

SECURITIES & EXCHANGE COMMISSION EDGAR FILING

GUIDED THERAPEUTICS INC

Form: 10-K

Date Filed: 2019-05-08

Corporate Issuer CIK: 924515

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

FORM 10-K

(Mark One)

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 For the fiscal year ended **December 31, 2018**.

OR

TRANSITION REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

Commission file number: 0-22179

GUIDED THERAPEUTICS, INC.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

5835 Peachtree Corners East, Suite B
Norcross, Georgia
(Address of principal executive offices)

58-2029543
(I.R.S. Employer
Identification No.)

30092
(Zip Code)

Registrant's telephone number (including area code):

(770) 242-8723

Securities registered under Section 12(b) of the Exchange Act: None
Securities registered under Section 12(g) of the Act: Common Stock, \$0.001 par value
(Title of class)

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

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

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 No

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of 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. Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. Large accelerated filer Accelerated filer Non-accelerated filer Smaller reporting company 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

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates was approximately \$800,000 as of December 31, 2018 (the last business day of the registrant's most recently completed fiscal quarter).

As of April 15, 2019, the registrant had 3,319,486 shares of common stock outstanding. The registrant completed a 1:800 reverse split on March 29, 2018.

DOCUMENTS INCORPORATED BY REFERENCE. None.

TABLE OF CONTENTS

| | |
|--|-----------|
| PART I | 3 |
| ITEM 1. BUSINESS | 3 |
| ITEM 1A. RISK FACTORS | 10 |
| ITEM 1B. UNRESOLVED STAFF COMMENTS | 20 |
| ITEM 2. PROPERTIES | 20 |
| ITEM 3. LEGAL PROCEEDINGS | 20 |
| ITEM 4. MINE SAFETY DISCLOSURES | 20 |
| PART II | 21 |
| ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES | 21 |
| ITEM 6. SELECTED FINANCIAL DATA | 21 |
| ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS | 22 |
| ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK. | 34 |
| ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA | 35 |
| ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE | 71 |
| ITEM 9A. CONTROLS AND PROCEDURES | 71 |
| ITEM 9B. OTHER INFORMATION | 72 |
| PART III | 73 |
| ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE | 73 |
| ITEM 11. EXECUTIVE COMPENSATION | 75 |
| ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS | 78 |
| ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS AND DIRECTOR INDEPENDENCE | 79 |
| ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES | 80 |
| PART IV | 81 |
| ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES | 81 |
| ITEM 16. FORM 10-K SUMMARY | 84 |
| SIGNATURES | 85 |

Item 1. Business

Overview

We are a medical technology company focused on developing innovative medical devices that have the potential to improve healthcare. Our primary focus is the sales and marketing of our LuViva® Advanced Cervical Scan non-invasive cervical cancer detection device. The underlying technology of LuViva primarily relates to the use of biophotonics for the non-invasive detection of cancers. LuViva is designed to identify cervical cancers and precancers painlessly, non-invasively and at the point of care by scanning the cervix with light, then analyzing the reflected and fluorescent light.

LuViva provides a less invasive and painless alternative to conventional tests for cervical cancer screening and detection. Additionally, LuViva improves patient well-being not only because it eliminates pain, but also because it is convenient to use and provides rapid results at the point of care. We focus on two primary applications for LuViva: first, as a cancer screening tool in the developing world, where infrastructure to support traditional cancer-screening methods is limited or non-existent, and second, as a triage following traditional screening in the developed world, where a high number of false positive results cause a high rate of unnecessary and ultimately costly follow-up tests.

Screening for cervical cancer represents one of the most significant demands on the practice of diagnostic medicine. As cervical cancer is linked to a sexually transmitted disease—the human papillomavirus (HPV)—every woman essentially becomes “at risk” for cervical cancer simply after becoming sexually active. In the developing world, there are approximately 2.0 billion women aged 15 and older who are potentially eligible for screening with LuViva. Guidelines for screening intervals vary across the world, but U.S. guidelines call for screening every three years. Traditionally, the Pap smear screening test, or Pap test, is the primary cervical cancer screening methodology in the developed world. However, in developing countries, cancer screening using Pap tests is expensive and requires infrastructure and skill not currently existing, and not likely to be developed in the near future, in these countries.

We believe LuViva is the answer to the developing world’s cervical cancer screening needs. Screening for cervical cancer in the developing world often requires working directly with foreign governments or non-governmental agencies (NGOs). By partnering with governments or NGOs, we can provide immediate access to cervical cancer detection to large segments of a nation’s population as part of national or regional governmental healthcare programs, eliminating the need to develop expensive and resource-intensive infrastructures.

In the developed world, we believe LuViva offers a more accurate and ultimately cost-effective triage medical device, to be used once a traditional Pap test or HPV test indicates the possibility of cervical cancer. Due to the high number of false positive results from Pap tests, traditional follow-on tests entail increased medical treatment costs. We believe these costs can be minimized by utilizing LuViva as a triage to determine whether follow-on tests are warranted.

We believe our non-invasive cervical cancer detection technology can be applied to the early detection of other cancers as well. In 2013, we announced a license agreement with Konica Minolta, Inc. allowing us to manufacture and develop a non-invasive esophageal cancer detection product from Konica Minolta based on our biophotonic technology platform. Early market analyses of our biophotonic technology indicated that skin cancer detection was also promising, but currently we are focused primarily on the large-scale commercialization of LuViva.

Cancer

Cancer is a group of many related diseases. All forms of cancer involve the out-of-control growth and spread of abnormal cells. Normal cells grow, divide, and die in an orderly fashion. Cancer cells, however, continue to grow and divide and can spread to other parts of the body. In America, half of all men and one-third of all women will develop some form of cancer during their lifetimes. According to the American Cancer Society, the sooner a cancer is found and treatment begins, the better a patient’s chances are of being cured. We began investigating the applications of our biophotonic technology to cancer detection before 1997, when we initiated a preliminary market analysis. We concluded that our biophotonic technology had applications for the detection of a variety of cancers through the exposure of tissue to light. We selected detection of cervical cancer and skin cancer from a list of the ten most promising applications to pursue initially, and ultimately focused primarily on our LuViva cervical cancer detection device.

Cervical cancer is a cancer that begins in the lining of the cervix (which is located in the lower part of the uterus). Cervical cancer forms over time and may spread to other parts of the body if left untreated. There is generally a gradual change from a normal cervix to a cervix with precancerous cells to cervical cancer. For some women, precancerous changes may go away without any treatment. While the majority of precancerous changes in the cervix do not advance to cancer, if precancers are treated, the risk that they will become cancers can be greatly reduced.

The Developing World

According to the most recent data published by the World Health Organization (WHO), cervical cancer is the fourth most frequent cancer in women worldwide, with an estimated 570,000 new cases in 2018, an increase of 40,000 cases from 2012. For women living in less developed regions, however, cervical cancer is the second most common cancer, and 9 out of 10 women who die from cervical cancer reside in low- and middle-income countries. In 2012, the most recent year reported for global cervical cancer mortality rates, approximately 270,000 women died from cervical cancer, with more than 85% of these deaths occurring in low- and middle-income countries.

As noted by the WHO, in developed countries, programs are in place that enable women to get screened, making most pre-cancerous lesions identifiable at stages when they can easily be treated. Early treatment prevents up to 80% of cervical cancers in these countries. In developing countries, however, limited access to effective screening means that the disease is often not identified until it is further advanced and symptoms develop. In addition, prospects for treatment of such late-stage disease may be poor, resulting in a higher rate of death from cervical cancer in these countries.

We believe that the greatest need and market opportunity for LuViva lies in screening for cervical cancer in developing countries where the infrastructure for traditional screening may be limited or non-existent.

We are actively working with distributors in the following countries to implement government-sponsored screening programs: Turkey, Indonesia, and Nigeria. The number of screening candidates in those countries is approximately 131 million and Indonesia and Nigeria represent 2 of the 10 most populous countries in the world.

The Developed World

The Pap test, which involves a sample of cervical tissue being placed on a slide and observed in a laboratory, is currently the most common form of cervical cancer screening. Since the introduction of screening and diagnostic methods, the number of cervical cancer deaths in the developed world has declined dramatically, due mainly to the increased use of the Pap test. However, the Pap test has a wide variation in sensitivity, which is the ability to detect the disease, and specificity, which is the ability to exclude false positives. A study by Duke University for the U.S. Agency for Health Care Policy and Research published in 1999 showed Pap test performance ranging from a 22%-95% sensitivity and 78%-10% specificity, although new technologies improving the sensitivity and specificity of the Pap test have recently been introduced and are finding acceptance in the marketplace. About 60 million Pap tests are given annually in the United States, at an average price of approximately \$26 per test.

After a Pap test returns a positive result for cervical cancer, accepted protocol calls for a visual examination of the cervix using a colposcope, usually followed by a biopsy, or tissue sampling, at one or more locations on the cervix. This method looks for visual changes attributable to cancer. There are about two million colposcope examinations annually in the United States and Europe. In 2003, the average cost of a stand-alone colposcope examination in the United States was \$185 and the average cost of a colposcopy with biopsy was \$277.

Given this landscape, we believe that there is a material need and market opportunity for LuViva as a triage device in the developed world where LuViva represents a more cost-effective method of verifying a positive Pap test than the alternatives.

The LuViva Advanced Cervical Scan

LuViva is designed to identify cervical cancers and precancers painlessly, non-invasively and at the point of care by scanning the cervix with light, then analyzing the light reflected from the cervix. The information presented by the light would be used to indicate the likelihood of cervical cancer or precancers. Our product, in addition to detecting the structural changes attributed to cervical cancer, is also designed to detect the biochemical changes that precede the development of visual lesions. In this way, cervical cancer may be detected earlier in its development, which should increase the chances of effective treatment. In addition to the device itself, operation of LuViva requires employment of our single-use, disposable calibration and alignment cervical guide.

To date, thousands of women in multiple international clinical settings have been tested with LuViva. As a result, more than 25 papers and presentations have been published regarding LuViva in a clinical setting, including at the International Federation of Gynecology and Obstetrics Congress in London in 2015 and at the Indonesian National Obstetrics and Gynecology (POGI) Meeting in Solo in 2016.

Internationally, we contract with country-specific or regional distributors. We believe that the international market will be significantly larger than the U.S. market due to the international demand for cervical cancer screening. We have executed formal distribution agreements covering 54 countries and still have active contracts in place for countries that cover roughly half of the world's population, including China and Southeast Asia (including Indonesia), Eastern Europe and Russia as well as the Middle East (including Turkey). In 2019, we intend to focus on other large markets such as India, Western Europe and certain Latin American countries, such as Mexico.

We have previously obtained regulatory approval to sell LuViva in Europe under our Edition 3 CE Mark. Additionally, LuViva has also obtained marketing approval from Health Canada, COFEPRIS in Mexico, Ministry of Health in Kenya and the Singapore Health Sciences Authority. In addition, in 2018, we were approved for sales and marketing in India. We currently are seeking regulatory approval to market LuViva in the United States but have not yet received approval from the U.S. Food and Drug Administration (FDA). As of December 31, 2018, we have sold 139 LuViva devices and approximately 76,640 single-use-disposable cervical guides to international distributors.

We believe our non-invasive cervical cancer detection technology can be applied to the early detection of other cancers as well. From 2008 to early 2013, we worked with Konica Minolta to explore the feasibility of adapting our microporation and biophotonic cancer detection technology to other areas of medicine and to determine potential markets for these products in anticipation of a development agreement. In February 2013, we replaced our existing agreements with Konica Minolta with a new agreement, pursuant to which, subject to the payment of a nominal license fee due upon FDA approval, Konica Minolta has granted us a five-year, world-wide, non-transferable and non-exclusive right and license to manufacture and to develop a non-invasive esophageal cancer detection product from Konica Minolta and based on our biophotonic technology platform. The license permits us to use certain related intellectual property of Konica Minolta. In return for the license, we have agreed to pay Konica Minolta a royalty for each licensed product we sell. We continue to seek new collaborative partners to further develop our biophotonic technology.

Manufacturing, Sales Marketing and Distribution

We manufacture LuViva at our Norcross, Georgia facility. Most of the components of LuViva are custom made for us by third-party manufacturers. We adhere to ISO 13485:2003 quality standards in our manufacturing processes. Our single-use cervical guides are manufactured by a vendor that specializes in injection molding of plastic medical products. On January 22, 2017, we entered into a license agreement with Shandong Yaohua Medical Instrument Corporation ("SMI") pursuant to which we granted SMI an exclusive global license to manufacture the LuViva device and related disposables (subject to a carve-out for manufacture in Turkey). On December 18, 2018, we entered into a co-development agreement with Newmars Technologies, Inc. ("NTI"), whereby NTI will perform final assembly of the LuViva device for its contracted distribution countries in Eastern Europe and Russia at its ISO 13485 facility in Hungary. This additional carve out has been agreed to by SMI.

We rely on distributors to sell our products. Distributors can be country exclusive or cover multiple countries in a region. We manage these distributors, provide them marketing materials and train them to demonstrate and operate LuViva. We seek distributors that have experience in gynecology and in introducing new technology into their assigned territories.

We have only limited experience in the production planning, quality system management, facility development, and production scaling that will be needed to bring production to increased sustained commercial levels. We will likely need to develop additional expertise in order to successfully manufacture, market, and distribute any future products.

Research, Development and Engineering

We have been engaged primarily in the research, development and testing of our LuViva non-invasive cervical cancer detection product and our core biophotonic technology. Since 2013, we have incurred approximately \$7.7 million in research and development expenses, net of about \$927,000 reimbursed through collaborative arrangements and government grants. Research and development costs were approximately \$0.2 and \$0.3 million in 2018 and 2017, respectively.

Since 2013, we have focused our research and development and our engineering resources almost exclusively on development of our biophotonic technology, with only limited support of other programs funded through government contracts or third-party funding. Because our research and clinical development programs for other cancers are at a very early stage, substantial additional research and development and clinical trials will be necessary before we can produce commercial prototypes of other cancer detection products.

Several of the components used in LuViva currently are available from only one supplier, and substitutes for these components could not be obtained easily or would require substantial modifications to our products.

Patents

We have pursued a course of developing and acquiring patents and patent rights and licensing technology. Our success depends in large part on our ability to establish and maintain the proprietary nature of our technology through the patent process and to license from other's patents and patent applications necessary to develop our products. As of December 31, 2018, we have 16 granted U.S. patents relating to our biophotonic cancer detection technology that were developed in-house and are owned by the Company. Currently we do not own third party patents nor do we make any outside payments for patents.

| Patent No. | Title | Ctry | Grant Date | Expiration Date |
|------------|--|------|------------|-----------------|
| 6,400,875 | Method for Protecting A Fiber Optic Probe And The Resulting Fiber Optic Probe | US | 06/04/2002 | 11/01/2019 |
| 6,577,391 | Apparatus And Method For Determining Tissue Characteristics | US | 06/10/2003 | 03/24/2020 |
| 6,590,651 | Apparatus and Method for Determining Tissue Characteristics | US | 07/08/2003 | 11/16/2020 |
| 6,792,982 | Vacuum Source For Harvesting Substances | US | 09/21/2004 | 07/23/2023 |
| 6,870,620 | Apparatus And Method For Determining Tissue Characteristics | US | 03/22/2005 | 03/24/2020 |
| 6,975,889 | Multi-Modal Optical Cancer Diagnostic System | US | 12/13/2005 | 03/09/2021 |
| 7,006,220 | Apparatus and Method for Determining Tissue Characteristics | US | 02/28/2006 | 11/16/2020 |
| 7,174,927 | Vacuum Source For Harvesting Substances | US | 02/13/2007 | 09/03/2024 |
| 7,301,629 | Apparatus and Method for Determining Tissue Characteristics | US | 11/27/2007 | 07/03/2023 |
| 7,335,166 | System And Methods For Fluid Extractions And Monitoring | US | 02/26/2008 | 05/22/2023 |
| 8,644,912 | Method and Apparatus For Determining Tissue Characteristics | US | 02/04/2014 | 11/16/2020 |
| 8,781,560 | Method and Apparatus For Rapid Detection and Diagnosis of Tissue Abnormalities | US | 07/15/2014 | 07/14/2031 |
| 9,561,003 | Method and Apparatus For Rapid Detection and Diagnosis of Tissue Abnormalities | US | 02/07/2017 | 07/14/2031 |
| D714453 | Mobile Cart and Hand Held Unit for Diagnostics of Measurement | US | 09/30/2014 | 09/30/2028 |
| D724199 | Medical Diagnostic Stand Off Tube | US | 03/10/2015 | 03/10/2029 |
| D746475 | Mobile Cart and Hand Held Unit for Diagnostics or Measurement | US | 12/29/2015 | 12/29/2029 |

In addition to the patents listed above, the Company owns four additional corresponding foreign patents and has applied for an two additional US patents, although there is no assurance that these patents will be granted. The Company's strategy is to continue improving its products and filing new patents to protect those improvements.

In the United States, additional years of patent protection may be added (on a case by case basis) beyond the standard patent terms under the 1984 Drug Price Competition and Patent Term Restoration Act, also known as the Hatch-Waxman Act. The Hatch-Waxman act includes Section 156, which provides for the extension of the term of a granted patent (PTE) under certain circumstances. The intent behind Section 156 is to extend patent life to compensate patent holders for patent term lost while developing their product and awaiting FDA approval. The Company's patents qualify under Section 156 because LuViva has not yet been commercialized in the United States and it is being regulated by FDA as a Class III Medical Device.

Competition

The medical device industry in general and the markets for cervical cancer detection in particular, are intensely competitive. If successful in our product development, we will compete with other providers of cervical cancer detection and prevention products.

Current cervical cancer screening and diagnostic tests, primarily the Pap test, HPV test, and colposcopy, are well established and pervasive. Improvements and new technologies for cervical cancer detection and prevention, such as Thin-Prep from Hologic and HPV testing from Qiagen, have led to other new competitors. In addition, there are other companies attempting to develop products using forms of biophotonic technologies in cervical cancer detection, such as Spectrascience, which has a very limited U.S. FDA approval to market its device for detection of cervical cancers, but has not yet entered the market. The approval limits use of the Spectrascience device only after a colposcopy, as an adjunct. In addition to the Spectrascience device, there are other technologies that are seeking to enter the market as adjuncts to colposcopy, including devices from Dysis and Zedco. While these technologies are not direct competitors to LuViva, modifications to them or other new technologies will require us to develop devices that are more accurate, easier to use or less costly to administer so that our products have a competitive advantage.

In April 2014, the U.S. FDA approved the use of the Roche cobas HPV test as a primary screener for cervical cancer. Using a sample of cervical cells, the cobas HPV test detects DNA from 14 high-risk HPV types. The test specifically identifies HPV 16 and HPV 18, while concurrently detecting 12 other types of high-risk HPVs. This could make HPV testing a competitor to the Pap test. However, due to its lower specificity, we believe that screening with HPV will increase the number of false positive results if widely adopted.

In June 2006, the U.S. FDA approved the HPV vaccine Gardasil from drug maker Merck. Gardasil is a prophylactic HPV vaccine, meaning that it is designed to prevent the initial establishment of HPV infections. For maximum efficacy, it is recommended that girls receive the vaccine prior to becoming sexually active. Since Gardasil will not block infection with all of the HPV types that can cause cervical cancer, the vaccine should not be considered a substitute for routine Pap tests. On October 16, 2009, GlaxoSmithKline PLC was granted approval in the United States for a similar preventive HPV vaccine, known as Cervarix. Due to the limited availability and lack of 100% protection against all potentially cancer-causing strains of HPV, we believe that the vaccines will have a limited impact on the cervical cancer screening and diagnostic market for many years.

Government Regulation

The medical devices that we manufacture are subject to regulation by numerous regulatory bodies, including the CFDA, the U.S. FDA, and comparable international regulatory agencies. These agencies require manufacturers of medical devices to comply with applicable laws and regulations governing the development, testing, manufacturing, labeling, marketing and distribution of medical devices. Devices are generally subject to varying levels of regulatory control, the most comprehensive of which requires that a clinical evaluation program be conducted before a device receives approval for commercial distribution.

In the European Union, medical devices are required to comply with the Medical Devices Directive and obtain CE Mark certification in order to market medical devices. The CE Mark certification, granted following approval from an independent "Notified Body," is an international symbol of adherence to quality assurance standards and compliance with applicable European Medical Devices Directives. During 2018 and 2017 we were unable to pay the annual registration fees to maintain our ISO 13485:2003 certification and our CE Mark. Once our financing is completed, we will make the required payments and reobtain both certifications. In addition, our December 21, 2018 agreement with Newmars, described above, will allow final assembly at their ISO 13485:2003 accredited facility.

China has a regulatory regime similar to that of the European Union, but due to interaction with the U.S. regulatory regime, the CFDA also shares some similarities with its U.S. counterpart. Devices are classified by the CFDA's Center for Medical Device Evaluation (CMDE) into three categories based on medical risk, with the level of regulatory oversight determined by degree of risk and invasiveness. CMDE's device classifications and definitions are as follows:

- Class I device: The safety and effectiveness of the device can be ensured through routine administration.
- Class II device: Further control is required to ensure the safety and effectiveness of the device.
- Class III device: The device is implanted into the human body; used for life support or sustenance; or poses potential risk to the human body, and thus must be strictly controlled in respect to safety and effectiveness.

Based on the above definitions and several discussions with regulatory consultants and potential partners, we believe that LuViva is most likely to be classified as a Class II device, however, this is not certain and the CFDA may determine that LuViva requires a Class III registration. Class III registrations are granted by the national CFDA office while Class I and II registrations occur at the provincial level. Typically, registration granted at the provincial level allows a medical device to be marketed in all of China's provinces.

While Class I devices usually do not require clinical trial data from Chinese patients and Class III devices almost always do, Class II medical devices sometimes do and sometimes do not require Chinese clinical trials, and this determination may depend on the claim for the device and quality of clinical trials conducted outside of China. If clinical trials conducted in China are required, they usually are less burdensome for Class II devices than Class III devices.

CFDA labs also conduct electrical, mechanical and electromagnetic emission safety testing for medical devices similar to those required for the CE Mark. As is the case with the U.S. FDA, manufacturers in China undergo periodic inspections and must comply with international quality standards such as ISO 13485 for medical devices. As part of our agreement with SMI, SMI will underwrite the cost of securing approval of LuViva with the CFDA.

In the United States, permission to distribute a new device generally can be met in one of two ways. The first process requires that a pre-market notification (510(k) Submission) be made to the U.S. FDA to demonstrate that the device is as safe and effective as, or substantially equivalent to, a legally marketed device that is not subject to premarket approval (PMA). A legally marketed device is a device that (1) was legally marketed prior to May 28, 1976, (2) has been reclassified from Class III to Class II or I, or (3) has been found to be substantially equivalent to another legally marketed device following a 510(k) Submission. The legally marketed device to which equivalence is drawn is known as the "predicate" device. Applicants must submit descriptive data and, when necessary, performance data to establish that the device is substantially equivalent to a predicate device. In some instances, data from human clinical studies must also be submitted in support of a 510(k) Submission. If so, these data must be collected in a manner that conforms with specific requirements in accordance with federal regulations. The U.S. FDA must issue an order finding substantial equivalence before commercial distribution can occur. Changes to existing devices covered by a 510(k) Submission which do not significantly affect safety or effectiveness can generally be made by us without additional 510(k) Submissions.

The second process requires that an application for premarket approval (PMA) be made to the U.S. FDA to demonstrate that the device is safe and effective for its intended use as manufactured. This approval process applies to most Class III devices, including LuViva. In this case, two steps of U.S. FDA approval are generally required before marketing in the United States can begin. First, investigational device exemption (IDE) regulations must be complied with in connection with any human clinical investigation of the device in the United States. Second, the U.S. FDA must review the PMA application, which contains, among other things, clinical information acquired under the IDE. The U.S. FDA will approve the PMA application if it finds that there is a reasonable assurance that the device is safe and effective for its intended purpose.

We completed enrollment in our U.S. FDA pivotal trial of LuViva in 2008 and, after the U.S. FDA requested two-years of follow-up data for patients enrolled in the study, the U.S. FDA accepted our completed PMA application on November 18, 2010, effective September 23, 2010, for substantive review. On March 7, 2011, we announced that the U.S. FDA had inspected two clinical trial sites and audited our clinical trial data base systems as part of its review process and raised no formal compliance issues. On January 20, 2012, we announced our intent to seek an independent panel review of our PMA application after receiving a "not-approvable" letter from the U.S. FDA. On November 14, 2012 we filed an amended PMA with the U.S. FDA. On September 6, 2013, we received a letter from the U.S. FDA with additional questions and met with the U.S. FDA on May 8, 2014 to discuss our response. On July 25, 2014, we announced that we had responded to the U.S. FDA's most recent questions.

We received a "not-approvable" letter from the U.S. FDA on May 15, 2015. We had a follow up meeting with the U.S. FDA to discuss a path forward on November 30, 2015, at which we agreed to submit a detailed clinical protocol for U.S. FDA review so that additional studies can be completed. These studies will not be completed in 2019, although we intend to pursue FDA approval and start studies in 2019 once funds are available. We remain committed to obtaining U.S. FDA approval, but we are focused on international sales growth, where we believe the commercial opportunities are larger and the clinical need is more significant.

The process of obtaining clearance to market products is costly and time-consuming in virtually all of the major markets in which we sell, or expect to sell, our products and may delay the marketing and sale of our products. Countries around the world have recently adopted more stringent regulatory requirements, which are expected to add to the delays and uncertainties associated with new product releases, as well as the clinical and regulatory costs of supporting those releases. No assurance can be given that our products will be approved on a timely basis in any particular jurisdiction, if at all. In addition, regulations regarding the development, manufacture and sale of medical devices are subject to future change. We cannot predict what impact, if any, those changes might have on our business. Failure to comply with regulatory requirements could have a material adverse effect on our business, financial condition and results of operations.

Noncompliance with applicable requirements can result in import detentions, fines, civil penalties, injunctions, suspensions or losses of regulatory approvals or clearances, recall or seizure of products, operating restrictions, denial of export applications, governmental prohibitions on entering into supply contracts, and criminal prosecution. Failure to obtain regulatory approvals or the restriction, suspension or revocation of regulatory approvals or clearances, as well as any other failure to comply with regulatory requirements, would have a material adverse effect on our business, financial condition and results of operations.

Regulatory approvals and clearances, if granted, may include significant labeling limitations and limitations on the indicated uses for which the product may be marketed. In addition, to obtain regulatory approvals and clearances, the U.S. FDA and some foreign regulatory authorities impose numerous other requirements with which medical device manufacturers must comply. U.S. FDA enforcement policy strictly prohibits the marketing of approved medical devices for unapproved uses. Any products we manufacture or distribute under U.S. FDA clearances or approvals are subject to pervasive and continuing regulation by the U.S. FDA. The U.S. FDA also requires us to provide it with information on death and serious injuries alleged to have been associated with the use of our products, as well as any malfunctions that would likely cause or contribute to death or serious injury.

The U.S. FDA requires us to register as a medical device manufacturer and list our products. We are also subject to inspections by the U.S. FDA and state agencies acting under contract with the U.S. FDA to confirm compliance with good manufacturing practice. These regulations require that we manufacture our products and maintain documents in a prescribed manner with respect to manufacturing, testing, quality assurance and quality control activities. The U.S. FDA also has promulgated final regulatory changes to these regulations that require, among other things, design controls and maintenance of service records. These changes will increase the cost of complying with good manufacturing practice requirements.

Distributors of medical devices may also be required to comply with other foreign regulatory agencies, and we or our distributors currently have marketing approval for LuViva from Health Canada, COFEPRIS in Mexico, the Ministry of Health in Kenya, and the Singapore Health Sciences Authority. The time required to obtain these foreign approvals to market our products may be longer or shorter than that required in China or the United States, and requirements for those approvals may differ from those required by the CFDA or the U.S. FDA.

We are also subject to a variety of other controls that affect our business. Labeling and promotional activities are subject to scrutiny by the U.S. FDA and, in some instances, by the U.S. Federal Trade Commission. The U.S. FDA actively enforces regulations prohibiting marketing of products for unapproved users. We are also subject, as are our products, to a variety of state and local laws and regulations in those states and localities where our products are or will be marketed. Any applicable state or local regulations may hinder our ability to market our products in those regions. Manufacturers are also subject to numerous federal, state and local laws relating to matters such as safe working conditions, manufacturing practices, environmental protection, fire hazard control and disposal of hazardous or potentially hazardous substances. We may be required to incur significant costs to comply with these laws and regulations now or in the future. These laws or regulations may have a material adverse effect on our ability to do business.

Although our marketing and distribution partners around the world assist in the regulatory approval process, ultimately, we are be responsible for obtaining and maintaining regulatory approvals for our products. The inability or failure to comply with the varying regulations or the imposition of new regulations would materially adversely affect our business, financial condition and results of operations.

Employees and Consultants

As of December 31, 2018, we had nine regular employees and one consultant to provide services to us on a full- or part-time basis. Of the ten-people employed or engaged by us, 2 are engaged in engineering, manufacturing and development, 4 are engaged in sales and marketing activities, 1 is engaged in clinical testing and regulatory affairs, and 3 are engaged in administration and accounting. No employees are covered by collective bargaining agreements, and we believe we maintain good relations with our employees.

Our ability to operate successfully and manage our potential future growth depends in significant part upon the continued service of key scientific, technical, managerial and finance personnel, and our ability to attract and retain additional highly qualified personnel in these fields. Two of these key employees have an employment contract with us; none are covered by key person or similar insurance. In addition, if we are able to successfully develop and commercialize our products, we likely will need to hire additional scientific, technical, marketing, managerial and finance personnel. We face intense competition for qualified personnel in these areas, many of whom are often subject to competing employment offers. The loss of key personnel or our inability to hire and retain additional qualified personnel in the future could have a material adverse effect on our business, financial condition and results of operations.

Corporate History

We are a Delaware corporation, originally incorporated in 1992 under the name "SpectRx, Inc.," and, on February 22, 2008, changed our name to Guided Therapeutics, Inc. At the same time, we renamed our wholly owned subsidiary, InterScan, which originally had been incorporated as "Guided Therapeutics."

Our principal executive and operations facility is located at 5835 Peachtree Corners East, Suite B, Norcross, Georgia 30092, and our telephone number is (770) 242-8723.

Item 1A. Risk Factors

In addition to the other information in this annual report on Form 10-K, the following risk factors should be considered carefully in evaluating us.

Risks Related to Our Business

Although we will be required to raise additional funds in 2019, there is no assurance that such funds can be raised on terms that we would find acceptable, on a timely basis, or at all.

Additional debt or equity financing will be required for us to continue as a going concern. We may seek to obtain additional funds for the financing of our cervical cancer detection business through additional debt or equity financings and/or new collaborative arrangements. Management believes that additional financing, if obtainable, will be sufficient to support planned operations only for a limited period. Management has implemented operating actions to reduce cash requirements. Any required additional funding may not be available on terms attractive to us, on a timely basis, or at all. If we cannot obtain additional funds or achieve profitability, we may not be able to continue as a going concern.

Because we must obtain additional funds through financing transactions or through new collaborative arrangements in order to grow the revenues of our cervical cancer detection product line, there exists substantial doubt about our ability to continue as a going concern. Therefore, it will be necessary to raise additional funds. There can be no assurance that we will be able to raise these additional funds. If we do not secure additional funding when needed, we will be unable to conduct all of our product development efforts as planned, which may cause us to alter our business plan in relation to the development of our products. Even if we obtain additional funding, we will need to achieve profitability thereafter.

Our independent registered public accountants' report on our consolidated financial statements as of and for the year ended December 31, 2018, indicated that there was substantial doubt about our ability to continue as a going concern because we had suffered recurring losses from operations and had an accumulated deficit of \$137.6 million at December 31, 2018 summarized as follows:

| | |
|---|------------------|
| Accumulated deficit, from inception to 12/31/2016 | \$127.6 million |
| Preferred dividends | \$ 0.2 million |
| Net Loss for fiscal year 2017, ended 12/31/2017 | \$ 10.7 million |
| Accumulated deficit, from inception to 12/31/2017 | \$138.5 million |
| Preferred dividends | \$ 0.1 million |
| Net Profit for year to date ended 12/31/2018 | \$ (1.0) million |
| Accumulated deficit, from inception to 12/31/2018 | \$137.6 million |

Our management has implemented reductions in operating expenditures and reductions in some development activities. We have determined to make cervical cancer detection the focus of our business. We are managing the development of our other programs only when funds are made available to us via grants or contracts with government entities or strategic partners. However, there can be no assurance that we will be able to successfully implement or continue these plans.

If we cannot obtain additional funds when needed, we will not be able to implement our business plan.

We require substantial additional capital to develop our products, including completing product testing and clinical trials, obtaining all required regulatory approvals and clearances, beginning and scaling up manufacturing, and marketing our products. We have historically financed our operations through the public and private sale of debt and equity, funding from collaborative arrangements, and grants. Any failure to achieve adequate funding in a timely fashion would delay our development programs and could lead to abandonment of our business plan. To the extent we cannot obtain additional funding, our ability to continue to manufacture and sell our current products, or develop and introduce new products to market, will be limited. Further, financing our operations through the public or private sale of debt or equity may involve restrictive covenants or other provisions that could limit how we conduct our business or finance our operations. Financing our operations through collaborative arrangements generally means that the obligations of the collaborative partner to fund our expenditures are largely discretionary and depend on a number of factors, including our ability to meet specified milestones in the development and testing of the relevant product. We may not be able to obtain an acceptable collaboration partner, and even if we do, we may not be able to meet these milestones, or the collaborative partner may not continue to fund our expenditures.

We do not have a long operating history, especially in the cancer detection field, which makes it difficult to evaluate our business.

Although we have been in existence since 1992, we have only recently begun to commercialize our cervical cancer detection technology. Because limited historical information is available on our revenue trends and manufacturing costs, it is difficult to evaluate our business. Our prospects must be considered in light of the substantial risks, expenses, uncertainties and difficulties encountered by entrants into the medical device industry, which is characterized by increasing intense competition and a high failure rate.

We have a history of losses, and we expect losses to continue.

We have never been profitable and we have had operating losses since our inception. We expect our operating losses to continue as we continue to expend substantial resources to complete commercialization of our products, obtain regulatory clearances or approvals; build our marketing, sales, manufacturing and finance capabilities, and conduct further research and development. The further development and commercialization of our products will require substantial development, regulatory, sales and marketing, manufacturing and other expenditures. We have only generated limited revenues from product sales. Our accumulated deficit was approximately \$137.6 million at December 31, 2018.

We are currently delinquent with our federal and applicable state tax returns filings. Some of the federal income tax returns are currently under examination by the U.S. Internal Revenue Service ("IRS"). Therefore, we may incur additional taxes and costs. At this time, we are not yet able to determine whether or not such additional taxes or costs would have a material adverse effect on the company or our net operating losses, as discussed below.

Although we have been experiencing recurring losses, we are obligated to file tax returns for compliance with IRS regulations and that of applicable state jurisdictions. At December 31, 2018 and 2017, we have approximately \$77.2 and \$82.9 million of net operating losses, respectively. This net operating loss will be eligible to be carried forward for tax purposes at federal and applicable states level, but the use of such net operating losses may be subject to restrictions under applicable tax law. A full valuation allowance has been recorded related to the deferred tax assets generated from the net operating losses.

Our ability to sell our products is controlled by government regulations, and we may not be able to obtain any necessary clearances or approvals.

The design, manufacturing, labeling, distribution and marketing of medical device products are subject to extensive and rigorous government regulation in most of the markets in which we sell, or plan to sell, our products, which can be expensive and uncertain and can cause lengthy delays before we can begin selling our products in those markets.

In foreign countries, including European countries, we are subject to government regulation, which could delay or prevent our ability to sell our products in those jurisdictions.

In order for us to market our products in Europe and some other international jurisdictions, we and our distributors and agents must obtain required regulatory registrations or approvals. We must also comply with extensive regulations regarding safety, efficacy and quality in those jurisdictions. We may not be able to obtain the required regulatory registrations or approvals, or we may be required to incur significant costs in obtaining or maintaining any regulatory registrations or approvals we receive. Delays in obtaining any registrations or approvals required for marketing our products, failure to receive these registrations or approvals, or future loss of previously obtained registrations or approvals would limit our ability to sell our products internationally. For example, international regulatory bodies have adopted various regulations governing product standards, packaging requirements, labeling requirements, import restrictions, tariff regulations, duties and tax requirements. These regulations vary from country to country. In order to sell our products in Europe, in 2018 we must undergo an inspection and re-file for ISO 13485:2003 and the CE Mark, which is an international symbol of quality and compliance with applicable European medical device directives. Failure to maintain ISO 13485:2003 certification or CE mark certification or other international regulatory approvals would prevent us from selling in some countries in the European Union.

In the United States, we are subject to regulation by the U.S. FDA, which could prevent us from selling our products domestically.

In order for us to market our products in the United States, we must obtain clearance or approval from the U.S. Food and Drug Administration, or U.S. FDA. We cannot be sure that:

- we, or any collaborative partner, will make timely filings with the U.S. FDA;
- the U.S. FDA will act favorably or quickly on these submissions;
- we will not be required to submit additional information or perform additional clinical studies; or
- we will not face other significant difficulties and costs necessary to obtain U.S. FDA clearance or approval.

It can take several years from initial filing of a PMA application and require the submission of extensive supporting data and clinical information. The U.S. FDA may impose strict labeling or other requirements as a condition of its clearance or approval, any of which could limit our ability to market our products domestically. Further, if we wish to modify a product after U.S. FDA approval of a PMA application, including changes in indications or other modifications that could affect safety and efficacy, additional clearances or approvals will be required from the U.S. FDA. Any request by the U.S. FDA for additional data, or any requirement by the U.S. FDA that we conduct additional clinical studies, could result in a significant delay in bringing our products to market domestically and require substantial additional research and other expenditures. Similarly, any labeling or other conditions or restrictions imposed by the U.S. FDA could hinder our ability to effectively market our products domestically. Further, there may be new U.S. FDA policies or changes in U.S. FDA policies that could be adverse to us.

Even if we obtain clearance or approval to sell our products, we are subject to ongoing requirements and inspections that could lead to the restriction, suspension or revocation of our clearance.

We, as well as any potential collaborative partners, will be required to adhere to applicable regulations in the markets in which we operate and sell our products, regarding good manufacturing practice, which include testing, control, and documentation requirements. Ongoing compliance with good manufacturing practice and other applicable regulatory requirements will be strictly enforced applicable regulatory agencies. Failure to comply with these regulatory requirements could result in, among other things, warning letters, fines, injunctions, civil penalties, recall or seizure of products, total or partial suspension of production, failure to obtain premarket clearance or premarket approval for devices, withdrawal of approvals previously obtained, and criminal prosecution. The restriction, suspension or revocation of regulatory approvals or any other failure to comply with regulatory requirements would limit our ability to operate and could increase our costs.

We depend on a limited number of distributors and any reduction, delay or cancellation of an order from these distributors or the loss of any of these distributors could cause our revenue to decline.

Each year we have had one or a few distributors that have accounted for substantially all of our limited revenues. As a result, the termination of a purchase order with any one of these distributors may result in the loss of substantially all of our revenues. We are constantly working to develop new relationships with existing or new distributors, but despite these efforts we may not be successful at generating new orders to maintain similar revenues as current purchase orders are filled. In addition, since a significant portion of our revenues is derived from a relatively few distributors, any financial difficulties experienced by any one of these distributors, or any delay in receiving payments from any one of these distributors, could have a material adverse effect on our business, results of operations, financial condition and cash flows.

To successfully market and sell our products internationally, we must address many issues with which we have limited experience.

All of our sales of LuViva to date have been to distributors outside of the United States. We expect that substantially all of our business will continue to come from sales in foreign markets, through increased penetration in countries where we currently sell LuViva, combined with expansion into new international markets. However, international sales are subject to a number of risks, including:

- difficulties in staffing and managing international operations;
- difficulties in penetrating markets in which our competitors' products may be more established;
- reduced or no protection for intellectual property rights in some countries;
- export restrictions, trade regulations and foreign tax laws;
- fluctuating foreign currency exchange rates;
- foreign certification and regulatory clearance or approval requirements;
- difficulties in developing effective marketing campaigns for unfamiliar, foreign countries;
- customs clearance and shipping delays;
- political and economic instability; and
- preference for locally produced products.

If one or more of these risks were realized, it could require us to dedicate significant resources to remedy the situation, and even if we are able to find a solution, our revenues may still decline.

To market and sell LuViva internationally, we depend on distributors and they may not be successful.

We currently depend almost exclusively on third-party distributors to sell and service LuViva internationally and to train our international distributors, and if these distributors terminate their relationships with us or under-perform, we may be unable to maintain or increase our level of international revenue. We will also need to engage additional international distributors to grow our business and expand the territories in which we sell LuViva. Distributors may not commit the necessary resources to market, sell and service LuViva to the level of our expectations. If current or future distributors do not perform adequately, or if we are unable to engage distributors in particular geographic areas, our revenue from international operations will be adversely affected

Risks Related to Our Intellectual Property

Our success largely depends on our ability to maintain and protect the proprietary information on which we base our products.

Our success depends in large part upon our ability to maintain and protect the proprietary nature of our technology through the patent process, as well as our ability to license from other's patents and patent applications necessary to develop our products. If any of our patents are successfully challenged, invalidated or circumvented, or our right or ability to manufacture our products was to be limited, our ability to continue to manufacture and market our products could be adversely affected. In addition to patents, we rely on trade secrets and proprietary know-how, which we seek to protect, in part, through confidentiality and proprietary information agreements. The other parties to these agreements may breach these provisions, and we may not have adequate remedies for any breach. Additionally, our trade secrets could otherwise become known to or be independently developed by competitors.

As of December 31, 2018, we have been issued, or have rights to, 16 U.S. patents (including those under license). In addition, we have filed for, or have rights to, four U.S. patents (including those under license) that are still pending. We also have three granted patents that apply to our interstitial fluid analysis system as well as seven international patents that apply to our noninvasive technologies. There are additional international patents and pending applications. One or more of the patents we hold directly or license from third parties, including those for our cervical cancer detection products, may be successfully challenged, invalidated or circumvented, or we may otherwise be unable to rely on these patents. These risks are also present for the process we use or will use for manufacturing our products. In addition, our competitors, many of whom have substantial resources and have made substantial investments in competing technologies, may apply for and obtain patents that prevent, limit or interfere with our ability to make, use and sell our products, either in the United States or in international markets.

The medical device industry has been characterized by extensive litigation regarding patents and other intellectual property rights. In addition, the U.S. Patent and Trademark Office, or USPTO, may institute interference proceedings. The defense and prosecution of intellectual property suits, USPTO proceedings and related legal and administrative proceedings are both costly and time consuming. Moreover, we may need to litigate to enforce our patents, to protect our trade secrets or know-how, or to determine the enforceability, scope and validity of the proprietary rights of others. Any litigation or interference proceedings involving us may require us to incur substantial legal and other fees and expenses and may require some of our employees to devote all or a substantial portion of their time to the proceedings. An adverse determination in the proceedings could subject us to significant liabilities to third parties, require us to seek licenses from third parties or prevent us from selling our products in some or all markets. We may not be able to reach a satisfactory settlement of any dispute by licensing necessary patents or other intellectual property. Even if we reached a settlement, the settlement process may be expensive and time consuming, and the terms of the settlement may require us to pay substantial royalties. An adverse determination in a judicial or administrative proceeding or the failure to obtain a necessary license could prevent us from manufacturing and selling our products.

We may be unable to commercialize our products if we are unable to protect our proprietary rights, and we may be liable for significant costs and damages if we face a claim of intellectual property infringement by a third party.

Our near and long-term prospects depend in part on our ability to obtain and maintain patents, protect trade secrets and operate without infringing upon the proprietary rights of others. In the absence of patent and trade secret protection, competitors may adversely affect our business by independently developing and marketing substantially equivalent or superior products and technology, possibly at lower prices. We could also incur substantial costs in litigation and suffer diversion of attention of technical and management personnel if we are required to defend ourselves in intellectual property infringement suits brought by third parties, with or without merit, or if we are required to initiate litigation against others to protect or assert our intellectual property rights. Moreover, any such litigation may not be resolved in our favor.

Although we and our licensors have filed various patent applications covering the uses of our product candidates, patents may not be issued from the patent applications already filed or from applications that we might file in the future. Moreover, the patent position of companies in the pharmaceutical industry generally involves complex legal and factual questions and has been the subject of much litigation. Any patents we own or license, now or in the future, may be challenged, invalidated or circumvented. To date, no consistent policy has been developed in the U.S. Patent and Trademark Office (the "PTO") regarding the breadth of claims allowed in biotechnology patents.

In addition, because patent applications in the U.S. are maintained in secrecy until patent applications publish or patents issue, and because publication of discoveries in the scientific or patent literature often lags behind actual discoveries, we cannot be certain that we and our licensors are the first creators of inventions covered by any licensed patent applications or patents or that we or they are the first to file. The PTO may commence interference proceedings involving patents or patent applications, in which the question of first inventorship is contested. Accordingly, the patents owned or licensed to us may not be valid or may not afford us protection against competitors with similar technology, and the patent applications licensed to us may not result in the issuance of patents.

It is also possible that our owned and licensed technologies may infringe on patents or other rights owned by others, and licenses to which may not be available to us. We may be unable to obtain a license under such patent on terms favorable to us, if at all. We may have to alter our products or processes, pay licensing fees or cease activities altogether because of patent rights of third parties.

In addition to the products for which we have patents or have filed patent applications, we rely upon unpatented proprietary technology and may not be able to meaningfully protect our rights with regard to that unpatented proprietary technology. Furthermore, to the extent that consultants, key employees or other third parties apply technological information developed by them or by others to any of our proposed projects, disputes may arise as to the proprietary rights to this information, which may not be resolved in our favor.

We may be involved in lawsuits to protect or enforce our patents, which could be expensive and time consuming.

The pharmaceutical industry has been characterized by extensive litigation regarding patents and other intellectual property rights, and companies have employed intellectual property litigation to gain a competitive advantage. We may become subject to infringement claims or litigation arising out of patents and pending applications of our competitors, or additional interference proceedings declared by the PTO to determine the priority of inventions. The defense and prosecution of intellectual property suits, PTO proceedings, and related legal and administrative proceedings are costly and time-consuming to pursue, and their outcome is uncertain. Litigation may be necessary to enforce our issued patents, to protect our trade secrets and know-how, or to determine the enforceability, scope, and validity of the proprietary rights of others. An adverse determination in litigation or interference proceedings to which we may become a party could subject us to significant liabilities, require us to obtain licenses from third parties, or restrict or prevent us from selling our products in certain markets. Although patent and intellectual property disputes might be settled through licensing or similar arrangements, the costs associated with such arrangements may be substantial and could include our paying large fixed payments and ongoing royalties. Furthermore, the necessary licenses may not be available on satisfactory terms or at all.

Competitors may infringe our patents, and we may file infringement claims to counter infringement or unauthorized use. This can be expensive, particularly for a company of our size, and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours is not valid or is unenforceable or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover its technology. An adverse determination of any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly.

Also, a third party may assert that our patents are invalid and/or unenforceable. There are no unresolved communications, allegations, complaints or threats of litigation related to the possibility that our patents are invalid or unenforceable. Any litigation or claims against us, whether or not merited, may result in substantial costs, place a significant strain on our financial resources, divert the attention of management and harm our reputation. An adverse decision in litigation could result in inadequate protection for our product candidates and/or reduce the value of any license agreements we have with third parties.

Interference proceedings brought before the PTO may be necessary to determine priority of invention with respect to our patents or patent applications. During an interference proceeding, it may be determined that we do not have priority of invention for one or more aspects in our patents or patent applications and could result in the invalidation in part or whole of a patent or could put a patent application at risk of not issuing. Even if successful, an interference proceeding may result in substantial costs and distraction to our management.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or interference proceedings, there is a risk that some of our confidential information could be compromised by disclosure. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If investors perceive these results to be negative, the price of our common stock could be adversely affected.

If we infringe the rights of third parties, we could be prevented from selling products, forced to pay damages, and defend against litigation.

If our products, methods, processes and other technologies infringe the proprietary rights of other parties, we could incur substantial costs and we may have to: obtain licenses, which may not be available on commercially reasonable terms, if at all; abandon an infringing product candidate; redesign our products or processes to avoid infringement; stop using the subject matter claimed in the patents held by others; pay damages; and/or defend litigation or administrative proceedings which may be costly whether we win or lose, and which could result in a substantial diversion of our financial and management resources.

Risks Related to Our Sales Strategy

We may not be able to generate sufficient sales revenues to sustain our growth and strategy plans.

Our cervical cancer diagnostic activities have been financed to date through a combination of government grants, strategic partners and direct investment. Growing revenues for this product are the main focus of our business. In order to effectively market the cervical cancer detection product, additional capital will be needed.

Additional product lines involve the modification of the cervical cancer detection technology for use in other cancers. These product lines are only in the earliest stages of research and development and are currently not projected to reach market for several years. Our goal is to receive enough funding from government grants and contracts, as well as payments from strategic partners, to fund development of these product lines without diverting funds or other necessary resources from the cervical cancer program.

Because our products, which use different technology or apply technology in different ways than other medical devices, are or will be new to the market, we may not be successful in launching our products and our operations and growth would be adversely affected.

Our products are based on new methods of cancer detection. If our products do not achieve significant market acceptance, our sales will be limited and our financial condition may suffer. Physicians and individuals may not recommend or use our products unless they determine that these products are an attractive alternative to current tests that have a long history of safe and effective use. To date, our products have been used by only a limited number of people, and few independent studies regarding our products have been published. The lack of independent studies limits the ability of doctors or consumers to compare our products to conventional products.

If we are unable to compete effectively in the highly competitive medical device industry, our future growth and operating results will suffer.

The medical device industry in general and the markets in which we expect to offer products in particular, are intensely competitive. Many of our competitors have substantially greater financial, research, technical, manufacturing, marketing and distribution resources than we do and have greater name recognition and lengthier operating histories in the health care industry. We may not be able to effectively compete against these and other competitors. A number of competitors are currently marketing traditional laboratory-based tests for cervical cancer screening and diagnosis. These tests are widely accepted in the health care industry and have a long history of accurate and effective use. Further, if our products are not available at competitive prices, health care administrators who are subject to increasing pressures to reduce costs may not elect to purchase them. Also, a number of companies have announced that they are developing, or have introduced, products that permit non-invasive and less invasive cancer detection. Accordingly, competition in this area is expected to increase. Furthermore, our competitors may succeed in developing, either before or after the development and commercialization of our products, devices and technologies that permit more efficient, less expensive non-invasive and less invasive cancer detection. It is also possible that one or more pharmaceutical or other health care companies will develop therapeutic drugs, treatments or other products that will substantially reduce the prevalence of cancers or otherwise render our products obsolete.

We have limited manufacturing experience, which could limit our growth.

We do not have manufacturing experience that would enable us to make products in the volumes that would be necessary for us to achieve significant commercial sales, and we rely upon our suppliers. In addition, we may not be able to establish and maintain reliable, efficient, full scale manufacturing at commercially reasonable costs in a timely fashion. Difficulties we encounter in manufacturing scale-up, or our failure to implement and maintain our manufacturing facilities in accordance with good manufacturing practice regulations, international quality standards or other regulatory requirements, could result in a delay or termination of production. In the past, we have had substantial difficulties in establishing and maintaining manufacturing for our products and those difficulties impacted our ability to increase sales. Companies often encounter difficulties in scaling up production, including problems involving production yield, quality control and assurance, and shortages of qualified personnel.

Since we rely on sole source suppliers for several of the components used in our products, any failure of those suppliers to perform would hurt our operations.

Several of the components used in our products or planned products, are available from only one supplier, and substitutes for these components could not be obtained easily or would require substantial modifications to our products. Any significant problem experienced by one of our sole source suppliers may result in a delay or interruption in the supply of components to us until that supplier cures the problem or an alternative source of the component is located and qualified. Any delay or interruption would likely lead to a delay or interruption in our manufacturing operations. For our products that require premarket approval, the inclusion of substitute components could require us to qualify the new supplier with the appropriate government regulatory authorities. Alternatively, for our products that qualify for premarket notification, the substitute components must meet our product specifications.

Because we operate in an industry with significant product liability risk, and we have not specifically insured against this risk, we may be subject to substantial claims against our products.

The development, manufacture and sale of medical products entail significant risks of product liability claims. We currently have no product liability insurance coverage beyond that provided by our general liability insurance. Accordingly, we may not be adequately protected from any liabilities, including any adverse judgments or settlements, we might incur in connection with the development, clinical testing, manufacture and sale of our products. A successful product liability claim, or series of claims brought against us that result in an adverse judgment against or settlement by us in excess of any insurance coverage could seriously harm our financial condition or reputation. In addition, product liability insurance is expensive and may not be available to us on acceptable terms, if at all.

The availability of third party reimbursement for our products is uncertain, which may limit consumer use and the market for our products.

In the United States and elsewhere, sales of medical products are dependent, in part, on the ability of consumers of these products to obtain reimbursement for all or a portion of their cost from third-party payors, such as government and private insurance plans. Any inability of patients, hospitals, physicians and other users of our products to obtain sufficient reimbursement from third-party payors for our products, or adverse changes in relevant governmental policies or the policies of private third-party payors regarding reimbursement for these products, could limit our ability to sell our products on a competitive basis. We are unable to predict what changes will be made in the reimbursement methods used by third-party health care payors. Moreover, third-party payors are increasingly challenging the prices charged for medical products and services, and some health care providers are gradually adopting a managed care system in which the providers contract to provide comprehensive health care services for a fixed cost per person. Patients, hospitals and physicians may not be able to justify the use of our products by the attendant cost savings and clinical benefits that we believe will be derived from the use of our products, and therefore may not be able to obtain third-party reimbursement.

Reimbursement and health care payment systems in international markets vary significantly by country and include both government-sponsored health care and private insurance. We may not be able to obtain approvals for reimbursement from these international third-party payors in a timely manner, if at all. Any failure to receive international reimbursement approvals could have an adverse effect on market acceptance of our products in the international markets in which approvals are sought.

We have a substantial amount of indebtedness, which may adversely affect our cash flow and our ability to operate our business.

Our outstanding indebtedness, which is considered ordinary course payables and accrued payroll liabilities, was \$6.3 million at December 31, 2018.

The terms of our indebtedness could have negative consequences to us, such as:

- we may be unable to obtain additional financing to fund working capital, operating losses, capital expenditures or acquisitions on terms acceptable to us, or at all;

- the amount of our interest expense may increase if we are unable to make payments when due;
- our assets might be subject to foreclosure if we default on our secured debt (see “— *We have outstanding debt that is collateralized by a general security interest in all of our assets, including our intellectual property. If we were to fail to repay the debt when due, the holders would have the right to foreclose on these assets.*”);
- our vendors or employees may, and some have, instituted proceedings to collect on amounts owed them;
- we have to use a substantial portion of our cash flows from operations to repay our indebtedness, including ordinary course accounts payable and accrued payroll liabilities, which reduces the amount of money we have for future operations, working capital, inventory, expansion, or general corporate or other business activities; and
- we may be unable to refinance our indebtedness on terms acceptable to us, or at all.

Our ability to meet our expenses and debt obligations will depend on our future performance, which will be affected by financial, business, economic, regulatory and other factors. We will be unable to control many of these factors, such as economic conditions. We cannot be certain that our earnings will be sufficient to allow us to pay the principal and interest on our debt and meet any other obligations. If we do not have enough money to service our debt, we may be required, but unable, to refinance all or part of our existing debt, sell assets, borrow money or raise equity on terms acceptable to us, if at all.

We have outstanding debt that is collateralized by a general security interest in all of our assets, including our intellectual property. If we were to fail to repay the debt when due, the holders would have the right to foreclose on these assets.

At May 2, 2019, we had notes outstanding that are collateralized by a security interest in our current and future inventory and accounts receivable. We also had a note outstanding that is collateralized by a security interest in all of our assets, including our intellectual property. When the debt is repaid, the holders' security interests on our assets will be extinguished. However, if an event of default occurs under the notes prior to their repayment, the holders may exercise their rights to foreclose on these secured assets for the payment of these obligations. Under “cross-default” provisions in each of the notes, an event of default under one note is automatically an event of default under the other notes. Any such default and resulting foreclosure would have a material adverse effect on our business, financial condition and results of operations.

We are subject to restrictive covenants under the terms of our outstanding secured debt. If we were to default under the terms of these covenants, the holders would have the right to foreclose on the assets that secure the debt.

The instruments governing our outstanding secured debt contain restrictive covenants. For example, our senior secured convertible note prohibits us from incurring additional indebtedness for borrowed money, repurchasing any outstanding shares of our common stock, or paying any dividends on our capital stock, in each case without the note holder's prior written consent. If we were to breach any of these covenants, the holder could declare an event of default on the note, and exercise its rights to foreclose on the assets securing the note.

Our success depends on our ability to attract and retain scientific, technical, managerial and finance personnel.

Our ability to operate successfully and manage our future growth depends in significant part upon the continued service of key scientific, technical, managerial and finance personnel, as well as our ability to attract and retain additional highly qualified personnel in these fields. We may not be able to attract and retain key employees when necessary, which would limit our operations and growth. In addition, if we are able to successfully develop and commercialize our products, we will need to hire additional scientific, technical, marketing, managerial and finance personnel. We face intense competition for qualified personnel in these areas, many of whom are often subject to competing employment offers.

Certain provisions of our certificate of incorporation that authorize the issuance of additional shares of preferred stock may make it more difficult for a third party to effect a change in control.

Our certificate of incorporation authorizes our board of directors to issue up to 5.0 million shares of preferred stock. Our undesignated shares of preferred stock may be issued in one or more series, the terms of which may be determined by the board without further stockholder action. These terms may include, among other terms, voting rights, including the right to vote as a series on particular matters, preferences as to liquidation and dividends, repurchase rights, conversion rights, redemption rights and sinking fund provisions. The issuance of any preferred stock could diminish the rights of holders of our common stock, and therefore could reduce the value of our common stock. In addition, specific rights granted to future holders of preferred stock could be used to restrict our ability to merge with or sell assets to a third party. The ability of our board to issue preferred stock could make it more difficult, delay, discourage, prevent or make it more costly to acquire or effect a change in control, which in turn could prevent our stockholders from recognizing a gain in the event that a favorable offer is extended and could materially and negatively affect the market price of our common stock.

Risks Related to Our Common Stock

On March 29, 2019, a 1:800 reverse stock split of all of our issued and outstanding common stock was implemented. There are risks associated with a reverse stock split.

On March 29, 2019, a 1:800 reverse stock split of all of our issued and outstanding common stock was implemented. As a result of the reverse stock split, every 800 shares of issued and outstanding common stock were converted into 1 share of common stock. All fractional shares created by the reverse stock split were rounded to the nearest whole share. The number of authorized shares of common stock did not change.

There are certain risks associated with the reverse stock split, including the following:

- We have additional authorized shares of common stock that the board could issue in future without stockholder approval, and such additional shares could be issued, among other purposes, in financing transactions or to resist or frustrate a third-party transaction that is favored by a majority of the independent stockholders. This could have an anti-takeover effect, in that additional shares could be issued, within the limits imposed by applicable law, in one or more transactions that could make a change in control or takeover of us more difficult.
- There can be no assurance that the reverse stock split will achieve the benefits that we hope it will achieve. The total market capitalization of our common stock after the reverse stock split may be lower than the total market capitalization before the reverse stock split.

The reverse stock split may decrease the liquidity of the shares of our common stock.

The liquidity of the shares of our common stock may be affected adversely by the reverse stock split given the reduced number of shares that were outstanding immediately following the reverse stock split, especially if the market price of our common stock does not increase as a result of the reverse stock split. In addition, the reverse stock split may have increased the number of stockholders who own odd lots of our common stock, creating the potential for such stockholders to experience an increase in the cost of selling their shares and greater difficulty effecting such sales.

Following the reverse stock split, the resulting market price of our common stock may not attract new investors, including institutional investors, and may not satisfy the investing requirements of those investors. Consequently, the trading liquidity of our common stock may not improve.

Although we believe that a higher market price of our common stock may help generate greater or broader investor interest, there can be no assurance that the reverse stock split will result in a share price that will attract new investors, including institutional investors. In addition, there can be no assurance that the market price of our common stock will satisfy the investing requirements of those investors. As a result, the trading liquidity of our common stock may not necessarily improve.

The number of shares of our common stock issuable upon the conversion of our outstanding convertible debt and preferred stock or exercise of outstanding warrants and options is substantial.

As of May 2, 2019, our outstanding convertible debt was convertible into an aggregate of 43,360,044 shares of our common stock, and the outstanding shares of our Series C, Series C1 and Series C2 preferred stock were convertible into an aggregate of 2,324,214 shares of common stock. Also, as of that date we had warrants outstanding that were exercisable for an aggregate of 23,589,630 shares, contractual obligations to issue 2,132 shares, and outstanding options to purchase 50 shares. The shares of common stock issuable upon conversion or exercise of these securities would have constituted approximately 96.0% of the total number of shares of common stock then issued and outstanding. However, please refer to *Footnote 11 - CONVERTIBLE DEBT IN DEFAULT* in the paragraph: Debt Restructuring for more information regarding our warrants.

Further, under the terms of our convertible debt and preferred stock, as well as certain of our outstanding warrants, the conversion price or exercise price, as the case may be, could be adjusted downward, causing substantial dilution. See "*Adjustments to the conversion price for our convertible debt and preferred stock, and the exercise price for certain of our warrants, will dilute the ownership interests of our existing stockholders.*"

Adjustments to the conversion price of our convertible debt and preferred stock, and the exercise price for certain of our warrants, will dilute the ownership interests of our existing stockholders.

Under the terms of a portion of our convertible debt, the conversion price fluctuates with the market price of our common stock. Additionally, under the terms of our Series C preferred stock, any dividends we choose to pay in shares of our common stock will be calculated based on the then-current market price of our common stock. Accordingly, if the market price of our common stock decreases, the number of shares of our common stock issuable upon conversion of the convertible debt or upon payment of dividends on our outstanding Series C preferred stock will increase, and may result in the issuance of a significant number of additional shares of our common stock.

Under the terms of our preferred stock and certain of our convertible notes and outstanding warrants, the conversion price or exercise price will be lowered if we issue common stock at a per share price below the then-conversion price or then-exercise price for those securities. Reductions in the conversion price or exercise price would result in the issuance of a significant number of additional shares of our common stock upon conversion or exercise, which would result in dilution in the value of the shares of our outstanding common stock and the voting power represented thereby.

Our stock is thinly traded, so you may be unable to sell at or near ask prices or at all.

The shares of our common stock are dually quoted on the OTCBB and the OTCQB. Shares of our common stock are thinly traded, meaning that the number of persons interested in purchasing our common shares at or near ask prices at any given time may be relatively small or non-existent. This situation is attributable to a number of factors, including:

- we are a small company that is relatively unknown to stock analysts, stock brokers, institutional investors and others in the investment community that generate or influence sales volume; and
- stock analysts, stock brokers and institutional investors may be risk-averse and be reluctant to follow a company such as ours that faces substantial doubt about its ability to continue as a going concern or to purchase or recommend the purchase of our shares until such time as we became more viable.

As a consequence, our stock price may not reflect an actual or perceived value. Also, there may be periods of several days or more when trading activity in our shares is minimal or non-existent, as compared to a seasoned issuer that has a large and steady volume of trading activity that will generally support continuous sales without an adverse effect on share price. A broader or more active public trading market for our common shares may not develop or if developed, may not be sustained. Due to these conditions, you may not be able to sell your shares at or near ask prices or at all if you need money or otherwise desire to liquidate your shares.

Trading in our common stock is subject to special sales practices and may be difficult to sell.

Our common stock is subject to the Securities and Exchange Commission's "penny stock" rule, which imposes special sales practice requirements upon broker-dealers who sell such securities to persons other than established distributors or accredited investors. Penny stocks are generally defined to be an equity security that has a market price of less than \$5.00 per share. For transactions covered by the rule, the broker-dealer must make a special suitability determination for the purchaser and receive the purchaser's written agreement to the transaction prior to the sale. Consequently, the rule may affect the ability of broker-dealers to sell our securities and also may affect the ability of our stockholders to sell their securities in any market that might develop.

Stockholders should be aware that, according to Securities and Exchange Commission, the market for penny stocks has suffered from patterns of fraud and abuse. Such patterns include:

- control of the market for the security by one or a few broker-dealers that are often related to the promoter or issuer;
- manipulation of prices through prearranged matching of purchases and sales and false and misleading press releases;
- "boiler room" practices involving high-pressure sales tactics and unrealistic price projections by inexperienced sales persons;
- excessive and undisclosed bid-ask differentials and markups by selling broker-dealers; and
- the wholesale dumping of the same securities by promoters and broker-dealers after prices have been manipulated to a desired level, along with the resulting inevitable collapse of those prices and with consequent investor losses.

Our management is aware of the abuses that have occurred historically in the penny stock market. Although we do not expect to be in a position to dictate the behavior of the market or of broker-dealers who participate in the market, management will strive within the confines of practical limitations to prevent the described patterns from being established with respect to our common stock.

Our need to raise additional capital in the near future or to use our equity securities for payments could have a dilutive effect on your investment.

In order to continue operations, we will need to raise additional capital. We may attempt to raise capital through the public or private sale of our common stock or securities convertible into or exercisable for our common stock. In addition, from time to time we have issued our common stock or warrants in lieu of cash payments. If we sell additional shares of our common stock or other equity securities, or issue such securities in respect of other claims or indebtedness, such sales or issuances will further dilute the percentage of our equity that you own. Depending upon the price per share of securities that we sell or issue in the future, if any, your interest in us could be further diluted by any adjustments to the number of shares and the applicable exercise price required pursuant to the terms of the agreements under which we previously issued convertible securities.

FORWARD LOOKING STATEMENTS

Statements in this report, which express “belief,” “anticipation” or “expectation,” as well as other statements that are not historical facts, are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, or Securities Act, and Section 21E of the Securities Exchange Act of 1934, or Exchange Act. These forward-looking statements are subject to risks and uncertainties that could cause actual results to differ materially from historical results or anticipated results, including those identified in the foregoing “Risk Factors” and elsewhere in this report. Examples of these uncertainties and risks include, but are not limited to:

- access to sufficient debt or equity capital to meet our operating and financial needs;
- the effectiveness and ultimate market acceptance of our products;
- whether our products in development will prove safe, feasible and effective;
- whether and when we or any potential strategic partners will obtain required regulatory approvals in the markets in which we plan to operate;
- our need to achieve manufacturing scale-up in a timely manner, and our need to provide for the efficient manufacturing of sufficient quantities of our products;
- the lack of immediate alternate sources of supply for some critical components of our products;
- our patent and intellectual property position;
- the need to fully develop the marketing, distribution, customer service and technical support and other functions critical to the success of our product lines;
- the dependence on potential strategic partners or outside investors for funding, development assistance, clinical trials, distribution and marketing of some of our products; and
- other risks and uncertainties described from time to time in our reports filed with the SEC.

Forward-looking statements should not be read as a guarantee of future performance or results, and will not necessarily be accurate indications of the times at, or by which, such performance or results will be achieved. Forward-looking information is based on information available at the time and/or management’s good faith belief with respect to future events, and is subject to risks and uncertainties that could cause actual performance or results to differ materially from those expressed in the statements.

Forward-looking statements speak only as of the date the statements are made. We assume no obligation to update forward-looking statements to reflect actual results, changes in assumptions or changes in other factors affecting forward-looking information except to the extent required by applicable securities laws. If we update one or more forward-looking statements, no inference should be drawn that we will make additional updates with respect thereto or with respect to other forward-looking statements.

Item 1B. Unresolved Staff Comments

Not applicable.

Item 2. Properties

Our corporate offices, which also comprise our administrative, research and development, marketing and production facilities, are located at 5835 Peachtree Corners East, Suite B, Norcross, Georgia 30092, where we lease approximately 12,800 square feet under a lease that expires in March 2021.

Item 3. Legal Proceedings

We are subject to claims and legal actions that arise in the ordinary course of business. However, we are not currently subject to any claims or actions that we believe would have a material adverse effect on our financial position or results of operations.

Item 4. Mine Safety Disclosures

Not applicable.

PART II

Item 5. Market for Registrant’s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Market for Common Stock; Holders

Our common stock is dually listed on the OTC Bulletin Board (OTCBB) and the OTCQB quotation systems under the ticker symbol “GTHP.” The number of record holders of our common stock at April 15, 2019 was 210.

A 1:800 reverse stock split of all of our issued and outstanding common stock was implemented on March 29, 2019. As a result of the reverse stock split, every 800 shares of issued and outstanding common stock were converted into 1 share of common stock. All fractional shares created by the reverse stock split were rounded to the nearest whole share. The number of authorized shares of common stock did not change.

The high and low common stock share prices for the second quarter of 2019 and calendar years 2018 and 2017, as reported by the OTCBB, are as set forth in the following table. All share prices set forth in the table have been retroactively adjusted to reflect the reverse stock split (as discussed above) for all periods presented.

| | 2019 | | 2018 | | 2017 | |
|-----------------|---------|---------|----------|---------|-------------|-----------|
| | High | Low | High | Low | High | Low |
| First Quarter | \$ 1.45 | \$ 0.02 | \$ 26.00 | \$ 4.48 | \$ 1,700.00 | \$ 248.00 |
| Second Quarter* | \$ 0.24 | \$ 0.01 | \$ 12.80 | \$ 2.40 | \$ 320.00 | \$ 120.00 |
| Third Quarter | | | \$ 3.20 | \$ 0.64 | \$ 144.00 | \$ 23.64 |
| Fourth Quarter | | | \$ 3.04 | \$ 0.08 | \$ 44.00 | \$ 10.12 |

*Through April 15, 2019.

Dividend Policy

We have not paid any dividends on our common stock since our inception and do not intend to pay any dividends in the foreseeable future.

Securities Authorized for Issuance Under Equity Compensation Plans

All the securities we have provided our employees, directors and consultants have been issued under our stock option plans, which are approved by our stockholders. We have issued common stock to other individuals that are not employees or directors, in lieu of cash payments, that are not part of any plan approved by our stockholders.

Securities authorized for issuance under equity compensation plans as of December 31, 2018:

| Plan category | Number of securities to be issued upon exercise of outstanding options, warrants and rights (a) | Weighted-average exercise price of outstanding options, warrants and rights (b) | Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column(a)) (c) |
|--|--|--|---|
| Equity compensation plans approved by security holders | 50 | \$ 44,786,278 | - |
| Equity compensation plans not approved by security holders | - | - | - |
| TOTAL | 50 | \$ 44,786,278 | - |

Item 6. Selected Financial Data

Not applicable.

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion should be read in conjunction with our financial statements and notes thereto included elsewhere in this report.

Overview

We are a medical technology company focused on developing innovative medical devices that have the potential to improve healthcare. Our primary focus is the sales and marketing of our LuViva® Advanced Cervical Scan non-invasive cervical cancer detection device. The underlying technology of LuViva primarily relates to the use of biophotonics for the non-invasive detection of cancers. LuViva is designed to identify cervical cancers and precancers painlessly, non-invasively and at the point of care by scanning the cervix with light, then analyzing the reflected and fluorescent light.

LuViva provides a less invasive and painless alternative to conventional tests for cervical cancer screening and detection. Additionally, LuViva improves patient well-being not only because it eliminates pain, but also because it is convenient to use and provides rapid results at the point of care. We focus on two primary applications for LuViva: first, as a cancer screening tool in the developing world, where infrastructure to support traditional cancer-screening methods is limited or non-existent, and second, as a triage following traditional screening in the developed world, where a high number of false positive results cause a high rate of unnecessary and ultimately costly follow-up tests.

We are a Delaware corporation, originally incorporated in 1992 under the name "SpectRx, Inc.," and, on February 22, 2008, changed our name to Guided Therapeutics, Inc. At the same time, we renamed our wholly owned subsidiary, InterScan, which originally had been incorporated as "Guided Therapeutics."

Since our inception, we have raised capital through the public and private sale of debt and equity, funding from collaborative arrangements, and grants.

Our prospects must be considered in light of the substantial risks, expenses and difficulties encountered by entrants into the medical device industry. This industry is characterized by an increasing number of participants, intense competition and a high failure rate. We have experienced operating losses since our inception and, as of December 31, 2018 we have an accumulated deficit of approximately \$137.6 million. To date, we have engaged primarily in research and development efforts and the early stages of marketing our products. We do not have significant experience in manufacturing, marketing or selling our products. We may not be successful in growing sales for our products. Moreover, required regulatory clearances or approvals may not be obtained in a timely manner, or at all. Our products may not ever gain market acceptance and we may not ever generate significant revenues or achieve profitability. The development and commercialization of our products requires substantial development, regulatory, sales and marketing, manufacturing and other expenditures. We expect our operating losses to continue for the foreseeable future as we continue to expend substantial resources to complete commercialization of our products, obtain regulatory clearances or approvals, build our marketing, sales, manufacturing and finance capabilities, and conduct further research and development.

Our product revenues to date have been limited. In 2018, the majority of our revenues were from the sale of LuViva devices and disposables. We expect that the majority of our revenue in 2019 will be derived from revenue from the sale of LuViva devices and disposables.

Current Demand for LuViva

Based on discussions with our distributors, we expect to generate purchase orders for approximately \$1.5 to \$2.0 million in LuViva devices and disposables in 2019 and expect those purchase orders to result in actual sales of \$0.5 to \$1.0 million in 2019, representing what we view as current demand for our products. We cannot be assured that we will generate all or any of these additional purchase orders, or that existing orders will not be canceled by the distributors or that parts to build product will be available to meet demand, such that existing orders will result in actual sales. Because we have a short history of sales of our products, we cannot confidently predict future sales of our products beyond this time frame and cannot be assured of any particular amount of sales. Accordingly, we have not identified any particular trends with regard to sales of our products.

Recent Developments

On December 18, 2018, we entered into a co-development agreement with Newmars Technologies, Inc. (“NTI”), whereby NTI will perform final assembly of the LuViva device for its contracted distribution countries in Eastern Europe and Russia at its ISO 13485 facility in Hungary. The agreement enables Newmars to manufacture LuViva® Advance Cervical Scan devices in Hungary for distribution in the nine Central and Eastern European countries for which Newmars has distribution rights. Guided Therapeutics will manufacture sub-assemblies and sell these and other parts to Newmars and will receive an additional \$2,000 royalty for each device sold in those countries, which include Russia, Ukraine, Poland, Romania, Hungary, Moldova, Kazakhstan, Belarus and Armenia, subject to certain minimum royalty payments and parts orders. The additional carve out for these territories has been agreed to by SMI. The Agreement with Newmars does not allow them to manufacture single use Cervical Guides, which the Company will continue to supply.

We received Regulatory Approval from the Indian Ministry of Health & Family Welfare to allow commercialization of the LuViva device and disposables. The Ministry concluded that the LuViva device is “Non Invasive” and as such is “not regulated under the Drugs and Cosmetics Act 1940 and Medical Device Rules 2017 thereunder.” As a result, LuViva can now be commercialized in India.

On August 31, 2018, we entered into agreements with certain holders of the our Series C1 preferred stock, par value \$0.001 per share (the “Series C1 Preferred Stock”), including John Imhoff, the chairman of our board of directors, and Mark Faupel, the Chief Operating Officer and a director of our company (the “Exchange Agreements”), pursuant to which those holders separately agreed to exchange each share of the Series C1 Preferred Stock held for one (1) share of our newly created Series C2 preferred stock, par value \$0.001 per share (the “Series C2 Preferred Stock”). In total, for 3,262 shares of Series C1 Preferred Stock to be surrendered, we issued 3,262 shares of Series C2 Preferred Stock.

On October 19, 2018, we held our 2018 Annual Meeting of Stockholders (the “Annual Meeting”). As described in the our Definitive Proxy Statement on Schedule 14A, as amended, originally filed with the Securities and Exchange Commission on October 11, 2018, at the Annual Meeting, stockholders voted and approved the following proposals: (1) the election of the director-nominees (the “Directors”) of our board of directors (the “Board”), with the five Directors receiving the highest number of affirmative votes cast by holders of shares of common stock and holders of Series C2 Preferred Stock, voting as a single class; (2) the ratification of the appointment of UHY LLP as our independent registered public accounting firm by a majority of the votes cast by the holders of common stock and of Series C2 Preferred Stock, voting as a single class; (3) an amendment to the Restated Certificate of Incorporation, as amended (the “Certificate of Incorporation”), to enable a potential reverse split of the issued and outstanding shares of common stock at a ratio of between 1-for-25 and 1-for-800, with such ratio to be determined at the sole discretion of the Board and with such reverse split to be effected at such time and date on or before March 31, 2019, if at all, as determined by the Board in its sole discretion (the “Reverse Split Amendment”) by a majority of the issued and outstanding common stock and Series C2 Preferred Stock voting as a single class; (4) the adoption of an amendment to the Certificate of Incorporation, to, among other things, increase our authorized common stock from 1,000,000,000 shares to 3,000,000,000 shares; and (5) the adoption of our 2018 Stock Option Plan and the material terms thereunder (the “Plan”) by a majority of the votes cast by the holders of common stock and of Series C2 Preferred Stock, voting as a single class.

On November 7, 2018, we increased the number of common stock shares authorized from one billion to three billion.

A 1:800 reverse stock split of all of our issued and outstanding common stock was implemented on March 29, 2019. As a result of the reverse stock split, every 800 shares of issued and outstanding common stock were converted into 1 share of common stock. All fractional shares created by the reverse stock split were rounded to the nearest whole share. The number of authorized shares of common stock did not change.

Critical Accounting Policies

Our material accounting policies, which we believe are the most critical to investors understanding of our financial results and condition, are discussed below. Because we are still early in our enterprise development, the number of these policies requiring explanation is limited. As we begin to generate increased revenue from different sources, we expect that the number of applicable policies and complexity of the judgments required will increase.

Revenue Recognition: ASC 606 Revenue from Contracts with Customers establishes a single and comprehensive framework which sets out how much revenue is to be recognized, and when. The core principle is that a vendor should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the vendor expects to be entitled in exchange for those goods or services. Revenue will now be recognized by a vendor when control over the goods or services is transferred to the customer. In contrast, Revenue based revenue recognition around an analysis of the transfer of risks and rewards; this now forms one of a number of criteria that are assessed in determining whether control has been transferred. The application of the core principle in ASC 606 is carried out in five steps: Step 1 – Identify the contract with a customer: a contract is defined as an agreement (including oral and implied), between two or more parties, that creates enforceable rights and obligations and sets out the criteria for each of those rights and obligations. The contract needs to have commercial substance and it is probable that the entity will collect the consideration to which it will be entitled. Step 2 – Identify the performance obligations in the contract: a performance obligation in a contract is a promise (including implicit) to transfer a good or service to the customer. Each performance obligation should be capable of being distinct and is separately identifiable in the contract. Step 3 – Determine the transaction price: transaction price is the amount of consideration that the entity can be entitled to, in exchange for transferring the promised goods and services to a customer, excluding amounts collected on behalf of third parties. Step 4 – Allocate the transaction price to the performance obligations in the contract: for a contract that has more than one performance obligation, the entity will allocate the transaction price to each performance obligation separately, in exchange for satisfying each performance obligation. The acceptable methods of allocating the transaction price include adjusted market assessment approach, expected cost plus a margin approach, and, the residual approach in limited circumstances. Discounts given should be allocated proportionately to all performance obligations unless certain criteria are met and reallocation of changes in standalone selling prices after inception is not permitted. Step 5 – Recognize revenue as and when the entity satisfies a performance obligation: the entity should recognize revenue at a point in time, except if it meets any of the three criteria, which will require recognition of revenue over time: the entity's performance creates or enhances an asset controlled by the customer, the customer simultaneously receives and consumes the benefit of the entity's performance as the entity performs, and the entity does not create an asset that has an alternative use to the entity and the entity has the right to be paid for performance to date.

Valuation of Deferred Taxes: We account for income taxes in accordance with the liability method. Under the liability method, we recognize deferred assets and liabilities based upon anticipated future tax consequences attributable to differences between financial statement carrying amounts of assets and liabilities and their respective tax bases. We establish a valuation allowance to the extent that it is more likely than not that deferred tax assets will not be utilized against future taxable income.

Valuation of Equity Instruments Granted to Employee, Service Providers and Investors: On the date of issuance, the instruments are recorded at their fair value as determined using either the Black-Scholes valuation model or Monte Carlo Simulation model.

Beneficial Conversion Features of Convertible Securities: Conversion options that are not bifurcated as a derivative pursuant to ASC 815 and not accounted for as a separate equity component under the cash conversion guidance are evaluated to determine whether they are beneficial to the investor at inception (a beneficial conversion feature) or may become beneficial in the future due to potential adjustments. The beneficial conversion feature guidance in ASC 470-20 applies to convertible stock as well as convertible debt which are outside the scope of ASC 815. A beneficial conversion feature is defined as a nondetachable conversion feature that is in the money at the commitment date. The beneficial conversion feature guidance requires recognition of the conversion option's in-the-money portion, the intrinsic value of the option, in equity, with an offsetting reduction to the carrying amount of the instrument. The resulting discount is amortized as a dividend over either the life of the instrument, if a stated maturity date exists, or to the earliest conversion date, if there is no stated maturity date. If the earliest conversion date is immediately upon issuance, the dividend must be recognized at inception. When there is a subsequent change to the conversion ratio based on a future occurrence, the new conversion price may trigger the recognition of an additional beneficial conversion feature on occurrence.

Allowance for Accounts Receivable: We estimate losses from the inability of our distributors to make required payments and periodically review the payment history of each of our distributors, as well as their financial condition, and revise our reserves as a result.

Inventory Valuation: All inventories are stated at lower of cost or net realizable value, with cost determined substantially on a "first-in, first-out" basis. Selling, general, and administrative expenses are not inventoried, but are charged to expense when purchased.

Reverse Stock Split: On March 29, 2019, the Company implemented a 1:800 reverse stock split of all of our issued and outstanding common stock. As a result of the reverse stock split, every 800 shares of issued and outstanding common stock were converted into 1 share of common stock. All fractional shares created by the reverse stock split were rounded to the nearest whole share. The number of authorized shares of common stock did not change. The reverse stock split decreased the Company's issued and outstanding shares of common stock from 2,135,478,405 shares of Common Stock to 2,669,348 shares as of that date.

Results of Operations

Comparison of 2018 and 2017

Sales Revenue, Cost of Sales and Gross Loss from Devices and Disposables: Revenues from the sale of LuViva devices for 2018 and 2017 were approximately \$57,000 and \$244,000, respectively. Revenues in 2018 were approximately, \$187,000 or 77% lower when compared to the same period in 2017, due to lack of funding to support sales and marketing efforts. Related costs of sales were approximately \$89,000 and \$530,000 in 2018 and 2017, respectively. Costs of sales in 2018, were approximately, \$441,000 or 83% lower when compared to the same period in 2017, due to increase in the inventory costs. This resulted in a gross loss of approximately \$32,000 on the sales of devices and disposables for 2018 compared with a gross loss of approximately \$286,000 for the same period in 2017.

Research and Development Expenses: Research and development expenses for 2018, decreased to approximately \$244,000, from approximately \$334,000 in 2017. The decrease of \$90,000, or 27%, was primarily due to cost reduction plans in research and development payroll expenses.

Sales and Marketing Expenses: Sales and marketing expenses for 2018, decreased to approximately \$195,000, compared to \$245,000 in 2017. The decrease, of approximately \$50,000, or 20% was primarily due to Company-wide expense reduction and cost savings efforts.

General and Administrative Expense: General and administrative expenses for 2018, decreased to approximately \$1,077,000, compared to \$2,256,000 for the same period in 2017. The decrease of approximately \$1,179,000, or 52%, was primarily related to lower compensation and option expenses incurred during the same period. For 2018, general and administrative expenses consisted primarily of professional fees, insurance, and paid and accrued compensation costs.

Other Income: Other income was approximately \$54,000 in 2018, compared to \$18,000 in the same period in 2017, an increase of \$36,000 or 200%. Other income consists of refunds from prior years for insurance policies.

Interest Expense: Interest expense for 2018 increased to approximately \$1,763,000, compared to \$1,106,000 for the same period in 2017. The increase of approximately \$657,000, or 59%, was primarily related to amortization expense of and interest recorded for the value of the beneficial conversion feature on convertible debt outstanding and amortization of debt issuance costs.

Fair Value of Warrants Recovery and Expense: Fair value of warrants recovery for 2018, increased to approximately \$3,234,000 compared to fair value of warrants expense of \$6,487,000 for the same period in 2017. The increase of approximately \$9,721,000, or 150% was primarily due to the favorable significant changes in warrant conversion prices and decrease in stock price, in the fiscal year ended December 31, 2018.

Gain from extinguishment of debt: Gain from the restructuring and exchange of debt due to officers for 2018 increased to approximately \$1,039,000, compared to nil for the same period in 2017.

Net Profit / Loss: Net profit attributable to common stockholders increased to approximately \$900,000, or \$1.95 per share, in 2018, from a net loss of \$10,974,000, or \$997.64 per share, in 2017. The decrease in the net loss of \$11,874,000, or 108% was for reasons outlined above. As stated previously, our net profit for the year ended December 31, 2018 was primarily realized due to a \$3.2 million gain in the fair value of warrants recorded in 2018 and a \$1.0 million gain from extinguishment of debt.

There was no income tax benefit recorded for 2018 or 2017, due to recurring net operating losses.

Liquidity and Capital Resources

Since our inception, we have raised capital through the public and private sale of debt and equity, funding from collaborative arrangements, and grants. At December 31, 2018, we had cash of less than \$1,000 and a negative working capital of approximately \$10,530,000.

Our major cash flows for the year ended December 31, 2018 consisted of cash out-flows of \$1.4 million from operations, including approximately \$1.0 million of net profit, and a net change from financing activities of \$1.4 million, which primarily represented the proceeds received from issuance of common stock and warrants, and proceeds from debt financing. Our net profit for the year ended December 31, 2018 was primarily realized due to a \$3.2 million gain in the fair value of warrants recorded in 2018.

On June 5, 2016, we entered into a license agreement with Shenghuo Medical, LLC pursuant to which we granted Shenghuo an exclusive license to manufacture, sell and distribute LuViva in Taiwan, Brunei Darussalam, Cambodia, Laos, Myanmar, Philippines, Singapore, Thailand, and Vietnam. Shenghuo was already our exclusive distributor in China, Macau and Hong Kong, and the license extended to manufacturing in those countries as well. Under the terms of the license agreement, once Shenghuo was capable of manufacturing LuViva in accordance with ISO 13485 for medical devices, Shenghuo would pay us a royalty equal to \$2.00 or 20% of the distributor price (subject to a discount under certain circumstances), whichever is higher, per disposable distributed within Shenghuo's exclusive territories. In connection with the license grant, Shenghuo would underwrite the cost of securing approval of LuViva with Chinese Food and Drug Administration. At its option, Shenghuo also would provide up to \$1.0 million in furtherance of our efforts to secure regulatory approval for LuViva from the U.S. Food and Drug Administration, in exchange for the right to receive payments equal to 2% of our future sales in the United States, up to an aggregate of \$4.0 million. Pursuant to the license agreement, Shenghuo had the option to have a designee appointed to our board of directors (and Richard Blumberg is that designee). As partial consideration for, and as a condition to, the license, and to further align the strategic interests of the parties, we have agreed to issue a convertible note to Shenghuo, in exchange for an aggregate cash investment of \$200,000. The note will provide for a payment to Shenghuo of \$300,000, expected to be due the earlier of 90 days from issuance and consummation of any capital raising transaction by us with net cash proceeds of at least \$1.0 million. The note will accrue interest at 20% per year on any unpaid amounts due after that date. The note will be convertible into shares of our common stock at a conversion price per share of \$11,137, subject to customary anti-dilution adjustment. The note will be unsecured, and is expected to provide for customary events of default. We will also issue Shenghuo a five-year warrant exercisable immediately for approximately 22 shares of common stock at an exercise price equal to the conversion price of the note, subject to customary anti-dilution adjustment. On January 22, 2017, we entered into a license agreement with SMI, pursuant to which we granted SMI an exclusive global license to manufacture the LuViva device and related disposables (subject to a carve-out for manufacture in Turkey) and exclusive distribution rights in the Peoples Republic of China, Macau, Hong Kong and Taiwan. In order to facilitate the SMI agreement, immediately prior to its execution we entered into an agreement with Shenghuo, regarding the previous license to Shenghuo. Under the terms of the new agreement, Shenghuo agreed to relinquish its manufacturing license and its distribution rights in SMI's territories, and to waive its rights under the original Shenghuo agreement, all for as long as SMI performs under the SMI agreement. See "—Recent Developments."

Between June 13, 2016 and June 14, 2016, we entered into various agreements with holders of certain warrants (including John Imhoff, one of our directors) originally issued in May 2013, and with GPB Debt Holdings II LLC, holder of a warrant issued February 12, 2016, pursuant to which each holder separately agreed to exchange warrants for either (1) shares of common stock equal to 166% of the number of shares of common stock underlying the surrendered warrants, or (2) new warrants exercisable for 200% of the number of shares underlying the surrendered warrants, but without certain anti-dilution protections included with the surrendered warrants. As a result of the exchanges, we effectively eliminate any potential exponential increase in the number of underlying shares issuable upon exercise of our outstanding warrants. In total, for surrendered warrants then-exercisable for an aggregate of 22,460,938 shares of common stock (but subject to exponential increase upon operation of certain anti-dilution provisions), we issued or are obligated to issue 21 shares of common stock and new warrants that, if exercised as of June 14, 2016, would have been exercisable for an aggregate of 4,511 shares of common stock. In certain circumstances, in lieu of presently issuing all of the shares (for each holder that opted for shares of common stock), we and the holder further agreed that we will, subject to the terms and conditions set forth in the applicable warrant exchange agreement, from time to time, be obligated to issue the remaining shares to the holder. No additional consideration will be payable in connection with the issuance of the remaining shares. The holders that elected to receive shares for their surrendered warrants have agreed that they will not sell shares on any trading day in an amount, in the aggregate, exceeding 20% of the composite aggregate trading volume of the common stock for that trading day. The holders that elected to receive new warrants will be required to surrender their old warrants upon consummation of our next public offering. The new warrants will have an initial exercise price equal to the exercise price of the surrendered warrants as of immediately prior to consummation of the offering, subject to customary "downside price protection" for as long as our common stock is not listed on a national securities exchange, and will expire five years from the date of issuance.

On September 6, 2016, we entered into a royalty agreement with one of our directors, John Imhoff, and another stockholder, Dolores Maloof, pursuant to which we sold to them a royalty of future sales of single-use cervical guides for LuViva. Under the terms of the royalty agreement, and for consideration of \$50,000, we will pay them an aggregate perpetual royalty initially equal to \$0.10, and from and after October 2, 2016, equal to \$0.20, for each disposable that we sell (or that is sold by a third party pursuant to a licensing arrangement with us).

On November 2, 2016, we entered into a lockup and exchange agreement with GHS Investments, LLC, holder of approximately \$221,000 in outstanding principal amount of our secured promissory note and all of the outstanding shares of our Series C preferred stock. Pursuant to the agreement, upon the effectiveness of the 1:800 reverse stock split and continuing for 45 days after, GHS and its affiliates were prohibited from converting any portion of the secured promissory note or any of the shares of Series C preferred stock or selling any of our securities that they beneficially owned. We agreed that, upon consummation of our next financing, we would use \$260,000 of net cash proceeds first, to repay GHS's portion of the secured promissory note and second, with any remaining amount from the \$260,000, to repurchase a portion of GHS's shares of Series C preferred stock. In addition, GHS has agreed to exchange the stated value per share (plus any accrued but unpaid dividends) of its remaining shares of Series C preferred stock for new securities of the same type that we separately issue in the next qualifying financing we undertake, on a dollar-for-dollar basis in a private placement exchange.

A 1:800 reverse stock split of all of our issued and outstanding common stock was implemented on November 7, 2016. As a result of the reverse stock split, every 800 shares of issued and outstanding common stock were converted into 1 share of common stock. All fractional shares created by the reverse stock split were rounded to the nearest whole share. The number of authorized shares of common stock did not change.

On December 7, 2016, we entered into an exchange agreement with GPB Debt Holdings II LLC with regard to the \$1,525,000 in outstanding principal amount of senior secured convertible note originally issued to GPB on February 11, 2016, and the \$306,863 in outstanding principal amount of our secured promissory note that GPB holds. Pursuant to the exchange agreement, upon completion of the next financing resulting in at least \$1 million in cash proceeds, GPB will exchange both securities for a new convertible note in principal amount of \$1,831,863. The new convertible note will mature on the second anniversary of issuance and will accrue interest at a rate of 19% per year. We will pay monthly interest coupons and, beginning one year after issuance, will pay amortized quarterly principal payments. Subject to resale restrictions under Federal securities laws and the availability of sufficient authorized but unissued shares of our common stock, the new convertible note will be convertible at any time, in whole or in part, at the holder's option, into shares of our common stock, at a conversion price equal to the price offered in the qualifying financing that triggers the exchange, subject to certain customary adjustments and anti-dilution provisions contained in the new convertible note. The new convertible note will include customary event of default provisions and a default interest rate of the lesser of 21% or the maximum amount permitted by law. Upon the occurrence of an event of default, GPB will be entitled to require us to redeem the new convertible note at 120% of the outstanding principal balance. The new convertible note will be secured by a lien on all of our assets, including our intellectual property, pursuant to the security agreement entered into by us and GPB in connection with the issuance of the original senior secured convertible note. We further agreed to amend the warrant issued with the original senior secured convertible note, to adjust the number of shares issuable upon exercise of the warrant to equal the number of shares that will initially be issuable upon conversion of the new convertible note (without giving effect to any beneficial ownership limitations set forth in the terms of the new convertible note). As an inducement to GPB to enter into these transactions, we agreed to increase the royalty payable to GPB pursuant to its consulting agreement with us from 3.5% to 3.85% of revenues from the sales of our products.

On December 28, 2016, we entered into a securities purchase agreement with an investor for the issuance and sale to investor of up to \$330,000 in aggregate principal amount of 10% original issuance discount convertible promissory notes, for an aggregate purchase price of \$300,000. On that date, we issued to the investor a note in the principal amount of \$222,000, for a purchase price of \$200,000. The note matures six months from their date of issuance and, in addition to the 10% original issue discount, accrue interest at a rate of 10% per year. We may prepay the notes, in whole or in part, for 115% of outstanding principal and interest until 30 days from issuance, for 125% of outstanding principal and interest at any time from 31 to 60 days from issuance, and for 130% of outstanding principal and interest at any time from 61 days from issuance until immediately prior to the maturity date. After six months from the date of issuance (i.e., if we fails to repay all principal and interest due under the notes at the maturity date), the investor may convert the notes, at any time, in whole or in part, into shares of our common stock, at a conversion price equal to 60% of the lowest volume weighted average price of our common stock during the 20 trading days prior to conversion, subject to certain customary adjustments and anti-dilution provisions contained in the note. As of December 31, 2018, we have fully amortized debt issuance costs \$30,000 and original issue discount of \$22,000. As of December 31, 2018, the balance due to the investor for the December 28, 2016 note, is zero.

On February 13, 2017, we entered into a securities purchase agreement with Auctus Fund, LLC for the issuance and sale to Auctus of \$170,000 in aggregate principal amount of a 12% convertible promissory note for an aggregate purchase price of \$156,400 (representing a \$13,600 original issue discount). On February 13, 2017, we issued the note to Auctus. Pursuant to the purchase agreement, we also issued to Auctus a warrant exercisable to purchase an aggregate of 250 shares of our common stock. The warrant is exercisable at any time, at an exercise price per share equal to \$4.11 (110% of the closing price of the common stock on the day prior to issuance), subject to certain customary adjustments and price-protection provisions contained in the warrant. The warrant has a five-year term. The note matured nine months from the date of issuance and, in addition to the original issue discount, accrues interest at a rate of 12% per year. We could have prepaid the note, in whole or in part, for 115% of outstanding principal and interest until 30 days from issuance, for 125% of outstanding principal and interest at any time from 31 to 60 days from issuance, and for 130% of outstanding principal and interest at any time from 61 days from issuance to 180 days from issuance. After six months from the date of issuance, Auctus may convert the note, at any time, in whole or in part, into shares of our common stock, at a conversion price equal to the lower of the price offered in our next public offering or a 40% discount to the average of the two lowest trading prices of the common stock during the 20 trading days prior to the conversion, subject to certain customary adjustments and price-protection provisions contained in the note. The note includes customary events of default provisions and a default interest rate of 24% per year. Upon the occurrence of an event of default, Auctus may require us to redeem the note (or convert it into shares of common stock) at 150% of the outstanding principal balance plus accrued and unpaid interest. In connection with the transaction, we agreed to reimburse Auctus for \$30,000 in legal and diligence fees, of which we paid \$10,000 in cash and \$20,000 in restricted shares of common stock, valued at \$320 per share (a 42.86% discount to the closing price of the common stock on the day prior to issuance). We allocated proceeds of \$90,000 to the warrants and common stock issued in connection with the financing. As of December 31, 2018, we have net debt of \$76,664.

On May 17, 2017, we entered into a securities purchase agreement with Eagle Equities, LLC, providing for the purchase by Eagle of two convertible redeemable notes in the aggregate principal amount of \$88,000, with the first note being in the amount of \$44,000, and the second note being in the amount of \$44,000. The first note was fully funded on May 19, 2017, upon which we received \$40,000 of net proceeds (net of a 10% original issue discount). The second note was issued on December 21, 2017 and was initially paid for by the issuance of an offsetting \$40,000 secured note issued by Eagle. Eagle was required to pay the principal amount of its secured note in cash and in full prior to executing any conversions under the second note we issued. The notes bear an interest rate of 8%, and are due and payable on May 17, 2018. The notes may be converted by Eagle at any time after five months from issuance into shares of our common stock (as determined in the notes) calculated at the time of conversion, except for the second note, which also requires full payment by Eagle of the secured note it issued to us before conversions may be made. The conversion price of the notes will be equal to 60% of the lowest trading price of the common stock for the 20 prior trading days including the day upon which we receive a notice of conversion. The notes may be prepaid in accordance with the terms set forth in the notes. The notes also contain certain representations, warranties, covenants and events of default including if we are delinquent in our periodic report filings with the SEC, and increases in the amount of the principal and interest rates under the notes in the event of such defaults. In the event of default, at Eagle's option and in its sole discretion, Eagle may consider the notes immediately due and payable. As of December 31, 2018, we have net debt of \$41,322, including unamortized original issue discount of \$5,214, unamortized and debt issuance costs of \$11,160.

On May 17, 2017, we entered into a securities purchase agreement with Adar Bays, LLC, providing for the purchase by Adar of two convertible redeemable notes in the aggregate principal amount of \$88,000, with the first note being in the amount of \$44,000, and the second note being in the amount of \$44,000. The first note was fully funded on May 19, 2017, upon which we received \$40,000 of net proceeds (net of a 10% original issue discount). The second note was issued on December 21, 2017 and was initially paid for by the issuance of an offsetting \$40,000 secured note issued by Adar. Adar was required to pay the principal amount of its secured note in cash and in full prior to executing any conversions under the second note we issued. The notes bear an interest rate of 8%, and are due and payable on May 17, 2018. The notes may be converted by Adar at any time after five months from issuance into shares of our common stock (as determined in the notes) calculated at the time of conversion, except for the second note, which also requires full payment by Adar of the secured note it issued to us before conversions may be made. The conversion price of the notes will be equal to 60% of the lowest trading price of the common stock for the 20 prior trading days including the day upon which we receive a notice of conversion. The notes may be prepaid in accordance with the terms set forth in the notes. The notes also contain certain representations, warranties, covenants and events of default including if we are delinquent in our periodic report filings with the SEC, and increases in the amount of the principal and interest rates under the notes in the event of such defaults. In the event of default, at Adar's option and in its sole discretion, Adar may consider the notes immediately due and payable. As of December 31, 2018, we have net debt of \$42,216, including unamortized original issue discount of \$5,214, unamortized and debt issuance costs of \$11,160.

On May 18, 2017, we entered into a securities purchase agreement with GHS Investments, LLC, an existing investor, providing for the purchase by GHS of a convertible promissory note in the aggregate principal amount of \$66,000, for \$60,000 in net proceeds (representing a 10% original issue discount). The transaction closed on May 19, 2017. The note matures upon the earlier of our receipt of \$100,000 from revenues, loans, investments, or any other means (other than the Eagle and Adar bridge financings) and December 31, 2018. In addition to the 10% original issue discount, the note accrues interest at a rate of 8% per year. We may prepay the note, in whole or in part, for 110% of outstanding principal and interest until 30 days from issuance, for 120% of outstanding principal and interest at any time from 31 to 60 days from issuance and for 140% of outstanding principal and interest at any time from 61 days to 180 days from issuance. The note may not be prepaid after 180 days. After six months from the date of issuance, the note will become convertible, at any time thereafter, in whole or in part, at the holder's option, into shares of our common stock, at a conversion price equal to 60% of the lowest trading price during the 25 trading days prior to conversion. The note includes customary event of default provisions and a default interest rate of the lesser of 20% per year or the maximum amount permitted by law. Upon the occurrence of an event of default, the holder of the note may require us to redeem the note (or convert it into shares of common stock) at 150% of the outstanding principal balance. As of December 31, 2018, we have net debt of \$66,000.

On August 18, 2017, we entered into a securities purchase agreement with Power Up Lending Group Ltd., providing for the purchase by Power Up of a convertible note in the aggregate principal amount of \$53,000. The note bears an interest rate of 12%, and is due and payable on May 19, 2018. The note may be converted by Power Up at any time after 180 days from issuance into shares of Company's common stock at a conversion price equal to 58% of the average of the lowest two-day trading prices of the common stock during the 15 trading days prior to conversion. The note may be prepaid in accordance with its terms, at premiums ranging from 15% to 40%, depending on the time of prepayment. The note contains certain representations, warranties, covenants and events of default, including if we are delinquent in its periodic report filings with the SEC, and provides for increases in principal and interest in the event of such defaults. As of December 31, 2018, we have a net debt of \$46,405, including unamortized debt issuance costs of \$6,595.

On October 12, 2017, we entered into a securities purchase agreement with Power Up Lending Group Ltd. ("Power Up"), providing for the purchase by Power Up of a convertible note in the aggregate principal amount of \$53,000. The note bears an interest rate of 12%, and is due and payable on July 20, 2018. The note may be converted by Power Up at any time after 180 days from issuance into shares of Company's common stock at a conversion price equal to 58% of the average of the lowest two-day trading prices of the common stock during the 15 trading days prior to conversion. The note may be prepaid in accordance with its terms, at premiums ranging from 15% to 40%, depending on the time of prepayment. The note contains certain representations, warranties, covenants and events of default, including if we are delinquent in its periodic report filings with the SEC, and provides for increases in principal and interest in the event of such defaults. As of December 31, 2018, we have a net debt of \$47,288, including unamortized debt issuance costs of \$5,722.

On December 11, 2017, we entered into a securities purchase agreement with Power Up Lending Group Ltd. ("Power Up"), providing for the purchase by Power Up of a convertible note in the aggregate principal amount of \$53,000. The note bears an interest rate of 12%, and is due and payable on September 20, 2018. The note may be converted by Power Up at any time after 180 days from issuance into shares of Company's common stock at a conversion price equal to 58% of the average of the lowest two-day trading prices of the common stock during the 15 trading days prior to conversion. The note may be prepaid in accordance with its terms, at premiums ranging from 15% to 40%, depending on the time of prepayment. The note contains certain representations, warranties, covenants and events of default, including if we are delinquent in its periodic report filings with the SEC, and provides for increases in principal and interest in the event of such defaults. As of December 31, 2018, we have a net debt of \$45,565, including unamortized debt issuance costs of \$7,435.

On August 7, 2017, we entered into a forbearance agreement with GPB, with regard to the senior secured convertible note. Under the forbearance agreement, GPB has agreed to forbear from exercising certain of its rights and remedies (but not waive such rights and remedies), arising as a result of our failure to pay the monthly interest due and owing on the note. In consideration for the forbearance, we agreed to waive, release, and discharge GPB from all claims against GPB based on facts existing on or before the date of the forbearance agreement in connection with the note, or the dealings between us and GPB, or our equity holders and GPB, in connection with the note. Pursuant to the forbearance agreement, we have reaffirmed our obligations under the note and related documents and executed a confession of judgment regarding the amount due under the note, which GPB may file upon any future event of default by us. During the forbearance period, we must continue to comply with all the terms, covenants, and provisions of the note and related documents.

The "Forbearance Period" shall mean the period beginning on the date hereof and ending on the earliest to occur of: (i) the date on which Lender delivers to Company a written notice terminating the Forbearance Period, which notice may be delivered at any time upon or after the occurrence of any Forbearance Default (as hereinafter defined), and (ii) the date Company repudiates or asserts any defense to any Obligation or other liability under or in respect of this Agreement or the Transaction Documents or applicable law, or makes or pursues any claim or cause of action against Lender; (the occurrence of any of the foregoing clauses (i) and (ii), a "Termination Event"). As used herein, the term "Forbearance Default" shall mean: (A) the occurrence of any Default or Event of Default other than the Specified Default; (B) the failure of Company to timely comply with any material term, condition, or covenant set forth in this Agreement; (C) the failure of any representation or warranty made by Company under or in connection with this Agreement to be true and complete in all material respects as of the date when made; or (D) Lender's reasonable belief that Company: (1) has ceased or is not actively pursuing mutually acceptable restructuring or foreclosure alternatives with Lender; or (2) is not negotiating such alternatives in good faith. Any Forbearance Default will not be effective until one (1) Business Day after receipt by Company of written notice from Lender of such Forbearance Default. Any effective Forbearance Default shall constitute an immediate Event of Default under the Transaction Documents.

2018 Items

On August 29, 2018, we issued a promissory note to an investor for \$150,000 in aggregate principal amount of a 6% promissory note for an aggregate purchase price of \$157,500 (representing a \$7,500 original issue discount). Pursuant to the promissory note the entire unpaid principal balance on the promissory note together with all accrued and unpaid interest and loan origination fees, if any, at the choice of the investor, shall be due and payable in full from the funds received by us from a financing of at least \$2,000,000, or at the option of the investor, to be included in our financing under the same terms as the new investors with the most favorable terms making a cash investment. If we do not complete a financing of at least \$2,000,000 within 90 days of the execution of this promissory note, any unpaid amounts shall be due in full to the investor and shall accrue interest at 12% (instead of 6%) per annum from the date thereof (90 days after execution), if not paid in full. In addition, the investor will be granted 1,500,000 warrants under this promissory note. The warrants shall be issued and vest upon the financing of at least \$2,000,000 and expire on the third anniversary of said financing. The warrant exercise price shall be set at the same price as for warrants granted to the investors with the most favorable terms as part of any \$2,000,000 or more financing or \$0.25, whichever is lower. The warrants shall have standard anti-dilution features to protect the holder from dilution due to down rounds of financing. As of December 31, 2018, we had not repaid the note and therefore the accrued interest rate increased to 12%.

On September 19, 2018, we issued a promissory note to an investor for \$50,000 in aggregate principal amount of a 6% promissory note for an aggregate purchase price of \$52,500 (representing a \$2,500 original issue discount). Pursuant to the promissory note the entire unpaid principal balance on the promissory note together with all accrued and unpaid interest and loan origination fees, if any, at the choice of the investor, shall be due and payable in full from the funds received from a financing of at least \$2,000,000, or at the option of the investor, to be included in the our financing under the same terms as the new investors with the most favorable terms making a cash investment. If we do not complete a financing of at least \$2,000,000 within 90 days of the execution of this promissory note, any unpaid amounts shall be due in full to the investor and shall accrue interest at 12% (instead of 6%) per annum from the date thereof (90 days after execution), if not paid in full. In addition, the investor will be granted 500,000 warrants under this promissory note. The warrants shall be issued and vest upon the financing of at least \$2,000,000 and expire on the third anniversary of said financing. The warrant exercise price shall be set at the same price as for warrants granted to the investors with the most favorable terms as part of any \$2,000,000 or more financing or \$0.25, whichever is lower. The warrants shall have standard anti-dilution features to protect the holder from dilution due to down rounds of financing. As of December 31, 2018, we had not repaid the note and therefore the accrued interest rate increased to 12%.

On July 20, 2018, we entered into an exchange agreement and promissory note with Dr. Cartwright. The agreements were entered into in order to extinguish and restructure current amounts owed to Dr. Cartwright. In the exchange agreement Dr. Cartwright, agreed to exchange outstanding amounts due to him for loans, interest, bonus, salary and vacation pay in the amount of \$1,621,499 for a \$319,204 promissory note. Pursuant to the exchange agreement the note will bear interest at 6%. In addition, Dr. Cartwright will receive 125 stock options, with 31 vesting immediately and the remaining vesting monthly over three years. As a result of the exchange agreement, we recorded a gain for extinguishment of debt of \$840,391 and a capital contribution of \$431,519. As of December 31, 2018, Dr. Cartwright's total undiscounted cash flow amount due was approximately \$349,590 including interest. The schedule below summarizes the detail of the outstanding amounts:

For Dr. Cartwright:

| | 2018 |
|---|-----------------|
| Salary | \$ 337 |
| Bonus | 675 |
| Vacation | - |
| Interest on compensation | 59 |
| Loans to Company | 528 |
| Interest on loans | 22 |
| Total outstanding | \$ 1,621 |
| Amount forgiven | 1,302 |
| Promissory note issued in exchange | 319 |

On July 24, 2018, we entered into an exchange agreement and promissory note with Dr. Faupel. The agreements were entered into in order to extinguish and restructure current amounts owed to Dr. Faupel. In the exchange agreement Dr. Faupel, agreed to exchange outstanding amounts due to him for loans, interest, bonus, salary and vacation pay in the amount of \$660,895 for \$207,111 promissory note. Pursuant to the exchange agreement the note will bear interest at 6%. In addition, Dr. Faupel will receive 94 stock options, with 31 vesting immediately and the remaining vesting monthly over three years. Dr. Faupel will also receive 560 options at \$200.00 or market price, whichever is less; contingent on shareholder vote and board approval. If the options are not granted, we shall owe Dr. Faupel \$113,000. As a result of the exchange agreement, we recorded a gain for extinguishment of debt of \$199,079 and a capital contribution of \$234,990. As of December 31, 2018, Dr. Faupel's total undiscounted cash flow amount due was approximately \$256,825 including interest. The schedule below summarizes the detail of the outstanding amounts:

For Dr. Faupel:

| | 2018 |
|---|---------------|
| Salary | \$ 134 |
| Bonus | 20 |
| Vacation | 95 |
| Interest on compensation | 67 |
| Loans to Company | 196 |
| Interest on loans | 149 |
| Total outstanding | \$ 661 |
| Amount forgiven | 454 |
| Promissory note issued in exchange | 207 |

On February 12, 2018, we entered into a securities purchase agreement with Adar Bays, LLC, providing for the purchase by Adar of three convertible redeemable notes in the aggregate principal amount of \$285,863, with the first note being in the amount of \$95,288, and the second and third note being in the same amount. The first note was fully funded on February 13, 2018, upon which we received \$75,000 of net proceeds (net of a 10% original issue discount). The notes bear an interest rate of 8% and were due and payable on October 12, 2018. The notes may be converted by Adar at any time after eight months from issuance into shares of our common stock (as determined in the notes) calculated at the time of conversion, except for the second note, which also requires full payment by Adar of the secured note it issued to us before conversions may be made. The conversion price of the notes will be equal to 60% of the lowest trading price of the common stock for the 20 prior trading days including the day upon which we receive a notice of conversion. The notes may be prepaid in accordance with the terms set forth in the notes. The notes also contain certain representations, warranties, covenants and events of default including if we are delinquent in our periodic report filings with the SEC and increases in the amount of the principal and interest rates under the notes in the event of such defaults. In the event of default, at Adar's option and in its sole discretion, Adar may consider the notes immediately due and payable. As of December 31, 2018, the note had been converted and no balance remained outstanding, as compared we had a net debt of \$69,761, including unamortized debt issuance costs of \$576, and unamortized discount of \$430 and accrued interest of \$3,617.

On February 22, 2018, we entered into a securities purchase agreement with Power Up, providing for the purchase by Power Up of a convertible note in the aggregate principal amount of \$53,000. The note bears an interest rate of 12% and is due and payable on November 30, 2018. The note may be converted by Power Up at any time after 180 days from issuance into shares of our common stock at a conversion price equal to 58% of the average of the lowest two-day trading prices of the common stock during the 15 trading days prior to conversion. The note may be prepaid in accordance with its terms, at premiums ranging from 15% to 40%, depending on the time of prepayment. The note contains certain representations, warranties, covenants and events of default, including if we are delinquent in its periodic report filings with the SEC, and provides for increases in principal and interest in the event of such defaults. As of December 31, the note had been converted and no balance remained outstanding.

On March 12, 2018, we entered into a securities purchase agreement with Eagle Equities, LLC, providing for the purchase by Eagle of a convertible redeemable note in the principal amount of \$66,667. The note was fully funded on March 14, 2018, upon which we received \$51,000 of net proceeds (net of a 10% original issue discount and other expenses). The note bears an interest rate of 8% and are due and payable on March 12, 2019. The note may be converted by Eagle at any time after twelve months from issuance into shares of our common stock (as determined in the notes) calculated at the time of conversion, except for the second note, which also requires full payment by Eagle of the secured note it issued to us before conversions may be made. The conversion price of the notes will be equal to 60% of the lowest trading price of the common stock for the 20 prior trading days including the day upon which we receive a notice of conversion. The notes may be prepaid in accordance with the terms set forth in the notes. The notes also contain certain representations, warranties, covenants and events of default including if we are delinquent in our periodic report filings with the SEC and increases in the amount of the principal and interest rates under the notes in the event of such defaults. In the event of default, at Eagle's option and in its sole discretion, Eagle may consider the notes immediately due and payable. As of December 31, 2018, the outstanding balance was \$3,312, including unamortized debt issuance costs of \$1,751, and unamortized discount of \$1,297 and accrued interest of \$177.

On March 20, 2018, we entered into a securities purchase agreement with Auctus Fund, LLC for the issuance and sale to Auctus of \$150,000 in aggregate principal amount of a 12% convertible promissory note. On March 20, 2018, we issued the note to Auctus. Pursuant to the purchase agreement, we also issued to Auctus a warrant exercisable to purchase an aggregate of 4,262 shares of the Company's common stock. The warrant is exercisable at any time, at an exercise price per share equal to \$1.82 (110% of the closing price of the common stock on the day prior to issuance), subject to certain customary adjustments and price-protection provisions contained in the warrant. The warrant has a five-year term. The note matures nine months from the date of issuance and accrues interest at a rate of 12% per year. We could have prepaid the note, in whole or in part, for 115% of outstanding principal and interest until 30 days from issuance, for 125% of outstanding principal and interest at any time from 31 to 60 days from issuance, and for 130% of outstanding principal and interest at any time from 61 days from issuance to 180 days from issuance. After nine months from the date of issuance, Auctus may convert the note, at any time, in whole or in part, into shares of the our common stock, at a conversion price equal to the lower of the price offered in the our next public offering or a 40% discount to the average of the two lowest trading prices of the common stock during the 20 trading days prior to the conversion, subject to certain customary adjustments and price-protection provisions contained in the note. The note includes customary events of default provisions and a default interest rate of 24% per year. Upon the occurrence of an event of default, Auctus may require us to redeem the note (or convert it into shares of common stock) at 150% of the outstanding principal balance plus accrued and unpaid interest. As of December 31, 2018, we had a net debt of \$133,870 and accrued interest of \$635.

On March 30, 2018, we entered into a securities purchase agreement with GHS Investments, LLC, an existing investor, providing for the purchase by GHS of a convertible promissory note in the aggregate principal amount of \$15,000. The note matures on November 30, 2018. The note accrues interest at a rate of 10% per year. The note includes customary event of default provisions and a default interest rate of the lesser of 20% per year or the maximum amount permitted by law. Upon the occurrence of an event of default, the holder of the note may require us to redeem the note. As of December 31, 2018, we had a net debt of \$15,000 and accrued interest of \$1,262.

On April 30, 2018, we entered into a securities purchase agreement with Power Up, providing for the purchase by Power Up of a convertible note in the aggregate principal amount of \$103,000. The note bears an interest rate of 12% and is due and payable on February 15, 2019. The note may be converted by Power Up at any time after 180 days from issuance into shares of our common stock at a conversion price equal to 58% of the average of the lowest two-day trading prices of the common stock during the 15 trading days prior to conversion. The note may be prepaid in accordance with its terms, at premiums ranging from 15% to 40%, depending on the time of prepayment. The note contains certain representations, warranties, covenants and events of default, including if we are delinquent in its periodic report filings with the SEC, and provides for increases in principal and interest in the event of such defaults. As of December 31, the note had been converted and no balance remained outstanding.

On May 17, 2018, we entered into a securities purchase agreement with GHS Investments, LLC, an existing investor, providing for the purchase by GHS of a convertible promissory note in the aggregate principal amount of \$9,250 (with \$750 representing a 10% original issue discount and \$1,000 for transaction costs). The note matures on June 17, 2019. In addition to the 10% original issue discount, the note accrues interest at a rate of 10% per year. We may prepay the note, in whole or in part, for 110% of outstanding principal and interest until 30 days from issuance, for 120% of outstanding principal and interest at any time from 31 to 60 days from issuance and for 140% of outstanding principal and interest at any time from 61 days to 180 days from issuance. The note may not be prepaid after 180 days. After nine months from the date of issuance, the note will become convertible, at any time thereafter, in whole or in part, at the holder's option, into shares of our common stock, at a conversion price equal to 30% of the lowest trading price during the 25 trading days prior to conversion (if note cannot be converted due to issues with DTC then rate increases to 40%). The note includes customary event of default provisions and a default interest rate of the lesser of 20% per year or the maximum amount permitted by law. Upon the occurrence of an event of default, the holder of the note may require us to redeem the note (or convert it into shares of common stock) at 150% of the outstanding principal balance. As of December 31, 2018, we had a net debt of \$14,187 (which includes \$4,937 for a default penalty), including unamortized debt issuance costs of \$424, unamortized discount of \$318 and accrued interest of \$1,135.

On June 7, 2018, we entered into a securities purchase agreement with Power Up, providing for the purchase by Power Up of a convertible note in the aggregate principal amount of \$53,000. The note bears an interest rate of 12% and is due and payable on March 30, 2019. The note may be converted by Power Up at any time after 180 days from issuance into shares of our common stock at a conversion price equal to 58% of the average of the lowest two-day trading prices of the common stock during the 15 trading days prior to conversion. The note may be prepaid in accordance with its terms, at premiums ranging from 15% to 40%, depending on the time of prepayment. The note contains certain representations, warranties, covenants and events of default, including if we are delinquent in its periodic report filings with the SEC, and provides for increases in principal and interest in the event of such defaults. As of December 31, 2018, the note had been fully converted.

On June 22, 2018, we entered into a securities purchase agreement with GHS Investments, LLC, an existing investor, providing for the purchase by GHS of a convertible promissory note in the aggregate principal amount of \$68,000 (with \$6,000 representing a 10% original issue discount and \$2,000 for transaction costs). The note matures on June 22, 2019. In addition to the 10% original issue discount, the note accrues interest at a rate of 10% per year. We may prepay the note, in whole or in part, for 110% of outstanding principal and interest until 30 days from issuance, for 120% of outstanding principal and interest at any time from 31 to 60 days from issuance and for 140% of outstanding principal and interest at any time from 61 days to 180 days from issuance. The note may not be prepaid after 180 days. After nine months from the date of issuance, the note will become convertible, at any time thereafter, in whole or in part, at the holder's option, into shares of our common stock, at a conversion price equal to 30% of the lowest trading price during the 25 trading days prior to conversion (if note cannot be converted due to issues with DTC then rate increases to 40%). The note includes customary event of default provisions and a default interest rate of the lesser of 20% per year or the maximum amount permitted by law. Upon the occurrence of an event of default, the holder of the note may require us to redeem the note (or convert it into shares of common stock) at 150% of the outstanding principal balance. As of December 31, 2018, we had a net debt of \$103,285 (which includes \$35,285 for a default penalty), including unamortized debt issuance costs of \$3,318, unamortized discount of \$2,844 and accrued interest of \$8,263.

On July 3, 2018, we entered into a securities purchase agreement with Auctus Fund, LLC for the issuance and sale to Auctus of \$89,250 in aggregate principal amount of a 12% convertible promissory note. On July 3, 2018, we issued the note to Auctus. The note matures on April 3, 2019 and accrues interest at a rate of 12% per year. We could have prepaid the note, in whole or in part, for 115% of outstanding principal and interest until 30 days from issuance, for 125% of outstanding principal and interest at any time from 31 to 60 days from issuance, and for 130% of outstanding principal and interest at any time from 61 days from issuance to 180 days from issuance. After nine months from the date of issuance, Auctus may convert the note, at any time, in whole or in part, into shares of the our common stock, at a conversion price equal to the lower of the price offered in the our next public offering or a 40% discount to the average of the two lowest trading prices of the common stock during the 20 trading days prior to the conversion, subject to certain customary adjustments and price-protection provisions contained in the note. The note includes customary events of default provisions and a default interest rate of 24% per year. Upon the occurrence of an event of default, Auctus may require us to redeem the note (or convert it into shares of common stock) at 150% of the outstanding principal balance plus accrued and unpaid interest. As of December 31, 2018, we had a net debt of \$81,528, including unamortized original issue discount of \$1,443, unamortized debt issuance costs of \$6,279 and accrued interest of \$5,385.

See “—Recent Developments” for information regarding capital-raising activities since December 31, 2018.

We will be required to raise additional funds through public or private financing, additional collaborative relationships or other arrangements, as soon as possible. We cannot be certain that our existing and available capital resources will be sufficient to satisfy our funding requirements through 2019. We are evaluating various options to further reduce our cash requirements to operate at a reduced rate, as well as options to raise additional funds, including loans.

Generally, substantial capital will be required to develop our products, including completing product testing and clinical trials, obtaining all required U.S. and foreign regulatory approvals and clearances, and commencing and scaling up manufacturing and marketing our products. Any failure to obtain capital would have a material adverse effect on our business, financial condition and results of operations. Based on discussions with our distributors, we expect to generate purchase orders for approximately \$2 million in LuViva devices and disposables in 2019 and expect those purchase orders to result in actual sales of \$1.5 million in 2019, representing what we view as current demand for our products. We cannot be assured that we will generate all or any of these additional purchase orders, or that existing orders will not be canceled by the distributors or that parts to build product will be available to meet demand, such that existing orders will result in actual sales. Because we have a short history of sales of our products, we cannot confidently predict future sales of our products beyond this time frame and cannot be assured of any particular amount of sales. Accordingly, we have not identified any particular trends with regard to sales of our products.

Our financial statements have been prepared and presented on a basis assuming we will continue as a going concern. The above factors raise substantial doubt about our ability to continue as a going concern, as more fully discussed in Note 1 to the consolidated financial statements contained herein and in the report of our independent registered public accounting firm accompanying our financial statements contained in our annual report on Form 10-K for the year ended December 31, 2018.

Off-Balance Sheet Arrangements

We have no material off-balance sheet arrangements, no special purpose entities, and no activities that include non-exchange-traded contracts accounted for at fair value.

Item 7A. Quantitative and Qualitative Disclosures about Market Risk.

Not applicable.



REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of
Guided Therapeutics, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Guided Therapeutics, Inc., Inc. (the "Company") as of December 31, 2018 and 2017, and the related consolidated statements of operations, stockholders' deficit, and cash flows for the years then ended, and the related notes (collectively, the "financial statements"). In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2018 and 2017, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Substantial Doubt about the Company's Ability to Continue as a Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note (1) to the consolidated financial statements, the Company has recurring losses from operations, limited cash flow, and an accumulated deficit. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note (1).

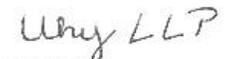
Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risk of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

We have served as the Company's auditor since 2007.


UHY LLP
Sterling Heights, Michigan
May 8, 2019

GUIDED THERAPEUTICS, INC. AND SUBSIDIARY
CONDENSED CONSOLIDATED BALANCE SHEETS (in thousands)
AS OF DECEMBER 31,

| ASSETS | 2018 | 2017 |
|---|------------------------|------------------------|
| CURRENT ASSETS: | | |
| Cash and cash equivalents | \$ - | \$ 1 |
| Accounts receivable, net of allowance for doubtful accounts of \$157 and \$160 at December 31, 2018 and 2017, respectively | 13 | 3 |
| Inventory, net of reserves of \$767 and \$716 at December 31, 2018 and 2017, respectively | 114 | 182 |
| Other current assets | 69 | 111 |
| Total current assets | <u>196</u> | <u>297</u> |
| Property and equipment, net | 21 | 49 |
| Other assets | 19 | 60 |
| Total noncurrent assets | <u>40</u> | <u>109</u> |
| TOTAL ASSETS | <u><u>236</u></u> | <u><u>406</u></u> |
| LIABILITIES AND STOCKHOLDERS' DEFICIT | | |
| CURRENT LIABILITIES: | | |
| Notes payable in default, including related parties | 700 | 1,091 |
| Short-term notes payable, including related parties | 899 | 447 |
| Convertible notes in default | 2,778 | 2,321 |
| Convertible notes payable, net | 380 | 783 |
| Accounts payable | 3,013 | 3,019 |
| Accrued liabilities | 3,156 | 4,164 |
| Customer deposits | 66 | 21 |
| Total current liabilities | <u>10,992</u> | <u>11,846</u> |
| Warrants, at fair value | 4,728 | 7,962 |
| Long-term debt-related parties | 340 | - |
| Total long-term debt | <u>5,068</u> | <u>7,962</u> |
| TOTAL LIABILITIES | <u><u>16,060</u></u> | <u><u>19,808</u></u> |
| COMMITMENTS & CONTINGENCIES (Note 8) | | |
| STOCKHOLDERS' DEFICIT: | | |
| Series C convertible preferred stock, \$.001 par value; 9.0 shares authorized, 0.3 and 0.9 shares issued and outstanding as of December 31, 2018 and 2017, respectively. (Liquidation preference of \$286 and \$970 at December 31, 2018 and 2017, respectively). | 105 | 355 |
| Series C1 convertible preferred stock, \$.001 par value; 20.3 shares authorized, 1.0 and 4.3 shares issued and outstanding as of December 31, 2018 and 2017, respectively. (Liquidation preference of \$1,049 and \$4,312 at December 31, 2018 and 2017, respectively). | 170 | 701 |
| Series C2 convertible preferred stock, \$.001 par value; 5,000 shares authorized, 3.3 and nil shares issued and outstanding as of December 31, 2018 and 2017, respectively. (Liquidation preference of \$3,263 and nil at December 31, 2018 and 2017, respectively). | 531 | - |
| Common stock, \$.001 par value; 1,000,000 shares authorized, 2,669 and 62 shares issued and outstanding as of December 31, 2018 and 2017, respectively | 2,877 | 791 |
| Additional paid-in capital | 118,259 | 117,416 |
| Treasury stock, at cost | (132) | (132) |
| Accumulated deficit | <u>(137,634)</u> | <u>(138,533)</u> |
| TOTAL STOCKHOLDERS' DEFICIT | <u><u>(15,824)</u></u> | <u><u>(19,402)</u></u> |
| TOTAL LIABILITIES AND STOCKHOLDERS' DEFICIT | <u><u>236</u></u> | <u><u>\$ 406</u></u> |

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

GUIDED THERAPEUTICS, INC. AND SUBSIDIARY
CONSOLIDATED STATEMENTS OF OPERATIONS (in thousands)
FOR THE YEARS ENDED DECEMBER 31,

| | 2018 | 2017 |
|--|------------------|--------------------|
| REVENUE: | | |
| Sales – devices and disposables, net | \$ 57 | \$ 244 |
| Cost of goods sold | 89 | 530 |
| Gross loss | <u>(32)</u> | <u>(286)</u> |
| OPERATING EXPENSES: | | |
| Research and development | 244 | 334 |
| Sales and marketing | 195 | 245 |
| General and administrative | 1,077 | 2,256 |
| Total operating expenses | <u>1,516</u> | <u>2,835</u> |
| Operating loss | <u>(1,548)</u> | <u>(3,121)</u> |
| OTHER INCOME (EXPENSES): | | |
| Other income | 54 | 18 |
| Interest expense | (1,763) | (1,106) |
| Gain from extinguishment of debt | 1,039 | - |
| Change in fair value of warrants | 3,234 | (6,487) |
| Total other income (expenses) | <u>2,564</u> | <u>(7,575)</u> |
| INCOME (LOSS) BEFORE INCOME TAXES | 1,016 | (10,696) |
| PROVISION FOR INCOME TAXES | - | - |
| NET INCOME (LOSS) | 1,016 | (10,696) |
| DEEMED DIVIDENDS | - | - |
| PREFERRED STOCK DIVIDENDS | (116) | (278) |
| NET INCOME (LOSS) ATTRIBUTABLE TO COMMON STOCKHOLDERS | \$ 900 | \$ (10,974) |
| NET INCOME (LOSS) PER SHARE ATTRIBUTABLE TO COMMON STOCKHOLDERS | | |
| BASIC | | |
| BASIC | <u>\$ 1.95</u> | <u>\$ 997.64</u> |
| DILUTED | <u>\$ 0.0138</u> | <u>\$ 997.64</u> |
| WEIGHTED AVERAGE SHARES OUTSTANDING | | |
| BASIC | <u>462</u> | <u>11</u> |
| DILUTED | <u>65,227</u> | <u>11</u> |

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

GUIDED THERAPEUTICS, INC. AND SUBSIDIARY
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' DEFICIT
FOR THE YEARS ENDED DECEMBER 31, 2018 AND 2017 (In Thousands)

| | Preferred Stock Series C | | Preferred Stock Series C1 | | Preferred Stock Series C2 | | Common Stock | | Additional Paid-In Capital | Treasury Stock | Accumulated Deficit | TOTAL |
|--|-----------------------------|---------------|------------------------------|---------------|------------------------------|---------------|--------------|-----------------|----------------------------------|-------------------|------------------------|--------------------|
| | Shares | Amount | Shares | Amount | Shares | Amount | Shares | Amount | | | | |
| BALANCE, January 1, 2017 | 2 | \$ 601 | 4 | \$ 701 | - | \$ - | 1 | \$ 742 | \$ 116,380 | \$ (132) | \$ (127,558) | \$ (9,266) |
| Preferred dividends | - | - | - | - | - | - | - | - | - | - | (2) | (2) |
| Conversion of Series C preferred stock to common stock | (1) | (246) | - | - | - | - | 22 | 17 | 506 | - | (277) | - |
| Conversion of debt into common stock | - | - | - | - | - | - | 39 | 32 | 436 | - | - | 468 |
| Issuance of common stock for note agreement | - | - | - | - | - | - | - | - | 35 | - | - | 35 |
| Stock-based compensation | - | - | - | - | - | - | - | - | 59 | - | - | 59 |
| Net loss | - | - | - | - | - | - | - | - | - | - | (10,696) | (10,696) |
| BALANCE, December 31, 2017 | 1 | \$ 355 | 4 | \$ 701 | - | \$ - | 62 | \$ 791 | \$ 117,416 | \$ (132) | \$ (138,533) | \$ (19,402) |
| Issuance of warrants with debt | - | - | - | - | - | - | - | - | 20 | - | - | 20 |
| Conversion of Series C preferred stock to common stock | (1) | (250) | - | - | - | - | 160 | 128 | 409 | - | (117) | 170 |
| Conversion of debt into common stock | - | - | - | - | - | - | 2,359 | 1,888 | (963) | - | - | 925 |
| Issuance of common stock | - | - | - | - | - | - | 88 | 70 | (23) | - | - | 47 |
| Exchange of Series C1 for C2 preferred stock | - | - | (3) | (531) | 3 | 531 | - | - | - | - | - | - |
| Beneficial conversion feature for convertible debt | - | - | - | - | - | - | - | - | 44 | - | - | 44 |
| Stock-based compensation | - | - | - | - | - | - | - | - | 689 | - | - | 689 |
| Forgiveness of debt | - | - | - | - | - | - | - | - | 667 | - | - | 667 |
| Net income | - | - | - | - | - | - | - | - | - | - | 1,016 | 1,016 |
| BALANCE, December 31, 2018 | - | \$ 105 | 1 | \$ 170 | 3 | \$ 531 | 2,669 | \$ 2,877 | \$ 118,259 | \$ (132) | \$ (137,634) | \$ (15,824) |

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

GUIDED THERAPEUTICS, INC. AND SUBSIDIARY
CONSOLIDATED STATEMENTS OF CASH FLOWS
FOR THE YEARS ENDED DECEMBER 31,
(In Thousands)

| | 2018 | 2017 |
|--|--------------------|--------------------|
| CASH FLOWS FROM OPERATING ACTIVITIES: | | |
| Net income (loss) | \$ 1,016 | \$ (10,696) |
| Adjustments to reconcile net income (loss) to net cash used in operating activities: | | |
| Bad debt expense | 1 | 174 |
| Depreciation | 27 | 213 |
| Amortization of debt issuance costs and discounts | 190 | - |
| Amortization of beneficial conversion feature | 645 | - |
| Stock based compensation | 44 | 59 |
| Change in fair value of warrants | (3,234) | 6,487 |
| Gain on extinguishment of debt | (1,039) | - |
| Changes in operating assets and liabilities: | | |
| Accounts receivable | (10) | (9) |
| Inventory | 151 | 508 |
| Other current assets | 42 | 152 |
| Other assets | 41 | 260 |
| Accounts payable | (6) | 420 |
| Deferred revenue | 45 | (13) |
| Accrued liabilities | 722 | 1,301 |
| Total adjustments | <u>(2,382)</u> | <u>9,552</u> |
| Net cash used in operating activities | <u>(1,365)</u> | <u>(1,144)</u> |
| CASH FLOWS FROM FINANCING ACTIVITIES: | | |
| Proceeds from debt financing, net of discounts and debt issuance costs | 1,386 | - |
| Payments made on notes and loans payable | (192) | (441) |
| Proceeds for future issuance of common stock | 126 | - |
| Net proceeds from issuance of common stock and warrants | <u>44</u> | <u>1,572</u> |
| Net cash provided by financing activities | <u>1,364</u> | <u>1,131</u> |
| NET CHANGE IN CASH AND CASH EQUIVALENTS | (1) | (13) |
| CASH AND CASH EQUIVALENTS, beginning of year | <u>1</u> | <u>14</u> |
| CASH AND CASH EQUIVALENTS, end of year | <u>\$ -</u> | <u>\$ 1</u> |
| SUPPLEMENTAL SCHEDULE OF: | | |
| Cash paid for: | | |
| Interest | <u>\$ 116</u> | <u>\$ 46</u> |
| NONCASH INVESTING AND FINANCING ACTIVITIES: | | |
| Issuance of common stock as debt repayment | <u>\$ 925</u> | <u>\$ 468</u> |
| Dividends on preferred stock | <u>\$ 116</u> | <u>\$ 278</u> |

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

GUIDED THERAPEUTICS, INC. AND SUBSIDIARY
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
DECEMBER 31, 2018 AND 2017

1. ORGANIZATION, BACKGROUND, AND BASIS OF PRESENTATION

Guided Therapeutics, Inc. (formerly SpectRx, Inc.), together with its wholly owned subsidiary, InterScan, Inc. (formerly Guided Therapeutics, Inc.), collectively referred to herein as the "Company", is a medical technology company focused on developing innovative medical devices that have the potential to improve healthcare. The Company's primary focus is the continued commercialization of its LuViva non-invasive cervical cancer detection device and extension of its cancer detection technology into other cancers, including esophageal. The Company's technology, including products in research and development, primarily relates to biophotonics technology for the non-invasive detection of cancers.

Basis of Presentation

All information and footnote disclosures included in the consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States.

A 1:800 reverse stock split of all of the Company's issued and outstanding common stock was implemented on March 29, 2019. As a result of the reverse stock split, every 800 shares of issued and outstanding common stock were converted into 1 share of common stock. All fractional shares created by the reverse stock split were rounded to the nearest whole share. The number of authorized shares of common stock did not change. The reverse stock split decreased the Company's issued and outstanding shares of common stock from 2,652,309,322 shares to 3,319,486 shares as of that date with rounding. See Note 4, Stockholders' Deficit. Unless otherwise specified, all per share amounts are reported on a post-stock split basis, as of December 31, 2018.

The Company's prospects must be considered in light of the substantial risks, expenses and difficulties encountered by entrants into the medical device industry. This industry is characterized by an increasing number of participants, intense competition and a high failure rate. The Company has experienced net losses since its inception and, as of December 31, 2018, it had an accumulated deficit of approximately \$137.6 million. To date, the Company has engaged primarily in research and development efforts and the early stages of marketing its products. The Company may not be successful in growing sales for its products. Moreover, required regulatory clearances or approvals may not be obtained in a timely manner, or at all. The Company's products may not ever gain market acceptance and the Company may not ever generate significant revenues or achieve profitability. The development and commercialization of the Company's products requires substantial development, regulatory, sales and marketing, manufacturing and other expenditures. The Company expects operating losses to continue for the foreseeable future as it continues to expend substantial resources to complete development of its products, obtain regulatory clearances or approvals, build its marketing, sales, manufacturing and finance capabilities, and conduct further research and development.

Certain prior year amounts have been reclassified in order to conform to the current year presentation.

Going Concern

The Company's consolidated financial statements have been prepared and presented on a basis assuming it will continue as a going concern. The factors below raise substantial doubt about the Company's ability to continue as a going concern. The financial statements do not include any adjustments that might be necessary from the outcome of this uncertainty.

At December 31, 2018, the Company had a negative working capital of approximately \$10.8 million, accumulated deficit of \$137.6 million, and incurred a net profit of \$1.0 million for the year then ended (the net profit for the year ended December 31, 2018 was primarily realized due to a \$3.2 million gain in the fair value of warrants recorded in 2018 and a \$1.0 million gain on the forgiveness of debt from officers). Stockholders' deficit totaled approximately \$15.8 million at December 31, 2018, primarily due to recurring net losses from operations, deemed dividends on warrants and preferred stock, offset by proceeds from the exercise of options and warrants and proceeds from sales of stock.

The Company's capital-raising efforts are ongoing and the Company has taken the following steps to increase the likelihood of a successful financing: 1) Debt has been significantly reduced and additional agreements are in place, contingent on a successful financing, to reduce debt even further either by forgiveness of debt and/or exchanges of debt for equity 2) Monthly operating expenses have been reduced by nearly 50% since the beginning of 2017 and 3) Variable rate loans for the most part have either been paid off or converted to equity. If sufficient capital cannot be raised during 2019, the Company will continue its plans of curtailing operations by reducing discretionary spending and staffing levels and attempting to operate by only pursuing activities for which it has external financial support. However, there can be no assurance that such external financial support will be sufficient to maintain even limited operations or that the Company will be able to raise additional funds on acceptable terms, or at all. In such a case, the Company might be required to enter into unfavorable agreements or, if that is not possible, be unable to continue operations, and to the extent practicable, liquidate and/or file for bankruptcy protection.

The Company had warrants exercisable for approximately 23.6 million shares of its common stock outstanding at December 31, 2018, with exercise prices ranging between \$0.06 and \$32.0 million per share. Exercises of these warrants would generate a total of approximately \$6.2 million in cash, assuming full exercise, although the Company cannot be assured that holders will exercise any warrants. Management may obtain additional funds through the public or private sale of debt or equity, and grants, if available. However, please refer to Footnote 11 - CONVERTIBLE DEBT IN DEFAULT in the paragraph: Debt Restructuring for more information regarding our warrants.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates. Significant areas where estimates are used include the allowance for doubtful accounts, inventory valuation and input variables for Black-Scholes, Monte Carlo simulations and binomial calculations. The Company uses the Monte Carlo simulations and binomial calculations in the calculation of the fair value of the warrant liabilities and the valuation of embedded conversion options and freestanding warrants.

Principles of Consolidation

The accompanying consolidated financial statements include the accounts of Guided Therapeutics, Inc. and its wholly owned subsidiary. All intercompany transactions are eliminated.

Accounting Standard Updates

Implemented

In May 2014, the Financial Accounting Standards Board ("FASB") issued ASU 2014-09, "Revenue from Contracts with Distributors (Topic 606)," ("ASU 2014-09"). ASU 2014-09 outlines a new, single comprehensive model for entities to use in accounting for revenue arising from contracts with distributors and supersedes most current revenue recognition guidance, including industry-specific guidance. This new revenue recognition model provides a five-step analysis in determining when and how revenue is recognized. The new model requires revenue recognition to depict the transfer of promised goods or services to distributors in an amount that reflects the consideration a company expects to receive. ASU 2014-09 also requires additional disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts, including significant judgments and changes in judgments and assets recognized from costs incurred to obtain or fulfill a contract. In August 2015, the FASB issued ASU 2015-14, "Deferral of the Effective Date", which amends ASU 2014-09. As a result, the effective date will be the first quarter of fiscal year 2018 with early adoption permitted in the first quarter of fiscal year 2017. Subsequently, the FASB has issued the following standards related to ASU 2014-09: ASU 2016-08, "Revenue from Contracts with Distributors (Topic 606), Principal versus Agent Considerations (Reporting Revenue Gross versus Net)," ("ASU 2016-08"); ASU 2016-10, "Revenue from Contracts with Distributors (Topic 606), Identifying Performance Obligations and Licensing," ("ASU 2016-10"); ASU 2016-12, "Revenue from Contracts with Distributors (Topic 606) Narrow-Scope Improvements and Practical Expedients," ("ASU 2016-12"); and ASU 2016-20, "Technical Corrections and Improvements to Topic 606, Revenue from Contracts with Distributors," ("ASU 2016-20"), which are intended to provide additional guidance and clarity to ASU 2014-09. The Company must adopt ASU 2016-08, ASU 2016-10, ASU 2016-12 and ASU 2016-20 along with ASU 2014-09 (collectively, the "New Revenue Standards"). The New Revenue Standards may be applied using one of two retrospective application methods: (1) a full retrospective approach for all periods presented, or (2) a modified retrospective approach that presents a cumulative effect as of the adoption date and additional required disclosures. The Company has evaluated the adoption of this guidance and has taken a modified retrospective approach to the presentation of revenue from contracts with distributors. The Company adopted this standard on January 1, 2018, using the modified retrospective method, with no impact on its 2018 financial statements. The cumulative effect of initially applying the new guidance had no impact on its financial statements in future periods.

In July 2015, the FASB issued ASU 2015-11, "Simplifying the Measurement of Inventory," ("ASU 2015-11"). ASU 2015-11 requires inventory be measured at the lower of cost and net realizable value and options that currently exist for market value be eliminated. ASU 2015-11 defines net realizable value as estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation. The guidance is effective for reporting periods beginning after December 15, 2016 and interim periods within those fiscal years with early adoption permitted. ASU 2015-11 should be applied prospectively. The Company has adopted this guidance during the year ended December 31, 2017 on a prospective basis. The adoption of this guidance did not have a significant impact on the operating results for the period ended December 31, 2017.

In August 2016, the FASB issued ASU 2016-15, "Statement of Cash Flows (Topic 230), Classification of Certain Cash Receipts and Cash Payments," ("ASU 2016-15"). ASU 2016-15 reduces the existing diversity in practice in financial reporting by clarifying existing principles in ASC 230, "Statement of Cash Flows," and provides specific guidance on certain cash flow classification issues. The effective date for ASU 2016-15 will be the first quarter of fiscal year 2018, with early adoption permitted. The Company adopted this guidance during the quarter ended March 31, 2018 on a prospective basis. The adoption of this guidance did not have a significant impact on the operating results for the year ended December 31, 2018.

In November 2016, the FASB issued ASU 2016-18, "Statement of Cash Flows (Topic 230) - Restricted Cash," ("ASU 2016-18"). ASU 2016-18 requires a statement of cash flows to explain the change during the period in the total of cash, cash equivalents, and amounts generally described as restricted cash or restricted cash equivalents. Amounts generally described as restricted cash and restricted cash equivalents should be included with cash and cash equivalents when reconciling the beginning-of-year and end-of-year total amounts shown on the statement of cash flows. The guidance is effective for annual periods, and interim periods within those annual periods beginning after December 15, 2017, with early adoption permitted. The Company adopted this guidance during the quarter ended March 31, 2018 on a prospective basis. The adoption of this guidance did not have a significant impact on the operating results for the year ended December 31, 2018.

In May 2017, the FASB issued ASU 2017-09, "Compensation – Stock Compensation (Topic 718), Scope of Modification Accounting" ("ASU 2017-09") which clarifies when changes to the terms or conditions of a share-based payment award must be accounted for as modifications. The new guidance will reduce diversity in practice and result in fewer changes to the terms of an award being accounted for as modifications. ASU 2017-09 will be applied prospectively to awards modified on or after the adoption date. The guidance is effective for annual periods, and interim periods within those annual periods beginning after December 15, 2017, with early adoption permitted. The Company adopted this guidance during the quarter ended March 31, 2018 on a prospective basis. The adoption of this guidance did not have a significant impact on the operating results for the year ended December 31, 2018.

In March 2018, the FASB issued ASU 2018-04, *Investments – Debt Securities (Topic 320) and Regulated Operations (Topic 980): Amendments to SEC Paragraphs Pursuant to SEC Staff Accounting Bulletin No. 117 and SEC Release No. 33-9273*. The amendment of ASU 2018-04 adds, amends and supersedes various paragraphs that contain SEC guidance in ASC 320, *Investments-Debt Securities* and ASC 980, *Regulated Operations*. The amendments in this update were effective upon issuance in March 2018. The adoption of this new standard did not have a material impact on the Company's consolidated financial statements.

In March 2018, the FASB issued ASU 2018-05, *Income Taxes (Topic 740): Amendments to SEC Paragraphs Pursuant to SEC Staff Accounting Bulletin No. 118*. The amendment of ASU 2018-05 adds various paragraphs that contain SEC guidance in ASC 740, *Income Taxes* and SEC Staff Accounting Bulletin No. 118. The amendments in this update were effective upon issuance in March 2018. The adoption of this new standard did not have a material impact on its consolidated financial statements.

In June 2018, the FASB issued ASU 2018-07, *Compensation – Stock Compensation (Topic 718), Improvements to Nonemployee Share-Based Payment Accounting*, which is intended to improve the usefulness of the information provided to the users of financial statements while reducing cost and complexity in financial reporting. Under the new standard, nonemployee share-based payment awards within the scope of Topic 718 are measured at grant-date fair value of the equity instruments that an entity is obligated to issue when conditions necessary to earn the right to benefit from the instruments have been satisfied. These equity-classified non-employee share-based payment awards are measured at the grant date. Consistent with the accounting for employee share-based payment awards, an entity considers the probability of satisfying performance conditions when nonemployee share-based payment awards contain such conditions. The new standard also eliminates the requirement to reassess classification of such awards upon vesting. The new standard is effective for annual periods, and interim periods within those annual periods, beginning after December 15, 2018. Early adoption is permitted, but no earlier than an entity's adoption date of Topic 606. The Company early adopted ASU 2018-07 effective January 1, 2018. The adoption of this new standard did not have a material impact on its consolidated financial statements.

In July 2018, FASB issued ASU 2018-09, “Codification Improvements.” This guidance affects a wide variety of topics in the codification and represents changes to clarify, correct errors in, or make minor improvements to the codification. The amendments make the codification easier to understand and easier to apply by eliminating inconsistencies and providing clarifications. The amendments apply to all reporting entities within the scope of the affected accounting guidance. Some of the amendments in ASU 2018-09 do not require transition guidance and will be effective upon issuance. However, many of the amendments do have transition guidance with effective dates for annual periods beginning after December 15, 2018, for public business entities. Adoption of this guidance did not have a significant impact on the Company’s consolidated financial statements.

Not Implemented

In February 2016, the FASB issued ASU 2016-02, “Leases (Topic 842)” that requires lessees to recognize on the balance sheet the assets and liabilities associated with the rights and obligations created by those leases. Under the new guidance, a lessee will be required to recognize assets and liabilities for leases with lease terms of more than 12 months. Consistent with current U.S. GAAP, the recognition, measurement, and presentation of expenses and cash flows arising from a lease by a lessee primarily will depend on its classification as finance or operating lease. The update is effective for reporting periods beginning after December 15, 2018. Adoption is not expected to have a material effect on the Company’s consolidated financial statements.

In June 2016, the FASB issued ASU 2016-13, “Financial Instruments - Credit Losses,” (“ASU 2016-13”). ASU 2016-13 sets forth a “current expected credit loss” model which requires the Company to measure all expected credit losses for financial instruments held at the reporting date based on historical experience, current conditions and reasonable supportable forecasts. The guidance in this new standard replaces the existing incurred loss model and is applicable to the measurement of credit losses on financial assets measured at amortized cost and applies to some off-balance sheet credit exposures. The effective date will be the first quarter of fiscal year 2020. The Company is evaluating the impact that adoption of this new standard will have on its consolidated financial statements.

In January 2017, the FASB issued ASU 2017-04, “Intangibles - Goodwill and Other (Topic 350): Simplifying the Test for Goodwill Impairment,” (“ASU 2017-04”). ASU 2017-04 eliminates Step 2 from the goodwill impairment test. Instead, an entity should perform its annual, or interim, goodwill impairment test by comparing the fair value of a reporting unit with its carrying amount. An entity should recognize an impairment charge for the amount by which the carrying amount exceeds the reporting unit’s fair value, if any. The loss recognized should not exceed the total amount of goodwill allocated to that reporting unit. Additionally, an entity should consider income tax effects from any tax-deductible goodwill on the carrying amount of the reporting unit when measuring the goodwill impairment. The effective date will be the first quarter of fiscal year 2020, with early adoption permitted in 2017. Adoption is not expected to have a material effect on the Company’s consolidated financial statements.

In February 2018, the FASB issued ASU 2018-02, *Income Statement – Reporting Comprehensive Income (Topic 220): Reclassification of Certain Tax Effects from Accumulated Other Comprehensive Income*. The amendment of ASU 2018-02 states an entity may elect to reclassify the income tax effects of the Tax Cuts and Jobs Act of 2017 (the “Tax Cuts and Jobs Act”) on items within accumulated other comprehensive income to retained earnings. The amendments in this update are effective for annual periods, and interim periods within those annual periods, beginning after December 15, 2018. Early adoption is permitted. Adoption is not expected to have a material effect on the Company’s consolidated financial statements.

In August 2018, the FASB issued ASU 2018-13, *Fair Value Measurement (Topic 820)*. The new standard modifies the disclosure requirements on fair value measurements in Topic 820, Fair Value Measurement, including removals of, modification to, and additional disclosure requirements from Topic 820. The amendment of ASU 2018-13 removes disclosure requirements from Topic 820 in the areas of (1) the amount of and reasons for transfers between Level 1 and Level 2 of the fair value hierarchy; (2) the policy for timing of transfers between levels, and (3) the valuation processes for Level 3 fair value measurements. The amendments in this update are effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019. Except for certain amendments related to Level 3 fair value measurements, all the other amendments should be applied retrospectively to all periods presented upon their effective date. Early adoption is permitted upon issuance of the ASU 2018-13. The Company believes that the adoption of this new standard will have no material impact on its consolidated financial position or results of operations and has not elected to early adopt the amendment.

In August 2018, the FASB issued ASU 2018-15, *Intangibles – Goodwill and Other – Internal-Use Software (Subtopic 350-40), Customer’s Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract* (or ASU 2018-15). ASU 2018-15 requires a customer that is a party to a cloud computing service contract to follow the internal-use software guidance in Subtopic 350-40 to determine which implementation costs to capitalize and which costs to expense. The amendments in this update are effective for annual reporting periods beginning after December 15, 2019, and interim periods within those fiscal years. Early adoption of the amendments in this update is permitted. The amendments in this update should be applied either retrospectively or prospectively to all implementation costs incurred after the date of adoption. The Company believes that the adoption of this new standard will have no material impact on its consolidated financial position or results of operations and has not elected to early adopt the amendment.

Except as noted above, the guidance issued by the FASB during the current year is not expected to have a material effect on the Company’s consolidated financial statements.

Cash Equivalents

The Company considers all highly liquid investments with an original maturity of three months or less when purchased to be a cash equivalent.

Accounts Receivable

The Company performs periodic credit evaluations of its distributors’ financial conditions and generally does not require collateral. The Company reviews all outstanding accounts receivable for collectability on a quarterly basis. An allowance for doubtful accounts is recorded for any amounts deemed uncollectable. The Company does not accrue interest receivable on past due accounts receivable.

Concentrations of Credit Risk

The Company, from time to time during the years covered by these consolidated financial statements, may have bank balances in excess of its insured limits. Management has deemed this a normal business risk.

The Company performs periodic credit evaluations of its distributors’ financial conditions and generally does not require collateral. The Company reviews all outstanding accounts receivable for collectability on a quarterly basis. An allowance for doubtful accounts is recorded for any amounts deemed uncollectable. The Company does not accrue interest receivable on past due accounts receivable.

Inventory Valuation

All inventories are stated at lower of cost or net realizable value, with cost determined substantially on a “first-in, first-out” basis. Selling, general, and administrative expenses are not inventoried, but are charged to expense when incurred. At December 31, 2018 and 2017, our inventories were as follows (in thousands):

| | Year Ended December 31, | |
|-------------------|-------------------------|--------|
| | 2018 | 2017 |
| Raw materials | \$ 783 | \$ 789 |
| Work in process | 81 | 82 |
| Finished goods | 17 | 27 |
| Inventory reserve | (767) | (716) |
| Total | \$ 114 | \$ 182 |

Property and Equipment

Property and equipment are recorded at cost. Depreciation is computed using the straight-line method over estimated useful lives of three to seven years. Leasehold improvements are amortized at the shorter of the useful life of the asset or the remaining lease term. Depreciation and amortization expense is included in general and administrative expense on the statement of operations. Expenditures for repairs and maintenance are expensed as incurred. Property and equipment are summarized as follows at December 31, 2018 and 2017 (in thousands):

| | Year Ended December 31, | |
|-------------------------------|-------------------------|--------------|
| | 2018 | 2017 |
| Equipment | \$ 1,378 | \$ 1,378 |
| Software | 740 | 740 |
| Furniture and fixtures | 124 | 124 |
| Leasehold Improvement | 199 | 199 |
| | 2,441 | 2,441 |
| Less accumulated depreciation | (2,420) | (2,392) |
| Total | \$ 21 | \$ 49 |

Debt Issuance Costs

Debt issuance costs are capitalized and amortized over the term of the associated debt. Debt issuance costs are presented in the balance sheet as a direct deduction from the carrying amount of the debt liability consistent with the debt discount.

Other Assets

Other assets primarily consist of short- and long-term deposits for various tooling inventory that are being constructed for the Company.

Patent Costs (Principally Legal Fees)

Costs incurred in filing, prosecuting, and maintaining patents are recurring, and expensed as incurred. Maintaining patents are expensed as incurred as the Company has not yet received U.S. FDA approval and recovery of these costs is uncertain. Such costs aggregated approximately \$11,000 and \$15,000 in 2018 and 2017, respectively.

Accrued Liabilities

Accrued liabilities are summarized as follows at December 31, 2018 and 2017 (in thousands):

| | Year Ended December 31, | |
|---------------------------------|-------------------------|-----------------|
| | 2018 | 2017 |
| Compensation | \$ 1,030 | \$ 2,122 |
| Professional fees | 203 | 223 |
| Interest | 892 | 511 |
| Warranty | 2 | 39 |
| Vacation | 53 | 152 |
| Preferred dividends | 120 | 291 |
| Stock subscription for licenses | 692 | 705 |
| Other accrued expenses | 164 | 121 |
| Total | \$ 3,156 | \$ 4,164 |

Revenue Recognition

The Company follows, ASC 606 Revenue from Contracts with Customers establishes a single and comprehensive framework which sets out how much revenue is to be recognized, and when. The core principle is that a vendor should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the vendor expects to be entitled in exchange for those goods or services. Revenue will now be recognized by a vendor when control over the goods or services is transferred to the customer. In contrast, Revenue based revenue recognition around an analysis of the transfer of risks and rewards; this now forms one of a number of criteria that are assessed in determining whether control has been transferred. The application of the core principle in ASC 606 is carried out in five steps: Step 1 – Identify the contract with a customer: a contract is defined as an agreement (including oral and implied), between two or more parties, that creates enforceable rights and obligations and sets out the criteria for each of those rights and obligations. The contract needs to have commercial substance and it is probable that the entity will collect the consideration to which it will be entitled. Step 2 – Identify the performance obligations in the contract: a performance obligation in a contract is a promise (including implicit) to transfer a good or service to the customer. Each performance obligation should be capable of being distinct and is separately identifiable in the contract. Step 3 – Determine the transaction price: transaction price is the amount of consideration that the entity can be entitled to, in exchange for transferring the promised goods and services to a customer, excluding amounts collected on behalf of third parties. Step 4 – Allocate the transaction price to the performance obligations in the contract: for a contract that has more than one performance obligation, the entity will allocate the transaction price to each performance obligation separately, in exchange for satisfying each performance obligation. The acceptable methods of allocating the transaction price include adjusted market assessment approach, expected cost plus a margin approach, and, the residual approach in limited circumstances. Discounts given should be allocated proportionately to all performance obligations unless certain criteria are met and reallocation of changes in standalone selling prices after inception is not permitted. Step 5 – Recognize revenue as and when the entity satisfies a performance obligation: the entity should recognize revenue at a point in time, except if it meets any of the three criteria, which will require recognition of revenue over time: the entity's performance creates or enhances an asset controlled by the customer, the customer simultaneously receives and consumes the benefit of the entity's performance as the entity performs, and the entity does not create an asset that has an alternative use to the entity and the entity has the right to be paid for performance to date.

Revenue by product line:

| | Year Ended December 31, | |
|--------------|-------------------------|---------------|
| | 2018 | 2017 |
| Devices | \$ 17 | \$ 177 |
| Disposables | 32 | 54 |
| Other | 1 | 3 |
| Warranty | 7 | 10 |
| Total | \$ 57 | \$ 244 |

Revenue by geographic location:

| | Year Ended December 31, | |
|---------------|-------------------------|---------------|
| | 2018 | 2017* |
| Asia | \$ 49 | \$ 288 |
| Africa | 8 | (15) |
| Europe | - | (14) |
| North America | - | (5) |
| South America | - | (10) |
| Total | \$ 57 | \$ 244 |

*During 2017, the Company had a buyback program on devices sold in prior years that totaled \$54,000.

Significant Distributors

In 2018 and 2017, the majority of the Company's revenues were from one and two distributors, respectively. Revenue from these distributors totaled approximately \$40,750 or 82% and approximately \$277,625 or 88% of gross revenue for the year ended December 31, 2018 and 2017, respectively. There were no amounts due from these distributors as of December 31, 2018 and 2017.

Deferred revenue

The Company defers payments received as revenue until earned based on the related contracts and applying ASC 606 as required. As of December 31, 2018, and 2017, the Company did not have deferred revenue, respectively.

Customer deposits

The Company follows the same principal as explained in Revenue Recognition and ASC 606. As of December 31, 2018, and 2017, the Company has received prepayments for devices and disposables and recorded this as customer deposits in the amount of \$66,000 and \$21,000, respectively.

Research and Development

Research and development expenses consist of expenditures for research conducted by the Company and payments made under contracts with consultants or other outside parties and costs associated with internal and contracted clinical trials. All research and development costs are expensed as incurred.

Income Taxes

The Company uses the liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are determined based on differences between the financial reporting and tax bases of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. Management provides valuation allowances against the deferred tax assets for amounts that are not considered more likely than not to be realized.

The Company is currently delinquent with its federal and applicable state tax return filings, payments and certain Federal and State Unemployment Tax filings. Some of the federal income tax returns are currently under examination by the U.S. Internal Revenue Service ("IRS"). The Company has entered into an agreed upon payment plan with the IRS for delinquent payroll taxes. The Company is currently in process of setting up a payment arrangement for its delinquent state income taxes with the State of Georgia and the returns are currently under review by state authorities. Although the Company has been experiencing recurring losses, it is obligated to file tax returns for compliance with IRS regulations and that of applicable state jurisdictions. At December 31, 2018 and 2017, the Company has approximately \$77.2 and \$82.9 million of net operating losses, respectively. This net operating loss will be eligible to be carried forward for tax purposes at federal and applicable states level. A full valuation allowance has been recorded related the deferred tax assets generated from the net operating losses.

Corporate tax rates in the U.S. have decreased from 34% to 21%.

Uncertain Tax Positions

The Company assesses each income tax position is assessed using a two-step process. A determination is first made as to whether it is more likely than not that the income tax position will be sustained, based upon technical merits, upon examination by the taxing authorities. If the income tax position is expected to meet the more likely than not criteria, the benefit recorded in the financial statements equals the largest amount that is greater than 50% likely to be realized upon its ultimate settlement. At December 31, 2018 and 2017 there were no uncertain tax positions.

Warrants

The Company has issued warrants, which allow the warrant holder to purchase one share of stock at a specified price for a specified period of time. The Company records equity instruments including warrants issued to non-employees based on the fair value at the date of issue. The fair value of warrants classified as equity instruments at the date of issuance is estimated using the Black-Scholes Model. The fair value of warrants classified as liabilities at the date of issuance is estimated using the Monte Carlo Simulation or Binomial model.

Stock Based Compensation

The Company records compensation expense related to options granted to non-employees based on the fair value of the award.

Compensation cost is recorded as earned for all unvested stock options outstanding at the beginning of the first year based upon the grant date fair value estimates, and for compensation cost for all share-based payments granted or modified subsequently based on fair value estimates.

For the years ended December 31, 2018 and 2017, share-based compensation for options attributable to employees, officers and Board members were approximately \$44,000 and \$59,000, respectively. These amounts have been included in the Company's statements of operations. Compensation costs for stock options which vest over time are recognized over the vesting period. As of December 31, 2018, the Company had approximately \$7,000 of unrecognized compensation costs related to granted stock options to be recognized over the remaining vesting period of approximately one year.

Beneficial Conversion Features of Convertible Securities

Conversion options that are not bifurcated as a derivative pursuant to ASC 815 and not accounted for as a separate equity component under the cash conversion guidance are evaluated to determine whether they are beneficial to the investor at inception (a beneficial conversion feature) or may become beneficial in the future due to potential adjustments. The beneficial conversion feature guidance in ASC 470-20 applies to convertible stock as well as convertible debt which are outside the scope of ASC 815. A beneficial conversion feature is defined as a nondetachable conversion feature that is in the money at the commitment date. The beneficial conversion feature guidance requires recognition of the conversion option's in-the-money portion, the intrinsic value of the option, in equity, with an offsetting reduction to the carrying amount of the instrument. The resulting discount is amortized as a dividend over either the life of the instrument, if a stated maturity date exists, or to the earliest conversion date, if there is no stated maturity date. If the earliest conversion date is immediately upon issuance, the dividend must be recognized at inception. When there is a subsequent change to the conversion ratio based on a future occurrence, the new conversion price may trigger the recognition of an additional beneficial conversion feature on occurrence.

Derivatives

The Company reviews the terms of convertible debt issued to determine whether there are embedded derivative instruments, including embedded conversion options, which are required to be bifurcated and accounted for separately as derivative financial instruments. In circumstances where the host instrument contains more than one embedded derivative instrument, including the conversion option, that is required to be bifurcated, the bifurcated derivative instruments are accounted for as a single, compound derivative instrument

Bifurcated embedded derivatives are initially recorded at fair value and are then revalued at each reporting date with changes in the fair value reported as non-operating income or expense. When the equity or convertible debt instruments contain embedded derivative instruments that are to be bifurcated and accounted for as liabilities, the total proceeds received are first allocated to the fair value of all the bifurcated derivative instruments. The remaining proceeds, if any, are then allocated to the host instruments themselves, usually resulting in those instruments being recorded at a discount from their face value. The discount from the face value of the convertible debt, together with the stated interest on the instrument, is amortized over the life of the instrument through periodic charges to interest expense.

3. FAIR VALUE OF FINANCIAL INSTRUMENTS

The guidance for fair value measurements, ASC820, Fair Value Measurements and Disclosures, establishes the authoritative definition of fair value, sets out a framework for measuring fair value, and outlines the required disclosures regarding fair value measurements. Fair value is the price that would be received to sell an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants at the measurement date. The Company uses a three-tier fair value hierarchy based upon observable and non-observable inputs as follow:

- Level 1 – Quoted market prices in active markets for identical assets and liabilities;
- Level 2 – Inputs, other than level 1 inputs, either directly or indirectly observable; and
- Level 3 – Unobservable inputs developed using internal estimates and assumptions (there is little or no market date) which reflect those that market participants would use.

The Company records its derivative activities at fair value, which consisted of warrants as of December 31, 2018. The fair value of the warrants was estimated using the Binomial Simulation model. Gains and losses from derivative contracts are included in net gain (loss) from derivative contracts in the statement of operations. The fair value of the Company's derivative warrants is classified as a Level 3 measurement, since unobservable inputs are used in the valuation.

The following table presents the fair value for those liabilities measured on a recurring basis as of December 31, 2018 and 2017:

FAIR VALUE MEASUREMENTS (In Thousands)

The following is summary of items that the Company measures at fair value on a recurring basis:

| | Fair Value at December 31, 2018 | | | Total |
|--|---------------------------------|-------------|-------------------|-------------------|
| | Level 1 | Level 2 | Level 3 | |
| Warrants issued in connection with Distributor Debt | - | - | (114) | (114) |
| Warrants issued in connection with Senior Secured Debt | - | - | (4,614) | (4,614) |
| Total long-term liabilities at fair value | <u>\$ -</u> | <u>\$ -</u> | <u>\$ (4,728)</u> | <u>\$ (4,728)</u> |

| | Fair Value at December 31, 2017 | | | Total |
|--|---------------------------------|-------------|-------------------|-------------------|
| | Level 1 | Level 2 | Level 3 | |
| Warrants issued in connection with Distributor Debt | - | - | (114) | (114) |
| Warrants issued in connection with Short-Term Loans | - | - | (11) | (114) |
| Warrants issued in connection with Senior Secured Debt | - | - | (7837) | (7,837) |
| Total long-term liabilities at fair value | <u>\$ -</u> | <u>\$ -</u> | <u>\$ (7,962)</u> | <u>\$ (7,962)</u> |

The following is a summary of changes to Level 3 instruments during the year ended December 31, 2018:

| | Fair Value Measurements Using Significant Unobservable Inputs (Level 3) | | | Total |
|--------------------------------------|---|---------------------|------------------|-------------------|
| | Short Term Loans | Senior Secured Debt | Distributor Debt | |
| Balance, December 31, 2017 | \$ (11) | \$ (7,837) | \$ (114) | \$ (7,962) |
| Warrants issued during the year | - | - | - | - |
| Change in fair value during the year | 11 | 3,223 | - | 3,234 |
| Balance, December 31, 2018 | <u>\$ -</u> | <u>\$ (4,614)</u> | <u>\$ (114)</u> | <u>\$ (4,728)</u> |

As of December 31, 2018, the fair value of warrants was approximately \$4.7 million. A net change of approximately \$3.2 million has been recorded to the accompanying statement of operations for the year ended.

4. STOCKHOLDER'S DEFICIT

Common Stock

The Company has authorized 1,000,000,000 shares of common stock with \$0.001 par value, of which 2,669,348 were issued and outstanding as of December 31, 2018. For the year ended December 31, 2017, there were 1,000,000,000 authorized shares of common stock, of which 61,954 were issued and outstanding.

For the year ended December 31, 2018, the Company issued 2,607,394 shares of common stock as listed below:

| | |
|--------------------------------------|-------------------------|
| Series C Preferred Stock Conversions | 107,974 |
| Series C Preferred Stock Dividends | 52,450 |
| Equity Financing Conversions | 87,500 |
| Convertible Debt Conversions | <u>2,359,470</u> |
| Total | <u>2,607,394</u> |
| Balance at December 31, 2017 | 61,954 |
| Issued in 2018 | <u>2,607,394</u> |
| Balance at December 31, 2018 | <u>2,669,348</u> |

On January 22, 2017, the Company entered into a license agreement with Shandong Yaohua Medical Instrument Corporation, or SMI, pursuant to which the Company granted SMI an exclusive global license to manufacture the LuViva device and related disposables (subject to a carve-out for manufacture in Turkey) and exclusive distribution rights in the Peoples Republic of China, Macau, Hong Kong and Taiwan. In exchange for the license, SMI will pay a \$1.0 million licensing fee, payable in five installments through November 2017, as well as a royalty on each disposable sold in the territories. As of December 31, 2018, SMI had paid \$750,000. SMI will also underwrite the cost of securing approval of LuViva with the Chinese Food and Drug Administration, or CFDA. Pursuant to the SMI agreement, SMI must become capable of manufacturing LuViva in accordance with ISO 13485 for medical devices by the second anniversary of the SMI agreement, or else forfeit the license. Based on the agreement, SMI must purchase no fewer than ten devices (with up to two devices pushed to 2018 if there is a delay in obtaining approval from the CFDA). SMI purchased five devices in 2017 and have not purchased any in 2018. In the three years following CFDA approval, SMI must purchase a minimum of 3,500 devices (500 in the first year, 1,000 in the second, and 2,000 in the third) or else forfeit the license. As manufacturer of the devices and disposables, SMI will be obligated to sell each to us at costs no higher than our current costs. As partial consideration for, and as a condition to, the license, and to further align the strategic interests of the parties, the Company agreed to issue \$1.0 million in shares of its common stock to SMI, in five installments through October 2017, at a price per share equal to the lesser of the average closing price for the five days prior to issuance and \$1.25. These shares have not been issued as of December 31, 2018.

In order to facilitate the SMI agreement, immediately prior to its execution the Company entered into an agreement with Shenghuo Medical, LLC, regarding its previous license to Shenghuo (see Note 7, Commitments and Contingencies). Under the terms of the new agreement, Shenghuo agreed to relinquish its manufacturing license and its distribution rights in SMI's territories, and to waive its rights under the original Shenghuo agreement, all for as long as SMI performs under the SMI agreement. As consideration, the Company agreed to split with Shenghuo the licensing fees and net royalties from SMI that the Company will receive under the SMI agreement. Should the SMI agreement be terminated, the Company have agreed to re-issue the original license to Shenghuo under the original terms. The Company's COO and director, Mark Faupel, is a shareholder of Shenghuo, and another director, Richard Blumberg, is a managing member of Shenghuo.

During 2018, the Company had exercised its rights under the \$10,000,000 GHS Equity Financing Agreement entered into on March 1, 2018, to exercise puts of \$47,320 for the issuance of 87,500 common stock shares. Pursuant to the agreement a put maybe executed for a price that is 80% of the "market price" which is the average of the two lowest volume weighted average prices of the Company's common stock for 15 consecutive trading days preceding the put date.

Preferred Stock

The Company has authorized 5,000,000 shares of preferred stock with a \$.001 par value. The board of directors has the authority to issue these shares and to set dividends, voting and conversion rights, redemption provisions, liquidation preferences, and other rights and restrictions. The board of directors designated 525,000 shares of preferred stock redeemable convertible preferred stock, none of which remain outstanding, 33,000 shares of preferred stock as Series B Preferred Stock, none of which remain outstanding, 9,000 shares of preferred stock as Series C Convertible Preferred Stock, (the "Series C1 Preferred Stock"), of which 286 and 970 were issued and outstanding at December 31, 2018 and 2017, respectively, and 20,250 shares of preferred stock as Series C1 Preferred Stock, of which 1,050 and 4,312 shares were issued and outstanding at December 31, 2018 and 2017, respectively.

On August 31, 2018, the Company entered into agreements with certain holders of the Company's Series C1 Preferred Stock, including the chairman of the Company's board of directors, and the Chief Operating Officer and a director of the Company (the "Exchange Agreements"), pursuant to which those holders separately agreed to exchange each share of the Series C1 Preferred Stock held for one (1) share of the Company's newly created Series C2 preferred stock, par value \$0.001 per share (the "Series C2 Preferred Stock"). In total, for 3,262.25 shares of Series C1 Preferred Stock to be surrendered, the Company issued 3,262.25 shares of Series C2 Preferred Stock.

Series C Convertible Preferred Stock

On June 29, 2015, the Company entered into a securities purchase agreement with certain accredited investors, including John Imhoff and Mark Faupel, members of the Board, for the issuance, exchange and sale of an aggregate of 6,737 shares of Series C convertible preferred stock, at a purchase price of \$750 per share and a stated value of \$1,000 per share. Additionally, during October 2015 the Company entered into an interim agreement amending the securities purchase agreement to provide for certain of the investors to purchase an additional aggregate of 1,166 shares. For a total of Series C convertible preferred stock issued of 7,903 shares. Of the 7,903 Series C convertible preferred stock issued, 1,835 were issued in exchange of Series B convertible preferred stock. Therefore 6,068 Series C preferred stock were issued at a purchase price of \$750 for gross proceeds of \$4,551,000. The Company received net cash proceeds of \$3,698,000, after cash and non-cash expenses of \$853,000.

Pursuant to the Series C certificate of designations, shares of Series C preferred stock are convertible into common stock by their holder at any time and may be mandatorily convertible upon the achievement of specified average trading prices for the Company's common stock. At December 31, 2018, there were 286 shares outstanding with a conversion price of \$2.099 per share, such that each share of Series C preferred stock would convert into approximately 476 shares of the Company's common stock, subject to customary adjustments, including for any accrued but unpaid dividends and pursuant to certain anti-dilution provisions, as set forth in the Series C certificate of designations. The conversion price will automatically adjust downward to 80% of the then-current market price of the Company's common stock 15 trading days after any reverse stock split of the Company's common stock, and 5 trading days after any conversions of the Company's outstanding convertible debt.

Holders of the Series C preferred stock are entitled to quarterly cumulative dividends at an annual rate of 12.0% until 42 months after the original issuance date (the "Dividend End Date"), payable in cash or, subject to certain conditions, the Company's common stock. In addition, upon conversion of the Series C preferred stock prior to the Dividend End Date, the Company will also pay to the converting holder a "make-whole payment" equal to the number of unpaid dividends through the Dividend End Date on the converted shares. At December 31, 2018, the "make-whole payment" for a converted share of Series C preferred stock would convert to 200 shares of the Company's common stock. The Series C preferred stock generally has no voting rights except as required by Delaware law. Upon the Company's liquidation or sale to or merger with another corporation, each share will be entitled to a liquidation preference of \$1,000, plus any accrued but unpaid dividends. In addition, the purchasers of the Series C preferred stock received, on a pro rata basis, warrants exercisable to purchase an aggregate of approximately 1 share of Company's common stock. The warrants contain anti-dilution adjustments in the event that the Company issues shares of common stock, or securities exercisable or convertible into shares of common stock, at prices below the exercise price of such warrants. As a result of the anti-dilution protection, the Company is required to account for the warrants as a liability recorded at fair value each reporting period. At December 31, 2018, the exercise price per share was \$512,000.

On May 23, 2016, an investor canceled certain of these warrants, exercisable into 903 shares of common stock. The same investor also transferred certain of these warrants, exercisable for 150 shares of common stock, to two investors who also had participated in the 2015 Series C financing.

Series C1 Convertible Preferred Stock

Between April 27, 2016 and May 3, 2016, the Company entered into various agreements with certain holders of Series C preferred stock, including directors John Imhoff and Mark Faupel, pursuant to which those holders separately agreed to exchange each share of Series C preferred stock held for 2.25 shares of the Company's newly created Series C1 Preferred Stock and 12 (9,600 pre-split) shares of the Company's common stock (the "Series C Exchanges"). In connection with the Series C Exchanges, each holder also agreed to roll over the \$1,000 stated value per share of the holder's shares of Series C1 Preferred Stock into the next qualifying financing undertaken by the Company on a dollar-for-dollar basis and, except in the event of an additional \$50,000 cash investment in the Company by the holder, to execute a customary "lockup" agreement in connection with the financing. In total, for 1,916 shares of Series C preferred stock surrendered, the Company issued 4,312 shares of Series C1 Preferred Stock and 29 shares of common stock. At December 31, 2018, there were 1,050 shares outstanding with a conversion price of \$2.099 per share, such that each share of Series C preferred stock would convert into approximately 381,098 shares of the Company's common stock.

On August 31, 2018, 3,262.25 shares of Series C1 Preferred Stock were surrendered, and the Company issued 3,262.25 shares of Series C2 Preferred Stock. At December 31, 2018, shares of Series C2 had a conversion price of \$2.099 per share, such that each share of Series C preferred stock would convert into approximately 476 shares of the Company's common stock.

The Series C1 preferred stock has terms that are substantially the same as the Series C preferred stock, except that the Series C1 preferred stock does not pay dividends (unless and to the extent declared on the common stock) or at-the-market "make-whole payments" and, while it has the same anti-dilution protections afforded the Series C preferred stock, it does not automatically reset in connection with a reverse stock split or conversion of our outstanding convertible debt.

Series C2 Convertible Preferred Stock

On August 31, 2018, the Company entered into agreements with certain holders of the Company's Series C1 Preferred Stock, including the chairman of the Company's board of directors, and the Chief Operating Officer and a director of the Company pursuant to which those holders separately agreed to exchange each share of the Series C1 Preferred Stock held for one (1) share of the Company's newly created Series C2 Preferred Stock. In total, for 3,262.25 shares of Series C1 Preferred Stock to be surrendered, the Company issued 3,262.25 shares of Series C2 Preferred Stock.

The terms of the Series C2 Preferred Stock are substantially the same as the Series C1 Preferred Stock, except that (i) shares of Series C1 Preferred Stock may not be convertible into the Company's common stock by their holder for a period of 180 days following the date of the filing of the Certificate of Designation (the "Lock-Up Period"); (ii) the Series C2 Preferred Stock has the right to vote as a single class with the Company's common stock on an as-converted basis, notwithstanding the Lock-Up Period; and (iii) the Series C2 Preferred Stock will automatically convert into that number of securities sold in the next Qualified Financing (as defined in the Exchange Agreement) determined by dividing the stated value (\$1,000 per share) of such share of Series C2 Preferred Stock by the purchase price of the securities sold in the Qualified Financing.

Warrants

The following table summarizes transactions involving the Company's outstanding warrants to purchase common stock for the year ended December 31, 2018:

| | Warrants (Underlying Shares) |
|--------------------------------|---|
| Outstanding, January 1, 2018 | 367,611 |
| Issuances | 23,184,246 |
| Exercised | - |
| Canceled / Expired | - |
| Outstanding, December 31, 2018 | <u>23,551,857</u> |

The Company had the following shares reserved for the warrants as of December 31, 2018:

| Warrants(Underlying Shares) | Exercise Price | Expiration Date |
|------------------------------------|---------------------------|------------------------|
| 13 (1) | \$60,000.00 per share | June 14, 2021 |
| 3 (2) | \$32,000,000.00 per share | April 23, 2019 |
| 7 (3) | \$28,800,000.00 per share | May 22, 2019 |
| 3 (4) | \$24,320,000.00 per share | September 10, 2019 |
| 1 (5) | \$29,491,840.00 per share | September 27, 2019 |
| 4 (6) | \$18,003,200.00 per share | December 2, 2019 |
| 2 (7) | \$5,760,000.00 per share | December 2, 2020 |
| 2 (8) | \$7,040,000.00 per share | December 2, 2020 |
| 1 (9) | \$7,603,200.00 per share | June 29, 2020 |
| 13 (9) | \$512,000.00 per share | September 21, 2020 |
| 24 (10) | \$512,000.00 per share | June 29, 2020 |
| 12 (11) | \$512,000.00 per share | September 4, 2020 |
| 1 (12) | \$7,603,200.00 per share | September 4, 2020 |
| 1 (13) | \$512,000.00 per share | October 23, 2020 |
| 1 (14) | \$7,603,200.00 per share | October 23, 2020 |
| 22,460,938 (15) | \$0.06 per share | June 14, 2021 |
| 1,078,125 (16) | \$0.06 per share | February 21, 2021 |
| 22 (17) | \$11,137.28 per share | June 6, 2021 |
| 250 (18) | \$1.82 per share | February 13, 2022 |
| 25 (19) | \$144.00 per share | May 16, 2022 |
| 688 (20) | \$15.20 per share | November 16, 2020 |
| 250 (21) | \$15.20 per share | December 28, 2020 |
| 75 (22) | \$16.08 per share | January 10, 2021 |
| 4,262 (23) | \$1.82 per share | March 19, 2021 |
| 1,875 (24) | \$16.08 per share | March 20, 2021 |
| 63 (25) | \$48.00 per share | April 30, 2021 |
| 125 (26) | \$48.00 per share | May 17, 2021 |
| 125 (27) | \$48.00 per share | May 25, 2021 |
| 500 (28) | \$48.00 per share | June 1, 2021 |
| 1,875 (29) | \$200.00 per share | August 22, 2021 |
| 625 (30) | \$200.00 per share | September 18, 2021 |
| 1,250 (31) | \$1.12 per share | October 23, 2021 |
| 19 (32) | \$0.64 per share | November 20, 2021 |
| 375 (33) | \$0.32 per share | December 5, 2021 |
| 100 (34) | \$0.16 per share | December 19, 2021 |
| 188 (35) | \$0.24 per share | December 23, 2021 |
| 14 (36) | \$0.24 per share | December 27, 2021 |
| 23,551,857* | | |

* However, please refer to *Footnote 11 - CONVERTIBLE DEBT IN DEFAULT* in the paragraph: Debt Restructuring for more information regarding our warrants.

- (1) Issued in June 2015 in exchange for warrants originally issued as part of a May 2013 private placement.
- (2) Issued to a placement agent in conjunction with an April 2014 private placement.
- (3) Issued to a placement agent in conjunction with a September 2014 private placement.
- (4) Issued as part of a September 2014 Regulation S offering.
- (5) Issued to a placement agent in conjunction with a 2014 public offering.
- (6) Issued in June 2015 in exchange for warrants originally issued as part of a 2014 public offering.
- (7) Issued as part of a March 2015 private placement.

- (8) Issued to a placement agent in conjunction with a June 2015 private placement.
- (9) Issued as part of a June 2015 private placement.
- (10) Issued as part of a June 2015 private placement.
- (11) Issued as part of a June 2015 private placement.
- (12) Issued to a placement agent in conjunction with a June 2015 private placement.
- (13) Issued as part of a June 2015 private placement.
- (14) Issued to a placement agent in conjunction with a June 2015 private placement.
- (15) Issued as part of a February 2016 private placement.
- (16) Issued to a placement agent in conjunction with a February 2016 private placement.
- (17) Issued pursuant to a strategic license agreement.
- (18) Issued as part of a February 2017 private placement.
- (19) Issued as part of a May 2017 private placement.
- (20) Issued to investors for a loan in November 2017.
- (21) Issued to investors for a loan in December 2017.
- (22) Issued to investors for a loan in January 2018.
- (23) Issued to investors for a loan in March 2018.
- (24) Issued to investors for a loan in March 2018.
- (25) Issued to investors for a loan in April 2018.
- (26) Issued to investors for a loan in May 2018.
- (27) Issued to investors for a loan in May 2018.
- (28) Issued to investors for a loan in June 2018
- (29) Issued to investors for a loan in August 2018
- (30) Issued to investors for a loan in September 2018
- (31) Issued to investors for a loan in October 2018
- (32) Issued to investors for a loan in November 2018
- (33) Issued to investors for a loan in December 2018
- (34) Issued to investors for a loan in December 2018
- (35) Issued to investors for a loan in December 2018
- (36) Issued to investors for a loan in December 2018

All outstanding warrant agreements provide for anti-dilution adjustments in the event of certain mergers, consolidations, reorganizations, recapitalizations, stock dividends, stock splits or other changes in the Company's corporate structure; except for (8). In addition, warrants subject to footnotes (1) and (9)-(11), (13), and (15) – (36) in the table above are subject to "lower price issuance" anti-dilution provisions that automatically reduce the exercise price of the warrants (and, in the cases of warrants subject to footnote (1), (15) and (16) in the table above, increase the number of shares of common stock issuable upon exercise), to the offering price in a subsequent issuance of the Company's common stock, unless such subsequent issuance is exempt under the terms of the warrants.

For the warrants to footnote (15), the Company further agreed to amend the warrant issued with the original senior secured convertible note, to adjust the number of shares issuable upon exercise of the warrant to equal the number of shares that will initially be issuable upon conversion of the new convertible note (without giving effect to any beneficial ownership limitations set forth in the terms of the new convertible note).

The warrants subject to footnote (1) are subject to a mandatory exercise provision. This provision permits the Company, subject to certain limitations, to require exercise of such warrants at any time following (a) the date that is the 30th day after the later of the Company's receipt of an approvable letter from the U.S. FDA for LuViva and the date on which the common stock achieves an average market price for 20 consecutive trading days of at least \$832,000.00 with an average daily trading volume during such 20 consecutive trading days of at least 250 shares, or (b) the date on which the average market price of the common stock for 20 consecutive trading days immediately prior to the date the Company delivers a notice demanding exercise is at least \$103,680,000.00 and the average daily trading volume of the common stock exceeds 250 shares for such 20 consecutive trading days. If these warrants are not timely exercised upon demand, they will expire. Upon the occurrence of certain events, the Company may be required to repurchase these warrants, as well as the warrants subject to footnote (1) in the table above. The holders of the warrants subject to footnote (1) in the table above have agreed to surrender the warrants, upon consummation of a qualified public financing, for new warrants exercisable for 200% of the number of shares underlying the surrendered warrants, but without certain anti-dilution protections included with the surrendered warrants.

The warrants subject to footnote (4) in the table above are also subject to a mandatory exercise provision. This provision permits the Company, subject to certain limitations; to require the exercise of such warrants should the average trading price of its common stock over any 30-consecutive day trading period exceed \$73,728.00.

The warrants subject to footnote (6) in the table above are also subject to a mandatory exercise provision. This provision permits the Company, subject to certain limitations, to require exercise of 50% of the then-outstanding warrants if the trading price of its common stock is at least two times the initial warrant exercise price for any 20-day trading period. Further, in the event that the trading price of the Company's common stock is at least 2.5 times the initial warrant exercise price for any 20-day trading period, the Company will have the right to require the immediate exercise of 50% of the then-outstanding warrants. Any warrants not exercised within the prescribed time periods will be canceled to the extent of the number of shares subject to mandatory exercise.

Series B Tranche B Warrants

As discussed in Note 3, Fair Value Measurements, between June 13, 2016 and June 14, 2016, the Company entered into various agreements with holders of the Company's "Series B Tranche B" warrants, pursuant to which each holder separately agreed to exchange the warrants for either (1) shares of common stock equal to 166% of the number of shares of common stock underlying the surrendered warrants, or (2) new warrants exercisable for 200% of the number of shares underlying the surrendered warrants, but without certain anti-dilution protections included with the surrendered warrants. In total, for surrendered warrants then-exercisable for an aggregate of 1,482 shares of common stock (but subject to exponential increase upon operation of certain anti-dilution provisions), the Company issued or is obligated to issue 21 shares of common stock and new warrants that, if exercised as of the date hereof, would be exercisable for an aggregate of 271 shares of common stock. As of December 31, 2018, the Company had issued 18 shares of common stock and rights to common stock shares for 3. In certain circumstances, in lieu of presently issuing all of the shares (for each holder that opted for shares of common stock), the Company and the holder further agreed that the Company will, subject to the terms and conditions set forth in the applicable warrant exchange agreement, from time to time, be obligated to issue the remaining shares to the holder. No additional consideration will be payable in connection with the issuance of the remaining shares. The holders that elected to receive shares for their surrendered warrants have agreed that they will not sell shares on any trading day in an amount, in the aggregate, exceeding 20% of the composite aggregate trading volume of the common stock for that trading day. The holders that elected to receive new warrants will be required to surrender their old warrants upon consummation of the Company's next financing resulting in net cash proceeds to the Company of at least \$1 million. The new warrants will have an initial exercise price equal to the exercise price of the surrendered warrants as of immediately prior to consummation of the financing, subject to customary "downside price protection" for as long as the Company's common stock is not listed on a national securities exchange and will expire five years from the date of issuance.

5. INCOME TAXES

The Company has incurred net operating losses ("NOLs") since inception. As of December 31, 2018, the company had NOL carryforwards available through 2037 of approximately \$77.2 million to offset its future income tax liability. The company has recorded deferred tax assets but reserved against, due to uncertainties related to utilization of NOLs as well as calculation of effective tax rate. Utilization of existing NOL carryforwards may be limited in future years based on significant ownership changes. The company is in the process of analyzing their NOL and has not determined if the company has had any change of control issues that could limit the future use of NOL. NOL carryforwards that were generated after 2017 may only be used to offset 80% of taxable income and are carried forward indefinitely. Components of deferred taxes are as follow at December 31 (in thousands):

| | 2018 | 2017 |
|----------------------------------|-----------------|-----------------|
| Deferred tax assets: | | |
| Warrant liability | \$ 1,182 | \$ 1,990 |
| Accrued executive compensation | 498 | 447 |
| Reserves and other | 488 | 301 |
| Net operating loss carryforwards | <u>19,297</u> | <u>20,726</u> |
| | 21,465 | 23,464 |
| Valuation allowance | <u>(21,465)</u> | <u>(23,464)</u> |
| Net deferred tax assets | <u>\$ 0</u> | <u>\$ 0</u> |

The following is a summary of the items that caused recorded income taxes to differ from taxes computed using the statutory federal income tax rate for the years ended December 31:

| | 2018 | 2017 |
|-------------------------------------|------|------|
| Statutory federal tax rate | 21% | 34% |
| State taxes, net of federal benefit | 4 | 4 |
| Nondeductible expenses | - | - |
| Valuation allowance | (25) | (38) |
| Effective tax rate | 0% | 0% |

On December 22, 2017, the U.S. government enacted comprehensive tax reform commonly referred to as the Tax Cuts and Jobs Act ("TCJA"). Under ASC 740, the effects of changes in tax rates and laws are recognized in the period which the new legislation is enacted. Among other things, the TCJA (1) reduces the U.S. statutory corporate income tax rate from 34% to 21% effective January 1, 2018 (2) eliminates the corporate alternative minimum tax (3) eliminates the Section 199 deduction (4) changes rules related to uses and limitations of net operating loss carryforwards beginning after December 31, 2018.

The Company applies the applicable authoritative guidance which prescribes a comprehensive model for the manner in which a company should recognize, measure, present and disclose in its financial statements all material uncertain tax positions that the Company has taken or expects to take on a tax return. As of December 31, 2018, the Company has no uncertain tax positions. There are no uncertain tax positions for which it is reasonably possible that the total amounts of unrecognized tax benefits will significantly increase or decrease within twelve months from December 31, 2018.

The Company files federal income tax returns and income tax returns in various state tax jurisdictions with varying statutes of limitations.

The provision for income taxes as of the dates indicated consisted of the following (in thousands) December 31:

| | 2018 | 2017 |
|---------------------------------------|------|----------|
| Current | \$ - | \$ - |
| Deferred | - | - |
| Deferred provision | - | - |
| Impact of change in enacted tax rates | - | 12,139 |
| Change in valuation allowance | - | (12,139) |
| Total provision for income taxes | \$ - | \$ - |

In 2018, our effective tax rate differed from the U.S. federal statutory rate due to the valuation allowance over our deferred tax assets.

In 2017, our effective tax rate differed from the U.S. federal statutory rate primarily due to re-measuring deferred income taxes at the new statutory tax rate and the related change of the valuation allowance over our deferred tax assets. At the date of enactment of the Tax Cuts and Jobs Act, we re-measured our deferred tax assets and liabilities using a rate of 21%, which is the rate expected to be in place when such deferred assets and liabilities are expected to reverse in the future. The re-measurement reduced our net deferred tax assets by \$12,139,043. The remeasurement was offset by a change in our valuation allowance, resulting in there being no impact on our deferred tax assets.

6. STOCK OPTIONS

The Company's 1995 Stock Plan (the "Plan") has expired pursuant to its terms, so zero shares remained available for issuance at December 31, 2018 and 2017. The Plan allowed for the issuance of incentive stock options, nonqualified stock options, and stock purchase rights. The exercise price of options was determined by the Company's board of directors, but incentive stock options were granted at an exercise price equal to the fair market value of the Company's common stock as of the grant date. Options historically granted have generally become exercisable over four years and expire ten years from the date of grant.

Due to the 1:800 reverse stock split of all of the Company's issued and outstanding common stock was implemented on March 29, 2019. As a result of the reverse stock split, every 800 shares of issued and outstanding common stock were converted into 1 share of common stock. This resulted in the number of stock options outstanding to be zero.

7. LITIGATION AND CLAIMS

From time to time, the Company may be involved in various legal proceedings and claims arising in the ordinary course of business. Management believes that the dispositions of these matters, individually or in the aggregate, are not expected to have a material adverse effect on the Company's financial condition. However, depending on the amount and timing of such disposition, an unfavorable resolution of some or all of these matters could materially affect the future results of operations or cash flows in a particular year.

As of December 31, 2018, and 2017, there was no accrual recorded for any potential losses related to pending litigation.

8. COMMITMENTS AND CONTINGENCIES

Operating Leases

In December 2009, the Company moved its offices, which comprise its administrative, research and development, marketing and production facilities to 5835 Peachtree Corners East, Suite B, Norcross, Georgia 30092. The Company leased approximately 23,000 square feet under a lease that expired in June 2017. In July 2017, the Company leased the offices on a month to month basis. On February 23, 2018, the Company modified its lease to reduce its occupancy to 12,835 square feet. The fixed monthly lease expense will be: \$13,859 each month for the period beginning January 1, 2018 and ending March 31, 2018; \$8,022 each month for the period beginning April 1, 2018 and ending March 31, 2019; \$8,268 each month for the period beginning April 1, 2019 and ending March 31, 2020; and \$8,514 each month for the period beginning April 1, 2020 and ending March 31, 2021. The Company recognizes rent expense on a straight-line basis over the estimated lease term. Future minimum rental payments at December 31, 2018 under non-cancellable operating leases for office space and equipment are as follows (in thousands):

| Year | Amount |
|------|--------|
| 2019 | 98 |
| 2020 | 101 |
| 2021 | 26 |

Related Party Contracts

On June 5, 2016, the Company entered into a license agreement with Shenghuo Medical, LLC pursuant to which the Company granted Shenghuo an exclusive license to manufacture, sell and distribute LuViva in Taiwan, Brunei Darussalam, Cambodia, Laos, Myanmar, Philippines, Singapore, Thailand, and Vietnam. Shenghuo was already the Company's exclusive distributor in China, Macau and Hong Kong, and the license extended to manufacturing in those countries as well. Under the terms of the license agreement, once Shenghuo was capable of manufacturing LuViva in accordance with ISO 13485 for medical devices, Shenghuo would pay the Company a royalty equal to \$2.00 or 20% of the distributor price (subject to a discount under certain circumstances), whichever is higher, per disposable distributed within Shenghuo's exclusive territories. In connection with the license grant, Shenghuo was to underwrite the cost of securing approval of LuViva with Chinese Food and Drug Administration. At its option, Shenghuo also would provide up to \$1.0 million in furtherance of the Company's efforts to secure regulatory approval for LuViva from the U.S. Food and Drug Administration, in exchange for the right to receive payments equal to 2% of the Company's future sales in the United States, up to an aggregate of \$4.0 million. Pursuant to the license agreement, Shenghuo had the option to have a designee appointed to the Company's board of directors (director Richard Blumberg is that designee). As partial consideration for, and as a condition to, the license, and to further align the strategic interests of the parties, the Company agreed to issue a convertible note to Shenghuo, in exchange for an aggregate cash investment of \$200,000. The note will provide for a payment to Shenghuo of \$300,000, expected to be due the earlier of 90 days from issuance and consummation of any capital raising transaction by the Company with net cash proceeds of at least \$1.0 million. The note will accrue interest at 20% per year on any unpaid amounts due after that date. The note will be convertible into shares of the Company's common stock at a conversion price per share of \$11,137, subject to customary anti-dilution adjustment. The note will be unsecured and is expected to provide for customary events of default. The Company will also issue Shenghuo a five-year warrant exercisable immediately for approximately 22 shares of common stock at an exercise price equal to the conversion price of the note, subject to customary anti-dilution adjustment. On January 22, 2017, the Company entered into a license agreement with Shandong Yaohua Medical Instrument Corporation, or SMI, pursuant to which the Company granted SMI an exclusive global license to manufacture the LuViva device and related disposables (subject to a carve-out for manufacture in Turkey) and exclusive distribution rights in the Peoples Republic of China, Macau, Hong Kong and Taiwan. In order to facilitate the SMI agreement, immediately prior to its execution the Company entered into an agreement with Shenghuo Medical, LLC, regarding its previous license to Shenghuo. Under the terms of the new agreement, Shenghuo agreed to relinquish its manufacturing license and its distribution rights in SMI's territories, and to waive its rights under the original Shenghuo agreement, all for as long as SMI performs under the SMI agreement.

On September 6, 2016, the Company entered into a royalty agreement with one of its directors, John Imhoff, and another stockholder, Dolores Maloof, pursuant to which the Company sold to them a royalty of future sales of single-use cervical guides for LuViva. Under the terms of the royalty agreement, and for consideration of \$50,000, the Company will pay them an aggregate perpetual royalty initially equal to \$0.10, and from and after October 2, 2016, equal to \$0.20, for each disposable that the Company sells (or that is sold by a third party pursuant to a licensing arrangement with the Company).

9. NOTES PAYABLE

As of December 31, 2018, there have been no principal or interest payments; however, Dr. Faupel and Dr. Cartwright did forgive debt. In the July 24, 2018 exchange agreement, Dr Faupel, agreed to exchange outstanding amounts due to him for loans, interest, bonus, salary and vacation pay in the amount of \$660,895 for a \$207,111 promissory note. In the July 20, 2018 exchange agreement, Dr, Cartwright, agreed to exchange outstanding amounts due to him for loans, interest, bonus, salary and vacation pay in the amount of \$1,621,499 for a \$319,204 promissory note. Debt due to officers has been allocated to short-term and long-term debt, of which \$266,286 and \$353,957 was allocated to short-term debt, for December 31, 2018 and 2017, respectively. At December 31, 2018, \$340,129 was allocated to long-term debt and nil for December 31, 2017. At December 31, 2018 the total undiscounted cash flow amount due was \$349,590 for Dr. Cartwright and \$256,825 for Dr. Faupel. The schedule below summarizes the detail of the outstanding amounts:

For Dr. Cartwright:

| | 2018 |
|---|-----------------|
| Salary | \$ 337 |
| Bonus | 675 |
| Vacation | - |
| Interest on compensation | 59 |
| Loans to Company | 528 |
| Interest on loans | 22 |
| Total outstanding | \$ 1,621 |
| Amount forgiven | 1,302 |
| Promissory note issued in exchange | 319 |
| Unpaid interest on promissory note | 10 |
| Allocated to short-term debt | 143 |
| Allocated to long-term debt | 206 |

For Dr. Faupel:

| | 2018 |
|---|---------------|
| Salary | \$ 134 |
| Bonus | 20 |
| Vacation | 95 |
| Interest on compensation | 67 |
| Loans to Company | 196 |
| Interest on loans | 149 |
| Total outstanding | \$ 661 |
| Amount forgiven | 454 |
| Promissory note issued in exchange | 207 |
| Unpaid interest on promissory note | 5 |
| Allocated to short-term debt | 123 |
| Allocated to long-term debt | 134 |

Notes Payable in Default

At December 31, 2018 and 2017, the Company maintained notes payable to both related and non-related parties totaling \$700,000 and \$1,091,000, respectively. These notes are short term, straight-line amortizing notes. The notes carry annual interest rates between 0% and 10% and have default rates as high as 20%. The Company is accruing interest at the default rate of 18.0% on two of the loans.

On March 30, 2018, the Company entered into a securities purchase agreement with GHS Investments, LLC, an existing investor, providing for the purchase by GHS of a promissory note in the aggregate principal amount of \$15,000. The note matured on November 30, 2018. The note accrues interest at a rate of 10% per year. The note includes customary event of default provisions and a default interest rate of the lesser of 20% per year or the maximum amount permitted by law. Upon the occurrence of an event of default, the holder of the note may require us to redeem the note. As of December 31, 2018, the Company has net debt of \$15,000 and accrued interest of \$1,262. In addition, at December 31, 2018, the Company recorded a \$6,429 beneficial conversion feature which was fully amortized at year end.

The following table summarizes the *Notes payable in default, including related parties* :

| | Year Ended December 31, | |
|--|-------------------------|-----------------|
| | 2018 | 2017 |
| Dr. Imhoff | \$ 199 | \$ 49 |
| Dr. Cartwright | 2 | 327 |
| Dr. Faupel | - | 304 |
| Ms. Rosenstock | 50 | 50 |
| Mr. Fowler | 26 | 26 |
| Mr. Mermelstein | 211 | 180 |
| GHS | 15 | - |
| GPB | 17 | 17 |
| Aquarius | 108 | 107 |
| Mr. Blumberg | 70 | 30 |
| Mr. James | 2 | 1 |
| Notes payable in default, including related parties | \$ 700 | \$ 1,091 |

Short Term Notes Payable

At December 31, 2018 and 2017, the Company maintained short term notes payable to both related and non-related parties totaling \$649,000 and \$447,000, respectively. These notes are short term, straight-line amortizing notes. The notes carry annual interest rates between 5% and 10%.

In July 2018, the Company entered into a premium finance agreement to finance its insurance policies totaling \$112,094. The note requires monthly payments of \$12,711, including interest at 4.91% and matures in May 2019. As of December 31, 2018, a balance of \$50,535 remained. The balance due on insurance policies totaled \$93,000 at December 31, 2017.

On August 22, 2018, the Company issued a promissory note to an investor for \$150,000 in aggregate principal amount of a 6% promissory note for an aggregate purchase price of \$157,500 (representing a \$7,500 original issue discount). Pursuant to the promissory note the entire unpaid principal balance on the promissory note together with all accrued and unpaid interest and loan origination fees, if any, at the choice of the investor, shall be due and payable in full from the funds received by the Company from a financing of at least \$2,000,000, or at the option of the investor, to be included in the Company's financing under the same terms as the new investors with the most favorable terms making a cash investment. If the Company does not complete a financing of at least \$2,000,000 within 90 days of the execution of this promissory note, any unpaid amounts shall be due in full to the investor and shall accrue interest at 12% (instead of 6%) per annum from the date thereof (90 days after execution), if not paid in full. In addition, the investor will be granted 1,500,000 warrants under this promissory note. The warrants shall be issued and vest upon the financing of at least \$2,000,000 and expire on the third anniversary of said financing. The warrant exercise price shall be set at the same price as for warrants granted to the investors with the most favorable terms as part of any \$2,000,000 or more financing of the Company or \$0.25, whichever is lower. The warrants shall have standard anti-dilution features to protect the holder from dilution due to down rounds of financing. As of December 31, 2018, the Company had not repaid the note and therefore the accrued interest rate increased to 12%.

On September 19, 2018, the Company issued a promissory note to an investor for \$50,000 in aggregate principal amount of a 6% promissory note for an aggregate purchase price of \$52,500 (representing a \$2,500 original issue discount). Pursuant to the promissory note the entire unpaid principal balance on the promissory note together with all accrued and unpaid interest and loan origination fees, if any, at the choice of the investor, shall be due and payable in full from the funds received by the Company from a financing of at least \$2,000,000, or at the option of the investor, to be included in the Company's financing under the same terms as the new investors with the most favorable terms making a cash investment. If the Company does not complete a financing of at least \$2,000,000 within 90 days of the execution of this promissory note, any unpaid amounts shall be due in full to the investor and shall accrue interest at 12% (instead of 6%) per annum from the date thereof (90 days after execution), if not paid in full. In addition, the investor will be granted 500,000 warrants under this promissory note. The warrants shall be issued and vest upon the financing of at least \$2,000,000 and expire on the third anniversary of said financing. The warrant exercise price shall be set at the same price as for warrants granted to the investors with the most favorable terms as part of any \$2,000,000 or more financing of the Company or \$0.25, whichever is lower. The warrants shall have standard anti-dilution features to protect the holder from dilution due to down rounds of financing. As of December 31, 2018, the Company had not repaid the note and therefore the accrued interest rate increased to 12%.

On July 20, 2018, the Company entered into an exchange agreement and promissory note with Dr. Cartwright. The agreements were entered into in order to extinguish and restructure current amounts owed to Dr. Cartwright. In the exchange agreement Dr. Cartwright, agreed to exchange outstanding amounts due to him for loans, interest, bonus, salary and vacation pay in the amount of \$1,621,499 for \$319,204 promissory note. Pursuant to the exchange agreement the note will bear interest at 6%. In addition, Dr. Cartwright will receive 125 stock options, with 31 vesting immediately and the remaining vesting monthly over three years. As a result of the exchange agreement, the Company recorded a gain for extinguishment of debt of \$840,391 and a capital contribution of \$431,519. As of December 31, 2018, Dr. Cartwright's total undiscounted cash flow amount due was approximately \$349,590 including interest.

On July 24, 2018, the Company entered into an exchange agreement and promissory note with Dr. Faupel. The agreements were entered into in order to extinguish and restructure current amounts owed to Dr. Faupel. In the exchange agreement Dr. Faupel, agreed to exchange outstanding amounts due to him for loans, interest, bonus, salary and vacation pay in the amount of \$660,895 for \$207,111 promissory note. Pursuant to the exchange agreement the note will bear interest at 6%. In addition, Dr. Faupel will receive 94 stock options, with 31 vesting immediately and the remaining vesting monthly over three years. Dr. Faupel will also receive 560 options at \$200.00 or market price, whichever is less; contingent on shareholder vote and board approval. If the options are not granted, the Company shall owe Dr. Faupel \$113,000. As a result of the exchange agreement, the Company recorded a gain for extinguishment of debt of \$199,079 and a capital contribution of \$234,990. As of December 31, 2018, Dr. Faupel's total undiscounted cash flow amount due was approximately \$256,825 including interest.

The following table summarizes the *Short-term notes payable, including related parties*:

| | Year Ended December 31, | |
|--|-------------------------|---------------|
| | 2018 | 2017 |
| Dr. Imhoff | \$ 135 | \$ 33 |
| Dr. Cartwright | 144 | 296 |
| Dr. Faupel | 123 | - |
| Mr. Maloof | 25 | 25 |
| Mr. Case | 150 | - |
| Mr. Gould | 50 | - |
| K2 | 177 | - |
| Premium Finance (insurance) | 50 | 93 |
| Mr. Blumberg | 45 | - |
| Short-term notes payable, including related parties | \$ 899 | \$ 447 |

The following table summarizes the *Long-term notes payable, including related parties*:

| | Year Ended December 31, | |
|---|-------------------------|---------------|
| | 2018 | 2017 |
| Dr. Cartwright | 206 | - |
| Dr. Faupel | 134 | - |
| Long-term notes payable, including related parties | \$ 340 | \$ 296 |

10. SHORT-TERM CONVERTIBLE DEBT

Related Party Convertible Note Payable – Short-Term

On June 5, 2016, the Company entered into a license agreement with a distributor pursuant to which the Company granted the distributor an exclusive license to manufacture, sell and distribute the Company's LuViva Advanced Cervical Cancer device and related disposables in Taiwan, Brunei Darussalam, Cambodia, Laos, Myanmar, Philippines, Singapore, Thailand, and Vietnam. The distributor was already the Company's exclusive distributor in China, Macau and Hong Kong, and the license will extend to manufacturing in those countries as well.

As partial consideration for, and as a condition to, the license, and to further align the strategic interests of the parties, the Company agreed to issue a convertible note to the distributor, in exchange for an aggregate cash investment of \$200,000. The note will provide for a payment to the distributor of \$240,000, due upon consummation of any capital raising transaction by the Company within 90 days and with net cash proceeds of at least \$1.0 million. As of December 31, 2018, the Company had a note due of \$432,000. The note accrues interest at 20% per year on any unpaid amounts due after that date. The note will be convertible into shares of the Company's common stock at a conversion price per share of \$11,137.28, subject to customary anti-dilution adjustment. The note will be unsecured, and is expected to provide for customary events of default. The Company will also issue the distributor a five-year warrant exercisable immediately for 22 shares of common stock at an exercise price equal to the conversion price of the note, subject to customary anti-dilution adjustment.

Convertible Note Payable – Short-Term

On December 28, 2016, the Company entered into a securities purchase agreement with an investor for the issuance and sale to investor of up to \$330,000 in aggregate principal amount of 10% original issuance discount convertible promissory notes, for an aggregate purchase price of \$300,000. On that date, the Company issued to the investor a note in the principal amount of \$222,000, for a purchase price of \$200,000. The note matures six months from their date of issuance and, in addition to the 10% original issue discount, accrue interest at a rate of 10% per year. The Company may prepay the notes, in whole or in part, for 115% of outstanding principal and interest until 30 days from issuance, for 125% of outstanding principal and interest at any time from 31 to 60 days from issuance, and for 130% of outstanding principal and interest at any time from 61 days from issuance until immediately prior to the maturity date. After six months from the date of issuance (i.e., if the Company fails to repay all principal and interest due under the notes at the maturity date), the investor may convert the notes, at any time, in whole or in part, into shares of the Company's common stock, at a conversion price equal to 60% of the lowest volume weighted average price of our common stock during the 20 trading days prior to conversion, subject to certain customary adjustments and anti-dilution provisions contained in the note. The convertible promissory note was paid off during 2017. As of December 31, 2018, and 2017 the note had been converted and no balance remained outstanding.

On February 13, 2017, the Company entered into a securities purchase agreement with Auctus Fund, LLC for the issuance and sale to Auctus of \$170,000 in aggregate principal amount of a 12% convertible promissory note for an aggregate purchase price of \$156,400 (representing a \$13,600 original issue discount). On February 13, 2017, the Company issued the note to Auctus. Pursuant to the purchase agreement, the Company also issued to Auctus a warrant exercisable to purchase an aggregate of 250 shares of the Company's common stock. The warrant is exercisable at any time, at an exercise price per share equal to \$4.11 (110% of the closing price of the common stock on the day prior to issuance), subject to certain customary adjustments and price-protection provisions contained in the warrant. The warrant has a five-year term. The note matured nine months from the date of issuance and, in addition to the original issue discount, accrues interest at a rate of 12% per year. The Company could have prepaid the note, in whole or in part, for 115% of outstanding principal and interest until 30 days from issuance, for 125% of outstanding principal and interest at any time from 31 to 60 days from issuance, and for 130% of outstanding principal and interest at any time from 61 days from issuance to 180 days from issuance. After six months from the date of issuance, Auctus may convert the note, at any time, in whole or in part, into shares of the Company's common stock, at a conversion price equal to the lower of the price offered in the Company's next public offering or a 40% discount to the average of the two lowest trading prices of the common stock during the 20 trading days prior to the conversion, subject to certain customary adjustments and price-protection provisions contained in the note. The note includes customary events of default provisions and a default interest rate of 24% per year. Upon the occurrence of an event of default, Auctus may require the Company to redeem the note (or convert it into shares of common stock) at 150% of the outstanding principal balance plus accrued and unpaid interest. In connection with the transaction, the Company agreed to reimburse Auctus for \$30,000 in legal and diligence fees, of which we paid \$10,000 in cash and \$20,000 in restricted shares of common stock, valued at \$320.00 per share (a 42.86% discount to the closing price of the common stock on the day prior to issuance). The Company allocated proceeds of \$90,000 to the warrants and common stock issued in connection with the financing. As of December 31, 2018, the notes had been converted and no balance remained outstanding as compared to net debt and accrued interest of \$76,664 for the period ended December 31, 2017.

On May 17, 2017, the Company entered into a securities purchase agreement with Eagle Equities, LLC, providing for the purchase by Eagle of two convertible redeemable notes in the aggregate principal amount of \$88,000, with the first note being in the amount of \$44,000, and the second note being in the amount of \$44,000. The first note was fully funded on May 19, 2017, upon which the Company received \$40,000 of net proceeds (net of a 10% original issue discount). The second note was issued on December 21, 2017 and was initially paid for by the issuance of an offsetting \$40,000 secured note issued by Eagle. Eagle was required to pay the principal amount of its secured note in cash and in full prior to executing any conversions under the second note the Company issued. The notes bear an interest rate of 8%, and are due and payable on May 17, 2018. The notes may be converted by Eagle at any time after five months from issuance into shares of our common stock (as determined in the notes) calculated at the time of conversion, except for the second note, which also requires full payment by Eagle of the secured note it issued to us before conversions may be made. The conversion price of the notes will be equal to 60% of the lowest trading price of the common stock for the 20 prior trading days including the day upon which the Company receive a notice of conversion. The notes may be prepaid in accordance with the terms set forth in the notes. The notes also contain certain representations, warranties, covenants and events of default including if the Company are delinquent in our periodic report filings with the SEC, and increases in the amount of the principal and interest rates under the notes in the event of such defaults. In the event of default, at Eagle's option and in its sole discretion, Eagle may consider the notes immediately due and payable. As of December 31, 2018, the notes had been converted and no balance remained outstanding, as compared to net debt of \$41,322, including unamortized original issue discount of \$5,214, unamortized and debt issuance costs of \$11,160 for the period ended December 31, 2017. In addition, at December 31, 2018, the Company recorded a \$29,333 beneficial conversion feature which was fully amortized at year end.

On May 17, 2017, the Company entered into a securities purchase agreement with Adar Bays, LLC, providing for the purchase by Adar of two convertible redeemable notes in the aggregate principal amount of \$88,000, with the first note being in the amount of \$44,000, and the second note being in the amount of \$44,000. The first note was fully funded on May 19, 2017, upon which the Company received \$40,000 of net proceeds (net of a 10% original issue discount). The second note was issued on December 21, 2017 and was initially paid for by the issuance of an offsetting \$40,000 secured note issued by Adar. Adar was required to pay the principal amount of its secured note in cash and in full prior to executing any conversions under the second note the Company issued. The notes bear an interest rate of 8%, and are due and payable on May 17, 2018. The notes may be converted by Adar at any time after five months from issuance into shares of our common stock (as determined in the notes) calculated at the time of conversion, except for the second note, which also requires full payment by Adar of the secured note it issued to us before conversions may be made. The conversion price of the notes will be equal to 60% of the lowest trading price of the common stock for the 20 prior trading days including the day upon which the Company receive a notice of conversion. The notes may be prepaid in accordance with the terms set forth in the notes. The notes also contain certain representations, warranties, covenants and events of default including if the Company are delinquent in our periodic report filings with the SEC, and increases in the amount of the principal and interest rates under the notes in the event of such defaults. In the event of default, at Adar's option and in its sole discretion, Adar may consider the notes immediately due and payable. As of December 31, 2018, the notes had been converted and no balance remained outstanding, as compared to net debt of \$42,216, including unamortized original issue discount of \$5,214, unamortized and debt issuance costs of \$11,160 for the period ended December 31, 2017. In addition, at December 31, 2018, the Company recorded a \$29,333 beneficial conversion feature which was fully amortized at year end.

On August 18, 2017, the Company entered into a securities purchase agreement with Power Up Lending Group Ltd., providing for the purchase by Power Up from the Company of a convertible note in the aggregate principal amount of \$53,000. The note bears an interest rate of 12%, and is due and payable on May 19, 2018. The note may be converted by Power Up at any time after 180 days from issuance into shares of Company's common stock at a conversion price equal to 58% of the average of the lowest two-day trading prices of the common stock during the 15 trading days prior to conversion. The note may be prepaid in accordance with its terms, at premiums ranging from 15% to 40%, depending on the time of prepayment. The note contains certain representations, warranties, covenants and events of default, including if the Company is delinquent in its periodic report filings with the SEC, and provides for increases in principal and interest in the event of such defaults. As of December 31, 2018, the notes had been converted and no balance remained outstanding as compared to a net debt of \$46,405, including unamortized debt issuance costs of \$6,595 at December 31, 2017. In addition, at December 31, 2018, the Company recorded a \$38,379 beneficial conversion feature which was fully amortized at year end.

On October 12, 2017, the Company entered into a securities purchase agreement with Power Up Lending Group Ltd. ("Power Up"), providing for the purchase by Power Up from the Company of a convertible note in the aggregate principal amount of \$53,000. The note bears an interest rate of 12%, and is due and payable on July 20, 2018. The note may be converted by Power Up at any time after 180 days from issuance into shares of Company's common stock at a conversion price equal to 58% of the average of the lowest two-day trading prices of the common stock during the 15 trading days prior to conversion. The note may be prepaid in accordance with its terms, at premiums ranging from 15% to 40%, depending on the time of prepayment. The note contains certain representations, warranties, covenants and events of default, including if the Company is delinquent in its periodic report filings with the SEC, and provides for increases in principal and interest in the event of such defaults. As of December 31, 2018, the note had been converted and no balance remained outstanding, as compared to net debt of \$47,288, including unamortized debt issuance costs of \$5,722 for the period ended December 31, 2017. In addition, at December 31, 2018, the Company recorded a \$38,379 beneficial conversion feature which was fully amortized at year end.

On December 11, 2017, the Company entered into a securities purchase agreement with Power Up Lending Group Ltd. ("Power Up"), providing for the purchase by Power Up from the Company of a convertible note in the aggregate principal amount of \$53,000. The note bears an interest rate of 12%, and is due and payable on September 20, 2018. The note may be converted by Power Up at any time after 180 days from issuance into shares of Company's common stock at a conversion price equal to 58% of the average of the lowest two-day trading prices of the common stock during the 15 trading days prior to conversion. The note may be prepaid in accordance with its terms, at premiums ranging from 15% to 40%, depending on the time of prepayment. The note contains certain representations, warranties, covenants and events of default, including if the Company is delinquent in its periodic report filings with the SEC, and provides for increases in principal and interest in the event of such defaults. As of December 31, 2018, the note had been converted and no balance remained outstanding, as compared to net debt of \$45,565, including unamortized debt issuance costs of \$7,435 for the period ended December 31, 2017.

On February 12, 2018, the Company entered into a securities purchase agreement with Adar Bays, LLC, providing for the purchase by Adar of three convertible redeemable notes in the aggregate principal amount of \$285,863, with the first note being in the amount of \$95,288, and the second and third note being in the same amount. The first note was fully funded on February 13, 2018, upon which the Company received \$75,000 of net proceeds (net of a 10% original issue discount). The notes bear an interest rate of 8% and were due and payable on October 12, 2018. The notes may be converted by Adar at any time after eight months from issuance into shares of our common stock (as determined in the notes) calculated at the time of conversion, except for the second note, which also requires full payment by Adar of the secured note it issued to us before conversions may be made. The conversion price of the notes will be equal to 60% of the lowest trading price of the common stock for the 20 prior trading days including the day upon which the Company receive a notice of conversion. The notes may be prepaid in accordance with the terms set forth in the notes. The notes also contain certain representations, warranties, covenants and events of default including if the Company are delinquent in our periodic report filings with the SEC and increases in the amount of the principal and interest rates under the notes in the event of such defaults. In the event of default, at Adar's option and in its sole discretion, Adar may consider the notes immediately due and payable. As of December 31, 2018, the note had been converted and no balance remained outstanding. In addition, at December 31, 2018, the Company recorded a \$63,525 beneficial conversion feature which was fully amortized at year end.

On February 22, 2018, the Company entered into a securities purchase agreement with Power Up, providing for the purchase by Power Up from the Company of a convertible note in the aggregate principal amount of \$53,000. The note bears an interest rate of 12% and is due and payable on November 30, 2018. The note may be converted by Power Up at any time after 180 days from issuance into shares of Company's common stock at a conversion price equal to 58% of the average of the lowest two-day trading prices of the common stock during the 15 trading days prior to conversion. The note may be prepaid in accordance with its terms, at premiums ranging from 15% to 40%, depending on the time of prepayment. The note contains certain representations, warranties, covenants and events of default, including if the Company is delinquent in its periodic report filings with the SEC, and provides for increases in principal and interest in the event of such defaults. As of December 31, the note had been converted and no balance remained outstanding. In addition, at December 31, 2018, the Company recorded a \$38,379 beneficial conversion feature which was fully amortized at year end.

On March 12, 2018, the Company entered into a securities purchase agreement with Eagle Equities, LLC, providing for the purchase by Eagle of a convertible redeemable note in the principal amount of \$66,667. The note was fully funded on March 14, 2018, upon which the Company received \$51,000 of net proceeds (net of a 10% original issue discount and other expenses). The note bears an interest rate of 8% and are due and payable on March 12, 2019. The note may be converted by Eagle at any time after twelve months from issuance into shares of our common stock (as determined in the notes) calculated at the time of conversion, except for the second note, which also requires full payment by Eagle of the secured note it issued to us before conversions may be made. The conversion price of the notes will be equal to 60% of the lowest trading price of the common stock for the 20 prior trading days including the day upon which the Company receive a notice of conversion. The notes may be prepaid in accordance with the terms set forth in the notes. The notes also contain certain representations, warranties, covenants and events of default including if the Company are delinquent in our periodic report filings with the SEC and increases in the amount of the principal and interest rates under the notes in the event of such defaults. In the event of default, at Eagle's option and in its sole discretion, Eagle may consider the notes immediately due and payable. As of December 31, 2018, the outstanding balance was \$3,095, including unamortized debt issuance costs of \$1,751, and unamortized discount of \$1,297 and accrued interest of \$177. In addition, at December 31, 2018, the Company recorded a \$44,444 beneficial conversion feature which \$35,701 was amortized leaving and unamortized balance of \$8,743.

On April 30, 2018, the Company entered into a securities purchase agreement with Power Up, providing for the purchase by Power Up from the Company of a convertible note in the aggregate principal amount of \$103,000. The note bears an interest rate of 12% and is due and payable on February 15, 2019. The note may be converted by Power Up at any time after 180 days from issuance into shares of Company's common stock at a conversion price equal to 58% of the average of the lowest two-day trading prices of the common stock during the 15 trading days prior to conversion. The note may be prepaid in accordance with its terms, at premiums ranging from 15% to 40%, depending on the time of prepayment. The note contains certain representations, warranties, covenants and events of default, including if the Company is delinquent in its periodic report filings with the SEC, and provides for increases in principal and interest in the event of such defaults. As of December 31, the note had been converted and no balance remained outstanding. In addition, at December 31, 2018, the Company recorded a \$74,586 beneficial conversion feature which was fully amortized at year end.

On June 7, 2018, the Company entered into a securities purchase agreement with Power Up, providing for the purchase by Power Up from the Company of a convertible note in the aggregate principal amount of \$53,000. The note bears an interest rate of 12% and is due and payable on March 30, 2019. The note may be converted by Power Up at any time after 180 days from issuance into shares of Company's common stock at a conversion price equal to 58% of the average of the lowest two-day trading prices of the common stock during the 15 trading days prior to conversion. The note may be prepaid in accordance with its terms, at premiums ranging from 15% to 40%, depending on the time of prepayment. The note contains certain representations, warranties, covenants and events of default, including if the Company is delinquent in its periodic report filings with the SEC, and provides for increases in principal and interest in the event of such defaults. As of December 31, 2018, the note had been fully converted. In addition, at December 31, 2018, the Company recorded a \$38,379 beneficial conversion feature which was fully amortized at year end.

The following table summarizes the *Convertible notes payable*:

| | Year Ended December 31, | |
|--|-------------------------|---------------|
| | 2018 | 2017 |
| Shenghuo | \$ 432 | \$ 357 |
| Eagle | 3 | 88 |
| Auctus | - | 91 |
| Debt Discount to be amortized | (10) | - |
| Debt Discount related to Beneficial Conversion | (45) | - |
| Power Up | - | 159 |
| Adar | - | 88 |
| Convertible notes payable | \$ 380 | \$ 783 |

11. CONVERTIBLE NOTES IN DEFAULT

Secured Promissory Note.

On September 10, 2014, the Company sold a secured promissory note to an accredited investor with an initial principal amount of \$1,275,000, for a purchase price of \$700,000 (an original issue discount of \$560,000). The Company may prepay the note at any time. The note is secured by the Company's current and future accounts receivable and inventory, pursuant to a security agreement entered into in connection with the sale. On March 10, 2015, May 4, 2015, June 1, 2015, June 16, 2015, June 29, 2015, January 21, 2016, January 29, 2016, and February 12, 2016 the Company amended the terms of the note to extend the maturity ultimately until August 31, 2016. During the extension, interest accrues on the note at a rate of the lesser of 18% per year or the maximum rate permitted by applicable law. On February 11, 2016, the Company consented to an assignment of the note to two accredited investors. In connection with the assignment, the holders waived an ongoing event of default under the notes related to the Company's minimum market capitalization and agreed to eliminate the requirement going forward. Pursuant to the terms of the amended note, the holder may convert the outstanding balance into shares of common stock at a conversion price per share equal to the lower of (1) \$20,000.00 or (2) 75% of the lowest daily volume weighted average price of the common stock during the five days prior to conversion. If the conversion price at the time of any conversion is lower than \$12,000.00, the Company has the option of delivering the conversion amount in cash in lieu of shares of common stock. On March 7, 2016, the Company further amended the note to eliminate the volume limitations on sales of common stock issued or issuable upon conversion. On July 13, 2016, the Company consented to the assignment by one of the accredited investors of its portion of the note of to a third accredited investor.

The balance due on the note was \$151,974 and \$184,245 at December 31, 2018 and December 31, 2017, respectively. The balance was reduced by \$306,863 as part of a debt restructuring on December 7, 2016.

Total debt issuance costs as originally capitalized were approximately \$130,000. This amount was amortized over nine months and was fully amortized as of December 31, 2015. The original issue discount of \$560,000 was fully amortized as of December 31, 2015.

On November 2, 2016, the Company entered into a lockup and exchange agreement with GHS Investments, LLC, holder of approximately \$221,000 in outstanding principal amount of the Company's secured promissory note and all the outstanding shares of the its Series C preferred stock. Pursuant to the agreement, upon the effectiveness of the 1:800 reverse stock split and continuing for 45 days after, GHS and its affiliates were prohibited from converting any portion of the secured promissory note or any of the shares of Series C preferred stock or selling any of the Company's securities that they beneficially owned. The Company agreed that, upon consummation of its next financing, the Company would use \$260,000 of net cash proceeds first, to repay GHS's portion of the secured promissory note and second, with any remaining amount from the \$260,000, to repurchase a portion of GHS's shares of Series C preferred stock. In addition, GHS has agreed to exchange the stated value per share (plus any accrued but unpaid dividends) of its remaining shares of Series C preferred stock for new securities of the same type that the Company separately issue in the next qualifying financing it undertakes, on a dollar-for-dollar basis in a private placement exchange.

Senior Secured Promissory Note

On February 11, 2016, the Company entered into a securities purchase agreement with GPB Debt Holdings II LLC for the issuance and sale on February 12, 2016 of \$1.4375 million in aggregate principal amount of a senior secured convertible note for an aggregate purchase price of \$1.15 million (a 20% original issue discount of \$287,500) and a discount for debt issuance costs paid at closing of \$121,000 for a total of \$408,500. In addition, GPB received a warrant exercisable to purchase an aggregate of approximately 2,246 shares of the Company's common stock. The Company allocated proceeds totaling \$359,555 to the fair value of the warrants at issuance. This was recorded as an additional discount on the debt. The convertible note matures on the second anniversary of issuance and, in addition to the 20% original issue discount, accrues interest at a rate of 17% per year. The Company is required to pay monthly interest coupons and beginning nine months after issuance, the Company is required to pay amortized quarterly principal payments. If the Company does not receive, on or before the first anniversary after issuance, an aggregate of at least \$3.0 million from future equity or debt financings or non-dilutive grants, then the holder will have the option of accelerating the maturity date to the first anniversary of issuance. The Company may prepay the convertible note, in whole or in part, without penalty, upon 20 days' prior written notice. Subject to resale restrictions under Federal securities laws and the availability of sufficient authorized but unissued shares of the Company's common stock, the convertible note is convertible at any time, in whole or in part, at the holder's option, into shares of the Company's common stock, at a conversion price equal to the lesser of \$640.00 per share or 70% of the average closing price per share for the five trading days prior to issuance, subject to certain customary adjustments and anti-dilution provisions contained in the convertible note. On May 28, 2016, in exchange for an additional \$87,500 in cash from GPB to the Company, the principal balance was increased by the same amount. The Company is currently in default as they are past due on the required monthly interest payments. In the event of default, the Company shall accrue interest at a rate the lesser of 22% or the maximum permitted by law. The Company has accrued \$117,000 for past due interest payments at December 31, 2016. Upon the occurrence of an event of default, the holder may require the Company to redeem the convertible note at 120% of the outstanding principal balance (but as of December 31, 2018, had not done so). As of December 31, 2018, the balance due on the convertible debt was \$2,198,236 as the Company has fully amortized debt issuance costs of \$47,675 and the debt discount of \$768,055 and recorded a 20% penalty totaling \$366,373. In addition, the Company has accrued \$699,743 of interest expense for the year ended December 31, 2018. As of December 31, 2017, the balance due on the convertible debt was \$2,136,863 as the Company has fully amortized debt issuance costs of \$47,675 and the debt discount of \$768,055 and recorded a 20% penalty totaling \$305,000. In addition, the Company has accrued \$498,91043 of interest expense for the year ended December 31, 2017. The convertible note is secured by a lien on all the Company's assets, including its intellectual property, pursuant to a security agreement entered into by the Company and GPB.

The warrant is exercisable at any time, pending availability of sufficient authorized but unissued shares of the Company's common stock, at an exercise price per share equal to the conversion price of the convertible note, subject to certain customary adjustments and anti-dilution provisions contained in the warrant. The warrant has a five-year term. As of December 31, 2018, the exercise price had been adjusted to \$0.06 and the number of common stock shares exchangeable for was 22,460,938. As of December 31, 2018, the effective interest rate considering debt costs was 29%.

The Company used a placement agent in connection with the transaction. For its services, the placement agent received a cash placement fee equal to 4% of the aggregate gross proceeds from the transaction and a warrant to purchase shares of common stock equal to an aggregate of 6% of the total number of shares underlying the securities sold in the transaction, at an exercise price equal to, and terms otherwise identical to, the warrant issued to the investor. Finally, the Company agreed to reimburse the placement agent for its reasonable out-of-pocket expenses.

In connection with the transaction, on February 12, 2016, the Company and GPB entered into a four-year consulting agreement, pursuant to which the investor will provide management consulting services to the Company in exchange for a royalty payment, payable quarterly, equal to 3.5% of the Company's revenues from the sale of products. As of December 31, 2018, and December 31, 2017, GPB had earned approximately \$31,000 and \$29,000 in royalties, respectively.

Debt Restructuring

On December 7, 2016, the Company entered into an exchange agreement with GPB with regard to the \$1,525,000 in outstanding principal amount of senior secured convertible note originally issued to GPB on February 11, 2016, and the \$306,863 in outstanding principal amount of the Company's secured promissory note that GPB holds (see "—Secured Promissory Note"). Pursuant to the exchange agreement, upon completion of the next financing resulting in at least \$1 million in cash proceeds, GPB will exchange both securities for a new convertible note in principal amount of \$1,831,863. The new convertible note will mature on the second anniversary of issuance and will accrue interest at a rate of 19% per year. The Company will pay monthly interest coupons and, beginning one year after issuance, will pay amortized quarterly principal payments. Subject to resale restrictions under Federal securities laws and the availability of sufficient authorized but unissued shares of the Company's common stock, the new convertible note will be convertible at any time, in whole or in part, at the holder's option, into shares of common stock, at a conversion price equal to the price offered in the qualifying financing that triggers the exchange, subject to certain customary adjustments and anti-dilution provisions contained in the new convertible note. The new convertible note will include customary event of default provisions and a default interest rate of the lesser of 21% or the maximum amount permitted by law. Upon the occurrence of an event of default, GPB will be entitled to require the Company to redeem the new convertible note at 120% of the outstanding principal balance. The new convertible note will be secured by a lien on all the Company's assets, including its intellectual property, pursuant to the security agreement entered into by the Company and GPB in connection with the issuance of the original senior secured convertible note. Additionally, the Company further agreed to amend the warrant issued with the original senior secured convertible note, to adjust the number of shares issuable upon exercise of the warrant to equal the number of shares that will initially be issuable upon conversion of the new convertible note (without giving effect to any beneficial ownership limitations set forth in the terms of the new convertible note). As an inducement to GPB to enter into these transactions, the Company agreed to increase the royalty payable to GPB pursuant to its consulting agreement with us on December 7, 2016 from 3.5% to 3.85% of revenues from the sales of the Company's products.

On August 8, 2017, the Company entered into a forbearance agreement with GPB, with regard to the senior secured convertible note. Under the forbearance agreement, GPB has agreed to forbear from exercising certain of its rights and remedies (but not waive such rights and remedies), arising as a result of the Company's failure to pay the monthly interest due and owing on the note. In consideration for the forbearance, the Company agreed to waive, release, and discharge GPB from all claims against GPB based on facts existing on or before the date of the forbearance agreement in connection with the note, or the dealings between the Company and GPB, or the Company's equity holders and GPB, in connection with the note. Pursuant to the forbearance agreement, the Company has reaffirmed its obligations under the note and related documents and executed a confession of judgment regarding the amount due under the note, which GPB may file upon any future event of default by the Company. During the forbearance period, the Company must continue to comply will all the terms, covenants, and provisions of the note and related documents.

The "Forbearance Period" shall mean the period beginning on the date hereof and ending on the earliest to occur of: (i) the date on which Lender delivers to Company a written notice terminating the Forbearance Period, which notice may be delivered at any time upon or after the occurrence of any Forbearance Default (as hereinafter defined), and (ii) the date Company repudiates or asserts any defense to any Obligation or other liability under or in respect of this Agreement or the Transaction Documents or applicable law, or makes or pursues any claim or cause of action against Lender; (the occurrence of any of the foregoing clauses (i) and (ii), a "Termination Event"). As used herein, the term "Forbearance Default" shall mean: (A) the occurrence of any Default or Event of Default other than the Specified Default; (B) the failure of Company to timely comply with any material term, condition, or covenant set forth in this Agreement; (C) the failure of any representation or warranty made by Company under or in connection with this Agreement to be true and complete in all material respects as of the date when made; or (D) Lender's reasonable belief that Company: (1) has ceased or is not actively pursuing mutually acceptable restructuring or foreclosure alternatives with Lender; or (2) is not negotiating such alternatives in good faith. Any Forbearance Default will not be effective until one (1) Business Day after receipt by Company of written notice from Lender of such Forbearance Default. Any effective Forbearance Default shall constitute an immediate Event of Default under the Transaction Documents.

Other Convertible Debt in Default

On May 18, 2017, the Company entered into a securities purchase agreement with GHS Investments, LLC, an existing investor, providing for the purchase by GHS of a convertible promissory note in the aggregate principal amount of \$66,000, for \$60,000 in net proceeds (representing a 10% original issue discount). The transaction closed on May 19, 2017. The note matures upon the earlier of our receipt of \$100,000 from revenues, loans, investments, or any other means (other than the Eagle and Adar bridge financings) and December 31, 2017. In addition to the 10% original issue discount, the note accrues interest at a rate of 8% per year. The Company may prepay the note, in whole or in part, for 110% of outstanding principal and interest until 30 days from issuance, for 120% of outstanding principal and interest at any time from 31 to 60 days from issuance and for 140% of outstanding principal and interest at any time from 61 days to 180 days from issuance. The note may not be prepaid after 180 days. After six months from the date of issuance, the note will become convertible, at any time thereafter, in whole or in part, at the holder's option, into shares of our common stock, at a conversion price equal to 60% of the lowest trading price during the 25 trading days prior to conversion. The note includes customary event of default provisions and a default interest rate of the lesser of 20% per year or the maximum amount permitted by law. Upon the occurrence of an event of default, the holder of the note may require us to redeem the note (or convert it into shares of common stock) at 150% of the outstanding principal balance. As of December 31, 2018, the Company's total outstanding amount was \$94,411, (which includes \$37,926 for a default penalty) and accrued interest of \$517. GHS converted \$29,642 of principal and accrued interest payable. This was compared to net debt of \$66,000 for the period ended December 31, 2017.

On March 20, 2018, the Company entered into a securities purchase agreement with Auctus Fund, LLC for the issuance and sale to Auctus of \$150,000 in aggregate principal amount of a 12% convertible promissory note. On March 20, 2018, the Company issued the note to Auctus. Pursuant to the purchase agreement, the Company also issued to Auctus a warrant exercisable to purchase an aggregate of 4,262 shares of the Company's common stock. The warrant is exercisable at any time, at an exercise price per share equal to \$1.82 (110% of the closing price of the common stock on the day prior to issuance), subject to certain customary adjustments and price-protection provisions contained in the warrant. The warrant has a five-year term. The note matures nine months from the date of issuance and accrues interest at a rate of 12% per year. The Company could have prepaid the note, in whole or in part, for 115% of outstanding principal and interest until 30 days from issuance, for 125% of outstanding principal and interest at any time from 31 to 60 days from issuance, and for 130% of outstanding principal and interest at any time from 61 days from issuance to 180 days from issuance. After nine months from the date of issuance, Auctus may convert the note, at any time, in whole or in part, into shares of the Company's common stock, at a conversion price equal to the lower of the price offered in the Company's next public offering or a 40% discount to the average of the two lowest trading prices of the common stock during the 20 trading days prior to the conversion, subject to certain customary adjustments and price-protection provisions contained in the note. The note includes customary events of default provisions and a default interest rate of 24% per year. Upon the occurrence of an event of default, Auctus may require the Company to redeem the note (or convert it into shares of common stock) at 150% of the outstanding principal balance plus accrued and unpaid interest. As of December 31, 2018, the Company has net debt of \$133,870 and accrued interest of \$635. In addition, at December 31, 2018, the Company recorded a \$97,685 beneficial conversion feature which was fully amortized at year end. Upon the occurrence of an event of default, Auctus may require the Company to redeem the note (or convert it into shares of common stock) at 150% of the outstanding principal balance plus accrued and unpaid interest, this has not occurred as of May 6, 2019.

On May 17, 2018, the Company entered into a securities purchase agreement with GHS Investments, LLC, an existing investor, providing for the purchase by GHS of a convertible promissory note in the aggregate principal amount of \$9,250 (with \$750 representing a 10% original issue discount and \$1,000 for transaction costs). The note matures on June 17, 2019. In addition to the 10% original issue discount, the note accrues interest at a rate of 10% per year. The Company may prepay the note, in whole or in part, for 110% of outstanding principal and interest until 30 days from issuance, for 120% of outstanding principal and interest at any time from 31 to 60 days from issuance and for 140% of outstanding principal and interest at any time from 61 days to 180 days from issuance. The note may not be prepaid after 180 days. After nine months from the date of issuance, the note will become convertible, at any time thereafter, in whole or in part, at the holder's option, into shares of our common stock, at a conversion price equal to 30% of the lowest trading price during the 25 trading days prior to conversion (if note cannot be converted due to issues with DTC then rate increases to 40%). The note includes customary event of default provisions and a default interest rate of the lesser of 20% per year or the maximum amount permitted by law. Upon the occurrence of an event of default, the holder of the note may require us to redeem the note (or convert it into shares of common stock) at 150% of the outstanding principal balance. As of December 31, 2018, the Company has net debt of \$14,187 (which includes \$4,937 for a default penalty), including unamortized debt issuance costs of \$424, unamortized discount of \$318 and accrued interest of \$1,135. In addition, at December 31, 2018, the Company recorded a \$3,964 beneficial conversion feature which \$2,280 was amortized leaving and unamortized balance of \$1,685.

On June 22, 2018, the Company entered into a securities purchase agreement with GHS Investments, LLC, an existing investor, providing for the purchase by GHS of a convertible promissory note in the aggregate principal amount of \$68,000 (with \$6,000 representing a 10% original issue discount and \$2,000 for transaction costs). The note matures on June 22, 2019. In addition to the 10% original issue discount, the note accrues interest at a rate of 10% per year. The Company may prepay the note, in whole or in part, for 110% of outstanding principal and interest until 30 days from issuance, for 120% of outstanding principal and interest at any time from 31 to 60 days from issuance and for 140% of outstanding principal and interest at any time from 61 days to 180 days from issuance. The note may not be prepaid after 180 days. After nine months from the date of issuance, the note will become convertible, at any time thereafter, in whole or in part, at the holder's option, into shares of our common stock, at a conversion price equal to 30% of the lowest trading price during the 25 trading days prior to conversion (if note cannot be converted due to issues with DTC then rate increases to 40%). The note includes customary event of default provisions and a default interest rate of the lesser of 20% per year or the maximum amount permitted by law. Upon the occurrence of an event of default, the holder of the note may require us to redeem the note (or convert it into shares of common stock) at 150% of the outstanding principal balance. As of December 31, 2018, the Company has net debt of \$103,285 (which includes \$35,285 for a default penalty), including unamortized debt issuance costs of \$3,318, unamortized discount of \$2,844 and accrued interest of \$8,263. In addition, at December 31, 2018, the Company recorded a \$29,143 beneficial conversion feature which \$15,288 was amortized leaving and unamortized balance of \$13,855.

On July 3, 2018, the Company entered into a securities purchase agreement with Auctus Fund, LLC for the issuance and sale to Auctus of \$89,250 in aggregate principal amount of a 12% convertible promissory note. On July 3, 2018, the Company issued the note to Auctus. The note matures on April 3, 2019 and accrues interest at a rate of 12% per year. The Company could have prepaid the note, in whole or in part, for 115% of outstanding principal and interest until 30 days from issuance, for 125% of outstanding principal and interest at any time from 31 to 60 days from issuance, and for 130% of outstanding principal and interest at any time from 61 days from issuance to 180 days from issuance. After nine months from the date of issuance, Auctus may convert the note, at any time, in whole or in part, into shares of the Company's common stock, at a conversion price equal to the lower of the price offered in the Company's next public offering or a 40% discount to the average of the two lowest trading prices of the common stock during the 20 trading days prior to the conversion, subject to certain customary adjustments and price-protection provisions contained in the note. The note includes customary events of default provisions and a default interest rate of 24% per year. Upon the occurrence of an event of default, Auctus may require the Company to redeem the note (or convert it into shares of common stock) at 150% of the outstanding principal balance plus accrued and unpaid interest. As of December 31, 2018, the Company has net debt of \$81,528, including unamortized original issue discount of \$1,443, unamortized debt issuance costs of \$6,279 and accrued interest of \$5,385. In addition, at December 31, 2018, the Company recorded a \$59,500 beneficial conversion feature which \$39,233 was amortized leaving and unamortized balance of \$20,267. Upon the occurrence of an event of default, Auctus may require the Company to redeem the note (or convert it into shares of common stock) at 150% of the outstanding principal balance plus accrued and unpaid interest, this has not occurred as of May 6, 2019.

The following table summarizes the *Convertible notes in default*:

| | Year Ended December 31, | |
|-------------------------------------|-------------------------|-----------------|
| | 2018 | 2017 |
| GPB | \$ 2,198 | \$ 2,137 |
| GHS | 364 | 184 |
| Auctus | 223 | - |
| Debt Discount to be amortized | (7) | - |
| Convertible notes in default | \$ 2,778 | \$ 2,321 |

12. INCOME (LOSS) PER COMMON SHARE

Basic net income (loss) per share attributable to common stockholders amounts are computed by dividing the net income (loss) plus preferred stock dividends and deemed dividends on preferred stock by the weighted average number of shares outstanding during the year.

Diluted net income (loss) per share attributable to common stockholders amounts are computed by dividing the net income (loss) plus preferred stock dividends, deemed dividends on preferred stock, after-tax interest on convertible debt and convertible dividends by the weighted average number of shares outstanding during the year, plus Series C convertible preferred stock, convertible debt, convertible preferred dividends and warrants convertible into common stock shares.

The following table sets forth pertinent data relating to the computation of basic and diluted net loss per share attributable to common shareholders.

In thousands

| | December 31, | |
|--|------------------|--------------------|
| | 2018 | 2017 |
| Net income (loss) | \$ 900 | \$ (10,974) |
| Basic weighted average number of shares outstanding | 462 | 11 |
| Net income (loss) per share (basic) | \$ 1.95 | \$ 997.64 |
| Diluted weighted average number of shares outstanding | 65,227 | - |
| Net income (loss) per share (diluted) | \$ 0.0138 | - |
| Dilutive equity instruments (number of equivalent units): | | |
| Stock options | - | - |
| Preferred stock | - | - |
| Convertible debt | 42,226 | - |
| Warrants | 22,530 | - |
| Total Dilutive instruments | 65,227 | - |

13. SUBSEQUENT EVENTS

On January 7, 2019 the Company entered into a promissory note for \$25,000 with Richard Blumberg. The entire unpaid principal balance due on this Promissory Note (this "Note"), together with all accrued and unpaid interest and fees, if any, at the choice of Mr. Blumberg, shall be due and payable in full from the funds received by the Company from a financing of at least \$1,000,000 or to be included as part of the Company's financing. Should the Company not complete a financing of at least \$1,000,000 within 90 days of the execution of this Promissory Note, any unpaid amounts shall be due in full to the Mr. Blumberg and shall accrue 6% annual interest from the date thereof if not paid in full. In addition, Mr. Blumberg shall be granted ten common stock warrants for each dollar loaned to the Company under this Promissory Note, representing 313 warrants. The warrants shall vest upon the financing of at least \$1,000,000 and expire on the third anniversary of said financing. The warrant exercise price shall be set at market price as defined by the five-day volume adjusted weighted price (VWAP), or alternatively the same as for warrants granted to investors as part of any \$1 million dollar or more financing of the Company.

On January 17, 2019 the Company entered into a promissory note for \$15,000 with Bryan Mamula. The entire unpaid principal balance due on this Promissory Note (this "Note"), together with all accrued and unpaid interest and fees, if any, at the choice of Mr. Mamula, shall be due and payable in full from the funds received by the Company from a financing of at least \$1,000,000 or to be included as part of the Company's financing. Should the Company not complete a financing of at least \$1,000,000 within 90 days of the execution of this Promissory Note, any unpaid amounts shall be due in full to Mr. Mamula and shall accrue 6% annual interest from the date thereof if not paid in full. In addition, Mr. Mamula shall be granted ten common stock warrants for each dollar loaned to the Company under this Promissory Note, representing 188 warrants. The warrants shall vest upon the financing of at least \$1,000,000 and expire on the third anniversary of said financing. The warrant exercise price shall be set at market price as defined by the five-day volume adjusted weighted price (VWAP), or alternatively the same as for warrants granted to investors as part of any \$1 million dollar or more financing of the Company.

On January 30, 2019 the Company entered into a promissory note for \$35,000 with Richard Blumberg. The entire unpaid principal balance due on this Promissory Note (this "Note"), together with all accrued and unpaid interest and fees, if any, at the choice of Mr. Blumberg, shall be due and payable in full from the funds received by the Company from a financing of at least \$1,000,000 or to be included as part of the Company's financing. Should the Company not complete a financing of at least \$1,000,000 within 90 days of the execution of this Promissory Note, any unpaid amounts shall be due in full to Mr. Blumberg and shall accrue 6% annual interest from the date thereof if not paid in full. In addition, Mr. Blumberg shall be granted ten common stock warrants for each dollar loaned to the Company under this Promissory Note, representing 438 warrants. The warrants shall vest upon the financing of at least \$1,000,000 and expire on the third anniversary of said financing. The warrant exercise price shall be set at market price as defined by the five-day volume adjusted weighted price (VWAP), or alternatively the same as for warrants granted to investors as part of any \$1 million dollar or more financing of the Company.

On February 14, 2019, the Company entered into a Purchase and Sale Agreement with Everest Business Funding for the sale of its accounts receivable. The transaction provided the Company with \$48,735 after \$1,265 in bank costs for a total purchase amount of \$50,000, in which the Company would have to repay \$68,500. At a minimum the Company would need to pay \$535.16 per day or 20.0% of the future collected accounts receivable or "receipts."

On February 8, 2019, a note payable in default as reported in *Footnote 9: Notes payable – Note payable in default*, was exchanged for a note with a convertible option. The note amount was for \$145,544. At the sole discretion of the Company, rather than paying the holder in cash, the note can be exchanged for equity in the new financing of at least \$1,000,000. The debt will be exchanged for C3 preferred shares. If the Company elects to pay the balance in cash, the note shall accrue simple interest of 6% per annum commencing on the date of the new financing of at least \$1,000,000.

On February 15, 2019 the Company entered into a promissory note for \$50,000 with John Gould. The entire unpaid principal balance due on this Promissory Note (this "Note"), together with all accrued and unpaid interest and fees, if any, at the choice of Mr. Gould, shall be due and payable in full from the funds received by the Company from a financing of at least \$1,000,000 or to be included as part of the Company's financing. Should the Company not complete a financing of at least \$1,000,000 within 90 days of the execution of this Promissory Note, any unpaid amounts shall be due in full to the Mr. Gould and shall accrue 6% annual interest from the date thereof if not paid in full. In addition, Mr. Gould shall be granted ten common stock warrants for each dollar loaned to the Company under this Promissory Note, representing 625 warrants. The warrants shall vest upon the financing of at least \$1,000,000 and expire on the third anniversary of said financing. The warrant exercise price shall be set at market price as defined by the five-day volume adjusted weighted price (VWAP), or alternatively the same as for warrants granted to investors as part of any \$1 million dollar or more financing of the Company.

During March 2019, the Company entered into promissory notes for \$46,000 with Richard Blumberg. The entire unpaid principal balance due on this Promissory Note (this "Note"), together with all accrued and unpaid interest and fees, if any, at the choice of Mr. Blumberg, shall be due and payable in full from the funds received by the Company from a financing of at least \$1,000,000 or to be included as part of the Company's financing. Should the Company not complete a financing of at least \$1,000,000 within 90 days of the execution of this Promissory Note, any unpaid amounts shall be due in full to the Mr. Gould and shall accrue 6% annual interest from the date thereof if not paid in full.

On March 29, 2019, the Company entered into a securities purchase agreement with Auctus Fund, LLC for the issuance and sale to Auctus of \$65,000 in aggregate principal amount of a 12% convertible promissory note. On March 29, 2019, the Company issued the note to Auctus. Pursuant to the purchase agreement, the Company also issued to Auctus a warrant exercisable to purchase an aggregate of 325,000 shares of the Company's common stock. The warrant is exercisable at any time, at an exercise price per share equal to \$0.176 (110% of the closing price of the common stock on the day prior to issuance), subject to certain customary adjustments and price-protection provisions contained in the warrant. The warrant has a five-year term. The note matures nine months from the date of issuance and accrues interest at a rate of 12% per year. The Company could have prepaid the note, in whole or in part, for 115% of outstanding principal and interest until 30 days from issuance, for 125% of outstanding principal and interest at any time from 31 to 60 days from issuance, and for 130% of outstanding principal and interest at any time from 61 days from issuance to 180 days from issuance. After nine months from the date of issuance, Auctus may convert the note, at any time, in whole or in part, into shares of the Company's common stock, at a conversion price equal to the lower of the price offered in the Company's next public offering or a 40% discount to the average of the two lowest trading prices of the common stock during the 20 trading days prior to the conversion, subject to certain customary adjustments and price-protection provisions contained in the note. The note includes customary events of default provisions and a default interest rate of 24% per year. Upon the occurrence of an event of default, Auctus may require the Company to redeem the note (or convert it into shares of common stock) at 150% of the outstanding principal balance plus accrued and unpaid interest.

On April 16, 2019, the Company entered into a promissory note for \$20,000 with Richard Blumberg. The entire unpaid principal balance due on this Promissory Note (this "Note"), together with all accrued and unpaid interest and fees, if any, at the choice of Mr. Blumberg, shall be due and payable in full from the funds received by the Company from a financing of at least \$1,000,000 or to be included as part of the Company's financing. Should the Company not complete a financing of at least \$1,000,000 within 90 days of the execution of this Promissory Note, any unpaid amounts shall be due in full to the Mr. Blumberg and shall accrue 6% annual interest from the date thereof if not paid in full.

On April 26, 2019, the Company entered into a promissory note for \$50,000 with Fred Grimm. The entire unpaid principal balance due on this Promissory Note (this "Note"), together with all accrued and unpaid interest and fees, if any, at the choice of Mr. Grimm, shall be due and payable in full from the funds received by the Company from a financing of at least \$1,000,000 or to be included as part of the Company's financing. Should the Company not complete a financing of at least \$1,000,000 within 90 days of the execution of this Promissory Note, any unpaid amounts shall be due in full to the Mr. Grimm and shall accrue 6% annual interest from the date thereof if not paid in full. If upon financing Mr. Grimm decides to exchange any amount remaining under this promissory note into equity as part of the Company's financing, Mr. Grimm shall receive a minimum of two common shares of the Company's common stock and warrants to purchase two additional common stock shares of the Company's common stock. In addition, Mr. Grimm shall be granted four common stock shares and four common stock warrants for each dollar loaned to the Company under this Promissory Note, representing 200,000 warrants. The warrants shall vest upon the financing of at least \$1,000,000 and expire on the third anniversary of said financing. The warrant exercise price shall be set at market price as defined by the five-day volume adjusted weighted price (VWAP), or alternatively the same as for warrants granted to investors as part of any \$1 million dollar or more financing of the Company.

The Company was not able to meet its filing date deadline for the 10K due to financial issues.

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

None.

Item 9A. Controls and Procedures

We maintain a set of disclosure controls and procedures designed to ensure that information required to be disclosed by us in reports that we file or submit under the Securities Exchange Act of 1934, as amended (the "Exchange Act") is recorded, processed, summarized, and reported, within the time periods specified in Securities and Exchange Commission ("Commission") rules and forms. We carried out an evaluation under the supervision and with the participation of our management, including the Chief Executive Officer/Acting Chief Financial Officer, Gene Cartwright, of the effectiveness of its disclosure controls and procedures. Based on that evaluation, the Chief Executive Officer/Acting Chief Financial Officer has concluded that our disclosure controls and procedures were ineffective as of December 31, 2018, due to the existence of a material weakness in our internal control over financial reporting, described below, that we have yet to fully remediate.

Management's Annual Report on Internal Control over Financial Reporting: Our management, including our Chief Executive Officer/Acting Chief Financial Officer, is responsible for establishing and maintaining adequate internal control over our financial reporting. Internal control over financial reporting is a process designed by, or under the supervision of, our Chief Executive Officer/Chief Financial Officer and implemented by our board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles and includes those policies and procedures that: (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of our assets; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorization of our management and directors; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the financial statements. Because of their inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Under the supervision and with the participation of our management, including our Principal Executive Officer/Principal Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the 2013 version of the Internal Control – Integrated Framework, issued by the Committee of Sponsoring Organizations of the Treadway Commission.

Based on our evaluation, our management concluded that our internal control over financial reporting was ineffective as of December 31, 2018, due to the existence of the material weakness described below:

The Company lacks the resources to properly research and account for complex transactions. This deficiency has resulted in a material weakness in our internal control over financial reporting.

This annual report does not include an attestation report of our independent registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by our independent registered public accounting firm pursuant to rules of the Commission that permit non-accelerated filers to provide only the management's report in their annual reports on Form 10-K.

Except as described above, there were no changes to the Company's internal controls over financial reporting occurred during the year ended December 31, 2018 that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

Item 9B. Other Information

None.

Item 10. Directors, Executive Officers and Corporate Governance

Our executive officers are elected by and serve at the discretion of our board of directors. The following table lists information about our directors and executive officers:

| Name | Age | Position with Guided Therapeutics |
|---------------------------|------------|---|
| Gene S. Cartwright, Ph.D. | 64 | Chief Executive Officer, President, Acting Chief Financial Officer and Director |
| Mark Faupel, Ph.D. | 63 | Chief Operating Officer and Director |
| Richard L. Fowler | 62 | Senior Vice President of Engineering |
| Richard P. Blumberg | 62 | Director |
| John E. Imhoff, M.D. | 69 | Director |
| Michael C. James | 60 | Chairman and Director |

Except as set forth below, all of the executive officers have been associated with us in their present or other capacities for more than the past five years. Officers are elected annually by the board of directors and serve at the discretion of the board. There are no family relationships among any of our executive officers and directors.

Gene S. Cartwright, Ph.D. joined us in January 2014 as the President, Chief Executive Officer and Acting Chief Financial Officer. He was elected as a director on January 11, 2014. His most recent position was with Omnyx, LLC, a Joint Venture between GE Healthcare and the University of Pittsburgh Medical Center, where, as CEO for over four years he founded and managed the successful development of products for the field of Digital Pathology. Prior to his work with Omnyx, LLC, he was President of Molecular Diagnostics for GE Healthcare. Prior to GE, Dr. Cartwright was Divisional Vice President/General Manager for Abbott Diagnostics' Molecular Diagnostics business. In his 24-year career at Abbott, he also served as Divisional Vice President for U.S. Marketing for five years. He received a Master of Management degree from Northwestern's Kellogg School of Management and also holds a Ph.D. in chemistry from Stanford University and an AB from Dartmouth College.

Dr. Cartwright brings over 30 years of experience working in the IVD diagnostics industry. He has great experience in the diagnostics market both in the development and introduction of new diagnostics technologies, as well as extensive successful commercial experience with global businesses. With his background and experience, Dr. Cartwright, as President and Chief Executive Officer, as well as Acting Chief Financial Officer, works with and advises the board as to how we can successfully market and build LuViva international sales.

Mark Faupel, Ph.D., rejoined us as Chief Operating Officer and director on December 8, 2016. He previously served on our board of directors through 2013 and has more than 30 years of experience in developing non-invasive alternatives to surgical biopsies and blood tests, especially in the area of cancer screening and diagnostics. Dr. Faupel was one of our co-founders and also served as our Chief Executive Officer from May 2007 through 2013. Prior thereto was our Chief Technical Officer from April 2001 to May 2007. Dr. Faupel has served as a National Institutes of Health reviewer, is the inventor on 26 U.S. patents and has authored numerous scientific publications and presentations, appearing in such peer-reviewed journals as *The Lancet*. Dr. Faupel earned his Ph.D. in neuroanatomy and physiology from the University of Georgia. Dr. Faupel is also a shareholder of Shenghuo Medical, LLC. See Item 13, Certain Relationships and Related Transactions and Director Independence

Rick Fowler, Senior Vice President of Engineering is an accomplished Executive with significant experience in the management of businesses that sell, market, produce and develop sophisticated medical devices and instrumentation. Mr. Fowler's 25 plus years of experience includes assembling and managing teams, leading businesses and negotiating contracts, conducting litigation, and developing ISO, CE, FDA QSR, GMP and GCP compliant processes and products. He is adept at providing product life cycle management through effective process definition and communication - from requirements gathering, R&D feasibility, product development, product launch, production startup and support. Mr. Fowler combines outstanding analytical, out-of-the-box, and strategic thinking with strong leadership, technical, and communication skills and he excels in dynamic, demanding environments while remaining pragmatic and focused. He is able to deliver high risk projects on time and under budget as well as enhance operational effectiveness through outstanding cross-functional team leadership (R&D, marketing, product development, operations, quality assurance, sales, service, and finance). In addition, Mr. Fowler is well versed in global medical device regulatory and product compliance requirements.

Richard P. Blumberg was appointed to the Board of Directors on November 10, 2016 and resigned on March 27, 2019. Mr. Blumberg has been a long-time investor in the Company. Since 1978, Mr. Blumberg has been a Principal at Webster, Mraz & Blumberg, a medical-legal and class action labor litigation firm. He is also currently the Managing Member of Elysian Medical, LLC, a company with world-wide rights for certain breast cancer detection technology. He served from 2004 to 2007 as Chief Executive Officer of Energy Logics, a wind power company that developed projects in Alberta, Canada and Montana. Mr. Blumberg holds a B.S. in Electrical Engineering and Computer Science from the University of Illinois and received a J. D. from Stanford University. He also brings extensive experience as a venture capitalist specializing in high-tech and life science companies. Mr. Blumberg is also a Managing Member of Shenghuo Medical, LLC. See Item 13, Certain Relationships and Related Transactions and Director Independence.

John E. Imhoff, M.D. has served as a member of our Board of Directors since April 2006. Dr. Imhoff is an ophthalmic surgeon who specializes in cataract and refractive surgery. He is one of our principal stockholders and invests in many other private and public companies. He has a B.S. in Industrial Engineering from Oklahoma State University, an M.D. from the University of Oklahoma and completed his ophthalmic residency at the Dean A. McGee Eye Institute. He has worked as an ophthalmic surgeon and owner of Southeast Eye Center since 1983.

Dr. Imhoff has experience in clinical trials and in other technical aspects of a medical device company. His background in industrial engineering is especially helpful to us, especially as Dr. Imhoff can combine this knowledge with clinical applications. His experience in the investment community is invaluable to a public company often undertaking capital raising efforts.

Michael C. James has served as a member of our Board of Directors since March 2007 and as Chairman of the Board since October 2013. Mr. James is also the Managing Partner of Kuekenhof Capital Management, LLC, a private investment management company, Chief Executive Officer and the Chief Financial Officer of Inergetics, Inc., a nutraceutical supplements company and also the Chief Financial Officer of Terra Tech Corporation, which is a hydroponic and agricultural company. He also holds the position of Managing Director of Kuekenhof Equity Fund, L.P. and Kuekenhof Partners, L.P. Mr. James currently sits on the Board of Directors of Inergetics; Inc. Mr. James was Chief Executive Officer of Nestor, Inc. from January 2009 to September 2009 and served on their Board of Directors from July 2006 to June 2009. He was employed by Moore Capital Management, Inc., a private investment management company from 1995 to 1999 and held position of Partner. He was employed by Buffalo Partners, L.P., a private investment management company from 1991 to 1994 and held the position of Chief Financial and Administrative Officer. He began his career in 1980 as a staff accountant with Eisner LLP. Mr. James received a B.S. degree in Accounting from Farleigh Dickinson University in 1980.

Mr. James has experience both in the areas of company finance and accounting, which is invaluable to us during financial audits and offerings. Mr. James has extensive experience in the management of both small and large companies and his entrepreneurial background is relevant as we develop as a company.

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Securities Exchange Act of 1934, as amended, requires our directors and executive officers and persons who beneficially own more than 10% of a registered class of our equity securities to file reports of ownership and reports of changes in ownership with the Securities and Exchange Commission. These persons are required by regulations of the Securities and Exchange Commission to furnish us with copies of all Section 16(a) forms they file.

Based solely on our review of the copies of these forms received by us, we believe that, with respect to fiscal year 2018, our officers, directors were in compliance with all applicable filing requirements.

Code of Ethics

We have adopted a code of ethics that applies to all of our directors, officers and employees. To obtain a copy without charge, contact our Corporate Secretary, Guided Therapeutics, Inc., 5835 Peachtree Corners East, Suite B, Norcross, Georgia 30092. If we amend our code of ethics, other than a technical, administrative or non-substantive amendment, or we grant any waiver, including any implicit waiver, from a provision of the code that applies to our principal executive officer, principal financial officer, principal accounting officer or controller, we will disclose the nature of the amendment or waiver on our website, www.guidedinc.com, under the "Investor Relations" tab under the tab "About Us." Also, we may elect to disclose the amendment or waiver in a report on Form 8-K filed with the Securities and Exchange Commission.

Material Changes to Security Holders Nomination Procedure

There has been no material change to the procedures by which security holders may recommend nominees to the registrant's board of directors, since the last disclosure.

Item 11. Executive Compensation

Summary Compensation Table

The following table lists specified compensation we paid or accrued during each of the fiscal years ended December 31, 2018 and 2017 to the Chief Executive Officer and our two other most highly compensated executive officers, collectively referred to as the "named executive officers," in 2018:

2018 and 2017 Summary Compensation Table

| Name and Principal Position | Year | Salary (\$) | Bonus (\$) | Option Awards (\$)(1) | Total (\$) |
|--|------|----------------|---------------|--------------------------|---------------|
| Gene S. Cartwright, Ph.D. President, CEO, Acting CFO and Director (2) | 2018 | - | - | - | - |
| | 2017 | - | - | - | - |
| Mark Faupel, Ph.D. COO and Director(3) | 2018 | - | - | - | - |
| | 2017 | - | - | - | - |
| Richard Fowler, Senior Vice President of Engineering | 2018 | 62,019 | - | - | 62,019 |
| | 2017 | 107,500 | - | - | 107,500 |

(1) See Note 4 to the audited consolidated financial statements that accompany this prospectus.

(2) All amounts reported as accrued. Dr. Cartwright has elected to get paid partial salary, due to our cash position.

(3) On December 8, 2016, the board of directors appointed Dr. Faupel as our new COO and director.

For 2018 and 2017, Dr. Cartwright did not receive salary compensation. As previously disclosed, on July 20, 2018, the Company entered into an exchange agreement and promissory note with Dr. Cartwright. The agreements were entered into in order to extinguish and restructure current amounts owed to Dr. Cartwright. In the exchange agreement Dr. Cartwright, agreed to exchange outstanding amounts due to him for loans, interest, bonus, salary and vacation pay in the amount of \$1,621,499 for \$319,204 promissory note. Pursuant to the exchange agreement the note will bear interest at 6%. In addition, Dr. Cartwright will receive 125 stock options, with 31 vesting immediately and the remaining vesting monthly over three years. As a result of the exchange agreement, the Company recorded a gain for extinguishment of debt of \$840,391 and a capital contribution of \$431,519. As of December 31, 2018, Dr. Cartwright's total undiscounted cash flow amount due was approximately \$349,590 including interest. The schedule below summarizes the detail of outstanding amounts:

For Dr. Cartwright:

| | 2018 |
|---|-----------------|
| Salary | \$ 337 |
| Bonus | 675 |
| Vacation | - |
| Interest on compensation | 59 |
| Loans to Company | 528 |
| Interest on loans | 22 |
| Total outstanding | \$ 1,621 |
| Amount forgiven | 1,302 |
| Promissory note issued in exchange | 319 |

Dr. Faupel's 2018 and 2017 compensation consisted of a base salary of zero and \$132,577, respectively, plus usual and customary company benefits. He received no bonus in the years ended December 31, 2018 and 2017. As previously disclosed, on July 24, 2018, the Company entered into an exchange agreement and promissory note with Dr. Faupel. The agreements were entered into in order to extinguish and restructure current amounts owed to Dr. Faupel. In the exchange agreement Dr. Faupel, agreed to exchange outstanding amounts due to him for loans, interest, bonus, salary and vacation pay in the amount of \$660,895 for \$207,111 promissory note. Pursuant to the exchange agreement the note will bear interest at 6%. In addition, Dr. Faupel will receive 94 stock options, with 31 vesting immediately and the remaining vesting monthly over three years. Dr. Faupel will also receive 560 options at \$200.00 shall owe Dr. Faupel \$113,000. As a result of the exchange agreement, the Company recorded a gain for extinguishment of debt of \$199,079 and a capital contribution of \$234,990. As of December 31, 2018, Dr. Faupel's total undiscounted cash flow amount due was approximately \$256,825 including interest. The schedule below summarizes the detail of outstanding amounts:

For Dr. Faupel:

| | 2018 |
|---|---------------|
| Salary | \$ 134 |
| Bonus | 20 |
| Vacation | 95 |
| Interest on compensation | 67 |
| Loans to Company | 196 |
| Interest on loans | 149 |
| Total outstanding | \$ 661 |
| Amount forgiven | 454 |
| Promissory note issued in exchange | 207 |

For 2018, Mr. Fowler accrued base salary of \$62,019. On March 2016, Mr. Fowler began working half-time and agreed to reduce his base salary compensation to \$107,500 from \$215,000 in 2015. For both years he received the usual and customary company benefits. He received no bonus in the years ended December 31, 2018 and 2017. In 2015, he received options to purchase 2 shares of common stock, which vest over 48 months. As of December 31, 2018, Mr. Fowler's total deferred salary plus interest was approximately \$496,631.

Outstanding Equity Awards to Officers at December 31, 2018

| Name and Principal Position | Number of Securities Underlying Options Exercisable #(1) | Number of Securities Underlying Options Unexercisable (#) | Option Awards | | |
|--|--|---|--|-----------------------------|------------------------|
| | | | Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options (#) | Option Exercise Price \$(2) | Option Expiration Date |
| Gene S. Cartwright, Ph.D. President, CEO, Acting CFO and Director | 2 | - | 2 | 22,688,000 | 12/31/2024 |
| Mark Faupel, Ph.D. COO and Director | 12 | - | 2 | 48,581,000 | 12/31/2024 |
| Richard Fowler Senior Vice President of Engineering | 5 | - | 2 | 39,987,000 | 12/31/2024 |

- (1) Represents fully vested options.
(2) Based on all outstanding options.

Outstanding Equity Awards to Directors at December 31, 2018

| Name and Principal Position | Option Awards | |
|--|-------------------|---------------------|
| | Option Awards (#) | Exercise Price (\$) |
| Ronald W. Hart, Ph.D., Director (resigned as of December 11, 2015) | 6 | 45,013,000 |
| John E. Imhoff, M.D., Director | 7 | 45,714,000 |
| Michael C. James, Chairman and Director | 6 | 45,013,000 |

Risk Oversight

Our board as a whole has responsibility for risk oversight, with reviews of certain areas being conducted by the relevant board committees that report on their deliberations to the full board, as further described below. Given the small size of the board, the board feels that this structure for risk oversight is appropriate (except for those risks that require risk oversight by independent directors only). The audit committee is specifically charged with discussing risk management (primarily financial and internal control risk), and receives regular reports from management and independent auditors on risks related to, among others, our financial controls and reporting. The compensation committee reviews risks related to compensation and makes recommendations to the board with respect to whether the Company's compensation policies are properly aligned to discourage inappropriate risk-taking, and is regularly advised by management. In addition, the Company's management regularly communicates with the board to discuss important risks for their review and oversight, including regulatory risk, and risks stemming from periodic litigation or other legal matters in which we are involved.

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

The following table lists information regarding the beneficial ownership of our equity securities as of April 15, 2019 by (1) each person whom we know to beneficially own more than 5% of the outstanding shares of our common stock, (2) each director, (3) each officer named in the summary compensation table below, and (4) all directors and executive officers as a group. Unless otherwise indicated, the address of each officer and director is 5835 Peachtree Corners East, Suite B, Norcross, Georgia 30092.

| Name and Address of Beneficial Owner (1) | Common Stock (2) | | Series C Preferred Stock (3) | | Series C1 Preferred Stock (4) | | Series C2 Preferred Stock (5) | |
|--|------------------|------------|------------------------------|------------|-------------------------------|------------|-------------------------------|------------|
| | Number of Shares | Percentage | Number of Shares | Percentage | Number of Shares | Percentage | Number of Shares | Percentage |
| John E. Imhoff (6) | 1,177,187 | 26.18% | - | - | - | - | 2,400.75 | 73.57% |
| Lynne Imhoff (7) | 321,562 | 8.83% | - | - | 675.00 | 64.33% | - | - |
| Michael C. James/Kuekenhof Equity Fund, LLP (8) | 12 | * | - | - | - | - | - | - |
| Gene Cartwright (9) | 93 | * | - | - | - | - | - | - |
| Richard L. Fowler (10) | 5 | * | - | - | - | - | - | - |
| Richard P. Blumberg (11) | 2,771 | * | - | - | - | - | - | - |
| Mark L. Faupel (12) | 141,950 | 4.10% | - | - | - | - | 300.00 | 9.19% |
| All directors and executive officers as a group (4 persons) (13) | 1,322,025 | 28.48% | - | - | - | - | 2,700.75 | 82.77% |

(*) Less than 1%.

- (1) Except as otherwise indicated in the footnotes to this table and pursuant to applicable community property laws, the persons named in the table have sole voting and investment power with respect to all shares of common stock.
- (2) Percentage ownership is based on 3,319,486 shares of common stock outstanding as of April 15, 2019. Beneficial ownership is determined in accordance with the rules of the SEC, based on factors that include voting and investment power with respect to shares. Shares of common stock subject to convertible securities convertible or exercisable within 60 days after the record date, are deemed outstanding for purposes of computing the percentage ownership of the person holding those securities but are not deemed outstanding for purposes of computing the percentage ownership of any other person. Note that certain of our outstanding securities, including certain warrants and the shares of Series C1 preferred stock held by the persons listed in this table, have anti-dilution "ratchet" or "price-protection" provisions that, when triggered, will increase the number of shares of common stock underlying such securities. Subject to customary exceptions, these provisions are triggered anytime we issue shares of common stock to third parties at a price lower than the then-current conversion price or exercise price of the subject securities. As a result, the beneficial ownership reported in this table is only as of the date presented, and the beneficial ownership amounts of the persons in this table may increase on a future date, even though such persons have not actually acquired any additional shares of common stock.
- (3) As of April 15, 2019, there were 286 shares of Series C preferred stock outstanding, and each such share was convertible into approximately 476 shares of common stock.
- (4) As of April 15, 2019, there were 1,049.25 shares of Series C1 preferred stock outstanding, and each such share was convertible into approximately 476 shares of common stock. Three shareholders elected to convert 3,263.00 of their Series C1 preferred stock for Series C2 preferred stock.
- (5) As of April 15, 2019, there were 3,262.25 shares of Series C2 preferred stock outstanding, and each such share was convertible into approximately 476 shares of common stock.
- (6) Shares of common stock consist of 17 shares of common stock directly held, 33,513 shares issuable upon exercise of warrants, 7 shares subject to options, and 1,143,650 shares issuable upon conversion of 2,400.75 shares of Series C2 preferred stock. Dr. Imhoff is on the board of directors.
- (7) Shares of common stock consist of 5 shares of common stock directly held, 6 shares issuable upon exercise of warrants, and 321,551 shares issuable upon conversion of 675.00 shares of Series C1 preferred stock.
- (8) Shares of commons stock consist of 1 shares of common stock directly held, 5 shares issuable upon exercise of warrants, and 6 shares subject to options. Mr. James is on the board of directors.
- (9) Shares of commons stock consist of 1 shares of common stock directly held, 90 shares issuable upon exercise of warrants, and 2 shares subject to options. Dr. Cartwright is the CEO and on the board of directors.
- (10) Shares of commons stock consist of 1 shares of common stock directly held and 4 shares subject to options.
- (11) Shares of common stock consist of 2 shares of common stock directly held and 2,769 shares issuable upon exercise of warrants. Mr. Blumberg was on the board of directors.
- (12) Shares of common stock consist of 2 shares of common stock directly held, 17 shares issuable upon exercise of warrants, 12 shares subject to options, and 141,919 shares issuable upon conversion of 300.00 shares of Series C2 preferred stock. Dr. Faupel is the COO and on the board of directors.
- (13) Shares of commons stock consists of 24 shares of common stock directly held, 36,381 shares issuable upon exercise of warrants, 31 shares subject to options, and 1,285,569 shares issuable upon conversion of 2,700.75 shares of Series C2 preferred stock.

See Item 5 of this report for information regarding Securities Authorized for Issuance under Equity Compensation Plans.

Item 13. Certain Relationships and Related Transactions and Director Independence

Our board recognizes that related person transactions present a heightened risk of conflicts of interest. The audit committee has the authority to review and approve all related party transactions involving our directors or executive officers.

Under the policy, when management becomes aware of a related person transaction, management reports the transaction to the audit committee and requests approval or ratification of the transaction. Generally, the audit committee will approve only related party transactions that are on terms comparable to those that could be obtained in arm's length dealings with an unrelated third person. The audit committee will report to the full board all related person transactions presented to it. Based on the definition of independence of the NASDAQ Stock Market, the board has determined that Mr. James and Dr. Imhoff are independent directors.

John E. Imhoff is one of our directors. In June 2015, Dr. Imhoff agreed to exchange certain of his warrants, originally issued in December 2014 and exercisable for 1 share of our common stock, for two new warrants that, unlike the original warrant, do not contain any price or share reset provisions. Each new warrant is exercisable for the same number of shares of our common stock as the original warrant, at any time until December 2, 2020. The exercise price of the first new warrant is \$57,600 per share and the second new warrant is \$70,400 per share but, aside from the exercise price, the new warrants are identical in terms to each other. As additional consideration, we issued Dr. Imhoff an additional 1 share of common stock. Dr. Imhoff participated on terms equal to those of other holders of the December 2014 warrants. As a result of these transactions, Dr. Imhoff's beneficial ownership of our common stock increased from approximately 11.7% immediately prior to the exchange, to approximately 11.8% immediately afterward.

In September 2015, Dr. Imhoff participated in our Series C preferred stock issuance by exchanging all of his shares of Series B preferred stock and investing \$300,000 in cash, for a total of 1,067 shares of Series C preferred stock and warrants to purchase 211 shares of common stock. Dr. Imhoff participated on terms equal to those of other Series C investors. As a result of these transactions, Dr. Imhoff's beneficial ownership of our common stock increased from approximately 14% immediately prior to his first acquisition of shares of Series C preferred stock, to 25% immediately afterward.

On March 11, 2016, Dr. Imhoff received 1 share of common stock as a dividend on his Series B preferred stock (previously accrued but unpaid), in accordance with the terms of the Series B preferred stock.

In April 2016, Dr. Imhoff exchanged his shares of Series C preferred stock for a total of 2,400.75 shares of Series C1 preferred stock and 16 shares of common stock. Dr. Imhoff participated on terms equal to those of other Series C1 investors. As a result of this transaction, Dr. Imhoff's beneficial ownership of our common stock increased from approximately 25% immediately prior to the transaction, to 77% immediately afterward.

In June 2016, Dr. Imhoff agreed to exchange certain of his warrants, exercisable for 6 shares of our common stock and subject to certain anti-dilution provisions, in exchange for new warrants, exercisable for 11 shares of our common stock, but without those anti-dilution provisions. Dr. Imhoff will be required to surrender his old warrants upon consummation of our next financing resulting in net cash proceeds to us of at least \$1 million. The new warrants will have an initial exercise price equal to the exercise price of the surrendered warrants as of immediately prior to consummation of the financing, subject to customary "downside price protection" for as long as our common stock is not listed on a national securities exchange, and will expire five years from the date of issuance.

On September 6, 2016, we entered into a royalty agreement with Dr. Imhoff and another party. Pursuant to the royalty agreement, in exchange for a payment of \$50,000 by Dr. Imhoff and the other party, we granted them a royalty on future sales of our single-use cervical guides. The royalty rate was initially \$0.10 per disposable, until October 2, 2016, at which point the royalty rate increased to \$0.20 per disposable. Any royalty payments will be split evenly between Dr. Imhoff and the other party.

Lynne Imhoff (no relation) currently beneficially owns in excess of 10% of our outstanding common stock. In September 2015, Ms. Imhoff participated in our Series C preferred stock issuance by exchanging all of her shares of Series B preferred stock and investing \$125,000 in cash, for a total of 300 shares of Series C preferred stock and warrants to purchase 1 shares of common stock. Ms. Imhoff participated on terms equal to those of other Series C investors. As a result of these transactions, Ms. Imhoff's beneficial ownership of our common stock increased from approximately 2% immediately prior to her first acquisition of shares of Series C preferred stock, to 4% immediately afterward.

In April 2016, Ms. Imhoff exchanged her shares of Series C preferred stock for a total of 675 shares of Series C1 preferred stock and 5 shares of common stock. Ms. Imhoff participated on terms equal to those of other Series C1 investors. As a result of this transaction, Ms. Imhoff's beneficial ownership of our common stock increased from approximately 4% immediately prior to the transaction, to 45% immediately afterward.

In June 2016, Ms. Imhoff agreed to exchange certain of her warrants, exercisable for 1 share of our common stock and subject to certain anti-dilution provisions, in exchange for new warrants, exercisable for 2 shares of our common stock, but without those anti-dilution provisions. Ms. Imhoff will be required to surrender her old warrants upon consummation of our next financing resulting in net cash proceeds to us of at least \$1 million. The new warrants will have an initial exercise price equal to the exercise price of the surrendered warrants as of immediately prior to consummation of the financing, subject to customary "downside price protection" for as long as our common stock is not listed on a national securities exchange, and will expire five years from the date of issuance.

Mark Faupel is one of our directors and our Chief Operating Officer, and Richard Blumberg is another one of our directors. Dr. Faupel is a shareholder of Shenghuo, and Mr. Blumberg, is a managing member of Shenghuo. We entered into a license agreement with Shenghuo pursuant to which we granted Shenghuo an exclusive license to manufacture, sell and distribute our LuViva Advanced Cervical Cancer device and related disposables in Taiwan, Brunei Darussalam, Cambodia, Laos, Myanmar, Philippines, Singapore, Thailand, and Vietnam. Shenghuo has been our exclusive distributor in China, Macau and Hong Kong, and the license extends to manufacturing in those countries as well. Pursuant to the license agreement, Shenghuo had the option to have a designee appointed to our board of directors. As partial consideration for, and as a condition to, the license, and to further align the strategic interests of the parties, we agreed to issue a convertible note to Shenghuo, in exchange for an aggregate cash investment of \$200,000. The note will provide for a payment to Shenghuo of \$300,000, expected to be due the earlier of 90 days from issuance and consummation of any capital raising transaction by us with net cash proceeds of at least \$1.0 million. The note will accrue interest at 20% per year on any unpaid amounts due after that date. The note will be convertible into shares of our common stock at a conversion price per share of \$11,136, subject to customary anti-dilution adjustment. The note will be unsecured, and is expected to provide for customary events of default. We will also issue Shenghuo a five-year warrant exercisable immediately for 22 shares of common stock at an exercise price equal to the conversion price of the note, subject to customary anti-dilution adjustment. As of December 31, 2018, the balance was \$432,000.

In September 2015, Dr. Faupel participated in our Series C preferred stock issuance by investing \$100,000 in cash, for a total of 133 shares of Series C preferred stock and warrants to purchase 1 share of common stock. Dr. Faupel participated on terms equal to those of other Series C investors. In April 2016, Dr. Faupel exchanged his shares of Series C preferred stock for a total of 300 shares of Series C1 preferred stock and 2 shares of common stock. Dr. Faupel participated on terms equal to those of other Series C1 investors.

Item 14. Principal Accountant Fees and Services

UHY LLP is our current independent registered public accounting firm. Representatives of UHY LLP are expected to attend the annual meeting of stockholders, will have the opportunity to make a statement if they desire, and will be available to respond to appropriate questions.

We were billed by UHY LLP \$168,405 and \$147,000 during the fiscal years ended December 31, 2018 and 2017, respectively, for professional services, which include fees associated with the annual audit of financial statements and review of our quarterly reports on Form 10-Q, and other SEC filings.

| | 2018 | 2017 |
|--------------------|-------------------|-------------------|
| Audit fees | \$ 150,000 | \$ 116,000 |
| Audit related fees | 12,500 | 24,000 |
| Tax fees | 5,905 | 7,000 |
| Total Fees | <u>\$ 168,405</u> | <u>\$ 147,000</u> |

Audit Committee Pre-Approval Policy and Permissible Non-Audit Services of Independent Registered Public Accounting Firm

Our Audit Committee pre-approves all audit and permissible non-audit services provided by our independent registered public accounting firm. These services may include audit services, audit-related services, tax services and other services. Pre-approval is generally provided for up to one year, and any pre-approval is detailed as to the particular service or category of services and is generally subject to a specific budget. Our independent registered public accounting firm and management are required to periodically report to the Audit Committee regarding the extent of services provided by the independent registered public accounting firm in accordance with the pre-approval, and the fees for the services performed to date. The Audit Committee may also pre-approve particular services on a case-by-case basis.

PART IV

Item 15. Exhibits and Financial Statement Schedules

The consolidated financial statements included in Item 8 of this report are filed as part of this report.

The exhibits listed below are filed as part hereof, or incorporated by reference into, this Report. All documents referenced below were filed pursuant to the Securities and Exchange Act of 1934 by Guided Therapeutics, Inc. (f/k/a SpectRx, Inc.), file number 0-22179, unless otherwise indicated.

EXHIBIT INDEX

| EXHIBIT NO. | DESCRIPTION |
|----------------------|--|
| 3.1 | Restated Certificate of Incorporation, as amended through November 3, 2016 |
| 3.2 | Amended and Restated Bylaws (incorporated by reference to Exhibit 3.1 to the current report on Form 8-K, filed March 23, 2012) |
| 4.1 | Specimen Common Stock Certificate (incorporated by reference to Exhibit 4.1 to the amended registration statement on Form S-1/A (No. 333-22429) filed April 24, 1997) |
| 4.2 | Secured Promissory Note, dated September 10, 2014 (incorporated by reference to Exhibit 4.1 to the current report on Form 8-K filed September 10, 2014) |
| 4.3 | Amendment #1 to Secured Promissory Note, dated March 10, 2015 (incorporated by reference to Exhibit 10.1 to the current report on Form 8-K filed March 19, 2015) |
| 4.4 | Amendment #2 to Secured Promissory Note, dated May 4, 2015 (incorporated by reference to Exhibit 10.1 to the current report on Form 8-K filed May 7, 2015) |
| 4.5 | Amendment #3 to Secured Promissory Note, dated June 1, 2015 (incorporated by reference to Exhibit 10.1 to the current report on Form 8-K filed June 5, 2015) |
| 4.6 | Amendment #4 to Secured Promissory Note, dated June 16, 2015 (incorporated by reference to Exhibit 10.4 to the current report on Form 8-K filed June 30, 2015) |
| 4.7 | Amendment #5 to Secured Promissory Note, dated June 29, 2015 (incorporated by reference to Exhibit 10.5 to the current report on Form 8-K filed June 30, 2015) |
| 4.8 | Amendment #6 to Secured Promissory Note, dated January 20, 2016 (incorporated by reference to Exhibit 10.1 to the current report on Form 8-K filed February 16, 2016) |
| 4.9 | Amendment #7 to Secured Promissory Note, dated February 11, 2016 (incorporated by reference to Exhibit 10.2 to the current report on Form 8-K filed February 16, 2016) |
| 4.10 | Amendment #8 to Secured Promissory Note, dated March 7, 2016 (incorporated by reference to Exhibit 10.1 to the current report on Form 8-K filed March 7, 2016) |
| 4.11 | Senior Secured Convertible Note, dated February 12, 2016 (incorporated by reference to Exhibit 4.1 to the current report on Form 8-K filed February 12, 2016) |
| 4.12 | Form of Exchange Note (GPB) (incorporated by reference to Exhibit 4.1 to the current report on Form 8-K filed December 7, 2016) |
| 4.13 | 10% OID Convertible Promissory Note (incorporated by reference to Exhibit 4.1 to the current report on Form 8-K filed December 30, 2016) |
| 4.14 | Convertible Promissory Note (incorporated by reference to Exhibit 4.1 to the current report on Form 8-K filed February 16, 2017) |
| 4.15 | Form of Warrant (Standard Form) (incorporated by reference to Exhibit 4.1 to the current report on Form 8-K, filed September 14, 2010) |
| 4.16 | Form of Warrant (InterScan) (incorporated by reference to Exhibit 4.13 to the annual report on Form 10-K for the year ended December 31, 2013, filed March 27, 2014) |
| 4.17 | Form of Warrant (November 2011 Private Placement) (incorporated by reference to Exhibit 4.1 to the current report on Form 8-K/A, filed November 28, 2011) |
| 4.18 | Form of Warrant (Series B-Tranche A) (incorporated by reference to Exhibit 10.2 to amendment no. 1 to the current report on Form 8-K, filed May 23, 2013) |
| 4.19 | Form of Warrant (Series B-Tranche B) (incorporated by reference to Exhibit 10.3 to amendment no. 1 to the current report on Form 8-K, filed May 23, 2013) |

| | |
|-----------------------|---|
| 4.20 | Form of Warrant (Regulation S) (incorporated by reference to Exhibit 4.1 to the current report on Form 8-K, filed September 8, 2014) |
| 4.21 | Form of Warrant (2014 Public Offering Placement Agent) (incorporated by reference to Exhibit 4.2 to the current report on Form 8-K filed December 4, 2014) |
| 4.22 | Form of Warrant (2014 Public Offering Warrant Exchanges) (incorporated by reference to Exhibit 4.1 to the current report on Form 8-K filed June 30, 2015) |
| 4.23 | Form of Warrant (Series C) (incorporated by reference to Exhibit 4.3 to the current report on Form 8-K filed June 30, 2015) |
| 4.24 | Form of Warrant (Senior Secured Convertible Note) (incorporated by reference to Exhibit 10.5 to the current report on Form 8-K filed February 12, 2016) |
| 4.25 | Form of Warrant (Series B-Tranche B Exchanges; GPB Exchange) (incorporated by reference to Exhibit 4.1 to the current report on Form 8-K filed June 14, 2016) |
| 4.26 | Common Stock Purchase Warrant (Convertible Promissory Note) (incorporated by reference to Exhibit 4.2 to the current report on Form 8-K filed February 16, 2017) |
| 10.1 | 1995 Stock Plan and form of Stock Option Agreement (incorporated by reference to Exhibit 10.2 to the registration statement on Form S-1 (No. 333-22429) filed February 27, 1997) |
| 10.2 | 2005 Amendment to 1995 Stock Plan (incorporated by reference to Appendix 1 to the proxy statement on Schedule 14A, filed May 10, 2005) |
| 10.3 | 2010 Amendment to 1995 Stock Plan (incorporated by reference to Exhibit 10.3 to the registration statement on Form S-8 (File No. 333-178261), filed December 1, 2011) |
| 10.4 | 2012 Amendment to 1995 Stock Plan (incorporated by reference to Annex 1 to the proxy statement on Schedule 14A, filed April 30, 2012) |
| 10.5 | Agreement and Release, dated August 30, 2011 (incorporated by reference to 10.2 to the current report on Form 8-K, filed September 2, 2011) |
| 10.6 | Employment Agreement between the Company and Mark Faupel dated March 24, 2013 (incorporated by reference to Exhibit 10.10 to the annual report on Form 10-K for the year ended December 31, 2013, filed March 27, 2014) |
| 10.7 | Employment Agreement between the Company and Gene Cartwright, dated January 6, 2014 (incorporated by reference to Exhibit 10.11 to the annual report on Form 10-K for the year ended December 31, 2013, filed March 27, 2014). |
| 10.8 | Employment Agreement between the Company and Rick L. Fowler, automatically renewed on May 9, 2013 (incorporated by reference to Exhibit 10.12 to the annual report on Form 10-K for the year ended December 31, 2013, filed March 27, 2014) |
| 10.9 | Consulting Agreement between the Company and GPB Debt Holdings II LLC, dated February 12, 2016 (incorporated by reference to Exhibit 10.6 to the current report on Form 8-K filed February 12, 2016) |
| 10.10 | Securities Purchase Agreement (Magna Note), dated April 23, 2014, by and between the Company and Hanover Holdings I, LLC (incorporated by reference to Exhibit 10.1 to the current report on Form 8-K, filed April 24, 2014). |
| 10.11 | Registration Rights Agreement (Magna Note), dated April 23, 2014, by and between the Company and Hanover Holdings I, LLC (incorporated by reference to Exhibit 10.2 to the current report on Form 8-K, filed April 24, 2014) |
| 10.12 | Standstill Agreement (Magna Note), dated as of November 6, 2014, by and between the Company and Magna Equities II, LLC (incorporated by reference to Exhibit 19 to the registration statement on Form S-1 (No. 333-198733) filed November 10, 2014) |
| 10.13 | Exchange Agreement (Magna Note), dated as of June 25, 2015 (incorporated by reference to Exhibit 10.3 to the current report on Form 8-K filed June 30, 2015) |
| 10.14 | Subscription Agreement (Regulation S), accepted September 2, 2014 (incorporated by reference to Exhibit 10.1 to the current report on Form 8-K, filed September 8, 2014) |
| 10.15 | Form of Registration Rights Agreement (Regulation S), dated September 8, 2014 by and between the Company and the investor party thereto (incorporated by reference to Exhibit 10.2 to the current report on Form 8-K, filed September 8, 2014) |
| 10.16 | Note Purchase Agreement (Secured Promissory Note), dated as of September 10, 2014, by and between the Company and Tonaquint, Inc. (incorporated by reference to Exhibit 10.1 to the current report on Form 8-K, filed September 10, 2014) |

- [10.17](#) Security Agreement (Secured Promissory Note), dated as of September 10, 2014, by the Company and Tonaquint, Inc. (incorporated by reference to Exhibit 10.2 to the current report on Form 8-K, filed September 10, 2014)
- [10.18](#) Form of Securities Purchase Agreement (2014 Public Offering) (incorporated by reference to Exhibit 10.1 to the current report on Form 8-K filed December 4, 2014)
- [10.19](#) Placement Agent Agreement (2014 Public Offering), by and between the Company and Olympus Securities, LLC (incorporated by reference to Exhibit 10.2 to the current report on Form 8-K filed December 4, 2014)
- [10.20](#) Amendment to Securities Purchase Agreement (2014 Public Offering), dated as of June 26, 2015 (incorporated by reference to Exhibit 10.2 to the current report on Form 8-K filed June 30, 2015)
- [10.21](#) Form of Letter Agreement (2014 Public Offering Warrant Exchanges) (incorporated by reference to Exhibit 10.1 to the current report on Form 8-K filed June 30, 2015)
- [10.22](#) Securities Purchase Agreement (Series C), dated June 29, 2015 (incorporated by reference to Exhibit 10.6 to the current report on Form 8-K filed June 30, 2015)
- [10.23](#) Registration Rights Agreement (Series C), dated June 29, 2015 (incorporated by reference to Exhibit 10.7 to the current report on Form 8-K filed June 30, 2015)
- [10.24](#) Form of Joinder Agreement (Series C) (incorporated by reference to Exhibit 10.1 to the current report on Form 8-K filed July 13, 2015)
- [10.25](#) Interim Securities Purchase Agreement (Series C), dated September 3, 2015 (incorporated by reference to Exhibit 10.1 to the current report on Form 8-K filed September 3, 2015)
- [10.26](#) Securities Purchase Agreement (Senior Secured Convertible Note), dated February 11, 2016 (incorporated by reference to Exhibit 10.3 to the current report on Form 8-K filed February 12, 2016)
- [10.27](#) Security Agreement (Senior Secured Convertible Note), dated February 11, 2016 (incorporated by reference to Exhibit 10.4 to the current report on Form 8-K filed February 12, 2016)
- [10.28](#) Rollover and Amendment Agreement, dated April 27, 2016, by and between the Company and Aquarius Opportunity Fund (incorporated by reference to Exhibit 10.2 to the current report on Form 8-K filed May 3, 2016)
- [10.29](#) Form of Letter Agreement (Series C Exchanges) (incorporated by reference to Exhibit 10.1 to the current report on Form 8-K filed May 3, 2016)
- [10.30](#) License Agreement, dated June 5, 2016 (incorporated by reference to Exhibit 10.1 to the current report on Form 8-K filed June 8, 2016)
- [10.31](#) Form of Warrant Exchange Agreement (Warrant-for-Shares) (incorporated by reference to Exhibit 10.1 to the current report on Form 8-K filed June 14, 2016)
- [10.32](#) Form of Warrant Exchange Agreement (Warrant-for-Warrant) (incorporated by reference to Exhibit 10.2 to the current report on Form 8-K filed June 14, 2016)
- [10.33](#) Royalty Agreement, dated September 6, 2016, between the Company and Imhoff and Maloof (incorporated by reference to Exhibit 10.1 to the current report on Form 8-K filed September 8, 2016)
- [10.34](#) Lockup and Exchange Agreement, dated November 2, 2016, by the Company and GHS Investments, LLC (incorporated by reference to Exhibit 10.1 to the current report on Form 8-K filed November 2, 2016)
- [10.35](#) Exchange Agreement, dated December 7, 2016, between the Company and GPB Debt Holdings II LLC (incorporated by reference to Exhibit 10.1 to the current report on Form 8-K filed December 7, 2016)
- [10.36](#) Amendment to Consulting Agreement, dated December 7, 2016, between the Company and GPB Debt Holdings II LLC (incorporated by reference to Exhibit 10.2 to the current report on Form 8-K filed December 7, 2016)
- [10.37](#) Securities Purchase Agreement, dated December 28, 2016, between the Company and RedDiamond (incorporated by reference to Exhibit 10.1 to the current report on Form 8-K filed December 30, 2016)
- [10.38](#) Agreement between Shandong Yaohua Medical Instrument Corporation and Guided Therapeutics, Inc., Confidential, Final 22 January 2017 (incorporated by reference to Exhibit 10.1 to the current report on Form 8-K filed January 26, 2017)
- [10.39](#) Guided Therapeutics-Shenghuo Medical Agreement, 22 Jan 2017 (incorporated by reference to Exhibit 10.2 to the current report on Form 8-K filed January 26, 2017)
- [10.40](#) Securities Purchase Agreement, dated as of February 13, 2017, by and between Guided Therapeutics, Inc. and Auctus Fund, LLC (incorporated by reference to Exhibit 10.2 to the current report on Form 8-K filed February 16, 2017)

| | |
|------------------------|--|
| 10.41 | Securities Purchase Agreement, dated as of March 17, 2017, by and between Guided Therapeutics, Inc. and Eagle Equities LLC and Adar Bays LLC and on May 18, 2017 with GHS Investments LLC (incorporated by reference to Exhibit 10.2 to the current report on Form 8-K filed May 24, 2017) |
| 10.42 | Forbearance Agreement, dated as of August 8, 2017, by and between Guided Therapeutics, Inc. and GPB Debt Holdings II LLC (incorporated by reference to Exhibit 10.2 to the current report on Form 8-K filed August 14, 2017) |
| 10.43 | Securities Purchase Agreement, dated as of August 18, 2017, by and between Guided Therapeutics, Inc. and Power Up Lending Group LTD (incorporated by reference to Exhibit 10.2 to the current report on Form 8-K filed August 24, 2017) |
| 10.44 | Securities Purchase Agreement, dated as of October 12, 2017, by and between Guided Therapeutics, Inc. and Power Up Lending Group LTD (incorporated by reference to Exhibit 10.2 to the current report on Form 8-K filed October 25, 2017) |
| 21.1 | Subsidiaries (incorporated by reference to Exhibit 21.1 to the registration statement on Form S-1 (No. 333-169755) filed October 5, 2010) |
| 23.1* | Consent of UHY LLP |
| 101.1* | Interactive Data File |

*Filed herewith

Item 16. Form 10-K Summary

None.

SIGNATURES

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

GUIDED THERAPEUTICS, INC.

Date: May 8, 2019

By: /s/ Gene S. Cartwright

Gene S. Cartwright
*President, Chief Executive Officer and Acting
Chief Financial Officer*

In accordance with the Exchange Act, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

| <u>DATE</u> | <u>SIGNATURE</u> | <u>TITLE</u> |
|-------------|---|---|
| May 8, 2019 | <u>/s/ Gene S. Cartwright</u> Gene S. Cartwright | President, Chief Executive Officer, Acting Chief Financial Officer (Principal Executive Officer and Principal Financial and Accounting Officer) |
| May 8, 2019 | <u>/s/ Michael C. James</u> Michael C. James | Chairman of the Board and Director |
| May 8, 2019 | <u>/s/ John E. Imhoff</u> John E. Imhoff | Director |
| May 8, 2019 | <u>/s/ Mark Faupel</u> Mark Faupel | Chief Operating Officer and Director |



CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Forms S-8 (No. 333-63758, 333-81326, 333-128082, 333-178261 and 333-183312) of Guided Therapeutics, Inc. and Subsidiary of our report dated May 8, 2019, relating to the consolidated financial statements, which appears in this Form 10-K for the year ended December 31, 2018.

Uhy LLP

Sterling Heights, Michigan
May 8, 2019

Rule 13a-14(a)/15(d)-14(a) Certifications

I, Gene Cartwright, certify that:

1. I have reviewed this annual report on Form 10-K of Guided Therapeutics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting.
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ Gene Cartwright
Gene Cartwright, President, Chief Executive Officer and
Acting Chief Financial Officer

Date: May 8, 2019
