

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, 2019

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 | Trading Symbol(s) | Name of Exchange on which Registered |
|---------------------|-------------------|--------------------------------------|
| None                | N/A               | 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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit 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: \$17,728,318 as of May 31, 2019.

As of February 25, 2020, there were 20,835,625 shares of the registrant's common stock, \$0.001 par value, outstanding.

**DOCUMENTS INCORPORATED BY REFERENCE**

None.

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## 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, 2019

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## PART I

### ITEM 1. BUSINESS

We are a commercial stage biotechnology acceleration and development company focused on acquiring and in-licensing pre-clinical, clinical-stage and approved life sciences therapeutic products. Currently, we have a portfolio of five therapeutic products, including two FDA approved radiopharmaceuticals for metastatic cancer bone pain (Strontium-89 and Metastron™) and three development stage products: QBM-001 for rare pediatric non-verbal autism spectrum disorder, Uttroside-B for liver cancer, and MAN 01 for glaucoma. Our licensed MAN platform has several potential therapeutics in development in various indications, including vascular and infectious diseases. The infectious diseases we may ultimately treat include influenza, Coronavirus, Ebola and others. 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 2020, we plan to generate revenue from our Metastron and Strontium-89 products for pain palliation in bone metastases as well as explore commencing a therapeutic expansion post-marketing phase 4 trial for Strontium-89. We also intend to file investigational new drug applications, or INDs late in 2020 or early 2021, with the FDA for each of our Uttroside-B and MAN 01 assets for the treatment of liver cancer and glaucoma, respectively. We also intend to advance our QBM-001 asset to address a non-verbal learning disorder in autistic children.

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; and
- (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 the fiscal years ended November 30, 2019 and 2018, we have incurred approximately \$3.5 million and \$3.2 million, respectively, on research and development activities.

## Metastron™ and Strontium-89 Chloride USP Injection

We have branded and generic Strontium-89 products for bone cancer pain therapy.

Strontium-89 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. Strontium-89 is a pure beta emitting radiopharmaceutical. It is a chemical analog of calcium and for this reason, localizes in bone. Strontium-89 is preferentially absorbed at the site of active osteoblastic activity, delivering a targeted dose of radiation therapy into the tumor environment. This is the biochemical basis for its use in treating metastatic bone disease.

Strontium-89 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 Strontium-89 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.

There are an estimated 10 million patients around the world afflicted with metastatic cancer in the bone causing pain. In the United States alone, 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 and as better primary treatments contribute to patients living longer with metastatic disease. There are over 500,000 External Beam Radiation Therapy (EBRT) treatments annually for painful metastatic cancer bone disease. We believe this group of patients would benefit from our therapy as an additional treatment that would address the micro-tumors that EBRT does not.

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. Additional therapeutic indications for Strontium-89 are possible, and we intend to pursue those in 2020, hopefully resulting in entry into a multi-billion dollar therapeutic area in a few years.

Our Strontium-89 radiopharmaceutical drug addresses an underserved patient group in the cancer pain palliation market, but also has a significant opportunity to expand into a much larger market through a planned phase IV study designed to expand the label from a pain palliation to a cancer therapeutic.

### *Our Generic Strontium-89 Product*

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 Strontium 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 restriction from trading until commercialization of the product and subsequent leak-out conditions. Once we funded up to \$850,000 in cash, we were allowed to exercise the option to acquire the BNI IP at no additional charge.

Prior to November 30, 2018, we believed that we had paid BNI all amounts required to exercise the option to acquire the asset. We exercised our option to acquire the BNI IP, but BNI did not transfer the BNI IP to us. As a result, 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.

On September 23, 2019, we entered into a settlement agreement with BNI and parties related to BNI. Pursuant to the terms of the Settlement Agreement, we settled our dispute with BNI and all parties to the litigation dismissed their claims in exchange for entering into a Second Amendment to the License Agreement (entered into on September 23, 2019) pursuant to which:

- BNI agreed to immediately transfer and/or assign to us all intellectual property, patents and products that is owned by BNI that is related to Strontium-Chloride 89;
- We agreed to issue BNI 50,000 shares of our common stock upon the entry into the settlement agreement and 100,000 shares of our common stock upon the approval of the U.S. Food and Drug Administration ("FDA") approval of BNI's Prior Approval Supplement (PAS) filing
- We agreed to make a cash payment to BNI of \$25,000;
- We agreed to an on-going royalty payment of 3% on all gross profits derived by us from the sale of Strontium-Chloride 89 and Metastron™; and
- We agreed to assume fees and expenses related to (i) all outstanding CMO fees owed by BNI to IsoTherapeutics relating to Strontium-Chloride 89 (approximately \$67,000), (ii) all outstanding fees owed by BNI to the FDA relating to Strontium-Chloride 89 (approximately \$208,000) and (iii) related fees for the development and approval of Strontium-Chloride 89 following the date of the Settlement Agreement.

### *Metastron, Our Branded Strontium-89 Product*

We acquired our branded Strontium-89 product, Metastron®, from GE Healthcare Limited ("GE") on November 23, 2018 pursuant to an Asset Sale Agreement ("ASA"). Metastron® is an FDA approved radiopharmaceutical drug that GE had sold for over 20 years. 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™ will occur only after the appropriate regulatory filings required by the jurisdictions in which it is to be sold.

### *Recent Developments*

On November 14, 2019, the Department of Health and Human Services notified us that our supplemental abbreviated new drug application for a new drug product manufacturing site, IsoTherapeutics Group, LLC, has been approved. IsoTherapeutics is now cleared to manufacture our FDA approved non-opioid cancer bone pain drug Strontium-89 Chloride USP.

In anticipation of production, we have on-boarded our commercial team tasked with infrastructure set-up, including medical information and pharmacovigilance, government contracting, marketing, contract sales and telesales. We have announced a distribution partnership with Julibilant Radiopharma who have the capabilities to access the US market, including warehousing/inventory management, invoicing and customer service/ordering. It also has a sales team that calls on major providers, a national network of U.S. nuclear pharmacies and distribution and coverage throughout the United States. We have completed a reimbursement landscape and set our

pricing strategy. Our scientific platform is complete which is informing a creative advertising campaign to coincide with the commercial launch of our product. We are assembling a scientific advisory board specific to this product to assist in market access and phase 4 clinical trial planning.

## **Mannin Intellectual Property**

On October 29, 2015, we entered into a Patent and Technology License and Purchase Option Agreement, as amended in April 2019, 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, like the recent Coronavirus outbreak. Pursuant to the exclusive license from Mannin, we may purchase the Mannin IP within six 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, 2019, we have funded an aggregate of \$6,231,500 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. We can make this all or part of this payment in stock, provided that such stock does not represent 15% or more of our issued and outstanding common 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 six 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.

On March 26, 2019, we extended the option period of the initial agreement that was entered into on October 29, 2015. The extension period was extended to October 29, 2021 and 100,000 shares was issued in exchange for the extension.

### *MAN 01 – New Vascular Therapeutics including Primary Open Angle Glaucoma*

Mannin is developing a unique set of therapeutics that target a variety of vascular diseases. Its lead program - MAN-01 for glaucoma, is based on a research platform that targets the activation of the Angiopoietin-Tie2 signaling pathway. While Mannin is not generating a vaccine against infectious diseases, it is developing a new drug that may increase the survival rate of patients by reducing the severity of disease through enhancement of host-directed therapeutic response.

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. Supported by a recent \$7.5 million grant awarded to Mannin in Germany, we aim to initiate IND enabling studies in 2020 and file an IND in late 2020 or early 2021, 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, like coronavirus. We expect to advance these efforts in 2020.

Mannin recently submitted a grant application to the U.S. National Institutes of Health for Small Business Technology Transfer Grant Applications for approximately US \$200,000 for the MAN-11 biologic. The studies will be conducted at Northwestern University to investigate treatment of vascular leakage to treat sepsis and other infectious diseases. Mannin is also working with Canada's National Research Council (NRC-CNRC) since December 2019 to support the development of the biologic. In September 2019, the German state of Saxony awarded Mannin an approximately US \$7.7 million grant to advance the Mannin portfolio of vascular diseases, including development of the biologic.

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

On March 9, 2019, the Company entered into an Exclusive License Agreement with Washington University for license of a diagnostic marker for determining the severity of glaucoma using the expression levels of Growth Differentiation Factor ("GDF"). In parallel, we and Mannin Research are working with the Biointerfaces Institute at McMaster University in Ontario, Canada to develop a GDF15 biomarker diagnostic kit for monitoring glaucoma severity and progression. Determining the severity of glaucoma using this biomarker will aid in treatment decisions for patients diagnosed with, and being treated for, glaucoma.

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.

## **ASD-002**

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, which was previously referred to as ASD-002 in our pipeline, and was intended to treat Disruption of Active Language Development (DALD) in toddlers developing Autism Spectrum Disorders. Under that agreement, we paid ASDERA \$50,000 and issued 125,000 shares of our common stock. On November 27, 2019, we notified ASDERA that we considered the Agreement to have been rescinded retroactively as of April 21, 2017. As a result of such rescission, we believe that we have no continuing material obligations to ASDERA. However, we will continue to develop unique technologies for the benefit of underserved patient populations.

## **QBM-001**

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. In parallel to ASD-002, we have been developing a product, QBM-001, intended to treat the rare condition - pediatric minimally verbal autism. Many of the children who miss this potential treatment window between the age of 2 and 5 years old, may become non-verbal for the rest of their lives. Currently, there is no treatment for this rare disorder.

QBM-001 is not intended to treat other ASDs or to be used beyond the specific group and the estimated treatment window. The “treatment window” results from independent research that revealed a decreased density in the cortex region of the brain in minimally verbal children with autism, who were 7 years of age. A biomarker study performed by us has directed us to conclude that QBM-001 cannot be used for other autistic groups. The study analyzed over 2000 known autistic markers and found two distinct biomarkers for children with pediatric minimally verbal autism. The biomarkers did not overlap with the high functioning group of autistic children, nor the intermediate group, which struggles with, but develops limited language. The biomarkers gave us insight into what was wrong with the children and has given us unique insight on how to ameliorate their condition with the goal of helping them develop the ability to speak.

The biomarker study also led us to evaluate and identify a rat model that contains the biomarkers and is thus a good model to test QBM-001. In addition, we have access to cell lines from deceased children who had pediatric minimally verbal autism. QBM-001 consists of a combination of products that target different mechanisms of action. Having the cell lines and rat model available to us provides us with an excellent preclinical path to validate the safety and efficacy of QBM-001.

We recently filed an orphan drug application for our QBM potential drug candidate and plan on filing an IND QBM-001 in 2021.

### *QBM-001 - Addressing Rare Pediatric Minimally Verbal Autism*

Causes of non-verbal learning disorder have been linked to several complications that range from a specific mutated gene as with Fragile X Syndrome, Rett Syndrome, Phelan McDermid 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.

Cognitive intervention is the only form for treatment that has shown to help improve speech capability and social interaction in autistic children, however, with minimal benefit with children with pediatric minimally verbal autism. As intervention does not lead to speech progression, being minimally verbal carries a lifetime burden of over \$5 million per person for cost of care. This is further compounded by additional expenses during the lifespan of the person due to loss in productivity in addition to severe emotional strain for the child and the parents.

As there are no treatment options for these patients, we believe there is a significant economic opportunity to bring a drug to market in this indication. The active ingredients in our compound are well known and have been approved by worldwide regulators for many years. Using a novel delivery and formulation for the ingredients, we intend to advance this drug through the 505(b)2 pathway.

## **RGCB and OMRF Intellectual Property**

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 was \$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 are obligated to undertake 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*

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.

The only currently marketed drug is a tryosine kinase inhibitor antineoplastic agent, sorafenib. Current sales of sorafenib are estimated at \$1 billion per year.

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.

As it is not feasible to use the plant as the source for a drug, we successfully synthesized the molecule thereby creating an exact replica of the naturally occurring chemical compound. In a joint research program with India-based Chemveda Life Sciences in 2017, we initiated this very complex and challenging synthesis program. After 2 years, the exceptional chemists at Chemveda and our scientists, succeeded. The synthetic molecule has now been tested in comparison to the original plant molecule and the results confirm the same efficacy against the same liver cancer cell lines. This is a remarkable feat. We are now preparing to advance this into the pre-clinical program leading to an IND by the end of 2020 and a proof of concept clinical program in 2021.

#### **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 and all other potential therapeutics that may originate from the platform, (ii) QBM-001, the combination 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, (iv) Metastron™, our branded Strontium-89 Chloride product candidate for metastatic cancer bone pain therapy and (iv) the Uttroside-B platform.

We have applied for some patents in our own right. Most patents and applications 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 Biologics License Application (“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 have product liability insurance in place at the time of product launch.

## Employees

As of November 30, 2019, we had 1 employee and 9 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. The litigation stems from a license agreement (the “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. BNI and parties related to BNI brought counterclaims against us for an alleged failure to pay amounts due under the License Agreement with BNI.

On September 23, 2019, we entered into a settlement agreement with BNI and parties related to BNI. Pursuant to the terms of the Settlement Agreement, we settled our dispute with BNI and all parties to the litigation dismissed their claims in exchange for entering into a Second Amendment to the License Agreement (entered into on September 23, 2019) pursuant to which:

- BNI agreed to immediately transfer and/or assign to us all intellectual property, patents and products that is owned by BNI that is related to Strontium-Chloride 89;
- We agreed to issue BNI 50,000 shares of our common stock upon the entry into the settlement agreement and 100,000 shares of our common stock upon the approval of the U.S. Food and Drug Administration (“FDA”) approval of BNI’s Prior Approval Supplements filing
- We agreed to make a cash payment to BNI of \$25,000;
- We agreed to an on-going royalty payment of 3% on all gross profits derived by us from the sale of Strontium-Chloride 89 and Metastron™; and
- We agreed to assume fees and expenses related to (i) all outstanding CMO fees owed by BNI to IsoTherapeutics relating to Strontium-Chloride 89 (approximately \$67,000), (ii) all outstanding fees owed by BNI to the FDA relating to Strontium-Chloride 89 (approximately \$208,000) and (iii) related fees for the development and approval of Strontium-Chloride 89 following the date of the Settlement Agreement.

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, 2019, we had cash and cash equivalents of approximately \$173,000. On December 6, 2019 and January 15, 2020, we netted approximately \$2 million from the registered sale of convertible notes. As such, we anticipate that we will have to raise additional funds 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, two of our assets are based on intellectual property that we have licensed from third parties. 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. 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 fully 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 and our non-licensed platforms (SR-89 and QBM-001). 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, SR-89 platform, the QBM-001 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 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. 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 have never had revenue from operations and have missed several expected dates by which we had anticipated to have revenues. If we generate revenues, we may never achieve profitability. Failure to generate revenues at a profitable level could 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 26% 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 QBM-001 platform and the Uttroside platform and any additional uses based on the SR-89 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 Metastron 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, 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 candidates, 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 candidates 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.

***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), Uttroside-B (OMRF), QBM001 and SR-89, we have not yet developed, and may never successfully develop, any marketed treatments using these products other than the SR89 product candidates 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, Uttroside-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 CEO and CLO also comprise the majority of 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.

***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. We maintain a \$5 Million product liability policy. 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. 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 confidentiality 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. 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. 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 13,503,668 of our outstanding shares of common stock recorded by our transfer agent as of February 25, 2020 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 8.4 million shares of common stock. Additionally, we have approximately \$3.9 million in outstanding convertible notes that are convertible into approximately 5.7

million shares using the floor price set out in such notes. 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 81% 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. PROPERTIES**

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 in the Supreme Court of New York, New York County. The litigation stems from a license agreement (the "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. BNI and parties related to BNI brought counterclaims against us for an alleged failure to pay amounts due under the License Agreement with BNI.

On September 23, 2019, we entered into a settlement agreement with BNI and parties related to BNI. Pursuant to the terms of the Settlement Agreement, we settled our dispute with BNI and all parties to the litigation dismissed their claims in exchange for entering into a Second Amendment to the License Agreement (entered into on September 23, 2019) pursuant to which:

- BNI agreed to immediately transfer and/or assign to us all intellectual property, patents and products that is owned by BNI that is related to Strontium-Chloride 89;
- We agreed to issue BNI 50,000 shares of our common stock upon the entry into the settlement agreement and 100,000 shares of our common stock upon the approval of the U.S. Food and Drug Administration ("FDA") approval of BNI's Prior Approval Supplements filing
- We agreed to make a cash payment to BNI of \$25,000;
- We agreed to an on-going royalty payment of 3% on all gross profits derived by us from the sale of Strontium-Chloride 89 and Metastron™, and
- We agreed to assume fees and expenses related to (i) all outstanding CMO fees owed by BNI to IsoTherapeutics relating to Strontium-Chloride 89 (approximately \$67,000), (ii) all outstanding fees owed by BNI to the FDA relating to Strontium-Chloride 89 (approximately \$208,000) and (iii) related fees for the development and approval of Strontium-Chloride 89 following the date of the Settlement Agreement.

## **ITEM 4. MINE SAFETY DISCLOSURES**

None.

## PART II

### ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, 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 following quotations reflect inter-dealer prices, without retail mark-up, markdown, or commissions, and may not reflect actual transactions.

|                                       | <u>High Bid</u> | <u>Low Bid</u> |
|---------------------------------------|-----------------|----------------|
| <b>Fiscal Year 2020</b>               |                 |                |
| December 1, 2019 to February 25, 2020 | \$ 3.45         | \$ 2.41        |
| <b>Fiscal Year 2019</b>               |                 |                |
| November 30, 2019                     | \$ 2.38         | \$ 0.37        |
| August 31, 2019                       | \$ 1.64         | \$ 0.91        |
| May 31, 2019                          | \$ 2.29         | \$ 1.53        |
| February 29, 2019                     | \$ 2.43         | \$ 0.95        |
| <b>Fiscal Year 2018</b>               |                 |                |
| November 30, 2018                     | \$ 3.37         | \$ 1.71        |
| August 31, 2018                       | \$ 3.62         | \$ 1.67        |
| May 31, 2018                          | \$ 3.95         | \$ 2.82        |
| February 29, 2018                     | \$ 5.50         | \$ 2.73        |
| <b>Fiscal Year 2017</b>               |                 |                |
| November 30, 2017                     | \$ 5.90         | \$ 3.35        |
| August 31, 2017                       | \$ 5.10         | \$ 3.19        |
| May 31, 2017                          | \$ 7.90         | \$ 3.35        |
| February 29, 2017                     | \$ 12.61        | \$ 3.20        |

The last reported sales price for our shares on the OTCQB as of February 25, 2020, was \$2.97 per share. As of February 25, 2020, we had approximately 54 shareholders of record and 6,160 round lot shareholders.

#### Holders

As of February 25, 2020, we had 20,835,625 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.

#### Unregistered Sales of Equity Securities and Use of Proceeds

On December 5, 2019, we issued 150,000 options to Ricardo Panicucci for his continued services as a director of our company. Each option is to purchase a share of our common stock for \$1.50 per share. One-fifth of the options vested immediately and an additional fifth vests each quarter thereafter.

On December 31, 2019, the Company issued 204,653 shares of common stock to a note holder in exchange for the conversion of \$204,653.15 of principal and interest on convertible notes.

The issuance of the Securities mentioned above qualified for the exemption from registration continued in section 4(a) of the Securities Act.

## 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 commercial stage 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.

Since the Company's inception, 4.5 years ago, we have been busy building significant value ranging from blockbuster potential drugs to imminent revenue producing opportunities. Our mission is to solve problems by accelerating the development of important therapies and availability of those therapies to patients.

### *Metastron™ and Strontium-89 Chloride USP Injection*

We have been working hard to commercialize Strontium-89 for the non-opiate treatment of metastatic cancer bone pain. We have settled our litigation with BioNucleonics Inc. and now have outright ownership of the generic Strontium-89 Chloride drug, which is FDA approved. We also own Metastron™, the branded drug, purchased from GE Healthcare in November of 2018. As a result, we now control significant market share for this injectable non-opioid metastatic cancer palliation drug in North America and much of the world.

On November 14, 2019, the Department of Health and Human Services notified us that our supplemental abbreviated new drug application for a new drug product manufacturing site, IsoTherapeutics Group, LLC, has been approved. IsoTherapeutics is now cleared to manufacture our FDA approved non-opioid cancer bone pain drug Strontium-89 Chloride USP.

On February 13th we announced the launch of our FDA approved non-opioid drug Strontium-89 (Strontium Chloride Sr-89 Injection, USP) which has been shown to relieve the persistent pain associated with cancer that has metastasized to bone. In several multicenter, placebo-controlled trials in cancer patients with persistent pain after external beam radiation therapy for bone metastases, pain relief occurred in more patients treated with a single injection of Strontium-89 than in patients treated with an injection of placebo\*, with a greater percentage of patients experiencing pain scores of zero with no use of rescue opioid analgesics. Median duration of pain palliation has been shown to be 2 to 5 months. Strontium-89 can be redosed every 90 days.

An estimated 10 million people are living with this condition, and due to the opioid crisis, doctors and patients are looking for an alternative to treat metastatic cancer associated bone pain. Given that Strontium-89 can be administered every three months and proven effective in approximately 80% of the patients who received the drug, Q BioMed is hopeful that broad market reacceptance will be swift.

We have already received orders from clinics and hospitals. Through our distribution partner, Jubilant Radiopharma™, we have the capability to reach patients in all 50 states. Our contract manufacturing facility, which is FDA approved to manufacture Strontium-89, is manufacturing initial commercial-scale quantities, with the first set of doses to be shipped in February 2020. Manufacturing will reach full production quantities in March and patients should start to receive treatment from March onwards. Commercial and marketing activities, including conferences and sales, will commence concurrent with commercial availability. Strontium-89 is reimbursed by Medicare and most insurance companies.

This is a major milestone for Q BioMed. We are now a revenue generating entity. This was a goal we set for ourselves when we founded the company almost 5 years ago. The journey to producing a commercial drug has not been easy, but we are now there. It's a great

achievement and a testament to all those who have helped get us to this point. We look forward to being able to help serve the unmet needs of the millions of patients suffering from debilitating pain associated with metastatic cancer in the bone. Years of well documented data prove that Strontium-89 benefits this patient population. We believe this drug has a very important role to play as clinicians move toward proven non-opioid therapeutics for pain palliation.

We plan to launch the drug in global markets including Europe in 2020. Q BioMed is also planning further research for Strontium-89 for potential label extension into therapeutic use for survival benefit in metastatic bone cancer through a Phase IV study.

In anticipation of the approval, we have proactively on-boarded our commercial team tasked with infrastructure set-up, including: medical information and pharmacovigilance, government contracting, marketing, contract sales and telesales. We have announced a distribution partnership with Jubilant Radiopharma who have all the capabilities we require to access the US market, including warehousing/inventory management, invoicing and customer service/ordering. It also has a sales team that calls on major providers, a national network of nuclear pharmacies in the U.S. and distribution and coverage throughout the U.S. We have completed a reimbursement landscape and set our pricing strategy. Our scientific platform is complete which is informing a creative advertising campaign to coincide with the commercial launch of our product. We are assembling a world class scientific advisory board specific to this product to assist in market access and phase 4 clinical trial planning.

Our Strontium-89 radiopharmaceutical drug addresses an underserved patient group in the cancer pain palliation market, but also has a significant opportunity to expand into a much larger market through our planned phase IV clinical trial designed to expand the label from a pain palliation to a cancer therapeutic. A similar radiopharmaceutical with a much narrower indication in metastatic disease, but with survival benefits (two months), was acquired by Bayer for \$2.9 billion in 2013 and is expected to have sales exceeding \$700 million this year.

The acquisition of Metastrom and global demand for access to generic drugs and non-opioid therapies has given Q BioMed access to a global market much sooner than expected and we continue to be extremely excited about its prospects to re-establish a deserved niche in the late stage cancer treatment landscape.

#### *QBM001*

There is currently no treatment for this 20,000 US and 250,000 worldwide subgroup of autistic children that are born each year and become minimally verbal or non-verbal. We recently filed for Orphan Drug Designation with the FDA and look forward to working with the regulators on this application. We worked with 7 centers of excellence for autism to define a differential diagnosis for our targeted subgroup, and all are on board. We completed a biomarker study that allows us to better define which children should be included in our planned trial. The biomarker also provided insight into how to improve the dosing. We believe that a very targeted population with an improved, targeted dose, will allow our planned trials to be smaller and increase the likelihood of being successful. Having also identified an autism animal model with our biomarkers will also now accelerate our path to IND in 2021.

#### *Uttroside-B*

Over 40,000 liver cancer patients in the US are diagnosed every year, and the total diagnoses per year has increased by 3% each year over the last 15 years. Each patient has a life expectancy of less than four months. Our initial data from both animals and cell lines suggests that our developing molecule could be very effective - as much as 10 times more effective than current treatments. As a result, we intend to bring this product to a proof of concept trial. If demonstrated, we will actively seek partnerships in order to realize a return on our investment. We believe that we are the only entity to have successfully synthesized Uttroside B and have filed a patent for the synthesis. The synthesized product is now being tested and has shown exact comparison to the natural product in the same liver cancer cell lines.

#### *MAN-01 and GDF15*

There are over 60 million patients worldwide with Primary Open-Angle Glaucoma. MAN-01 aims to reduce the pressure build-up in the eye by assisting with, and correcting, drainage problems in tiny vessels in the eye called the Schlemm's Canal. MAN-01 is being designed to target these unique and extremely important vessels, as over 70% of all fluid in the eye flows through the Schlemm's Canal. Currently, the MAN-01 program is finalizing its preclinical lead candidate optimization by completing a series of ophthalmic in vivo studies to demonstrate efficacy. After successful completion of the in vivo studies, Mannin Research will begin preparing for preclinical toxicology and filing of its IND. Our research shows that the drug's mechanism of action may ameliorate vessel damage in several other diseases such as: kidney disease, cardiovascular disease, and against infectious diseases, such as influenza and the current corona virus outbreak. We believe these programs comprise a multi-disease platform technology that has several valuable applications. Adding the GDF15 biomarker to our portfolio is a significant step to securing a unique product offering that put precision medicine and patient specific treatment in the hands of clinicians. GDF15 is a companion diagnostic marker to the MAN-01 drug for determining the severity of glaucoma using the expression levels of Growth Differentiation Factor 15 (GDF15). Determining the severity of glaucoma using this biomarker will aid in treatment decisions for patients diagnosed with, and being treated for, glaucoma. Recent buyouts in the Biotechnology space has us believing that large pharma companies could be looking for valuable assets like this with multiple downlines because of expiring patient protection on current drugs. Our collaborators at the Washington University in St. Louis are currently examining the effectiveness of GDF15 as a clinical biomarker in a clinical trial. In parallel, Q BioMed and Mannin Research are working with the BioInterfaces Institute at McMaster University in Ontario, Canada to develop a GDF15 biomarker diagnostic kit for monitoring glaucoma severity and progression. The aim is to develop a simple integrated diagnostic test that can be performed at a physician's office with no external, expensive equipment.

#### *The MAN Platform for other indications:*

Mannin presented positive data on a potential new treatment for acute kidney injury (AKI) at the American Society for Nephrology 2019 Annual Meeting on November 7 in Washington DC.

The data presented demonstrates the Ang-Tie2 signaling pathway as a promising therapeutic target for renal protection from acute kidney injury following ischemic reperfusion. Ischemia-reperfusion (IR) injury to the kidney occurs in a range of clinically important scenarios including hypotension, sepsis and in surgical procedures such as cardiac bypass surgery and kidney transplantation, leading

to AKI. In-hospital mortality for patients with AKI has recently been estimated to be between 20 and 25% and mortality rates in excess of 50% have been reported in critically ill patients with AKI requiring dialysis. For those patients who survive, complications include chronic kidney disease (CKD) and end-stage renal disease (ESRD); cardiovascular events, and reduced quality of life. In the United States, AKI is associated with an increase in hospitalization costs that range from \$5.4 to \$24.0 billion. No effective treatments have been approved by the FDA. This represents a very significant opportunity to advance a therapeutic in an underserved patient population.

Mannin is developing new therapeutics to treat a variety of vascular diseases, including the new coronavirus which originated in Wuhan, China, with a rapidly rising number of deaths and confirmed cases. The Coronavirus has been declared a Global Health Emergency by the World Health Organization (WHO).

While Mannin is not generating a vaccine against infectious diseases, it is developing a new drug that may increase the survival rate of patients by reducing the severity of disease through enhancement of host-directed therapeutic response.

Mannin recently submitted a grant application to the U.S. National Institutes of Health for Small Business Technology Transfer Grant Applications for approximately US \$200,000 for the MAN-11 biologic. The studies will be conducted at Northwestern University to investigate treatment of vascular leakage to treat sepsis and other infectious diseases. Mannin is also working with Canada's National Research Council (NRC.CNRC) since December 2019 to support the development of the biologic. In September 2019, the German state of Saxony awarded Mannin an approximately US \$7.7 million grant to advance the Mannin portfolio of vascular diseases, including development of the biologic.

While we continue to advance all our assets, our key focus for both capital expense and time is on the commercialization of Strontium-89 Chloride USP Injection. This is a near-term revenue generator and we believe a significant catalyst and long-term value driver for us.

## 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, 2019 and 2018. 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, 2019 and 2018. 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*

Effective December 1, 2018, the Company adopted ASU 2018-07, by which the accounting for share-based payments to non-employees and employees is substantially aligned. Non-employee share-based payment awards are measured at grant-date fair value of the equity instruments that the Company is obligated to issue when the good has been delivered or the service has been rendered and any other conditions necessary to earn the right to benefit from the instruments have been satisfied. There was no cumulative effect of the adoption of this standard.

Share-based compensation cost is recorded for all option grants and awards of non-vested stock based on the grant date fair value of the award and is recognized over the service period required for the award. Prior to December 1, 2018, share-based compensation cost for non-employees was remeasured over the vesting term as earned.

Stock-based compensation expense is recognized in the consolidated financial statements based on the fair value of the awards granted. Stock-based compensation cost is measured at the grant date based on the fair value of the award and is recognized as expense over the requisite service period, which generally represents the vesting period. We calculate the fair value of stock options using the Black-Scholes option-pricing model at grant date.

#### *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, 2019, 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, 2019. Management is currently unaware of any issues under review that could result in significant payments, accruals or material deviations from our position.

### *Recent accounting pronouncements*

For a summary of recent accounting pronouncements applicable to our consolidated financial statements, see Note 3, Summary of Significant Accounting Policies, in Part II, Item 8, Notes to Consolidated Financial Statements.

## Results of Operation for the years ended November 30, 2019 and 2018

|  | <b>For the year ended</b>           |                                    |
|--|-------------------------------------|------------------------------------|
|  | <b>2019</b>                         | <b>2018</b>                        |
| <b>Operating expenses:</b>                   |                                     |                                    |
| General and administrative expenses          | \$ 4,480,577                        | \$ 5,781,613                       |
| Research and development expenses            | 3,539,381                           | 3,238,060                          |
| Total operating expenses                     | <u>8,019,958</u>                    | <u>9,019,673</u>                   |
| <b>Other expenses:</b>                       |                                     |                                    |
| Interest expense                             | 1,460,384                           | 162,104                            |
| Change in fair value of embedded derivatives | 208,240                             | 89,000                             |
| Loss on conversion of debt                   | 591,148                             | -                                  |
| Total other expenses                         | <u>2,259,772</u>                    | <u>251,104</u>                     |
| <b>Net loss</b>                              | <b><u><u>\$(10,279,730)</u></u></b> | <b><u><u>\$(9,270,777)</u></u></b> |

### *Operating expenses*

We incur various costs and expenses in the execution of our business. The decrease in operating expenses was mainly due to less professional and research & development fees incurred in connection with the license agreements with Mannin and Washington University.

### *Interest expenses*

The following table summarizes interest expenses incurred during the year ended November 30, 2019 and 2018, respectively:

|  | <b>For the year ended November 30,</b> |                   |
|--|--|-------------------|
|  | <b>2019</b>                            | <b>2018</b>       |
| Interest expense based on the coupon interest rate of the outstanding debt | \$ 327,966                             | \$ 29,756         |
| Accretion of debt discount   | 1,001,153                              | 132,348           |
| Interest expense related to deferral fee                                   | 131,265                                | -                 |
| Total interest expense   | <u>\$ 1,460,384</u>                    | <u>\$ 162,104</u> |

### *Change in fair value of embedded derivatives*

We recognized a loss of approximately \$208,000 and \$89,000 resulting from the change in fair value of embedded contingent put options in convertible notes during the year ended November 30, 2019 and 2018, respectively. The increase is due to an increased in our outstanding convertible notes balance at November 30, 2019 compared to November 30, 2018.

### *Loss on conversion of debt*

During the year ended November 30, 2019, we recognized a loss of approximately \$591,000 resulting from conversion of partial 2018 Debentures and 2019 Debenture.

### *Net loss*

In the years ended November 30, 2019 and 2018, we incurred net losses of approximately \$10.3 million and \$9.3 million, respectively. Our management expects to continue to incur net losses for the foreseeable future, due to our need to continue to establish a broader pipeline of assets, expenditure on R&D 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 \$173,000 in cash as of November 30, 2019. 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:

|                                 | <b>For the year ended</b>   |                            |
|---------------------------------|-----------------------------|----------------------------|
|                                 | <b>2019</b>                 | <b>2018</b>                |
| Net cash (used in) provided by: |                             |                            |
| Operating activities            | \$(4,105,027)               | \$(6,450,621)              |
| Investing activities            | -                           | (500,000)                  |
| Financing activities            | 1,593,250                   | 8,810,251                  |
| Net (decrease) increase in cash | <b><u>\$(2,511,777)</u></b> | <b><u>\$ 1,859,630</u></b> |

Net cash used in operating activities was approximately \$4.1 million for the year ended November 30, 2019 as compared to approximately \$6.5 million for the year ended November 30, 2018. The decrease in net cash used in operating activities results from the net loss of approximately \$10.3 million for the year ended November 30, 2019, partially offset by aggregate non-cash expenses of approximately \$4.7 million. 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.

Net cash used in investing activities was \$500,000 for the year ended November 30, 2018, resulting from purchase of intangible assets.

Net cash provided by financing activities was approximately \$1.6 million for the year ended November 30, 2019, resulting from proceeds received from the issuance of convertible notes payable of approximately \$1.0 million and the issuance of common stock and warrants of approximately \$0.6 million. 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.

### 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.

We believe that we fulfilled the obligations under the agreement to exercise an option to acquire the BNI IP and notified BNI of such exercise, but BNI did not transfer the BNI IP to us. As a result, we commenced litigation to, among other actions, obtain all of the BNI IP. We also sought judgments against BNI and related parties for the misappropriation of funds, breach of contract, fraud and fraudulent inducement. In February 2019, such lawsuit was removed to the Federal court located in the Southern District of New York.

On September 23, 2019, we entered into a settlement agreement with BNI and parties related to BNI. Pursuant to the terms of the settlement agreement, we settled our dispute with BNI and all parties to the litigation dismissed their claims in exchange for entering into a Second Amendment to the License Agreement (entered into on September 23, 2019) pursuant to which:

- BNI agreed to immediately transfer and/or assign to us all intellectual property, patents and products that is owned by BNI that is related to Strontium-Chloride 89;

- We agreed to issue BNI 50,000 shares of our common stock upon the entry into the settlement agreement and 100,000 shares of our common stock upon the approval of the U.S. Food and Drug Administration (“FDA”) approval of BNI’s Prior Approval Supplements filing

- We agreed to make a cash payment to BNI of \$25,000
- We agreed to an on-going royalty payment of 3% on all gross profits derived by us from the sale of Strontium-Chloride 89 and Metastron™; and
- We agreed to assume fees and expenses related to (i) all outstanding CMO fees owed by BNI to IsoTherapeutics relating to Strontium-Chloride 89 (approximately \$67,000), (ii) all outstanding fees owed by BNI to the FDA relating to Strontium-Chloride 89 (approximately \$208,000) and (iii) related fees for the development and approval of Strontium-Chloride 89 following the date of the settlement agreement.

#### *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 ended in December 2019 and has been further 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:

|              | <b>For the year ended November 30,</b> |             |
|--------------|--|-------------|
|              | <b>2019</b>                            | <b>2018</b> |
| Rent expense | \$ 30,000                              | \$ 30,000   |

#### *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.

On March 26, 2019, we entered into an amendment to the Patent and Technology License and Purchase Option Agreement that it initially entered into with Mannin Research Inc. on October 29, 2015 (the “Mannin Agreement”). Under such amendment, the term of the option granted under the Mannin Agreement was extended to October 29, 2021 in exchange for our issuing 100,000 shares to Mannin Research Inc. on April 9, 2019.

During the years ended November 30, 2019 and 2018, we incurred approximately \$2.1 million and \$2.1 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.

##### **Washington University**

On March 9, 2019, we entered into an Exclusive License Agreement with Washington University for license of a diagnostic marker for determining the severity of glaucoma using the expression levels of Growth Differentiation Factor 15. The agreement calls for us to pay an initial fee of approximately \$88,000, pay annual maintenance fees ranging from \$15,000 to \$75,000, make additional payments upon the following milestones:

- The first commercial sale of a companion diagnostic product;
- Initiation of a clinical trial for a diagnostic product to support FDA PMA or 510(k) regulatory approval or the foreign equivalent;
- PMA or 510(k) regulatory approval by the FDA or the foreign equivalent; and
- The first commercial sale of a diagnostic product.

In addition to the above payments, royalty payments based upon sales of a companion diagnostic product or diagnostic product are required.

#### *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:

|                               | <b>For the year ended November 30,</b> |             |
|-------------------------------|--|-------------|
|                               | <b>2019</b>                            | <b>2018</b> |
| Consulting and legal expenses | \$ 531,751                             | \$ 295,000  |

#### **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. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

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

|   | <u>PAGE</u>         |
|---|---------------------|
| <a href="#">Report of Independent Registered Public Accounting Firm (fiscal year ended in 2019)</a> | <a href="#">F-2</a> |
| <a href="#">Consolidated Balance Sheets</a>   | <a href="#">F-3</a> |
| <a href="#">Consolidated Statements of Operations</a>   | <a href="#">F-4</a> |
| <a href="#">Consolidated Statement of Changes in Stockholders' Equity (Deficit)</a>                 | <a href="#">F-5</a> |
| <a href="#">Consolidated Statements of Cash Flows</a>   | <a href="#">F-6</a> |
| <a href="#">Notes to Consolidated Financial Statements</a>  | <a href="#">F-7</a> |

## 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, 2019, management has 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 effective to detect the inappropriate application of US GAAP. Management has identified the following material weaknesses set forth below in our internal control over financial reporting.

1. Due to our size and nature, segregation of all conflicting duties may not always be possible and may not be economically feasible, however segregation of duties has been implemented, with regards to the initiation of transactions, the custody of assets and the recording of transactions performed by separate individuals.

2. 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.
3. We have determined that oversight over our external financial reporting and internal control over our financial reporting is ineffective as we don't have an audit committee in place.

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 engaged a professional firm to perform an audit and risk assessment during the year and many of the issues from last year that have been remediated. 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.

| <u>Name</u>        | <u>Age</u> | <u>Positions</u>                                | <u>Held Position Since</u> |
|--------------------|------------|---|----------------------------|
| Denis Corin        | 46         | Chief Executive Officer and Director (Chairman) | 2015                       |
| William Rosenstadt | 51         | General Counsel and Director                    | 2015                       |
| Rick Panicucci     | 59         | 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's 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 Ortol 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. No such fees have been paid to any director since incorporation. 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, 2019 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) | Warrants Awards (\$) (5) | Option Awards (\$) (6) | All Other Compensations (\$) (1) | Total (\$) |
|------------------------------|------|-------------|------------|-----------------------|--------------------------|------------------------|----------------------------------|------------|
| Denis Corin (2)              | 2019 | \$ 320,000  | \$ -       | \$ 20,000             | \$ 30,000                | \$ 206,000             | \$ -                             | \$ 576,000 |
| Chief Executive Officer      | 2018 | \$ 240,000  | \$ -       | \$ -                  | \$ -                     | \$ 438,000             | \$ -                             | \$ 678,000 |
| William Rosenstadt (3)       | 2019 | \$ -        | \$ -       | \$ 72,000             | \$ 99,000                | \$ 206,000             | \$ 313,000                       | \$ 690,000 |
| General Counsel and Director | 2018 | \$ -        | \$ -       | \$ 59,000             | \$ -                     | \$ 438,000             | \$ 331,000                       | \$ 828,000 |

- (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) Mr. Corin was granted 40,000 shares of common stock on November 25, 2019 with grant date fair value of \$20,000.  
Mr. Rosenstadt was granted 115,761 shares of common stock on October 15, 2019 with grant date fair value of \$72,000.  
Mr. Rosenstadt was granted 20,000 shares of common stock on September 21, 2018 with grant date fair value of \$59,000.
- (5) 500,000 warrants held by Mr. Corin was amended on October 1, 2019. The \$30,000 represents the incremental value received by Mr. Corin.  
Mr. Rosenstadt was granted 173,641 warrants on October 15, 2019 with grant date fair value of \$59,000.  
800,000 warrants held by Mr. Rosenstadt was amended on October 1, 2019. The \$40,000 represents the incremental value received by Mr. Rosenstadt.
- (6) On May 31, 2019, Mr. Corin and Mr. Rosenstadt were each granted 150,000 stock options. The fair value on the grant date was \$206,000, which included \$40,000 incremental value from the amendment on October 1, 2019.  
On June 1, 2018, Mr. Corin and Mr. Rosenstadt were each granted 150,000 stock options. The fair value on the grant date was \$438,000.

## 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 25, 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 Ortolini 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) |
|--|---|----------------------|
| <b>Directors and Officers:</b>           |   |                      |
| Denis Corin (3)                          | 3,391,800                                 | 16.3%                |
| William Rosenstadt (4)                   | 2,042,222                                 | 9.8%                 |
| Rick Panicucci                           | 110,000                                   | 0.21%                |
| Directors and Officers as a Group (3)(4) | 5,544,022                                 | 26.2%                |
| <b>Major Stockholders:</b>               |   |                      |
| Ari Jatwes (5)                           | 1,375,000                                 | 6.46%                |

- (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: (1) 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 25, 2019.
- (2) This percentage is based upon 20,835,625 shares of common stock outstanding as of February 25, 2020 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 issued in July 2016 for director fees, (ii) 350,000 five-year warrants issued in June 5, 2017 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, (iv) 150,000 five-year options issued in June 2018 for services as a director and officer through June 1, 2019 and (v) 150,000 five-year options issued in June 2019 for services as a director and officer through June 1, 2020, all of which are exercisable within 60 days of the date as of which the information is provided.
- (4) Includes (i) 250,000 five-year warrants issued in January 2016 to the law firm at Mr. Rosenstadt is a partner, (ii) 50,000 five-year warrants issued in July 2016 which were issued to the law firm at Mr. Rosenstadt is a partner, (iii) 150,000 five-year warrants issued in July 15, 2016 for director fees through June 1, 2017, (iv) 350,000 five-year warrants issued in June 2017 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, (vi) 150,000 five-year options issued in June 2018 for services as a director and officer through June 1, 2019 and (vii) 150,000 five-year options issued in June 2019 for services as a director and officer through June 1, 2020, all of which are exercisable within 60 days of the date as of which the information is provided.
- (5) Includes (i) 75,000 warrants issued in July 2016, (ii) 85,000 warrants issued in June 2017, (iii) 150,000 options issued in June 2017, (iv) 50,000 options issued in July 2018, (v) 50,000 options issued in September 2019 and (vi) 300,000 warrants issued in February 2020.

### 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 \$370,000 and \$295,000 for the year ended November 30, 2019 and 2018, 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, 2019 and 2018 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

| <b>SERVICES</b>    | <b>2019</b>              | <b>2018</b>             |
|--------------------|--------------------------|-------------------------|
| Audit fees         | \$ 138,000               | \$ 95,000               |
| Audit-related fees |                          |                         |
| Tax fees           | -                        | -                       |
| All other fees     | -                        | -                       |
| <b>Total fees</b>  | <b><u>\$ 138,000</u></b> | <b><u>\$ 95,000</u></b> |

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.

| <b>Exhibit No.</b>    | <b>Description</b>   |
|-----------------------|--|
| <a href="#">3.1</a>   | <a href="#">Articles of Incorporation filed as Exhibit 3 (a) to Form S-1 filed on January 13, 2014 and incorporated herein by reference</a>  |
| <a href="#">3.2</a>   | <a href="#">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</a>  |
| <a href="#">3.3</a>   | <a href="#">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</a>   |
| <a href="#">3.4</a>   | <a href="#">Articles of Incorporation filed as Exhibit 3 (b) to Form S-1 filed on January 13, 2014 and incorporated herein by reference</a>  |
| <a href="#">4.1</a>   | <a href="#">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 12, 2018</a>  |
| <a href="#">4.2</a>   | <a href="#">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</a>   |
| <a href="#">4.3</a>   | <a href="#">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</a>  |
| <a href="#">4.4</a>   | <a href="#">Description of Securities*</a>   |
| <a href="#">10.1</a>  | <a href="#">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</a>   |
| <a href="#">10.2</a>  | <a href="#">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</a>  |
| <a href="#">10.3</a>  | <a href="#">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</a>   |
| <a href="#">10.4</a>  | <a href="#">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</a>   |
| <a href="#">10.5</a>  | <a href="#">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</a>   |
| <a href="#">10.6</a>  | <a href="#">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</a>   |
| <a href="#">10.7</a>  | <a href="#">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</a>  |
| <a href="#">10.9</a>  | <a href="#">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</a>   |
| <a href="#">10.10</a> | <a href="#">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 +</a>  |
| <a href="#">10.11</a> | <a href="#">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 +</a>                                       |
| <a href="#">10.12</a> | <a href="#">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 +</a>               |
| <a href="#">10.13</a> | <a href="#">License Agreement on Patent &amp; 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 +</a>                                  |
| <a href="#">10.14</a> | <a href="#">Executive Services Agreement, dated June 5, 2017, between Q BioMed Cayman SEZC and Denis Corin filed as Exhibit 10.1 to our current report on Form 8-K filed on June 9, 2017 and incorporated herein by reference</a>  |
| <a href="#">10.15</a> | <a href="#">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 +</a> |
| <a href="#">10.16</a> | <a href="#">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</a>  |
| <a href="#">10.17</a> | <a href="#">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</a>  |
| <a href="#">10.18</a> | <a href="#">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</a>  |

10.19 [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++](#)

- [10.20](#) [Securities Purchase Agreement, dated August 28, 2019, filed as Exhibit 10.1 to our current report on Form 8-K \(as amended\) on September 6, 2019 and incorporate herein by reference](#)
- [10.21](#) [Form of Debenture pursuant to the Securities Purchase Agreement entered into on August 28, 2019, filed as Exhibit 10.2 to our current report on Form 8-K \(as amended\) on September 6, 2019 and incorporate herein by reference](#)
- [10.22](#) [Securities Purchase Agreement, dated October 11, 2019, filed as Exhibit 10.1 to our current report on Form 8-K on October 15, 2019 and incorporate herein by reference](#)
- [10.23](#) [Form of Debenture pursuant to the Securities Purchase Agreement entered into on October 11, 2019, filed as Exhibit 10.2 to our current report on Form 8-K on October 15, 2019 and incorporate herein by reference](#)
- [10.24](#) [Securities Purchase Agreement, dated December 5, 2019, filed as Exhibit 10.1 to our current report on Form 8-K on December 12, 2019 and incorporate herein by reference](#)
- [10.25](#) [Form of Debenture pursuant to the Securities Purchase Agreement entered into on December 5, 2019, filed as Exhibit 10.2 to our current report on Form 8-K on December 12, 2019 and incorporate 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.

## **ITEM 16. FORM 10-K SUMMARY**

We have elected not to provide a summary of the information provided in this annual report on Form 10-K.

## 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: February 28, 2020

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.

| <u>Signature</u>                                    | <u>Title</u>  | <u>Date</u>       |
|---|---|-------------------|
| <u>/s/ Denis Corin</u><br>Denis Corin               | President, Chief Executive Officer and Director<br>(Principal Executive Officer and Acting Principal Financial and<br>Accounting Officer) | February 28, 2020 |
| <u>/s/ William Rosenstadt</u><br>William Rosenstadt | General Counsel and Director  | February 28, 2020 |
| <u>/s/ Rick Panicucci</u><br>Rick Panicucci         | Director  | February 28, 2020 |

**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, 2019 and 2018, the related consolidated statements of operations, stockholders’ equity and cash flows for each of the two years in the period ended November 30, 2019, 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, 2019 and 2018, and the results of its operations and its cash flows for each of the two years in the period ended November 30, 2019, 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  
February 28, 2020

**Q BIOMED INC.**  
**Consolidated Balance Sheets**

|  | As of November 30, |                     |
|--|--------------------|---------------------|
|  | 2019               | 2018                |
| <b>ASSETS</b>  |                    |                     |
| Current assets:  |                    |                     |
| Cash   | \$ 172,636         | \$ 2,684,413        |
| Prepaid expenses and other current assets  | 17,662             | 12,500              |
| Total current assets   | 190,298            | 2,696,913           |
| Intangible assets, net   | 450,000            | 500,000             |
| <b>Total Assets</b>  | <b>\$ 640,298</b>  | <b>\$ 3,196,913</b> |
| <b>LIABILITIES AND STOCKHOLDERS' DEFICIT</b>   |                    |                     |
| Current liabilities:   |                    |                     |
| Accounts payable   | \$ 652,051         | \$ 172,628          |
| Accrued expenses   | 1,145,660          | 219,602             |
| Accrued expenses - related party   | 7,500              | 7,500               |
| Accrued interest payable   | 189,801            | 29,639              |
| Convertible note payable, net  | 3,243,292          | -                   |
| Total current liabilities  | 5,238,304          | 429,369             |
| Long-term liabilities:   |                    |                     |
| Convertible notes payable, net   | 447,335            | 2,873,272           |
| Total long term liabilities  | 447,335            | 2,873,272           |
| <b>Total Liabilities</b>   | <b>5,685,639</b>   | <b>3,302,641</b>    |
| <b>Commitments and Contingencies (Note 7)</b>  |                    |                     |
| <b>Stockholders' Deficit:</b>  |                    |                     |
| Preferred stock, \$0.001 par value; 100,000,000 shares authorized; no shares issued and outstanding as of November 30, 2019 and 2018                                   | -                  | -                   |
| Common stock, \$0.001 par value; 250,000,000 shares authorized; 19,709,068 and 14,290,236 shares issued and outstanding as of November 30, 2019 and 2018, respectively | 19,709             | 14,290              |
| Additional paid-in capital   | 37,328,827         | 31,994,129          |
| Accumulated deficit  | (42,393,877)       | (32,114,147)        |
| <b>Total Stockholders' Deficit</b>   | (5,045,341)        | (105,728)           |
| <b>Total Liabilities and Stockholders' Deficit</b>   | <b>\$ 640,298</b>  | <b>\$ 3,196,913</b> |

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

**Q BIOMED INC.**  
**Consolidated Statements of Operations**

|   | For the year ended<br>November 30, |                       |
|---|------------------------------------|-----------------------|
|   | 2019                               | 2018                  |
| <b>Operating expenses:</b>                                    |                                    |                       |
| General and administrative expenses                           | \$ 4,480,577                       | \$ 5,781,613          |
| Research and development expenses                             | 3,539,381                          | 3,238,060             |
| Total operating expenses                                      | 8,019,958                          | 9,019,673             |
| <b>Other expenses:</b>  |                                    |                       |
| Interest expense  | 1,460,384                          | 162,104               |
| Change in fair value of embedded derivatives                  | 208,240                            | 89,000                |
| Loss on conversion of debt                                    | 591,148                            | -                     |
| Total other expenses  | 2,259,772                          | 251,104               |
| <b>Net loss</b>   | <b>\$ (10,279,730)</b>             | <b>\$ (9,270,777)</b> |
| <b>Net loss per share - basic and diluted</b>                 | \$ (0.68)                          | \$ (0.67)             |
| <b>Weighted average shares outstanding, basic and diluted</b> | 15,040,513                         | 13,735,134            |

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

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

|  | <b>Common Stock</b> |                  | <b>Additional Paid in<br/>Capital</b> | <b>Accumulated<br/>Deficit</b> | <b>Total<br/>Stockholders'<br/>Equity (Deficit)</b> |
|--|---------------------|------------------|---------------------------------------|--------------------------------|---|
|  | <b>Shares</b>       | <b>Amount</b>    |                                       |                                |   |
| <b>Balance as of December 1, 2017</b>  | <b>12,206,409</b>   | <b>\$ 12,206</b> | <b>\$ 23,187,408</b>                  | <b>\$ (22,843,370)</b>         | <b>\$ 356,244</b>                                   |
| 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)   |
| <b>Balance as of November 30, 2018</b>   | <b>14,290,236</b>   | <b>14,290</b>    | <b>31,994,129</b>                     | <b>(32,114,147)</b>            | <b>(105,728)</b>                                    |
| Issuance of common stock and warrants for cash, net of offering costs          | 1,521,602           | 1,522            | 621,728                               | -                              | 623,250   |
| Share based compensation for services  | 1,577,131           | 1,577            | 2,494,719                             | -                              | 2,496,296   |
| Issuance of common stock to convert notes payable                              | 2,320,099           | 2,320            | 2,218,251                             | -                              | 2,220,571   |
| Net loss   | -                   | -                | -                                     | (10,279,730)                   | (10,279,730)  |
| <b>Balance as of November 30, 2019</b>   | <b>19,709,068</b>   | <b>\$ 19,709</b> | <b>\$ 37,328,827</b>                  | <b>\$ (42,393,877)</b>         | <b>\$ (5,045,341)</b>                               |

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

**Q BIOMED INC.**  
**Consolidated Statement of Cash Flows**

|  | <b>For the year ended<br/>November 30,</b> |                     |
|--|--|---------------------|
|  | <b>2019</b>                                | <b>2018</b>         |
| <b>Cash flows from operating activities:</b>   |  |                     |
| Net loss   | \$ (10,279,730)                            | \$ (9,270,777)      |
| Adjustments to reconcile net loss to net cash used in operating activities                               |  |                     |
| Share based compensation for services  | 2,496,296                                  | 2,650,477           |
| Change in fair value of embedded conversion option   | 208,240                                    | 89,000              |
| Accretion of debt discount   | 1,001,153                                  | 132,349             |
| Amortization expense   | 50,000                                     | -                   |
| Loss on conversion of debt   | 591,148                                    | -                   |
| Non-cash interest expense  | 131,265                                    | -                   |
| Changes in operating assets and liabilities:   |  |                     |
| Prepaid expenses   | (5,162)                                    | (10,000)            |
| Accounts payable and accrued expenses  | 1,405,481                                  | (71,309)            |
| Accrued interest payable   | 296,282                                    | 29,639              |
| <b>Net cash used in operating activities</b>   | <b>(4,105,027)</b>                         | <b>(6,450,621)</b>  |
| <b>Cash flows from investing activities:</b>   |  |                     |
| Purchase of intangible assets  | -  | (500,000)           |
| <b>Net cash used in investing activities</b>   | <b>-</b>                                   | <b>(500,000)</b>    |
| <b>Cash flows from financing activities:</b>   |  |                     |
| Proceeds received from issuance of convertible note, net of original issuance discount and lender's fees | 970,000                                    | 3,865,000           |
| Proceeds received for issuance of common stock and warrants, net of offering costs                       | 623,250                                    | 4,945,251           |
| <b>Net cash provided by financing activities</b>   | <b>1,593,250</b>                           | <b>8,810,251</b>    |
| <b>Net (decrease) increase in cash</b>   | <b>(2,511,777)</b>                         | <b>1,859,630</b>    |
| <b>Cash at beginning of the year</b>   | <b>2,684,413</b>                           | <b>824,783</b>      |
| <b>Cash at end of the year</b>   | <b>\$ 172,636</b>                          | <b>\$ 2,684,413</b> |
| <b>Supplemental disclosures:</b>   |  |                     |
| Cash paid for interest   | \$ 31,524                                  | \$ -                |
| Cash paid for income taxes   | \$ -                                       | \$ -                |
| <b>Supplemental disclosures for noncash investing and financing activities:</b>                          |  |                     |
| Issuance of common stock to convert notes payable and accrued interest                                   | \$ 1,493,511                               | \$ -                |
| Issuance of common stock in connection with issuance convertible notes                                   | \$ -                                       | \$ 222,750          |

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

**Q BIOMED INC.**  
**Notes to 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”). On August 13, 2019, the Company formed its wholly-owned subsidiary in Germany, “QBMG Q BioMed Germany UG”. There are no activities through November 30, 2019.

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.

The Company has not generated any revenue from operations since inception and has limited assets upon which to commence its business operations. 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 will be forced to scale back the Company’s operations or cease its 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 are insured by the Federal Deposit Insurance Corporation ("FDIC") up to \$250,000. At November 30, 2019, the Company had a cash balance that is insured by the FDIC limit. 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, 2019 and 2018. 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*

Effective December 1, 2018, the Company adopted ASU 2018-07, by which the accounting for share-based payments to non-employees and employees is substantially aligned. Non-employee share-based payment awards are measured at grant-date fair value of the equity instruments that the Company is obligated to issue when the good has been delivered or the service has been rendered and any other conditions necessary to earn the right to benefit from the instruments have been satisfied. There was no cumulative effect of the adoption of this standard.

Share-based compensation cost is recorded for all option grants and awards of non-vested stock based on the grant date fair value of the award, and is recognized over the service period required for the award. Prior to December 1, 2018, share-based compensation cost for non-employees was remeasured over the vesting term as earned.

Stock-based compensation expense is recognized in the consolidated financial statements based on the fair value of the awards granted. Stock-based compensation cost is measured at the grant date based on the fair value of the award and is recognized as expense over the requisite service period, which generally represents the vesting period. The Company calculates the fair value of stock options using the Black-Scholes option-pricing model at grant date.

### *General and administrative expenses*

The significant components of general and administrative expenses consist of 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, 2019, 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, 2019. Management is currently unaware of any issues under review that could result in significant payments, accruals or material deviations from its position.

### *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 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 does not expect the adoption of the new standard to have a material impact on its Consolidated Financial Statements.

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 does not expect the adoption of the new standard to have a material impact on its consolidated financial statements.

In December 2019, the FASB issued ASU No. 2019-12, "Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes ("ASU 2019-12"), which is intended to simplify various aspects related to accounting for income taxes. ASU 2019-12 removes certain exceptions to the general principles in Topic 740 and also clarifies and amends existing guidance to improve consistent application. This guidance is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2020, with early adoption permitted. The Company is currently evaluating the impact of this standard on its consolidated financial statements and related disclosures.

#### *Recent adopted pronouncements*

In May 2014, the FASB issued ASU 2014-09, *Revenue from Contracts with Customers (Topic 606), as modified by ASU 2015-14, Revenue from Contracts with Customers (Topic 606): Deferral of the Effective Date*, ASU 2016-08, *Revenue from Contracts with Customers (Topic 606): Principal versus Agent Considerations (Reporting Revenue Gross versus Net)*, ASU 2016-10, *Revenue from Contracts with Customers (Topic 606): Identifying Performance Obligations and Licensing*, and ASU 2016-12, *Revenue from Contracts with Customers (Topic 606): Narrow-Scope Improvements and Practical Expedients*. The revenue recognition principle in ASU 2014-09 is that an entity should recognize revenue to depict the transfer of goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. In addition, new and enhanced disclosures will be required. Companies may adopt the new standard either using the full retrospective approach, a modified retrospective approach with practical expedients, or a cumulative effect upon adoption approach. The adoption of this standard on December 1, 2018 did not impact the Company's 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. The adoption of this standard on December 1, 2018 did not impact the Company's 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. The adoption of this standard on December 1, 2018 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.



| <b>Potentially dilutive securities</b> | <b>November 30, 2019</b> | <b>November 30, 2018</b> |
|--|--------------------------|--------------------------|
| Warrants                               | 7,179,994                | 4,984,058                |
| Convertible Notes                      | 5,732,000                | 2,014,819                |
| Stock Options                          | 1,200,000                | 900,000                  |

#### 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, 2019 was \$50,000. 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 30,</u> |                   |
|--------------------------------|-------------------|
| 2020                           | \$ 50,000         |
| 2021                           | 50,000            |
| 2022                           | 50,000            |
| 2023                           | 50,000            |
| 2024                           | 50,000            |
| Thereafter                     | 200,000           |
|                                | <u>\$ 450,000</u> |

#### Note 6 – Convertible Notes

|   | <b>November 30, 2019</b> | <b>November 30, 2018</b> |
|---|--------------------------|--------------------------|
| <b>Convertible Notes Payable, current:</b>                        |                          |                          |
| Principal value of 2018 Debentures                                | \$ 2,730,000             | \$ -                     |
| Fair value of bifurcated contingent put option                    | 74,299                   | -                        |
| Debt discount   | (61,173)                 | -                        |
| Carrying value of 2018 Debentures                                 | <u>2,743,126</u>         | -                        |
| Principal value of 2019 August Debenture                          | 550,000                  | -                        |
| Debt discount   | (49,834)                 | -                        |
| Carrying value of 2019 August Debenture                           | <u>500,166</u>           | -                        |
| <b>Total carrying value of convertible notes payable, current</b> | <b>\$ 3,243,292</b>      | <b>\$ -</b>              |
| <b>Convertible Notes Payable, long-term:</b>                      |                          |                          |
| Principal value of 2018 Debentures                                | \$ -                     | \$ 4,000,000             |
| Fair value of bifurcated contingent put option                    | -                        | 262,000                  |
| Debt discount   | -                        | (1,388,728)              |
| Carrying value of 2018 Debentures                                 | <u>-</u>                 | <u>2,873,272</u>         |
| Principal value of 2019 October Debenture                         | 500,000                  | 4,000,000                |
| Fair value of bifurcated contingent put option                    | 29,382                   | 262,000                  |
| Debt discount   | (82,047)                 | (1,388,728)              |
| Carrying value of 2019 October Debenture                          | <u>447,335</u>           | <u>2,873,272</u>         |
| <b>Total carrying value of convertible notes, long-term</b>       | <b>\$ 447,335</b>        | <b>\$ 2,873,272</b>      |



### *2019 August Debenture*

On August 28, 2019, the Company entered into a securities purchase agreement with an accredited investor pursuant to which the Company sold a convertible debenture (the “August Debenture”) with a maturity date of twelve months after the issuance thereof for \$500,000. The August Debenture is in the aggregate principal amount of \$550,000, which amount includes an original issue discount of \$40,000, and payment of the lenders legal fees of \$10,000. The August Debenture carries an interest rate of 10% per annum upon an event of default, as defined, the outstanding balance of the August Debenture bears interest at a rate of 18% per annum. The Company may prepay the August Debenture at 110% of the outstanding aggregate principal amount within the first six months of issuance and at 125% of the outstanding aggregate principal amount thereafter. Since the Company can elect to settle the August Debenture in either cash or in shares, the Company will recognize any payment in addition to the principal amount as part of debt extinguishment upon the occurrence of the payment event.

In certain circumstances, a premium is due upon the outstanding balance upon written notice from the lender. A premium of fifteen percent is due for each occurrence of any major default, a premium of ten percent is due for each occurrence of an unapproved variable security issuance default, and a premium of five percent is due for each occurrence of any minor default.

The lender has the right to convert the outstanding aggregate principal amount at any time at the conversion price of \$2.50 per share. At any time that is six months after the issuance, the lender may redeem a portion of the August Debenture, not to exceed \$150,000 in any month. The Company may pay such a redemption in cash and/or shares of its common stock. Any payment of such a redemption in shares of common stock shall be made at the lesser of \$2.50 or 93% of the average of the four lowest VWAPs in the prior ten trading day, provided that no such conversion price shall be less than \$2.00. Any payment of such a redemption in cash shall be at 120% of the amount being redeemed. Moreover, the Company has the right to defer up to two (2) separate redemptions for up to thirty (30) days each by providing written notice to the lender within three (3) trading days of its receipt of a redemption notice. In the event the Company elects to exercise its deferral right, the August Debenture’s outstanding balance shall automatically be increased by ten percent (10%) of the redemption amount to which such deferral relates.

### *2019 October Debenture*

On October 11, 2019, the Company entered into another securities purchase agreement with an accredited investor to place Convertible Debentures (the “October Debenture”) with a maturity date of eighteen months after the issuance thereof in the aggregate principal amount of up to \$750,000 provided that in case of an event of default, the October Debenture may become at the holder’s election immediately due and payable. The initial closing occurred on October 11, 2019, when the Company issued a Debenture in the aggregate principal amount of \$500,000 for proceeds of \$485,000.

The October Debenture may be converted at any time on or prior to maturity at the lower of \$1.00 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 is not in default under the October Debenture, the conversion price may never be less than \$0.50. The Company may not convert any portion of a October Debenture if such conversion would result in the holder beneficially owning more than 4.99% of our then issued and common stock, provided that such limitation may be waived by the holder with 65 days’ notice.

Any time after the six-month anniversary of the issuance of the October Debenture that the daily VWAP is less than \$0.50 for a period of twenty consecutive trading days (the “Triggering Date”) and only for so long as such conditions exist after a Triggering Date, 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 October Debenture, the Company recognized a debt discount of approximately \$89,000, resulting from the recognition of issuance costs of \$15,000 and a bifurcated embedded derivative of \$74,000. The monthly payment provision within the October Debenture 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 fair value estimate is a Level 3 measurement. The Company estimated the fair value of the monthly payment provision by estimating the probability of the occurrence of a Triggering Date and applying the probability to the discounted maximum redemption premium for any given payment with the following key inputs:

|                | <u>November 30, 2019</u> | <u>October 11, 2019</u> |
|----------------|--------------------------|-------------------------|
| Strike price   | \$ 1.00                  | \$ 1.00                 |
| Terms (years)  | 1.4                      | 1.5                     |
| Volatility     | 99.5%                    | 93.4%                   |
| Risk-free rate | 1.6%                     | 1.7%                    |
| Dividend yield | 0%                       | 0%                      |

### *2018 Debentures*

On September 21, 2018, the Company entered into a securities purchase agreement with an accredited investor to place Convertible Debentures (the “2018 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 2018 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 2018 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 2018 Debentures.

The 2018 Debentures 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 2018 Debentures, 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 2018 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 2018 Debentures. The monthly payment provision within the 2018 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 fair value estimate is a Level 3 measurement. The Company estimated the fair value of the monthly payment provision by estimating the probability of the occurrence of a Triggering Date and applying the probability to the discounted maximum redemption premium for any given payment with the following key inputs:

|                | November 30,<br>2019 | November 30,<br>2018 |
|----------------|----------------------|----------------------|
| Strike price   | \$ 1.00              | \$1.95 - \$2.97      |
| Terms (years)  | 0.8                  | 1.2 - 1.4            |
| Volatility     | 99.5%                | 72.1% - 76.5%        |
| Risk-free rate | 1.6%                 | 2.4% - 2.5%          |
| Dividend yield | 0%                   | 0%                   |

#### *Debt Conversion*

The following table summarizes debt conversion during the year ended November 30, 2019:

|  |                           |
|--|---------------------------|
| Principal value of 2018 Debentures                         | \$1,270,000               |
| Accrued interest   | 136,120                   |
| Fair value of bifurcated contingent put option             | 112,900                   |
| Debt discount  | (25,509)                  |
| <b>Sub-total</b>   | <b><u>\$1,493,511</u></b> |
| <br>   |                           |
| Fair value of common stock issued (2,320,099 shares)       | <b><u>\$2,220,571</u></b> |
| <br>   |                           |
| <b>Loss on conversion of debt</b>                          | <b><u>\$ 595,795</u></b>  |
| <b>Interest expense recognized from conversion of debt</b> | <b><u>\$ 131,265</u></b>  |

#### *Debt Extinguishment*

On September 23, 2019, the Company amended the conversion price of the 2018 Debentures (the “Amendment”). The conversion price of the 2018 Debentures was reduced to the lower of (i) \$1.00, (ii) 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 is not in default under the Debentures, the conversion price may never be less than \$0.50. Additionally, the maturity date of the 2018 Debentures was extended to September 21, 2020.



The Amendment was treated as an extinguishment for accounting purposes. The following table summarizes the Amendment on September 23, 2019, which resulted in a \$gain from debt extinguishment of approximately \$5,000. The gain is presented net in the Consolidated Statements of Operations with loss on the conversion of debt.

|  |                         |
|--|-------------------------|
| Principal value of 2018 Debentures                                 | \$3,565,000             |
| Fair value of bifurcated contingent put option                     | 697,000                 |
| Debt discount  | <u>(418,115)</u>        |
| <b>Carrying value of 2018 Debentures on September 23, 2019</b>     | <b><u>3,843,885</u></b> |
| Principal value of modified 2018 Debentures                        | 3,565,000               |
| Fair value of bifurcated contingent put option                     | 369,401                 |
| Debt discount  | <u>(95,164)</u>         |
| <b>Fair value of amended 2018 Debentures on September 23, 2019</b> | <b><u>3,839,237</u></b> |
| <b>Gain from debt extinguishment</b>                               | <b><u>\$ 4,648</u></b>  |

#### *Interest expense*

Interest expense, included in the accompanying Consolidated Statements of Operations, is comprised of the following for each period presented:

|  | <b>For the year ended November</b> |                   |
|--|------------------------------------|-------------------|
|  | <b>30,</b>                         |                   |
|  | <b>2019</b>                        | <b>2018</b>       |
| Interest expense based on the coupon interest rate of the outstanding debt | \$ 327,966                         | \$ 29,756         |
| Accretion of debt discount   | 1,001,153                          | 132,348           |
| Interest expense related to deferral fee                                   | <u>131,265</u>                     | <u>-</u>          |
| Total interest expense   | <u>\$ 1,460,384</u>                | <u>\$ 162,104</u> |

#### **Note 7 – Commitments and Contingencies**

##### *Legal*

Periodically, the Company reviews the status of significant matters, if any exist, and assesses its 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.

##### *BNI matter*

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.

The Company believes that it has fulfilled the obligations under the agreement to exercise an option to acquire the BNI IP and has notified BNI of such exercise, but BNI has not transferred the BNI IP to the Company. 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. In February 2019, such lawsuit was removed to the Federal court located in the Southern District of New York. On September 23, 2019, the Company entered into a settlement agreement with BNI and parties related to BNI. Pursuant to the terms of the settlement agreement, the Company settled its dispute with BNI and all parties to the litigation dismissed their claims in exchange for entering into a Second Amendment to the License Agreement (entered into on September 23, 2019) pursuant to which:

- BNI agreed to immediately transfer and/or assign to the Company all intellectual property, patents and products that is owned by BNI that is related to Strontium-Chloride 89;
- The Company agreed to issue BNI 50,000 shares of its common stock upon the entry into the settlement agreement and 100,000 shares of its common stock upon the approval of the U.S. Food and Drug Administration (“FDA”) approval of BNI’s Prior Approval Supplements filing
- The Company agreed to make a cash payment to BNI of \$25,000
- The Company agreed to an on-going royalty payment of 3% on all gross profits derived by the Company from the sale of Strontium-Chloride 89 and Metastron™; and
- The Company agreed to assume fees and expenses related to (i) all outstanding CMO fees owed by BNI to IsoTherapeutics relating to Strontium-Chloride 89 (approximately \$67,000), (ii) all outstanding fees owed by BNI to the FDA relating to Strontium-Chloride 89 (approximately \$208,000) and (iii) related fees for the development and approval of Strontium-Chloride 89 following the date of the settlement agreement.

#### *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 ended in December 2019 and the Company has renewed its office lease agreement for another three years with the same terms.

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:

|              | <b>For the year ended November 30,</b> |             |
|--------------|--|-------------|
|              | <b>2019</b>                            | <b>2018</b> |
| Rent expense | \$ 30,000                              | \$ 30,000   |

#### *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.

On March 26, 2019, the Company entered into an amendment to the Patent and Technology License and Purchase Option Agreement that it initially entered into with Mannin Research Inc. on October 29, 2015 (the “Mannin Agreement”). Under such amendment, the term of the option granted under the Mannin Agreement was extended to October 29, 2021 in exchange for the Company issuing 100,000 shares to Mannin Research Inc. on April 9, 2019.

During the years ended November 30, 2019 and 2018, the Company incurred approximately \$2.1 million and \$2.1 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.

### **Washington University**

On March 9, 2019, the Company entered into an Exclusive License Agreement with Washington University for license of a diagnostic marker for determining the severity of glaucoma using the expression levels of Growth Differentiation Factor 15. The agreement calls for the Company to pay an initial fee of approximately \$88,000, pay annual maintenance fees ranging from \$15,000 to \$75,000, make additional payments upon the following milestones:

- The first commercial sale of a companion diagnostic product;

- Initiation of a clinical trial for a diagnostic product to support FDA PMA or 510(k) regulatory approval or the foreign equivalent;
- PMA or 510(k) regulatory approval by the FDA or the foreign equivalent; and
- The first commercial sale of a diagnostic product.

In addition to the above payments, royalty payments based upon sales of a companion diagnostic product or diagnostic product are required.

#### **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:

|                               | <b>For the year ended November<br/>30,</b> |             |
|-------------------------------|--|-------------|
|                               | <b>2019</b>                                | <b>2018</b> |
| Consulting and legal expenses | \$ 531,751                                 | \$ 295,000  |

#### **Note 9 - Stockholders' Equity (Deficit)**

As of November 30, 2019, and 2018, 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.

##### *2019 activity*

##### *Issuance of units in private placement offerings*

In September 2019, the Company executed securities purchase agreements with various investors to purchase 335,887 units, each unit consisting of (i) one share of common stock and (ii) one and one half (1.5) warrants to purchase a share of common stock, at \$0.86, which is 110% of the closing price of the Company's common stock as listed on OTCQB on September 18, 2019, raising approximately \$208,000 in cash.

In October and November 2019, the Company entered into a series of securities purchase agreements for the sale of 1,185,715 units at a \$0.35 per unit sales price. The Company raised approximately \$415,000 in cash. Each unit consisted of one share and one warrant to purchase a share of common stock at an exercise price of \$0.50.

##### *Issuance of shares and units for services*

During the year ended November 30, 2019, the Company issued an aggregate of 1,428,870 shares of the Company common stock to various vendors for advisory services, valued at approximately \$1.5 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.

During the year ended November 30, 2019, the Company issued 148,261 units (with each unit consisting of one share of common stock and 1.5 warrants to purchase a share of common stock) to the Company's legal counsel in exchange for \$92,000 of services provided. The fair value of the units on the issuance date was approximately \$168,000. The Company recorded \$76,000 as settlement cost, which is the value in excess of the services provided. The Company's Chief Legal Officer and a Director is the Managing Partner at the law firm where these services were provided.

##### *Issuance shares for debt conversion*

During the year ended November 30, 2019, the Company issued approximately 2.3 million shares of common stock to convert \$1.4 million outstanding debt, including \$136,000 accrued interest (see Note 6).



## 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.

## 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, 2019 and 2018 and the changes during the period then ended:

|                                  | Warrants    | Weighted Average<br>Exercise Price | Weighted Average<br>Remaining<br>Contractual<br>Life (years) | Intrinsic<br>Value |
|----------------------------------|-------------|------------------------------------|--|--------------------|
| Outstanding at December 1, 2017  | 3,083,995   | \$ 3.67                            | 4.0  | \$ 250,000         |
| Issued                           | 1,977,563   | 3.19                               | 4.1  | -                  |
| Forfeited/expired                | (77,500)    | 3.96                               | -  | -                  |
| Outstanding at November 30, 2018 | 4,984,058   | \$ 3.48                            | 3.5  | \$ 250,000         |
| Issued                           | 3,655,936   | 0.93                               | 3.7  | -                  |
| Forfeited/expired                | (1,460,000) | 3.28                               | -  | -                  |
| Outstanding at November 30, 2019 | 7,179,994   | \$ 2.22                            | 3.2  | \$ 2,463,340       |
| Exercisable at November 30, 2019 | 7,129,994   | \$ 2.22                            | 3.2  | \$ 2,463,340       |

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

|                | For the year ended November<br>30, |                 |
|----------------|------------------------------------|-----------------|
|                | 2019                               | 2018            |
| Strike price   | \$0.39 - \$2.02                    | \$2.02 - \$3.40 |
| Term (years)   | 1.3 - 5.0                          | 3.0 - 5.0       |
| Volatility     | 79% - 130%                         | 123% - 130%     |
| Risk-free rate | 1.5% - 2.8%                        | 2.5% - 2.8%     |
| Dividend yield | 0.0%                               | 0.0%            |



### Options issued for services

The following represents a summary of all outstanding options to purchase the Company's common stock at November 30, 2019 and 2018 and the changes during the period then ended:

|                                  | <b>Options</b> | <b>Weighted Average<br/>Exercise Price</b> | <b>Weighted Average<br/>Remaining<br/>Contractual<br/>Life (years)</b> | <b>Intrinsic<br/>Value</b> |
|----------------------------------|----------------|--|--|----------------------------|
| Outstanding at December 1, 2017  | 450,000        | \$ 4.00                                    | 4.5  | \$ 220,500                 |
| Issued                           | 450,000        | 3.37                                       | 4.5  | -                          |
| Outstanding at November 30, 2018 | 900,000        | \$ 3.68                                    | 4.0  | \$ -                       |
| Issued                           | 1,450,000      | 1.31                                       | 2.7  | -                          |
| Forfeited/expired                | (1,150,000)    | 3.13                                       | -  | -                          |
| Outstanding at November 30, 2019 | 1,200,000      | \$ 1.35                                    | 3.4  | \$ 402,500                 |
| Exercisable at November 30, 2019 | 1,125,000      | \$ 1.35                                    | 3.3  | \$ 376,250                 |

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

|                       | <b>For the year ended November<br/>30,</b> |                 |
|-----------------------|--|-----------------|
|                       | <b>2019</b>                                | <b>2018</b>     |
| Exercise price        | \$0.43 - \$1.61                            | \$3.00 - \$3.61 |
| Expected term (years) | 2.7 - 5.0                                  | 5.0             |
| Volatility            | 87% - 98%                                  | 128% - 130%     |
| Risk-free rate        | 1.5% - 2.0%                                | 2.5% - 2.7%     |
| Dividend yield        | 0.00%                                      | 0.00%           |

### Repricing of Existing Warrants and Options

On September 24, 2019, the Company modified an aggregated of 2,610,000 stock options and warrants (the "Options and Warrants") that were originally granted to Mr. Denis Corin, the Company's Chief Executive Officer and Chairman, Mr. William Rosenstadt, the Company's Chief Legal Officer and a Director, and two other consultants for services provided to the Company. The exercise price of the Options and Warrants were reduced to \$1.25 per share.

The Company immediately recognized \$141,550 incremental stock-based compensation on October 1, 2019, and the remaining \$6,000, to be fully recognized on February 29, 2020.

### Stock-based Compensation

Stock-based compensation expense is classified within general and administrative expenses as a result of the shares, outstanding warrants and options issued to consultants and employees and included in the accompanying Consolidated Statements of Operations as follows:

|                                  | <b>For the year ended November 30,</b> |              |
|----------------------------------|--|--------------|
|                                  | <b>2019</b>                            | <b>2018</b>  |
| Stock-based compensation expense | \$ 2,496,296                           | \$ 2,650,477 |

As of November 30, 2019, the estimated unrecognized stock-based compensation associated with these agreements is approximately \$31,000 and will be fully recognized by February 29, 2020.

### Note 11 - Income Taxes

At November 30, 2019, the Company has a net operating loss ("NOL") carryforward for Federal and state income tax purposes totaling approximately \$24 million available to reduce future taxable income. Of this amount, approximately \$14.1 million of Federal net operating losses are carried over indefinitely, while the remaining amount begins to expire in 2034. Some of the state net operating losses follow the Federal Tax Cuts and Jobs Act and are carried over indefinitely, and others have various expiration dates.

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, 2019. 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, 2019 and 2018. The valuation allowance increased by approximately \$3.0 million and \$1.2 million for the fiscal years ended November 30, 2019 and 2018.

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

|  | <b>As of November 30,</b> |              |
|--|---------------------------|--------------|
|  | <b>2019</b>               | <b>2018</b>  |
| Deferred tax assets:                   |                           |              |
| Net-operating loss carryforward        | \$ 8,322,959              | \$ 5,666,313 |
| Stock-based compensation               | 4,417,762                 | 4,014,863    |
| License agreement                      | 476,906                   | 463,269      |
| Tax amortization for license agreement | (613,954)                 | (221,988)    |
| Charitable contributions               | 303                       | 294          |
| Other accrued expenses                 | 399,411                   | 76,411       |
| Total deferred tax assets              | 13,003,387                | 9,999,162    |
| Valuation allowance                    | (13,003,387)              | (9,999,162)  |
| 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:

|  | <b>For the year ended November 30,</b> |             |
|--|--|-------------|
|  | <b>2019</b>                            | <b>2018</b> |
| Statutory Federal income tax rate  | (21.0)%                                | (22.1)%     |
| State and local taxes, net of Federal tax benefit  | (13.6)%                                | (11.6)%     |
| Deferred tax true-up   | 0.4%                                   | (4.4)%      |
| Gain/loss on conversion and extinguishment of debt   | 2.0%                                   | 0.0%        |
| Loss on settlement   | 0.3%                                   | 0.0%        |
| Change in fair value of embedded conversion option and related accretion of interest expense | 4.2%                                   | 0.8%        |
| Meals and entertainment  | 0.1%                                   | 0.0%        |
| Non-U.S. operations  | 1.4%                                   | 1.3%        |
| Deferred tax rate change   | (3.0)%                                 | 22.7%       |
| Change in Valuation Allowance  | 29.2%                                  | 13.3%       |
| 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 2014 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**

On December 6, 2019, the Company issued a debenture for \$1,000,000 pursuant to a securities purchase agreement with an accredited investor. The debenture has a maturity date of June 6, 2021. The debenture bears interest at the rate of 5.5% per annum, and on issuance, the Company paid to the holder a commitment fee equal to 2.5% of the amount of the debenture.

On January 15, 2020, the Company issued another debenture for \$1,000,000 pursuant to the same securities purchase agreement dated December 6, 2019. The debenture has a maturity date of June 6, 2021, provided that in case of an event of default, the debenture may become at the holder's election immediately due and payable. The debenture bears interest at the rate of 5.5% per annum, and on issuance, the Company paid to the holder a commitment fee equal to 2.5% of the amount of the debenture.

On February 10, 2020, the Company issued 885,000 warrants to certain consultants and service providers in exchange for services rendered. The warrants are exercisable into shares of the Company's common stock for five years from the date of issuance at an exercise price of \$2.12 per share.

On February 10, 2020, the Company issued 1,500,000 warrants to the Company's two officers in exchange for services rendered. The warrants are exercisable into shares of the Company's common stock in six months from their issuance until five years from the date of issuance at an exercise price of \$2.12 per share.

### **DESCRIPTION OF SECURITIES**

*As of February 26, 2020, Q BioMed Inc. (the "Company") had one class of securities registered under Section 12 of the Securities Exchange Act of 1934, as amended: common stock, par value \$0.001 per share ("common stock"). The following description of the Company's common stock is a summary and is not complete. For a complete description, please refer to our articles of incorporation (as amended to date, our "Articles of Incorporation") and bylaws (as amended to date, our "Bylaws"), which we have incorporated by reference as exhibits to the Company's Annual Report on Form 10-K for the year ended November 30, 2019. Stockholders are also encouraged to refer to the application provisions of the Nevada Revised Statutes and Administrative Codes for additional information. References to "we," "our" and "us" refer to the Company, unless the context otherwise requires. References to "stockholders" refer to holders of our common stock, unless the context otherwise requires.*

#### **Authorized Capital Stock**

We are authorized by our Articles of Incorporation to issue an aggregate of 250,000,000 shares of common stock, par value \$0.001 per share, and 100,000,000 shares of preferred stock, par value \$0.001 per share.

#### **Outstanding Capital Stock**

As of February 25, 2020, there were 20,835,625 shares of common stock and none preferred stock outstanding. Our Board of Directors is authorized to issue additional shares of our capital stock without stockholder approval.

#### **Common Stock**

*Voting Rights.* Holders of our common stock are entitled to one vote for each share held of record on each matter submitted to a vote of stockholders. Except as otherwise required by Nevada law, and subject to the rights of the holders of preferred stock, if any, all stockholder action is taken by the vote of a majority of the outstanding shares of common stock voting as a single class present at a meeting of stockholders at which a quorum consisting of one-half of the outstanding shares of common stock is present in person or proxy.

*Dividends.* Subject to the prior rights of any class or series of preferred stock which may from time to time be outstanding, if any, holders of our common stock are entitled to receive ratably, dividends when, as, and if declared by our board of directors out of funds legally available for that purpose and, upon our liquidation, dissolution, or winding up, are entitled to share ratably in all assets remaining after payment of liabilities and payment of accrued dividends and liquidation preferences on the preferred stock.

### ***Anti-Takeover Provisions***

The provisions of Nevada law and our bylaws may have the effect of delaying, deferring or preventing another party from acquiring control of the company. These provisions may discourage and prevent coercive takeover practices and inadequate takeover bids.

#### *Nevada Law*

Nevada law contains a provision governing “acquisition of controlling interest.” This law provides generally that any person or entity that acquires 20% or more of the outstanding voting shares of a publicly-held Nevada corporation in the secondary public or private market may be denied voting rights with respect to the acquired shares, unless a majority of the disinterested stockholders of the corporation elects to restore such voting rights in whole or in part. The control share acquisition act provides that a person or entity acquires “control shares” whenever it acquires shares that, but for the operation of the control share acquisition act, would bring its voting power within any of the following three ranges: 20 to 33-1/3%; 33-1/3 to 50%; or more than 50%.

A “control share acquisition” is generally defined as the direct or indirect acquisition of either ownership or voting power associated with issued and outstanding control shares. The stockholders or Board of Directors of a corporation may elect to exempt the stock of the corporation from the provisions of the control share acquisition act through adoption of a provision to that effect in the articles of incorporation or bylaws of the corporation. Our articles of incorporation and bylaws do not exempt our common stock from the control share acquisition act.

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The control share acquisition act is applicable only to shares of “Issuing Corporations” as defined by the Nevada law. An Issuing Corporation is a Nevada corporation which (i) has 200 or more stockholders, with at least 100 of such stockholders being both stockholders of record and residents of Nevada, and (ii) does business in Nevada directly or through an affiliated corporation.

At this time, we do not believe we have 100 stockholders of record resident of Nevada and we do not conduct business in Nevada directly. Therefore, the provisions of the control share acquisition act are believed not to apply to acquisitions of our shares and will not until such time as these requirements have been met. At such time as they may apply, the provisions of the control share acquisition act may discourage companies or persons interested in acquiring a significant interest in or control of us, regardless of whether such acquisition may be in the interest of our stockholders.

The Nevada “Combination with Interested Stockholders Statute” may also have an effect of delaying or making it more difficult to effect a change in control of us. This statute prevents an “interested stockholder” and a resident domestic Nevada corporation from entering into a “combination,” unless certain conditions are met. The statute defines “combination” to include any merger or consolidation with an “interested stockholder,” or any sale, lease, exchange, mortgage, pledge, transfer or other disposition, in one transaction or a series of transactions with an “interested stockholder” having (i) an aggregate market value equal to 5% or more of the aggregate market value of the assets of the corporation, (ii) an aggregate market value equal to 5% or more of the aggregate market value of all outstanding shares of the corporation, or (iii) representing 10% or more of the earning power or net income of the corporation.

An “interested stockholder” means the beneficial owner of 10% or more of the voting shares of a resident domestic corporation, or an affiliate or associate thereof. A corporation affected by the statute may not engage in a “combination” within three years after the interested stockholder acquires its shares unless the combination or purchase is approved by the Board of Directors before the interested stockholder acquired such shares. If approval is not obtained, then after the expiration of the three-year period, the business combination may be consummated with the approval of the Board of Directors or a majority of the voting power held by disinterested stockholders, or if the consideration to be paid by the interested stockholder is at least equal to the highest of (i) the highest price per share paid by the interested stockholder within the three years immediately preceding the date of the announcement of the combination or in the transaction in which he became an interested stockholder, whichever is higher, (ii) the market value per common share on the date of announcement of the combination or the date the interested stockholder acquired the shares, whichever is higher, or (iii) if higher for the holders of preferred stock, the highest liquidation value of the preferred stock.

#### *Articles of Incorporation and Bylaws*

Our articles of incorporation are silent as to cumulative voting rights in the election of our directors. Nevada law requires the existence of cumulative voting rights to be provided for by a corporation's articles of incorporation. In the event that a few stockholders end up owning a significant portion of our issued and outstanding common stock, the lack of cumulative voting would make it more difficult for other stockholders to replace our Board of Directors or for a third party to obtain control of us by replacing our Board of Directors. Our articles of incorporation and bylaws do not contain any explicit provisions that would have an effect of delaying, deferring or preventing a change in control of us.

#### **Transfer Agent and Registrar**

The transfer agent and registrar for our common stock is V Stock Transfer, LLC, 18 Lafayette Place, Woodmere, NY 11598, Phone: (212) 828-8436.

#### **Listing**

Our common stock are quoted on the OTCQB under the symbol “QBIO”.

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**Exhibit 31**

**CERTIFICATION OF THE CHIEF EXECUTIVE OFFICER PURSUANT TO  
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Denis Corin, certify that:

- (1) I have reviewed this annual report on Form 10-K for the year ended November 30, 2019 of Q BioMed Inc.;

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

Dated: February 28, 2020

/s/ Denis Corin

Denis Corin  
Chief Executive Officer (Principal Executive Officer and  
Acting Principal Financial and Accounting Officer)

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**Exhibit 32**

CERTIFICATION OF THE CHIEF EXECUTIVE OFFICER  
PURSUANT TO 18 U.S. C. SECTION 1350  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the annual report on Form 10-K of BioMed Inc. (the "Company") for the fiscal year ended November 30, 2019, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Denis Corin, Chief Executive Officer (Principal Executive Officer and Acting Principal Financial and Accounting Officer) of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: February 28, 2020

/s/ Denis Corin

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Denis Corin  
Chief Executive Officer (Principal Executive Officer and  
Acting Principal Financial and Accounting Officer)

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