated	Agency	Status
ALLERCEPT Allergy Treatment Sets	United States	Yes	USDA	Licensed
SOLO STEP CH	United States	Yes	USDA	Licensed
	EU	No-in most countries	CCVB	Licensed
	Canada	Yes	MAFF	Licensed
	Japan	Yes	ADAFF	Licensed
	Australia	Yes		
SOLO STEP CH Batch Test Strips	United States	Yes	USDA	Licensed
	Canada	Yes	CCVB	Licensed
SOLO STEP FH	United States	Yes	USDA	Licensed
	Canada	Yes	CCVB	Licensed
	Australia	Yes	ADAFF	Licensed
TRI-HEART Plus Heartworm Preventive	United States			
	Japan			