

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549**

FORM 10-K

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

For the fiscal year ended November 30, 2018

or

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

For the Transition Period from _____ to _____

Commission File Number: **000-55535**

Q BIOMED INC.

(Exact name of registrant specified in its charter)

Nevada

(State or Other Jurisdiction of Incorporation or Organization)

46-4013793

(I.R.S. Employer Identification No.)

**c/o Ortol Rosenstadt LLP
366 Madison Avenue, 3rd Floor
New York, NY 10017**

(Address of Principal Executive Offices)

Registrant's telephone number, including area code: **(212) 588-0022**

Securities Registered Pursuant to Section 12(b) of the Exchange Act:

Title of Each Class	Name of Exchange on which Registered
None	None

Securities Registered Pursuant to Section 12(g) of the Act: Common Stock

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 Exchange 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 every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit 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 the registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

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

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 Exchange Act). Yes No

The aggregate market value of the voting and non-voting common equity held by non-affiliates computed by reference to the most recent price at which the common equity was sold as of the last business day of the registrant's most recently completed second fiscal quarter: \$34,809,642 as of May 31, 2018.

As of February 26, 2019 there were 14,466,155 shares of the registrant's common stock, \$0.001 par value, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

None.

FORWARD LOOKING STATEMENTS

This annual report contains forward-looking statements that involve risks and uncertainties. Any statements contained herein that are not statements of historical fact may be deemed to be forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as “may”, “will”, “should”, “expect”, “plan”, “intend”, “anticipate”, “believe”, “estimate”, “predict”, “potential” or “continue”, the negative of such terms or other comparable terminology. In evaluating these statements, you should consider various factors, including the assumptions, risks and uncertainties outlined in this annual report. Any of these items may cause our actual results to differ materially from any forward-looking statement made in this annual report. Forward-looking statements in this annual report include, among others, statements regarding our capital needs, business plans and expectations.

While these forward-looking statements, and any assumptions upon which they are based, are made in good faith and reflect our current judgment regarding future events, our actual results will likely vary, sometimes materially, from any estimates, predictions, projections, assumptions or other future performance suggested herein. Some of the risks and assumptions include:

- our need for additional financing;
- our limited operating history;
- our history of operating losses;
- our lack of insurance coverage;
- the competitive environment in which we operate;
- changes in governmental regulation and administrative practices;
- our dependence on key personnel;
- conflicts of interest of our directors and officers;
- our ability to fully implement our business plan;
- our ability to effectively manage our growth; and
- other regulatory, legislative and judicial developments.

We advise the reader that these cautionary remarks expressly qualify in their entirety all forward-looking statements attributable to us or persons acting on our behalf. The forward-looking statements in this annual report are made as of the date of this annual report and we do not intend or undertake to update any of the forward-looking statements to conform these statements to actual results, except as required by applicable law, including the securities laws of the United States.

AVAILABLE INFORMATION

Q Biomed Inc. files annual, quarterly and current reports, proxy statements and other information with the Securities and Exchange Commission (the “SEC”). You may read and copy documents referred to in this Annual Report on Form 10-K that have been filed with the SEC at the SEC’s Public Reference Room, 450 Fifth Street, N.W., Washington, D.C. You may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. You can also obtain copies of our SEC filings by going to the SEC’s website at <http://www.sec.gov>.

REFERENCES

As used in this annual report: (i) the terms “we”, “us”, “our” and the “Company” mean Q BioMed Inc. and, where applicable, our wholly-owned subsidiary; (ii) “SEC” refers to the Securities and Exchange Commission; (iii) “Securities Act” refers to the United States *Securities Act of 1933*, as amended; (iv) “Exchange Act” refers to the United States *Securities Exchange Act of 1934*, as amended; and (v) all dollar amounts refer to United States dollars unless otherwise indicated.

FORM 10-K
For the fiscal year ended November 30, 2018

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PART I

ITEM 1. DESCRIPTION OF BUSINESS

We are a biotechnology acceleration and development company focused on acquiring and in-licensing pre-clinical, clinical-stage and approved life sciences therapeutic products. We aim to accelerate the monetization of biomedical technologies through rapid innovation and collaborative partnerships with industry leading researchers. We have acquired or licensed assets in oncology, vascular disease, and rare orphan diseases that address unmet medical needs in large markets. Currently, we have a portfolio therapeutic products, including two FDA approved products, Metastron™ (approved in 22 countries) and its generic, Strontium 89 Chloride, a radiopharmaceutical for the non-opiate treatment of metastatic cancer bone pain, and several development stage products including: QBM-001 for rare pediatric non-verbal autism spectrum disorder, Uttroside-B for liver cancer, and MAN 01 for glaucoma as well as other MAN assets in development for infectious diseases, cardiovascular diseases and kidney disease. We aim to maximize risk-adjusted returns by focusing on multiple assets throughout the discovery and development cycle. We expect to benefit from early positioning in illiquid and/or less well known privately-held assets, thereby enabling us to capitalize on valuation growth as these assets move forward in their development.

Our mission is to:

- (i) license and acquire pre-commercial innovative life sciences assets in different stages of development and therapeutic areas from academia or small private companies;
- (ii) license and acquire FDA approved drugs and medical devices with limited current and commercial activity; and
- (iii) accelerate and advance our assets to the next value inflection point by providing: strategic capital, business development and financial advice and experienced sector specific advisors.

In 2019, we plan: (i) to generate revenue from our Metastron and Strontium 89 products for pain palliation in bone metastases as well as commence a therapeutic expansion post-marketing phase 4 trial for this product; and (ii) to commence a phase 2/3 pivotal trial with our QBM-001 asset to address a non-verbal learning disorder in autistic children.

We also intend to file investigational new drug applications, or INDs late in 2019 or early 2020, with the FDA for each of our Uttroside-B and MAN 01 assets for the treatment of liver cancer and glaucoma, respectively.

Following is a summary of our product pipeline.

Our Strategy

Our goal is to become a leading biotechnology acceleration and development company with a diversified portfolio of therapeutic products commercially available and in development. To achieve this goal, we are executing on the following strategy:

- ***Strategically collaborate or in- and out-license select programs.*** We seek to collaborate or in- and out-license certain potentially therapeutic candidate products to biotechnology or pharmaceutical companies for preclinical and clinical development and commercialization.
- ***Highly leverage external talent and resources.*** We plan to maintain and further build our team which is skilled in evaluating technologies for development and product development towards commercialization. By partnering with industry specific experts, we are able to identify undervalued assets that we can fund and assist in enhancing inherent value. We plan to continue to rely on the extensive experience of our management team to execute on our objectives.
- ***Evaluate commercialization and monetization strategies on a product-by-product basis in order to maximize the value of our product candidates or future potential products.*** As we move our drug candidates through development toward regulatory approval, we will evaluate several options for each drug candidate's commercialization or monetization strategy. These options include building our own internal sales force; entering into a joint marketing partnership with another pharmaceutical or biotechnology company, whereby we jointly sell and market the product; and out-licensing any product that we develop by ourselves or jointly with another party, whereby another pharmaceutical or biotechnology company sells and markets such product and pays us a royalty on sales. Our decision will be made separately for each product and will be based on a number

of factors including capital necessary to execute on each option, size of the market to be addressed and terms of potential offers from other pharmaceutical and biotechnology companies. It is too early for us to know which of these options we will pursue for our drug candidates, assuming their successful development.

- ***Acquire commercially or near-commercially ready products and build out the current market for such.*** In addition to acquiring pre-clinical products, in assembling a diversified portfolio of healthcare assets, we plan on acquiring assets that are either FDA approved or are reasonably expected to be FDA approved within 12 months of our acquiring them. We anticipate hiring a contract sales organization to assume the bulk of the sales and distribution efforts related to any such product.

General Information

We were incorporated in the State of Nevada on November 22, 2013 under the name ISMO Technology Solutions. On August 5, 2015, we recorded a stock split effectuated in the form a stock dividend. The stock dividend was paid at a rate of 1.5 “new” shares for every one issued and outstanding share held. On June 1, 2015, our Board of Directors determined it was in the best interest of the Company to establish a base of operations in the biomedical industry. As a result, the Board of Directors approved a change in the Company’s name from “ISMO Tech Solutions, Inc.” to “Q BioMed Inc.” Q BioMed Inc. established its business as a biomedical acceleration and development company focused on licensing, acquiring and providing strategic resources to life sciences and healthcare companies.

On October 27, 2015, we filed a Certificate of Amendment to our Articles of Incorporation with the Secretary of State of Nevada to increase the number of shares of common stock that we are authorized to issue from 100,000,000 shares to 250,000,000 shares. The Certificate of Amendment affected no provisions of our Articles of Incorporation other than the number of common stock that we are authorized to issue, and we are still authorized to issue 100,000,000 shares of preferred stock.

Our Drug Discovery Approach

We aim to acquire or license and have assembled a pipeline of multiple therapeutics in development stages ranging from early pre-clinical to commercial ready. Our model seeks to diversify risk by broadening the therapeutic areas we work in as well as providing multiple catalysts as we advance assets through the clinical and regulatory process.

Our mission is to:

- (i) license and acquire pre-commercial innovative life sciences assets in different stages of development and therapeutic areas from academia or small private companies;
- (ii) license and acquire FDA approved drugs and medical devices with limited current and commercial activity;
- (iii) accelerate and advance our assets to the next value inflection point by providing: (A) strategic capital, (B) business development and financial advice and (C) experienced sector specific advisors.

Our Research and Development Activities

As a biomedical acceleration and development company, research and development is a core aspect of our business. In addition to fulfilling our obligations under the agreements pursuant to which we license some of our intellectual property, in our coming fiscal year we intend to incur research and development expenses for the initiation of the Phase IV study for our Metastron product, initiate IND enabling studies and filings for our QBM01 Non-Verbal Autism Spectrum drug and Man 01 our Open Angle Glaucoma Drug as well as our chemotherapeutic liver cancer drug Uttroside B. In the fiscal years ended November 30, 2018 and 2017, we have incurred approximately \$3.2 million and \$3.1 million, respectively, on research and development activities.

Metastron

On November 23, 2018, we entered into an Asset Sale Agreement (“ASA”) with GE Healthcare Limited (“GE”) whereby we acquired GE’s radiopharmaceutical drug, Metastron®, for cancer bone pain therapy. Metastron® is an FDA approved drug that GE had sold for over 20 years. In addition to continuing the sales of Metastron®, we plan on exploring options to broaden the technology platform in scope to uses beyond metastatic cancer bone pain. Under the ASA, we also acquired all related intellectual property including, but not limited to sales and distribution data, market authorizations and trademarks for Metastron® in various countries. We acquired these assets in exchange for an upfront payment of \$500,000, a one-time milestone payment based on future sales, and royalty payments based on future sales. We did not acquire any workforce, manufacturing, inventory, sales agreements, or distribution agreements associated with Metastron®. Our first commercial sale of Metastron™ by the Company will occur only after the establishment of new manufacturing sites for Metastron® and under the appropriate regulatory filings required by the jurisdictions in which it is sold. Metastron has regulatory approval in 22 countries around the world. We are working with GE and the regulatory authorities to transfer

the ownership of Metastron to Q BioMed and make the required regulatory filings in each jurisdiction. We are intending supply Metastron from a US based contract manufacturer and we are investigating establishing a European based facility to augment our capabilities for Europe and Asian markets. These efforts will take some time, but we do anticipate generating revenue in 2019. We are currently preparing the required regulatory filing for the US FDA to approve our US based contract manufacturer to produce Metastron.

About Metastron (Strontium89 Chloride Injection USP)

Metastron (Strontium89) is an FDA approved drug for pain palliation in bone metastases, primarily from breast, prostate and lung cancers. It is Medicare and Healthcare insurance reimbursable. It is a pure beta emitting radiopharmaceutical. It is a chemical analog of calcium and for this reason, localizes in bone. There is a significant concentration of both calcium and strontium analogs at the site of active osteoblastic activity. This is the biochemical basis for its use in treating metastatic bone disease.

Strontium89 shows prolonged retention in metastatic bone lesions with a biological half-life of over 50 days, remaining up to 100 days after injection of the radiopharmaceutical, whereas the half-life in normal bone tissue is approximately 14 days. Strontium-89 has been shown to decrease pain in patients with osteoblastic metastases resulting from prostate cancer. When Strontium89 Chloride is used, pain palliation occurs in up to 80% of patients within 2 to 3 weeks after administration and lasts from 3 to 12 months with an average of about 6 months.

The National Institute for Health and Care Excellence's clinical guideline on "Prostate cancer: diagnosis and treatment" (2014) stated that "Strontium-89 should be considered for men with hormone-relapsed prostate cancer and painful bone metastases, especially those men who are unlikely to receive myelosuppressive chemotherapy".

It is estimated the approximately 2,000,000 around the world are suffering from pain associated with metastatic disease in the bone. In the United States, of the estimated 450,000 individuals newly diagnosed with either breast or prostate cancer, one in three will develop bone metastases, a common cause of pain in cancer patients. These figures are expected to increase as the potential patient population ages.

Strontium-89 is a non-opioid drug for the treatment of debilitating metastatic cancer pain in the bone. We believe there is a significant opportunity to market this effective drug as practitioners and caregivers are being encouraged to reexamine their use of opiates for treating patients in pain. We estimate the palliation market to be approximately \$300 million annually. Additional therapeutic indications for Strontium 89 are possible, and we intend to pursue those in 2019, hopefully resulting in entry into a multi-billion dollar therapeutic.

BioNucleonics Intellectual Property

On May 30, 2016, we entered into a Patent and Technology License and Purchase Option Agreement with BNI, which agreement was amended on September 6, 2016, whereby we were granted a worldwide, exclusive license on certain BNI intellectual property and the option to acquire the BNI IP within three years of the BNI.

The BNI IP consists of generic Strontium89 Chloride - SR89 (Generic Metastron®) and all of BNI's intellectual property relating to it. Currently, SR89 is a radiopharmaceutical therapeutic for cancer bone pain therapy. We plan on exploring options to broaden the technology platform in scope to uses beyond metastatic cancer bone pain. In exchange for the consideration, we agreed, upon reaching various milestones, to issue to BNI an aggregate of 110,000 shares of common stock that are subject to certain restrictions from trading. Once we have funded up to \$850,000 in cash, we may exercise the option to acquire the BNI IP at no additional charge. As of November 30, 2018, we have paid BNI in excess of \$1.0 Million.. We have exercised our option to acquire the BNI IP, but BNI has not transferred the BNI IP to us. As a result, we have commenced litigation to, among other actions, obtain all of the BNI IP. We also seek judgments against BNI and related parties for the misappropriation of funds, breach of contract, fraud and fraudulent inducement.

In the event that: (i) we do not exercise the option to purchase the BNI IP; (ii) we fail to invest the \$850,000 within three years from the date of the exclusive license; or (iii) we fail to make a diligent, good faith and commercially reasonable effort to progress the BNI IP, all BNI IP shall revert back to BNI and we shall be granted the right to collect twenty percent of the monies invested through that date of reversion by way of a royalty until such time that the aggregate of royalties paid exceeds twice the aggregate of all total cash investment paid by Q Bio along with other consideration which may be perpetual.

Over the last 12 months we have funded the setup and validation of a manufacturing suite at our contract manufacturing facility in south Texas. Raw materials have been purchased and several validation lots of the drug have been produced for testing and stability as required by the FDA. All of these efforts to support various regulatory filings required by the FDA to approve the facility as a commercial production facility for Strontium 89. These filings included a CBE (Change Being Affected in 30 days) with the FDA required to be resubmitted as a PAS (Prior Approval Supplement), a more substantial dossier. These filings were completed and the FDA and BNI are going through the Q&A process. An inspection of facility is expected at any time, subsequent to which, if cleared, we expect to be in a position to produce commercial drug and initiate sales.

Mannin Intellectual Property

On October 29, 2015, we entered into a Patent and Technology License and Purchase Option Agreement with Mannin whereby we were granted a worldwide, exclusive license on, and option to acquire, certain Mannin intellectual property, or IP, within a four-year term.

The Mannin IP is initially focused on developing a first-in-class eye drop treatment for glaucoma. The technology platform may be expanded in scope beyond ophthalmological uses and may include cystic kidney disease, cardiovascular diseases and infectious disease. This platform technology has application in many disease states that result in 'leaky' vessels and the inefficient flow of fluids. Pursuant to the exclusive license from Mannin, we may purchase the Mannin IP within four years of entry into the agreement in exchange for investing a minimum of \$4,000,000 into the development of the Mannin IP. Through November 30, 2018, we have funded an aggregate of \$5.1 million to Mannin under the Exclusive License. The purchase price for the Mannin IP is \$30,000,000 less the amount of cash paid by us for development and the value of the common stock issued to the vendor. This payment may be made in stock and cannot exceed 15% of the issued and outstanding Q BioMed stock.

In the event that: (i) we do not exercise the option to purchase the Mannin IP; (ii) we fail to invest the \$4,000,000 within four years from the date of the exclusive license; or (iii) we fail to make a diligent, good faith and commercially reasonable effort to progress the Mannin IP, all Mannin IP shall revert back to Mannin and we shall be granted the right to collect twice the monies invested through that date of reversion by way of a royalty along with other consideration which may be perpetual.

MAN 01 – New Vascular Therapeutics including Primary Open Angle Glaucoma

Mannin is utilizing a proprietary research platform technology to address the need for a new class of drugs to treat various vascular diseases. Our lead indication is for a first-in-class therapeutic eye-drop for the treatment of Primary Open Angle Glaucoma.

We are developing a first-in-class drug targeting the Schlemm's canal and its role in regulating interocular eye pressure, one of the leading causes of glaucoma. No other glaucoma company is targeting the Schlemm's canal, the main drainage pathway in the eye. This unique vessel is responsible for 70-90% of the fluid drainage in the eye. The MAN 01 drug is currently in the lead optimization stage of its pre-clinical testing. We have also partnered with expert formulation and drug delivery specialists to assist in the final formulation of the novel eye drop treatment. We aim to initiate IND enabling studies in 2019 and file an IND in late 2019 or early 2020, to be followed by a short phase 1 clinical trial lasting approximately 3 months.

A deep pipeline of novel therapeutics is being developed from this research platform, which would treat a spectrum of vascular diseases including Cystic Kidney Disease, cardiovascular disease and infectious diseases. We expect to advance these efforts in 2019.

GDF15 - A Novel Biomarker for the detection and measurement of Glaucoma

We have an option to exclusively license GDF15, a diagnostic marker for determining the severity of glaucoma using the expression levels of Growth Differentiation Factor 15 (GDF15) from the Washington University in St. Louis. Determining the severity of glaucoma using this biomarker will aid in treatment decisions for patients diagnosed with, and being treated for, glaucoma. We expect to exercise our option in the next 30 days.

Currently, no single examination or diagnostic test is able to accurately predict disease progression. Accurate monitoring for disease progression is critical to preserve visual function in glaucoma patients. Today, physicians only have surrogate measures to evaluate glaucomatous neurodegeneration. GDF15 represents an attractive biomarker for glaucoma with distinct advantages including early detection, over conventional clinical tests and has the potential to be a first-in-class diagnostic test. GDF15 was discovered by Dr. Rajendra Apte, the Paul A. Cibis Distinguished Professor of Ophthalmology and Visual Sciences at Washington University School of Medicine. Dr Apte is currently conducting a clinical trial to further validate GDF15 as a surrogate clinical tool in the treatment of Glaucoma patients.

Q BioMed plans to offer the GDF15 biomarker as a companion diagnostic to its MAN-01 small molecule therapeutic with a novel mechanism of action for Primary Open-Angle Glaucoma. By offering both a diagnostic and a therapeutic, Q BioMed and its technology partner Mannin Research Inc. are addressing the needs of both patients and physicians, as well as bringing innovation to the global glaucoma market.

ASDERA Intellectual Property – QBM001 Drug for the Treatment of Non-Verbal Autistic Spectrum Disorder

On April 21, 2017, we entered into a License Agreement on Patent & Know-How Technology with ASDERA whereby we were granted a worldwide, exclusive, license on certain ASDERA intellectual property.

Among the more than 60,000 US children who develop autism spectrum disorders, or ASD, every year, approximately 20,000 become nonverbal and will have to rely on assisted living for the rest of their lives. The ASDERA IP is intended to treat the rare pediatric condition (nonverbal disorder) during the second year of life, when children learn to speak. Many of the children who miss this treatment window will become non-verbal for all of their lives. Currently, there is no treatment for this nonverbal disorder. The ASDERA IP is not intended to treat other aspects of ASD or to be used beyond the estimated treatment window. The ASDERA IP consists of patent-rights and know-how relating to a product candidate named ASD-002 (now identified as QBM001).

The initial cost to acquire the exclusive license from ASDERA was \$50,000 and the issuance of 125,000 shares of our unregistered common stock subject to a leak-out conditions after the Rule 144 period has ended. In addition to royalties based upon net sales of the product candidate, if any, we are required to make additional payments upon the following milestones:

- the filing of an investigational new drug application, or IND, with the US Food and Drug Administration;

- successful interim results of Phase II/III clinical trial of the product candidate;
- FDA acceptance of a new drug application;
- FDA approval of the product candidate; and
- achieving certain worldwide net sales.

Subject to the terms of the Agreement, we will be in control of the development and commercialization of the product candidate and are responsible for the costs of such development and commercialization. We have undertaken a good-faith commitment to (i) initiate a Phase II/III clinical trial at the earlier of the two-year anniversary of the Agreement or one year from the FDA's approval of the IND and (ii) to make our first commercial sale by the fifth-anniversary of the Agreement. Failure to show a good-faith effort to meet those goals would mean that the ASDERA IP would revert to ASDERA. Upon such reversion, ASDERA would be obligated to pay us royalties on any sales of products derived from the ASDERA IP until such time that ASDERA has paid us twice the sum that we had provided ASDERA prior to the reversion.

About QBM-001 - Addressing Rare Pediatric Non-verbal Spectrum Disorder

Causes of non-verbal learning disorder have been linked to several complications that range from a specific mutated gene as with Fragile X Syndrome and Dravet Syndrome or autoimmunity, where the body's immune system is attacking parts of the brain. Trauma, microbial infections and environmental factors have also been linked to non-verbal learning disorder. Ongoing research is helping to further explain the root cause of why children become non-verbal or minimally verbal.

Children born into families where there is a genetic history of autism or epileptic spectrum disorders or that have a sibling that has been diagnosed with an autistic or epileptic spectrum disorder have a much higher chance of becoming non-verbal.

More than 60,000 US children develop Autism Spectrum Disorders ("ASD") every year, of whom 20,000 become non-verbal. A similar number of children with ASD symptoms in Europe develop pediatric non-verbal disorder each year. No drugs are currently available to ameliorate this condition. In the United States, of the estimated 20,000 who become non- or minimally verbal and will require assisted living for the rest of their life. The lifetime cost of that care is estimated at \$10 million per person.

Cognitive intervention is the only form for treatment that has shown to help improve speech capability and social interaction, however, it has not been able to alleviate the lifetime burden of \$10 million per person for cost of care. This is compounded by an additional \$10 million during the lifespan of the person due to loss in productivity in addition to severe emotional strain for the child and the parents. The US healthcare system bears an annual cost of over \$200 Billion to treat non-verbal patients.

QBM-001 is proposed to be given to high-risk genetically identified children during the second year of life to regulate faulty membrane channels that are known to cause migraines and/or seizures. This drug acts as an allosteric regulator of these faulty channels in the brain to potentially alleviate the condition and allow toddlers to actively develop language and speech and avoid life-long speech and intellectual disability of being non-verbal

As there are no treatment option for these patients, we believe there is a significant economic opportunity to bring a drug to market in this indication. The active ingredient in our compound is well known and has been approved by worldwide regulators for many years. New research and clinical data has further validated our approach and given us insight into additional pathways we could be targeting to ameliorate this condition. As a result, a multi-component formulation is being investigated, that we hope will be more effective than previously planned. Using a novel delivery and formulation for the active ingredient, we intend to advance this drug through the 505(b)2 pathway in a single phase 2/3 clinical trial expected to commence in 2019, subject to FDA feedback and approval of an IND. We expect to also file an Orphan Drug application for this drug in 2019.

RGCB and OMRF Intellectual Property – Uttroside B Liver Cancer Chemotherapeutic

On June 15, 2017, we entered into a Technology License Agreement with RGCB and OMRF whereby they granted us a worldwide, exclusive, license on intellectual property related to Uttroside-B. Uttroside-B is a chemical compound derived from the plant *Solanum nigrum* Linn, also known as Black Nightshade or Makoi. We seek to use the Uttroside-B IP to create a chemotherapeutic agent against liver cancer.

The initial cost to acquire the exclusive license for Uttroside is \$10,000. In addition to royalties based upon net sales of the product candidate, if any, we are required to make additional payments upon the following milestones:

- the completion of certain preclinical studies;
- the filing of an investigational new drug application with the US Food and Drug Administration or the filing of the equivalent application with an equivalent governmental agency;
- successful completion of each of Phase I, Phase II and Phase III clinical trials;

- FDA approval of the product candidate;
- approval by the foreign equivalent of the FDA of the product candidate;
- achieving certain worldwide net sales; and
- a change of control of our Company.

Subject to the terms of the exclusive license for Uttroside, we will be in control of the development and commercialization of the product candidate and are responsible for the costs of such development and commercialization. We have undertaken a good-faith commitment to (i) fund the pre-clinical trials and (ii) to initiate a Phase II clinical trial within six years of the date of the Agreement. Failure to show a good-faith effort to meet those goals would mean that the exclusive license for Uttroside would revert to the licensors.

UTTROSIDE-B - A Novel Chemotherapeutic for Liver Cancer

Hepatocellular carcinoma (HCC) is the fifth most diagnosed cancer in the world and the third leading cause of death. Incidence rates have tripled since 1980. Unfortunately, when diagnosed two thirds of patients have an advanced disease for which only palliative treatment can be proposed and most likely systemic therapy. Today, very few systemic therapies have been validated in the treatment of advanced HCC, tyrosine kinase inhibitors (TKI): Sorafenib (Nexavar) and regorafenib (Stivarga), and lenvatinib (Lenvima). Treatment options are therefore lacking. Other TKIs have been studied with some disappointing results. Current sales of Sorafenib are estimated at \$1 billion per year.

The liver is the football-sized organ in the upper right area of the belly. Symptoms of liver cancer are uncommon in the early stages. Liver cancer treatments vary, but may include removal of part of the liver, liver transplant, chemotherapy, and in some cases radiation. Primary liver cancer (hepatocellular carcinoma) tends to occur in livers damaged by birth defects, alcohol abuse, or chronic infection with diseases such as hepatitis B and C, hemochromatosis (a hereditary disease associated with too much iron in the liver), and cirrhosis. In the United States, the average age at onset of liver cancer is 63 years. Men are more likely to develop liver cancer than women, by a ratio of 2 to 1.

Uttroside-B appears to affect phosphorylated JNK (pro survival signaling) and capcase activity (apoptosis in liver cancer). It is a natural compound fractionated Saponin derived from the Solarim Nigrum plant. It is a small molecule that showed in early investigation to increase the cytotoxicity of a variety of liver cancer cell types and importantly to be up to ten times more potent than Sorafenib in pre-clinical studies. This potency motivates us to work with our partners to synthesize the molecule and move into a clinical program. After completing some very complicated chemistry work, we believe we will have a final molecule and several analogues in Q1 2019. We plan to initiate pre-clinical testing shortly thereafter and clinical work in late 2019.

Patents and Intellectual Property Rights

If products we acquired do not have adequate intellectual protection, we will take the necessary steps to protect our proprietary therapeutic product candidate assets and associated technologies that are important to our business consisting of seeking and maintaining domestic and international patents. These may cover our products and compositions, their methods of use and processes for their manufacture and any other inventions that may be commercially important to the development of our business. We also rely on trade secrets to protect aspects of our business. Our competitive position depends on our ability to obtain patents on our technologies and our potential products, to defend our patents, to protect our trade secrets and to operate without infringing valid and enforceable patents or trade secrets of others. We seek licenses from others as appropriate to enhance or maintain our competitive position.

We hold a license to all intellectual property related to each of (i) MAN 01, the drug candidate for the treatment of Primary Open Angle Glaucoma, (ii) ASD-002 (QBM001), the drug candidate related to a nonverbal disorder associated with autism, (iii) SR89, our generic Strontium 89 Chloride product candidate for metastatic cancer bone pain therapy, and (iv) the Uttroside platform.

We do not hold, and have not applied for, any patents in our own right. All patents are held in the licensors or inventors names and are assignable under license agreements to Q BioMed Inc.

Competition

We operate in highly competitive segments of the biotechnology and biopharmaceutical markets. We face competition from many different sources, including commercial pharmaceutical and biotechnology enterprises, academic institutions, government agencies, and private and public research institutions. Our product candidates, if successfully developed and approved, will compete with established therapies, as well as new treatments that may be introduced by our competitors. Many of our competitors have significantly greater financial, product development, manufacturing and marketing resources than us. Large pharmaceutical companies have extensive experience in clinical testing and obtaining regulatory approval for drugs. In addition, many universities and private and public research institutes are active in the fields in which we research, some in direct competition with us. We also may compete with these organizations to recruit management, scientists and clinical development personnel. Smaller or early-stage companies may also

prove to be significant competitors, particularly through collaborative arrangements with large and established companies. New developments, including the development of other biological and pharmaceutical technologies and methods of treating disease, occur in the pharmaceutical and life sciences industries at a rapid pace. Developments by competitors may render our product candidates obsolete or noncompetitive. We will also face competition from these third parties in recruiting and retaining qualified personnel, establishing clinical trial sites and patient registration for clinical trials and in identifying and in-licensing new product candidates.

Government Regulation

The clinical development, manufacturing, labeling, storage, record-keeping, advertising, promotion, import, export, marketing and distribution of our product candidates are subject to extensive regulation by the FDA in the United States and by comparable health authorities in foreign markets. In the United States, we are not permitted to market our product candidates until we receive approval of a BLA from the FDA. The process of obtaining BLA approval is expensive, often takes many years and can vary substantially based upon the type, complexity and novelty of the products involved. In addition to the significant clinical testing requirements, our ability to obtain marketing approval for these products depends on obtaining the final results of required non-clinical testing, including characterization of the manufactured components of our product candidates and validation of our manufacturing processes. The FDA may determine that our product manufacturing processes, testing procedures or facilities (or those of third parties upon which we rely) are insufficient to justify approval. Approval policies or regulations may change and the FDA has substantial discretion in the pharmaceutical approval process, including the ability to delay, limit or deny approval of a product candidate for many reasons. Despite the time and expense invested in clinical development of product candidates, regulatory approval is never guaranteed.

The FDA or another regulatory agency can delay, limit or deny approval of a product candidate for many reasons, including, but not limited to:

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA that a product candidate is safe and effective for any indication;
- the FDA may not accept clinical data from trials which are conducted by individual investigators or in countries where the standard of care is potentially different from the United States;
- the results of clinical trials may not meet the level of statistical significance required by the FDA for approval;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA may disagree with our interpretation of data from preclinical studies or clinical trials;
- the FDA may fail to approve our manufacturing processes or facilities or those of third-party manufacturers with which we or our collaborators contract for clinical and commercial supplies; or
- the approval policies or regulations of the FDA may significantly change in a manner rendering our clinical data insufficient for approval.

With respect to foreign markets, approval procedures vary among countries and, in addition to the aforementioned risks, can involve additional product testing, administrative review periods and agreements with pricing authorities. In addition, recent events raising questions about the safety of certain marketed pharmaceuticals may result in increased cautiousness by the FDA and comparable foreign regulatory authorities in reviewing new pharmaceuticals based on safety, efficacy or other regulatory considerations and may result in significant delays in obtaining regulatory approvals. Any delay in obtaining, or inability to obtain, applicable regulatory approvals would prevent us from commercializing our product candidates.

Costs and Effects of Compliance with Environmental Laws

Federal, state, and international environmental laws may impose certain costs and restrictions on our business. We do not believe that we have yet spent or lost money due to these laws and regulations.

Product Liability and Insurance

We face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials and the eventual sale and use of any product candidates, and claims could be brought against us if use or misuse of one of our product candidates causes, or merely appears to have caused, personal injury or death. While we have and intend to maintain product liability insurance relating to our clinical trials, our coverage may not be sufficient to cover claims that may be made against us and we may be unable to maintain such insurance. Any claims against us, regardless of their merit, could severely harm our financial condition, strain

our management and other resources or destroy the prospects for commercialization of the product which is the subject of any such claim. We are unable to predict if we will be able to obtain or maintain product liability insurance for any products that may be approved for marketing. Additionally, we have entered into various agreements where we indemnify third parties for certain claims relating to our product candidates. These indemnification obligations may require us to pay significant sums of money for claims that are covered by these indemnifications. We currently do not maintain product liability insurance.

Employees

As of November 30, 2018, we had 1 employee and 20 consultants and management consultants.

Properties

We do not own any properties. We have leased office space in the Cayman Islands.

Legal Proceedings

On December 28, 2018, we commenced litigation against BioNucleonics, Inc. (“BNI”) and parties related to BNI in the Supreme Court of New York, New York County (removed to federal court in February 2019). The litigation stems from a license agreement that we entered into with BNI in 2016 and amended from time to time. Under the agreement with BNI, we were granted a worldwide, exclusive license on certain BNI intellectual property and the option to acquire the BNI IP within three years of the agreement. The BNI IP consists of generic Strontium Chloride SR89 (generic Metastron®) (“SR89”) and all of BNI’s intellectual property relating to it (“BNI IP”). SR89 is a radiopharmaceutical therapeutic for cancer bone pain therapy.

In exchange for the consideration, we agreed, upon reaching various milestones, to issue to BNI an aggregate of up to 110,000 shares of common stock and to provide funding to BNI for an aggregate of \$850,000 in cash. Under the agreement, once we have funded up to \$850,000 in cash, we may exercise the option to acquire the BNI IP at no additional charge. By our accounts, we have provided BNI with over \$950,000 in cash. We have exercised our option to acquire the BNI IP, but BNI has not transferred the BNI IP to us. As a result, we have commenced litigation to, among other actions, obtain all of the BNI IP. We also seek judgments against BNI and related parties for the misappropriation of funds, breach of contract, fraud and fraudulent inducement.

Except for the above, we are not a party to any material pending legal proceeding, arbitration or governmental investigation, and to the best of our knowledge, no such proceedings have been initiated against us.

ITEM 1A. RISK FACTORS

Investing in our securities involves a high degree of risk. You should carefully consider and evaluate all of the information included and incorporated by reference or deemed to be incorporated by reference in this report. Our business, results of operations or financial condition could be adversely affected by any of these risks or by additional risks and uncertainties not currently known to us or that we currently consider immaterial.

Risks Related to our Company

If we do not obtain additional financing, our business may be at risk or execution of our business plan may be delayed.

As of the date hereof, we have raised our operating funds through contacts, high net-worth individuals and strategic investors situated in the United States and Cayman Islands. We have not generated any revenue from operations since inception. We have limited assets upon which to commence our business operations and to rely otherwise. At November 30, 2018, we had cash and cash equivalents of approximately \$2.7 million. On September 21 and November 1, 2018, we netted approximately \$3.9 million from the registered sale of convertible notes. As such, we anticipate that we will have to raise additional funds and/or generate revenue from drug sales within twelve months to continue operations. Additional funding will be needed to implement our business plan that includes various expenses such as fulfilling our obligations under licensing agreements, legal, operational set-up, general and administrative, marketing, employee salaries and other related start-up expenses. Obtaining additional funding will be subject to a number of factors, including general market conditions, investor acceptance of our business plan and initial results from our business operations. These factors may impact the timing, amount, terms or conditions of additional financing available to us. If we are unable to raise sufficient funds, we will be forced to scale back or cease our operations.

Our independent registered public accountant has issued a going concern opinion after auditing our consolidated financial statements; our ability to continue depends on our ability to raise additional capital and our operations could be curtailed if we are unable to obtain required additional funding when needed.

We will be required to expend substantial amounts of working capital in order to acquire and market our proposed products and establish the necessary relationships to implement our business plan. We were incorporated on November 22, 2013. Our operations to date were funded entirely by capital raised from our private offering of securities. Notwithstanding the offering, we will continue to require additional financing to execute our business strategy. We totally depend on external sources of financing for the foreseeable future. Failure to raise additional funds in the future will adversely affect our business operations, and may require us to suspend our operations, which in turn may result in a loss to the purchasers of our common stock. We entirely depend on our ability to attract and receive additional funding from either the sale of securities or the issuance of debt securities. Needed funds might never be available to us on acceptable terms or at all. The inability to obtain sufficient funding of our operations in the future could restrict our ability to grow and reduce our ability to continue to conduct business operations. The report of our independent registered public accounting firm on our consolidated financial statements, included herein, raised substantial doubt about our ability to continue as a going concern. Our ability to continue as a going concern depends on our ability to raise additional capital. If we are unable to obtain necessary financing,

we will likely be required to curtail our development plans which could cause us to become dormant. Any additional equity financing may involve substantial dilution to our then existing stockholders.

Our business relies on intellectual property owned by third parties, and this reliance exposes us to the termination of the right to use that intellectual property and may result in inadvertent infringement of patents and proprietary rights of others.

Currently, we have four assets. Our business depends on:

- our ability to continuously use the technology related to an eye drop treatment for glaucoma, our Mannin platform, that we have licensed from Mannin Research Inc.,
- our ability to continuously use our intellectual property relating to generic Strontium Chloride-89, our BioNucleonics platform, that we have licensed from Bio-Nucleonics, Inc.,
- our ability to continuously use our intellectual property relating to a rare pediatric condition (nonverbal disorder), our ASDERA platform, that we have licensed from ASDERA LLC and
- our ability to continuously use our intellectual property relating to a chemical compound derived from the plant *Solanum nigrum* Linn, also known as Black Nightshade or Makoi, that we seek to use to create a chemotherapeutic agent against liver cancer, our Uttroside platform, and that we have licensed from the Rajiv Gandhi Centre for Biotechnology, an autonomous research institute under the Government of India, known as RGCB, and the Oklahoma Medical Research Foundation, or the OMRF.

If the licenses were to terminate, we would lose the ability to conduct our business pursuant to our plan of operations. Our ability to pursue our business plan would then depend on finding alternative platforms to license. We may not be able to find an attractive platform on a timely and cost effective basis, and even if we did, such platform might be inferior to the ones we currently have a license to use and may not be attractive to potential customers.

Many entities, including some of our competitors, have or may obtain patents and other intellectual property rights that cover or affect products or services related to those assets that we license. If a court determines that one or more aspect of the licensed platform infringes on intellectual property owned by others, we may be required to cease using that platform, to obtain licenses from the owners of the intellectual property or to redesign the platform in such a way as to avoid infringing the intellectual property rights. If a third party holds intellectual property rights, it may not allow us to use its intellectual property at any price, which could materially adversely affect our competitive position.

The Mannin platform, BioNucleonics platform, the ASDERA platform and the Uttroside platform may potentially infringe other intellectual property rights. U.S. patent applications are generally confidential until the Patent and Trademark Office issues a patent. Therefore, we cannot evaluate the extent to which the licensed platform may infringe claims contained in pending patent applications. Further, without lengthy litigation, it is often not possible to determine definitively whether a claim of infringement is valid. We may not be in a position to protect the intellectual property that we license as we are not the owners of that intellectual property and do not currently have the financial resources to engage in lengthy litigation.

Failure to maintain the license for, or to acquire, the intellectual property underlying any license or sublicense on which our plan of operations is based may force us to change our plan of operations.

We have to meet certain conditions to maintain the licenses for the intellectual property underlying the Mannin platform, the ASDERA platform and the Uttroside platform and to acquire such intellectual property. Such conditions include payments of cash and shares of common stock, obtaining certain governmental approvals, initiating sales of products based on the intellectual property and other matters. We might not have the resources to meet these conditions and as a result may lose the licenses to the intellectual property that is vital to our business.

We lack an operating history and have not generated any revenues to date. Future operations might never result in revenues. If we cannot generate sufficient revenues to operate profitably, we may have to cease operations.

As we were incorporated on November 22, 2013 and more recently changed business direction, we do not have any operating history upon which an evaluation of our future success or failure can be made. Our ability to achieve and maintain profitability and positive cash flow depends upon our ability to manufacture a product and to earn profit by attracting enough clients who will buy our products or services. We might never generate revenues or, if we generate revenues, achieve profitability. Failure to generate revenues and profit will eventually cause us to suspend, curtail or cease operations.

We may be exposed to potential risks and significant expenses resulting from the requirements under section 404 of the Sarbanes-Oxley Act of 2002.

We are required, pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, to include in our annual report our assessment of the effectiveness of our internal control over financial reporting. We expect to incur significant continuing costs, including accounting fees and staffing costs, in order to maintain compliance with the internal control requirements of the Sarbanes-Oxley Act of 2002. Our management concluded that our internal controls and procedures were not effective to detect the inappropriate application of US GAAP for our most recent fiscal year. As we develop our business, hire employees and consultants and seek to protect our intellectual property rights, our current design for internal control over financial reporting must be strengthened to enable management to determine that our internal controls are effective for any period, or on an ongoing basis. Accordingly, as we develop our business, such development and growth will necessitate changes to our internal control systems, processes and information systems, all of which will require additional costs and expenses.

In the future, if we fail to complete the annual Section 404 evaluation in a timely manner, we could be subject to regulatory scrutiny and a loss of public confidence in our internal controls. In addition, any failure to implement required new or improved controls, or difficulties encountered in their implementation, could harm our operating results or cause us to fail to meet our reporting obligations.

Limited oversight of our management may lead to corporate conflicts.

We have only three directors, of whom two are also officers. Accordingly, we cannot establish board committees comprised of independent members to oversee functions like compensation or audit issues. In addition, since we only have three directors, they have significant control over all corporate issues.

Because we are not subject to compliance with rules requiring the adoption of certain corporate governance measures, our shareholders have limited protections against interested director transactions, conflicts of interest and similar matters. The Sarbanes-Oxley Act of 2002, as well as rules enacted by the SEC, the New York Stock Exchange and the Nasdaq Stock Market, requires the implementation of various measures relating to corporate governance. These measures are designed to enhance the integrity of corporate management and the securities markets and apply to securities which are listed on the New York Stock Exchanges or the Nasdaq Stock Market. Because we are not presently required to comply with many of the corporate governance provisions, we have not yet adopted these measures and, currently, would not be able to comply with such corporate governance provisions. We do not have an audit or compensation committee comprised of independent directors. Two of our three directors who perform these functions and are not independent directors. Thus, there is a potential conflict in that our directors are also engaged in management and participate in decisions concerning management compensation and audit issues that may affect management performance.

Until we have a larger board of directors that would include a majority of independent members, if ever, there will be limited oversight of our directors' decisions and activities and little ability for minority shareholders to challenge or reverse those activities and decisions, even if they are not in the best interests of minority shareholders.

Additionally, our directors beneficially own approximately 27% of our common stock. Although it is possible for them to be outvoted by the remaining shareholders at a general or special meeting if the two directors voted together, the size of their shareholdings and the absence of any other person beneficially owning more than 10% of our common stock would make this a difficult undertaking.

Because the results of preclinical studies and early clinical trials are not necessarily predictive of future results, any product candidate we advance into clinical trials may not have favorable results in later clinical trials, if any, or receive regulatory approval.

Pharmaceutical development has inherent risk. We will be required to demonstrate through well-controlled clinical trials for our product candidates for our Mannin platform, the ASDERA platform and the Uttroside platform and any additional uses based on the BioNucleonics and Metastron platforms that our product candidates are effective with a favorable benefit-risk profile for use in their target indications before we can seek regulatory approvals for their commercial sale. Success in early clinical trials does not mean that later clinical trials will be successful as product candidates in later-stage clinical trials may fail to demonstrate sufficient safety or efficacy despite having progressed through initial clinical testing. We also may need to conduct additional clinical trials that are not currently anticipated. Companies frequently suffer significant setbacks in advanced clinical trials, even after earlier clinical trials have shown promising results. In addition, only a small percentage of drugs under development result in the submission of a New Drug Application or Biologics License Application, known as BLA, to the U.S. Food and Drug Administration and even fewer are approved for commercialization.

Any product candidates we advance into clinical development are subject to extensive regulation, which can be costly and time consuming, cause unanticipated delays or prevent the receipt of the required approvals to commercialize our product candidates.

The clinical development, manufacturing, labeling, storage, record-keeping, advertising, promotion, import, export, marketing and distribution of our product candidate, Man-01, are subject to extensive regulation by the FDA in the United States and by comparable health authorities in foreign markets. In the United States, we are not permitted to market our product candidates until we receive approval of a BLA from the FDA. The process of obtaining BLA approval is expensive, often takes many years and can vary substantially based upon the type, complexity and novelty of the products involved. In addition to the significant clinical testing requirements, our ability to obtain marketing approval for these products depends on obtaining the final results of required non-clinical testing, including characterization of the manufactured components of our product candidates and validation of our manufacturing processes. The FDA may determine that our product manufacturing processes, testing procedures or facilities are insufficient to justify approval. Approval policies or regulations may change and the FDA has substantial discretion in the pharmaceutical approval process, including the ability to delay, limit or deny approval of a product candidate for many reasons. Despite the time and expense invested in clinical development of product candidates, regulatory approval is never guaranteed.

The FDA or another regulatory agency can delay, limit or deny approval of a product candidate for many reasons, including, but not limited to:

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA that a product candidate is safe and effective for any indication;
- the FDA may not accept clinical data from trials which are conducted by individual investigators or in countries where the standard of care is potentially different from the United States;
- results of clinical trials may not meet the level of statistical significance required by the FDA for approval;

- we may be unable to demonstrate that a product candidate’s clinical and other benefits outweigh its safety risks;
- the FDA may disagree with our interpretation of data from preclinical studies or clinical trials;
- the FDA may fail to approve our manufacturing processes or facilities or those of third-party manufacturers with which we or our collaborators contract for clinical and commercial supplies; or
- the approval policies or regulations of the FDA may significantly change in a manner rendering our clinical data insufficient for approval.

With respect to foreign markets, approval procedures vary among countries and, in addition to the aforementioned risks, can involve additional product testing, administrative review periods and agreements with pricing authorities. In addition, recent events raising questions about the safety of certain marketed pharmaceuticals may result in increased cautiousness by the FDA and comparable foreign regulatory authorities in reviewing new pharmaceuticals based on safety, efficacy or other regulatory considerations and may result in significant delays in obtaining regulatory approvals. Any delay in obtaining, or inability to obtain, applicable regulatory approvals would prevent us from commercializing our product candidates.

Any product candidate we manufacture or advance into clinical trials may cause unacceptable adverse events or have other properties that may delay or prevent their regulatory approval or commercialization or limit their commercial potential.

Unacceptable adverse events caused by any of our product candidates that we manufacture or advance into clinical trials could cause us or regulatory authorities to interrupt, delay or halt production or clinical trials and could result in the denial of regulatory approval by the FDA or other regulatory authorities for any or all targeted indications and markets. This, in turn, could prevent us from commercializing the affected product candidate and generating revenues from its sale.

Except for our Strontium Chloride 89, known as SR89, and Metastrom product candidates, there is not yet completed testing of any of our product candidates for the treatment of the indications for which we intend to seek product approval in humans, and we currently do not know the extent of adverse events, if any, that will be observed in patients who receive any of our product candidates. If any of our product candidates cause unacceptable adverse events in clinical trials, we may not be able to obtain regulatory approval or commercialize such product or, if such product candidate is approved for marketing, future adverse events could cause us to withdraw such product from the market.

Delays in the commencement of our clinical trials could result in increased costs and delay our ability to pursue regulatory approval.

The commencement of clinical trials can be delayed for a variety of reasons, including delays in:

- obtaining regulatory clearance to commence a clinical trial;
- identifying, recruiting and training suitable clinical investigators;
- reaching agreement on acceptable terms with prospective clinical research organizations (“CROs”) and trial sites, the terms of which can be subject to extensive negotiation, may be subject to modification from time to time and may vary significantly among different CROs and trial sites;
- obtaining sufficient quantities of a product candidate for use in clinical trials;
- obtaining Investigator Review Board, or IRB, or ethics committee approval to conduct a clinical trial at a prospective site;
- identifying, recruiting and enrolling patients to participate in a clinical trial; and
- retaining patients who have initiated a clinical trial but may withdraw due to adverse events from the therapy, insufficient efficacy, fatigue with the clinical trial process or personal issues.

Any delays in the commencement of our clinical trials will delay our ability to pursue regulatory approval for our product candidates. In addition, many of the factors that cause, or lead to, a delay in the commencement of clinical trials may also ultimately lead to the denial of regulatory approval of a product candidate.

Suspensions or delays in the completion of clinical testing could result in increased costs to us and delay or prevent our ability to complete development of that product or generate product revenues.

Once a clinical trial has begun, patient recruitment and enrollment may be slower than we anticipate. Clinical trials may also be delayed as a result of ambiguous or negative interim results or difficulties in obtaining sufficient quantities of product manufactured in accordance with regulatory requirements and on a timely basis. Further, a clinical trial may be modified, suspended or terminated by us, an IRB, an ethics committee or a data safety monitoring committee overseeing the clinical trial, any clinical trial site with respect to that site, or the FDA or other regulatory authorities due to a number of factors, including:

- failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols;
- inspection of the clinical trial operations or clinical trial sites by the FDA or other regulatory authorities resulting in the imposition of a clinical hold;
- stopping rules contained in the protocol;
- unforeseen safety issues or any determination that the clinical trial presents unacceptable health risks; and
- lack of adequate funding to continue the clinical trial.

Changes in regulatory requirements and guidance also may occur and we may need to amend clinical trial protocols to reflect these changes. Amendments may require us to resubmit our clinical trial protocols to IRBs for re-examination, which may impact the costs, timing and the likelihood of a successful completion of a clinical trial. If we experience delays in the completion of, or if we must suspend or terminate, any clinical trial of any product candidate, our ability to obtain regulatory approval for that product candidate will be delayed and the commercial prospects, if any, for the product candidate may suffer as a result. In addition, any of these factors may also ultimately lead to the denial of regulatory approval of a product candidate.

Our product candidates (if approved) or any other product candidates that we may develop and market may be later withdrawn from the market or subject to promotional limitations.

We may not be able to obtain the labeling claims necessary or desirable for the promotion of our product candidates if approved. We may also be required to undertake post-marketing clinical trials. If the results of such post-marketing studies are not satisfactory or if adverse events or other safety issues arise after approval, the FDA or a comparable regulatory agency in another country may withdraw marketing authorization or may condition continued marketing on commitments from us that may be expensive and/or time consuming to complete. In addition, if we or others identify adverse side effects after any of our products are on the market, or if manufacturing problems occur, regulatory approval may be withdrawn and reformulation of our products, additional clinical trials, changes in labeling of our products and additional marketing applications may be required. Any reformulation or labeling changes may limit the marketability of our products if approved.

Our dependence on third party suppliers or our inability to successfully produce any product could adversely impact our business.

We rely on third parties to supply us with component and materials required for the development and manufacture of our product candidates. If they fail to provide the required components or we are unable to find a partner to manufacture the necessary products, there would be a significant interruption of our supply, which would materially adversely affect clinical development and potential commercialization of the product. In the event that the FDA or such other agencies determine that we or any third-party suppliers have not complied with cGMP, our clinical trials could be terminated or subjected to a clinical hold until such time as we or any third party are able to obtain appropriate replacement material. Furthermore, if any contract manufacturers who supply us cannot successfully manufacture material that conforms to our specifications and with FDA regulatory requirements, we will not be able to secure and/or maintain FDA approval for our product candidates. We, and any third-party suppliers are and will be required to maintain compliance with cGMPs and will be subject to inspections by the FDA or comparable agencies in other jurisdictions to confirm such compliance.

We do and will also rely on our partners and manufacturers to purchase from third-party suppliers the materials necessary to produce our product candidates for our anticipated clinical trials. We do not have any control over the process or timing of the acquisition of raw materials by our manufacturers. Moreover, we currently do not have any agreements for the commercial production of these raw materials. Any significant delay in the supply of a product candidate or the raw material components thereof for an ongoing clinical trial could considerably delay completion of our clinical trials, product testing and potential regulatory approval of our product candidates.

We may not have the resources or capacity to commercially manufacture our product candidates, and we will likely continue to be dependent upon third party manufacturers. Our current inability, or our dependence on third parties, to manufacture and supply us with clinical trial materials and any approved products may adversely affect our ability to develop and commercialize our product candidates on a timely basis or at all.

We intend to contract with third parties either directly or through our licensors for the manufacture of our product candidates. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or that such supply will not be available to us at an acceptable cost, which could delay, prevent or impair our commercialization efforts.

We do not have any manufacturing facilities. We expect to use third-party manufacturers for the manufacture of our product candidates and have entered into contracts with manufacturers through the licensor of our radio-pharmaceutical product, SR89. Even with such contracts in place, reliance on third-party manufacturers entails additional risks, including:

- reliance on the third party for regulatory compliance and quality assurance;
- the possible breach of the manufacturing agreement by the third party;
- the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us; and

- reliance on the third party for regulatory compliance, quality assurance, and safety and pharmacovigilance reporting.

Third-party manufacturers may not be able to comply with current good manufacturing practices, or cGMP, regulations or similar regulatory requirements outside the United States. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or medicines, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our medicines and harm our business and results of operations.

Any product that we may produce may compete with other product candidates and products for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us. Any performance failure on the part of future manufacturers could result in a decrease or end to revenue. If any a contract manufacturer cannot perform as agreed, we may be required to replace that manufacturer. We may incur added costs and delays in identifying and qualifying any such replacement.

Our anticipated future dependence upon others for the manufacture of our product candidates may adversely affect our future profit margins and our ability to commercialize any medicines that receive marketing approval on a timely and competitive basis.

We will likely rely on third parties to conduct our clinical trials. If these third parties do not meet our deadlines or otherwise conduct the trials as required, our clinical development programs could be delayed or unsuccessful and we may not be able to obtain regulatory approval for or commercialize our product candidates when expected or at all.

We do not have the ability to conduct all aspects of our preclinical testing or clinical trials ourselves. We intend to use and do use Mannin, BioNucleonics, ASDERA, RGCB, OMRF and CROs to conduct our planned clinical trials and will and do rely upon such CROs, as well as medical institutions, clinical investigators and consultants, to conduct our trials in accordance with our clinical protocols. Our CROs, investigators and other third parties will and do play a significant role in the conduct of these trials and the subsequent collection and analysis of data from the clinical trials.

There is no guarantee that any CROs, investigators and other third parties upon which we rely for administration and conduct of our clinical trials will devote adequate time and resources to such trials or perform as contractually required. If any of these third parties fail to meet expected deadlines, fail to adhere to our clinical protocols or otherwise perform in a substandard manner, our clinical trials may be extended, delayed or terminated. If any of our clinical trial sites terminate for any reason, we may experience the loss of follow-up information on patients enrolled in our ongoing clinical trials unless we are able to transfer the care of those patients to another qualified clinical trial site. In addition, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive cash or equity compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, the integrity of the data generated at the applicable clinical trial site may be jeopardized.

If our competitors develop treatments for the target indications of our product candidates that are approved more quickly, marketed more successfully or demonstrated to be more effective than our product candidates, our commercial opportunity will be reduced or eliminated.

We operate in highly competitive segments of the biotechnology and biopharmaceutical markets. We face competition from many different sources, including commercial pharmaceutical and biotechnology enterprises, academic institutions, government agencies, and private and public research institutions. Our product candidates, if successfully manufactured and/or developed and approved, will compete with established therapies, as well as new treatments that may be introduced by our competitors. Many of our competitors have significantly greater financial, product development, manufacturing and marketing resources than us. Large pharmaceutical companies have extensive experience in clinical testing and obtaining regulatory approval for drugs. In addition, many universities and private and public research institutes are active in cancer research, some in direct competition with us. We also may compete with these organizations to recruit management, scientists and clinical development personnel. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. New developments, including the development of other biological and pharmaceutical technologies and methods of treating disease, occur in the pharmaceutical and life sciences industries at a rapid pace. Developments by competitors may render our product candidates obsolete or noncompetitive. We will also face competition from these third parties in recruiting and retaining qualified personnel, establishing clinical trial sites and patient registration for clinical trials and in identifying and in-licensing new product candidates.

If competitors introduce their own generic equivalent of our SR89 product candidate, our revenues and gross margin from such products could decline rapidly.

Revenues and gross margin derived from generic pharmaceutical products often follow a pattern based on regulatory and competitive factors that we believe are unique to the generic pharmaceutical industry. As the patent(s) for a brand name product or the statutory marketing exclusivity period (if any) expires, the first generic manufacturer to receive regulatory approval for a generic equivalent of the product often is able to capture a substantial share of the market. However, as other generic manufacturers receive regulatory approvals for their own generic versions, that market share, and the price of that product, will typically decline depending on several factors, including the number of competitors, the price of the branded product and the pricing strategy of the new competitors. The number of our competitors producing a generic version equivalent to our SR89 product candidate could increase to such an extent that

we may stop marketing our product for which we previously obtained approval, which would have a material adverse impact on our revenues, if we ever achieve revenues, and gross margin.

If we are unable to establish sales and marketing capabilities or fail to enter into agreements with third parties to market, distribute and sell any products we may successfully develop, we may not be able to effectively market and sell any such products and generate product revenue.

We do not currently have the infrastructure for the sales, marketing and distribution of any of our product candidates, and must build this infrastructure or make arrangements with third parties to perform these functions in order to commercialize any products that we may successfully develop. The establishment and development of a sales force, either by us or jointly with a partner, or the establishment of a contract sales force to market any products we may develop will be expensive and time-consuming and could delay any product launch. If we, or our partners, are unable to establish sales and marketing capability or any other non-technical capabilities necessary to commercialize any products we may successfully develop, we will need to contract with third parties to market and sell such products. We may not be able to establish arrangements with third parties on acceptable terms, or at all.

We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications for which there may be a greater likelihood of success.

Because we have limited financial and managerial resources, we will focus on a limited number of research programs and product candidates for specific indications. As a result, we may forego or delay pursuit of opportunities with other product candidates for other indications for which there may be a greater likelihood of success or may prove to have greater commercial potential. Notwithstanding our investment to date and anticipated future expenditures on MAN 01 (Mannin), Utroside-B (OMRF), QBM001 (Asdera) and the BioNucleonics IP, we have not yet developed, and may never successfully develop, any marketed treatments using these products other than the SR89 product candidate for which there is FDA approval. Research programs to identify new product candidates or pursue alternative indications for current product candidates require substantial technical, financial and human resources. Although we intend to, and do, support certain investigator-sponsored clinical trials of MAN 01, Utroside-B, QBM001 evaluating various indications, as well as other uses of SR89, these activities may initially show promise in identifying potential product candidates or indications, yet fail to yield product candidates or indications for further clinical development.

We depend upon the services of our key management personnel, and the loss of their services would likely result in disruptions of our operations and have a material adverse effect on our business.

Our management and operations are dependent on the services of our management team, namely Mr. Denis Corin, our Chief Executive Officer and Chairman, and Mr. William Rosenstadt, our Chief Legal Officer and a Director. We do not have employment or non-compete agreements with or maintain key-man life insurance in respect of either of these individuals. Because of their knowledge of the industry and our operations and their experience with us, we believe that our future results depend upon their efforts, and the loss of the services of either of these individuals for any reason could result in a disruption of our operations which will likely have a material adverse effect on our business.

Other than our Chief Executive Officer, we currently do not have full-time employees, but we retain the services of independent contractors/consultants on a contract-employment basis. Our ability to manage growth effectively will require us to continue to implement and improve our management systems and to recruit and train new employees. We might not be able to successfully attract and retain skilled and experienced personnel.

If we fail to attract and retain key management and clinical development personnel, we may be unable to successfully develop or commercialize our product candidates.

We will need to expand and effectively manage our managerial, operational, financial and other resources in order to successfully pursue our clinical development and commercialization efforts. As a company with a limited number of personnel, we highly depend on the development, regulatory, commercial and financial expertise of the members of our senior management and advisors, in particular Denis Corin, our chairman and chief executive officer. The loss of this individual or the services of any of our other senior management could delay or prevent the further development and potential commercialization of our product candidates and, if we are not successful in finding suitable replacements, could harm our business. Our success also depends on our continued ability to attract, retain and motivate highly qualified management and scientific personnel and we may not be able to do so in the future due to the intense competition for qualified personnel among biotechnology and pharmaceutical companies, as well as universities and research organizations. If we are not able to attract and retain the necessary personnel, we may experience significant impediments to our ability to implement our business strategy.

Applicable regulatory requirements, including those contained in and issued under the Sarbanes-Oxley Act of 2002, may make it difficult for us to retain or attract qualified officers and directors, which could adversely affect the management of our business and

our ability to retain listing of our common stock.

We may be unable to attract and retain those qualified officers, directors and members of board committees required to provide for effective management because of the rules and regulations that govern publicly-held companies, including, but not limited to, certifications by principal executive officers. The enactment of the Sarbanes-Oxley Act has resulted in the issuance of a series of related rules and regulations and the strengthening of existing rules and regulations by the SEC, as well as the adoption of new and more stringent rules by the stock exchanges. The perceived increased personal risk associated with these changes may deter qualified individuals from accepting roles as directors and executive officers.

Further, some of these changes heighten the requirements for board or committee membership, particularly with respect to an individual's independence from our business and level of experience in finance and accounting matters. We may have difficulty attracting and retaining directors with the requisite qualifications. If we are unable to attract and retain qualified officers and directors, the management of our business and our ability to obtain or retain listing of our shares of common stock on any stock exchange could be adversely affected.

We may be exposed to potential risks and significant expenses resulting from the requirements under section 404 of the Sarbanes-Oxley Act of 2002.

We are required, pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, to include in our annual report our assessment of the effectiveness of our internal control over financial reporting. We expect to incur significant continuing costs, including accounting fees and staffing costs, in order to maintain compliance with the internal control requirements of the Sarbanes-Oxley Act of 2002. Our management concluded that our internal controls and procedures were not effective to detect the inappropriate application of US GAAP for our most recent fiscal year. As we develop our business, hire employees and consultants and seek to protect our intellectual property rights, our current design for internal control over financial reporting must be strengthened to enable management to determine that our internal controls are effective for any period, or on an ongoing basis. Accordingly, as we develop our business, such development and growth will necessitate changes to our internal control systems, processes and information systems, all of which will require additional costs and expenses.

In the future, if we fail to complete the annual Section 404 evaluation in a timely manner, we could be subject to regulatory scrutiny and a loss of public confidence in our internal controls. In addition, any failure to implement required new or improved controls, or difficulties encountered in their implementation, could harm our operating results or cause us to fail to meet our reporting obligations.

Because of the small size of our company, we do not have separate Chairman, Chief Executive Officer and Chief Financial Officer positions, which may expose us to potential risks, including our failure to produce reliable financial reports and prevent and/or detect fraud.

We have not adopted a formal policy to separate or combine the positions of Chairman and Chief Executive Officer, both of which are currently held by Denis Corin who is also our acting principal financial officer. In addition, our two employees also comprise our Board of Directors. As such, there is no division of labor between our management and of our Board of Directors. This structure exposes us to a number of risks, including a failure to maintain adequate internal controls, our failure to produce reliable financial reports and our failure to prevent and/or detect financial fraud. Any such failures would adversely affect our financial condition and overall business operations.

We are required, pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, to include in our annual report our assessment of the effectiveness of our internal control over financial reporting. We expect to incur significant continuing costs, including accounting fees and staffing costs, in order to maintain compliance with the internal control requirements of the Sarbanes-Oxley Act of 2002. Our management concluded that our internal controls and procedures were not effective to detect the inappropriate application of US GAAP for our most recent fiscal year. As we develop our business, hire employees and consultants and seek to protect our intellectual property rights, our current design for internal control over financial reporting must be strengthened to enable management to determine that our internal controls are effective for any period, or on an ongoing basis. Accordingly, as we develop our business, such development and growth will necessitate changes to our internal control systems, processes and information systems, all of which will require additional costs and expenses. Among other outcomes, a downturn in general economic conditions could:

- increase the cost of raising, or decrease our ability to raise, additional funds; as we do not anticipate generating sufficient revenue in the next twelve months to cover our operating costs, we may need to raise additional funding to implement our business if we do not raise sufficient funds in this offering. A recession or other negative economic factors could make this more difficult or prohibitive; or
- interfere with services provided by third parties; we use third parties for research purposes and intend to use third parties for the production and distribution of our generic SR89 product candidate, and a general recession or other economic conditions could jeopardize the ability of any third parties to fulfill their obligations to us;

In the future, if we fail to complete the annual Section 404 evaluation in a timely manner, we could be subject to regulatory scrutiny and a loss of public confidence in our internal controls. In addition, any failure to implement required new or improved controls, or difficulties encountered in their implementation, could harm our operating results or cause us to fail to meet our reporting obligations.

Two of our assets may compete with each other and we will need to address how to proceed with each asset

Our Strontium Chloride 89 product from BNI is the generic version of our Metastron product that we acquired from GE Healthcare Limited. Having two products based on the same [drug] for the same bone cancer pain mediation therapy may prove to be redundant. We have not yet decided how to proceed with these assets if they prove to be redundant, but we may have to abandon one of the

products or severely curtail our plans for its development. Any such abandonment or curtailment would reduce potential income from such product.

We might not be successful in our litigation against BNI

On December 28, 2018, we commenced litigation against and parties related to BNI in connection with a license agreement that we entered into with BNI in 2016 and amended from time to time. Under the agreement with BNI, we were granted a worldwide, exclusive license on certain BNI intellectual property and the option to acquire the BNI IP within three years of the agreement. The BNI IP consists of generic Strontium Chloride SR89 (generic Metastron®) (“SR89”) and all of BNI’s intellectual property relating to it (“BNI IP”). SR89 is a radiopharmaceutical therapeutic for cancer bone pain therapy.

Under the agreement, once we have funded up to \$850,000 in cash, we may exercise the option to acquire the BNI IP at no additional charge. By our accounts, we have provided BNI with over \$950,000 in cash. We have exercised our option to acquire the BNI IP, but BNI has not transferred the BNI IP to us. As a result, we have commenced litigation to, among other actions, obtain all of the BNI IP. We also seek judgments against BNI and related parties for the misappropriation of funds, breach of contract, fraud and fraudulent inducement.

If we are not successful in our litigation, the BNI IP could remain the property of BNI or be sold by BNI to a third party. Not only would our potential income be reduced if the BNI IP were not ours, but it could directly compete with our Metastron product.

Risks Related to our Industry

We are subject to general economic conditions outside of our control.

Projects for the acquisition and development of our products are subject to many factors, which are outside our control. These factors include general economic conditions in North America and worldwide (such as recession, inflation, unemployment, and interest rates), shortages of labor and materials and price of materials and competitive products and the regulation by federal and state governmental authorities. If any or several of these facts develop in a way that is adverse to our interest, we will not be in a position to reverse them, and we may not be able to survive such a development.

If any product candidate that we successfully develop does not achieve broad market acceptance among physicians, patients, healthcare payors and the medical community, the revenues that it generates from their sales will be limited.

Even if we successfully produce product candidates, they may not gain market acceptance among physicians, patients, healthcare payors and the medical community. Coverage and reimbursement of our product candidates by third-party payors, including government payors, generally is also necessary for commercial success. The degree of market acceptance of any approved products will depend on a number of factors, including:

- the efficacy and safety as demonstrated in clinical trials;
- the clinical indications for which the product is approved;
- acceptance by physicians, major operators of hospitals and clinics and patients of the product as a safe and effective treatment;
- acceptance of the product by the target population;
- the potential and perceived advantages of product candidates over alternative treatments;
- the safety of product candidates seen in a broader patient group, including its use outside the approved indications;
- the cost of treatment in relation to alternative treatments;
- the availability of adequate reimbursement and pricing by third parties and government authorities;
- relative convenience and ease of administration;
- the prevalence and severity of adverse events;
- the effectiveness of our sales and marketing efforts; and
- unfavorable publicity relating to the product.

If any product candidate is approved but does not achieve an adequate level of acceptance by physicians, hospitals, healthcare payors and patients, we may not generate sufficient revenue from these products and may not become or remain profitable.

We may incur substantial product liability or indemnification claims relating to the clinical testing and/or use of our product candidates.

We face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials, as well as related to the manufacture and consumption of product candidates that we successfully commercialize. Claims could be brought against us if use or misuse of one of our product candidates causes, or merely appears to have caused, personal injury or death. While the manufacturer of our SR89 product maintains a \$5 Million product liability policy, and BioNucleonics, the holder of the Abbreviated New Drug Application (“ANDA”)s are responsible for having their own coverage, we intend to obtain supplemental coverage, but do not currently have our own product liability insurance. When we initiate commercial activity or additional clinical trials, we intend to obtain the relevant coverage. As a result, such coverage may not be sufficient to cover claims that may be made against us and we may be unable to maintain such insurance. Any claims against us, regardless of their merit, could severely harm our financial condition, strain our management and other resources or destroy the prospects for commercialization of the product which is the subject of any such claim. We are unable to predict if we will be able to obtain or maintain product liability insurance for any products that may be

approved for marketing. Additionally, we have entered into various agreements where we indemnify third parties for certain claims relating to our product candidates. These indemnification obligations may require us to pay significant sums of money for claims that are covered by these indemnifications.

Healthcare reform and restrictions on reimbursements may limit our financial returns.

Our ability or the ability of our collaborators to commercialize any of our product candidates that we successfully develop may depend, in part, on the extent to which government health administration authorities, private health insurers and other organizations will reimburse consumers for the cost of these products. These third parties are increasingly challenging both the need for and the price of new drug products. Significant uncertainty exists as to the reimbursement status of newly approved therapeutics. Adequate third-party reimbursement may not be available for our product candidates to enable us or our collaborators to maintain price levels sufficient to realize an appropriate return on their and our investments in research and product development.

Our success depends upon intellectual property, proprietary technologies and regulatory market exclusivity periods, and the intellectual property protection for our product candidates depends significantly on third parties.

Our success depends, in large part, on obtaining and maintaining patent protection and trade secret protection for our product candidates and their formulations and uses, as well as successfully defending these patents against third-party challenges. The parties from which we license our intellectual property are responsible for prosecuting and maintaining patent protection relating to the intellectual property to which we have a license from that party. If any of these parties fails to appropriately prosecute and maintain patent protection for the intellectual property, our ability to develop and commercialize the respective product candidate may be adversely affected and we may not be able to prevent competitors from making, using and selling competing products. This failure to properly protect the intellectual property rights could have a material adverse effect on our financial condition and results of operations.

The patent application process is subject to numerous risks and uncertainties, and we or our partners might not be successful in protecting our product candidates by obtaining and defending patents. These risks and uncertainties include the following:

- patent applications may not result in any patents being issued;
- patents that may be issued or in-licensed may be challenged, invalidated, modified, revoked, circumvented, found to be unenforceable, or otherwise may not provide any competitive advantage;
- our competitors, many of which have substantially greater resources than we or our partners and many of which have made significant investments in competing technologies, may seek, or may already have obtained, patents that will limit, interfere with, or eliminate our ability to make, use and sell our potential products;
- there may be significant pressure on the U.S. government and other international governmental bodies to limit the scope of patent protection both inside and outside the United States for disease treatments that prove successful as a matter of public policy regarding worldwide health concerns; and
- countries other than the United States may have patent laws less favorable to patentees than those upheld by U.S. courts, allowing foreign competitors a better opportunity to create, develop, and market competing products.

In addition to patents, we and our partners also rely on trade secrets and proprietary know-how. Although we have taken steps to protect our trade secrets and unpatented know-how, including entering into confidentiality agreements with third parties, and confidential information and inventions agreements with employees, consultants and advisors, third parties may still obtain this information or come upon this same or similar information independently.

We also intend to rely on our ability to obtain and maintain a regulatory period of market exclusivity for any of our biologic product candidates that are successfully developed and approved for commercialization. Although this period in the United States is currently 12 years from the date of marketing approval, there is a risk that the U.S. Congress could amend laws to significantly shorten this exclusivity period, as proposed by President Obama. Once any regulatory period of exclusivity expires, depending on the status of our patent coverage and the nature of the product, we may not be able to prevent others from marketing products that are biosimilar to or interchangeable with our products, which would materially adversely affect us.

In addition, U.S. patent laws may change which could prevent or limit us from filing patent applications or patent claims to protect our products and/or technologies or limit the exclusivity periods that are available to patent holders. For example, on September 16, 2011, the Leahy-Smith America Invents Act, or the America Invents Act, was signed into law, and includes a number of significant changes to U.S. patent law. These include changes to transition from a “first-to-invent” system to a “first-to-file” system and to the way issued patents are challenged. These changes may favor larger and more established companies that have more resources to devote to patent application filing and prosecution. The U.S. Patent and Trademark Office implemented the America Invents Act on March 16, 2013,

and it remains to be seen how the judicial system and the U.S. Patent and Trademark Office will interpret and enforce these new laws. Accordingly, it is not clear what impact, if any, the America Invents Act will ultimately have on the cost of prosecuting our patent applications, our ability to obtain patents based on our discoveries and our ability to enforce or defend our issued patents.

If we or our partners are sued for infringing intellectual property rights of third parties, it will be costly and time consuming, and an unfavorable outcome in that litigation would have a material adverse effect on our business.

Our success also depends on our ability and the ability of any of our current or future collaborators to develop, manufacture, market and sell our product candidates without infringing the proprietary rights of third parties. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing products, some of which may be directed at claims that overlap with the subject matter of our intellectual property. Because patent applications can take many years to issue, there may be currently pending applications, unknown to us, which may later result in issued patents that our product candidates or proprietary technologies may infringe. Similarly, there may be issued patents relevant to our product candidates of which we are not aware.

There is a substantial amount of litigation involving patent and other intellectual property rights in the biotechnology and biopharmaceutical industries generally. If a third-party claims that we or any of our licensors, suppliers or collaborators infringe the third party's intellectual property rights, we may have to:

- obtain licenses, which may not be available on commercially reasonable terms, if at all;
- abandon an infringing product candidate or redesign our products or processes to avoid infringement;
- pay substantial damages, including the possibility of treble damages and attorneys' fees, if a court decides that the product or proprietary technology at issue infringes on or violates the third party's rights;
- pay substantial royalties, fees and/or grant cross licenses to our technology; 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.

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

Competitors may infringe our patents or the patents of our licensors. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated, found to be unenforceable, or interpreted narrowly and could put our patent applications at risk of not issuing. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation.

We may be subject to claims that our consultants or independent contractors have wrongfully used or disclosed alleged trade secrets of their other clients or former employers to us.

As is common in the biotechnology and pharmaceutical industry, we engage the services of consultants to assist us in the development of our product candidates. Many of these consultants were previously employed at, or may have previously been or are currently providing consulting services to, other biotechnology or pharmaceutical companies, including our competitors or potential competitors. We may become subject to claims that we or these consultants have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers or their former or current customers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

Risks Related to our Securities

Our shares of common stock are subject to the "penny stock" rules of the securities and exchange commission and the trading market in our securities will be limited, which will make transactions in our stock cumbersome and may reduce the value of an investment in our stock.

The U.S. Securities and Exchange Commission has adopted rules that regulate broker-dealer practices in connection with transactions in "penny stocks." Penny stocks generally are equity securities with a price of less than \$5 (other than securities registered on certain national securities exchanges or quoted on the NASDAQ system, provided that current price and volume information with respect to transactions in such securities is provided by the exchange or system). Penny stock rules require a broker-dealer, prior to a transaction in a penny stock not otherwise exempt from those rules, to deliver a standardized risk disclosure document prepared by the SEC, which specifies information about penny stocks and the nature and significance of risks of the penny stock market. A broker-dealer must also provide the customer with bid and offer quotations for the penny stock, the compensation of the broker-dealer, and sales person in the

transaction, and monthly account statements indicating the market value of each penny stock held in the customer's account. In addition, the penny stock rules require that, prior to a transaction in a penny stock not otherwise exempt from those rules, the broker-dealer must make a special written determination that the penny stock is a suitable investment for the purchaser and receive the purchaser's written agreement to the transaction. These disclosure requirements may have the effect of reducing the trading activity in the secondary market for stock that becomes subject to those penny stock rules. If a trading market for our common stock develops, our common stock will probably become subject to the penny stock rules, and shareholders may have difficulty in selling their shares.

Any additional financing may dilute existing shareholders and decrease the market price for shares of our common stock.

If we raise additional capital, our existing shareholders may incur substantial and immediate dilution. We estimate that we will need approximately \$20,000,000 in additional funds over the next two years to complete our business plan. The most likely source of future funds available to us is through the sale of additional shares of common stock. Such sales might occur below market price and below the price of which existing shareholders purchased their shares.

Our Articles of Incorporation provide indemnification for officers, directors and employees.

Our governing instruments provide that officers, directors, employees and other agents and their affiliates shall only be liable to our Company for losses, judgments, liabilities and expenses that result from the negligence, misconduct, fraud or other breach of fiduciary obligations. Thus certain alleged errors or omissions might not be actionable by us. The governing instruments also provide that, under the broadest circumstances allowed under law, we must indemnify our officers, directors, employees and other agents and their affiliates for losses, judgments, liabilities, expenses and amounts paid in settlement of any claims sustained by them in connection with our Company, including liabilities under applicable securities laws.

The market price of our common stock may be volatile and may fluctuate in a way that is disproportionate to our operating performance.

Our shares of common stock trading on the OTCQB will fluctuate significantly. There is a volatility associated with Bulletin Board securities in general and the value of your investment could decline due to the impact of any of the following factors upon the market price of our common stock:

- sales or potential sales of substantial amounts of our common stock;
- delay or failure in initiating or completing pre-clinical or clinical trials or unsatisfactory results of these trials;
- announcements about us or about our competitors, including clinical trial results, regulatory approvals or new product introductions;
- developments concerning our licensors, product manufacturers or our ability to produce Man-01;
- developments concerning our licensors, product manufacturers or our ability to produce SR89;
- litigation and other developments relating to our patents or other proprietary rights or those of our competitors;
- conditions in the pharmaceutical or biotechnology industries;
- governmental regulation and legislation;
- variations in our anticipated or actual operating results;
- change in securities analysts' estimates of our performance, or our failure to meet analysts' expectations;
- change in general economic trends; and
- investor perception of our industry or our prospects.

Many of these factors are beyond our control. The stock markets in general, and the market for pharmaceutical and biotechnological companies in particular, have historically experienced extreme price and volume fluctuations. These fluctuations often have been unrelated or disproportionate to the operating performance of these companies. These broad market and industry factors could reduce the market price of our common stock, regardless of our actual operating performance.

Sales of a substantial number of shares of our common stock, or the perception that such sales may occur, may adversely impact the price of our common stock.

A large number of our shares may be sold without restriction in public markets. These include:

- approximately 10,000,000 of our outstanding shares of common stock recorded by our transfer agent as of November 30, 2018 as unrestricted and freely tradable;
- shares of our common stock that are, or are eligible to be, unrestricted and free trading pursuant to Rule 144 or other exemptions from registration under the Securities Act that have not yet been recorded by our transfer agent as such;

Any such sales, or the fear of such sales, could substantially decrease the market price of our common stock and the value of your investment.

We have not paid dividends to date and do not intend to pay any dividends in the near future.

We have never paid dividends on our common stock and presently intend to retain any future earnings to finance the operations of our business. You may never receive any dividends on our shares.

The exercise of warrants and options or future sales of our common stock may further dilute the shares of common stock you receive in this offering.

As of the date hereof, we have outstanding vested and unvested options and warrants exercisable into 5,768,558 shares of common stock. The issuance of any shares of common stock pursuant to exercise of such options and warrants or the conversion of such notes would dilute your percentage ownership of our Company, and the issuance of any shares of common stock pursuant to exercise of such options and warrants or the conversion of such notes at a per share price below the offering price of shares being acquired in this offering which would dilute the net tangible value per share for such investor.

Our Board of Directors is authorized to sell additional shares of common stock, or securities convertible into shares of common stock, if in their discretion they determine that such action would be beneficial to us. Approximately 95% of our authorized shares of common stock and 100% of our shares of preferred stock are available for issuance. Any such issuance would dilute the ownership interest of persons acquiring common stock in this offering, and any such issuance at a share price lower than then net tangible book value per share at the time an investor purchased its shares would dilute the net tangible value per share for such investor.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. DESCRIPTION OF PROPERTY

The Company maintains a corporate office at 366 Madison Avenue, 3rd Floor, New York, NY 10017. Such office is solely for the purpose of maintaining a physical presence to receive correspondence, and it is at no cost as our general counsel maintains his offices at that location. The company also maintains an office in Grand Cayman, where the Company's President and Chairman, Mr. Denis Corin, resides, at the cost of \$30,000 per annum.

ITEM 3. LEGAL PROCEEDINGS

On December 28, 2018, we commenced litigation against BioNucleonics, Inc. ("BNI") and parties related to BNI. The litigation stems from a license agreement that we entered into with BNI in 2016, as amended. Under the agreement with BNI, we were granted a worldwide, exclusive license on certain BNI intellectual property and the option to acquire the BNI IP within three years of the agreement. The BNI IP consists of generic Strontium Chloride SR89 (generic Metastron®) ("SR89") and all of BNI's intellectual property relating to it ("BNI IP"). SR89 is a radiopharmaceutical therapeutic for cancer bone pain therapy.

Under the agreement, once we have funded up to \$850,000 in cash, we may exercise the option to acquire the BNI IP at no additional charge. By our accounts, we have provided BNI with over \$950,000 in cash. We have exercised our option to acquire the BNI IP, but BNI has not transferred the BNI IP to us. As a result, we have commenced litigation to, among other actions, obtain all of the BNI IP. We also seek judgments against BNI and related parties for the misappropriation of funds, breach of contract, fraud and fraudulent inducement.

ITEM 4. MINE SAFETY DISCLOSURES

None.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY AND RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Information

Our common stock is listed on the Over the Counter QB ("OTCQB") under the symbol "QBIO". The market for our common stock is limited, volatile and sporadic. The following table sets forth, for the periods indicated, the high and low bid prices of our common stock on the OTCQB as reported by Google Finance.

The last reported sales price for our shares on the OTCQB as of February 26, 2018, was \$1.85 per share. As of February 26, 2018, we had approximately 7700 non-objecting beneficial shareholders (NOBO list November 2018) who held stock through securities position listings.

Holdings

As of February 26, 2018, we had 14,466,155 shares of \$0.001 par value common stock issued and outstanding. Our Transfer Agent is VStock Transfer, LLC, 18 Lafayette Place, Woodmere, NY 11598, Phone: (212) 828-8436.

Dividends

We have never declared or paid any cash dividends on our common stock. For the foreseeable future, we intend to retain any earnings to finance the development and expansion of our business and do not anticipate paying any cash dividends on our common stock. Any future determination to pay dividends will be at the discretion of the Board of Directors and will depend upon then existing conditions, including our financial condition and results of operations, capital requirements, contractual restrictions, business prospects and other factors that the board of directors considers relevant.

ITEM 6. SELECTED FINANCIAL DATA

We are a smaller reporting company as defined by Rule 12b-2 of the Exchange Act and are not required to provide the information required under this item.

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion of our financial condition and results of operations should be read in conjunction with our consolidated financial statements and related notes included elsewhere in this report. This discussion contains certain forward-looking statements that involve risk and uncertainties. Our actual results may differ materially from those discussed below. Factors that could cause or contribute to such differences include, but are not limited to, those identified below and those set forth under the Section entitled "Risk Factors", and other documents we file with the Securities and Exchange Commission. Historical results are not necessarily indicative of future results.

Overview

Q BioMed Inc. (or "the Company") was incorporated in the State of Nevada on November 22, 2013 and is a biomedical acceleration and development company focused on licensing, acquiring and providing strategic resources to life sciences and healthcare companies. We intend to mitigate risk by acquiring multiple assets over time and across a broad spectrum of healthcare related products, companies and sectors. We intend to develop these assets to provide returns via organic growth, revenue production, out-licensing, sale or spin out.

Recent Developments

Capital Raising

On February 1, 2018 we closed a \$5.48 million equity financing. This financing with a small group of hedge funds and accredited investors provides the capital to advance all assets and the capital to meet near term catalysts.

On September 21, 2018 and November 1, 2018, we sold an aggregate of \$4,000,000 worth of convertible notes to an investor. The conversion price for the convertible notes is the lesser of (i) \$4.00 and (ii) 93% of the four lowest VWAPs during the last ten trading days immediately preceding the date of such conversion, but in no event will the conversion price be less than \$2.00. The convertibles notes have a term of eighteen months and bear interest at the rate of 5.5% per annum.

BioNucleonics Inc. Litigation

On December 28, 2018, we commenced litigation against BioNucleonics, Inc. (“BNI”) and parties related to BNI to, among other actions, obtain all of the BNI IP. Under the license agreement that we entered into with BNI in 2016, as amended, we were granted a worldwide, exclusive license on certain BNI intellectual property (Strontium 89 Chloride radiopharmaceutical drug) and the option to acquire the BNI IP within three years of the agreement once we funded up to \$850,000 in cash. By our accounts, we have provided BNI with over \$950,000 in cash. We have exercised our option to acquire the BNI IP, but BNI has not transferred the BNI IP to us. We also seek judgments against BNI and related parties for the misappropriation of funds, breach of contract, fraud and fraudulent inducement.

Metastron

On November 23, 2018, we entered into an Asset Sale Agreement (“ASA”) with GE Healthcare Limited (“GE”) whereby we acquired GE’s radiopharmaceutical drug, Metastron® and all related intellectual property including, but not limited to sales and distribution data, market authorizations and trademarks for Metastron® in various countries. We did not acquire any workforce, manufacturing, inventory, sales agreements, or distribution agreements associated with Metastron®.

Financial Overview

Critical Accounting Policies and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our audited consolidated financial statements, which have been prepared in accordance with United States generally accepted accounting principles (“U.S. GAAP”). The preparation of the consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the consolidated financial statements, as well as the reported revenue generated and expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions and any such differences may be material. We believe that the accounting policies discussed below are critical to understanding our historical and future performance, as these policies relate to the more significant areas involving management's judgments and estimates.

Fair value of financial instruments

Fair value estimates discussed herein are based upon certain market assumptions and pertinent information available to management as of November 30, 2018 and 2017. The respective carrying value of certain on-balance-sheet financial instruments approximated their fair values. These financial instruments include cash and accounts payable. Fair values were assumed to approximate carrying values for cash and accounts payable because they are short term in nature.

FASB Accounting Standards Codification (ASC) 820 “*Fair Value Measurements and Disclosures*” (ASC 820) defines fair value as the exchange price that would be received for 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 on the measurement date. ASC 820 also establishes a fair value hierarchy that distinguishes between (1) market participant assumptions developed based on market data obtained from independent sources (observable inputs) and (2) an entity’s own assumptions about market participant assumptions developed based on the best information available in the circumstances (unobservable inputs). The fair value hierarchy consists of three broad levels, which gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1) and the lowest priority to unobservable inputs (Level 3). The three levels of the fair value hierarchy are described below:

- **Level 1:** The preferred inputs to valuation efforts are “quoted prices in active markets for identical assets or liabilities,” with the caveat that the reporting entity must have access to that market. Information at this level is based on direct observations of transactions involving the same assets and liabilities, not assumptions, and thus offers superior reliability. However, relatively few items, especially physical assets, actually trade in active markets.
- **Level 2:** FASB acknowledged that active markets for identical assets and liabilities are relatively uncommon and, even when they do exist, they may be too thin to provide reliable information. To deal with this shortage of direct data, the board provided a second level of inputs that can be applied in three situations.

- **Level 3:** If inputs from levels 1 and 2 are not available, FASB acknowledges that fair value measures of many assets and liabilities are less precise. The board describes Level 3 inputs as “unobservable,” and limits their use by saying they “shall be used to measure fair value to the extent that observable inputs are not available.” This category allows “for situations in which there is little, if any, market activity for the asset or liability at the measurement date”. Earlier in the standard, FASB explains that “observable inputs” are gathered from sources other than the reporting company and that they are expected to reflect assumptions made by market participants.

Fair value measurements discussed herein are based upon certain market assumptions and pertinent information available to management as of and during the years ended November 30, 2018 and 2017. The respective carrying value of cash and accounts payable approximated their fair values as they are short term in nature.

Intangible Assets

Intangible assets subject to amortization include acquired intellectual property for a marketable product acquired in November 2018. The intellectual property is being amortized over the estimated life remaining at the time of acquisition, which is 10 years.

Intangible assets are monitored for potential impairment whenever events or circumstances indicate that the carrying amount may not be recoverable and are also reviewed annually to determine whether any impairment is necessary. The annual review of intangible assets is performed via a two-step process. First, a qualitative assessment is performed to determine if it is more likely than not that the intangible asset is impaired. If required, a quantitative assessment is performed and, if necessary, impairment is recorded.

Debt Issuance Costs

Direct costs incurred to issue non-revolving debt instruments are recognized as a reduction to the related debt balance in the accompanying Consolidated Balance Sheets and amortized to interest expense over the contractual term of the related debt using the effective interest method.

Embedded Conversion Features

We evaluate embedded conversion features within convertible debt to determine whether the embedded conversion feature(s) should be bifurcated from the host instrument and accounted for as a derivative at fair value with changes in fair value recorded in the Statement of Operations. If the conversion feature does not require recognition of a bifurcated derivative, the convertible debt instrument is evaluated for consideration of any beneficial conversion feature (“BCF”) requiring separate recognition. When we record a BCF, the intrinsic value of the BCF is recorded as a debt discount against the face amount of the respective debt instrument (offset to additional paid-in capital) and amortized to interest expense over the life of the debt.

Derivative Financial Instruments

We do not use derivative instruments to hedge exposures to cash flow, market, or foreign currency risks. We evaluate all of our financial instruments, including issued stock purchase warrants, to determine if such instruments are derivatives or contain features that qualify as embedded derivatives. For derivative financial instruments that are accounted for as liabilities, the derivative instrument is initially recorded at its fair value and is then re-valued at each reporting date, with changes in the fair value reported in the Statement of Operations. Depending on the features of the derivative financial instrument, we use either the Black-Scholes option-pricing model or a binomial model to value the derivative instruments at inception and subsequent valuation dates. The classification of derivative instruments, including whether such instruments should be recorded as liabilities or as equity, is re-assessed at the end of each reporting period.

Stock Based Compensation Issued to Nonemployees

Common stock issued to non-employees for acquiring goods or providing services is recognized at fair value when the goods are obtained or over the service period. If the award contains performance conditions, the measurement date of the award is the earlier of the date at which a commitment for performance by the non-employee is reached or the date at which performance is reached. A performance commitment is reached when performance by the non-employee is probable because of sufficiently large disincentives for nonperformance.

Research and Development

We expense the cost of research and development as incurred. Research and development expenses comprise costs incurred in funding research and development activities, license fees, and other external costs. Nonrefundable advance payments for goods and services that will be used in future research and development activities are expensed when the activity is performed or when the goods have been received, rather than when payment is made, in accordance with ASC 730, *Research and Development*.

Income Taxes

Deferred tax assets and liabilities are computed based upon the difference between the financial statement and income tax basis of assets and liabilities using the enacted marginal tax rate applicable when the related asset or liability is expected to be realized or settled. Deferred income tax expenses or benefits are based on the changes in the asset or liability each period. If available evidence suggests that it is more likely than not that some portion or all of the deferred tax assets will not be realized, a valuation allowance is required to reduce the deferred tax assets to the amount that is more likely than not to be realized. Future changes in such valuation allowance are included in the provision for deferred income taxes in the period of change.

Deferred income taxes may arise from temporary differences resulting from income and expense items reported for financial accounting and tax purposes in different periods. Deferred taxes are classified as current or non-current, depending on the classification of assets and liabilities to which they relate. Deferred taxes arising from temporary differences that are not related to an asset or liability are classified as current or non-current depending on the periods in which the temporary differences are expected to reverse.

We apply a more-likely-than-not recognition threshold for all tax uncertainties, which only allows the recognition of those tax benefits that have a greater than fifty percent likelihood of being sustained upon examination by the taxing authorities. As of November 30, 2018, we reviewed our tax positions and determined there were no outstanding, or retroactive tax positions with less than a 50% likelihood of being sustained upon examination by the taxing authorities, therefore this standard has not had a material effect on us.

Our policy for recording interest and penalties associated with audits is to record such expense as a component of income tax expense. There were no amounts accrued for penalties or interest during the years ended November 30, 2018. Management is currently unaware of any issues under review that could result in significant payments, accruals or material deviations from our position.

On December 22, 2017, the United States enacted new tax legislation, the Tax Cuts and Jobs Act (the "Tax Act"). The Tax Act includes significant changes to corporate taxation, including reduction of the U.S. corporate tax rate from 35% to 21%, effective January 1, 2018, limitation of the tax deduction for interest expense to 30% of earnings (except for certain small businesses), limitation of the deduction for net operating losses to 80% of current year taxable income and elimination of net operating loss carrybacks. The Tax Act states that the 21% U.S. federal corporate tax rate is effective for tax years beginning on or after January 1, 2018. However, existing tax law, which was not amended under the Tax Act, governs when a change in tax rate is effective. Existing tax law provides that if the taxable year includes the effective date of any rate change (unless the change is the first date of the taxable year), taxes should be calculated by applying a blended rate to the taxable income for the year. Consequently, we have recorded a decrease related to deferred tax assets, exclusive of the corresponding change in the valuation allowance, for the year ended November 30, 2018. Due to the full valuation allowance on the deferred tax assets, there is no net adjustment to deferred tax expense or benefit due to the reduction of the corporate tax rate.

In conjunction with the tax law changes, the SEC staff issued Staff Accounting Bulletin No. 118 ("SAB 118") to address the application of U.S. GAAP in situations when a registrant does not have the necessary information available, prepared, or analyzed (including computations) in reasonable detail to complete the accounting for certain income tax effects of the Tax Act. The ultimate impact, which is expected to be recorded by November 30, 2018, may differ from any provisional amounts, due to, among other things, additional analysis, changes in interpretations and assumptions we have made, additional regulatory guidance that may be issued, and

actions we may take as a result of the tax Act, and the fact that we cannot definitively predict what our deferred tax balance will ultimately be as of November 30, 2018.

Recent accounting pronouncements

On February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)*. Under the new guidance, lessees will be required to recognize all leases (with the exception of short-term leases) on the balance sheet as a lease liability, which is a lessee's obligation to make lease payments arising from a lease, measured on a discounted basis and a right-of-use asset, which is an asset that represents the lessee's right to use, or control the use of, a specified asset for the lease term. The new standard is effective for us on December 1, 2019. We are currently evaluating the effect the guidance will have on our Consolidated Financial Statements.

In August 2016, the FASB issued ASU No. 2016-15, *Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments*. This new standard clarifies certain aspects of the statement of cash flows, including the classification of debt prepayment or debt extinguishment costs or other debt instruments with coupon interest rates that are insignificant in relation to the effective interest rate of the borrowing, contingent consideration payments made after a business combination, proceeds from the settlement of insurance claims, proceeds from the settlement of corporate-owned life insurance policies, distributions received from equity method investees and beneficial interests in securitization transactions. This new standard also clarifies that an entity should determine each separately identifiable source of use within the cash receipts and payments on the basis of the nature of the underlying cash flows. In situations in which cash receipts and payments have aspects of more than one class of cash flows and cannot be separated by source or use, the appropriate classification should depend on the activity that is likely to be the predominant source or use of cash flows for the item. This new standard is effective for us on December 1, 2018. Our adoption of the new standard is not expected to have a significant impact on reported cash flows.

In July 2017, the FASB issued ASU 2017-11, *Earnings Per Share (Topic 260); Distinguishing Liabilities from Equity (Topic 480); Derivatives and Hedging (Topic 815): (Part I) Accounting for Certain Financial Instruments with Down Round Features, (Part II) Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception*. The ASU allows companies to exclude a down round feature when determining whether a financial instrument (or embedded conversion feature) is considered indexed to the entity's own stock. As a result, financial instruments (or embedded conversion features) with down round features may no longer be required to be accounted classified as liabilities. A company will recognize the value of a down round feature only when it is triggered and the strike price has been adjusted downward. For equity-classified freestanding financial instruments, such as warrants, an entity will treat the value of the effect of the down round, when triggered, as a dividend and a reduction of income available to common shareholders in computing basic earnings per share. For convertible instruments with embedded conversion features containing down round provisions, entities will recognize the value of the down round as a beneficial conversion discount to be amortized to earnings. The guidance in ASU 2017-11 is effective for us on December 1, 2019. Early adoption is permitted, and the guidance is to be applied using a full or modified retrospective approach. We are currently evaluating the impact of the new standard on our consolidated financial statements.

In June 2018, the FASB issued ASU 2018-07, *Compensation – Stock Compensation (Topic 718), Improvements to Nonemployee Share-Based Payment Accounting*. This ASU is intended to simplify aspects of share-based compensation issued to non-employees by making the guidance consistent with the accounting for employee share-based compensation. It is effective for us on December 1, 2019. We are currently evaluating the impact of the new standard on our consolidated financial statements.

In August 2018, the FASB issued ASU 2018-13, *Fair Value Measurement (Topic 820), Disclosure Framework, Changes to the Disclosure Requirements for Fair Value Measurement*, which makes a number of changes meant to add, modify or remove certain disclosure requirements associated with the movement amongst or hierarchy associated with Level 1, Level 2 and Level 3 fair value measurements. This guidance is effective for us on December 1, 2020. Early adoption is permitted upon issuance of the update. We do not expect the adoption of this guidance to have a material impact on our Consolidated Financial Statements.

Recent adopted pronouncements

In May 2017, the FASB issued ASU 2017-09, *Compensation – Stock Compensation (Topic 718): Scope of Modification Accounting*. The new standard provides guidance about which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting in Topic 718. Early adoption is permitted, including adoption in any interim period. We adopted ASU 2017-09 as of December 1, 2017. The adoption of this standard did not impact our consolidated financial statements.

Results of Operation for the years ended November 30, 2018 and 2017

	For the year ended November 30,	
	2018	2017
Operating expenses:		
General and administrative expenses	\$ 5,781,613	\$ 9,271,804
Research and development expenses	3,238,060	3,099,971
Total operating expenses	<u>9,019,673</u>	<u>12,371,775</u>
Other income (expenses):		
Interest expense	(162,104)	(760,314)
Interest income	-	138
Loss on conversion of debt	-	(463,578)
Loss on extinguishment of debt	-	(76,251)
Change in fair value of embedded derivatives	(89,000)	(810,017)
Change in fair value of warrant liability	-	(59,870)
Total other income (expenses)	<u>(251,104)</u>	<u>(2,169,892)</u>
Net loss	<u>\$ (9,270,777)</u>	<u>\$ (14,541,667)</u>
Net loss per share - basic and diluted	\$ (0.67)	\$ (1.39)
Weighted average shares outstanding, basic and diluted	13,735,134	10,466,648

Operating expenses

We incur various costs and expenses in the execution of our business. Our operating expenses decreased to \$9.0 million for the year ended November 30, 2018 from \$12.4 million for the corresponding period in 2017. The decrease in operating expenses was mainly due to a decrease in stock-based compensation.

Other (income) expenses

Our total other expenses decreased to \$251,000 during the year ended November 30, 2018 from \$2.2 million during the prior year, primarily as the result of decrease in interest expense, losses on the conversion and extinguishment of debt, the change in fair value of embedded derivatives and the change in fair value of warrant liability.

During the year ended November 30, 2018, interest expense decreased to \$162,000 from \$760,000 in the prior year. Interest expense in the year ended November 30, 2018 is comprised of approximately \$132,000 accretion of debt discount and approximately \$30,000 of accrued interest expense based on the coupon interest rate of the debt in connection with our issuance of \$ 4 million in principal of convertible notes. Interest expense in the year ended November 30, 2017 is comprised of approximately \$628,000 accretion of debt discount and approximately \$132,000 of accrued interest expense based on the coupon interest rate of the outstanding debt. The decrease in interest expense results from all of the Company's outstanding debt either being converted or extinguished during the year ended November 30, 2017.

During the year ended November 30, 2018, we recognized a loss of \$89,000 resulting from the change in fair value of embedded contingent put options in convertible notes with a principal balance of \$4 million. During the year ended November 30, 2017, we recognized a loss of \$810,000 for the change in fair value of embedded derivatives and contingent put options embedded in various convertible notes. The year-over-year decrease results from all of the Company's outstanding debt either being converted or extinguished during the year ended November 30, 2017.

Net loss

In the years ended November 30, 2018 and 2017, we incurred net losses of approximately \$9.3 million and \$14.5 million, respectively. Our management expects to continue to incur net losses for the foreseeable future, due to our need to continue to open a new head office, improve our website and implement other aspects of our business plan.

Liquidity and Capital Resources

We prepared the accompanying consolidated financial statements assuming that we will continue as a going concern, which contemplates the realization of assets and liquidation of liabilities in the normal course of business.

We have not yet established an ongoing source of revenues and must cover our operating through debt and equity financings to allow us to continue as a going concern. We had approximately \$2.7 million in cash as of November 30, 2018. Our ability to continue as a going concern depends on the ability to obtain adequate capital to fund operating losses until we generate adequate cash flows from operations to fund our operating costs and obligations. If we are unable to obtain adequate capital, we could be forced to cease operations.

We depend upon our ability, and will continue to attempt, to secure equity and/or debt financing. We cannot be certain that additional funding will be available on acceptable terms, or at all. Our management determined that there was substantial doubt about our ability to continue as a going concern within one year after the consolidated financial statements were issued, and management's concerns about our ability to continue as a going concern within the year following this report persist.

The accompanying consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or amounts and classification of liabilities that might result from this uncertainty.

Cash Flows

The following table sets forth the significant sources and uses of cash for the periods addressed in this report:

	For the years ended November 30,	
	2018	2017
Net cash (used in) provided by:		
Operating activities	\$ (6,450,621)	\$ (5,584,451)
Investing activities	(500,000)	-
Financing activities	8,810,251	4,940,510
Net (decrease) increase in cash	\$ 1,859,630	\$ (643,941)

Net cash used in operating activities was approximately \$6.5 million for the year ended November 30, 2018 as compared to approximately \$5.6 million for the year ended November 30, 2017. The increase in net cash used in operating activities results from the net loss of approximately \$9.3 million for the year ended November 30, 2018, partially offset by aggregate non-cash expenses of approximately \$2.9 million. The increase in net cash used in operating activities results from the net loss of approximately \$14.5 million for the year ended November 30, 2017, partially offset by aggregate non-cash expenses of approximately \$8.9 million.

Net cash used in investing activities was \$500,000 for the year ended November 30, 2018, resulting from purchase of intangible assets. During the year ended November 30, 2017, there were no activities.

Net cash provided by financing activities was approximately \$8.8 million for the year ended November 30, 2018, resulting from proceeds received from the issuance of convertible notes payable of approximately \$3.9 million and the issuance of common stock and warrants of approximately \$5.4 million, offset by offering costs of approximately \$0.5 million. Net cash provided by financing activities was approximately \$4.9 million for the year ended November 30, 2017, resulting mainly from proceeds received from the issuance of convertible notes payable and note payable and issuance of common stock and warrants through the private placement.

Obligations and Commitments

Legal

On December 28, 2018, we commenced litigation against BioNucleonics, Inc. ("BNI") and parties related to BNI in the Supreme Court of New York, New York County. The litigation stems from a license agreement that we entered into with BNI in 2016 and amended from time to time. Under the agreement with BNI, we were granted a worldwide, exclusive license on certain BNI intellectual property and the option to acquire the BNI IP within three years of the agreement. The BNI IP consists of generic Strontium Chloride SR89 (generic Metastron®) ("SR89") and all of BNI's intellectual property relating to it ("BNI IP"). SR89 is a radiopharmaceutical therapeutic for cancer bone pain therapy.

In exchange for the consideration, we agreed, upon reaching various milestones, to issue to BNI an aggregate of up to 110,000 shares of common stock and to provide funding to BNI for an aggregate of \$850,000 in cash. Under the agreement, once we have funded up to \$850,000 in cash, we may exercise the option to acquire the BNI IP at no additional charge. By our accounts, we have provided BNI with over \$950,000 in cash. We have exercised our option to acquire the BNI IP, but BNI has not transferred the BNI IP to us. As a

result, we have commenced litigation to, among other actions, obtain all of the BNI IP. We also seek judgments against BNI and related parties for the misappropriation of funds, breach of contract, fraud and fraudulent inducement.

Periodically, we review the status of significant matters, if any exist, and assesses our potential financial exposure. If the potential loss from any claim or legal claim is considered probable and the amount can be estimated, we accrue a liability for the estimated loss. Legal proceedings are subject to uncertainties, and the outcomes are difficult to predict. Because of such uncertainties, accruals are based on the best information available at the time. As additional information becomes available, we reassess the potential liability related to pending claims and litigation.

Advisory Agreements

We entered into customary consulting arrangements with various counterparties to provide consulting services, business development and investor relations services, pursuant to which we agreed to issue shares of common stock as services are received.

Lease Agreement

In December 2016, we entered into a lease agreement for office space located in Cayman Islands for \$30,000 per annum. The initial term of the agreement ends in December 2019 and can be renewed for another three years.

Rent expense is classified within general and administrative expenses on a straight-line basis and included in the accompanying Consolidated Statements of Operations as follows:

	For the year ended November 30,	
	2018	2017
Rent expense	\$ 30,000	\$ 27,000

License Agreements

Mannin

On October 29, 2015, we entered into a Patent and Technology License and Purchase Option Agreement (“Exclusive License”) with a vendor whereby we were granted a worldwide, exclusive, license on, and option to, acquire certain intellectual property (“Mannin IP”) which initially focused on developing a first-in-class eye drop treatment for glaucoma within the four-year term of the Exclusive License.

During the years ended November 30, 2018 and 2017, we incurred approximately \$2.1 million and \$1.9 million, respectively, in research and development expenses to fund the costs of development of the eye drop treatment for glaucoma pursuant to the Exclusive License. Pursuant to the exclusive license from Mannin, we may purchase the Mannin IP within the next four years in exchange for investing a minimum of \$4,000,000 into the development of the Mannin IP. Through November 30, 2018, we have funded an aggregate of \$5.1 million to Mannin under the Exclusive License and has not purchased the Mannin IP. The purchase price for the Mannin IP is \$30,000,000 less the amount of cash paid by us for development and the value of the common stock issued to the vendor. This amount may be paid in stock and may not exceed 15% of the issued and outstanding stock of Q BioMed.

Bio-Nucleonics

On September 6, 2016, we entered into the Patent and Technology License and Purchase Option Agreement (the “BNI Exclusive License”) with Bio-Nucleonics Inc. (“BNI”) whereby we were granted a worldwide, exclusive, perpetual, license on, and option to, acquire certain BNI intellectual property (“BNI IP”) within the three-year term of the BNI Exclusive License.

During the years ended November 30, 2018 and 2017, we incurred approximately \$580,000 and \$467,000, respectively, in research and development expenses pursuant to the BNI Exclusive License. As of November 30, 2018, we have funded cumulatively \$1.0 million to BNI out of the maximum \$850,000 cash funding requirement.

Related Party Transactions

We entered into consulting agreements with certain management personnel and stockholders for consulting and legal services. Consulting and legal expenses resulting from such agreements were included within general and administrative expenses in the accompanying Consolidated Statements of Operations as follows:

	For the year ended November 30,	
	2018	2017
Consulting and legal expenses	\$ 295,000	\$ 420,000

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK

We are a smaller reporting company as defined by Rule 12b-2 of the Exchange Act and are not required to provide the information required under this item.

ITEM 8. CONSOLIDATED FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The following documents (pages F-1 to F-23) form part of the report on the Consolidated Financial Statements

	PAGE
Report of Independent Registered Public Accounting Firm (fiscal year ended in 2018)	F-2
Consolidated Balance Sheets	F-3
Consolidated Statements of Operations	F-4
Consolidated Statement of Changes in Stockholders' Equity (Deficit)	F-5
Consolidated Statements of Cash Flows	F-6
Notes to Consolidated Financial Statements	F-7

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURES

We have not had any disagreements with our accountants or auditors that would need to be disclosed pursuant to Item 304 of Regulation S-K promulgated under the Securities Act of 1933.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Management is required to maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our reports, filed under the Securities Exchange Act of 1934, is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our chief executive officer and chief financial officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable and not absolute assurance of achieving the desired control objectives. In reaching a reasonable level of assurance, management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. In addition, the design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Over time, a control may become inadequate because of changes in conditions or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

As required by the SEC Rules 13a-15(b) and 15d-15(b), an evaluation is required to be carried out under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered by this report. Our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were not effective at the reasonable assurance level due to the material weaknesses described below.

To address these material weaknesses, management engaged financial consultants, performed additional analyses and other procedures to ensure that the financial statements included herein fairly present, in all material respects, our financial position, results of operations and cash flows for the periods presented.

Management's Annual Report on Internal Control Over Financial Reporting

The management of the Company is responsible for establishing and maintaining adequate internal control over financial reporting ("ICFR") for the Company. Our internal control system was designed to, in general, provide reasonable assurance to the Company's management and board regarding the preparation and fair presentation of published financial statements, but because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

As of November 30, 2018, management has not completed a proper evaluation, risk assessment and monitoring of the Company's internal controls over financial reporting based on the 2013 Committee of Sponsoring Organizations (COSO) framework. Management concluded that, during the period covered by this report, that our internal controls and procedures were not effective to detect the

inappropriate application of US GAAP. Management identified the following material weaknesses set forth below in our internal control over financial reporting.

1. We do not have written documentation of our internal control policies and procedures. Written documentation of key internal controls over financial reporting is a requirement of Section 404 of the Sarbanes-Oxley Act which is applicable to us for the year ended November 30, 2018. Failure to have written documentation signifies that management could not evaluate the design adequacy of our internal controls nor perform tests over their operating effectiveness.
2. We do not have sufficient resources in our accounting function, which restricts the Company's ability to gather, analyze and properly review information related to financial reporting in a timely manner. In addition, due to our size and nature, segregation of all conflicting duties may not always be possible and may not be economically feasible. However, to the extent possible, the initiation of transactions, the custody of assets and the recording of transactions should be performed by separate individuals.
3. We do not have in-house personnel with sufficient experience with United States generally accepted accounting principles to address complex transactions. These functions have been outsourced.
4. We have inadequate controls to ensure that information necessary to properly record transactions is adequately communicated on a timely basis from non-financial personnel to those responsible for financial reporting.
5. We have determined that oversight over our external financial reporting and internal control over our financial reporting by our audit committee is ineffective. The audit committee has not provided adequate review of the Company's SEC's filings and consolidated financial statements and has not provided adequate supervision and review of the Company's accounting personnel or oversight of the independent registered accounting firm's audit of the Company's consolidated financial statement.

We have begun to take steps to remediate some of the weaknesses described above, including by engaging a financial reporting advisor with expertise in accounting for complex transactions. We have also engaged a professional firm to perform an audit and risk assessment to begin to remediate these issues. This year we have added an independent director and have interviewed several others to add to our board. We have drafted a full set of compliance documents and will be rolling those out in due course. We intend to continue to address these weaknesses as resources permit.

Notwithstanding the material weaknesses identified herein, we believe that our consolidated financial statements contained in this Annual Report fairly present our financial position, results of operations and cash flows for the years covered thereby in all material respects.

This annual report does not include an attestation report of our registered public accounting firm regarding internal control over financial reporting.

Changes in Internal Control Over Financial Reporting

Our internal control over financial reporting has not changed during the fourth quarter covered by this Annual Report on Form 10-K.

ITEM 9B. OTHER INFORMATION

Not Applicable.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The following table sets forth information with respect to persons who are serving as directors and officers of the Company. Each director holds office until the next annual meeting of shareholders or until his successor has been elected and qualified.

Name	Age	Positions	Held Position Since
Denis Corin	45	Chief Executive Officer and Director (Chairman)	2015
William Rosenstadt	50	General Counsel and Director	2015
Rick Panicucci	57	Director	2018

Biography of Directors and Officers

Mr. Denis Corin has been the Chief Executive Officer and Chairman of the Board of the Company since April 21, 2015. Mr. Corin is a management consultant. He has worked for large pharmaceutical (Novartis) and diagnostic instrumentation companies (Beckman Coulter) in their sales organizations responsible for sales in multi-product disciplines including pharmaceuticals and diagnostics and diagnostic automation equipment. After Novartis and Beckman Coulter, he served as Director of Investor Relations in the small-cap biotech arena at MIV Therapeutics Inc, a company specializing in next generation drug delivery and drug eluting cardiovascular stents. Mr. Corin served as an executive and on the board of directors of TapImmune Inc. from July 2009 to May 2012. He received his Bachelor degrees in Economics and Marketing from the University of Natal, South Africa in 1996.

Mr. William Rosenstadt was appointed as the Company's general counsel and member of the Company's board of directors on June 1, 2015. Mr. Rosenstadt is a practicing corporate and securities lawyer. He is also the founding member and the managing partner of Ortoli Rosenstadt LLP, a law firm, formed in 2006. Mr. Rosenstadt received his Juris Doctorate from Benjamin N. Cardozo School of Law in 1995 and his Bachelor of Arts from Syracuse University in 1990.

Dr. Rick Panicucci was appointed as a member of the Company's board of directors on February 13, 2018. Dr. Panicucci specializes in the early stages of drug discovery for various companies. His responsibilities include solid state chemistry and formulation development of all small molecule therapeutics in early development and developing novel drug delivery technologies for small molecules and large molecules including siRNA. Since September 2015, Dr. Panicucci has been working with one of our licensors, Mannin Research Inc., in the development plan for MAN-01, a novel drug candidate that we license for the topical treatment of open-angle glaucoma. Since February 2015, he has served as the Vice President of Pharmaceutical Development at WuXi AppTec, where he is responsible for providing scientific leadership in the areas of Developability, Formulation Development and GMP Manufacturing. Prior to WuXi he held the position of Global Head of Chemical and Pharmaceutical Profiling (CPP) at Novartis from 2004 to 2015, where he led the development and implementation of innovative dosage form designs and continuous manufacturing paradigms. He has also held positions as the Director of Formulation Development at Vertex Pharmaceuticals and Senior Scientist at Biogen.

Dr. Panicucci received his Ph.D. in Physical Organic Chemistry at the University of Toronto and has two postdoctoral fellowships at University of California at Santa Barbara and the Ontario Cancer Institute. Dr. Panicucci will continue advise on the scientific and commercial development of our MAN-01 glaucoma drug with Mannin Research Inc. He will also now provide insight and guidance on all our pipeline assets.

In connection with his service as a director, we have entered into an agreement with Dr. Panicucci pursuant to which he will earn options to acquire up to 50,000 shares of our common stock. The options will vest in quarterly installments of 12,500 each and are exercisable for 5 years at \$3.00 per option.

Section 16(a) Beneficial Ownership Reporting Compliance

Based solely upon a review of Forms 3, 4 and 5, we believe that those persons who, at any time during our most recent fiscal year, were either a director, officer or beneficial owner of more than ten percent of our common stock filed those reports required by section 16(a) of the Exchange Act. We do not believe that all of those reports were filed on a timely basis.

ITEM 11. EXECUTIVE COMPENSATION

Our directors do not receive any stated salary for their services as directors or members of committees of the board of directors, but have received stock options for director services and, by resolution of the board, a fixed fee may be allowed for attendance at each meeting. Directors may also serve the Company in other capacities as an officer, agent or otherwise, and may receive compensation for their services in such other capacity. Reasonable travel expenses are reimbursed.

Summary Compensation Table

The following table sets forth information concerning all cash compensation awarded to, earned by or paid to all individuals serving as the Company's principal executive officers during the last two completed fiscal years ended November 30, 2017 and 2018, respectively and all non-cash compensation awarded to those same individuals in those time periods.

Name and Principal Position	Year	Salary (\$)	Bonus (\$)	Stock Awards (\$) (4)	Option Awards (\$) (5)	Non-Equity Incentive Plan Compensation (\$) (6)	Non-qualified Deferred Compensation Earnings (\$) (7)	All Other Compensations (\$) (8)	Total (\$)
Denis Corin (2)	2018	\$ 240,000	\$ -	\$ -	\$ 438,000	\$ -	\$ -	\$ -	\$ 678,000
Chief Executive Officer	2017	\$ 45,000	\$ -	\$ -	\$ 1,545,000	\$ -	\$ -	\$ 175,000	\$ 1,765,000
William Rosenstadt (3)	2018	\$ -	\$ -	\$ 59,400	\$ 438,000	\$ -	\$ -	\$ 331,261	\$ 828,661
General Counsel and Director	2017	\$ -	\$ -	\$ -	\$ 1,545,000	\$ -	\$ -	\$ 280,248	\$ 1,825,248

- (1) The amounts represent fees paid or accrued by us to the executive officers during the past year pursuant to various employment and consulting services agreements, as between us and the executive officers, which are described below. Our executive officers are also reimbursed for any out-of-pocket expenses incurred in connection with corporate duties. We presently have no pension, health, annuity, insurance, profit sharing or similar benefit plans.
- (2) Mr. Denis Corin was appointed as Chief Executive Officer and Director on April 21, 2015.
- (3) Mr. William Rosenstadt was appointed as General Counsel and Director on June 5, 2015.
- (4) Represents the aggregate grant date fair value of 20,000 common stock issued on September 21, 2018 to Mr. Rosenstadt in accordance with FASB ASC.
- (5) Represents the aggregate grant date fair value of options to purchase 150,000 common stock issued on June 1, 2018 to Mr. Corin and options to purchase 150,000 common stock issued on June 1, 2018 to Mr. Rosenstadt, respectively, in accordance with FASB ASC.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

Security Ownership of Certain Beneficial Owners and Management

The following table sets forth, as of February 26, 2019, certain information regarding the ownership of our common stock by (i) each person known by us to be the beneficial owner of more than 5% of our outstanding shares of common stock, (ii) each of our directors, (iii) our Principal Executive Officer and (iv) all of our executive officers and directors as a group. Unless otherwise indicated, the address of each person shown is c/o Ortoli Rosenstadt LLP, 366 Madison Avenue 3rd Floor, New York, New York 10017. Beneficial ownership, for purposes of this table, includes options to purchase common stock that are either currently exercisable or will be exercisable within 60 days of the date of this annual report.

Name and Address of Beneficial Owner	Amount and Nature of Beneficial Owner (1)	Percent of Class (2)
Directors and Officers:		
Denis Corin (3)	3,241,800	21.2%
William Rosenstadt (4)	1,583,00	10.2%
Rick Panicucci	50,000	0.3%
Directors and Officers as a Group (3)(4)	4,874,800	26.6%
Major Stockholders:		
Ari Jatwes (5)	1,075,000	7.3%

- (1) Under Rule 13d-3, a beneficial owner of a security includes any person who, directly or indirectly, through any contract, arrangement, understanding, relationship, or otherwise has or shares: (i) voting power, which includes the power to vote, or to direct the voting of shares; and (ii) investment power, which includes the power to dispose or direct the disposition of shares. Certain shares may be deemed to be beneficially owned by more than one person (if, for example, persons share the power to vote or the power to dispose of the shares). In addition, shares are deemed to be beneficially owned by a person if the person has the right to acquire the shares (for example, upon the exercise of an option) within 60 days of the date as of which the information is provided. In computing the percentage ownership of any person, the amount of shares outstanding is deemed to include the amount of shares beneficially owned by such person (and only such person) by reason of these acquisition rights. As a result, the percentage of outstanding shares of any person as shown in this table does not necessarily reflect the person's actual ownership or voting power with respect to the number of shares of common stock actually outstanding as of February 26, 2019.
- (2) This percentage is based upon 14,466,155 shares of common stock outstanding as of February 26, 2019 and any warrants exercisable by such person within 60 days of the date as of which the information is provided.
- (3) Includes (i) 150,000 five-year warrants exercisable at \$1.45 which expire on July 15, 2021 for director fees through June 1, 2017, (ii) 350,000 five-year warrants exercisable at \$4.00 which expire on June 5, 2022 as a bonus for officer services through the date thereof, (iii) 150,000 five-year options issued on June 5, 2017 for services as a director and officer through June 1, 2018 and (iv) 150,000 five-year options for services as a director and officer through June 1, 2019, all of which are exercisable within 60 days of the date as of which the information is provided. This amount excludes those options that have been granted but that have not vested and do not vest within the next 60 days.
- (4) Includes (i) 250,000 five-year warrants exercisable at \$4.15 which expire on January 1, 2021 which were issued to the law firm at Mr. Rosenstadt is a partner, (ii) 50,000 five-year warrants exercisable at \$1.45 which expire on July 15, 2021 which were issued to the law firm at Mr. Rosenstadt is a partner, (iii) 150,000 five-year warrants exercisable at \$1.45 which expire on July 15, 2021 for director fees through June 1, 2017, (iv) 350,000 five-year warrants exercisable at \$4.00 which expire on June 5, 2022 as a bonus for officer services through the date thereof, (v) 150,000 five-year options issued on June 5, 2017 for services as a director and officer through June 1, 2018 and (vi) 150,000 five-year options issued for services as a director and officer through June 1, 2018, all of which are exercisable within 60 days of the date as of which the information is provided. An aggregate of 450,000 warrants are exercisable within 60 days of the date as of which the information is provided.
- (5) Includes, (i) 750,000 shares, (ii) 150,000 options issued in June 2017 and (iii) 150,000 options issued in June 2018, all of which are exercisable within 60 days of the date as of which the information is provided.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

We entered into consulting agreements with certain management personnel and stockholders for consulting and legal services. Consulting and legal expenses resulting from such agreements were approximately \$295,000 and \$420,000 for the year ended November 30, 2018 and 2017, respectively. We do not have any obligations outstanding to other persons who beneficially own more than 10% of our common stock.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The following table sets forth fees billed to us by our independent auditors for the years ended November 30, 2018 and 2017 for (i) services rendered for the audit of our annual consolidated financial statements and the review of our quarterly consolidated financial statements, (ii) services rendered that are reasonably related to the performance of the audit or review of our consolidated financial statements that are not reported as Audit Fees, and (iii) services rendered in connection with tax preparation, compliance, advice and assistance.

Marcum LLP

	SERVICES	2018	2017
Audit fees		\$ 95,000	\$ 85,000
Audit-related fees			10,000
Tax fees		-	-
All other fees		-	-
Total fees		<u>\$ 95,000</u>	<u>\$ 95,000</u>

Audit fees and audit related fees represent amounts billed for professional services rendered for the audit of our annual consolidated financial statements and the review of our interim consolidated financial statements. Before our independent accountants were engaged to render these services, their engagement was approved by our Directors.

PART IV

ITEM 15. EXHIBITS, CONSOLIDATED FINANCIAL STATEMENTS SCHEDULE

The following exhibits are filed as part of this registration statement. Exhibit numbers correspond to the exhibit requirements of Regulation S-K.

Exhibit No.	Description
3.1	Articles of Incorporation filed as Exhibit 3 (a) to Form S-1 filed on January 13, 2014 and incorporated herein by reference
3.2	Amendment to Articles of Incorporation, dated July 20, 2015, filed as Exhibit 3.1 to our periodic report filed on Form 8-K on August 3, 2015 and incorporated herein by reference
3.3	Amendment to Articles of Incorporation, dated October 27, 2015, filed as Exhibit 3.1 to our periodic report filed on Form 8-K on October 29, 2015 and incorporated herein by reference
3.4	Articles of Incorporation filed as Exhibit 3 (b) to Form S-1 filed on January 13, 2014 and incorporated herein by reference
4.1	Form of Warrant in connection with our February 1, 2018 offering filed as Exhibit 4.1 to our registration statement on Form S-1 filed on January 10, 2018
4.2	Form of Warrant as filed as Exhibit 4.2 to our current report on Form 8-K filed on June 9, 2017 and incorporated herein by reference
4.3	Form of Warrant as filed as Exhibit 10.3 to our current report on Form 8-K filed on August 2, 2017 and incorporated herein by reference
10.1	Form of Non-Institutional Promissory Note filed as Exhibit 10.1 to our current report on Form 8-K filed on January 13, 2016 and incorporated herein by reference
10.2	Stock Purchase Agreement for Institutional Promissory Note, dated January 8, 2016, with CMGT filed as Exhibit 10.2 to our current report on Form 8-K filed on January 13, 2016 and incorporated herein by reference
10.3	Form of Institutional Promissory Note filed as Exhibit 10.4 to our current report on Form 8-K filed on January 13, 2016 and incorporated herein by reference
10.4	Advisory Agreement, dated September 8, 2015, with Wombat Capital Ltd. filed as Exhibit 10.5 to our current report on Form 8-K filed on January 13, 2016 and incorporated herein by reference
10.5	Advisory Agreement, dated June 1, 2015, with Ari Jatwes filed as Exhibit 10.6 to our current report on Form 8-K filed on January 13, 2016 and incorporated herein by reference
10.6	Consulting Agreement, dated November 13, 2015, Pharmafor Ltd. filed as Exhibit 10.7 to our current report on Form 8-K filed on January 13, 2016 and incorporated herein by reference
10.7	Executive Services Agreement, dated June 1, 2017, between Denis Corin and Q BioMed Cayman SEZC filed as Exhibit 10.1 to our current report on Form 8-K filed on June 9, 2017 and incorporated herein by reference
10.9	Form of Non-Qualified Stock Option Agreement filed as Exhibit 4.1 to our current report on Form 8-K filed on June 9, 2017 and incorporated herein by reference
10.10	Patent and Technology License and Purchase Option Agreement, dated October 29, 2015, with Mannin Research Inc. filed as Exhibit 10.1 to our annual report on Form 10-K filed on March 11, 2016 and incorporated herein by reference +
10.11	Patent and Technology License and Purchase Option Agreement, dated May 30, 2016, with Bio-Nucleonics Inc., filed as Exhibit 10.1 to our quarterly report on Form 10-Q filed on October 17, 2016 and incorporated herein by reference +
10.12	First Amendment to Patent and Technology License and Purchase Option Agreement, dated September 6, 2016, with Bio-Nucleonics Inc., filed as Exhibit 10.2 to our quarterly report on Form 10-Q filed on October 17, 2016 and incorporated herein by reference +
10.13	License Agreement on Patent & Know-How Technology, dated April 21, 2017, between Q BioMed Inc. and ASDERA LLC filed as Exhibit 10.1 to our quarterly report on Form 10-Q filed on April 25, 2017 and incorporated herein by reference +
10.14	Technology License Agreement, dated June 15, 2017, among Q BioMed Inc., Oklahoma Medical Research Foundation and Rajiv Gandhi Centre for BioTechnology filed as Exhibit 10.1 to our current report on Form 8-K filed on June 15, 2017 and incorporated herein by reference +
10.15	Form of Placement Agent Agreement in connection with our February 1, 2018 offering filed as Exhibit 10.15 to our registration statement on Form S-1 filed on January 12, 2018
10.16	Form of Securities Purchase Agreement in connection with our February 1, 2018 offering filed as Exhibit 10.16 to our registration statement on Form S-1 filed on January 12, 2018
10.17	Securities Purchase Agreement, dated September 21, 2018, filed as Exhibit 10.1 to our current report on Form 8-K filed on September 24, 2018 and incorporated herein by reference
10.18	Asset Purchase Agreement with GE Healthcare Limited, dated November 23, 2018, filed as Exhibit 10.1 to our current report on Form 8-K filed on November 28, 2018 and incorporated herein by reference++
31	Certification of Principal Executive Officer and Acting Principal Accounting Officer pursuant to Securities Exchange Act of 1934 Rule 13a-14(a) or 15d-14(a)*
32	Certification of Principal Executive Officer and Acting Principal Accounting Officer pursuant to 18 U.S.C. Section 1350*
101.INS	XBRL Instance Document*
101.SCH	XBRL Taxonomy Extension Schema Document*
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document*

101.DEF XBRL Taxonomy Extension Definition Linkbase Document*
101.LAB XBRL Taxonomy Extension Label Linkbase Document*
101.PRE XBRL Taxonomy Extension Presentation Linkbase Document*

*Filed herewith

+ Portions of this exhibit have been omitted pursuant to a request for confidential treatment, and the SEC has granted confidential treatment pursuant to Rule 406 under the Securities Act. Confidential information has been omitted from the exhibit in places marked “****” and has been filed separately with the SEC.

SIGNATURES

In accordance with Section 13 or 15(d) of the Securities Exchange Act, the Registrant caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Q BioMed Inc.

Date: March 7, 2019

By: /s/ Denis Corin

Name: Denis Corin

Title: President, Chief Executive Officer and Acting Principal
Financial and Accounting Officer

SIGNATURES

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

Signature	Title	Date
<u>/s/ Denis Corin</u> Denis Corin	President, Chief Executive Officer and Director (Principal Executive Officer and Acting Principal Financial and Accounting Officer)	March 7, 2019
<u>/s/ William Rosenstadt</u> William Rosenstadt	General Counsel and Director	March 7, 2019
<u>/s/ Rick Panicucci</u> Rick Panicucci	Director	March 7, 2019

Q BIOMED INC.
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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and Board of Directors of
Q BioMed, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Q BioMed, Inc. (the "Company") as of November 30, 2018 and 2017, the related consolidated statements of operations, stockholders' equity and cash flows for each of the two years in the period ended November 30, 2018, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of November 30, 2018 and 2017, and the results of its operations and its cash flows for each of the two years in the period ended November 30, 2018, in conformity with accounting principles generally accepted in the United States of America.

Explanatory Paragraph – Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As more fully described in Note 2, the Company has a significant working capital deficiency, has incurred significant losses and needs to raise additional funds to meet its obligations and sustain its operations. 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 2. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

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 audits 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 risks 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.

/s/ Marcum LLP

Marcum LLP

We have served as the Company's auditor since 2015.

New York, NY
March 7, 2019

Q BIOMED INC.
Consolidated Balance Sheets

	As of November 30,	
	2018	2017
ASSETS		
Current assets:		
Cash	\$ 2,684,413	\$ 824,783
Prepaid expenses	12,500	2,500
Total current assets	2,696,913	827,283
Intangible assets, net	500,000	-
Total Assets	\$ 3,196,913	\$ 827,283
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued expenses	\$ 392,230	\$ 463,539
Accrued expenses - related party	7,500	7,500
Accrued interest payable	29,639	-
Total current liabilities	429,369	471,039
Long-term liabilities:		
Convertible notes payable, net	2,873,272	-
Total long term liabilities	2,873,272	-
Total Liabilities	3,302,641	471,039
Commitments and Contingencies (Note 7)		
Stockholders' Equity:		
Preferred stock, \$0.001 par value; 100,000,000 shares authorized; no shares issued and outstanding as of November 30, 2018 and 2017	-	-
Common stock, \$0.001 par value; 250,000,000 shares authorized; 14,290,236 and 12,206,409 shares issued and outstanding as of November 30, 2018 and 2017, respectively	14,290	12,206
Additional paid-in capital	31,994,129	23,187,408
Accumulated deficit	(32,114,147)	(22,843,370)
Total Stockholders' Equity	(105,728)	356,244
Total Liabilities and Stockholders' Equity	\$ 3,196,913	\$ 827,283

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

Q BIOMED INC.
Consolidated Statements of Operations

	For the year ended November 30,	
	2018	2017
Operating expenses:		
General and administrative expenses	\$ 5,781,613	\$ 9,271,804
Research and development expenses	3,238,060	3,099,971
Total operating expenses	<u>9,019,673</u>	<u>12,371,775</u>
Other income (expenses):		
Interest expense	(162,104)	(760,314)
Interest income	-	138
Loss on conversion of debt	-	(463,578)
Loss on extinguishment of debt	-	(76,251)
Change in fair value of embedded derivatives	(89,000)	(810,017)
Change in fair value of warrant liability	-	(59,870)
Total other income (expenses)	<u>(251,104)</u>	<u>(2,169,892)</u>
Net loss	<u>\$ (9,270,777)</u>	<u>\$ (14,541,667)</u>
Net loss per share - basic and diluted	\$ (0.67)	\$ (1.39)
Weighted average shares outstanding, basic and diluted	13,735,134	10,466,648

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

Q BIOMED INC.
Consolidated Statement of Changes in Shareholders' Equity (Deficit)

	<u>Common Stock</u>		<u>Additional Paid in Capital</u>	<u>Accumulated Deficit</u>	<u>Total Stockholders' Equity (Deficit)</u>
	<u>Shares</u>	<u>Amount</u>			
Balance as of November 30, 2016	9,231,560	\$ 9,231	\$ 6,249,357	\$ (8,301,703)	\$ (2,043,115)
Issuance of additional common stock to convertible notes holders	25,641	26	98,179	-	98,205
Issuance of common stock, warrants and options for services	153,705	154	6,399,431	-	6,399,585
Issuance of common stock for acquired in-process research and development	125,000	125	487,375	-	487,500
Beneficial conversion feature in connection with issuance of convertible notes	-	-	645,000	-	645,000
Issuance of common stock upon conversion of convertible notes payable	1,650,379	1,650	5,972,236	-	5,973,886
Issuance of common stock and warrants in exchange for extinguishment of convertible notes payable	162,000	162	518,238	-	518,400
Issuance of common stock in exchange for extinguishment of OID Note	46,875	47	149,953	-	150,000
Issuance of common stock and warrants for cash, net of offering costs	791,249	791	2,369,719	-	2,370,510
Reclassification of warrant liability to equity	-	-	227,940	-	227,940
Exercise of warrants	20,000	20	69,980	-	70,000
Net loss	-	-	-	(14,541,667)	(14,541,667)
Balance as of November 30, 2017	<u>12,206,409</u>	<u>\$ 12,206</u>	<u>\$ 23,187,408</u>	<u>\$ (22,843,370)</u>	<u>\$ 356,244</u>
Issuance of common stock, warrants and options for services	296,952	297	2,650,180	-	2,650,477
Issuance of common stock and warrants for cash, net of offering costs	1,711,875	1,712	4,943,539	-	4,945,251
Issuance of common stock in connection with issuance of convertible notes	75,000	75	222,675	-	222,750
Beneficial conversion feature in connection with issuance of convertible notes	-	-	990,327	-	990,327
Net loss	-	-	-	(9,270,777)	(9,270,777)
Balance as of November 30, 2018	<u>14,290,236</u>	<u>\$ 14,290</u>	<u>\$ 31,994,129</u>	<u>\$ (32,114,147)</u>	<u>\$ (105,728)</u>

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

Q BIOMED INC.
Consolidated Statement of Cash Flows

	For the year ended November 30,	
	2018	2017
Cash flows from operating activities:		
Net loss	\$ (9,270,777)	\$ (14,541,667)
Adjustments to reconcile net loss to net cash used in operating activities		
Issuance of common stock, warrants and options for services	2,650,477	6,399,585
Issuance of common stock for acquired in-process research and development	-	487,500
Change in fair value of embedded conversion option	89,000	810,017
Change in fair value of warrant liability	-	59,870
Accretion of debt discount	132,349	628,026
Loss on conversion of debt	-	463,578
Loss on extinguishment of debt	-	76,251
Changes in operating assets and liabilities:		
Prepaid expenses	(10,000)	(2,500)
Accounts payable and accrued expenses	(71,309)	(34,397)
Accrued expenses - related party	-	(63,002)
Accrued interest payable	29,639	132,288
Net cash used in operating activities	(6,450,621)	(5,584,451)
Cash flows from investing activities:		
Purchase of intangible assets	(500,000)	-
Net cash used in investing activities	(500,000)	-
Cash flows from financing activities:		
Proceeds from issuance of convertible notes, net of issuance costs	3,865,000	2,500,000
Proceeds received from exercise of warrants	-	70,000
Proceeds received for issuance of common stock and warrants, net of offering costs	4,945,251	2,370,510
Net cash provided by financing activities	8,810,251	4,940,510
Net (decrease) increase in cash	1,859,630	(643,941)
Cash at beginning of period	824,783	1,468,724
Cash at end of period	\$ 2,684,413	\$ 824,783
Non-cash financing activities:		
Issuance of common stock in connection with issuance convertible notes	\$ 222,750	\$ -
Issuance of common stock upon conversion of convertible notes payable	\$ -	\$ 5,608,514
Issuance of common stock and warrants in exchange for extinguishment of convertible notes payable	\$ -	\$ 442,149
Issuance of common stock in exchange for extinguishment of OID Note	\$ -	\$ 150,000
Reclassification of warrant liability to equity	\$ -	\$ 227,940
Supplemental disclosures:		
Cash paid for interest	\$ -	\$ -
Cash paid for income taxes	\$ -	\$ -

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

Note 1 - Organization of the Company and Description of the Business

Q BioMed Inc. (“Q BioMed” or “the Company”), incorporated in the State of Nevada on November 22, 2013, is a biomedical acceleration and development company focused on licensing, acquiring and providing strategic resources to life sciences and healthcare companies. Q BioMed intends to mitigate risk by acquiring multiple assets over time and across a broad spectrum of healthcare related products, companies and sectors. The Company intends to develop these assets to provide returns via organic growth, revenue production, out-licensing, sale or spinoff new public companies.

On December 7, 2016, the Company formed its wholly-owned subsidiary in Cayman Islands, “Q BioMed Cayman SEZC” (the “Subsidiary”). The accompanying consolidated financial statements include the accounts of the Company’s wholly-owned subsidiary. All intercompany balances and transactions have been eliminated in consolidation.

Note 2 - Basis of Presentation and Going Concern

The accompanying consolidated financial statements are presented in U.S. dollars and have been prepared in accordance with accounting principles generally accepted in the United States of America (“US GAAP”) and pursuant to the accounting and disclosure rules and regulations of the U.S. Securities and Exchange Commission (the “SEC”).

The Company currently operates in one business segment focusing on licensing, acquiring and providing strategic resources to life sciences and healthcare companies. The Company is not organized by market and is managed and operated as one business. A single management team reports to the chief operating decision maker, the Chief Executive Officer, who comprehensively manages the entire business. The Company does not currently operate any separate lines of business.

Going Concern

The accompanying consolidated financial statements are prepared assuming the Company will continue as a going concern, which contemplates the realization of assets and liquidation of liabilities in the normal course of business.

The Company has and is expected to incur net losses and cash outflows from operations in pursuit of extracting value from its acquired intellectual property. These matters, amongst others, raise doubt about the Company’s ability to continue as a going concern.

As of November 30, 2018, the Company has raised operating funds through contacts, high net-worth individuals and strategic investors. The Company has not generated any revenue from operations since inception and has limited assets upon which to commence its business operations. At November 30, 2018, the Company had cash and cash equivalents of approximately \$2.7 million. On February 2, 2018, the Company netted approximately \$4,915,000 from the registered sale of common stock and warrants to purchase common stock. As such, management anticipates that the Company will have to raise additional funds and/or generate revenue from drug sales within twelve months to continue operations. Additional funding will be needed to implement the Company’s business plan that includes various expenses such as fulfilling our obligations under licensing agreements, legal, operational set-up, general and administrative, marketing, employee salaries and other related start-up expenses. Obtaining additional funding will be subject to a number of factors, including general market conditions, investor acceptance of our business plan and initial results from our business operations. These factors may impact the timing, amount, terms or conditions of additional financing available to us. If the Company is unable to raise sufficient funds, management we will be forced to scale back the Company’s operations or cease our operations.

Management has determined that there is substantial doubt about the Company’s ability to continue as a going concern within one year after the consolidated financial statements are issued. The accompanying consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts, or amounts and classification of liabilities that might result from this uncertainty.

Note 3 – Summary of Significant Accounting Policies

Use of estimates

The preparation of consolidated financial statements in conformity with U.S. GAAP 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 consolidated financial statements and the reported amounts of revenue and expenses during the reporting period. Actual results may differ from those estimates, and such differences may be material to the consolidated financial statements. The more significant

estimates and assumptions by management include among others: the valuation allowance of deferred tax assets resulting from net operating losses, the valuation of warrants on the Company's stock and the valuation of embedded derivatives within the Company's convertible notes payable.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to concentration of credit risk consist of cash accounts in a financial institution which, at times may exceed the Federal depository insurance coverage ("FDIC") of \$250,000. At November 30, 2018, the Company had a cash balance on deposit that exceeded the balance insured by the FDIC limit by approximately \$2,434,000 with two institutions. The Company had not experienced losses on these accounts and management believes the Company is not exposed to significant risks on such accounts.

Fair value of financial instruments

Fair value is defined as the price that would be received for sale of an asset or paid for transfer of a liability, in an orderly transaction between market participants at the measurement date. U.S. GAAP establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1 measurements) and the lowest priority to unobservable inputs (Level 3 measurements). These tiers include:

- Level 1, defined as observable inputs such as quoted prices for identical instruments in active markets;
- Level 2, defined as inputs other than quoted prices in active markets that are either directly or indirectly observable such as quoted prices for similar instruments in active markets or quoted prices for identical or similar instruments in markets that are not active; and
- Level 3, defined as unobservable inputs in which little or no market data exists, therefore requiring an entity to develop its own assumptions, such as valuations derived from valuation techniques in which one or more significant inputs or significant value drivers are unobservable.

Fair value measurements discussed herein are based upon certain market assumptions and pertinent information available to management as of and during the years ended November 30, 2018 and 2017. The respective carrying value of cash and accounts payable approximated their fair values as they are short term in nature.

Intangible Assets

Intangible assets subject to amortization include acquired intellectual property for a marketable product acquired in November 2018. The intellectual property is being amortized over the estimated life remaining at the time of acquisition, which is 10 years.

Intangible assets are monitored for potential impairment whenever events or circumstances indicate that the carrying amount may not be recoverable and are also reviewed annually to determine whether any impairment is necessary. The annual review of intangible assets is performed via a two-step process. First, a qualitative assessment is performed to determine if it is more likely than not that the intangible asset is impaired. If required, a quantitative assessment is performed and, if necessary, impairment is recorded.

Debt Issuance Costs

Direct costs incurred to issue non-revolving debt instruments are recognized as a reduction to the related debt balance in the accompanying Consolidated Balance Sheets and amortized to interest expense over the contractual term of the related debt using the effective interest method.

Embedded Conversion Features

The Company evaluates embedded conversion features within convertible debt to determine whether the embedded conversion feature(s) should be bifurcated from the host instrument and accounted for as a derivative at fair value with changes in fair value recorded in the Statement of Operations. If the conversion feature does not require recognition of a bifurcated derivative, the convertible debt instrument is evaluated for consideration of any beneficial conversion feature ("BCF") requiring separate recognition. When the Company records a BCF, the intrinsic value of the BCF is recorded as a debt discount against the face amount of the respective debt instrument (offset to additional paid-in capital) and amortized to interest expense over the life of the debt.

Derivative Financial Instruments

The Company does not use derivative instruments to hedge exposures to cash flow, market, or foreign currency risks. The Company evaluates all of its financial instruments, including issued stock purchase warrants, to determine if such instruments are derivatives or contain features that qualify as embedded derivatives. For derivative financial instruments that are accounted for as liabilities, the derivative instrument is initially recorded at its fair value and is then re-valued at each reporting date, with changes in the fair value reported in the Statement of Operations. Depending on the features of the derivative financial instrument, the Company uses either the Black-Scholes option-pricing model or a binomial model to value the derivative instruments at inception and subsequent valuation dates. The classification of derivative instruments, including whether such instruments should be recorded as liabilities or as equity, is re-assessed at the end of each reporting period.

Stock Based Compensation Issued to Nonemployees

Common stock issued to non-employees for acquiring goods or providing services is recognized at fair value when the goods are obtained or over the service period. If the award contains performance conditions, the measurement date of the award is the earlier of the date at which a commitment for performance by the non-employee is reached or the date at which performance is reached. A performance commitment is reached when performance by the non-employee is probable because of sufficiently large disincentives for nonperformance.

General and administrative expenses

The significant components of general and administrative expenses consist of interest expense, bank fees, printing, filing fees, other office expenses, and business license and permit fees.

Research and development

The Company expenses the cost of research and development as incurred. Research and development expenses include costs incurred in funding research and development activities, license fees, and other external costs. Nonrefundable advance payments for goods and services that will be used in future research and development activities are expensed when the activity is performed or when the goods have been received, rather than when payment is made.

Income Taxes

Deferred tax assets and liabilities are computed based upon the difference between the financial statement and income tax basis of assets and liabilities using the enacted marginal tax rate applicable when the related asset or liability is expected to be realized or settled. Deferred income tax expenses or benefits are based on the changes in the asset or liability each period. If available evidence suggests that it is more likely than not that some portion or all of the deferred tax assets will not be realized, a valuation allowance is required to reduce the deferred tax assets to the amount that is more likely than not to be realized. Future changes in such valuation allowance are included in the provision for deferred income taxes in the period of change.

Deferred income taxes may arise from temporary differences resulting from income and expense items reported for financial accounting and tax purposes in different periods. Deferred taxes are classified as current or non-current, depending on the classification of assets and liabilities to which they relate. Deferred taxes arising from temporary differences that are not related to an asset or liability are classified as current or non-current depending on the periods in which the temporary differences are expected to reverse.

The Company applies a more-likely-than-not recognition threshold for all tax uncertainties, which only allows the recognition of those tax benefits that have a greater than fifty percent likelihood of being sustained upon examination by the taxing authorities. As of November 30, 2018, the Company reviewed its tax positions and determined there were no outstanding, or retroactive tax positions with less than a 50% likelihood of being sustained upon examination by the taxing authorities, therefore this standard has not had a material effect on the Company.

The Company's policy for recording interest and penalties associated with audits is to record such expense as a component of income tax expense. There were no amounts accrued for penalties or interest during the years ended November 30, 2018. Management is currently unaware of any issues under review that could result in significant payments, accruals or material deviations from its position.

On December 22, 2017, the United States enacted new tax legislation, the Tax Cuts and Jobs Act (the "Tax Act"). The Tax Act includes significant changes to corporate taxation, including reduction of the U.S. corporate tax rate from 35% to 21%, effective January 1, 2018, limitation of the tax deduction for interest expense to 30% of earnings (except for certain small businesses), limitation of the deduction for net operating losses to 80% of current year taxable income and elimination of net operating loss carrybacks. The Tax Act states that the 21% U.S. federal corporate tax rate is effective for tax years beginning on or after January 1, 2018. However, existing tax law, which was not amended under the Tax Act, governs when a change in tax rate is effective. Existing tax law provides that if the taxable year includes the effective date of any rate change (unless the change is the first date of the taxable year), taxes should be calculated by applying a blended rate to the taxable income for the year. Consequently, the Company has recorded a decrease related to deferred tax assets, exclusive of the corresponding change in the valuation allowance, for the year ended November 30, 2018. Due to the full valuation allowance on the deferred tax assets, there is no net adjustment to deferred tax expense or benefit due to the reduction of the corporate tax rate.

In conjunction with the tax law changes, the SEC staff issued Staff Accounting Bulletin No. 118 ("SAB 118") to address the application of U.S. GAAP in situations when a registrant does not have the necessary information available, prepared, or analyzed (including computations) in reasonable detail to complete the accounting for certain income tax effects of the Tax Act. The ultimate impact, which is expected to be recorded by November 30, 2018, may differ from any provisional amounts, due to, among other things, additional analysis, changes in interpretations and assumptions the Company have made, additional regulatory guidance that may be issued, and actions the Company may take as a result of the tax Act, and the fact that the Company cannot definitively predict what the Company's deferred tax balance will ultimately be as of November 30, 2018.

Recent accounting pronouncements

On February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)*. Under the new guidance, lessees will be required to recognize all leases (with the exception of short-term leases) on the balance sheet as a lease liability, which is a lessee's obligation to make lease payments arising from a lease, measured on a discounted basis and a right-of-use asset, which is an asset that represents the lessee's right to use, or control the use of, a specified asset for the lease term. The new standard is effective for the Company on December 1, 2019. The Company is currently evaluating the effect the guidance will have on its Consolidated Financial Statements.

In August 2016, the FASB issued ASU No. 2016-15, *Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments*. This new standard clarifies certain aspects of the statement of cash flows, including the classification of debt prepayment or debt extinguishment costs or other debt instruments with coupon interest rates that are insignificant in relation to the effective interest rate of the borrowing, contingent consideration payments made after a business combination, proceeds from the settlement of insurance claims, proceeds from the settlement of corporate-owned life insurance policies, distributions received from

equity method investees and beneficial interests in securitization transactions. This new standard also clarifies that an entity should determine each separately identifiable source of use within the cash receipts and payments on the basis of the nature of the underlying cash flows. In situations in which cash receipts and payments have aspects of more than one class of cash flows and cannot be separated by source or use, the appropriate classification should depend on the activity that is likely to be the predominant source or use of cash flows for the item. This new standard is effective for the Company on December 1, 2018. The Company's adoption of the new standard is not expected to have a significant impact on reported cash flows.

In July 2017, the FASB issued ASU 2017-11, *Earnings Per Share (Topic 260); Distinguishing Liabilities from Equity (Topic 480); Derivatives and Hedging (Topic 815): (Part I) Accounting for Certain Financial Instruments with Down Round Features, (Part II) Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception*. The ASU allows companies to exclude a down round feature when determining whether a financial instrument (or embedded conversion feature) is considered indexed to the entity's own stock. As a result, financial instruments (or embedded conversion features) with down round features may no longer be required to be accounted classified as liabilities. A company will recognize the value of a down round feature only when it is triggered and the strike price has been adjusted downward. For equity-classified freestanding financial instruments, such as warrants, an entity will treat the value of the effect of the down round, when triggered, as a dividend and a reduction of income available to common shareholders in computing basic earnings per share. For convertible instruments with embedded conversion features containing down round provisions, entities will recognize the value of the down round as a beneficial conversion discount to be amortized to earnings. The guidance in ASU 2017-11 is effective for the Company on December 1, 2019. Early adoption is permitted, and the guidance is to be applied using a full or modified retrospective approach. The Company is currently evaluating the impact of the new standard 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*. This ASU is intended to simplify aspects of share-based compensation issued to non-employees by making the guidance consistent with the accounting for employee share-based compensation. It is effective for the Company on December 1, 2019. The Company is currently evaluating the impact of the new standard on its consolidated financial statements.

In August 2018, the FASB issued ASU 2018-13, *Fair Value Measurement (Topic 820), Disclosure Framework, Changes to the Disclosure Requirements for Fair Value Measurement*, which makes a number of changes meant to add, modify or remove certain disclosure requirements associated with the movement amongst or hierarchy associated with Level 1, Level 2 and Level 3 fair value measurements. This guidance is effective for the Company on December 1, 2020. Early adoption is permitted upon issuance of the update. The Company does not expect the adoption of this guidance to have a material impact on its Consolidated Financial Statements.

Recent adopted pronouncements

In May 2017, the FASB issued ASU 2017-09, *Compensation – Stock Compensation (Topic 718): Scope of Modification Accounting*. The new standard provides guidance about which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting in Topic 718. Early adoption is permitted, including adoption in any interim period. The Company adopted ASU 2017-09 as of December 1, 2017. The adoption of this standard did not impact the Company's consolidated financial statements.

Note 4 – Loss per share

Basic net loss per share was calculated by dividing net loss by the weighted-average common shares outstanding during the period. Diluted net loss per share was calculated by dividing net loss by the weighted-average common shares outstanding during the period using the treasury stock method or the two-class method, whichever is more dilutive. The table below summarizes potentially dilutive securities that were not considered in the computation of diluted net loss per share because they would be anti-dilutive.

<u>Potentially dilutive securities</u>	<u>November 30, 2018</u>	<u>November 30, 2017</u>
Warrants (Note 10)	4,984,058	3,083,995
Convertible Debentures (Note 6)	2,014,819	-
Stock Options (Note 10)	900,000	450,000

Note 5 – Asset Acquisition

On November 23, 2018, the Company entered into an Asset Sale Agreement (“ASA”) with GE Healthcare Limited (“GE”) whereby the Company acquired GE’s radiopharmaceutical drug, Metastron® and all related intellectual property including, but not limited to sales and distribution data, market authorizations and trademarks for Metastron® in various countries in exchange for an upfront payment of \$500,000, a one-time milestone payment based on future sales, and royalty payments based on future sales. The Company did not acquire any workforce, manufacturing, inventory, sales agreements, or distribution agreements associated with Metastron®. The first commercial sale of Metastron™ by the Company will occur only after the successful transfer or assignment of all intellectual property, material sales and distribution data, technical transfer and the establishment of new manufacturing sites by the Company and under the appropriate regulatory filings required by the jurisdictions in which Metastron™ is sold.

The acquired assets are concentrated in a single asset and the set is not considered a business. As such, the transaction is recognized as the acquisition of a finite-lived intangible asset. The one-time milestone payment based on future sales, and royalty payments based on future sales will be recognized when the payments are probable and estimable, which is expected to be when the related sales targets are achieved and the payments payable to GE. The acquired asset is being amortized on a straight-line basis over its estimated 10 year life. Amortization expense for the year ended November 30, 2018 was not significant. The estimated remaining amortization expense for each of the five succeeding fiscal year:

<u>Year ended November 31,</u>	
2019	\$ 50,000
2020	50,000
2021	50,000
2022	50,000
2023	50,000
Thereafter	250,000
	<u>\$ 500,000</u>

Note 6 – Convertible Notes

	<u>November 30, 2018</u>	<u>November 30, 2017</u>
Convertible Debenture:		
Principal value of 5.5%, convertible at \$2.00 at November 30, 2018, due March 21, 2020	\$ 4,000,000	\$ -
Fair value of bifurcated contingent put option of convertible debenture	262,000	-
Debt discount	(1,388,728)	-
Carrying value of convertible debenture note	<u>2,873,272</u>	<u>-</u>
Total long-term carrying value of convertible notes	<u>\$ 2,873,272</u>	<u>\$ -</u>

Convertible Debentures

On September 21, 2018, the Company entered into a securities purchase agreement with an accredited investor to place Convertible Debentures (the “Debentures”) with a maturity date of eighteen months after the issuance thereof in the aggregate principal amount of up to \$4,000,000 (the “Transaction”), provided that in case of an event of default, the Debentures may become at the holder’s election

immediately due and payable. The initial closing of the Transaction occurred on September 21, 2018 when the Company issued a Debenture for \$2,000,000. The second closing occurred on November 1, 2018, when the Company issued another Debenture for \$2,000,000. The Debentures bear interest at the rate of 5.5% per annum. In addition, the Company paid to the holder an up-front fee equal to 2.5% of the amount of the Debentures.

The Debenture may be converted at any time on or prior to maturity at the lower of \$4.00 or 93% of the average of the four lowest daily VWAPs during the 10 consecutive trading days immediately preceding the conversion date, provided that as long as the Company are not in default under the Debenture, the conversion price may never be less than \$2.00.

Any time after the six-month anniversary of the issuance of a Debenture that the daily VWAP is less than \$2.00 for a period of twenty consecutive trading days (the “Triggering Date”) and only for so long as such conditions exist after a Triggering Date as that term is defined in the Transaction documents, the Company shall make monthly payments beginning on the last calendar day of the month when the Triggering Date occurred. Each monthly payment shall be in an amount equal to the sum of (i) the principal amount outstanding as of the Triggering Date divided by the number of such monthly payments until maturity, (ii) a redemption premium of 20% in respect of such principal amount and (iii) accrued and unpaid interest hereunder as of each payment date. The Company may, no more than twice, obtain a thirty-day deferral of a monthly payment due as a result of a Triggering Date through the payment of a deferral fee in the amount equal to 10% of the total amount of such monthly payment. Each deferral payment may be paid by the issuance of such number of shares as is equal to the applicable deferral payment divided by a price per share equal to 93% of the average of the four lowest daily VWAPs during the 10 consecutive Trading Days immediately preceding the due date in respect of such monthly payment being deferred, provided that such shares issued will be immediately freely tradable shares in the hands of the holder.

Upon issuance of the Debentures, the Company recognized a debt discount of approximately \$1.5 million, resulting from the recognition of a beneficial conversion feature of \$1.0 million, issuance costs of \$358,000 and a bifurcated embedded derivative of \$173,000. The beneficial conversion feature was recognized as the intrinsic value of the embedded derivatives on issuance of the Debentures. The monthly payment provision within the Debentures is a contingent put option that is required to be separately measured at fair value, with subsequent changes in fair value recognized in the Consolidated Statement of Operations. The maximum redemption was discounted at 35.17%, the calculated effective rate of the Debenture before measurement of the contingent put option. The fair value estimate is a Level 3 measurement. The Company estimated the fair value of the monthly payment provision, as of November 30, 2018, using probability analysis of the occurrence of a Triggering Date applied to the discounted maximum redemption premium for any given payment with the following key inputs:

	For the year ended November 30, 2018
Stock price	\$1.95 - \$2.97
Terms (years)	1.2 - 1.4
Volatility	72.1% - 76.5%
Risk-free rate	2.4% - 2.5%
Dividend yield	0.00%

On September 21, 2018, the Company issued an aggregate of 75,000 shares of the Company common stock to various vendors in connection with issuance costs of convertible notes, valued at approximately \$223,000 based on the estimated fair market value of the stock on the date of grant and was recognized within convertible notes payable in the accompanying consolidated balance sheets as of November 30, 2018.

Note 7 – Commitments and Contingencies

Legal

On December 28, 2018, the Company commenced litigation against BioNucleonics, Inc. (“BNI”) and parties related to BNI in the Supreme Court of New York, New York County (removed to federal court in February 2019). The litigation stems from a license agreement that the Company entered into with BNI in 2016 and amended from time to time. Under the agreement with BNI, the Company were granted a worldwide, exclusive license on certain BNI intellectual property and the option to acquire the BNI IP within three years of the agreement. The BNI IP consists of generic Strontium Chloride SR89 (generic Metastron®) (“SR89”) and all of BNI’s intellectual property relating to it (“BNI IP”). SR89 is a radiopharmaceutical therapeutic for cancer bone pain therapy.

In exchange for the consideration, the Company agreed, upon reaching various milestones, to issue to BNI an aggregate of up to 110,000 shares of common stock and to provide funding to BNI for an aggregate of \$850,000 in cash. Under the agreement, once the Company has funded up to \$850,000 in cash, the Company may exercise the option to acquire the BNI IP at no additional charge. By our accounts, the Company have provided BNI with over \$950,000 in cash. The Company has exercised our option to acquire the BNI IP, but BNI has not transferred the BNI IP to us. As a result, the Company has commenced litigation to, among other actions, obtain all of the BNI IP. The Company also seeks judgments against BNI and related parties for the misappropriation of funds, breach of contract, fraud and fraudulent inducement.

Periodically, the Company reviews the status of significant matters, if any exist, and assesses our potential financial exposure. If the potential loss from any claim or legal claim is considered probable and the amount can be estimated, the Company accrues a liability for the estimated loss. Legal proceedings are subject to uncertainties, and the outcomes are difficult to predict. Because of such uncertainties, accruals are based on the best information available at the time. As additional information becomes available, the Company reassesses the potential liability related to pending claims and litigation.

Advisory Agreements

The Company entered into customary consulting arrangements with various counterparties to provide consulting services, business development and investor relations services, pursuant to which the Company agreed to issue shares of common stock as services are received.

Lease Agreement

In December 2016, the Subsidiary entered into a lease agreement for its office space located in Cayman Islands for \$30,000 per annum. The initial term of the agreement ends in December 2019 and can be renewed for another three years.

Rent expense is classified within general and administrative expenses on a straight-line basis and included in the accompanying Consolidated Statements of Operations as follows:

	For the year ended November 30,	
	2018	2017
Rent expense	\$ 30,000	\$ 27,000

License Agreements

Mannin

On October 29, 2015, the Company entered into a Patent and Technology License and Purchase Option Agreement (“Exclusive License”) with a vendor whereby the Company was granted a worldwide, exclusive, license on, and option to, acquire certain intellectual property (“Mannin IP”) which initially focused on developing a first-in-class eye drop treatment for glaucoma within the four-year term of the Exclusive License.

During the years ended November 30, 2018 and 2017, the Company incurred approximately \$2.1 million and \$1.9 million, respectively, in research and development expenses to fund the costs of development of the eye drop treatment for glaucoma pursuant to the Exclusive License. Pursuant to the exclusive license from Mannin, the Company may purchase the Mannin IP within the next four years in exchange for investing a minimum of \$4,000,000 into the development of the Mannin IP. Through November 30, 2018, the Company has funded an aggregate of \$5.1 million to Mannin under the Exclusive License and has not purchased the Mannin IP. The purchase price for the Mannin IP is \$30,000,000 less the amount of cash paid by the Company for development and the value of the common stock issued to the vendor. This amount may be paid in stock and may not exceed 15% of the issued and outstanding shares in Q BioMed.

Note 8 - Related Party Transactions

The Company entered into consulting agreements with certain management personnel and stockholders for consulting and legal services. Consulting and legal expenses resulting from such agreements were included within general and administrative expenses in the accompanying Consolidated Statements of Operations as follows:

	For the year ended November 30,	
	2018	2017
Consulting and legal expenses	\$ 295,000	\$ 420,000

Note 9 - Stockholders' Equity (Deficit)

As of November 30, 2018, and 2017, the Company is authorized to issue up to 250,000,000 shares of its \$0.001 par value common stock and up to 100,000,000 shares of its \$0.001 par value preferred stock.

2018 activity

Issued for services

The Company entered into customary consulting arrangements with various counterparties to provide consulting services, business development and investor relations services. During the year ended November 30, 2018, the Company issued an aggregate of 296,952 shares of the Company common stock to various vendors for investor relation and introductory services, valued at approximately \$800,000 based on the estimated fair market value of the stock on the date of grant and was recognized within general and administrative expenses in the accompanying consolidated statements of operations for the year ended November 30, 2018.

In June 2018, the Company issued warrants to purchase up to 84,000 shares of the Company's common stock to one vendor for services. The warrants are exercisable for three years at a per share price of \$3.61.

In September 2018, the Company issued warrants to purchase up to 100,000 shares of the Company's common stock to one vendor for services. The warrants are exercisable for five years at a per share price of \$2.15.

Registered public financing

On February 1, 2018, the Company sold an aggregate of 1,711,875 shares of common stock, and 1,711,875 warrants to purchase shares of common stock, in a registered public offering for gross proceeds of approximately \$5,478,000. The warrants are exercisable for five years at \$3.20 per share. The Company paid placement agent commissions of approximately \$438,000 and issued the placement agent five-year warrants to purchase 81,688 shares of common stock at \$3.84 per share. After the placement agents' commissions and other offering expenses, the Company netted approximately \$4,945,000 of proceeds.

2017 activity

Issued for services

The Company entered into customary consulting arrangements with various counterparties to provide consulting services, business development and investor relations services. During the year ended November 30, 2017, the Company issued an aggregate of 153,705 shares of the Company common stock to various vendors for investor relation and introductory services, valued at approximately \$0.7 million based on the estimated fair market value of the stock on the date of grant and was recognized within general and administrative expenses in the accompanying consolidated statements of operations for the year ended November 30, 2017.

In September 2017, the Company issued warrants to purchase up to 50,000 shares of the Company's common stock to two vendors for services. The warrants are exercisable for three years at a per share price of \$4.00.

On October 3, 2017, the Company amended the Debentures to extend the maturity date from November 30, 2017 to November 30, 2018, and issued 25,641 restricted shares of its common stock to the holder of the Debentures as consideration.

Note 10 - Warrants and Options

Summary of warrants

The following represents a summary of all outstanding warrants to purchase the Company's common stock, including warrants issued to vendors for services and warrants issued as part of the units sold in the private placements, at November 30, 2018 and 2017 and the changes during the period then ended:

	Warrants	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (years)	Intrinsic Value
Outstanding at November 30, 2017	3,083,995	\$ 3.67	4.02	\$ 2,539,185
Issued	1,977,563	\$ 3.19	4.13	\$ -
Expired	(77,500)	\$ 3.96	-	\$ -
Outstanding at November 30, 2018	4,984,058	\$ 3.48	3.51	\$ 250,000
Exercisable at November 30, 2018	4,835,058	\$ 3.50	3.50	\$ 250,000

Fair value of all outstanding warrants issued to non-employees for services was calculated with the following key inputs:

	For the year ended November 30,	
	2018	2017
Stock price	\$2.02 - \$3.40	\$3.40 - \$5.60
Term (years)	3.0 - 5.0	1.75 - 5.0
Volatility	123.32% - 129.79%	129.64% - 143.47%
Risk-free rate	2.54% - 2.83%	1.42% - 2.14%
Dividend yield	0.00%	0.00%

Options issued for services

The following represents a summary of all outstanding options to purchase the Company's common stock at November 30, 2018 and 2017 and the changes during the period then ended:

	Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (years)	Intrinsic Value
Outstanding at November 30, 2017	450,000	\$ 4.00	4.51	\$ 220,500
Issued	450,000	\$ 3.37	4.47	\$ -
Outstanding at November 30, 2018	900,000	\$ 3.68	3.99	\$ -
Exercisable at November 30, 2018	687,500	\$ 3.78	3.84	\$ -

Fair value of all outstanding options was calculated with the following key inputs:

	For the year ended November 30,	
	2018	2017
Exercise price	\$3.00 - \$3.61	\$4.00
Expected term (years)	5.0	5
Volatility	128.00% - 130.00%	130.00%
Risk-free rate	2.52% - 2.71%	1.71%
Dividend yield	0.00%	0.00%

Stock-based Compensation

The Company recognized general and administrative expenses of approximately \$1.8 million and \$6.4 million, as a result of the shares, outstanding warrants and options issued to consultants and employees during the year ended November 30, 2018 and 2017, respectively.

As of November 30, 2018, the estimated unrecognized stock-based compensation associated with these agreements is approximately \$239,000 and will be recognized over the next 0.4 year.

Note 11 - Income Taxes

On December 22, 2017, the United States enacted new tax legislation, the Tax Cuts and Jobs Act. The Company has recorded a decrease related to deferred tax assets, exclusive of the corresponding change in the valuation allowance, for the year ended November 30, 2018. Due to the full valuation allowance on the deferred tax assets, there is no net adjustment to deferred tax expense or benefit due to the reduction of the corporate tax rate.

At November 30, 2018, the Company has a net operating loss (“NOL”) carryforward for Federal and state income tax purposes totaling approximately \$16.8 million available to reduce future taxable income which, if not utilized, will begin to expire in the year 2038. The NOL carry forward is subject to review and possible adjustment by the Internal Revenue Service and state tax authorities. Under the Internal Revenue Code (“IRC”) Sections 382 and 383, annual use of the Company’s net operating loss carryforwards to offset taxable income may be limited based on cumulative changes in ownership. The Company has not completed an analysis to determine whether any such limitations have been triggered as of November 30, 2018. The amount of the annual limitation, if any, will be determined based on the value of the Company immediately prior to the ownership change. Subsequent ownership changes may further affect the limitation in future years.

The Company has evaluated the positive and negative evidence bearing upon the realizability of its deferred tax assets. Based on the Company’s history of operating losses since inception, the Company has concluded that it is more likely than not that the benefit of its deferred tax assets will not be realized. Accordingly, the Company has provided a full valuation allowance for deferred tax assets as of November 30, 2018 and 2017. The valuation allowance increased by approximately \$1.2 million and \$5.9 million for the fiscal years ended November 30, 2018 and 2017.

The tax effects of the temporary differences and carry forwards that give rise to deferred tax assets consist of the following:

	<u>As of November 30,</u>	
	<u>2018</u>	<u>2017</u>
Deferred tax assets:		
Net-operating loss carryforward	\$ 5,666,313	\$ 3,810,498
Stock-based compensation	4,014,863	4,466,254
License agreement	463,269	595,780
Tax amortization for license agreement	(221,988)	(102,747)
Charitable contributions	294	387
Other accrued expenses	76,411	-
Total deferred tax assets	9,999,162	8,770,172
Valuation allowance	(9,999,162)	(8,770,172)
Deferred tax asset, net of allowance	<u>\$ -</u>	<u>\$ -</u>

A reconciliation of the statutory income tax rates and the Company's effective tax rate is as follows:

	For the year ended November 30,	
	2018	2017
Statutory Federal income tax rate	(22.1)%	(34.0)%
State and local taxes, net of Federal tax benefit	(11.6)%	(10.3)%
Deferred tax true-up	(4.4)%	-%
Loss on conversion of debt	-%	1.4%
Gain/ loss on extinguishment of convertible note	-%	0.2%
Change in fair value of embedded conversion option and related accretion of interest expense	0.8%	4.4%
Change in fair value of warrant liability	-%	0.2%
Non-U.S. operations	1.3%	0.3%
Deferred tax rate change	22.7%	-%
Change in Valuation Allowance	13.3%	37.8%
Income Taxes Provision (Benefit)	<u>0.0%</u>	<u>0.0%</u>

The Company's major tax jurisdictions are the United States and New York. All of the Company's tax years will remain open starting 2013 for examination by the Federal and state tax authorities from the date of utilization of the net operating loss. The Company does not have any tax audits pending.

Note 12 - Subsequent Events

Issuance of shares for services

On January 4, 2019, the Company issued an aggregate of 175,919 shares of the Company common stock to various vendors for advisory services.