UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of The Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): December 20, 2018

ZOMEDICA PHARMACEUTICALS CORP.

(Exact name of registrant as specified in its charter)

Alberta, Canada	**001-38298**	**N/A**
(State or other jurisdiction of incorporation)	*(Commission File Number)*	*(IRS Employer Identification No.)*

100 Phoenix Drive, Suite 190, Ann Arbor, Michigan	**48108**
(Address of principal executive offices)	*(Zip Code)*

Registrant's telephone number, including area code: **(734) 369-2555**

(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☒

Item 8.01 Other Events.

Updating Business Section and Risk Factors

Zomedica Pharmaceuticals Corp. (the "Company") is filing the business description attached hereto as Exhibit 99.1 and the risk factors attached hereto as Exhibit 99.2 for the purpose of supplementing and updating the business description and risk factor disclosures contained in its Annual Report on Form 10-K for the fiscal year ended December 31, 2017, filed with the Securities and Exchange Commission (the "SEC") on February 28, 2018, as previously updated in the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2018, filed with the SEC on November 13, 2018. The updated business description and risk factors are filed as Exhibit 99.1 and Exhibit 99.2 to this current report on Form 8-K and are incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	**Description**
99.1	Business Description
99.2	Risk Factors

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

ZOMEDICA PHARMACEUTICALS CORP.

Date: December 20, 2018

By: /s/ Shameze Rampertab
Name: Shameze Rampertab
Title: Chief Financial Officer

BUSINESS

Overview

We are a development stage veterinary diagnostic and pharmaceutical company creating products for companion animals (canine, feline, and equine) by focusing on the unmet needs of clinical veterinarians. We believe that we have identified and are developing diagnostics and therapeutics that have the potential to significantly improve the diagnosis and treatment of various diseases affecting companion animals. We believe that there are significant unmet medical needs for pets, and that the pet diagnostic and therapeutic segments of the animal health industry are likely to grow substantially as new diagnostic tools and treatments are identified, developed, and marketed specifically for companion animals.

Together with our strategic partners, we are developing three diagnostic platforms, a Bulk Acoustic Wave sensor-based veterinary point-of-care diagnostic platform for performing immunodiagnostic testing a Raman spectroscopy-based point-of-care diagnostic platform for the detection of pathogens, and liquid biopsy assays for the detection of cancer, along with related consumables. We believe that the regulatory pathway to approval of companion animal diagnostics is significantly shorter than for similar diagnostic products intended for human use. In certain cases, pre-market clearance may be unnecessary, depending on the intended use of the diagnostic.

We also have identified a number of drugs which have proven safe and effective in humans that we are developing for use in canines and felines. We believe this development approach enables us to reduce the risks associated with obtaining regulatory approval for unproven product candidates and shortens the development timeline necessary to bring our product candidates to market. We have four drug product candidates in early development and have identified several other potential product candidates for further investigation.

In addition, we are investigating the development of alternative drug delivery technologies for our drug product candidates. Many of the human-approved therapeutics used in companion animals are only available in pill or injectable form. However, it can be difficult to give a companion animal an injection or to assure that the animal has swallowed a pill. As a result, we believe that compliance with treatment regimens is a significant problem for veterinarians and pet owners. The challenges associated with medicating pets are unique, and we believe that developing product candidates that can be easily taken by the pet or easily administered by pet owners will help increase compliance.

Market Opportunity

U.S. consumers will spend an estimated $72 billion on their pets in 2018, according to the American Pet Products Association, or APPA, an increase of approximately 4% from 2017. The veterinary care segment is expected to account for an estimated $17 billion in revenue in 2018, an increase of approximately 2.4%% from 2017. According to dvm360 Magazine's State of the Profession survey for 2015, diagnostics comprise 18%, and vaccinations, pharmaceuticals and biologicals comprise 25% of gross revenue at the veterinary practice level.

The dvm360 Magazine survey also states that 61% of respondents indicated that they were providing more diagnostic services than the prior year. Similarly, a 2016 Credit Suisse survey of veterinarians found that 73% of respondents expected their diagnostic testing to increase over the next 12 months. According to MarketsandMarkets™, the veterinary diagnostics market is expected to grow at a CAGR of 9.3% between 2017 and 2022, reaching $3.62 billion in sales by 2022, with North America accounting for the largest market share in 2016. The companion animal segment is expected to register the highest growth during the forecast period.

Packaged Facts' Pet Medications, in its U.S. report for 2017, estimated the size of the U.S. pet medication market, the largest companion animal market worldwide, at $8.6 billion in 2017, up from $7 billion in 2015. Future Market Insights estimates that the global companion animal drug market is expected to grow at a compounded annual growth rate of 4.9% from 2015 - 2025.

We believe that several factors have contributed and will continue to contribute to an increase in spending on pet therapeutics. Companion animals are generally living longer, with the average lifespan for dogs increasing by half a year to 11 years between 2002 and 2012, according to a study by Banfield Pet Hospital. In 2015, the American Animal Hospital Association estimated that the average dog will account for approximately $3,600 in veterinary bills over its lifespan. According to Pet Supplies Plus, baby boomers are adopting pets in record numbers. In its December 2015 issue, Pet Business magazine predicted that the millennial generation would continue the trend of the baby boomers in their enthusiasm for and interest in their pets and pet products and services. This, we believe, along with the increasing awareness of, as the U.S. Public Health Service states, "the mental and emotional benefits of companion animals" and our use of companion animals to address or assist in a range of health and wellness issues including post-traumatic stress disorder and autism, will bolster the growth and development of the pet therapeutics and diagnostics market.

Pet owners in the United States generally pay for diagnostics and therapeutics for their companion animals out-of-pocket. According to statistics from the North American Pet Health Insurance Association, only about 2.0 million dogs and cats in the United States and Canada were covered by an insurance plan in 2018. This represents less than 1% of the nearly 184 million dogs and cats that the American Pet Products Association estimates are owned in the United States alone. We believe that this results in less pricing pressure than in human health care, although the limited adoption of insurance may also reduce the ability of pet owners to pay for diagnostics and therapeutics recommended by their veterinarians.

Development of Companion Animal Diagnostics

The development of companion animal diagnostics continues to evolve with the addition of new technologies to diagnostic portfolios. We believe that these new technologies may allow for the following:

- Enhanced capability to detect the frequency of occurrence and severity of diseases and conditions that impact companion animals;
- Increased accuracy and faster means to obtain test results;
- Wider availability of new diagnostic tools; and
- Enhanced economic benefits for veterinarians.

Compared to human diagnostic development, the development of companion animal diagnostics is generally faster and less expensive since it typically requires smaller clinical studies, with fewer subjects. We believe that the lower cost of developing companion animal diagnostics enables us to pursue multiple diagnostic candidates simultaneously and to spread the risk of failure across a number of candidates, rather than concentrating all of our resources on one diagnostic candidate that may ultimately fail to achieve regulatory approval or market acceptance.

Development of Companion Animal Therapeutics

Compared to human drug development, the development of companion animal therapeutics is generally faster and less expensive since it requires fewer clinical studies involving fewer subjects and can be conducted directly in the target species. Based on our progress since commencing business in May 2015, we believe that we will be able to develop product candidates, from the initial opening of an INAD with the FDA-CVM through to marketing approval, in approximately five years at a cost of approximately $6 million per product candidate. According to the Tufts Center for the Study of Drug Development, the successful development of a new drug for use in humans can take more than 10 years and requires an average out-of-pocket expenditure of approximately $1.4 billion. The lower cost associated with the development of companion animal therapeutics permits us to pursue multiple product candidates simultaneously and to spread the risk of failure across a number of product candidates, rather than concentrating all of our resources on one novel candidate that may ultimately fail to achieve regulatory approval or market acceptance.

Because we are developing product candidates based on drugs that have been successfully developed and approved for human use—as opposed to drugs based on new active pharmaceutical ingredients (APIs)—we believe that we will be able to avoid or minimize the expenses associated with the human drug development process and more rapidly advance our development programs, while continuing to comply with current good manufacturing practices, or cGMP, for our product candidates. Since we are not pursuing entirely new chemical entities with our drug product candidates, we believe the risk of failure of a specific drug product candidate is significantly lower compared to developing a novel compound.

The respective businesses of developing and commercializing therapeutics for companion animals and humans share a number of characteristics, including the need to:

- Demonstrate safety and efficacy in clinical trials;
- Obtain FDA-CVM or other regulatory approval for marketing;
- Manufacture the therapeutics in facilities compliant with cGMP requirements; and
- Market the therapeutics only for their intended indication based on claims permitted in the product label, and not for other uses, which is referred to as "off-label" use.

However, despite these similarities, there are a number of important differences between the companion animal therapeutics and human therapeutics businesses, including:

- *Faster, less expensive and more predictable development.* The development of therapeutics for companion animals requires fewer clinical studies in fewer subject animals than the development of human therapeutics and, unlike human therapeutics, studies are conducted directly in the target species. We believe that our strategy of selecting APIs with demonstrated efficacy and safety in humans and that are currently being used by veterinarians in their human compounded form enhances the predictability of results and probability of success of our pivotal trials relative to novel compounds 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 medications directly from their veterinarians. However, veterinarians often are required to have human drugs specially compounded by third-party compounding pharmacies for use in smaller companion animals, resulting in the loss of much of the associated prescription revenue and an increase in the uncertainty around precise dosing and administration. We believe that therapeutics specifically developed for companion animals will enable veterinarians to provide potentially superior treatment options, while also increasing revenue streams from the sale of these therapeutics.
- *Less generic competition and strong brand loyalty.* There is less generic competition in the companion animal therapeutics industry than in the human health care industry. According to the Generic Animal Drug Alliance, 86% of FDA-approved animal drugs do not have a generic version. We believe that stronger brand loyalty and a lack of the mandatory generic drug substitution that exists in the human pharmaceutical market, partially explains the low penetration of generics in veterinary medicine.

Unmet Medical Needs

Diagnostics

We believe that there is a significant unmet medical need for cost-effective and accurate disease/condition detection solutions for veterinarians. We believe that we have identified potential diagnostic assays that have the potential to satisfy unmet needs or improve upon existing diagnostic processes frequently used by companion animal veterinarians.

For example, cancer is a prevalent disease in canines that can be difficult and costly to diagnose using existing diagnostic testing. According to the Veterinary Cancer Society, 50% of all dogs over the age of 10 will develop cancer and one in four dogs will develop cancer at some stage in their life. Diagnosing certain cancers in canines is difficult because the location of the tumor may make it difficult or risky to obtain cell material through a biopsy. In addition, the overall health of a canine may increase the risk of performing a biopsy. Other diagnostic technologies, such as advanced imaging, are expensive while others, such as histopathologic examination, may take several days or more to provide a definitive diagnosis. Many more canine cancer cases may go undetected due to cost constraints and other factors. To address these shortcomings, we are developing a circulating tumor cell detection assay for use in the detection of certain cancers in companion animals.

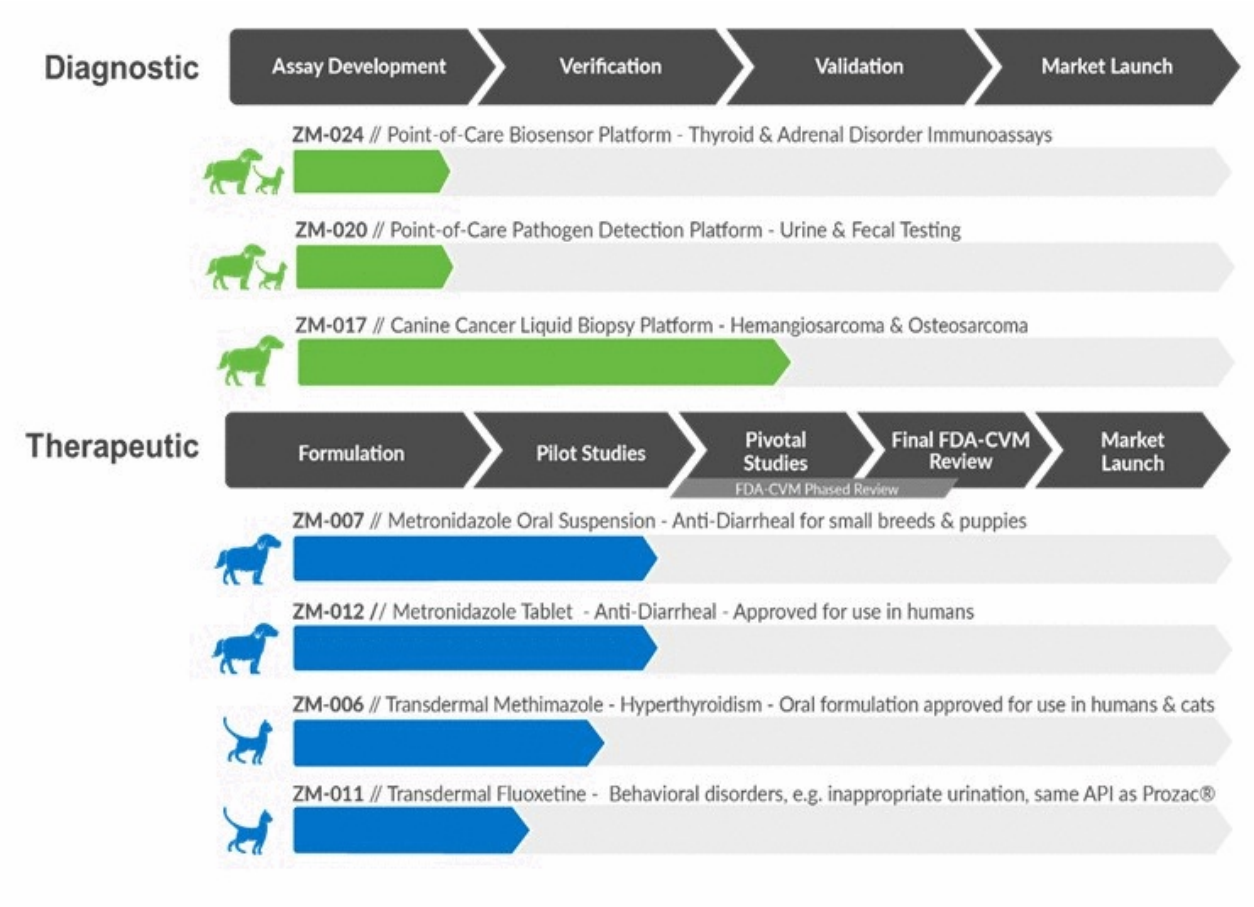
Therapeutics

Despite the growing market for pet therapeutics, there are relatively few treatment options approved for use in companion animals, as compared to those approved for humans. As a result, veterinarians often must resort to prescribing products approved for use in humans, but not approved or formulated for use in companion animals. Based on our own research, we estimate that more than half of the therapeutics used in animals are unapproved for such use. As a result, veterinarians must rely upon trial and error or untested rules of thumb to assess the proper dosage needed to be effective in the particular species without undue risk of side effects. The veterinarian must also find a way to administer the human product to animals and determine the actual dosage amount, tasks which are important and potentially overlooked as practical considerations in the treatment of companion animals. To do this, veterinarians often rely on compounding pharmacies to formulate human drugs into species' appropriate doses and formulations. As a result, veterinarians are forced to rely on therapeutics not proven safe and effective for their patients and on formulations for which no regulatory approval has been obtained. At the same time, the use of compounding pharmacies results in the veterinary clinic's loss of much of the associated prescription revenue.

We believe that therapeutics specifically developed for companion animals can extend and improve the quality of the lives of such animals, help veterinarians achieve improved medical outcomes, and make the process of administering therapeutics to companion animals much safer and more convenient. Advances in human medicines have created new therapeutics for managing many chronic diseases. Pets often suffer from many of these same diseases. In many cases, the biology of these diseases in companion animals is very similar to that in humans, which explains why animal efficacy models are used for human drug development. Because of the similarity of the diseases and their symptoms and effects, many human drugs, when formulated properly and administered in proper doses, are effective in companion animals. However, most human drugs are not specially formulated or approved for use in animals.

Many of the human therapeutics used in companion animals are only available in pill or injectable form. However, it can be difficult to give a companion animal a shot or to assure that it has swallowed a pill. It can also be difficult to divide human pills into small enough portions to achieve an appropriate dosage for companion animals. Consequently, we believe that compliance with treatment regimens is a significant problem for veterinarians and pet owners. The challenges associated with medicating pets are unique, and we believe that developing product candidates that can be easily taken by the pet or that can be easily administered by pet owners will help increase compliance.

Product Pipeline



Diagnostics

We are developing with our strategic partner a veterinary diagnostic assay, ZM-024, which is a Bulk Acoustic Wave sensor-based veterinary point-of-care diagnostic platform for performing immunodiagnostic testing. The diagnostic platform uses our partner's differentiated Bulk Acoustic Wave (BAW) sensor, derived from the fundamental BAW filter technology that is deployed in millions of mobile devices worldwide, to enable a non-optical and fluorescence-free detection system. The final product is expected to be comprised of a table-top instrument that uses disposable assay cartridges to test a range of samples including whole blood, serum, plasma, and urine. Our partner has conducted preliminary analytical and functional sensitivity testing on its investigational BAW platform as well as feasibility testing for certain initial immunoassay candidates in its other development work. We believe ZM-024 may have potential utility in other veterinary diagnostic areas such as molecular diagnostics and multiplexing capabilities. The joint development work initially targets five assay cartridge candidates to detect the following thyroid and adrenal disorders in dogs and cats, which currently require reference lab immunoassay testing for reliable diagnostic results: hypothyroidism in dogs, one of the most common endocrine diseases, hyperthyroidism in cats, a significant cause of morbidity in older cats, and Cushing's disease in dogs, another common endocrine disorder.

We expect to complete assay verifications for ZM-024 in the fourth quarter of 2019, followed by validations in first quarter of 2020. Assuming the development work is successful, we expect to commence the marketing of this platform in the first half of 2020 for the initial five assay candidates, which we believe do not require pre-market regulatory approval by U.S. regulators.

Together with our strategic partner, we are developing a novel pathogen detection system in the form of an innovative point-of-care diagnostic instrument, ZM-020. We believe ZM-020 may deliver multiple benefits, including speed of results and an enhanced workflow with minimal sample preparation time. We believe that ZM-020 does not require pre-market regulatory approval for use with companion animals in the United States. We expect that ZM-020 will use Raman spectral measurements to provide real-time, reagentless and automated identification of pathogens and disease indicators. We expect that ZM-020 will use recent advances in the field of Raman spectroscopy, a laser-based spectroscopy technique, to enable the identification of biological and biochemical signatures in complex biological samples, beginning with the examination of urine and fecal samples. We intend to develop additional applications for the ZM-020 platform including further development of the pathogen detection library for urine and fecal analysis as well as for respiratory and dermatological analysis. ZM-020 is comprised of a bench-top instrument and consumables intended to analyze unprocessed biological samples.

In our early development work the ZM-020 platform has successfully detected 13 unique urine pathogen signatures in water including seven different gram positive and gram negative bacteria species and three types of crystals with greater than 93.93 percent sensitivity and 99.32 percent specificity in over 6,000 samples. Our next development phase will seek to further optimize these results by moving beyond "spiked" water samples to automated detection of these signatures in urine samples. If development work progresses as anticipated, we expect to commence validation for the UTI assay and verification for the fecal assay in the first quarter of 2019. Assuming our development work is successfully completed we expect to commence marketing ZM-020 in the first half of 2020.

Together with our strategic partner, we are developing a circulating tumor cell, or CTC, assay, ZM-017, also known as a "liquid biopsy," for use by veterinarians as a cancer diagnostic. The liquid biopsy is a blood test that we believe has the potential to detect the presence of CTCs, which are cells that have shed from a primary tumor into neighboring blood vessels and are transported throughout the body's circulatory system. Diagnosing certain cancers in canines is difficult because the location of the tumor may make it difficult or risky to obtain cell material through a biopsy. In addition, the overall health of a canine may increase the risk of performing a biopsy. We are focusing our initial development work on testing for difficult to biopsy cancers such as hemangiosarcoma and osteosarcoma in canines. Other diagnostic technologies, such as advanced imaging, are expensive while others, such as histopathologic examination, may take several days or more to provide a definitive diagnosis. We believe that the detection of CTCs in the blood could provide strong clinical support for a cancer diagnosis without the need for an invasive tissue biopsy or other expensive or time-consuming diagnostic test. If we successfully develop ZM-017, we expect that ZM-017 will provide veterinarians with a faster, more affordable, and less invasive test for certain cancers in canines compared to existing detection methods. We expect to initiate verification and validation efforts for a lymphoma assay in 2019 as well. According to The Merck Veterinary Manual canine lymphoma is reported to be the most common blood-borne cancer in dogs with an estimated incidence rate approaching 0.1%.

Zomedica extended validation of its initial cancer assay after continued verification efforts, performed in parallel with early clinical validation steps during 2018, revealed opportunities to further optimize the assay to achieve broader commercial potential. Assuming successful completion of the clinical validation, we expect to commence the marketing of ZM-017 during the second half of 2020.

Therapeutics

We have four drug product candidates. Our lead drug product candidate is ZM-007, an oral suspension formulation of metronidazole targeting the treatment of acute diarrhea in small dog breeds and puppies under nine pounds or four kilograms. Metronidazole suspension is only available as a compounded drug and is not approved by the FDA-CVM. An Investigational New Animal Drug, or INAD, was opened for ZM-007 with the Food and Drug Administration's Center for Veterinary Medicine, or FDA-CVM, in October 2016. The API in ZM-007 is metronidazole, which has been the subject of multiple studies in humans and has been approved for use in humans for decades. We do not believe that the API in ZM-007 is protected by any patents or other proprietary rights of third parties in the U.S. We had a pre-submission meeting on December 13, 2017 with the FDA-CVM specific to the product development strategy for ZM-007 and ZM-012, a bioequivalent to ZM-007. Based on the feedback received from the FDA-CVM at that meeting and in light of additional market research demonstrating approved alternatives to compounded drugs, we have decided to prioritize development of ZM-007 over ZM-012. We expect to commence a pivotal safety study of ZM-007 in the first half of 2019.

Our second drug product candidate is ZM-012, a novel tablet formulation of metronidazole and a complementary formulation to ZM-007, targeting the treatment of acute diarrhea in dogs. Metronidazole tablets are currently only available as human generics. An INAD was opened for ZM-012 with the FDA-CVM in April 2016. We have finalized the formulation and completed pilot testing of ZM-012 as a beef-flavored oral tablet intended for dogs greater than nine pounds or four kilograms and we completed pilot testing of ZM-012 in the fourth quarter of 2017. We intend to pursue regulatory approval of ZM-012 as a bioequivalent to ZM-007 following approval of ZM-007 by FDA-CVM. Drugs that are considered to be bioequivalent are, for regulatory purposes, essentially the same, meaning the absence of significant difference between the extent and rate of absorption over the course of a specific period of time at the same dose and under the same conditions. The implementation of this bioequivalent strategy is contingent on FDA-CVM approval of the new animal drug application (NADA) for ZM-007. If the FDA-CVM permits us to rely on the bioequivalence of ZM-012 to ZM-007, we anticipate that this regulatory pathway will conserve significant development costs because a bioequivalence study could replace the need for pivotal safety and efficacy studies for ZM-012.

Our third drug product candidate is ZM-006, a transdermal gel formulation of methimazole targeting the chronic treatment of hyperthyroidism in cats. Hyperthyroidism is one of the most commonly diagnosed endocrine disorders in middle-aged to older cats according to the American Association of Feline Practitioners. We are investigating ZM-006 pursuant to an INAD opened with the FDA-CVM in June 2016. The API in ZM-006, methimazole, has been the subject of multiple studies in humans and has been approved for oral use in humans for decades. Our transdermal gel formulation is intended to provide an alternative to an oral tablet formulation already approved by the FDA-CVM for cats. We do not believe that the API in ZM-006 is protected by any patents or other proprietary rights of third parties. ZM-006 is intended for application to the inside of the cat's ear . The formulation of ZM-006 has been completed. We completed pilot testing of ZM-006 to support our pivotal safety study in the fourth quarter of 2018 and are analyzing the results. We expect to present and confirm the regulatory strategy and development plan for ZM-006 with the FDA-CVM in the first quarter of 2019. Assuming pilot testing is successful, we intend to commence a pivotal safety study of ZM-006 in the first half of 2019. We also intend to initiate a pilot efficacy study in the first half of 2019.

Our fourth drug product candidate is ZM-011, a transdermal gel formulation of fluoxetine, most commonly known as Prozac®, its human pharmaceutical brand name. We believe that Fluoxetine in pill or compounded form is frequently prescribed by veterinarians to treat feline behavioral disorders such as inappropriate urination. We are investigating ZM-011 pursuant to an INAD opened with the FDA-CVM in January 2017. The API, fluoxetine, has been the subject of multiple studies in humans and has been approved for use in humans for decades. We do not believe that the API in ZM-011 is protected by any patents or other proprietary rights of third parties. ZM-011 is a transdermal gel formulation intended for application to the inside of the cat's ear. The formulation of ZM-011 has been completed. We completed pilot testing of ZM-011 to support our pivotal safety study in the fourth quarter of 2018 and are analyzing the results. Assuming such pilot testing is successful, we intend to commence our pivotal safety study of ZM-011 in the second half of 2019.

License Agreements

In November 2018, we entered into a development and supply agreement with Qorvo Biotechnologies, LLC, or Qorvo, a wholly-owned subsidiary of Qorvo, Inc. focused on bringing Qorvo's piezo-electric BAW sensor to the veterinary health sector. Under the terms of this agreement, we have exclusive, global rights to develop and market Qorvo's investigational point-of-care diagnostic platform for veterinary use. Under the agreement, Qorvo and we will collaborate on the development of veterinary diagnostic assays. The joint development work initially targets five assay cartridge candidates to detect the thyroid and adrenal disorders in dogs and cats. Qorvo is responsible for the development of the assay cartridges and the instrument. We have agreed to pay for the associated non-recurring engineering costs of up to $500,000 per assay cartridge and the instrument, and are responsible for the validation of the assay cartridges and the instrument. Qorvo will supply us, on an exclusive basis, with the instruments and the related assay cartridges to be developed under the agreement pursuant to a rolling forecast, subject to specified minimum purchase requirements, at prices specified in the agreement. We will be responsible for the marketing and sale of the disposable assay cartridges and instruments.

The agreement, which is exclusive worldwide in the practice of veterinary medicine for the health and wellbeing of any non-human animal, has an initial term of ten years (subject to early termination and extension in certain circumstances).

We paid Qorvo $1.0 million and issued to Qorvo unregistered common shares having a value of $3.9 million, consisting of an aggregate of 2,565,789 common shares with an ascribed price of $1.52 per share. We have agreed to pay Qorvo additional milestone payments in cash or, if elected by Qorvo, additional unregistered common shares having a value calculated as specified in the agreement. The total amount of additional milestone payments (if all milestones are met) will be $10 million (if paid entirely with cash) or up to $10.9 million (consisting of cash in the amount of $7 million and unregistered common shares having a value of $3.9 million, if Qorvo elects to receive compensation partially in equity). In connection with the agreement, we entered into a registration rights agreement providing Qorvo with certain registration rights with respect to the common shares to be issued by us under the agreement.

In May 2018, we entered into a development, commercialization and exclusive distribution agreement with Seraph Biosciences, Inc., or Seraph, a human biomedical device company. Under the terms of this agreement, we have exclusive global veterinary industry rights to develop and market a novel pathogen detection system in the form of a point-of-care diagnostic instrument. The agreement covers development and validation of ZM-020. We are responsible for development and validation, and their associated costs. Seraph will supply us, on an exclusive basis, with the hardware platform, associated software and the consumables to be developed under the agreement, pursuant to a rolling forecast, at prices specified in the agreement. We will be responsible for the marketing and sale of the hardware platform, associated software and the consumables. The agreement, which is exclusive to the field of global veterinary diagnostic applications, has a term of seven years (subject to adjustment in certain circumstances) and automatically renews for additional one-year terms thereafter.

We paid Seraph up-front fees of $500,000 and issued to Seraph unregistered common shares having a value of $1,250,000, consisting of an aggregate of 641,717 common shares at an ascribed price of $1.9479 per share. Seraph is entitled to additional payments for development costs. Seraph will be entitled to receive up to an additional $7,000,000, payable 50 percent in cash and 50 percent in additional unregistered common shares, upon the achievement of a series of staged, specified milestones, including completion of laboratory studies and field studies, production and commercial shipment of products. Future issuances of shares will be subject to TSX-V approval and will be priced relative to market at the time of issuance. Seraph is entitled to certain registration rights with respect to the common shares to be issued by us under the agreement. In addition, we have agreed to pay Seraph license fees based on a percentage of gross profit from commercial sales of ZM-020.

In January 2017, we entered into a collaborative research agreement with Celsee, Inc., or Celsee, a developer of diagnostics for the detection and quantification of cells and other markers. Subsequent to this agreement, in December 2017, we entered into a license and supply agreement with Celsee for exclusive global rights to develop and market Celsee's liquid biopsy platform. The agreement with Celsee covers the development and commercialization of liquid biopsy assays and related consumables for the detection of cancer in companion animals. We are responsible for the clinical development and commercialization of the assays. Celsee will supply us on an exclusive basis with the assays and the consumables for the products to be developed under the agreement pursuant to a rolling forecast to be provided by us at prices specified in the agreement. We will be responsible for the marketing and sale of the assays and the related consumables. The agreement, which is exclusive in the field of veterinary cancer diagnostic applications, has a term of seven years (subject to termination in certain circumstances) and automatically renews for additional one-year terms thereafter.

We paid Celsee up-front fees of $500,000 and issued to Celsee unregistered common shares having a value of $250,000, consisting of an aggregate of 112,314 common shares at an ascribed price of $2.2259 per share. Celsee is entitled to additional payments totaling up to an additional $1 million, payable 50 percent in cash and 50 percent in additional unregistered common shares, upon the achievement of specified milestones—namely, completion of product development (in respect of 50 percent of the foregoing cash and share payments) and upon successful completion of manufacturing milestones (as to the remaining 50 percent of the foregoing cash and share payments). Future issuances of shares will be subject to TSX-V approval and will be priced relative to market at the time of issuance. Celsee is entitled to certain registration rights with respect to the common shares issued by us under the agreement.

In April 2016, we entered into a collaboration agreement with CTX Technology, Inc., or CTX, which has developed a peptide-based skin penetration platform technology for the topical delivery of a range of APIs. Under this agreement, we have an option to obtain an exclusive worldwide license to use CTX's technology platform in animals. In the event that we exercise the option, we would be required to pay CTX a one-time license fee of $20,000 and to pay CTX a royalty in the low single digits on any products that we sell that incorporates their technology. Unless we exercise our option prior thereto, this agreement will terminate on March 1, 2019.

Research and Development

Together with our strategic partners, we are performing development work on our diagnostic platforms. Our drug product candidate development programs focus on the development of product candidates for target indications that have already demonstrated safety and efficacy in humans and the development of therapeutics based on these drugs for appropriate target indications in companion animals. In addition, we are investigating the development of alternative drug delivery systems for our drug product candidates. We use various contract research organizations, or CROs, to assist in performing our research and development activities.

In connection with these activities, we have incurred and will continue to incur significant research and development expenses. Our research and development expenses were $3,765,332 and $1,586,179 for the nine months ended September 30, 2018 and September 30, 2017, respectively, and $2,751,326 and $1,518,589 for the years ended December 31, 2017and December 31, 2016, respectively.

Sales and Marketing

We intend to commercialize any product candidate for which we receive regulatory approval in the United States with a direct sales force. We intend to sell products directly to veterinarians whom we believe are self-motivated to utilize advanced diagnostics and prescribe innovative therapeutics that are safe, effective, and supported by reliable clinical data and regulatory approval in order to improve the health of companion animals, while also generating additional revenue.

We also intend to market certain of our products to reference labs. Our commercialization strategy is to sell ZM-024 and ZM-020 to veterinarians, and to sell ZM-017 to reference lab(s), while driving utilization of the tests by veterinarians. We believe this strategy is consistent with the current practice of veterinarians who perform some of their own diagnostic tests and send other diagnostic samples to reference labs for analysis.

We also intend to selectively utilize distributors, which we believe will enable us to expand our commercial reach to a majority of all veterinarians in our chosen markets. We believe that we can compete effectively with a combination of our own direct sales force and complementary distributors.

To support our marketing efforts, we introduced a unique "Voice of the Vet™" program in the fourth quarter of 2016 to gather insights and better understand the needs of veterinarians and their practices, and to gauge interest for potential future product offerings, while building brand awareness as a valued veterinary partner. Our Voice of the Vet™ program allows veterinarians, practice managers and veterinary technicians to participate in conversations where they can share ideas and experiences with each other, as well as with us through an interactive platform.

During 2018, we have increased our investment to build brand and product awareness as a valued veterinary partner with clinical practitioners. In the fourth quarter of 2018, we initiated a strategic customer development initiative, which includes expansion activities for its Voice of the Vet™ programming for veterinarians, veterinary technicians and nurses, practice managers and hospital administrators, as well as veterinary students.

Additionally, we are continuing to conduct comprehensive market research across the United States with private, corporate and institutional clinics along with key opinion leaders and academia to obtain feedback on our product development efforts and to build relationships with key market influencers. We are also finalizing science-based educational white papers for our ZM-017 canine cancer diagnostic platform and our ZM-20 point-of-care pathogen detection platform.

During 2019, we expect to increase our product marketing efforts. Our goal is to be in a position toward the end of 2019 to begin soliciting and accepting commercial orders and deposits for our point-of-care diagnostic products for delivery in 2020 as described elsewhere herein.

Manufacturing

We have no internal manufacturing capabilities for our diagnostic and therapeutic product candidates.

Under our license and supply agreements, Qorvo, Seraph and Celsee are responsible for the manufacture and supply of the equipment and consumables to us. Our strategic partners have primary responsibility for assuring that all products will be manufactured in accordance with applicable laws and meet all agreed upon specifications.

To ensure a dependable and high quality supply of the APIs for our pilot studies and pivotal trials, we rely on cGMP-compliant contract manufacturers. Because the APIs in our drug product candidates are used in human drugs that are no longer subject to patent protection, we believe that there are multiple contract manufacturers for our drug product candidates that have demonstrated the ability to provide high-quality formulated products more cost effectively than we could on our own. We believe that the contract manufacturers of our trial supplies will be able to provide commercial supplies of any of our drug product candidates that are approved for marketing.

While we and our contract manufacturers have historically been able to obtain supplies of the APIs for development of our drug product candidates, neither we nor our contract manufacturers have long-term supply agreements with the API manufacturers. We also have no agreements for commercial-scale supply of the API or manufacture of any of our drug product candidates.

Intellectual Property

We intend to rely primarily upon a combination of in-licensing exclusive rights, regulatory exclusivity, proprietary know-how, and confidentiality agreements to protect our diagnostic assays, product formulations, processes, methods and other technologies and to preserve any trade secrets and operate without infringing on the proprietary rights of other parties, both in the United States and in other countries. We currently do not own any issued patents.

Our diagnostic technologies are dependent on intellectual property developed by our strategic partners and licensed to us. We do not own the intellectual property rights that underlie these licenses. Our rights to use the technology we license are subject to the negotiation of, continuation of and compliance with the terms of our licenses. However, we have filed three provisional patents to date, two of which cover methods of using antibody based cancer detection and another compositions and method patent for identifying lymphoma all of which relate to our ZM-017 platform.

Because our drug product candidates are based on approved human drugs that no longer are subject to patent protection, there is little, if any, composition-of-matter patent protection available for the API in these product candidates. Where feasible, however, we intend to pursue the broadest intellectual property protection possible for our compounds and any proprietary technology through enhanced formulations of our drug product candidates. However, even intellectual property protection, if available, may not afford us with complete protection against competitors.

We depend upon the skills, knowledge and experience of our management personnel, as well as that of our other employees, advisors, consultants and contractors, none of which are patentable. To help protect our know-how, and any inventions for which patents may be difficult to obtain or enforce, we require all of our employees, consultants, advisors and other contractors to enter into customary confidentiality and inventions agreements that prohibit the disclosure of confidential information and, where applicable, require disclosure and assignment to us of the ideas, developments, discoveries and inventions important to our business.

Competition

Diagnostics

Our potential competitors include large human pharmaceutical and medical diagnostics companies, small businesses focused on animal health, and reference laboratory services provided by academic institutions and in-clinic product providers. These competitors include Idexx Laboratories, Inc., Antech Diagnostics, a unit of VCA Inc., Abaxis, Inc., a wholly-owned subsidiary of Zoetis Inc., Heska Corporation and Zoetis Inc.

Therapeutics

If our drug product candidate is the first one approved by the FDA-CVM for use in animals, it may be eligible for between three and seven years of regulatory exclusivity in the United States, depending on the type of product and its intended use. However, while there are fewer competitors in the pet therapeutics industry than in the human pharmaceutical industry, the development and commercialization of new animal health medicines is highly competitive, and we expect competition from major pharmaceutical, biotechnology and specialty animal health medicine companies.

Our potential competitors include large animal health companies, which currently derive a significant portion of their revenue from livestock medications. Large animal health companies include Merck Animal Health, the animal health division of Merck & Co., Inc.; Elanco; Bayer Animal Health, the animal health division of Bayer AG; Novartis Animal Health, the animal health division of Novartis AG; Boehringer Ingelheim Animal Health, the animal health division of Boehringer Ingelheim GmbH; and Zoetis, Inc., as well as European companies such as Virbac S.A., Vetoquinol S.A., and Dechra Pharmaceuticals PLC. We are also aware of several smaller early stage companies that are developing products for use in the pet therapeutics market, including Kindred Biosciences, Inc., Aratana Therapeutics, Inc., Parnell Pharmaceuticals Holdings Ltd., and Jaguar Animal Health, Inc. Our drug product candidates will also face competition from medicines and products approved for use in humans that are used off-label for pets. Private organizations, academic institutions and government agencies conducting animal health product research are also considered potential competitors.

General

Many of our competitors and potential competitors have substantially more financial, technical, and human resources than we do. Many also have far more experience in the development, manufacture, regulation and worldwide commercialization of animal diagnostics and 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 fields of animal diagnostics and animal health medicines. 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, we may be unable to effectively compete in the markets in which we participate.

Government Regulation

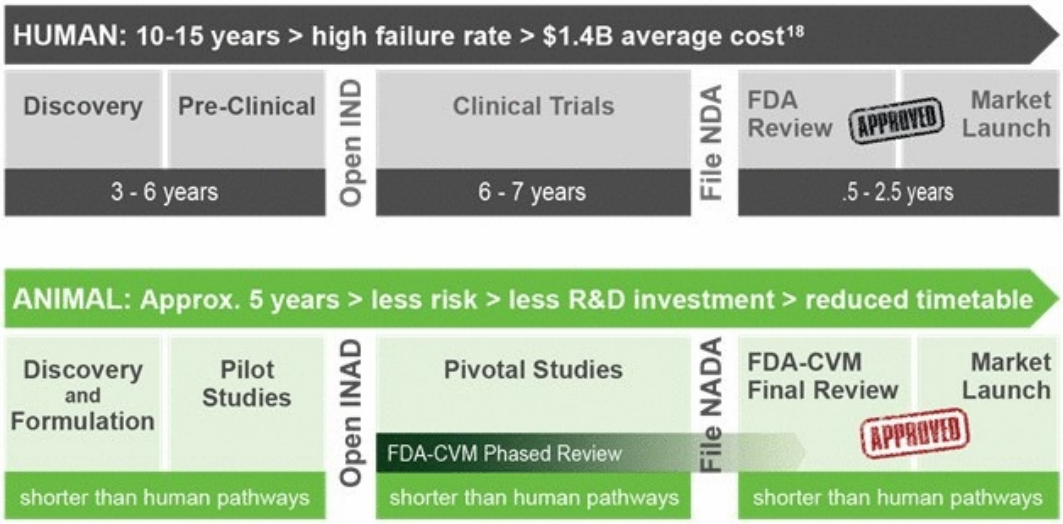
Diagnostic Product Candidates

Our diagnostic product candidates may be subject to regulatory review by the USDA-CVB and/or post-marketing oversight by the USDA-CVB or FDA-CVM. Generally speaking, full diagnostic kits aimed at the detection or diagnosis of an infectious disease in animals, including the materials required for testing along with instructions for use and interpretation of results, used at the point-of-care, including in-office diagnostic tests, may be subject to pre-market regulatory review and approval by the USDA-CVB. The USDA-CVB's review process for diagnostics is subject to some variability based on the type of diagnostic kit being reviewed, however, the USDA-CVB will generally review the results of specific tests that are required to be conducted in accordance with the USDA-CVB's testing criteria. These include diagnostic sensitivity/specificity studies, conducted using a large number of samples of U.S. origin, reproducibility/repeatability/suitability studies used to evaluate test kits under field conditions in participating laboratories and ruggedness studies in which manufacturers measure the ruggedness or robustness of the diagnostic test kits based on the capacity of the assay to remain unaffected by small variations in or deviations from the instructions for use (for example, not allowing the samples to reach the designated temperature). Diagnostic products and testing kits that do not claim to detect or diagnose an infectious disease and that are not designed for use at the point-of-care are generally subject only to post-marketing oversight by the FDA-CVM or the USDA-CVB. While the sale of these products does not require premarket approval by the FDA-CVM and does not subject us to the FDA-CVM's cGMP requirements, these products must not be adulterated, mislabeled or misbranded under the Federal Food, Drug and Cosmetic Act, or the FDC Act, and are subject to post-marketing review.

Drug Product Candidates

The FDA-CVM regulates animal pharmaceuticals under the FDC Act. In order to obtain regulatory approval to market a drug product candidate in the U.S., an applicant must demonstrate that the product candidate is safe, effective and produced by a consistent method of manufacture. Post-approval monitoring of products is required by law, with reports being provided to the FDA-CVM's Surveillance and Compliance group. Reports of product quality defects, adverse events or unexpected results are required in accordance with the law.

Prior to commencing testing of a drug product candidate, an applicant is required to open an INAD with the FDA-CVM. Formulation work and pilot testing occurs once the INAD is opened. This is followed by a pre-submission conference with the FDA-CVM to discuss and agree on a proposed development plan, including the design of pivotal safety and clinical trials that would support approval of a new animal drug application, or NADA.



Early pilot studies may be conducted in laboratory animals to establish clinical endpoints and the dose range for a new drug product candidate. Data on how well the drug is absorbed when dosed by different routes of administration and the relationship of the dose to the effectiveness are studied.

During development, the applicant will usually submit a proposed pivotal trial protocol to the FDA-CVM for review and concurrence prior to conducting the trial. The applicant must gather and submit data on manufacturing, safety and effectiveness to the FDA-CVM for review, which will be conducted according to timelines specified in the Animal Drug User Fee Act, or ADUFA. ADUFA also imposes certain fees including a sponsor fee of $125,990 per year, an application fee of $449,348 per product candidate submission, and certain administrative application and manufacturing fees imposed per product candidate per year based on sales.

The pivotal clinical trial must be conducted with the formulation of the drug product candidate that is intended to be commercialized, and is a multi-site, randomized, controlled study, generally with a placebo control. To reduce bias in the study, individuals doing the assessment are not told whether the subject is in the group receiving the treatment being tested or the placebo group.

Once all data have been submitted and reviewed for each technical section - safety, effectiveness and chemistry, manufacturing and controls, or CMC - the FDA-CVM issues a “technical section complete letter” as each section review is completed, and when all three letters have been issued, the applicant prepares a draft of the Freedom of Information Summary, the proposed labeling, and all other relevant information, and submits these for FDA review. An administrative NADA is a NADA that is submitted after all of the technical sections that fulfill the requirements for the approval of the new drug product candidate have been reviewed by FDA-CVM and FDA-CVM has issued a technical section complete letter for each of those technical sections. Although this process is not required and submission of a non-administrative NADA is also acceptable, we plan to take advantage of the administrative NADA process to obtain a timelier phased review. Because FDA-CVM has already reviewed the individual technical sections before the administrative NADA is filed, FDA-CVM is committed under ADUFA to reviewing and acting on 90% of administrative NADAs within 60 days after submission. The FDA-CVM user fee goal is to review and act on 90% of non-administrative NADAs within 180 days after submission. After approval, we will be required to collect reports of adverse events and submit them on a regular basis to the FDA.

Other Regulatory Considerations

Regulatory rules relating to human food safety, food additives, or drug residues in food will not apply to our product candidates because our product candidates are not intended for use in food animals or food production animals.

Advertising and promotion of animal health products is controlled by regulations in the United States. These rules generally restrict advertising and promotion to those claims and uses that have been reviewed and authorized by the FDA-CVM.

Any drug product candidate, if approved, may eventually face generic competition in the United States. In the United States, a generic animal drug may be approved pursuant to an Abbreviated New Animal Drug Application, or ANADA. Instead of demonstrating the drug's safety and effectiveness in the target species as required in a NADA, a generic applicant must only show that the proposed generic product is the same as, and bioequivalent to, the approved brand name product. However, if any of our drug product candidates is the first one approved by the FDA-CVM for use in animals, it will be eligible for between three and seven years of regulatory exclusivity in the United States, depending on the type of product and its intended use.

We will be required to conduct post-approval monitoring of any approved product and to submit reports of product quality defects, adverse events or unexpected results, and be subject to regulatory inspection from time to time. Safety, quality, or efficacy concerns can lead to product recalls, withdrawals or suspended or declining sales, as well as product liability and other claims.

Employees

As of December 15, 2018, we had 27 employees including one employee who is a doctor of veterinary medicine. Of our employees, ten are engaged in research and development activities, seven are engaged in business development and marketing activities, and ten are engaged in corporate and administrative activities. None of our employees are represented by labor unions or covered by collective bargaining agreements.

Properties

Our corporate headquarters and research and development laboratory is located in Ann Arbor, Michigan, where we lease approximately 26,500 square feet pursuant to a lease that expires February 2022. We have the option to extend that lease for two, five year renewal periods. We believe that our facilities are sufficient for our existing and expected future needs.

Legal Proceedings

We are not currently a party to any material legal proceedings.

Corporate Information

Zomedica Pharmaceuticals Corp. (formerly, Wise Oakwood Ventures Inc.) was originally incorporated as Wise Oakwood Ventures Inc. on January 7, 2013 under the *Business Corporations Act* (Alberta). On October 28, 2013, we completed our initial public offering in Canada and became classified as a Capital Pool Company, as defined under the rules of the TSX Venture Exchange, or TSX-V. On April 21, 2016, we changed our name to Zomedica Pharmaceuticals Corp. and consolidated our common shares on a one-for-two and one-half (2½) basis. ZoMedica Pharmaceuticals Inc., or ZoMedica Inc., was incorporated on May 14, 2015 under the *Canada Business Corporations Act*. On April 21, 2016, we completed a qualifying transaction, or the Qualifying Transaction, under TSX-V Policy 2.4 – *Capital Pool Companies*, consisting of a three-cornered amalgamation among our company, ZoMedica Inc. and our wholly-owned subsidiary. Under the Qualifying Transaction, ZoMedica Inc. and our subsidiary were amalgamated to form Zomedica Pharmaceuticals Ltd., or Zomedica Ltd. As consideration for the amalgamation, shareholders of ZoMedica Inc. became the owners of 97.6% (non-diluted) of our common shares, and ZoMedica Ltd. became our wholly-owned subsidiary. Subsequent to the Qualifying Transaction, Zomedica Ltd. was vertically amalgamated into our company. We have one wholly-owned subsidiary, Zomedica Pharmaceuticals, Inc., a Delaware company. ZoMedica Inc. entered into the Qualifying Transaction in order to accomplish the following:

- Enable its shareholders to own shares in a company that was publicly traded on the TSX-V;
- Expand its shareholder base to include the public shareholders of Wise Oakwood; and
- Obtain access to the cash resources raised by Wise Oakwood in its initial public offering.

On November 10, 2017, our shares were approved for listing on the NYSE American under the symbol "ZOM". On November 20, 2017 the U.S. Securities and Exchange Commission declared our registration statement on Form S-1 effective. Our common shares commenced trading on the NYSE American on November 21, 2017.

Our principal executive offices are located at 100 Phoenix Drive, Suite 190, Ann Arbor, MI 48108, and our telephone number is (734) 369-2555. Our website address is www.zomedica.com. The information contained in, or accessible through, our website is not part of the registration statement of which this prospectus forms a part.

Risks Related to Our Business

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

We are a development stage veterinary diagnostic and pharmaceutical company creating products for companion animals (canine, feline and equine) by focusing on the unmet needs of clinical veterinarians. Since the commencement of our business in May 2015, our operations have been primarily limited to the identification of product candidates and research and development of our diagnostic and drug product candidates. As a result, we have limited historical operations upon which to evaluate our business and prospects and we have not yet demonstrated an ability to obtain approval for any of our product candidates or successfully overcome the risks and uncertainties frequently encountered by companies in emerging fields such as the companion animal pharmaceuticals and health care solutions industries.

We also have not generated any revenue to date, and we expect to continue to incur significant research and development costs and other expenses. Our net loss and comprehensive loss for the three months ended September 30, 2018 and September 30, 2017 was $1,910,278 and $2,080,682, respectively, for the nine months ended September 30, 2018 and September 30, 2017 was $8,226,005 and $5,501,788, respectively, and for the years ended December 31, 2017 and December 31, 2016 was $8,065,072 and $5,740,492, respectively. Our accumulated deficit as of September 30, 2018 was $23,852,105. As of September 30, 2018, we had total shareholders' equity of $2,910,267. We expect to continue to incur losses for the foreseeable future, which will increase significantly from historical levels as we expand our product development activities (including conducting required clinical studies and trials), seek necessary approvals for our product candidates, and begin commercialization activities. Even if we succeed in developing and broadly commercializing one or more of our 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, then we may be unable to continue our operations at planned levels and be forced to reduce or cease operations.

We will need to raise additional capital to achieve our goals.

We do not have any products approved for sale. Although we believe that we do not require pre-market approval from the U.S. Food and Drug Administration's Center for Veterinary Medicine, or the FDA-CVM, to market and sell ZM-024, a Bulk Acoustic Wave sensor-based veterinary point-of-care diagnostic platform for performing immunodiagnostic testing, ZM-020, our Raman spectroscopy-based point-of-care diagnostic platform, or ZM-017, the circulating tumor cell, or CTC, diagnostic assay that we are developing, we do not expect to commence marketing of these solutions until the first half of 2020.

Until, and unless, we receive approval from the FDA-CVM for our drug product candidates, we cannot market or sell our drug products in the United States and will have no material drug product revenue. Our lead drug product candidates are in the formulation, optimization and/or pilot study stage, and we have not yet begun pivotal trials. We anticipate that each of our drug product candidates will require approximately five years of development at a cost of approximately $6 million per drug product candidate before we expect to be able to apply for marketing approval in the United States. In addition, certain assays that we may choose to pursue for use in our diagnostic platforms may require pre-market regulatory approval.

We are also seeking to identify potential complementary opportunities in the veterinary diagnostics and therapeutics sectors. We will continue to expend substantial resources for the foreseeable future to develop our existing product candidates and any other product candidates that we may develop or acquire. These expenditures will include: costs of developing and validating our diagnostic product candidates and related assays and consumables; costs associated with drug formulation; costs associated with conducting pilot and pivotal trials and clinical studies; costs associated with completing other research and development activities; costs of identifying additional potential product candidates; costs associated with payments to technology licensors and maintaining other intellectual property; costs of obtaining regulatory approvals; costs associated with securing contract manufacturers to meet our commercial manufacturing and supply capabilities; and costs associated with marketing and selling our products. In addition, under our existing development agreements, we are required make significant cash milestone payments to our development partners and to pay certain development costs. We do not control the timing of these payments. We also may incur unanticipated costs. Because the outcome of our development activities and commercialization efforts is inherently uncertain, the actual amounts necessary to successfully complete the development and commercialization of our existing or future product candidates may be greater or less than we anticipate.

As a result, we will need to obtain additional capital to fund the development of our business. Except for our $5,000,000 unsecured working capital loan we have no existing agreements or arrangements with respect to any financings, and any such financings may result in dilution to our shareholders, the imposition of debt covenants and repayment obligations or other restrictions that may adversely affect our business or the value of our common shares.

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

- the scope, progress, results and costs of researching and developing our existing or future diagnostics and product candidates;
- the extent to which any of our future diagnostic assays may be subject to USDA-CVB pre-market regulation;
- the timing of, and the costs involved in, obtaining regulatory approvals for any of our existing or future diagnostics or product candidates;
- the number and characteristics of the diagnostics and/or product candidates we pursue;
- the cost of contract manufacturers to manufacture our existing and future diagnostics and product candidates and any products we successfully commercialize;
- the cost of commercialization activities if any of our existing or future diagnostics and 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 partnerships, licensing or other arrangements and the financial terms of such agreements; and
- the costs involved in preparing and filing patent applications, maintaining any successfully obtained patents and protecting and enforcing any such patents.

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 lead product candidates, and cannot be certain that any of them will be approved for marketing, to the extent applicable, or successfully commercialized.

We have no products approved for sale in any jurisdiction and are focused primarily on the development of our lead diagnostic and drug product candidates. Accordingly, our near-term prospects, including our ability to generate material product revenue, or enter into potential strategic transactions, will depend heavily on the successful development and commercialization of one or more of our lead candidates, which in turn will depend on a number of factors, including the following:

- the successful completion of clinical validation of our diagnostic product candidates, which may take significantly longer than we anticipate and will depend, in part, upon the satisfactory performance of our strategic partners and third-party contractors;
- the successful completion of pilot testing and pivotal efficacy and safety trials of one or more of our drug product candidates, which may take significantly longer than we anticipate and will depend, in part, upon the satisfactory performance of third-party contractors;
- our ability to demonstrate to the satisfaction of the FDA-CVM or the USDA Center for Veterinary Biologics, or USDA-CVB, as applicable, the safety and efficacy of our drug product candidates and to obtain regulatory approvals;
- the ability of our third-party contract 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 market any product candidate for which marketing approval is received, whether alone or in partnership with others;
- the availability, perceived advantages, relative cost, relative safety and relative efficacy of our product candidates 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 United States Patent and Trademark Office ("USPTO").

Many of these factors are beyond our control. Accordingly, we cannot assure you that we will be successful in developing or commercializing any of our product candidates. If we are unsuccessful or are significantly delayed in developing and commercializing our product candidates, our business and prospects will be materially adversely affected and you may lose all or a portion of your investment.

We face unproven markets for our products candidates.

The companion animal therapeutic and diagnostic markets are less developed than the human therapeutic and diagnostic markets and as a result no assurance can be given that our product candidates will be successful. Veterinarians, pet owners or other veterinary health providers in general may not accept or utilize any products that we may develop.

The companion animal care industry is subject to rapidly changing technology, which could make our product candidates obsolete.

The companion animal care industry is characterized by rapid technological changes, frequent new product introductions and enhancements, and evolving industry standards, all of which could make our product candidates obsolete. Our future success will depend on our ability to keep pace with the evolving needs of our customers on a timely and cost-effective basis and to pursue new market opportunities that develop as a result of technological and scientific advances. We must continuously enhance our product offerings to keep pace with evolving standards of care. If we do not update our product offerings to reflect new scientific knowledge or new standards of care, our product candidates could become obsolete, which would have a material adverse effect on our business, financial condition, and results of operations.

Our ability to successfully develop and commercialize our existing and any future product candidates will depend on several factors, including:

- our ability to convince the veterinary community of the clinical utility of our products and their potential advantages over existing tests and therapies;
- the willingness or ability by pet owners to pay for our products and the willingness of veterinarians to recommend our products;
- the willingness of veterinarians to utilize our diagnostic tests; and
- where applicable, the willingness of testing labs to buy our assay equipment.

Our dependence on suppliers could limit our ability to develop and commercialize certain products

We rely on third-party suppliers to provide components in our product candidates, manufacture products that we do not manufacture ourselves and perform services that we do not provide ourselves. Because these suppliers are independent third parties with their own financial objectives, actions taken by them could have a materially negative effect on our results of operations. The risks of relying on suppliers include our inability to enter into contracts with third-party suppliers on reasonable terms, inconsistent or inadequate quality control, relocation of supplier facilities, supplier work stoppages and suppliers' failure to comply with applicable regulations or their contractual obligations. Problems with suppliers could materially negatively impact our ability to complete development, supply the market, lead to higher costs or damage our reputation with our customers.

In addition, we currently purchase many products and materials from sole or single sources. Some of the products that we purchase from these sources are proprietary and, therefore, cannot be readily or easily replaced by alternative sources. To mitigate risks associated with sole and single source suppliers, we will seek when possible to enter into long-term contracts that provide for an uninterrupted supply of products at predictable prices. However, some suppliers may decline to enter into long-term contracts and we are required to purchase products with short term contracts or on a purchase order basis. There can be no assurance that suppliers with which we do not have contracts will continue to supply our requirements for products, that suppliers with which we do have contracts will always fulfill their obligations under these contracts, or that any of our suppliers will not experience disruptions in their ability to supply our requirements for products. In cases where we purchase sole and single source products or components under purchase orders, we are more susceptible to unanticipated cost increases or changes in other terms of supply. In addition, under some contracts with suppliers we have minimum purchase obligations, and our failure to satisfy those obligations may result in loss of some or all of our rights under these contracts or require us to compensate the supplier. If we are unable to obtain adequate quantities of products in the future from sole and single source suppliers, we may be unable to supply the market, which could have a material adverse effect on our results of operations.

The commercial potential of our product candidates is difficult to predict. The market for any product candidate, or for companion animal diagnostics and therapeutics overall, is uncertain and may be smaller than we anticipate, which could significantly and negatively impact our revenue, results of operations and financial condition.

We believe that the emerging nature of our industry and our unproven business plan make it difficult to estimate the commercial potential of any of our product candidates. The market for any product that we seek to commercialize will depend on important factors such as the cost, utility and ease of use of our diagnostic assays, the safety and efficacy of our drug candidates compared to other available treatments, including potentially less expensive human pharmaceutical 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. Because relatively few pet owners purchase insurance for their companion animals, pet owners are more likely to have to pay for our products directly and may be unwilling or unable to pay for any such products.

We face competition from the validated human drugs from which our drug candidates are developed which are not subject to patent protection and which are already used "off-label" in animals.

Our lead drug product candidates include APIs already demonstrated safe and effective in humans and we expect that our future drug product candidates will be similarly based on such APIs. We do not engage in research or discovery of novel therapeutics, but focus on drug product candidates with APIs that have been successfully commercialized or demonstrated to be safe and effective in humans, which we sometimes refer to as validated. We expect that there will be little, if any, third-party patent protection of the APIs in our drug product candidates. As a result, our drug product candidates may face competition from their human equivalents in situations where such equivalents are available and used in unapproved animal indications, which is known as off-label use. There is no assurance that the eventual prices of our drug products will be lower than or competitive with the prices of the human equivalents used off-label, or that a palatable, easy-to-administer formulation will be sufficient to differentiate them from their human equivalents.

Our product candidates will face significant competition and may be unable to compete effectively.

The development and commercialization of veterinary diagnostics and pharmaceuticals is highly competitive and our success depends on our ability to compete effectively with other products in the market.

There are a number of competitors in the diagnostic market that have substantially greater financial and operational resources and established marketing, sales and service organizations. We expect to compete primarily with commercial clinical laboratories, hospitals' clinical laboratories and other veterinary diagnostic equipment manufacturers. Our principal competitors in the veterinary diagnostic market are Idexx Laboratories, Inc., Antech Diagnostics, a unit of VCA Inc., Abaxis, Inc., Heska Corporation and Zoetis Inc. We must develop our distribution channels and build our direct sales force in order to compete effectively in these markets. If we are unable to effectively manage our distribution channels in our highly competitive industry, we may fail to retain customers or obtain new customers and our business will suffer.

If our drug product candidates are approved, we expect to compete with large animal health companies including Merck Animal Health, the animal health division of Merck &Co., Inc.; Elanco Animal Health Incorporated; Bayer Animal Health, the animal health division of Bayer AG; Boehringer Ingelheim Animal Health, the animal health business unit of Boehringer Ingelheim GmbH; and Zoetis, Inc., as well as European companies such as Virbac S.A., Vetoquinol S.A. and Dechra Pharmaceuticals PLC We are also aware of several smaller early stage companies that are developing products for use in the pet therapeutics market, including Kindred Biosciences, Inc., Aratana Therapeutics, Inc., Parnell Pharmaceuticals Holdings Ltd. and Jaguar Animal Health, Inc. We also expect to compete with academic institutions, governmental agencies and private organizations that are conducting research in the field of animal health medicines.

We target drug product candidates for which the API, while having been approved for use in human drugs, has not been previously approved for use in animals. If we are the first to gain approval for the use of such API in animals, our drug products will benefit from between three and seven years of marketing exclusivity in the United States for the approved indication. We also plan to differentiate our products, where possible, with alternative drug delivery systems that are more conducive to dosing for the target companion animal species, but we cannot assure you that we will be able to prevent our competitors from developing substantially similar products and bringing those products to market earlier than we are able to.

Our drug product candidates will face competition from various products approved for use in humans that are used off-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 drug 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 fields of animal diagnostics and animal health. If such competing products are commercialized 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 therapeutic products, we may be unable to compete effectively in the markets in which we participate. Contractual agreements between clinics and from competitors may limit practices' ability to use other tests and technologies due to predetermined minimums in those agreements.

Our ability to develop, manufacture and commercialize our drug product candidates is dependent on our establishing and maintaining relationships with GMP-compliant third party manufacturers.

We have no internal manufacturing capabilities and we do not plan to develop such capabilities. As a result, our ability to manufacture and commercialize our product candidates is substantially dependent on our ability to ensure a dependable and high quality supply of the APIs required for our pilot studies and pivotal trials and for future commercial manufacturing. We currently believe that, because the APIs used in our drug product candidates have been used in human drugs, there are multiple GMP-compliant manufacturers available that will be able to supply these APIs and that the contract manufacturers we currently use for our trial supplies will be able to provide commercial supplies of any of our drug product candidates. While we have historically been able to obtain the necessary supplies of our APIs for our development work, we cannot be certain that either we or our contract manufacturers will continue to be able to provide the necessary API supply. Neither we nor our contract manufacturers have long-term supply contracts with API manufacturers and we have no agreements in place for the commercial-scale supply of any API or the manufacture of any of our drug product candidates. If we are unable to procure the requisite apply of an API or to contract with a GMP-complaint third-party manufacturer, we may be unable to continue to develop, manufacture or commercialize any of our product candidates and our business may fail to grow or develop.

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 drug product candidates under applicable regulatory requirements or maintain any regulatory approval obtained. The denial, delay or loss of any regulatory approval would prevent or delay our commercialization efforts and adversely affect our financial condition and results of operations.

The research, testing, manufacturing, labeling, approval, sale, marketing and distribution of our product candidates are subject to extensive regulation. We will not be permitted to market our drug product candidates in the United States until we receive approval of a New Animal Drug Application, or NADA, from the FDA-CVM and may not be able to market and sell any point-of-care diagnostic products without pre-marketing approval from the USDA-CVB. To gain approval to market a pet pharmaceutical or point-of-care diagnostic product kit for a particular species, we must provide the FDA-CVM or the USDA-CVB, as applicable, with efficacy data from pivotal trials that adequately demonstrate that our product candidates are safe and effective in the target species for the intended indications. In addition, we must provide manufacturing data. For the FDA-CVM, we must provide data from safety testing and clinical data, also called target animal safety studies. Similarly, for the USDA-CVB, we must provide the results of specific tests required to be conducted in accordance with the USDA-CVB's guidelines demonstrating the sensitivity/specificity, reproducibility/repeatability/suitability and the ruggedness or robustness of the relevant diagnostic kit. Either of the FDA-CVM or the USDA-CVB may also require us to conduct costly post-approval testing and/or collect post-approval safety data to maintain our approval for any product candidate or diagnostic. The results of our pivotal studies and other initial development activities, and the results 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 or after pivotal studies and other development activities by us or our contract research organizations or CROs. Our pivotal studies 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 the 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-CVM or the USDA-CVB can delay, limit, deny or revoke approval of any of our product candidates for many reasons, including:

- if the FDA-CVM or USDA-CVB 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-CVM or the USDA-CVB that the product candidate is safe and effective for the target indication;
- if the FDA-CVM or USDA-CVB requires additional studies or changes its approval policies or regulations;
- if the FDA-CVM or USDA-CVB does not approve of the formulation, labeling or the specifications of our existing and future product candidates;
- if the FDA-CVM or USDA-CVB fails to approve the manufacturing processes of our third-party contract manufacturers; and
- if any approved product candidate subsequently fails post-approval testing required by the FDA-CVM or the USDA-CVB.

Further, even if we receive approval of our product candidates, such approval may be for a more limited indication than we originally requested, the FDA-CVM or USDA-CVB may not approve the labeling that we believe is necessary or desirable for the successful commercialization of our product candidates and we may be required to conduct costly post-approval testing. 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.

Development of product candidates for use in companion animal health is an inherently expensive, time-consuming and uncertain, and any delay or discontinuance of validation or pivotal studies for our current or future product candidates would significantly harm our business and prospects.

Development of product candidates for use in companion animals is an inherently lengthy, expensive and uncertain process, and there is no assurance that our development activities will be successful. We do not know whether the validation studies or the pivotal studies of our drug 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, the occurrence of adverse events or, in the case of our validation studies, sensitivity and selectivity results that vary from our expectations;
- 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 any regulatory 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.

Our strategic partnerships are important to our business. If we are unable to maintain any of these partnerships, or if these partnerships are not successful, our business could be adversely affected.

We have entered into a number of strategic partnerships that are important to our business and we expect to enter into similar partnerships as part of our growth strategy. These partnerships may pose a number of risks, including:

- partners may have significant discretion in determining the efforts and resources that they will apply to these partnerships;
- partners may not perform their obligations as expected;
- partners may not pursue development of our product candidates or may elect not to continue or renew development based on development results, changes in the partners' strategic focus or available funding, or external factors, such as an acquisition, that divert resources or create competing priorities;
- partners could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates if the partners believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours, which may cause partners to cease to devote resources to the development of our product candidates;
- disagreements with partners, including disagreements over proprietary rights, contract interpretation or the preferred course of development, might cause delays or termination of the research and development of product candidates, might lead to additional responsibilities for us with respect to product candidates, or might result in litigation or arbitration, any of which would be time-consuming and expensive;
- partners may not properly maintain or defend their intellectual property rights or may use proprietary information in such a way as to invite litigation that could jeopardize or invalidate the intellectual property or proprietary information or expose us to potential litigation;
- partners may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability;
- partners may learn about our technology and use this knowledge to compete with us in the future;
- there may be conflicts between different partners that could negatively affect those partnerships and potentially others; and

- the number and type of our partnerships could adversely affect our attractiveness to future partners or acquirers.

If any partnerships we enter into do not result in the successful development of our product candidates or if one of our partners terminates its agreement with us, we may not be able to successfully develop our product candidates, our continued development of our product candidates could be delayed and we may need additional resources to develop additional product candidates. All of the risks relating to our product development, regulatory approval and commercialization also apply to the activities of our partners and there can be no assurance that our partnerships will produce positive results or successful products on a timely basis or at all.

Additionally, subject to its contractual obligations to us, if a partner of ours is involved in a business combination or otherwise changes its business priorities, the partner might deemphasize or terminate the development of any technology licensed to it by us. If one of our partners terminates its agreement with us, we may find it more difficult to attract new partners and our perception in the business and financial communities and our stock price could be adversely affected.

We may in the future determine to partner with additional pharmaceutical and technology companies for development of additional product candidates. We face significant competition in seeking appropriate partners. Our ability to reach a definitive agreement for partnership will depend, among other things, upon our assessment of the partner's resources and expertise, the terms and conditions of the proposed partnership and the proposed partner's evaluation of a number of factors. If we are unable to reach agreements with suitable partners on a timely basis, on acceptable terms, or at all, we may not be able to access technologies that are important for the future development of our business. If we elect to fund and undertake development activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms or at all. If we fail to enter into partnerships and do not have sufficient funds or expertise to undertake the necessary development activities, we may not be able to further develop our product candidates and our business may be materially and adversely affected.

Under the terms of our partnership arrangements, we are required to make significant milestone and pother payments to our strategic partners. The timing of any such payments is uncertain and could adversely affect our cash flows and results of operations. If we are not able to make such payments when due, our business could be materially and adversely affected.

In November 2018, we entered into a development and supply agreement with Qorvo Biotechnologies, LLC, or Qorvo, a wholly-owned subsidiary of Qorvo, Inc. Under this agreement, Qorvo is responsible for the development of certain assay cartridges and the related instrument. We agreed to pay the associated non-recurring engineering costs of up to $500,000 per assay cartridge and the instrument, and are responsible for the validation of the assay cartridges and the instrument. Under the terms of this agreement, we are required to pay Qorvo additional milestone payments in cash or, if elected by Qorvo, additional unregistered common shares having a value calculated as specified in the agreement. The total amount of additional milestone payments (if all milestones are met) will be $10 million (if paid entirely with cash) or up to $10.9 million (consisting of cash in the amount of $7 million and unregistered common shares having a value of $3.9 million, if Qorvo elects to receive compensation partially in equity).

In May 2018, we entered into a development, commercialization and exclusive distribution agreement with Seraph Biosciences, Inc., or Seraph. Under this agreement, we are responsible for development and validation, and their associated costs. Seraph is entitled to additional payments for development costs. Seraph will be entitled to receive up to an additional $7,000,000, payable 50 percent in cash and 50 percent in additional unregistered common shares, upon the achievement of a series of staged, specified milestones, including completion of laboratory studies and field studies, production and commercial shipment of products. . In addition, we have agreed to pay Seraph license fees based on a percentage of gross profit from commercial sales of ZM-020.

In January 2017, we entered into a collaborative research agreement with Celsee, Inc., or Celsee. Under this agreement, we are responsible for the clinical development and commercialization of the assays to be developed under this agreement. Celsee is entitled to payments totaling up to an additional $1 million, payable 50 percent in cash and 50 percent in additional unregistered common shares, upon the achievement of specified milestones—namely, completion of product development (in respect of 50 percent of the foregoing cash and share payments) and upon successful completion of manufacturing milestones (as to the remaining 50 percent of the foregoing cash and share payments).

In April 2016, we entered into a collaboration agreement with CTX Technology, Inc., or CTX, Under this agreement, we have an option to obtain an exclusive worldwide license to use CTX's technology platform in animals. In the event that we exercise the option, we would be required to pay CTX a one-time license fee of $20,000 and to pay CTX a royalty in the low single digits on any products that we sell that incorporates their technology.

The timing of our achievement of these events and corresponding milestone payments becoming due to our partners is subject to factors relating to the development and commercialization of the related product candidates, as applicable, many of which are beyond our control. We may become obligated to make a milestone payment during a period in which we do not have the cash on hand to make such payment, which could require us to delay our development work, curtail our operations, scale back our commercialization and marketing efforts, seek funds to meet these obligations at terms unfavorable to us or default on our license agreements, which could result in license termination and the loss of our rights to the related technology. If we are not able to make such payments when due, our business could be materially and adversely affected.

We will rely on third parties to conduct certain portions of our development activities. 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 product candidates.

We have used contract manufacturing organizations ("CMOs") and contract research organizations ("CROs") to conduct our manufacturing and research and development activities. We expect to continue to do so, including with respect to our manufacturing, clinical validation, pilot studies and pivotal trials of our diagnostic and therapeutic product candidates. These CMOs and 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 product candidates is manufactured using good manufacturing practices and studies are conducted in accordance with the development plans and trial protocols, and any failure by our CMOs and 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-CVM also requires us and our CMOs and CROs to comply with regulations and standards, commonly referred to as good manufacturing practices, or GMPs, good clinical practices, or GCPs, and good laboratory practices, or GLPs, collectively called GXPs, for conducting, monitoring, recording and reporting the results of our manufacturing and studies to ensure that the data and results are scientifically credible and accurate.

Our agreements with our CMOs and CROs may allow termination by the CMOs and CROs in certain circumstances with little or no advance notice to us. These agreements generally will require our CMOs and CROs to reasonably cooperate with us at our expense for an orderly winding down of the CMOs' and CROs' services under the agreements. If the CMOs and CROs conducting our manufacturing and 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 GXPs or for any other reason, we may need to secure new arrangements with alternative CMOs and 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.

The failure of any CMO and CRO to perform adequately or the termination of any arrangements with any of them may adversely affect our business.

We rely on third-party manufacturers to produce our product candidates. If we experience problems with any of these suppliers, the manufacturing of our product candidates or products could be delayed.

We do not have the capability to manufacture our product candidates and do not intend to develop that capability. As a result, we rely on CMOs to produce our product candidates. We expect to enter into contracts with CMOs for the commercial scale production of the products we intend to commercialize. Reliance on CMOs involves risks, including:

- the inability to meet our product specifications and quality requirements consistently;
- inability to access production facilities on a timely basis;
- inability or delay in increasing manufacturing capacity;
- manufacturing and product quality issues related to the scale-up of manufacturing;
- costs and validation of new equipment and facilities required for commercial level activity;
- a failure to satisfy any applicable FDA-CVM cGMP requirements on a consistent basis;
- the inability to negotiate manufacturing agreements with third parties under commercially reasonable terms;
- termination or nonrenewal of manufacturing agreements with third parties in a manner or at a time that is costly or damaging to us;
- the reliance on a single sources of supply which, if unavailable, would delay our ability to complete the development and testing and commercialization of our products;
- the lack of qualified backup suppliers for supplies that are currently purchased from a single source supplier;
- operations of our CMOs or suppliers could be disrupted by conditions unrelated to our business or operations, including the bankruptcy of the CMO or supplier;
- carrier disruptions or increased costs that are beyond our control; and
- the failure to deliver products under specified storage conditions and in a timely manner.

Any of these risks could cause the delay of validation studies, clinical trials, regulatory submissions, the receipt of any required approvals or the commercialization of our products, cause us to incur higher costs and prevent us from commercializing our product candidates successfully. Manufacturing of our product candidates and any approved products subject to cGMP could be disrupted or halted if our CMOs do not comply with cGMP, even if the compliance failure does not relate to our product candidates or approved products. Furthermore, if our CMOs fail to deliver the required commercial quantities of finished product on a timely basis and at commercially reasonable prices and we are unable to find one or more replacement manufacturers capable of production at a substantially equivalent cost, in substantially equivalent volumes and quality and on a timely basis, we would likely be unable to meet demand for our products and could lose potential revenue. It may take several years to establish an alternative source of supply for our product candidates and to have any such new source approved by the FDA-CVM in the event that such approval is required.

Even if our product candidates obtain regulatory approval, they may never achieve market acceptance or commercial success.

Even if we obtain FDA-CVM, USDA-CVB or other regulatory approvals, our product candidates may not achieve market acceptance among veterinarians and pet owners, and may not be commercially successful. Market acceptance of any of our product candidates for which we receive approval depends on a number of factors, including:

- the safety of our products as demonstrated in our target animal studies;
- the indications for which our products are approved;
- the acceptance by veterinarians and pet owners of the product as a safe and effective treatment;
- the proper training and administration or use of our products by veterinarians;
- the potential and perceived advantages of our product candidates over alternative treatments or diagnostics, including products approved for use by humans that are used off label;
- the cost of treatment in relation to alternative treatments and willingness to pay for our products, if approved, on the part of veterinarians and pet owners;
- the willingness of pet owners to pay for our treatments, relative to other discretionary items, especially during economically challenging times;
- the relative convenience and ease of administration;
- the prevalence and severity of adverse side effects; and
- the effectiveness of our sales and marketing efforts.

If our approved products fail to achieve market acceptance or commercial success, our business could fail and you could lose your entire investment.

Pharmaceuticals for companion animals, like human pharmaceuticals, 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 pharmaceuticals for companion animals, in general, and of our products, in particular. Unanticipated safety or efficacy concerns can arise with respect to approved 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 compounds upon which our drug product candidates are based could impact our products. 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.

Changes in the distribution channels for companion animal products could negatively impact our market share, margins and distribution of our products.

In most markets, pet owners typically purchase their animal health products directly from veterinarians. In recent years, pet owners have increasingly been afforded the option to purchase animal health products from sources other than veterinarians, such as Internet-based retailers, "big-box" retail stores or other over-the-counter distribution channels. Pet owners also could decrease their reliance on, and visits to, veterinarians as they rely more on Internet-based animal health information. Since we intend to market our products through the veterinarian distribution channel, any decrease in visits to veterinarians by pet owners could reduce our market share for such products and materially adversely affect our operating results and financial condition. In addition, pet owners may substitute human health products for animal health products if human health products are deemed to be lower-cost alternatives.

We do not currently carry liability insurance; however, as we continue our development and commercialization activities, future federal and state legislation may result in increased exposure to product liability claims, which could result in substantial losses to us.

We do not currently carry any product liability insurance. Under existing federal and state laws, companion animals are generally considered to be the personal property of their owners and, as such, pet owners' recovery for product liability claims involving their companion animals may be limited to the replacement value of the animals. 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 companion animals 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. We do not currently have product liability insurance and we may not be able to obtain or maintain this type of insurance in the future.

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 existing or future product candidates, if approved, or generate product revenue.

We do not currently have a sales organization. We intend to commercialize any product candidate for which we received regulatory approval in the United States with a direct sales force and through third-party distributors. To achieve this, we will be required to build a direct sales organization and to establish relationships with distributors of veterinary products. We also will have to build our marketing, sales, managerial and other non-technical capabilities and make arrangements with third parties for distribution and to perform certain of these other services, and we may not be successful in doing so. Building an internal sales organization is time consuming and expensive and will significantly increase our compensation expense. We may be unable to secure third-party distribution contracts with distributors on favorable terms or at all. We have no prior experience in the marketing, sale and distribution of pharmaceuticals or diagnostic products for companion animals and there are significant risks involved in building and managing a sales organization, including our ability 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. If we are unable to build an effective sales organization and/or if we are unable to secure relationships with third-party distributors for our product candidates, we will not be able to successfully commercialize any product for which we receive marketing approval, our future product revenue will suffer and we would incur significant additional losses.

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, it at all.

If we fail to attract and keep senior management and key scientific personnel, we may be unable to successfully develop any of our existing or future product candidates, conduct our in-licensing and development efforts and commercialize any of our existing or future drug candidates.

Our success depends in part on our continued ability to attract, retain and motivate highly qualified management and scientific personnel. We are highly dependent upon our senior management, particularly Gerald Solensky, Jr., our President and Chief Executive Officer, Bruk Herbst, our Chief Commercial Officer, Stephanie Morley, DVM, our Chief Operations Officer and Vice President of Product Development, and Shameze Rampertab, CPA, CA, our Chief Financial Officer. The loss of services of any of these individuals could delay or prevent the successful development of our existing or future product pipeline, completion of our planned development efforts or the commercialization of our product candidates. Although we have entered into employment agreements with Dr. Morley and Mr. Herbst for one year terms (automatically extending for one year terms thereafter) there can be no assurance that either of Dr. Morley or Mr. Herbst will extend their terms of service. We have also entered into employment agreements with Mr. Solensky and Mr. Rampertab, each without a fixed term of service.

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 companion animal pharmaceutical and diagnostic products 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 will need to significantly expand our organization and systems to support our future expected growth. If we fail to manage our growth effectively, we will not be successful and our business could fail.

Our research and development relies on testing in animals, which is controversial and may become subject to bans or additional regulations.

We must test our product candidates in target animals to obtain marketing approval. 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.

Because our directors may serve as directors or officers of other companies, they may have a conflict of interest in making decisions for our business.

Our directors may serve as directors or officers of other companies or have significant shareholdings in other veterinary pharmaceutical or diagnostic products companies and, to the extent that such other companies may participate in ventures in which we may participate, our directors may have a conflict of interest in negotiating and concluding terms respecting the extent of such participation. In the event that such a conflict of interest arises at a meeting of our directors, we expect that the director who has such a conflict will declare his conflict, abstain from voting for or against the approval of such participation or such terms and, if deemed necessary or advisable, recuse himself from any discussion concerning the matters in question. In some circumstances, a director may be unable to manage such conflicts and may therefore need to resign. Our directors are required to act honestly, in good faith and in our best interests. In determining whether or not we will participate in a particular business opportunity or enter into a particular business arrangement, we expect that the directors and officers will be guided by their fiduciary duties and take into account such matters as they deem relevant, including considering the degree of risk to which we may be exposed and our financial position at that time.

We may seek to raise additional funds in the future through debt financing which may impose operational restrictions on our business and may result in dilution to existing or future holders of our common shares.

We expect that we will need to raise additional capital in the future to help fund our business operations. Debt financing, if available, may require restrictive covenants, which may limit our operating flexibility and may restrict or prohibit us from:

- paying dividends and/or making certain distributions, investments and other restricted payments;
- incurring additional indebtedness or issuing certain preferred shares;
- selling some or all of our assets;
- entering into transactions with affiliates;
- creating certain liens or encumbrances;
- merging, consolidating, selling or otherwise disposing of all or substantially all of our assets; and
- designating our subsidiaries as unrestricted subsidiaries.

Debt financing may also involve debt instruments that are convertible into or exercisable for our common shares. The conversion of the debt to equity financing may dilute the equity position of our existing shareholders.

We may not be able to obtain or maintain sufficient insurance on commercially reasonable terms or with adequate coverage against potential liabilities in order to protect ourselves against product liability claims.

Our business exposes us to potential product liability risks that are inherent in the testing, manufacturing and marketing of veterinary therapeutic and diagnostic products. We may become subject to product liability claims resulting from the use of our product candidates. We do not currently have product liability insurance and we may not be able to obtain or maintain this type of insurance for any future trials or product candidates. In addition, product liability insurance is becoming increasingly expensive. Being unable to obtain or maintain product liability insurance in the future on acceptable terms or with adequate coverage against potential liabilities could have a material adverse effect on our business.

We may acquire other businesses or form joint ventures that may be unsuccessful and could adversely dilute your ownership of our company.

As part of our business strategy, we may pursue in-licenses or acquisitions of other complementary assets and businesses and may also pursue strategic alliances. We have no experience in acquiring other assets or businesses and have limited experience in forming such alliances. We may not be able to successfully integrate any acquisitions into our existing business, and we could assume unknown or contingent liabilities or become subject to possible stockholder claims in connection with any related-party or third-party acquisitions or other transactions. We also could experience adverse effects on our reported results of operations from acquisition-related charges, amortization of acquired technology and other intangibles and impairment charges relating to write-offs of goodwill and other intangible assets from time to time following an acquisition. Integration of an acquired company requires management resources that otherwise would be available for ongoing development of our existing business. We may not realize the anticipated benefits of any acquisition, technology license or strategic alliance.

To finance future acquisitions, we may choose to issue shares of our common stock as consideration, which would dilute your ownership interest in us. Alternatively, it may be necessary for us to raise additional funds through public or private financings. Additional funds may not be available on terms that are favorable to us and, in the case of equity financings, may result in dilution to our stockholders.

Risks Related to Government Regulation

Various government regulations could limit or delay our ability to develop and commercialize our products or otherwise negatively impact our business.

In the U.S., the manufacture and sale of certain diagnostic products are regulated by agencies such as the USDA, the FDA or the EPA. While our point-of-care Raman spectroscopy-based diagnostic solution and our diagnostic test for canine cancer do not require approval by the USDA prior to sale in the U.S., these diagnostic solutions will be subject to post-marketing oversight by the FDA-CVM. In addition, delays in obtaining regulatory approvals for new products or product upgrades could have a negative impact on our growth and profitability.

The manufacture and sale of our products, as well as our research and development processes, are subject to similar and potentially more stringent laws in foreign countries.

We are also subject to a variety of federal, state, local and international laws and regulations that govern, among other things, the importation and exportation of products; our business practices in the U.S. and abroad, such as anti-corruption and anti-competition laws; and immigration and travel restrictions. These legal and regulatory requirements differ among jurisdictions around the world and are rapidly changing and increasingly complex. The costs associated with compliance with these legal and regulatory requirements are significant and likely to increase in the future.

Any failure to comply with applicable legal and regulatory requirements could result in fines, penalties and sanctions; product recalls; suspensions or discontinuations of, or limitations or restrictions on, our ability to design, manufacture, market, import, export or sell our products; and damage to our reputation.

Even if we receive regulatory approval for a product candidate, we will be subject to ongoing FDA-CVM or USDA-CVB obligations and continued regulatory oversight, 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-CVM or USDA-CVB approves any of our existing or future therapeutic product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for the product will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, establishment registration, and product listing, as well as continued compliance with GMP, GLP and GCP for any studies that we conduct post-approval. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market, or voluntary product recalls;
- fines, warning letters or holds on target animal studies;
- refusal by the FDA-CVM or USDA-CVB 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-CVM's or USDA-CVB'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 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.

Our ability to market our drug candidates in the United States, if approved, will be limited to use for the treatment of the indications for which they are approved, and if we want to expand the indications for which we may market our product candidates, we will need to obtain additional FDA-CVM approvals, which may not be granted.

We expect to seek FDA-CVM approval in the United States for our drug product candidates. If these drug product candidates are approved, the FDA-CVM will restrict our ability to market or advertise them for the treatment of indications other than the indications for which they are approved, which could limit their adoption by veterinarian and pet owners. We may attempt to develop, promote and commercialize new treatment indications and protocols for our drug product candidates in the future, but we cannot predict when or if we will receive the approvals required to do so. In addition, we would be required to conduct additional target animal studies to support our applications, which would utilize additional resources and may produce results that do not result in FDA-CVM approvals. If we do not obtain additional FDA-CVM approvals, our ability to expand our business in the United States will be limited.

If approved, any of our existing or future therapeutic 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 existing or future therapeutic product candidates, we will be required to report 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 veterinary pharmaceuticals or health care solutions may make it more difficult and costly for us to obtain regulatory clearance or approval of any of our existing 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 that could significantly change the statutory provisions governing the testing, regulatory clearance or approval, manufacture, and marketing of regulated products. In addition, FDA-CVM and USDA-CVB regulations and guidance are often revised or reinterpreted by the FDA-CVM and USDA-CVB 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 may impose additional costs or lengthen review times of any of our existing or future product candidates. We cannot determine what effect changes in regulations, statutes, legal interpretation or policies, when and if promulgated, enacted or adopted may have on our business in the future. Such changes could, among other things, require:

- changes to manufacturing methods;
- recall, replacement or discontinuance of certain products; and
- additional record-keeping.

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

Risks Related to Intellectual Property

Our ability to obtain intellectual property protection for our product candidates is limited.

Our diagnostic technologies are dependent on intellectual property developed by our strategic partners and licensed to us. We do not own the intellectual property rights that underlie these licenses. Our rights to use the technology we license are subject to the negotiation of, continuation of and compliance with the terms of our licenses. However, we have filed three provisional patents to date, two of which cover methods of using antibody based cancer detection and another compositions and method patent for identifying lymphoma all of which relate to our ZM-017 platform. No assurance can be given that such provisional patents will be issued. Even if such provisional patents are issued, we do not expect that they will provide significant protection for our intellectual property.

With respect to our drug product candidates, because our business strategy is to develop APIs already approved for use in humans for veterinary use, our ability to obtain a proprietary intellectual property position for our product candidates is limited. We do not currently own any issued patents for our drug product candidates.

Our current and any future patent applications may never result in the issuance of patents, and/or patents issued to us may be dominated by the patents of third parties, including for example, patents issued to analogous human drugs or biological compositions and their usages. Furthermore, even if any future patents are unchallenged by third parties, our patents, if issued, may not adequately protect our intellectual property or prevent others from designing around them. It is possible that we will not receive patents to cover any future approved products, and/ or that we will have little to no commercial protection against competing products. In such cases, we would then have to rely solely on other forms of exclusivity, such as regulatory exclusivity provided by the FDA-CVM approval, which may provide less protection to our competitive position.

Patent reform legislation could increase the uncertainties and costs surrounding the prosecution of any future patent applications and the enforcement or defense of any patents that issue. On September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art, may affect patent litigation, and switch the U.S. patent system from a "first-to-invent" system to a "first-to-file" system. Under a "first-to-file" system, assuming the other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to the patent on an invention regardless of whether another inventor had made the invention earlier. The USPTO recently developed new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first-to-file provisions, only became effective on March 16, 2013. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of any patents that issue, all of which could have a material adverse effect on our business and financial condition.

Some of our products may or may not be covered by a patent. Further if an application is filed, it is not certain that a patent will be granted or if granted whether it will be held to be valid. All of which may impact our market share and ability to prevent others (competitor third parties) from making, selling, or using our products.

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. We may not be successful in protecting our intellectual property rights, including our unpatented proprietary know-how and trade secrets, or in avoiding claims that we infringed on the intellectual property rights of others. In addition to relying on patent and trademark rights, we rely on unpatented proprietary know-how and trade secrets, and employ various methods, including confidentiality agreements with employees and consultants, customers and suppliers to protect our know-how and trade secrets. However, these methods and our patents and trademarks may not afford complete protection and there can be no assurance that others will not independently develop the know-how and trade secrets or develop better production methods than us. Further, we may not be able to deter current and former employees, contractors and other parties from breaching confidentiality agreements and misappropriating proprietary information and it is possible that third parties may copy or otherwise obtain and use our information and proprietary technology without authorization or otherwise infringe on our intellectual property rights. In the future, we may also rely on litigation to enforce our intellectual property rights and contractual rights, and, if not successful, we may not be able to protect the value of our intellectual property. Any litigation could be protracted and costly and could have a material adverse effect on our business and results of operations regardless of its outcome.

If we are unable to obtain trademark registrations for our products our business could be adversely affected.

We have pending trademark applications for our company name and composite marks comprised of our company name, logo and/or slogan in the U.S., Canada, European Union, the United Kingdom, Brazil and Mexico. In addition, we have pending trademark applications for our "Voice of the Vet" mark in the U.S. and Canada. We have secured two registrations in the European Union for our company name and logo and for the mark Voice of the Vet powered by Zomedica & Design. While we cannot make assurances that these trademark applications will mature to registration in any pending jurisdiction, some of these applications are poised to mature to registration. The applications in Brazil and Mexico were recently filed, and we may face rejections to one or more of our pending trademark applications. Although we are given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in most jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademark applications/registrations, and our trademark applications/registrations may not survive such proceedings.

In particular, the European Union Intellectual Property Office recently determined that our proposed trademark application for certain contested goods and services was likely to cause confusion with an existing registered trademark. The opponent in that matter has also opposed trademark applications in Canada for our company name and logo, but did not oppose our applications in the United States after it sent a letter to us in June 2016 demanding that we cease use of the Zomedica mark and abandon all applications for such mark. While we believe that our mark does not violate any trademark rights of the opponent, we can provide no assurance that we will ultimately prevail in the Canadian opposition.

Finally, we may need to enforce our trademark rights against third parties and expend significant additional resources to enforce such rights against infringements. Moreover, any name we propose to use with our product candidates in the United States must be approved by the FDA-CVM or the USDA-CVB regardless of whether we have registered it, or applied to register it, as a trademark. The FDA-CVM typically conducts a review of proposed product names, including an evaluation of potential for confusion with other product names. If the FDA-CVM or the USDA-CVB object 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-CVM and the USDA-CVB.

Third parties may have intellectual property rights, which may require us to obtain a license or other applicable rights to make, sell or use our products. If such rights are not granted or obtained, I could have a material adverse effect on our business, financial condition and results of operations.

Our success depends in part on our ability to obtain, or license from third parties, patents, trademarks, trade secrets and similar proprietary rights without infringing on the proprietary rights of third parties. Although we believe our intellectual property rights are sufficient to allow us to conduct our business without incurring liability to third parties, our products may infringe on the intellectual property rights of such persons. Furthermore, no assurance can be given that we will not be subject to claims asserting the infringement of the intellectual property rights of third parties seeking damages, the payment of royalties or licensing fees and/or injunctions against the sale of our products. Any such litigation could be protracted and costly and could have a material adverse effect on our business, financial condition and results of operations.

Our diagnostic technologies depend on certain technologies that are licensed to us. We do not control these technologies and any loss of our rights to them could prevent us from marketing our diagnostic product candidates.

Our diagnostic technologies are dependent on intellectual property developed by our strategic partners and licensed to us. We do not own the intellectual property rights that underlie these licenses. Our rights to use the technology we license are subject to the negotiation of, continuation of and compliance with the terms of our licenses. We do not control the prosecution, maintenance or filing of the patents and other intellectual property licensed to us, or the enforcement of these intellectual property rights against third parties. The patents and patent applications underlying our licenses were not written by us or our attorneys, and we do not have control over the drafting and prosecution of such rights. Our partners might not have given the same attention to the drafting and prosecution of patents and patent applications as we would have if we had been the owners of the intellectual property rights and had control over such drafting and prosecution. We cannot be certain that drafting and/or prosecution of the licensed patents and patent applications has been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents and other intellectual property rights.

Our intellectual property agreements with third parties may be subject to disagreements over contract interpretation, which could narrow the scope of our rights to the relevant intellectual property or technology or increase our financial or other obligations to our licensors.

Certain provisions in our intellectual property agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could affect the scope of our rights to the relevant intellectual property or technology, or affect financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

In addition, while it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact conceives or develops intellectual property that we regard as our own. Our assignment agreements may not be self-executing or may be breached, and we may be forced to bring claims against third parties, or defend claims they may bring against us, to determine the ownership of what we regard as our intellectual property.

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 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 Our Common Shares

We believe that we will be a "passive foreign investment company," or PFIC for the current taxable year, which could subject certain U.S. shareholders to materially adverse U.S. federal income tax consequences.

We believe we were classified as a PFIC during our taxable year ended 2017, and based on current business plans and financial expectations, we expect to be a PFIC for the current and future taxable years. If we are a PFIC for any year in which you hold shares and you are a U.S. Holder (as defined below, in "Material United States Federal Income Tax Considerations"), unless you make a timely and effective Qualified Electing Fund election, or QEF Election or a mark-to-market election, or Mark-to-Market Election with respect to our common shares, you will not be eligible for the reduced tax rates associated with "qualified dividend income" with respect to distributions made to you or long-term capital gain upon a disposition of your common shares. Instead, all such distributions and gain will be taxable to you at the higher rates for ordinary income. In addition, a portion of any gain and distribution may be allocated to prior years during which you have owned our common shares and subjected to tax at the highest tax rate applicable to ordinary income in each such year. You would also be required to pay an interest charge on that portion of such gain or distribution.

If you are a U.S. Holder and make a timely and effective QEF Election, you generally must report on a current basis your share of our net capital gain and ordinary earnings for any year in which we are a PFIC, whether or not we distribute any amount to you, thus giving rise to so-called "phantom income" and to a potential tax liability. At this time, we intend to provide U.S. Holders with information required annually in order to allow such holders to make effective QEF Elections, but we cannot guarantee that we will be able to do so.

If you are a U.S. Holder and make a timely and effective Mark-to-Market Election, you generally must include as ordinary income each year the excess of the fair market value of your common shares over your tax basis therein, thus also possibly giving rise to phantom income and a potential tax liability. Ordinary loss generally is recognized only to the extent of net mark-to-market gains previously included in income.

Each U.S. shareholder should consult its own tax advisors regarding the PFIC rules and the U.S. federal income tax consequences of the acquisition, ownership, and disposition of our common shares

If the Internal Revenue Service determines that we are not a PFIC and you previously paid taxes pursuant to a QEF Election or a Mark-to-Market Election, you may pay more taxes than you legally owe.

If the Internal Revenue Service, or the IRS, makes a determination that we are not a PFIC and you previously paid taxes pursuant to a QEF Election or Mark-to-Market Election, then you may have paid more taxes than you legally owed due to such election. If you do not, or are unable to, file a refund claim before the expiration of the applicable statute of limitations, you will not be able to claim a refund for those taxes.

If securities or industry analysts do not publish research or reports about our company, or if they issue adverse or misleading opinions regarding us or our stock, our stock price and trading volume could decline.

Although we have research coverage by securities and industry analysts, if coverage is not maintained, the market price for our stock may be adversely affected. Our stock price also may decline if any analyst who covers us issues an adverse or erroneous opinion regarding us, our business model, our intellectual property or our stock performance, or if our target animal studies and operating results fail to meet analysts' expectations. If one or more analysts cease coverage of us or fail to regularly publish reports on us, we could lose visibility in the financial markets, which could cause our stock price or trading volume to decline and possibly adversely affect our ability to engage in future financings.

We expect that the price of our common shares will fluctuate substantially.

You should consider an investment in our common shares risky and invest only if you can withstand a significant loss and wide fluctuations in the market value of your investment. The price of our common shares that will prevail in the market after the sale of our common shares by a selling shareholder may be higher or lower than the price you have paid. Numerous factors, including many over which we have no control, may have a significant impact on the market price of our common shares. These risks include those described or referred to in this "Risk Factors" section and elsewhere in this report as well as, among other things:

- any delays in, or suspension or failure of, our existing and future studies;
- announcements of regulatory approval or disapproval of any of our existing or future product candidates or of regulatory actions affecting us or our industry;
- delays in the commercialization of our existing or future product candidates;
- manufacturing and supply issues related to our development programs and commercialization of our existing or future product candidates;
- quarterly variations in our results of operations or those of our competitors;
- changes in our earnings estimates or recommendations by securities analysts or adverse publicity about us or our product candidates;
- announcements by us or our competitors of new product candidates, significant contracts, commercial relationships, acquisitions or capital commitments;
- announcements relating to future development or license agreements including termination of such agreements;
- 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 pharmaceuticals or diagnostic products;
- 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 shares. Any sudden decline in the market price of our common shares could trigger securities class-action lawsuits against us. If any of our shareholders 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.

Our management owns a significant percentage of our common shares and will be able to exert significant control over matters subject to shareholder approval.

Based on shares outstanding as of February 27, 2018, our executive officers and directors and their respective affiliates beneficially own 56,733,040 or 59.2% of our voting shares. These shareholders will have the ability to influence us through this ownership position and may be able to determine all matters requiring shareholder approval. For example, these shareholders may be able to control 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 shares that you may feel are in your best interest as one of our shareholders.

We are an "emerging growth company," as defined under the JOBS Act and if we take advantage of reduced disclosure requirements applicable to "emerging growth companies," our common shares could be less attractive to investors.

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012, as amended, or the JOBS Act, and, for as long as we continue to be an "emerging growth company," we may choose to take advantage of certain exemptions from various reporting requirements applicable to other public companies but not to "emerging growth companies," including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act of 2002, as amended, or SOX, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved. We could be an "emerging growth company" for up to five years, or until

the earliest of (i) the last day of the first fiscal year in which our annual gross revenues exceed $1.07 billion, (ii) the date that we become a "large accelerated filer" as defined in Rule 12b-2 under the Exchange Act, which would occur if the market value of our common shares that is held by non-affiliates exceeds $700 million as of the last business day of our most recently completed second fiscal quarter, or (iii) the date on which we have issued more than $1 billion in non-convertible debt during the preceding three year period. We cannot predict if investors will find our common shares less attractive if we choose to continue to rely on these exemptions. If some investors find our common shares less attractive as a result of any choices to reduce future disclosure, there may be a less active trading market for our common shares and our stock price may be more volatile.

In addition, Section 107 of the JOBS Act provides that an "emerging growth company" can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. An "emerging growth company" can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have chosen to "opt out" of such extended transition period, however, and, as a result, we are required to 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 to opt out of the extended transition period for complying with new or revised accounting standards is irrevocable.

Our Articles of Incorporation (as amended and restated) authorize us to issue an unlimited number of common shares and preferred shares without shareholder approval and we may issue additional equity securities, or engage in other transactions that could dilute your ownership interest, which may adversely affect the market price of our common shares

Our Articles of Incorporation (as amended or restated) authorize our Board of Directors, subject to the provisions of the ABCA, to issue an unlimited number of common shares and preferred shares without shareholder approval. Our Board of Directors may determine from time to time to raise additional capital by issuing common shares, preferred shares or other equity securities. We are not restricted from issuing additional securities, including securities that are convertible into or exchangeable for, or that represent the right to receive, common shares or preferred shares. Because our decision to issue securities in any future offering will depend on market conditions and other factors beyond our control, we cannot predict or estimate the amount, timing, or nature of any future offerings, or the prices at which such offerings may be affected. Additional equity offerings may dilute the holdings of our existing shareholders or reduce the market price of our common shares, or both. Holders of our common shares are not entitled to pre-emptive rights or other protections against dilution. New investors also may have rights, preferences and privileges that are senior to, and that adversely affect, the then-current holders of our common shares. Additionally, if we raise additional capital by making offerings of debt or preference shares, upon our liquidation, holders of our debt securities and preferred shares, and lenders with respect to other borrowings, may receive distributions of our available assets before the holders of our common shares.

We will incur significant costs as a result of operating as a U.S. public company, and our management will devote substantial time to new compliance initiatives.

As a Canadian public company, we were not required to comply with certain U.S. corporate governance and financial reporting practices and policies required of a U.S. publicly-traded company. As a U.S. publicly-traded company, we will incur significant legal, accounting and other expenses that we were not required to incur in the recent past, particularly after we are no longer an "emerging growth company" as defined under the JOBS Act. 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 promulgated and to be promulgated 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, have created uncertainty for U.S. public companies and increased our costs and time that our board of directors and management must devote to complying with these rules and regulations. We expect these rules and regulations to increase our legal and financial compliance costs and lead to a diversion of management time and attention from revenue generating activities.

Furthermore, the need to establish the corporate infrastructure demanded of a U.S. public company may divert management's attention from implementing our growth strategy, which could prevent us from improving our business, results of operations and financial condition. We have made, and will continue to make, changes to our internal controls and procedures for financial reporting and accounting systems to meet our reporting obligations as a U.S. public company. However, the measures we take may not be sufficient to satisfy our obligations as a U.S. public company.

For as long as we remain an "emerging growth company" as defined in the JOBS Act, we may choose to take advantage of certain exemptions from various reporting requirements that are applicable to other U.S. public companies that are not "emerging growth companies." These exceptions provide for, but are not limited to, relief from the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, less extensive disclosure obligations regarding executive compensation in our periodic reports and proxy statements, exemptions from the requirements to hold a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved and an extended transition period for complying with new or revised accounting standards. We may take advantage of these reporting exemptions until we are no longer an "emerging growth company." We may remain an "emerging growth company" for up to five years. See "JOBS Act" in this report. To the extent we are no longer eligible to use exemptions from various reporting requirements under the JOBS Act, we may be unable to realize our anticipated cost savings from those exemptions.

Failure to maintain effective internal control over financial reporting in accordance with Section 404 of the Sarbanes-Oxley Act could have a material adverse effect on our business and share price.

As a Canadian public company, we were not required to evaluate our internal control over financial reporting in a manner that meets the standards of U.S. public companies required by Section 404 of the Sarbanes-Oxley Act, or Section 404. We were required to meet these standards in the course of preparing our financial statements as of and for the year ended December 31, 2017, and our management has reported on the effectiveness of our internal control over financial reporting for such year. Additionally, under the JOBS Act, our independent registered public accounting firm is not required to attest to the effectiveness of our internal control over financial reporting pursuant to Section 404 of the Sarbanes-Oxley Act until we are no longer an "emerging growth company." The rules governing the standards that must be met for our management to assess our internal control over financial reporting are complex and require significant documentation, testing and possible remediation.

In connection with the implementation of the necessary procedures and practices related to internal control over financial reporting, we may identify deficiencies that we may not be able to remediate in time to meet the deadline imposed by the Sarbanes-Oxley Act for compliance with the requirements of Section 404. In addition, we may encounter problems or delays in completing the implementation of any requested improvements and receiving a favorable attestation in connection with the attestation provided by our independent registered public accounting firm. We will be unable to issue securities in the public markets through the use of a shelf registration statement if we are not in compliance with Section 404. Furthermore, failure to achieve and maintain an effective internal control environment could have a material adverse effect on our business and share price and could limit our ability to report our financial results accurately and timely.

If we sell common shares in future financings, shareholders may experience immediate dilution and, as a result, our share price may decline.

We may from time to time issue additional common shares at a discount from the existing trading price of our common shares. As a result, our shareholders would experience immediate dilution upon the sale of any shares of our common shares at such discount. In addition, as opportunities present themselves, we may enter into financing or similar arrangements in the future, including the issuance of debt securities, preferred shares or common shares. If we issue common shares or securities convertible into common shares, our common shareholders would experience additional dilution and, as a result, our share price may decline.

Future sales of our common shares by our shareholders or the perception that these sales may occur could cause our stock price to decline.

As of December 25, 2018, we had 97,536,998 common shares outstanding, including a total of 3,319,820 common shares issued to our strategic partners. We are contractually obligated to register those common shares for resale or other disposition under the Securities Act. We intend to file a registration statement on Form S-3 to permit the sale or other disposition of these common shares along with additional common shares we have issued in two private placements during 2018. In addition, substantially all of our other outstanding common shares have been registered for resale or other disposition by the holders thereof or are otherwise freely tradable by the holders thereof.

Sales of a substantial number of our common shares by our shareholders or the perception that these sales may occur, could depress the market price of our common shares and could impair our ability to raise capital through the sale of additional equity securities, even if there is no relationship between such sales and the performance of our business.

We have never and do not, in the future, intend to pay dividends on our common shares, and your ability to achieve a return on your investment will depend on appreciation in the market price of our common shares.

We have never paid and do not expect to pay dividends on our common shares in the future. We intend to invest our future earnings, if any, to fund our growth and not to pay any cash dividends on our common shares. 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 shares. There is no assurance that our common shares will appreciate in price.

An active, liquid and orderly market for our common shares may not develop or be sustained, and you may not be able to sell your common shares.

Our common shares trade on the TSX-V and NYSE American exchanges. We cannot assure you that an active trading market for our common shares will develop or be sustained. The lack of an active market may impair your ability to sell the common shares at the time you wish to sell them or at a price that you consider reasonable. An inactive market may also impair our ability to raise capital by selling common shares and may impair our ability to acquire other businesses, applications or technologies using our common shares as consideration, which, in turn, could materially adversely affect our business.

We can provide no assurance that our common shares will continue to meet NYSE American listing requirements. If we fail to comply with the continuing listing standards of the NYSE American, our common shares could be delisted.

If we fail to satisfy the continued listing requirements of the NYSE American, such as the corporate governance requirements or the minimum closing bid price requirement, the NYSE American may take steps to delist our common shares. Such a delisting would likely have a negative effect on the price of our common shares and would impair your ability to sell or purchase common shares when you wish to do so. In the event of a delisting, we can provide no assurance that any action taken by us to restore compliance with listing requirements would allow our common shares to become listed again, stabilize the market price or improve the liquidity of our common shares, prevent our common shares from dropping below the NYSE American minimum bid price requirement or prevent future non-compliance with NYSE American's listing requirements.