United Health Products, Inc. Form 10-K April 15, 2014

#### SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

#### FORM 10-K

x ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934

FOR THE FISCAL YEAR ENDED DECEMBER 31, 2013

COMMISSION FILE NUMBER: 814-00717

### UNITED HEALTH PRODUCTS, INC.

(Exact name of Registrant as specified in its charter)

Nevada 84-1517723

(State of jurisdiction of incorporation or (I.R.S. Employee Identification Number)

organization)

c/o Morse & Morse, PLLC, 1400 Old

Country Road,

Suite 302, Westbury, NY 11590 (Address of principal executive offices) (Zip Code)

Registrant's telephone number, including

area code:

(516) 487-1431

Securities registered pursuant to Section 12

(b) of the Act:

None

Securities registered pursuant to Section 12

Common Stock, \$.001 Par Value

(g) of the Act:

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

Check whether the Registrant is not required to file reports pursuant to Section 13 or 15(d) of the Exchange Act. o

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

Indicate by check mark whether the Registrant has submitted electronically and posted on it corporate Web site, if any, every Interactive data file required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit

and post such files). Yes o No o

Indicate by check mark if disclosure of delinquent filers in response to Item 405 of Regulation S-K is not contained in this form, and no disclosure will be contained, to the best of Registrant's knowledge, in definitive proxy or information statements incorporated by reference in part III of this Form 10-K or any amendment to this Form 10 K o.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company as defined by Rule 12b-2 of the Exchange Act: smaller reporting company x.

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

As of June 30, 2013, the number of shares held by non-affiliates was approximately 82,554,000 shares. The approximate market value based on the last sale (i.e. \$.04 per share as of June 28, 2013, the last business day of the second quarter) of the Company's Common Stock was approximately \$3,302,160.

The number of shares outstanding of the Registrant's Common Stock, as of the filing date of this Form 10-K was 102,647,640 after giving effect to the cancellation of 2,090,000 shares that Dr. Forman has agreed to cancel.	

### Forward-looking Statements

Statements in this annual report on Form 10-K that are not historical facts constitute forward-looking statements which are made pursuant to the safe harbor provisions of Section 21E of the Securities Exchange Act of 1934, or the Exchange Act. These statements relate to future events or our future financial performance and involve known and unknown risks, uncertainties and other factors that may cause our or our industry's actual results, levels of activity, performance or achievements to be materially different from any future results, levels of activity, performance or achievements expressed or implied by these forward-looking statements. Those factors include, among other things, those listed under "Risk Factors" and elsewhere in this annual report. In some cases, you can identify forward-looking statements by terminology such as "may," "will," "should," "expects," "plans," "anticipates," "believes," "estimates," "predict or "continue" or the negative of these terms or other comparable terminology. These statements are only predictions. Actual events or results may differ materially. Moreover, neither we nor any other person assumes responsibility.

#### PART I

#### **ITEM 1. BUSINESS**

#### Company Overview

United Health Products, Inc. ("United" or the "Company") develops, manufactures, and markets a patented hemostatic gauze for the healthcare and wound care sectors. The product HemoStyp<sup>TM</sup>, is derived from regenerated oxidized cellulose, which is all natural, and designed to absorb exudate/drainage from superficial wounds and helps control bleeding. The Company is focused on identifying new markets and applications for its product as well as ramping up sales in its current markets. The Company has received orders from the dental and medical markets and is pursuing multiple markets for HemoStyp<sup>TM</sup>, including the medical, sports, dental, military and veterinary sectors, each of which represents a multi-million dollar market.

# Recent History of the Company

The Company was a closed-end management investment company that in February 2006 elected to be treated as a business development company ("BDC") under the Investment Company Act of 1940, (the "1940 Act"). The Company was originally formed in February 1997 as MNS Eagle Equity Group III, Inc.; however, it conducted no operations until electing to be a BDC through which it provided capital and other assistance to start-up and micro-cap companies. During this time, United acquired and established its initial interest in the medical, pharmaceutical and healthcare industry by acquiring certain intellectual property rights and creating Epic Wound Care, Inc. ("Epic"), which was the Company's primary operating platform in this industry until that subsidiary was dissolved by the State of Florida and the assets were absorbed by the Company. The Company also completed two minority equity investments in companies that are not strategic to our healthcare strategy.

In February 2010, our Board of Directors and the holders of a majority of our outstanding shares of common stock authorized management to withdraw the election to be regulated as a BDC. This decision was in part prompted by the actuality that the majority of the Company's resources were allocated to managing the operating activities of its holdings and, in addition, management found that the Company may not have been in compliance with certain BDC provisions of the 1940 Act. On July 7, 2010, the Company filed an Information Statement with the SEC providing notice of shareholder action in lieu of a Meeting of Shareholders, taken pursuant to the written consent of certain shareholders, referred to as the consenting shareholders. Specifically, the consenting shareholders approved the withdrawal of the Company's election to be a BDC. This action became effective on August 17, 2010 when the Company filed the applicable Notice concerning the withdrawal with the Securities and Exchange Commission. Further, in recognition of the change in its operations, the Company changed its name from United EcoEnergy Corp. to United Health Products, Inc., effective as of September 30, 2010.

As a result of the decision to withdraw the Company's election to be treated as a BDC and become an operating company, the fundamental nature of the Company's business changed from that of investing in a portfolio of securities with the goal of achieving gains on appreciation and dividend income, to that of being actively engaged in the ownership and management of a holding company with the goal of generating income from the operations of those businesses. The decision to withdraw the Company's election as a BDC under the 1940 Act necessitated a significant change in the Company's method of accounting. The Company formerly utilized the BDC financial statement presentation and that accounting utilized the value method of accounting used by investment companies, which allows BDCs to recognize income and value their investments at market value as opposed to historical cost. As an operating company, the Company was required to adopt the financial statement presentation and accounting for securities held which provides for either fair value or historical cost methods of accounting, depending on the classification of the investment and the Company's intent with respect to the period of time it intends to hold the investment. This change

in the Company's method of accounting could impact the market value of its investments in privately held companies by eliminating the Company's ability to report an increase in the value of its holdings as the increase occurs. As an operating company, the Company, effective December 31, 2009, consolidated its financial statements with its controlled subsidiaries, thus eliminating the portfolio company reporting benefits available to BDCs.

### Acquisition of Intellectual Property Rights

In June 2009, the Company acquired the intellectual property rights of Epic Wound Care, LLC, through its former wholly-owned subsidiary, Epic. The intellectual property includes the right to manufacture and distribute innovative gauze to serve the wound care market. The acquisition cost for the rights was 30 million shares of Company's common stock, of which 20 million shares were escrowed with the voting rights controlled by the Company pending attainment of certain performance targets over 18 months from the closing date of the transaction. The Company valued the rights acquired at \$500,000 based upon the Company's expectation for commercialization of the rights less costs to effectuate applicable approvals.

On March 8, 2011, the Company and Epic Wound Car, LLC entered into a global settlement and release agreement (the "Settlement Agreement") with various parties to resolve disputes regarding the Agreement and Plan of Acquisition, dated May 19, 2009, entered into by the Company in connection with its acquisition of the business and assets of Epic Wound Care, LLC (the "Acquisition Agreement"). The parties had differences of opinion concerning the satisfaction of certain milestones and conditions in the Acquisition Agreement in connection with the release of the escrowed shares mentioned above. The settlement provided for the release of 20 million escrowed shares to the sellers of the business and assets and the contribution of 2 million shares of the Company's common stock to the capital of the Company (which were cancelled) to facilitate the settlement by certain non-controlling shareholders who provided investment advice to the Company on a regular periodic basis, including investment advice related to the Acquisition Agreement. As a condition to the settlement, the Board of the Directors of the Company waived certain milestones and conditions regarding the release of the escrowed shares as set forth in the Acquisition Agreement and the parties to the Settlement Agreement agreed to mutual releases and to resolve and settle any and all claims, controversies, disputes and causes of action, whether asserted or unasserted, known or unknown, real or potential, or whether in law, equity or otherwise, relating to, arising out of, or in any way concerning the Acquisition Agreement and the escrowed shares, without any admission of fault, liability or wrongdoing on the part of or on behalf of any party.

# **Primary Strategy**

The Company's gauze products are designed for the wound care market and manufactured to our specifications by a manufacturing agent in China. The gauze can be used on any wound where bleeding is present. Upon contact with moisture, the gauze forms a gel-like substance that acts as a hemostatic agent to address bleeding quickly. The hemostatic gauze derived from regenerated oxidized/cellulose, which is all natural and designed to absorb exudate/drainage from superficial wounds and helps to control bleeding. Once bleeding has ceased and coagulation has occurred, the product can be rinsed away with saline solution or lukewarm water. After acquiring the intellectual property rights, in 2009, we have devoted our time to obtaining necessary approvals to enable the hemostatic gauze product to be sold worldwide as well as establishing an international distribution network.

In August 2012, the Company's manufacturing agent in China of its gauze products which is registered and branded in the United States under the trademark HemoStyp<sup>TM</sup>, received 510(k) approval from the U.S. Food and Drug Administration ("FDA") to be sold as a Class I device. The Company has the ability to represent to distributors and customers that its gauze products meet all FDA requirements as a Class I device. This approval now allows us to expand our potential customer base and pursue accounts that requested a current 510(k) FDA approval, including the prescription based medical arena, retail, hospital, EMS, military, state and national governmental agencies and veterinary markets. Our gauze products can be used to stop nose bleeds and for post dialysis treatment and venipuncture.

The Company's strategy is to engage distributors to market the Company's gauze products to the various worldwide markets. In 2013, the Company laid an initial foundation for the distribution of its hemostatic gauze products by entering into agreements with our first three distributors/partners (covering the dental, U..S. military and worldwide

equestrian markets and Australasia). In 2014, the Company is seeking to expand on this base and is seeking to enter the international dialysis market. No assurances can be given that the Company will be successful in expanding its distribution market on terms satisfactory to us, if at all. See "Item 1A.

### Our HemoStyp<sup>TM</sup> Gauze Products

HemoStyp<sup>TM</sup> Hemostatic Gauze is a collagen-like natural substance created from chemically treated cellulose. It is an effective hemostatic agent registered with the FDA to help control bleeding from open wounds and body cavities. The HemoStyp<sup>TM</sup> hemostatic material contains no chemical additives, thrombin or collagen, and is hypoallergenic. When it comes in contact with blood it expands slightly and converts to an adhesive gel that subsequently dissolves into glucose and saline. Because of its purity and the fact it simply degradates to these end products, it does not cause significant delay in healing as do other hemostatic materials that may have a similar appearance. Our HemoStyp<sup>TM</sup> gauze products are sold in three different sizes for use in superficial trauma cases. It is also sold as a dental gauze and as a nasal dressing.

HemoStyp<sup>TM</sup> Hemostatic Gauze is applied by simply folding the gauze once or twice, depending on the size of the wound, and then putting it as far into the wound as possible. Putting a bandage on top of the gauze is optional and in many cases unnecessary. On smaller cuts, it may be helpful to first cut the Gauze in half before applying it to the wound. When this is done, it may not be necessary to fold it first. Since EMS work is pre-hospital, rinsing the gauze out with saline or water is not necessary. This is because after the patient reaches the hospital, a wound will be debrided and possibly reopened prior to suturing.

The Company's hemostatic gauze product line includes various configurations. The Company's product line has been developed to address the specific needs of our market segments and our existing customers, including the U.S. military. The Company's hemostatic gauze product line now includes the following new products:

Dental gauze for oral surgery; Four versions of Trauma Gauze<sup>TM</sup> for battlefield trauma; and Two island dressings to support intravenous procedures.

# Sales and Marketing

Our technology is marketed as HemoStyp<sup>TM</sup> Gauze, but is also available to customers with customized private labeling. We are customer driven. We intend to distribute both nationally and internationally. We intend to service our customers through distributors, sales representatives, industry-specialized telephone support, and the Internet. Our potential customer base includes, without limitation:

Hospitals, Clinics, and Physicians
EMS, Fire Departments and Other First Responders
Public Safety, Police Departments and Military
Correctional Facilities
Schools, Universities and Day Care Facilities
Nursing Homes and Assisted Living Environments
Home Care Providers
Dental offices
Sports Medicine Providers
Veterinarians
Municipalities and Government Agencies and
Occupational and Industrial Healthcare Professionals

On December 19, 2012, the Company announced that its hemostatic gauze was featured in the clinicians report for the second time in 2012. This report is a published scientific testimonial that features products which have met the criteria and approval of the dental community. This report is distributed to over 10,000 dental care providers. In the December issue, the Company's HemoStyp<sup>TM</sup> was listed among the best products evaluated during 2012 with 83% of the evaluators stating that they would recommend the product. On January 22, 2013, the Company announced that its HemoStyp<sup>TM</sup> was featured in the January 2013 edition of Dentistry Today. Dentistry Today is a top dental industry report offering comprehensive coverage of the latest news and developing technologies from within the dental industry.

In August 2013, we entered into a consulting agreement with Douglas Beplate for the exclusive purpose of retaining his services to develop and market our hemostatic gauze products. As a result of Mr. Beplate's efforts, we have succeeded in obtaining distribution/partner agreements for the dental, equestrian and U.S. military markets as well as Austalasia. In November 2013, our Board of Directors asked Mr. Beplate to become Chief Operating Officer of the Company, a position he accepted. Management believes that we will enter into other distribution agreements for territories in the United States and in International markets in 2014, although no assurances can be given in this regard. See "Item 1A."

### Manufacturing and Packaging of our Products

On October 1, 2013, the Company entered into an Operating Agreement with Hemo Manufacturing LLC. Hemo Manufacturing is to act as the exclusive supplier of manufactured products for the Company's products. Hemo Manufacturing is responsible for overseeing quality control of products at our overseas (non-exclusive) manufacturer in China as well as the packaging and labeling of our products for distribution. Pursuant to said agreement, 2,000,000 restricted shares of the Company's Common Stock were issued upon execution of the agreement. Under certain conditions, an additional 2,000,000 shares of the Company's Common Stock would be issued in the event the Company is bought out by a third party. The Company anticipates booking all sales directly to customers and making payment for goods directly to Hemo Manufacturing. The managing member of Hemo Manufacturing will retain 100% of the profits earned by Hemo Manufacturing unless the Company is sold to a third party. In the event of such a sale, the managing member of Hemo Manufacturing and the Company would have equal share in the gross profits. While the managing member of Hemo Manufacturing LLC owns 51% of this entity and the Company owns 49% of this entity, in practicality these ownership percentages only relate to control of the entity and not to our profits and losses of being split.

#### Competition

The disposable medical supply market in the United States is dominated by large companies such as Baxter International, Bristol-Myers Squibb Company, Johnson & Johnson and 3M Company. Our hemostatic gauze product will directly compete in the gauze markets dominated by these majors. However, the market for hemostatic products, which includes gauzes, gels, bandages and powders, is largely composed of smaller, privately-held companies with the exception of Johnson & Johnson, which manufactures Surgicel®. In this market, competitive factors include price, product offerings, value-added service programs, service and delivery, credit terms, and customer support.

# Government Regulation

We are subject to oversight by various federal and state governmental entities and we are subject to, and affected by, a variety of federal and state laws, regulations and policies.

The U.S. Drug Enforcement Administration ("DEA"), the U.S. Food and Drug Administration ("FDA") and various state regulatory authorities regulate the purchase, storage, and/or distribution of pharmaceutical products. The DEA, FDA and state regulatory authorities have broad enforcement powers, including the ability to seize or recall products and

impose significant criminal, civil and administrative sanctions for violations of applicable laws and regulations. As a wholesale distributor of pharmaceuticals and certain related products, we are subject to these laws and regulations. We have all necessary licenses or other regulatory approvals and believe that we are in compliance with all applicable pharmaceutical wholesale distribution requirements needed to conduct our operations.

On April 29, 2010, the Company's then wholly-owned subsidiary, Epic Wound Care, Inc., submitted a Section 510(k) premarket notification of intent to market its hemostatic gauze as a Class III device to the U.S. Food and Drug Administration ("FDA"). On August 3, 2010, the FDA sent Epic a notice that the application was insufficient to allow the FDA to make the determination. In August 2012, our non-affiliated manufacturing agent in China had its Section 510(k) pre-market notification approved as a Class I device as described herein.

In recent years, some states have passed or proposed laws and regulations that are intended to protect the safety of the pharmaceutical supply channel. These laws and regulations are designed to prevent the introduction of counterfeit, diverted, adulterated or mislabeled pharmaceuticals into the distribution system. In addition, the FDA Amendments Act of 2007 (the "2007 Act") requires the FDA to establish standards and identify and validate effective technologies for the purpose of securing the pharmaceutical supply chain against counterfeit drugs. These standards may include track-and-trace or authentication technologies, such as radio frequency identification devices and other technologies. The 2007 Act required the FDA to develop a standardized numerical identifier by April 1, 2010.

As a result of political, economic and regulatory influences, the healthcare delivery industry in the United States is under intense scrutiny and subject to fundamental changes. Although there was substantial Federal legislation enacted during 2010 that impacted our healthcare system in the United States, we expect that the administration, Congress and certain state legislatures will continue to review and assess alternative healthcare delivery systems and payment methods in order to reform the healthcare system. Thus, we cannot predict the impact on us of the 2010 legislation and/or additional regulation governing the delivery or pricing of healthcare products that may be passed. Nor can we predict the impact on us of potential changes to the structure of the present healthcare delivery system, if any, when they may be adopted.

The costs associated with complying with federal and state regulations could be significant and the failure to comply with any such legal requirements could have a significant impact on our results of operations and financial condition.

# **Environmental Matters**

Our business activities are subject to extensive federal, state, and local environmental laws and regulations relating to water, air, hazardous substances and wastes that may restrict or limit such business activities. Although the Company does not currently directly manufacture its own products, we may still be subject to existing environmental laws by way of regulatory agencies or other third party claimants. Examples of U.S. Federal environmental legislation that may have adverse effects on the Company include the Toxic Substances Control Act, the Clean Air Act, the Clean Water Act, Compensation and Liability Act (aka CERCLA or Superfund) and the Resource Conservation and Recovery Act. By no means do we certify this list as being complete, as there are many laws and regulations that exist or that may come to pass that we cannot foresee that may also have an impact on the Company. The multitude of regulations issued by federal, state, provincial and local administrative agencies can be burdensome and costly and we determined to change our business model as a result. There are currently no pending legal proceedings with any government regulatory agencies.

#### RESEARCH AND DEVELOPMENT EXPENDITURES

We have not incurred any research or development expenditures since our incorporation.

#### PATENTS AND TRADEMARKS

In September 2012, the Company announced that its hemostatic gauze products were granted patent protection by the U.S. Patent and Trademark Office. Also, the Company has trademark protection for HemoStyp®. However, if our intellectual property positions are challenged, invalidated, circumvented or expire, or if we fail to prevail in future

intellectual property litigation, our business could be adversely affected. Our success depends in part on our ability to defend our intellectual property rights. The patent positions of pharmaceutical and biotechnology companies can be highly uncertain and often involve complex legal, scientific and factual questions. Third parties may seek to challenge, invalidate or circumvent our intellectual property rights. In addition, our patent positions might not protect us against competitors with similar products or technologies because competing products or technologies may not infringe our patents. Also, there are third parties who have patents or pending patent applications that they may claim necessitate payment of a royalty or prevent us from commercializing our patent in certain territories. Patent disputes are frequent, costly and can preclude, delay or increase the cost of commercialization of products.

#### **EMPLOYEES**

As of December 31, 2013, we have no employees of the Company. The Company's Chief Executive Officer, Dr. Phillip Forman, currently has no employment contract and is devoting such time to the Company's affairs as is necessary for the fulfillment of his duties. Douglas Beplate, our Chief Operating Officer, has a consulting agreement which was entered into with the Company prior to him becoming Chief Operating Officer. In 2014, we anticipate hiring staff and executives as our operations increase.

#### ITEM 1A. RISK FACTORS

We are engaged in the sale and distribution of hemostatic gauze products to stop superficial bleeding. As we develop our business, there are numerous and varied risks, known and unknown, that may prevent us from achieving our goals. If any of these risks actually occur, our business, financial condition or results of operation may be materially adversely affected. In such case, the trading price of our common stock could decline and investors could lose all or part of their investment.

#### RISKS RELATED TO OUR BUSINESS

We have a history of operating losses and may continue to lose money in the future.

For the years ended December 31, 2013, 2012, 2011, 2010 and 2009, the Company had a net loss of \$(1,126,366), \$(281,413), \$(1,588,362), \$(2,895,602) and \$(910,007), respectively. While the Company's hemostatic gauze products have 510(k) FDA approval from the FDA for our manufacturing agent in China to manufacture these products, we can provide no assurances that our operations will be profitable in the future.

We have limited operating history. Accordingly, you will have no basis upon which to evaluate our ability to achieve our business objectives.

We have limited operating history, which makes it difficult for potential investors to evaluate our business or prospective operations. Our business plan is to develop the U.S. and International market for the sale of our hemostatic gauze product line. Our plans are subject to all of the risks inherent in the financing, expenditures, complications and delays inherent in a relatively new business. Investors should evaluate an investment in our Company in light of the uncertainties frequently encountered by companies developing markets for new products. We may never overcome these obstacles. In addition, our business is speculative and depends upon the implementation of our business plan and our ability to enter into agreements with third parties on terms that will be commercially viable for us. There can be no assurance that our efforts will be successful or that we will be able to attain profitability.

Our independent registered public accounting firm has expressed substantial doubt about our ability to continue as a going concern. This could make it more difficult for us to raise funds and adversely affect our relationships with lenders, investors and suppliers.

Our independent registered public accounting firm has expressed doubt about our ability to continue as a going concern. This indicates that our auditors believe that substantial doubt exists regarding our ability to continue to remain in business. We cannot provide any assurance that we will in fact operate our business profitably or obtain sufficient financing to sustain our business in the event we are not successful in our efforts to generate sufficient revenue and operating cash flow. The expression of such doubt by our independent registered public accounting firm or our inability to overcome the factors leading to such doubt could have a material adverse effect on our relationships with prospective customers, lenders, investors and suppliers, and therefore could have a material adverse effect on our business.

We will need additional financing to execute our business plan and fund operations, which additional financing may not be available.

We currently have a working capital deficit, minimal cash and limited sales of our products. As result of the Company's financial position, we may not be able to execute our current business plan and fund business operations long enough to achieve profitability. Our ultimate success may depend upon our ability to raise additional capital. There can be no assurance that additional funds will be available when needed from any source or, if available, will be available on terms that are acceptable to us.

We may be required to pursue sources of additional capital through various means, including joint venture projects and debt or equity financings. Future financings through equity investments are likely to be dilutive to existing stockholders. Also, the terms of securities we may issue in future capital transactions may be more favorable for our new investors. Newly issued securities may include preferences, superior voting rights, the issuance of warrants or other derivative securities, and the issuances of incentive awards under equity employee incentive plans, which may have additional dilutive effects. Further, we may incur substantial costs in pursuing future capital and/or financing, including investment banking fees, legal fees, accounting fees, printing and distribution expenses and other costs. We may also be required to recognize non-cash expenses in connection with certain securities we may issue, such as convertible notes and warrants, which will adversely impact our financial condition.

Our ability to obtain needed financing may be impaired by such factors as the capital markets, both generally and specifically in the healthcare industry, and the fact that we are not profitable, which could impact the availability and cost of future financings. If the amount of capital we are able to raise from financing activities, together with our revenues from operations, is not sufficient to satisfy our capital needs, even to the extent that we reduce our operations accordingly, we may be required to cease operations.

No guarantee of market acceptance.

Our success is dependent on market acceptance of our hemostatic gauze products. We cannot assure you that healthcare market professionals will conclude that our hemostatic gauze products are useful and/or safe. We cannot assure you that our hemostatic gauze products will ultimately achieve or maintain significant market acceptance among distributors, patients, physicians, or healthcare payers in general.

We are dependent upon strategic relationships and distribution agreements to conduct our operations.

To market and sell our hemostatic gauze products business, we will endeavor to use the business relationships of our management to enter into strategic relationships, which may take the form of joint ventures with private parties and contractual arrangements with other resource companies. We may not be able to establish these strategic relationships, or if established, we may not be able to maintain them. In addition, the dynamics of our relationships with strategic partners may require us to incur expenses or undertake activities we would not otherwise be inclined to in order to fulfill our obligations to these partners or maintain our relationships. If our strategic relationships are not established or maintained, our business prospects may be limited, which could diminish our ability to conduct our operations. To date, we have entered into distribution/partner agreements for the dental, equestrian and military markets as well as for Australasia for our hemostatic gauze products. We can provide no assurances that additional distribution agreements will be entered into on terms satisfactory to us, if at all or that our operations will be profitable as a result of these distribution agreements.

We could experience difficulties in our supply chain.

We do not maintain our own manufacturing facilities. Our exclusive contract manufacturer oversees the manufacture of our hemostatic gauze products through a manufacturing agent in China on a non-exclusive basis, which agent has obtained 510(k) approval with the FDA for the manufacturing of the Company's hemostatic gauze products as a Class 1 device. If the Company's manufacturing agent in China should experience difficulties in the process of manufacturing, such as changes in environmental regulations, rising wages, late deliveries, shortages of components or raw materials, cash problems or excessive transport costs, there would be an adverse impact on our ability to generate revenue. Our contract manufacturer is also responsible for quality control in China and overseeing the packaging and labeling of our products for distribution. We are dependent upon the services of our contract manufacturer to perform its obligations in a satisfactory manner.

We are currently dependent on one hemostatic gauze product line to generate income.

The Company's hemostatic gauze product line is currently our only product line from which we can derive revenue. Lack of success in developing a commercial market for this product line will materially adversely affect our operations.

Our business may suffer if we do not attract and retain talented personnel.

Our success will depend in large measure on the abilities, expertise, judgment, discretion, integrity and good faith of our management and other personnel in conducting our intended business. In addition, we depend on management and employees to interpret market data correctly and to interpret and respond to economic, market and other conditions to locate and adopt appropriate business opportunities. We presently have a small management team, which we intend to expand in conjunction with our planned operations and growth. We will have to ensure that management and any key employees are appropriately compensated; however, their services cannot be guaranteed. If we are unable to attract and retain additional key management personnel and enter into satisfactory employment and other agreements, our business may be adversely affected.

We may not be able to adequately protect our technologies or intellectual property rights.

Our commercial success will depend in part on maintaining patent protection and trade secret protection of our technologies as well as successfully defending our intellectual property against third-party challenges. We will only be able to protect our technologies from unauthorized use by third parties to the extent that valid and enforceable patents or trade secrets cover them. Furthermore, the degree of future protection of our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage.

#### RISKS RELATED TO OUR INDUSTRY

The healthcare industry is subject to extensive government regulation, which can result in increased costs, delays, limits on its operating flexibility and competitive disadvantages.

The healthcare industry is generally subject to extensive regulatory requirements. Many of these requirements result in significant costs that may adversely affect our business and financial results. If we are unable to pass those costs on it would negatively impact our profit margin.

Healthcare insurance legislation may lead to unintended adverse effects for businesses involved in our industry. New legislation that gives the Federal government greater regulatory powers may lead to negative consequences for certain aspects of our business. The full scope of the recently passed healthcare legislation may not be felt for several years, it is therefore difficult to predict any future consequences that would be challenges to our Company, or if we can overcome them.

Failure to comply with laws or government regulations could result in penalties.

Certain government requirements for technologies in the healthcare market may require licensure or mandatory minimum standards relating to the provision of services. Failure to comply with these requirements could materially affect our ability to expand into new or existing markets. Future regulatory developments may also cause disruptions to our operations.

### Risks Relating to Our Organization

We are subject to the reporting requirements of the federal securities laws, which can be expensive.

We are a public reporting company and, accordingly, subject to the information and reporting requirements of the Exchange Act and other federal and state securities laws, including compliance with the Sarbanes-Oxley Act of 2002. The costs of preparing and filing annual and quarterly reports, proxy statements and other information with the SEC and furnishing audited reports to stockholders increase our operating costs.

It is time consuming, difficult and costly for us to develop and implement the internal controls and reporting procedures required by the Sarbanes-Oxley Act. We may need to hire additional financial reporting, internal controls and other finance personnel in order to develop and implement appropriate internal controls and reporting procedures. If we are unable to comply with the internal controls requirements of the Sarbanes-Oxley Act, we may not be able to obtain the independent accountant certifications required by that Act.

Failure to achieve and maintain effective disclosure controls or internal controls could have a material adverse effect on our ability to report our financial results timely and accurately.

As result of our analysis of our system of internal accounting controls and accounting and financial reporting processes, we have identified a material weakness in our disclosure controls and internal controls. These are more specifically discussed in Item 9A of this Annual Report. As a result of these deficiencies, we must perform additional analysis and other post-closing procedures to insure that our financial statements are prepared in accordance with US generally accepted accounting principles. As a result, we will incur expenses and devote significant management resources to this review process. Furthermore, effective internal controls and procedures are necessary for us to continue to provide reliable financial reports. If we continue to have material weaknesses in our internal controls and procedures, we may not be able to provide reliable financial reports and our business and operating results could be harmed.

Public company compliance requirements may make it more difficult to attract and retain officers and directors.

The Sarbanes-Oxley Act and rules subsequently implemented by the SEC have required changes in corporate governance practices of public companies. Compliance with the new rules and regulations increases our operating costs and makes certain activities more time consuming and costly than if we were not a public company. As a public company, these new rules and regulations make it more difficult and expensive for us to obtain director and officer liability insurance. As a result, it may be more difficult for us to attract and retain qualified persons to serve on our Board of Directors or as executive officers.

There exist risks to stockholders relating to dilution: authorization of additional securities and reduction of percentage share ownership following investment.

To the extent that additional shares of common stock are issued, the stockholders would experience dilution of their respective ownership interests in the Company. Additionally, if the Company issues a substantial number of shares of common stock in connection with or following an investment, a change in control of the Company may occur which may affect, among other things, the Company's ability to utilize net operating loss carry forwards, if any. Furthermore, the issuance of a substantial number of shares of common stock may adversely affect prevailing market prices, if any, for the common stock and could impair the Company's ability to raise additional capital through the sale of its equity securities. The Company may use consultants and other third parties providing goods and services or additional capital. These consultants or third parties may be paid in cash, stock, options or other securities of the Company, and the consultants or third parties may be Placement Agents or their affiliates.

#### RISKS RELATING TO OUR SECURED DEBT AND RECENTLY COMMENCED LITIGATION

LeadDog Capital LP is our secured lender and we are currently in default.

As of December 31, 2013, our books and records indicate that we owe approximately \$ 504,603 in principal and accrued interest thereon to our secured lender, LeadDog Capital LP. This indebtedness could lead to material adverse consequences to the Company, its business plans and potential results of operations.

The Company has commenced a lawsuit against LeadDog Capital LP, our secured lender, LeadDog Capital Markets, a company under common control with our secured lender, Christopher Messalas, the control person of the aforementioned entities, and Jan Chason, the chief liquidator of LeadDog Capital LP and our former Chief Executive Officer.

As described in Item 3 below, the Company has a pending lawsuit against LeadDog Capital LP, our secured lender, LeadDog Capital Markets, a company under common control with our secured lender, Christopher Messalas, the control person of the aforementioned entities, and Jan Chason, the chief liquidator of LeadDog Capital LP and our former Chief Executive Officer. This lawsuit may cause the defendants to file one or more counterclaims against the Company and for LeadDog Capital LP to seek to foreclose on its secured debt. No assurances can be given that this lawsuit will have a favorable outcome for the Company or that such outcome will not materially adversely affect our operations. See "Item 3" below.

#### RISKS RELATING TO OUR COMMON STOCK

Our stock price may be volatile.

The market price of our common stock is likely to be highly volatile and could fluctuate widely in price in response to various factors, many of which are beyond our control, including the following:

- · changes in the healthcare industry;
- · competitive pricing pressures;
- · our ability to obtain working capital financing;
- · additions or departures of key personnel;
- · limited "public float", in the hands of a small number of persons whose sales or lack of sales, could result in positive or negative pricing pressure on the market price for our common stock;
- · our ability to execute our business plan;
- · operating results that fall below expectations;
- · loss of any strategic relationship;
- · regulatory developments;
- · economic and other external factors; and
- · period-to-period fluctuations in our financial results.

In addition, the securities markets have from time to time experienced significant price and volume fluctuations that are unrelated to the operating performance of particular companies. These market fluctuations may also materially and adversely affect the market price of our common stock.

We have not paid dividends in the past and do not expect to pay dividends in the future. Any return on investment may be limited to the value of our common stock.

We have never paid cash dividends on our common stock and do not anticipate doing so in the foreseeable future. The payment of cash dividends on our common stock will depend on earnings, financial condition and other business and economic factors affecting us at such time as our board of directors may consider relevant. If we do not pay dividends, our common stock may be less valuable because a return on investment will only occur if our stock price appreciates.

There is currently established market for our common stock and we cannot ensure that one will ever develop or be sustained.

The Company's common stock is available for trading on the OTCQB. While our common stock has an average daily trading volume as of February 25, 2014, of approximately 130,000 shares, Management considers the market for our common stock to be limited. We can provide no assurances that an established trading market for our common stock will exist in the future.

Our common stock is deemed a "penny stock", which may make it more difficult for our investors to sell their shares.

Our common stock is subject to the "penny stock" rules adopted under Section 15(g) of the Securities Exchange Act of 1934. The penny stock rules apply to companies whose common stock is not listed on a national securities exchange and trades at less than \$5.00 per share or that have tangible net worth of less than \$5,000,000 (\$2,000,000 if the company has been operating for three or more years). These rules require, among other things, that brokers who trade penny stock to persons other than "established customers" complete certain documentation, make suitability inquiries of investors and provide investors with certain information concerning trading in the security, including a risk disclosure document and quote information under certain circumstances. Many brokers have decided not to trade penny stocks because of the requirements of the penny stock rules and, as a result, the number of broker-dealers willing to act as market makers in such securities is limited. If we remain subject to the penny stock rules for any significant period, it could have an adverse effect on the market, if any, for our securities. In as much as our securities are subject to the penny stock rules, investors will find it more difficult to dispose of our securities.

Offers or availability for sale of a substantial number of shares of our common stock may cause the price of our common stock to decline.

If our stockholders sell substantial amounts of our common stock in the public market, or upon the expiration of any holding period under Rule 144, or expiration of lock-up periods applicable to outstanding shares, or issued upon the exercise of outstanding options or warrants, it could create a circumstance commonly referred to as an "overhang" and in anticipation of which the market price of our common stock could fall. The existence of an overhang, whether or not sales have occurred or are occurring, also could make more difficult ou