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

FORM 10-K

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

For the fiscal year ended: **December 31, 2019**

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

Commission file number: **000-53223**

MARIZYME INC.
(Exact name of registrant as specified in its charter)

Nevada	**82-5464863**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

109 Ambersweet Way, #401
Davenport, FL 33897
(Address of principal executive offices)

(732) 723-7395
Issuer's telephone number

With a copy to:
Louis A. Bevilacqua, Esq.
Bevilacqua, PLLC
1050 Connecticut Ave, NW, Suite 500
Washington, DC 20036
T: (202) 869-0888
F: (202) 203-8665
lou@bevilacquapllc.com

Securities registered under Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
None	**N/A**	**N/A**

Securities registered under Section 12(g) of the Act:
Common Stock, $0.001 par value
(Title of class)

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

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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).
Yes [x] No[]

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. [ ]

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer [ ]	Accelerated filer [ ]
Non-accelerated filer [x]	Smaller reporting company [x]
	Emerging growth company [x]

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 checkmark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act).

Yes [ ] No [x]

State the aggregate market value of the voting and non-voting common equity held by non-affiliates computed by reference to the price at which the common equity was last sold, or the average bid and asked price of such common equity, as of the last business day of the registrant’s most recently completed second fiscal quarter.

At June 30, 2019 aggregate market value of the voting and non-voting common equity held by non-affiliates was approximately $20,057,528, based on $1.01 (the closing sales price of the Company’s Common Stock on June 30, 2019).

As of April 15, 2020, there were 20,163,939 shares of Common Stock issued and outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

None

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Forward Looking Statements

This Annual Report on Form 10-K contains forward-looking statements which relate to future events or our future financial performance. In some cases, you can identify forward-looking statements by terminology such as "may," should,"" expect," "plan," "anticipate," "believe", "estimate," "predict," "potential" or "continue" or the negative of these terms or other comparable terminology. These statements are only predictions and involve known and unknown risks, uncertainties and other factors, including the risks in the section entitled "Risk Factors" included herein that may cause our or our industry's actual results, levels of activity, performance or achievements to be materially different from any future results, levels of activity, performance or achievements expressed or implied by these forward-looking statements.

While these forward-looking statements, and any assumptions upon which they are based, are made in good faith and reflect our current judgment regarding the direction of our business, actual results will almost always vary, sometimes materially, from any estimates, predictions, projections, assumptions or other future performance suggested herein. Except as required by applicable law, including the securities laws of the United States, we do not intend to update any of the forward-looking statements to conform these statements to actual results. The safe harbor for forward-looking statements provided in the Private Securities Litigation Reform Act of 1995 does not apply to this annual report.

Unless otherwise noted, all references in this Form 10-K to "Marizyme," "GBS Enterprises," "GBS," "GBSX," "MRZM," the "Company," "we," "us," "our" and similar terms and expressions shall mean Marizyme, Inc., a Nevada corporation formerly known as GBS Enterprises Incorporated, and its former subsidiaries, including, but not limited to, its minority owned GBS Software AG ("GROUP").

PART I

Item 1. Business

Overview

Marizyme, Inc., a Nevada corporation formerly known as GBS Enterprises Incorporated, conducted its primary business through its majority owned subsidiary, GBS Software AG ("GROUP"), a German-based public-company.

By December 31, 2016, we sold the controlling interest in GROUP and other subsidiaries, keeping only a minority interest in GROUP. On March 21, 2018, we formed a wholly-owned subsidiary named Marizyme, Inc., a Nevada corporation, and merged with it, effectively changing the Company's name to Marizyme, Inc. On June 1, 2018, we exchanged the shares of GROUP and all the intercompany assets and liabilities for 100% of the shares of X-Assets Enterprises, Inc, a Nevada Corporation. As part of a type-D business restructuring on September 5, 2018, we then distributed the X-Assets shares to our own shareholders on a 1 for 1 basis.

Beginning after the X-Assets share distribution, Marizyme refocused on the life sciences and began to seek technologies to acquire.

On September 12, 2018 we consummated an asset acquisition with ACB Holding AB, Reg. No. 559119-5762, a Swedish corporation to acquire all right, title and interest in their Krillase technology in exchange for 16.98 Million shares of Common Stock. Krillase is a naturally occurring enzyme that acts to break protein bonds and has applications in dental care, wound healing and thrombosis.

The Company's common stock, $0.001 par value per share (the "Common Stock") is currently quoted on the OTC Markets under the ticker symbol "MRZM."

Historically, we grew our operations by acquiring companies which have developed software and specialized services for the Lotus Notes and Domino market. These products and services may no longer remain in use. New technologies, especially in the areas of Cloud Computing and Mobile applications, have grown in popularity due to the potential cost savings and operational efficiencies they can offer. The associated software and consulting offerings were no longer needed.

Former GBS Enterprises Products & Services

Messaging and Business Applications Software & Solutions

Under our former business, our GBS Messaging and Business Application Software & Solutions product lines included software and advisory services for email and Instant Messaging (IM) Management, Security, Compliance, Archiving and Productivity, CRM Applications, Governance, Risk & Compliance (GRC) Management software, Workflow and Business Process Management software,

ePDF Archiving & Document Management.

GBS developed, sold and installed well-known business process and management software suites based on Lotus Notes/Domino and IBM Portal technology, mainly for major international companies and medium-sized customers.

Marizyme no longer provides software products or services.

Current Business Focus

Going forward, the Company is focusing on the life sciences business and currently has acquired its first biotechnology assets. Marizyme is also seeking additional biotechnology assets to acquire.

On September 12, 2018, we consummated an asset acquisition with ACB Holding AB, Reg. No. 559119-5762, a Swedish corporation, to acquire all right, title and interest in their Krillase technology in exchange for 16.98 million unregistered shares of Common Stock. These shares were issued to certain individuals and entities set forth in the asset purchase agreement. Krillase is a naturally occurring enzyme extract that acts to break protein bonds and has potential applications in dental care, wound healing and thrombolysis.

Krillase's activity is unique. Unlike many other enzymes currently approved to be used as enzymatic products, Krillase is the only product based on a co-operative multi-enzyme system involving both endo- and exopeptidases. The proteolytic enzymes of Krillase are composed of eight natural enzymes acting in a synergetic manner. They include: (1) Three serine proteinases with trypsin-like activity (two endo/exopeptidases, one endopeptidase), (2) One serine proteinase with chymotrypsin-like activity, and (3) Four exopeptidases (two carboxypeptidases A and two carboxypeptidases B).

Krill enzymes are also unique in that they are mutually protected against the degrading effect of each other and they act in a two-step fashion when breaking down proteinaceous substrates. First, endopeptidases attack peptide bonds of the infrastructural parts of the polypeptide chains. The resulting peptide fragments are subsequently cleaved by exopeptidases into small peptides and free amino acids.

Marizyme currently has 4 product candidates derived from the protease enzyme platform acquired from ACB Holding AB. The first product candidate is MB101 which is targeted to be used to debride and heal human wounds. MB101 is a clinical stage candidate which was tested in 13 human clinical stage studies conducted by ACB Holding AB prior to this drug candidate's acquisition by us. In these studies, which were designed as Phase II efficacy studies and conducted in Sweden, Germany, Finland, Switzerland, United Kingdom and the Netherlands, more than 500 patients were treated for wound debriding and healing. No clinical trials of MB101 have been conducted in the United States. The second product candidate is MB102 which is targeted for acute cerebral ischemic stroke in pediatric patients. It is derived from the same protease enzymes that MB101 is comprised of. MB102 is in preclinical stage of development. In June 2018, prior to our consummation of the asset acquisition, ACB Holding AB filed a Pre-IND for MB102 and received an FDA letter giving advice towards an Investigative Drug Application for MB102, which we expect to file in late 2019. MB103 is Marizyme's third product candidate and is in preclinical development. It is derived from the same protease enzymes as MB101 and is targeted to treat acute myocardial infarction, or AMI, in human adults. The fourth and last product candidate is MB104 which is targeted to treat deep vein thrombosis. It is in early preclinical development and is derived from the same protease enzymes as MB101.

Krillase received medical device status in the European Union for debridement of deep partial and full-thickness wounds in hospitalized patients, on July 19, 2005. Marizyme is currently investigating if a medical device status is still accepted as the Medical Device Directive was updated in 2007.

On November 7, 2019, the Company signed a definitive License and Distribution Agreement with Somahlutions that gives Marizyme license to manufacture, distribute and sell the Sonahlution's Duragraft product in Mexico, South America and in European countries upon expiration of the current distributors' agreements.

On December 15, 2019, Marizyme, Inc. entered into an asset purchase agreement with Somahlution, LLC, Somahlution, Inc. and Somaceutica, LLC, companies duly organized under the laws of Florida (collectively, "Somah"). Somah is engaged in developing products to prevent ischemic injury to organs and tissues and its products (the "Somah Products") include DuraGraft, a one-time intraoperative vascular graft treatment for use in vascular and bypass surgeries that maintains endothelial function and structure, and other related properties. Pursuant to the terms of the Agreement, the Company has agreed to purchase (the "Acquisition") all of the assets of Somah, including all of the intellectual property relating to the Somah Products. Under the Agreement, the Company will not acquire any of the liabilities of Somah. As consideration for this acquisition, the Company has agreed to issue to Somah's equity owners (the "Somah Designees") 10 million restricted shares of Company common stock and five-year warrants to purchase an additional three million restricted shares of Marizyme common stock with an exercise price of $5.00 per share. The Company has also agreed to pay the Somah Designees royalties and issue additional warrants to them based on future sales, or FDA approval, of certain Somah Products. The Somah Designees will receive a liquidation preference on payouts relating to future Company sales of Somah related assets. Somah will also be entitled to appoint two members to the Company's board of directors. As a condition to the closing of the Acquisition, in addition to satisfactory due diligence by each party to the Agreement, the Company will be required to raise at least $10 million in funding to be used as working capital to develop the Somah Products post-closing. The Agreement may be terminated at any time prior

to the closing by mutual consent of the Company and Somah or, after March 28, 2020, by either party if the Company has not raised the agreed upon $10 million in funding by that date or other conditions to closing have not been met. There can be no assurances that the Company will be able to raise this funding or that the Acquisition will close.

Changes in Corporate Governance

On May 7, 2018, Joerg Ott resigned as the sole executive officer of the Company. Mr. Ott, Mr. John Moore and Mr. Mohammad Shihadah resigned as members of the Board of Directors and they simultaneously appointed Mr. Nicholas P. DeVito as Chief Executive Officer and Chairman of the Board.

Effective September 13, 2018, Mr. DeVito resigned from the Board of Directors and as our Chief Executive Officer, President, Secretary and Treasurer. Mr. Juan Francisco Gutierrez was appointed to our Board of Directors and as the Company's President and Secretary and Marcos Nicolaides was appointed as the Company's Treasurer. On September 14, 2018, Mr. Michael Handley was appointed as Chief Executive Officer and Director by Mr. Gutierrez.

On December 6, 2018, Mr. Gutierrez appointed Mr. Terry Brostowin as a Board member and Mr. James Sapirstein as Executive Chairman of the Board. Mr. Gutierrez also resigned on December 7, 2018 for health reasons and Mr. Nicolaides resigned as Treasurer.

On March 28, 2019, Mr. Michael Handley resigned from his position as CEO and also resigned from the Board of Directors.

On July 13, 2019, Mr. Nicholas DeVito returned as Interim Chief Executive Offices and Interim Chief Financial Officer.

On February 17, 2020, we entered into an employment agreement with Ralph Makar pursuant to which Mr. Makar agreed to become the Company's President and Chief Executive Officer effective on or about April 1, 2020, subject to the Company's obtaining director and officer liability insurance. Upon Mr. Makar's taking office as our Chief Executive officer, Mr. DeVito will resign from his position as our Interim Chief Executive Officer.

The current Board is comprised of Mr. Sapirstein and Mr. Brostowin.

Subsidiaries

The Company has no subsidiaries.

Intellectual Property

We acquired patents and patent applications in biotechnology pursuant to that certain Asset Purchase Agreement dated September 12, 2018, between ACB Holding AB, Reg. No. 559119-5762, a Swedish corporation, and Marizyme, Inc. As a result of this asset acquisition, Marizyme acquired the following patent and patent applications**:**

Registered Patent:

a. Dental Plaque Granted Patent (US 7,947,270) – "Removing Dental Plaque with Krill Enzymes" (Own Patent, Expires Dec 31, 2023, Method of Use, US patent)

Patent Applications:

a. Thrombolytic Patent Application (US 62/691,319) – "Pharmaceutical Compositions and Methods for the Treatment of Thrombosis and Delivery by Medical Devices" (Own Patent Application, Not Issued, Composition and Method of Use, US patent application)

b. Thrombosis (EP 15003450.2) – "Set of Pharmaceutical Compositions and Device for the Treatment of Thrombosis" (Own Patent Application, Not Issued, Composition and Method of Use, European patent application)

c. Controlled Release (EP07865205.4/2144625) – "A Controlled Release Enzymatic Composition and Methods of Use" (Own Patent Application, Not Issued, Composition and Method of Use, European patent application)

d. Biofilm (EP 13712728.8/2833906) – "Mixture of Enzymes from Antarctic Krill for use in the Removal of a Biofilm"

(Own Patent Application, Not Issued, Composition and Method of Use, European patent application)

We own the internet domain names, www.marizyme.com and www.marizymebiotech.com. The information contained in the Company's websites is not incorporated by reference herein.

We generally control access to and use of our proprietary technology and other confidential information through the use of internal and external controls, including contractual protections with employees, contractors, customers, and partners, and our software is protected by U.S. and international copyright laws. Despite our efforts to protect our trade secrets and proprietary rights through intellectual property rights, licenses, and confidentiality agreements, unauthorized parties may still copy or otherwise obtain and use our software and technology. In addition, the laws of some foreign countries in which we sold products do not protect our proprietary rights as fully as do the laws of the United States. There can be no assurance that our means of protecting our proprietary rights in the United States or abroad were adequate or that competition will not independently develop similar technology.

Research and Development

We expect to continue to develop our planned biotechnology related operations, including expanding research and development, funding clinical trials, purchasing of capital equipment, hiring new personnel, commercializing our products, and continuing activities as an operating public company. This plan, discussed in more detail elsewhere in this Annual Report, will depend on our raising additional capital and there can be no assurances that we will be successful in this endeavor.

Government Regulation

The product candidates that we, or our collaborators, are attempting to acquire and develop require regulatory approval to advance through clinical development and to ultimately be marketed and sold and are subject to extensive and rigorous domestic and foreign government regulation.

Competition

The medical, biotechnology and pharmaceutical industries are intensely competitive and subject to significant technological change and changes in practice. While we believe that our innovative technology, focus on treatment of acute care issues, knowledge, experience and scientific resources provide us with competitive advantages, we may face competition from many different sources with respect to Krillase and our product candidates that we may seek to develop or commercialize in the future. Possible competitors may be medical practitioners, pharmaceutical and wound care companies, academic and medical institutions, governmental agencies and public and private research institutions, among others. Any product that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future.

In addition, we face pricing competition from current standard of care "SOC." The current SOC for eschar removal in severe wounds is surgery, where debridement can be performed by tangential excision, dermabrasion or hydro jet, or non-surgical alternatives, such as applying topical medications to the eschar to facilitate the natural healing process. Consequently, we face competition from surgical procedures and the only FDA approved enzymatic topical agent such as Smith & Nephew Plc's, Santyl, a collagenase-based product indicated for the debriding chronic dermal ulcers and severely burned area and MediWound's NexoBrid European approved product.

Although we are in the preclinical phases for our product candidates for debridement of chronic and other hard-to-heal wounds, if one of our product candidates obtains approval in the future, we would compete with traditional surgery and existing non-surgical treatments. In chronic and other hard-to-heal wounds, we expect to face competition from other debriding agents and wound bed preparation techniques, such as topical medication, mechanical debridement and surgery. We also cannot confirm at this stage of development that our product candidates, if approved, will be superior or comparable to Santyl, the only FDA approved enzymatic therapy for chronic dermal ulcers.

Revenues

We are focused on acquiring life sciences assets although no assurances can be provided that we will consummate additional transactions.

We do not expect to realize revenues from the life-sciences space in the short term and no guarantees can be given as to when revenues might begin, if at all.

Employees

As of April 15, 2020, the Company has one executive officer, Nicholas P. DeVito (Interim Chief Executive Officer and Interim Chief Financial Officer). On February 17, 2020, we entered into an employment agreement with Ralph Makar pursuant to which Mr. Makar

agreed to become the Company's President and Chief Executive Officer effective on or about April 1, 2020, subject to the Company's obtaining director and officer liability insurance. Upon Mr. Makar's taking office as our Chief Executive officer, Mr. DeVito will resign from his position as our Interim Chief Executive Officer.

General Corporate History

We were incorporated in Nevada on March 20, 2007 as SWAV Enterprises Ltd. ("SWAV"). SWAV had a different management team and was in a different industry.

On September 6, 2010, SWAV's name was changed to GBS Enterprises Incorporated. On October 14, 2010, the Company's trading symbol on the OTC Bulletin Board was changed from SWAV to GBSX.

On March 21, 2018, GBS formed a wholly owned subsidiary named Marizyme, Inc., a Nevada corporation, and merged it with GBS Enterprises effectively renaming the company Marizyme, Inc.

On January 5, 2018, we received a written consent by the holders of a majority of the outstanding voting capital stock of the Company approving a 1-for-29 reverse-split of our outstanding Common Stock. On March 20, 2018, we filed a Certificate of Amendment to effectuate the split on March 30, 2018. We completed this reverse split in the OTC marketplace on July 27, 2018.

On May 4, 2018 we exchanged all of our shares of GROUP for the shares of the newly formed X-ASSETS, to effect a Type-D business restructuring.

On August 8, 2018, our Board of Directors approved by written consent in lieu of a meeting as permitted by NRS and the Company's bylaws to separate X-Assets from the Company by distributing the shares of X-Assets Common Stock owned by the Company to the Marizyme stockholders of record as of the August 21, 2018, subject to FINRA approval. FINRA approved the spin-off on August 24, 2018. The shares of X-Assets were distributed to our stockholders on September 5, 2018.

On September 12, 2018, we consummated an asset acquisition with ACB Holding AB, Reg. No. 559119-5762, a Swedish corporation, to acquire all right, title and interest in the Krillase technology in exchange for 16.98 million unregistered shares of Common Stock. These shares were issued to certain individuals and entities set forth in the asset purchase agreement. Krillase is a naturally occurring enzyme extract that acts to break protein bonds and has applications in dental care, wound healing and thrombosis. The transaction resulted in a change of control of the Company.

Executive Offices

Our principal executive office is located at 109 Ambersweet Way, #401 Davenport, Florida 33897 and our telephone number is (732) 723-7395.

Item 1A. Risk Factors

Our operating results and financial condition have varied in the past and could in the future vary significantly depending on a number of factors. From time to time, information provided by us or statements made by our employees contain "forward-looking" information that involves risks and uncertainties. In particular, statements contained in this Annual Report, and in the documents incorporated by reference into this Annual Report, that are not historical facts, constitute forward-looking statements and are made under the safe harbor provisions of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). These statements are neither promises nor guarantees. Our actual results of operations and financial condition could vary materially from those stated in any forward-looking statements. The following factors, among others, could cause actual results to differ materially from those contained in forward-looking statements made in this Annual Report on Form 10-K, in the documents incorporated by reference into this Annual Report on Form 10-K or presented elsewhere by our management from time to time. Such factors, among others, could have a material adverse effect upon our business, results of operations and financial condition. We caution readers not to place undue reliance on any forward-looking statements, which only speak as of the date made. We undertake no obligation to update any forward-looking statement to reflect events or circumstances after the date on which such statement is made.

RISKS RELATED TO OUR BUSINESS AND INDUSTRY

An investment in our Common Stock involves a high degree of risk. Before making an investment decision, you should give careful consideration to the following risk factors, in addition to the other information included in this annual report, including our financial statements and related notes, before deciding whether to invest in shares of our Common Stock. The occurrence of any of the adverse developments described in the following risk factors could materially and adversely harm our business, financial condition, results of operations or prospects. In that case, the trading price of our Common Stock could decline, and you may lose all or part of your investment.

Risks Related to Our Business

We have incurred losses since inception, anticipate that we will incur continued losses for the foreseeable future and our independent registered public accounting firm's report, contained herein, includes an explanatory paragraph that expresses substantial doubt about our ability to continue as a going concern, indicating the possibility that we may not be able to operate in the future.

As of December 31, 2019, we had an accumulated deficit of $30.2 million. We expect to incur significant and increasing operating losses for the next several years as we expand our acquisition efforts, continue clinical trials, acquire or license technologies, advance other product candidates into clinical development, complete clinical trials, seek regulatory approval and, if we receive FDA approval, commercialize our products. Primarily as a result of our losses incurred to date, our expected continued future losses, and limited cash balances, our independent registered public accounting firm has included in its report an explanatory paragraph expressing substantial doubt about our ability to continue as a going concern. Our ability to continue as a going concern is contingent upon, among other factors, the sale of the shares of our common stock or obtaining alternate financing. We cannot provide any assurance that we will be able to raise additional capital.

If we are unable to secure additional capital, we may be required to curtail our research and development initiatives and take additional measures to reduce costs in order to conserve our cash in amounts sufficient to sustain operations and meet our obligations. These measures could cause significant delays in our clinical and regulatory efforts, which is critical to the realization of our business plan. The accompanying financial statements do not include any adjustments that may be necessary should we be unable to continue as a going concern. It is not possible for us to predict at this time the potential success of our business. The revenue and income potential of our proposed business and operations are currently unknown. If we cannot continue as a viable entity, you may lose some or all of your investment in our company.

We have a limited operational history.

We have a limited history upon which an evaluation of our prospects and future performance can be made. Our proposed operations are subject to all business risks associated with new enterprises. The likelihood of our success must be considered in light of the problems, expenses, difficulties, complications, and delays frequently encountered in connection with the expansion of a business operation in an emerging industry, and the continued development of advertising, promotions, and a corresponding customer base. There is a possibility that we could sustain losses in the future, and there are no assurances that we will ever operate profitably.

Our operational strategy is changing to be refocused on the Life Sciences space.

We expect much of our growth to be generated through future acquisitions of life sciences assets. No assurances can be made if any additional acquisitions will be consummated.

If we fail to effectively manage our growth, our future operating results could be adversely affected.

Historically, the scope of our operations, the number of our employees and the geographic area of our operations have grown rapidly. In addition, we have acquired both domestic and international companies. This growth and the assimilation of acquired operations and their employees could continue to place a significant strain on our managerial, operational and financial resources as our future acquisition activities accelerate our business expansion. We need to continue to implement and improve additional management and financial systems and controls. We may not be able to manage the current scope of our operations or future growth effectively and still exploit market opportunities for our products and services in a timely and cost-effective way and we may not meet our scalability expectations. Our future operating results could be adversely affected if we are unable to manage our expanding product lines, our marketing and sales organizations and our client support organization to the extent required for any increase in installations of our products.

If we do not generate sufficient cash flow from operations in the future, we may not be able to fund our product development efforts and acquisitions or fulfill our future obligations.

Our ability to generate sufficient cash flow from operations to fund our operations and product development efforts, including the payment of cash consideration in acquisitions and the payment of our other obligations, depends on a range of economic, competitive and business factors, many of which are outside of our control. We cannot assure you that our business will generate sufficient cash flow from operations, or that we will be able to liquidate our investments, repatriate cash and investments held in our overseas subsidiaries, sell assets or raise equity or debt financings when needed or desirable. An inability to fund our operations or fulfill outstanding obligations could have a material adverse effect on our business, financial condition and results of operations. For further information, please refer to "Management's Discussion and Analysis of Financial Condition and Results of Operations-Liquidity and Capital Resources."

Acquisitions present many risks, and we may not realize the financial and strategic goals we anticipate at the time of an acquisition.

Our growth is dependent upon market growth, our ability to enhance existing products and services, and our ability to introduce new products and services on a timely basis. In recent years, we have addressed and intend to continue to address the need to develop new products and services and enhance existing products and services through acquisitions of other companies, product lines and/or technologies. However, acquisitions, including those of high-technology companies, are inherently risky. We cannot provide any assurance that any of our acquisitions or future acquisitions will be successful in helping us reach our financial and strategic goals. The risks we commonly encounter in undertaking, managing and integrating acquisitions are:

- an uncertain revenue and earnings stream from the acquired company, which could dilute our earnings;
- difficulties and delays integrating the personnel, operations, technologies, products and systems of the acquired companies;
- our ongoing business may be disrupted and our management's attention may be diverted by acquisition, transition or integration activities;
- the need to implement controls, procedures and policies appropriate for a larger public company at companies that prior to acquisition had lacked such controls, procedures and policies;
- difficulties managing or integrating an acquired company's technologies or lines of business;
- potential difficulties in completing projects associated with purchased in-process research and development;
- entry into markets in which we have no or limited direct prior experience and where competitors have stronger market positions and which are highly competitive;
- the potential loss of key employees of the acquired company;
- potential difficulties integrating the acquired products and services into our sales channel;
- assuming pre-existing contractual relationships of an acquired company that we would not have otherwise entered into, the termination or modification of which may be costly or disruptive to our business;
- being subject to unfavorable revenue recognition or other accounting treatment as a result of an acquired company's practices; and
- intellectual property claims or disputes.

Our failure to manage growth effectively and successfully integrate acquired companies due to these or other factors could have a material adverse effect on our business, results of operations and financial condition. In addition, we may not have the opportunity to make suitable acquisitions on favorable terms in the future, which could negatively impact the growth of our business. We expect that other companies in our industry will compete with us to acquire compatible businesses. This competition could increase prices for businesses and technologies that we would likely pursue, and our competitors may have greater resources than we do to complete these acquisitions.

We will require substantial additional funding which may not be available to us on acceptable terms, or at all. If we fail to raise the necessary additional capital, we may be unable to complete the development and commercialization of our product candidates, or continue our development programs.

We expect to significantly increase our spending to advance the preclinical and clinical development of our product candidates and launch and commercialize any product candidate for which we receive regulatory approval, including building our own commercial organizations to address certain markets. We will require additional capital for the further development and commercialization of our product candidates, as well as to fund our other operating expenses and capital expenditures.

We cannot be certain that additional funding will be available on acceptable terms, or at all. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us we may have to significantly delay, scale back or discontinue the development or commercialization of our product candidate. We may also seek collaborators for one or more of our current or future product candidates at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available. Any of these events could significantly harm our business, financial condition and prospects.

Our future capital requirements will depend on many factors, including:

- the progress of the development of our product candidates;
- the number of product candidates we pursue;
- the time and costs involved in obtaining regulatory approvals;
- the costs involved in filing and prosecuting patent applications and enforcing or defending patent claims;
- our plans to establish sales, marketing and/or manufacturing capabilities;
- the effect of competing technological and market developments;

- the terms and timing of any collaborative, licensing and other arrangements that we may establish;
- general market conditions for offerings from biopharmaceutical companies;
- our ability to establish, enforce and maintain selected strategic alliances and activities required for product commercialization; and
- our revenues, if any, from successful development and commercialization of our product candidates.

In order to carry out our business plan and implement our strategy, we anticipate that we will need to obtain additional financing from time to time and may choose to raise additional funds through strategic collaborations, licensing arrangements, public or private equity or debt financing, bank lines of credit, asset sales, government grants, or other arrangements. We cannot be sure that any additional funding, if needed, will be available on terms favorable to us or at all. Furthermore, any additional equity or equity-related financing may be dilutive to our stockholders, and debt or equity financing, if available, may subject us to restrictive covenants and significant interest costs. If we obtain funding through a strategic collaboration or licensing arrangement, we may be required to relinquish our rights to certain of our product candidate or marketing territories. Our inability to raise capital when needed would harm our business, financial condition and results of operations, and could cause our stock price to decline or require that we wind down our operations altogether.

Our future product candidates may be in the early stages of development and their commercial viability remains subject to the successful outcome of current and future preclinical studies, clinical trials, regulatory approvals and the risks generally inherent in the development of a pharmaceutical product candidate. If we are unable to successfully advance or develop our product candidates, our business will be materially harmed.

In the near-term, failure to successfully acquire and advance the development of our product candidates may have a material adverse effect on us. To date, we have not successfully acquired, developed or commercially marketed, distributed or sold any product candidate. The success of our business depends primarily upon our ability to successfully acquire and advance the development of our product candidates through preclinical studies and clinical trials, have these product candidates approved for sale by the FDA or regulatory authorities in other countries, and ultimately have these product candidates successfully commercialized by us or a strategic partner. We cannot assure you that the results of our acquisition efforts or future clinical trials will support or justify the continued development of our product candidates, or that we will receive approval from the FDA, or similar regulatory authorities in other countries, to advance the development of our product candidates.

Our future product candidates must satisfy rigorous regulatory standards of safety and efficacy before we can advance or complete their clinical development or they can be approved for sale. To satisfy these standards, we must engage in expensive and lengthy preclinical studies and clinical trials, develop acceptable manufacturing processes, and obtain regulatory approval of our product candidates. Despite these efforts, our product candidates may not:

- offer therapeutic or other medical benefits over existing drugs or other product candidates in development to treat the same patient population;
- be proven to be safe and effective in current and future preclinical studies or clinical trials;
- have the desired effects;
- be free from undesirable or unexpected effects;
- meet applicable regulatory standards;
- be capable of being formulated and manufactured in commercially suitable quantities and at an acceptable cost; or
- be successfully commercialized by us or by collaborators.

Even if we demonstrate favorable results in preclinical studies and early-stage clinical trials, we cannot assure you that the results of late-stage clinical trials will be favorable enough to support the continued development of our product candidates. A number of companies in the pharmaceutical and biopharmaceutical industries have experienced significant delays, setbacks and failures in all stages of development, including late-stage clinical trials, even after achieving promising results in preclinical testing or early-stage clinical trials. Accordingly, results from completed preclinical studies and early-stage clinical trials of our product candidates may not be predictive of the results we may obtain in later-stage trials. Furthermore, even if the data collected from preclinical studies and clinical trials involving our product candidates demonstrate a satisfactory safety and efficacy profile, such results may not be sufficient to support the submission of a New Drug Application, or NDA or a biologics license application, or BLA to obtain regulatory approval from the FDA in the U.S., or other similar regulatory agencies in other jurisdictions, which is required to market and sell the product.

Our future product candidates will require significant additional research and development efforts, the commitment of substantial financial resources, and regulatory approvals prior to advancing into further clinical development or being commercialized by us or collaborators. We cannot assure you that our product candidates will successfully progress through the drug development process or will result in commercially viable products. We do not expect our product candidates to be commercialized by us or collaborators for at least several years.

Our future product candidates may exhibit undesirable side effects when used alone or in combination with other approved pharmaceutical products or investigational new drugs, which may delay or preclude further development or regulatory approval, or limit their use if approved.

Throughout the drug development process, we must continually demonstrate the safety and tolerability of our product candidates to obtain regulatory approval to further advance clinical development or to market them. Even if our future product candidates demonstrate biologic activity and clinical efficacy, any unacceptable adverse side effects or toxicities, when administered alone or in the presence of other pharmaceutical products, which can arise at any stage of development, may outweigh potential benefits. We may observe adverse or significant adverse events or drug-drug interactions in future preclinical studies or clinical trial candidates, which could result in the delay or termination of development, prevent regulatory approval, or limit market acceptance if ultimately approved.

If the actual or perceived therapeutic benefits of future product candidates are not sufficiently different from existing generic drugs we may terminate the development at any time, or our ability to generate significant revenue from the sale of that product, if approved, may be limited and our potential profitability could be harmed.

Generic drugs are compounds that have no remaining patent protection, and generally have an average selling price substantially lower than drugs that are protected by patents and intellectual property rights. Unless a patented drug can differentiate itself from generic drugs treating the same condition or disease in a clinically meaningful manner, the existence of generic competition in any indication may impose significant pricing pressure on patented drugs. Accordingly, if at any time we believe that future product candidates may not provide meaningful therapeutic benefits, perceived or real, over these existing generic drugs, we may delay or terminate its future development. We cannot provide any assurance that later-stage clinical trials will demonstrate any meaningful therapeutic benefits over existing generic drugs sufficient to justify its continued development. Further, if we successfully develop a candidate and it is approved for sale, we cannot assure you that any real or perceived therapeutic benefits of that candidate over generic drugs will result in it being, accepted for sale by insurance company or hospital formularies, prescribed by physicians or commanding a price higher than the existing generic drugs.

If the results of preclinical studies or clinical trials for our product candidates, including those that are subject to existing or future license or collaboration agreements, are unfavorable or delayed, we could be delayed or precluded from the further development or commercialization of our product candidates, which could materially harm our business.

In order to further advance the development of, and ultimately receive regulatory approval to sell, our product candidates, we must conduct extensive preclinical studies and clinical trials to demonstrate their safety and efficacy to the satisfaction of the FDA or similar regulatory authorities in other countries, as the case may be. Preclinical studies and clinical trials are expensive, complex, can take many years to complete, and have highly uncertain outcomes. Delays, setbacks, or failures can occur at any time, or in any phase of preclinical or clinical testing, and can result from concerns about safety or toxicity, a lack of demonstrated efficacy or superior efficacy over other similar products that have been approved for sale or are in more advanced stages of development, poor study or trial design, and issues related to the formulation or manufacturing process of the materials used to conduct the trials. The results of prior preclinical studies or clinical trials are not necessarily predictive of the results we may observe in later stage clinical trials. In many cases, product candidates in clinical development may fail to show desired safety and efficacy characteristics despite having favorably demonstrated such characteristics in preclinical studies or earlier stage clinical trials.

In addition, in the future, we may experience numerous unforeseen events during, or as a result of, preclinical studies and the clinical trial process, which could delay or impede our ability to advance the development of, receive regulatory approval for, or commercialize our product candidates, including, but not limited to:

- communications with the FDA, or similar regulatory authorities in different countries, regarding the scope or design of a trial or trials;

- regulatory authorities (including an Institutional Review Board or Ethical Committee) or IRB or EC, not authorizing us to commence or conduct a clinical trial at a prospective trial site;

- enrollment in our clinical trials being delayed, or proceeding at a slower pace than we expected, because we have difficulty recruiting patients or participants dropping out of our clinical trials at a higher rate than we anticipated;

- our third-party contractors, upon whom we will rely for conducting preclinical studies, clinical trials and manufacturing of our trial materials, may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner;

- having to suspend or ultimately terminate our clinical trials if participants are being exposed to unacceptable health or safety risks;

- IRBs, ECs or regulators requiring that we hold, suspend or terminate our preclinical studies and clinical trials for various reasons, including non-compliance with regulatory requirements; and

- the supply or quality of drug material necessary to conduct our preclinical studies or clinical trials being insufficient, inadequate or unavailable.

Even if the data collected from preclinical studies or clinical trials involving our product candidates demonstrate a satisfactory safety and efficacy profile, such results may not be sufficient to support the submission of an NDA or BLA to obtain regulatory approval from the FDA in the U.S., or other similar foreign regulatory authorities in foreign jurisdictions, which is required to market and sell the product.

If third party vendors upon whom we intend to rely on to conduct our future preclinical studies or clinical trials do not perform or fail to comply with strict regulations, these studies or trials of our product candidates may be delayed, terminated, or fail, or we could incur significant additional expenses, which could materially harm our business.

We have limited resources dedicated to designing, conducting and managing preclinical studies and clinical trials. We intend to rely on third parties, including clinical research organizations, consultants and principal investigators, to assist us in designing, managing, monitoring and conducting our preclinical studies and clinical trials. We intend to rely on these vendors and individuals to perform many facets of the drug development process, including certain preclinical studies, the recruitment of sites and patients for participation in our clinical trials, maintenance of good relations with the clinical sites, and ensuring that these sites are conducting our trials in compliance with the trial protocol, including safety monitoring and applicable regulations. If these third parties fail to perform satisfactorily, or do not adequately fulfill their obligations under the terms of our agreements with them, we may not be able to enter into alternative arrangements without undue delay or additional expenditures, and therefore the future preclinical studies and clinical trials of our product candidates may be delayed or prove unsuccessful. Further, the FDA, or other similar foreign regulatory authorities, may inspect some of the clinical sites participating in our clinical trials in the U.S., or our third-party vendors' sites, to determine if our clinical trials are being conducted according to Good Clinical Practices or GCPs. If we or the FDA determine that our third-party vendors are not in compliance with, or have not conducted our clinical trials according to, applicable regulations we may be forced to delay, repeat or terminate such clinical trials.

We have limited capacity for recruiting and managing clinical trials, which could impair our timing to initiate or complete future clinical trials of our product candidates and materially harm our business.

We have limited capacity to recruit and manage the clinical trials necessary to obtain FDA approval or approval by other regulatory authorities. By contrast, larger pharmaceutical and bio-pharmaceutical companies often have substantial staff with extensive experience in conducting clinical trials with multiple product candidates across multiple indications. In addition, they may have greater financial resources to compete for the same clinical investigators and patients that we are attempting to recruit for our clinical trials.

As a result, we may be at a competitive disadvantage that could delay the initiation, recruitment, timing, completion of our clinical trials and obtaining regulatory approvals, if at all, for our product candidates.

We, and our collaborators, must comply with extensive government regulations in order to advance our product candidates through the development process and ultimately obtain and maintain marketing approval for our products in the U.S. and abroad.

The product candidates that we, or our collaborators, are attempting to acquire and develop require regulatory approval to advance through clinical development and to ultimately be marketed and sold, and are subject to extensive and rigorous domestic and foreign government regulation. In the U.S., the FDA regulates, among other things, the development, testing, manufacture, safety, efficacy, record-keeping, labeling, storage, approval, advertising, promotion, sale and distribution of pharmaceutical and biopharmaceutical products. Our future product candidates are also subject to similar regulation by foreign governments to the extent we seek to develop or market them in those countries. We, or our collaborators, must provide the FDA and foreign regulatory authorities, if applicable, with preclinical and clinical data, as well as data supporting an acceptable manufacturing process, that appropriately demonstrate our product candidates' safety and efficacy before they can be approved for the targeted indications. Our product candidates have not been approved for sale in the U.S. or any foreign market, and we cannot predict whether we or our collaborators will obtain regulatory approval for any product candidates we are developing or plan to develop. The regulatory review and approval process can take many years, is dependent upon the type, complexity, novelty of, and medical need for the product candidates, requires the expenditure of substantial resources, and involves post-marketing surveillance and vigilance and ongoing requirements for post-marketing studies or Phase 4 clinical trials.

In addition, we or our collaborators may encounter delays in, or fail to gain, regulatory approval for our product candidates based upon additional governmental regulation resulting from future legislative, administrative action or changes in FDA's or other similar foreign regulatory authorities' policy or interpretation during the period of product development. Delays or failures in obtaining regulatory approval to advance our product candidates through clinical development, and ultimately commercialize them, may:

- adversely impact our ability to raise sufficient capital to fund the development of our product candidates;
- adversely affect our ability to further develop or commercialize our product candidates;
- diminish any competitive advantages that we or our collaborators may have or attain; and
- adversely affect the receipt of potential milestone payments and royalties from the sale of our products or product revenues.

Furthermore, any regulatory approvals, if granted, may later be withdrawn. If we or our collaborators fail to comply with applicable regulatory requirements at any time, or if post-approval safety concerns arise, we or our collaborators may be subject to restrictions or a number of actions, including:

- delays, suspension or termination of any future clinical trials related to our products;
- refusal by regulatory authorities to review pending applications or supplements to approved applications;
- product recalls or seizures;
- suspension of manufacturing;
- withdrawals of previously approved marketing applications; and
- fines, civil penalties and criminal prosecutions.

Additionally, at any time we or our collaborators may voluntarily suspend or terminate the preclinical or clinical development of a product candidate, or withdraw any approved product from the market if we believe that it may pose an unacceptable safety risk to patients, or if the product candidate or approved product no longer meets our business objectives. The ability to develop or market a pharmaceutical product outside of the U.S. is contingent upon receiving appropriate authorization from the respective foreign regulatory authorities. Foreign regulatory approval processes typically include many, if not all, of the risks and requirements associated with the FDA regulatory process for drug development and may include additional risks.

We have limited experience in the development of life sciences product candidates and therefore may encounter difficulties developing our product candidates or managing our operations in the future.

We have limited experience in life sciences discovery, development and manufacturing. In order to successfully develop these product candidates, we must continuously supplement our research, clinical development, regulatory, medicinal chemistry, virology and manufacturing capabilities through the addition of key employees, consultants or third-party contractors to provide certain capabilities and skill sets that we do not possess.

Furthermore, we have adopted an operating model that largely relies on the outsourcing of a number of responsibilities and key activities to third-party consultants, and contract research and manufacturing organizations in order to advance the development of our product candidate. Therefore, our success depends in part on our ability to retain highly qualified key management, personnel, and directors to develop, implement and execute our business strategy, operate the company and oversee the activities of our consultants and contractors, as well as academic and corporate advisors or consultants to assist us in this regard. We are currently highly dependent upon the efforts of our management team. In order to develop our product candidates, we need to retain or attract certain personnel, consultants or advisors with experience in the drug development activities of small molecules that include a number of disciplines, including research and development, clinical trials, medical matters, government regulation of pharmaceuticals, manufacturing, formulation and chemistry, business development, accounting, finance, regulatory affairs, human resources and information systems. We are highly dependent upon our senior management and scientific consultants, particularly Nicholas DeVito, our Chief Executive Officer. The loss of services of Mr. DeVito or one or more of our other members of senior management could delay or prevent the successful completion of our planned clinical trials or the commercialization of our product candidates.

Our success depends in part on our continued ability to attract, retain and motivate highly qualified management, clinical and scientific personnel and on our ability to develop and maintain important relationships with leading academic institutions, clinicians and scientists. The competition for qualified personnel in the biotechnology and pharmaceuticals field is intense. We will need to hire additional personnel as we expand our clinical development and commercial activities. While we have not had difficulties recruiting qualified individuals, to date, we may not be able to attract and retain quality personnel on acceptable terms given the competition for such

personnel among biotechnology, pharmaceutical and other companies. Although we have not experienced material difficulties in retaining key personnel in the past, we may not be able to continue to do so in the future on acceptable terms, if at all. If we lose any key managers or employees, or are unable to attract and retain qualified key personnel, directors, advisors or consultants, the development of our product candidate could be delayed or terminated and our business may be harmed.

We will need to obtain FDA approval of any proposed product brand names, and any failure or delay associated with such approval may adversely impact our business.

A pharmaceutical product cannot be marketed in the U.S. or other countries until we have completed rigorous and extensive regulatory review processes, including approval of a brand name. Any brand names we intend to use for our product candidate will require approval from the FDA regardless of whether we have secured a formal trademark registration from the U.S. Patent and Trademark Office, or the PTO. The FDA typically conducts a review of proposed product brand names, including an evaluation of potential for confusion with other product names. The FDA may also object to a product brand name if the FDA believes the name inappropriately implies medical claims. If the FDA objects to any of our proposed product brand names, we may be required to adopt an alternative brand name for our product candidates. If we adopt an alternative brand name, we would lose the benefit of our existing trademark applications for such product candidates and may be required to expend significant additional resources in an effort to identify a suitable product brand name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. We may be unable to build a successful brand identity for a new trademark in a timely manner or at all, which would limit our ability to commercialize our product candidates.

Clinical trials involve a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results.

Our product candidates may not prove to be safe and efficacious in clinical trials and may not meet all the applicable regulatory requirements needed to receive regulatory approval. In order to receive regulatory approval for the commercialization of our product candidates, we must conduct, at our own expense, extensive preclinical testing and clinical trials to demonstrate safety and efficacy of our product candidates for the intended indication of use. Clinical testing is expensive, can take many years to complete, if at all, and its outcome is uncertain. Failure can occur at any time during the clinical trial process.

The results of preclinical studies and early clinical trials of new drugs do not necessarily predict the results of later-stage clinical trials. The design of our clinical trials is based on many assumptions about the expected effects of our product candidates, and if those assumptions are incorrect it may not produce statistically significant results. Preliminary results may not be confirmed on full analysis of the detailed results of an early clinical trial. Product candidates in later stages of clinical trials may fail to show safety and efficacy sufficient to support intended use claims despite having progressed through initial clinical testing. The data collected from clinical trials of our product candidates may not be sufficient to support the filing of an NDA or to obtain regulatory approval in the United States or elsewhere. Because of the uncertainties associated with drug development and regulatory approval, we cannot determine if or when we will have an approved product for commercialization or achieve sales or profits.

Delays in clinical testing could result in increased costs to us and delay our ability to generate revenue.

We may experience delays in clinical testing of our product candidates. We do not know whether planned clinical trials will begin on time, will need to be redesigned or will be completed on schedule, if at all. Clinical trials can be delayed for a variety of reasons, including delays in obtaining regulatory approval to commence a clinical trial, in securing clinical trial agreements with prospective sites with acceptable terms, in obtaining institutional review board approval to conduct a clinical trial at a prospective site, in recruiting patients to participate in a clinical trial or in obtaining sufficient supplies of clinical trial materials. Many factors affect patient enrollment, including the size of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the clinical trial, competing clinical trials and new drugs approved for the conditions we are investigating. Clinical investigators will need to decide whether to offer their patients enrollment in clinical trials of our product candidates versus treating these patients with commercially available drugs that have established safety and efficacy profiles. Any delays in completing our clinical trials will increase our costs, slow down our product development, timeliness and approval process and delay our ability to generate revenue.

The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed.

The time required to obtain approval by the FDA and comparable foreign authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. We have not obtained regulatory approval for any product candidate and it is possible that our existing product candidates or any product candidate we may seek to develop in the future will ever obtain regulatory approval.

Our product candidates could fail to receive regulatory approval for many reasons, including the following:

- 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 or comparable foreign regulatory authorities that a product candidate is safe and effective for its proposed indication;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of an NDA or other submission or to obtain regulatory approval in the United States or elsewhere;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies;
- the FDA or comparable foreign regulatory authorities may fail to approve the companion diagnostics we contemplate developing with partners; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

This lengthy approval process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval to market our product candidates, which would significantly harm our business, results of operations and prospects.

In addition, even if we were to obtain approval, regulatory authorities may approve our product candidates for fewer or more limited indications than we request, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates.

We, have not previously submitted a biologics license application, or BLA, or a New Drug Application, or NDA, to the FDA, or similar drug approval filings to comparable foreign authorities, for our product candidate, and we cannot be certain that our product candidates will be successful in clinical trials or receive regulatory approval. Further, our product candidates may not receive regulatory approval even if they are successful in clinical trials. If we do not receive regulatory approvals for our product candidates, we may not be able to continue our operations. Even if we successfully obtain regulatory approvals to market one or more of our product candidates, our revenues will be dependent, in part, upon our collaborators' ability to obtain regulatory approval of the companion diagnostics to be used with our product candidates, as well as the size of the markets in the territories for which we gain regulatory approval and have commercial rights. If the markets for patients that we are targeting for our product candidates are not as significant as we estimate, we may not generate significant revenues from sales of such products, if approved.

We plan to seek regulatory approval and to commercialize our product candidates, directly or with a collaborator, worldwide including the United States, the European Union and other additional foreign countries which we have not yet identified. While the scope of regulatory approval is similar in other countries, to obtain separate regulatory approval in many other countries we must comply with numerous and varying regulatory requirements of such countries regarding safety and efficacy and governing, among other things, clinical trials and commercial sales, pricing and distribution of our product candidates, and we cannot predict success in these jurisdictions.

We may be required to suspend or discontinue future clinical trials due to unexpected side effects or other safety risks that could preclude approval of our product candidates.

Our future clinical trials may be suspended at any time for a number of reasons. For example, we may voluntarily suspend or terminate our clinical trials if at any time we believe that they present an unacceptable risk to the clinical trial patients. In addition, the FDA or other regulatory agencies may order the temporary or permanent discontinuation of our clinical trials at any time if they believe that the clinical trials are not being conducted in accordance with applicable regulatory requirements or that they present an unacceptable safety risk to the clinical trial patients.

Administering any of our product candidates to humans may produce undesirable side effects. These side effects could interrupt, delay or halt clinical trials of our product candidates and could result in the FDA or other regulatory authorities denying further development or approval of our product candidates for any or all targeted indications. Ultimately, some or all of our product candidates may prove to

be unsafe for human use. Moreover, we could be subject to significant liability if any volunteer or patient suffers, or appears to suffer, adverse health effects as a result of participating in our clinical trials.

If we fail to comply with healthcare regulations, we could face substantial enforcement actions, including civil and criminal penalties and our business, operations and financial condition could be adversely affected.

As a developer of pharmaceuticals, even though we do not intend to make referrals of healthcare services or bill directly to Medicare, Medicaid or other third-party payers, certain federal and state healthcare laws and regulations pertaining to fraud and abuse, false claims and patients' privacy rights are and will be applicable to our business. We could be subject to healthcare fraud and abuse laws and patient privacy laws of both the federal government and the states in which we conduct our business. The laws include:

- the federal healthcare program anti-kickback law, which prohibits, among other things, persons from soliciting, receiving or providing remuneration, directly or indirectly, to induce either the referral of an individual, for an item or service or the purchasing or ordering of a good or service, for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs;

- federal false claims laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payers that are false or fraudulent, and which may apply to entities like us which provide coding and billing information to customers;

- the federal Health Insurance Portability and Accountability Act of 1996, which prohibits executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters and which also imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information;

- the Federal Food, Drug, and Cosmetic Act, which among other things, strictly regulates drug manufacturing and product marketing, prohibits manufacturers from marketing drug products for off-label use and regulates the distribution of drug samples; and

- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payer, including commercial insurers, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by federal laws, thus complicating compliance efforts.

If our operations are found to be in violation of any of the laws described above or any governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines and the curtailment or restructuring of our operations. Any penalties, damages, fines, curtailment or restructuring of our operations could adversely affect our ability to operate our business and our financial results. Although compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, the risks cannot be entirely eliminated. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert management's attention from the operation of our business. Moreover, achieving and sustaining compliance with applicable federal and state privacy, security and fraud laws may prove costly

If we are unable to satisfy regulatory requirements, we may not be able to commercialize our product candidates.

We need FDA approval prior to marketing our product candidates in the United States. If we fail to obtain FDA approval to market our product candidates, we will be unable to sell our product candidates in the United States and we will not generate any revenue.

The FDA's review and approval process, including among other things, evaluation of preclinical studies and clinical trials of a product candidate as well as the manufacturing process and facility, is lengthy, expensive and uncertain. To receive approval, we must, among other things, demonstrate with substantial evidence from well-designed and well-controlled pre- clinical testing and clinical trials that the product candidate is both safe and effective for each indication for which approval is sought. Satisfaction of these requirements typically takes several years and the time needed to satisfy them may vary substantially, based on the type, complexity and novelty of the pharmaceutical product. We cannot predict if or when we will submit an NDA for approval for our product candidates currently under development. Any approvals we may obtain may not cover all of the clinical indications for which we are seeking approval or may contain significant limitations on the conditions of use.

The FDA has substantial discretion in the NDA review process and may either refuse to file our NDA for substantive review or may decide that our data is insufficient to support approval of our product candidates for the claimed intended uses. Following any regulatory approval of our product candidates, we will be subject to continuing regulatory obligations such as safety reporting, required and additional post marketing obligations, and regulatory oversight of promotion and marketing. Even if we receive regulatory approvals, the FDA may subsequently seek to withdraw approval of our NDA if we determine that new data or a reevaluation of existing data show the product is unsafe for use under the conditions of use upon the basis of which the NDA was approved, or based on new evidence of adverse effects or adverse clinical experience, or upon other new information. If the FDA does not file or approve our NDA or withdraws

approval of our NDA, the FDA may require that we conduct additional clinical trials, preclinical or manufacturing studies and submit that data before it will reconsider our application. Depending on the extent of these or any other requested studies, approval of any applications that we submit may be delayed by several years, may require us to expend more resources than we have available, or may never be obtained at all.

We will also be subject to a wide variety of foreign regulations governing the development, manufacture and marketing of our products to the extent we seek regulatory approval to develop and market our product candidates in a foreign jurisdiction. As of the date hereof we have not identified any foreign jurisdictions which we intend to seek approval from. Whether or not FDA approval has been obtained, approval of a product by the comparable regulatory authorities of foreign countries must still be obtained prior to marketing the product in those countries. The approval process varies and the time needed to secure approval in any region such as the European Union or in a country with an independent review procedure may be longer or shorter than that required for FDA approval. We cannot assure you that clinical trials conducted in one country will be accepted by other countries or that an approval in one country or region will result in approval elsewhere.

If our product candidates are unable to compete effectively with marketed drugs targeting similar indications as our product candidates, our commercial opportunity will be reduced or eliminated.

We face competition generally from established pharmaceutical and biotechnology companies, as well as from academic institutions, government agencies and private and public research institutions. Many of our competitors have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Small or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Our commercial opportunity will be reduced or eliminated if our competitors develop and commercialize any drugs that are safer, more effective, have fewer side effects or are less expensive than our product candidate. These potential competitors compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient enrollment for clinical trials, as well as in acquiring technologies and technology licenses complementary to our programs or advantageous to our business.

We expect that our ability to compete effectively will depend upon our ability to:

- successfully identify and develop key points of product differentiations from currently available therapies;
- successfully and rapidly complete clinical trials and submit for and obtain all requisite regulatory approvals in a cost-effective manner;
- maintain a proprietary position for our products and manufacturing processes and other related product technology;
- attract and retain key personnel;
- develop relationships with physicians prescribing these products; and
- build an adequate sales and marketing infrastructure for our product candidates.

Because we will be competing against significantly larger companies with established track records, we will have to demonstrate that, based on experience, clinical data, side-effect profiles and other factors, our products, if approved, are competitive with other products. If we are unable to compete effectively and differentiate our products from other marketed shingles drugs, we may never generate meaningful revenue.

We currently have no sales and marketing organization. If we are unable to establish a direct sales force in the United States to promote our products, the commercial opportunity for our products may be diminished.

We currently have no sales and marketing organization. We will incur significant additional expenses and commit significant additional management resources to establish our sales force. We may not be able to establish these capabilities despite these additional expenditures. We will also have to compete with other pharmaceutical and biotechnology companies to recruit, hire and train sales and marketing personnel. If we elect to rely on third parties to sell our product candidates in the United States, we may receive less revenue than if we sold our products directly. In addition, although we would intend to use due diligence in monitoring their activities, we may have little or no control over the sales efforts of those third parties. In the event we are unable to develop our own sales force or collaborate with a third party to sell our product candidates, we may not be able to commercialize our product candidate which would negatively impact our ability to generate revenue.

We may need others to market and commercialize our product candidates in international markets.

In the future, if appropriate regulatory approvals are obtained, we may commercialize our product candidates in international markets. However, we have not decided how to commercialize our product candidates in those markets. We may decide to build our own sales force or sell our products through third parties. If we decide to sell our product candidates in international markets through a third party, we may not be able to enter into any marketing arrangements on favorable terms or at all. In addition, these arrangements could result in lower levels of income to us than if we marketed our product candidates entirely on our own. If we are unable to enter into a marketing arrangement for our product candidates in international markets, we may not be able to develop an effective international sales force to successfully commercialize those products in international markets. If we fail to enter into marketing arrangements for our products and are unable to develop an effective international sales force, our ability to generate revenue would be limited.

If the manufacturers upon whom we will rely on in the future fail to produce our product candidates, in the volumes that we may require on a timely basis, or fail to comply with stringent regulations applicable to pharmaceutical drug manufacturers, we may face delays in the development and commercialization of our product candidate.

We do not currently possess internal manufacturing capacity. We plan to utilize the services of contract manufacturers to manufacture our clinical supplies. In addition, because regulatory authorities must generally approve raw material sources for pharmaceutical products, changes in raw material suppliers may result in production delays or higher raw material costs.

We plan to pursue active pharmaceutical ingredients, or API, and drug product supply agreements with third party manufacturers. We may be required to agree to minimum volume requirements, exclusivity arrangements or other restrictions with the contract manufacturers. We may not be able to enter into long-term agreements on commercially reasonable terms, or at all. If we change or add manufacturers, the FDA and comparable foreign regulators may require approval of the changes. Approval of these changes could require new testing by the manufacturer and compliance inspections to ensure the manufacturer is conforming to all applicable laws and regulations and good manufacturing practices or GMP. In addition, the new manufacturers would have to be educated in or independently develop the processes necessary for the production of our product candidate.

The manufacture of pharmaceutical products requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of pharmaceutical products may encounter difficulties in production, particularly in scaling up production. These problems include difficulties with production costs and yields, quality control, including stability of the product and quality assurance testing, shortages of qualified personnel, as well as compliance with federal, state and foreign regulations. In addition, any delay or interruption in the supply of clinical trial supplies could delay the completion of our clinical trials, increase the costs associated with conducting our clinical trials and, depending upon the period of delay, require us to commence new clinical trials at significant additional expense or to terminate a clinical trial.

We will be responsible for ensuring that each of our future contract manufacturers comply with the GMP requirements of the FDA and other regulatory authorities from which we seek to obtain product approval. These requirements include, among other things, quality control, quality assurance and the maintenance of records and documentation. The approval process for NDAs includes a review of the manufacturer's compliance with GMP requirements. We are responsible for regularly assessing a contract manufacturer's compliance with GMP requirements through record reviews and periodic audits and for ensuring that the contract manufacturer takes responsibility and corrective action for any identified deviations. Manufacturers our product candidates may be unable to comply with these GMP requirements and with other FDA and foreign regulatory requirements, if any.

While we will oversee compliance by our future contract manufacturers, ultimately, we will not have control over our manufacturers' compliance with these regulations and standards. A failure to comply with these requirements may result in fines and civil penalties, suspension of production, suspension or delay in product approval, product seizure or recall, or withdrawal of product approval. If the safety our product candidates is compromised due to a manufacturers' failure to adhere to applicable laws or for other reasons, we may not be able to obtain regulatory approval for or successfully commercialize our product candidates, and we may be held liable for any injuries sustained as a result. Any of these factors could cause a delay of clinical trials, regulatory submissions, approvals or commercialization of other product candidates, entail higher costs or result in us being unable to effectively commercialize our product candidates. Furthermore, if our manufacturers fail to deliver the required commercial quantities on a timely basis and at commercially reasonable prices, we may be unable to meet demand for any approved products and would lose potential revenues.

We may not be able to manufacture our product candidates in commercial quantities, which would prevent us from commercializing our product candidates.

To date, our product candidates were previously manufactured by ACB Holding or its predecessor in small quantities for preclinical studies. If our any of our product candidates are approved by the FDA or comparable regulatory authorities in other countries for commercial sale, we will need to manufacture such product candidates in larger quantities. We may not be able to ramp up successfully the manufacturing capacity for our product candidates in a timely or economic manner, or at all. Significant scale-up of manufacturing may require additional validation studies, which the FDA must review and approve. If we are unable to ramp up successfully the manufacturing capacity for a product candidate, the clinical trials as well as the regulatory approval or commercial launch of that product candidate may be delayed or there may be a shortage in supply. Our product candidates require precise, high quality manufacturing. Our failure to achieve and maintain these high quality manufacturing standards in collaboration with future third-party manufacturers,

including the incidence of manufacturing errors, could result in patient injury or death, product recalls or withdrawals, delays or failures in product testing or delivery, cost overruns or other problems that could harm our business, financial condition and results of operations.

Materials necessary to manufacture our product candidates may not be available on commercially reasonable terms, or at all, which may delay the development and commercialization of our product candidates.

We will rely on the third-party manufacturers of our product candidates to purchase from third-party suppliers the materials necessary to produce bulk APIs, and product candidates for our future clinical trials, and we will rely on such manufacturers to purchase such materials to produce the APIs and finished products for any commercial distribution of our products if we obtain marketing approval. Suppliers may not sell these materials to our manufacturers at the time they need them in order to meet our required delivery schedule or on commercially reasonable terms, if at all. We do not have any control over the process or timing of the acquisition of these materials by our manufacturers. Moreover, we currently do not have any agreements for the production of these materials. If our future manufacturers are unable to obtain these materials for our clinical trials, testing of the affected product candidates would be delayed, which may significantly impact our ability to develop the product candidates. If we or our future manufacturers are unable to purchase these materials after regulatory approval has been obtained for one of our products, the commercial launch of such product would be delayed or there would be a shortage in supply of such product, which would harm our ability to generate revenues from such product and achieve or sustain profitability.

Our product candidates, if approved for sale, may not gain acceptance among physicians, patients and the medical community, thereby limiting our potential to generate revenues.

If any of our product candidates is approved for commercial sale by the FDA or other regulatory authorities, the degree of market acceptance of any approved product by physicians, healthcare professionals and third-party payers and our profitability and growth will depend on a number of factors, including:

- demonstration of safety and efficacy;
- changes in the practice guidelines and the standard of care for the targeted indication;
- relative convenience and ease of administration;
- the prevalence and severity of any adverse side effects;
- budget impact of adoption of our product on relevant drug formularies and the availability, cost and potential advantages of alternative treatments, including less expensive generic drugs;
- pricing, reimbursement and cost effectiveness, which may be subject to regulatory control;
- effectiveness of our or any of our partners' sales and marketing strategies;
- the product labeling or product insert required by the FDA or regulatory authority in other countries; and
- the availability of adequate third-party insurance coverage or reimbursement.

If any product candidates that we develop does not provide a treatment regimen that is as beneficial as, or is perceived as being as beneficial as, the current standard of care or otherwise does not provide patient benefit, that product candidates, if approved for commercial sale by the FDA or other regulatory authorities, likely will not achieve market acceptance. Our ability to effectively promote and sell any approved products will also depend on pricing and cost-effectiveness, including our ability to produce a product at a competitive price and our ability to obtain sufficient third-party coverage or reimbursement. If any product candidate is approved but does not achieve an adequate level of acceptance by physicians, patients and third-party payers, our ability to generate revenues from that product would be substantially reduced. In addition, our efforts to educate the medical community and third-party payers on the benefits of our product candidates may require significant resources, may be constrained by FDA rules and policies on product promotion, and may never be successful.

Guidelines and recommendations published by various organizations can impact the use of our product.

Government agencies promulgate regulations and guidelines directly applicable to us and to our product. In addition, professional societies, practice management groups, private health and science foundations and organizations involved in various diseases from time to time may also publish guidelines or recommendations to the health care and patient communities. Recommendations of government agencies or these other groups or organizations may relate to such matters as usage, dosage, route of administration and use of concomitant therapies. Recommendations or guidelines suggesting the reduced use of our products or the use of competitive or alternative products that are followed by patients and health care providers could result in decreased use of our proposed product.

If third-party contract manufacturers upon whom we rely to formulate and manufacture our product candidates do not perform, fail to manufacture according to our specifications or fail to comply with strict regulations, our preclinical studies or clinical trials could be adversely affected and the development of our product candidates could be delayed or terminated or we could incur significant additional expenses.

We do not own or operate any manufacturing facilities. We intend to rely on third-party contractors, at least for the foreseeable future, to formulate and manufacture these preclinical and clinical materials. Our reliance on third- party contract manufacturers exposes us to a number of risks, any of which could delay or prevent the completion of our preclinical studies or clinical trials, or the regulatory approval or commercialization of our product candidate, result in higher costs, or deprive us of potential product revenues. Some of these risks include:

- our third-party contractors failing to develop an acceptable formulation to support later-stage clinical trials for, or the commercialization of, our product candidates;
- our contract manufacturers failing to manufacture our product candidates according to their own standards, our specifications, cGMPs, or otherwise manufacturing material that we or the FDA may deem to be unsuitable in our clinical trials;
- our contract manufacturers being unable to increase the scale of, increase the capacity for, or reformulate the form of our product candidates. We may experience a shortage in supply, or the cost to manufacture our products may increase to the point where it adversely affects the cost of our product candidates. We cannot assure you that our contract manufacturers will be able to manufacture our products at a suitable scale, or we will be able to find alternative manufacturers acceptable to us that can do so;
- our contract manufacturers placing a priority on the manufacture of their own products, or other customers' products;
- our contract manufacturers failing to perform as agreed or not remain in the contract manufacturing business; and
- our contract manufacturers' plants being closed as a result of regulatory sanctions or a natural disaster.

Manufacturers of pharmaceutical products are subject to ongoing periodic inspections by the FDA, the U.S. Drug Enforcement Administration ("DEA") and corresponding state and foreign agencies to ensure strict compliance with FDA-mandated current good marketing practices or cGMPs, other government regulations and corresponding foreign standards. While we are obligated to audit their performance, we do not have control over our third-party contract manufacturers' compliance with these regulations and standards. Failure by our third-party manufacturers, or us, to comply with applicable regulations could result in sanctions being imposed on us or the drug manufacturer from the production of other third-party products. These sanctions may include fines, injunctions, civil penalties, failure of the government to grant pre-market approval of drugs, delays, suspension or withdrawal of approvals, seizures or recalls of product, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect our business.

In the event that we need to change our third-party contract manufacturers, our preclinical studies, clinical trials or the commercialization of our product candidates could be delayed, adversely affected or terminated, or such a change may result in significantly higher costs.

Due to regulatory restrictions inherent in an IND, NDA or BLA, various steps in the manufacture of our product candidate may need to be sole-sourced. In accordance with cGMPs, changing manufacturers may require the re-validation of manufacturing processes and procedures, and may require further preclinical studies or clinical trials to show comparability between the materials produced by different manufacturers. Changing our current or future contract manufacturers may be difficult for us and could be costly, which could result in our inability to manufacture our product candidate for an extended period of time and therefore a delay in the development of our product candidate. Further, in order to maintain our development time lines in the event of a change in our third-party contract manufacturer, we may incur significantly higher costs to manufacture our product candidates.

The life-sciences industry is highly competitive and subject to rapid technological changes. As a result, we may be unable to compete successfully or develop innovative products, which could harm our business.

The life-sciences industry is highly competitive and characterized by rapid technological change. Key competitive factors in our industry include, among others, the ability to successfully advance the development of a product candidate through preclinical and clinical trials; the efficacy, toxicological, safety, resistance or cross-resistance, and dosing profile of a product or product candidate; the timing and scope of regulatory approvals, if ever achieved; reimbursement rates for and the average selling price of competing products and pharmaceutical products in general; the availability of raw materials and qualified contract manufacturing and manufacturing capacity; manufacturing costs; establishing and maintaining intellectual property and patent rights and their protection; and sales and marketing capabilities. If ultimately approved, any other product candidate we may develop, would compete against existing therapies or other product candidates in various stages of clinical development that we believe may potentially become available in the future.

Developing a pharmaceutical product candidate is a highly competitive, expensive and risky activity with a long business cycle. Many organizations, including the large pharmaceutical and biopharmaceutical companies that have existing products on the market or in clinical development that could compete with our product candidates have substantially more resources than we have, and much greater capabilities and experience than we have in research and discovery, designing and conducting preclinical studies and clinical trials, operating in a highly regulated environment, manufacturing drug substances and drug products, and marketing and sales. Our competitors may be more successful than we are in obtaining FDA or other regulatory approvals for their product candidates and achieving broad market acceptance once they are approved. Our competitors' drugs or product candidates may be more effective, have fewer negative side effects, be more convenient to administer, have a more favorable resistance profile, or be more effectively marketed and sold than any drug we, or our potential collaborators, may develop or commercialize. New drugs or classes of drugs from competitors may render our product candidate obsolete or non-competitive before we are able to successfully develop them or, if approved, before we can recover the expenses of developing and commercializing them. We anticipate that we or our collaborators will face intense and increasing competition as new drugs and drug classes enter the market and advanced technologies or new drug targets become available. If our product candidate does not demonstrate any competitive advantages over existing drugs, new drugs or product candidate, we or our future collaborators may terminate the development or commercialization of our product candidate at any time.

We anticipate that our product candidates if successfully developed and approved, will compete directly or indirectly with existing drugs, some of which are generic. Generic drugs are drugs whose patent protection has expired, and generally have an average selling price substantially lower than drugs protected by intellectual property rights. Unless a patented drug can differentiate itself from a generic drug in a meaningful manner, the existence of generic competition in any indication may impose significant pricing pressure on competing patented drugs.

We also face, and will continue to face, intense competition from other companies for collaborative arrangements with pharmaceutical and biopharmaceutical companies, and for attracting investigators and clinical sites capable of conducting our preclinical studies and clinical trials. These competitors, either alone or with their collaborators, may succeed in developing technologies or products that are safer, more effective, less expensive or easier to administer than ours. Accordingly, our competitors may succeed in obtaining FDA or other regulatory approvals for their product candidates more rapidly than we can. Companies that can complete clinical trials, obtain required regulatory approvals and commercialize their products before their competitors may achieve a significant competitive advantage, including certain patent and FDA marketing exclusivity rights that could delay the ability of competitors to market certain products. We cannot assure you that product candidates resulting from our research and development efforts, or from joint efforts with our collaborators, will be able to compete successfully with our competitors' existing products or products under development.

We do not currently have any internal drug discovery capabilities, and therefore we are dependent on in-licensing or acquiring development programs from third parties in order to obtain additional product candidates.

If in the future we decide to add assets to a development pipeline, we will be dependent on in-licensing or acquiring product candidates as we do not have significant internal discovery capabilities at this time. Accordingly, in order to generate and expand our development pipeline, we have relied, and will continue to rely, on obtaining discoveries, new technologies, intellectual property and product candidates from third-parties through sponsored research, in-licensing arrangements or acquisitions. We may face substantial competition from other biotechnology and pharmaceutical companies, many of which may have greater resources then we have, in obtaining these in-licensing, sponsored research or acquisition opportunities. Additional in-licensing or acquisition opportunities may not be available to us on terms we find acceptable, if at all. In-licensed compounds that appear promising in research or in preclinical studies may fail to progress into further preclinical studies or clinical trials.

If a product liability claim is successfully brought against us for uninsured liabilities, or such claim exceeds our insurance coverage, we could be forced to pay substantial damage awards that could materially harm our business.

The use of any of our existing or future product candidates in clinical trials and the sale of any approved pharmaceutical products may expose us to significant product liability claims. We currently have no product liability insurance coverage for future clinical trials. Such insurance coverage may not protect us against any or all of the product liability claims that may be brought against us in the future. We may not be able to acquire or maintain adequate product liability insurance coverage at a commercially reasonable cost or in sufficient amounts or scope to protect us against potential losses. In the event a product liability claim is brought against us, we may be required to pay legal and other expenses to defend the claim, as well as uncovered damage awards resulting from a claim brought successfully against us. In the event our product candidate is approved for sale by the FDA and commercialized, we may need to substantially increase the amount of our product liability coverage. Defending any product liability claim or claims could require us to expend significant financial and managerial resources, which could have an adverse effect on our business.

If our use of hazardous materials results in contamination or injury, we could suffer significant financial loss.

Our research activities, through third parties, involve the controlled use of certain hazardous materials and medical waste. Notwithstanding the regulations controlling the use and disposal of these materials, as well as the safety procedures we undertake, we cannot eliminate the risk of accidental contamination or injury from these materials. In the event of an accident or environmental

discharge or exposure, we may be held liable for any resulting damages, which may exceed our financial resources and have an adverse effect on our business.

Risks Relating to the Commercialization of our Product Candidates

We may delay or terminate the development of a product candidate at any time if we believe the perceived market or commercial opportunity does not justify further investment, which could materially harm our business.

Even though the results of preclinical studies and clinical trials that we have conducted or may conduct in the future may support further development of one or more of our product candidates, we may delay, suspend or terminate the future development of a product candidate at any time for strategic, business, financial or other reasons, including the determination or belief that the emerging profile of the product candidate is such that it may not receive FDA approval, gain meaningful market acceptance, generate a significant return to stockholders, or otherwise provide any competitive advantages in its intended indication or market.

If we fail to enter into collaborations, license agreements or other transactions with third parties to accelerate the development of our product candidates, we will bear the risk of developmental failure.

We plan to seek out-licensing opportunities as a way to accelerate the development of our product candidates. There is no guarantee that we will enter into a future transaction on favorable terms, or at all, or that discussions will initiate or progress on our desired timelines. Completing transactions of this nature is difficult and time-consuming. Potentially interested parties may decline to re-engage or may terminate discussions based upon their assessment of our competitive, financial, regulatory or intellectual property position or for any other reason. Furthermore, we may choose to defer consummating a transaction relating to our product candidates until additional clinical data are obtained. If we decide to not actively pursue a transaction until we have additional clinical data, we and our stockholders will bear the risk that our product candidate fails prior to any future transaction.

If we fail to enter into or maintain collaborations or other sales, marketing and distribution arrangements with third parties to commercialize our product candidates, or otherwise fail to establish marketing and sales capabilities, we may not be able to successfully commercialize our products.

We currently have no infrastructure to support the commercialization of our product candidates, and have little, if any, experience in the commercialization of pharmaceutical products. Therefore, if any of our product candidates is successfully developed and ultimately approved for sale, our future profitability will depend largely on our ability to access or develop suitable marketing and sales capabilities. We anticipate that we will need to establish relationships with other companies, through license and collaborations agreements, to commercialize our product candidates in the U.S. and in other countries around the world. To the extent that we enter into these license and collaboration agreements, or marketing and sales arrangements with other companies to sell, promote or market our products in the U.S. or abroad, our product revenues, which may be in the form of indirect revenue, a royalty, or a split of profits, will depend largely on their efforts, which may not be successful. In the event we develop a sales force and marketing capabilities, this may result in us incurring significant costs before the time that we may generate any significant product revenues. We may not be able to attract and retain qualified third parties or marketing or sales personnel, or be able to establish marketing capabilities or an effective sales force.

If government and third-party payers fail to provide adequate reimbursement or coverage for our products or those we develop through collaborations, our revenues and potential for profitability will be harmed.

In the U.S. and most foreign markets, our product revenues, and therefore the inherent value of our product candidate, will depend largely upon the reimbursement rates established by third-party payers for such product candidate or products. Such third-party payers include government health administration authorities, managed-care organizations, private health insurers and other similar organizations. These third-party payers are increasingly challenging the price and examining the cost effectiveness of medical products, services and pharmaceuticals. In addition, significant uncertainty exists as to the reimbursement status, if any, of newly approved drugs or pharmaceutical products. Further, the comparative effectiveness of new compounds over existing therapies and the assessment of other non-clinical outcomes are increasingly being considered in the decision by these payers to establish reimbursement rates. We may also need to conduct post-marketing clinical trials in order to demonstrate the cost-effectiveness of our products. Such studies may require us to commit a significant amount of management time and financial resources. We cannot assure you that any products we successfully develop will be reimbursed in part, or at all, by any third-party payers in any countries.

Domestic and foreign governments continue to propose legislation designed to expand the coverage, yet reduce the cost, of healthcare, including pharmaceutical drugs. In some foreign markets, governmental agencies control prescription drugs' pricing and profitability. In the U.S. significant changes in federal health care policy have been recently approved and will mostly likely result in reduced reimbursement rates in the future. We expect that there will continue to be federal and state proposals to implement more governmental control over reimbursement rates of pharmaceutical products. In addition, we expect that increasing emphasis on managed care and government intervention in the U.S. healthcare system will continue to put downward pressure on the pricing of pharmaceutical products domestically. Cost control initiatives could decrease the price that we receive for any of our product candidates that may be approved for sale in the future, which would limit our revenues and profitability. Accordingly, legislation and regulations affecting the pricing of

pharmaceutical products may change before our product candidate is approved for sale, which could further limit or eliminate reimbursement rates for our product candidate.

If any product candidate that we develop independently or through collaborations is approved but does not gain meaningful acceptance in its intended market, we are not likely to generate significant revenues or become profitable.

Even if any of our product candidates is successfully developed and we or a collaborator obtain the requisite regulatory approvals to commercialize it in the future, it may not gain market acceptance or utilization among physicians, patients or third party payers. The degree of market acceptance that our product candidates may achieve will depend on a number of factors, including:

- the therapeutic efficacy or perceived benefit of the product relative to existing therapies, if they exist;
- the timing of market approval and existing market for competitive drugs;
- the level of reimbursement provided by payers to cover the cost of the product to patients;
- the net cost of the product to the user or payer;
- the convenience and ease of administration of our product;
- the product's potential advantages over existing or alternative therapies;
- the actual or perceived safety of similar classes of products;
- the actual or perceived existence, prevalence and severity of negative side effects;
- the effectiveness of sales, marketing and distribution capabilities; and
- the scope of the product label approved by the FDA.

There can be no assurance that physicians will choose to prescribe or administer our product, if approved, to the intended patient population. If our product does not achieve meaningful market acceptance, or if the market for our product proves to be smaller than anticipated, we may not generate significant revenues or ever become profitable.

Even if we or a collaborator achieve market acceptance for our product, we may experience downward pricing pressure on the price of our product due to social or political pressure to lower the cost of drugs, which would reduce our revenue and future profitability.

Pressure from social activist groups and future government regulations, whose goal it is to reduce the cost of drugs, particularly in less developed nations, also may put downward pressure on the price of drugs, which could result in downward pressure on the prices of our product in the future.

We may be unable to successfully develop a product candidate that is the subject of collaboration if our collaborator does not perform, terminates our agreement, or delays the development of our product candidates.

We expect to continue to enter into and rely on license and collaboration agreements or other business arrangements with third parties to further develop and/or commercialize our existing and future product candidates. Such collaborators or partners may not perform as agreed upon or anticipated, fail to comply with strict regulations, or elect to delay or terminate their efforts in developing or commercializing our product candidates even though we have met our obligations under the arrangement. For example, if an existing or future collaborator does not devote sufficient time and resources to our collaboration arrangement, we may not realize the full potential benefits of the arrangement, and our results of operations may be adversely affected.

A majority of the potential revenue from existing and future collaborations will likely consist of contingent payments, such as payments for achieving development or regulatory milestones and royalties payable on the sales of approved products. The milestone and royalty revenues that we may receive under these collaborations will depend primarily upon our collaborator's ability to successfully develop and commercialize our product candidate. In addition, our collaborators may decide to enter into arrangements with third parties to commercialize products developed under our existing or future collaborations using our technologies, which could reduce the milestone and royalty revenue that we may receive, if any. In many cases, we will not be directly involved in the development or commercialization of our product candidate and, accordingly, will depend entirely on our collaborators. Our collaboration partners may fail to develop or effectively commercialize our product candidates because they:

- do not allocate the necessary resources due to internal constraints, such as limited personnel with the requisite scientific expertise, limited capital resources, or the belief that other product candidates or other internal programs may have a higher likelihood of obtaining regulatory approval or may potentially generate a greater return on investment;

- do not have sufficient resources necessary to fully support the product candidates through clinical development, regulatory approval and commercialization;

- are unable to obtain the necessary regulatory approvals; or
- may re-evaluate the importance and their support for developing our product candidates due to a change in management, business operations or financial strategy.

In addition, a collaborator may decide to pursue the development of a competitive product candidate developed outside of our collaboration with them. Conflicts may also arise if there is a dispute about the progress of, or other activities related to, the clinical development or commercialization of a product candidate, the achievement and payment of a milestone amount, the ownership of intellectual property that is developed during the course of the collaborative arrangement, or other licensing agreement terms. If a collaboration partner fails to develop or effectively commercialize our product candidate for any of these reasons, we may not be able to replace them with another partner willing to develop and commercialize our product candidate under similar terms, if at all. Similarly, we may disagree with a collaborator as to which party owns newly or jointly-developed intellectual property. Should an agreement be revised or terminated as a result of a dispute and before we have realized the anticipated benefits of the collaboration, we may not be able to obtain certain development support or revenues that we anticipated receiving. We may also be unable to obtain, on terms acceptable to us, a license from such collaboration partner to any of its intellectual property that may be necessary or useful for us to continue to develop and commercialize the product candidate.

If we are unable to adequately protect or expand our intellectual property related to our current or future product candidates, our business prospects could be harmed.

Our success, competitive position and future revenues will depend in part on our ability to obtain and maintain patent protection for our product candidates, methods, processes and other technologies, to preserve our trade secrets, to prevent third parties from infringing on our proprietary rights and to operate without infringing the proprietary rights of third parties.

We will be able to protect our proprietary intellectual property rights from unauthorized use by third parties only to the extent that our proprietary rights are covered by valid and enforceable patents or are effectively maintained as trade secrets. The patent position of pharmaceutical and biopharmaceutical companies involves complex legal and factual questions, and, therefore, we cannot predict with certainty whether we will be able to ultimately enforce our patents or proprietary rights. Therefore, any issued patents that we own or otherwise have intellectual property rights to may be challenged, invalidated or circumvented, and may not provide us with the protection against competitors that we anticipate. The degree of future protection for our proprietary intellectual property rights is uncertain because issued patents and other legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. Our future patent position will be influenced by the following factors:

- we or our licensors may not have been the first to discover the inventions covered by each of our or our licensors' pending patent applications and issued patents, and we may have to engage in expensive and protracted interference proceedings to determine priority of invention;

- our or our licensors' pending patent applications may not result in issued patents;

- our or our licensors' issued patents may not provide a basis for commercially viable products, may not provide us with any competitive advantages, or may be challenged by third parties; and

- third parties may develop intellectual property around our or our licensors' patent claims to design competitive intellectual property and ultimately product candidates that fall outside the scope of our or our licensors' patents.

Because of the extensive time required for the development, testing and regulatory review and approval of a product candidate, it is possible that before our product candidate can be approved for sale and commercialized, our relevant patent rights may expire, or such patent rights may remain in force for only a short period following approval and commercialization. Patent expiration could adversely affect our ability to protect future product development and, consequently, our operating results and financial position. Also, patent rights may not provide us with adequate proprietary protection or competitive advantages against competitors with similar technologies. The laws of certain foreign countries do not protect our intellectual property rights to the same extent as do the laws of the U.S. and those countries may lack adequate rules and procedures for defending our intellectual property rights. For example, we may not be able to prevent a third party from infringing our patents in a country that does not recognize or enforce patent rights, or that imposes compulsory licenses on or restricts the prices of life-saving drugs. Changes in either patent laws or in interpretations of patent laws in the U.S. and other countries may diminish the value of our intellectual property.

We may not develop or obtain rights to products or processes that are patentable. Even if we or our licensors do obtain patents, such patents may not adequately protect the products or technologies we own or have licensed, or otherwise be limited in scope. In addition, we may not have total control over the patent prosecution of subject matter that we license from others. Accordingly, we may be unable to exercise the same degree of control over this intellectual property as we would over our own. Others may challenge, seek to invalidate, infringe or circumvent any pending or issued patents we own or license, and rights we receive under those issued patents may not provide competitive advantages to us. We cannot assure you as to the degree of protection that will be afforded by any of our issued or pending patents, or those licensed by us.

If a third party claims we are infringing on its intellectual property rights, we could incur significant expenses, or be prevented from further developing or commercializing our product candidates.

Our success will also depend on our ability to operate without infringing the patents and other proprietary intellectual property rights of third parties. This is generally referred to as having the "freedom to operate". The biotechnology and pharmaceutical industries are characterized by extensive litigation regarding patents and other intellectual property rights. The defense and prosecution of intellectual property claims, United States Patent and Trademark Office, or USPTO, interference proceedings and related legal and administrative proceedings, both in the U.S. and internationally, involve complex legal and factual questions. As a result, such proceedings are lengthy, costly and time-consuming and their outcome is highly uncertain. We may become involved in protracted and expensive litigation in order to determine the enforceability, scope and validity of the proprietary rights of others, or to determine whether we have the freedom to operate with respect to the intellectual property rights of others.

Patent applications in the U.S. are, in most cases, maintained in secrecy until approximately 18 months after the patent application is filed. The publication of discoveries in the scientific or patent literature frequently occurs substantially later than the date on which the underlying discoveries were made. Therefore, patent applications relating to products similar to our product candidate may have already been filed by others without our knowledge. In the event that a third party has also filed a patent application covering our product candidate or other claims, we may have to participate in an adversarial proceeding, known as an interference proceeding in the USPT office, or similar proceedings in other countries to determine the priority of invention. In the event an infringement claim is brought against us, we may be required to pay substantial legal fees and other expenses to defend such a claim and, if we are unsuccessful in defending the claim, we may be prevented from pursuing the development and commercialization of a product candidate and may be subject to injunctions and/or damage awards.

In the future, the USPT or a foreign patent office may grant patent rights to our product candidate or other claims to third parties. Subject to the issuance of these future patents, the claims of which will be unknown until issued, we may need to obtain a license or sublicense to these rights in order to have the appropriate freedom to further develop or commercialize them. Any required licenses may not be available to us on acceptable terms, if at all. If we need to obtain such licenses or sublicenses, but are unable to do so, we could encounter delays in the development of our product candidate, or be prevented from developing, manufacturing and commercializing our product candidate at all. If it is determined that we have infringed an issued patent and do not have the freedom to operate, we could be subject to injunctions, and/or compelled to pay significant damages, including punitive damages. In cases where we have in-licensed intellectual property, our failure to comply with the terms and conditions of such agreements could harm our business.

It is becoming common for third parties to challenge patent claims on any successful product candidate or approved drug. If we or our collaborators become involved in any patent litigation, interference or other legal proceedings, we could incur substantial expense, and the efforts of our technical and management personnel will be significantly diverted. A negative outcome of such litigation or proceedings may expose us to the loss of our proprietary position or to significant liabilities, or require us to seek licenses that may not be available from third parties on commercially acceptable terms, if at all. We may be restricted or prevented from developing, manufacturing and selling our product candidate in the event of an adverse determination in a judicial or administrative proceeding, or if we fail to obtain necessary licenses.

We cannot be sure that any patents will be issued or that patents licensed to us will be issued from any of our patent applications or, should any patents issue, that we will be provided with adequate protection against potentially competitive products. Furthermore, we cannot be sure that patents issued or licensed to us will be of any commercial value, or that private parties or competitors will not successfully challenge these patents or circumvent our patent position in the U.S. or abroad. In the absence of adequate patent protection, our business may be adversely affected by competitors who develop comparable technology or products.

Confidentiality agreements with employees and others may not adequately prevent disclosure of trade secrets and other proprietary information and may not adequately protect our intellectual property.

We rely on trade secrets to protect our technology, especially where we do not believe patent protection is obtainable, or prior to us filing patent applications on inventions we may make from time to time. However, trade secrets are difficult to protect. In order to protect our proprietary technology and processes, we also rely in part on confidentiality and intellectual property assignment agreements with our corporate partners, employees, consultants, outside scientific collaborators and sponsored researchers and other advisors. These agreements may not effectively prevent disclosure of confidential information nor result in the effective assignment to us of intellectual property, and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information or other breaches

of the agreements. In addition, others may independently discover our trade secrets and proprietary information, and in such case, we could not assert any trade secret rights against such party. Enforcing a claim that a third-party illegally obtained and is using our trade secrets is difficult, expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the U.S. may be less willing to protect trade secrets. Costly and time-consuming litigation could be necessary to seek to enforce and determine the scope of our proprietary rights, and failure to obtain or maintain trade secret protection could adversely affect our competitive business position.

Our failure to successfully discover, acquire, develop and market additional product candidates or approved products would impair our ability to grow.

As part of our growth strategy, we intend to develop and market additional products and product candidates. We expect to be pursuing various therapeutic opportunities through our product candidates. We may spend several years completing our development of any particular current or future internal product candidate, and failure can occur at any stage. The product candidates to which we allocate our resources may not end up being successful. In addition, because our internal research capabilities are limited, we may be dependent upon pharmaceutical and biotechnology companies, academic scientists and other researchers to sell or license products or technology to us. The success of this strategy depends partly upon our ability to identify, select, discover and acquire promising pharmaceutical product candidates and products. Failure of this strategy would impair our ability to grow.

The process of proposing, negotiating and implementing a license or acquisition of a product candidate or approved product is lengthy and complex. Other companies, including some with substantially greater financial, marketing and sales resources, may compete with us for the license or acquisition of product candidates and approved products. We have limited resources to identify and execute the acquisition or in-licensing of third-party products, businesses and technologies and integrate them into our current infrastructure. Moreover, we may devote resources to potential acquisitions or in-licensing opportunities that are never completed, or we may fail to realize the anticipated benefits of such efforts. We may not be able to acquire the rights to additional product candidates on terms that we find acceptable, or at all.

In addition, future acquisitions may entail numerous operational and financial risks, including:

- disruption of our business and diversion of our management's time and attention to develop acquired products or technologies;
- incurrence of substantial debt, dilutive issuances of securities or depletion of cash to pay for acquisitions;
- higher than expected acquisition and integration costs;
- difficulty in combining the operations and personnel of any acquired businesses with our operations and personnel;
- increased amortization expenses;
- impairment of relationships with key suppliers or customers of any acquired businesses due to changes in management and ownership;
- inability to motivate key employees of any acquired businesses; and
- assumption of known and unknown liabilities.

Further, any product candidate that we acquire may require additional development efforts prior to commercial sale, including extensive clinical testing and approval by the FDA and applicable foreign regulatory authorities. All product candidates are prone to risks of failure typical of pharmaceutical product development, including the possibility that a product candidate will not be shown to be sufficiently safe and effective for approval by regulatory authorities.

Even if our product candidates receive regulatory approval, it may still face future development and regulatory difficulties.

Even if U.S. regulatory approval is obtained, the FDA may still impose significant restrictions on a product's indicated uses or impose ongoing requirements for potentially costly post-approval studies. Our product candidates would also be subject to ongoing FDA requirements governing the labeling, packaging, storage, advertising, promotion, recordkeeping and submission of safety and other post-market information. In addition, manufacturers of drug products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with GMP regulations. If we or a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions on that product or the manufacturer, including requiring withdrawal of the product from the market or suspension of manufacturing. If we, our product candidate or the manufacturing facilities for our product candidate fail to comply with applicable regulatory requirements, a regulatory agency may:

- issue warning letters;

- impose civil or criminal penalties;
- suspend regulatory approval;
- suspend any ongoing clinical trials;
- refuse to approve pending applications or supplements to applications filed by us;
- impose restrictions on operations, including costly new manufacturing requirements;
- seize or detain products or request us to initiate a product recall; or
- pursue and obtain an injunction.

Even if our product candidate receives regulatory approval in the United States, we may never receive approval to commercialize it outside of the United States.

In the future, we may seek to commercialize our product candidates in foreign countries outside of the United States. In order to market any products outside of the United States, we must establish and comply with numerous and varying regulatory requirements of other jurisdictions regarding safety and efficacy. Approval procedures vary among jurisdictions and can involve product testing and administrative review periods different from, and greater than, those in the United States. The time required to obtain approval in other jurisdictions might differ from that required to obtain FDA approval. The regulatory approval process in other jurisdictions may include all of the risks detailed above regarding FDA approval in the United States as well as other risks. Regulatory approval in one jurisdiction does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory processes in others. Failure to obtain regulatory approvals in other jurisdictions or any delay or setback in obtaining such approvals could have the same adverse effects detailed above regarding FDA approval in the United States. As described above, such effects include the risks that our product candidates may not be approved for all indications for use included in proposed labeling or for any indications at all, which could limit the uses of our product candidates and have an adverse effect on our products' commercial potential or require costly post-marketing studies.

We intend to rely on third parties to conduct our clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to seek or obtain regulatory approval for or commercialize our product candidate.

We intend to enter into agreements with third-party contract research organizations, or CROs, under which we will delegate to the CROs the responsibility to coordinate and monitor the conduct of our clinical trials and to manage data for our clinical programs. We, our CROs and our clinical sites are required to comply with current Good Clinical Practices, or cGCPs, regulations and guidelines issued by the FDA and by similar governmental authorities in other countries where we are conducting clinical trials. We have an ongoing obligation to monitor the activities conducted by our CROs and at our clinical sites to confirm compliance with these requirements. In the future, if we, our CROs or our clinical sites fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA may require us to perform additional clinical trials before approving our marketing applications. In addition, our clinical trials must be conducted with product produced under cGMP regulations, and will require a large number of test subjects. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced, or if the quality or accuracy of the clinical data they obtain is compromised due to their failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for or successfully commercialize our product candidate. As a result, our financial results and the commercial prospects for our product candidate would be harmed, our costs could increase, and our ability to generate revenue could be delayed.

We will need to increase the size of our organization.

We are a small company with 1 employee as of September 30, 2018. To execute our business plan, including the future conducting of clinical trials and the expected commercialization of our product candidates, we will need to expand our employee base for managerial, operational, financial and other resources. Future growth will impose significant added responsibilities on members of management, including the need to identify, recruit, maintain and integrate additional employees. Over the next 12 months depending on the progress of our acquisition efforts and future planned business development and capital raising efforts, we plan to add additional employees to assist us with our development programs. Our future financial performance and our ability to commercialize our product candidates and to compete effectively will depend, in part, on our ability to manage any future growth effectively. To that end, we must be able to:

- manage development efforts effectively;
- manage any future clinical trials effectively;
- integrate additional management, administrative, manufacturing and sales and marketing personnel;
- maintain sufficient administrative, accounting and management information systems and controls; and
- hire and train additional qualified personnel.

We may not be able to accomplish these tasks, and our failure to accomplish any of them could harm our financial results and impact our ability to achieve development milestones.

Reimbursement may not be available for our product candidates, which would impede sales.

Market acceptance and sales of our product candidate may depend on coverage and reimbursement policies and health care reform measures. Decisions about formulary coverage as well as levels at which government authorities and third- party payers, such as private health insurers and health maintenance organizations, reimburse patients for the price they pay for our products as well as levels at which these payers pay directly for our products, where applicable, could affect whether we are able to commercialize these products. We cannot be sure that reimbursement will be available for any of these products. Also, we cannot be sure that coverage or reimbursement amounts will not reduce the demand for, or the price of, our products. We have not commenced efforts to have our product candidate reimbursed by government or third party payers. If coverage and reimbursement are not available or are available only at limited levels, we may not be able to commercialize our products.

In recent years, officials have made numerous proposals to change the health care system in the United States. These proposals include measures that would limit or prohibit payments for certain medical treatments or subject the pricing of drugs to government control. In addition, in many foreign countries, particularly the countries of the European Union, the pricing of prescription drugs is subject to government control. If our products are or become subject to government regulation that limits or prohibits payment for our products, or that subjects the price of our products to governmental control, we may not be able to generate revenue, attain profitability or commercialize our products.

As a result of legislative proposals and the trend towards managed health care in the United States, third-party payers are increasingly attempting to contain health care costs by limiting both coverage and the level of reimbursement of new drugs. They may also impose strict prior authorization requirements and/or refuse to provide any coverage of uses of approved products for medical indications other than those for which the FDA has granted market approvals. As a result, significant uncertainty exists as to whether and how much third-party payers will reimburse patients for their use of newly- approved drugs, which in turn will put pressure on the pricing of drugs.

Healthcare reform measures could hinder or prevent our product candidate's commercial success.

The U.S. government and other governments have shown significant interest in pursuing healthcare reform. Any government-adopted reform measures could adversely impact the pricing of healthcare products and services in the United States or internationally and the amount of reimbursement available from governmental agencies or other third-party payers. The continuing efforts of the U.S. and foreign governments, insurance companies, managed care organizations and other payers of health care services to contain or reduce health care costs may adversely affect our ability to set prices for our products which we believe are fair, and our ability to generate revenues and achieve and maintain profitability.

New laws, regulations and judicial decisions, or new interpretations of existing laws, regulations and decisions, that relate to healthcare availability, methods of delivery or payment for products and services, or sales, marketing or pricing, may limit our potential revenue, and we may need to revise our research and development programs. The pricing and reimbursement environment may change in the future and become more challenging due to several reasons, including policies advanced by the current executive administration in the United States, new healthcare legislation or fiscal challenges faced by government health administration authorities. Specifically, in both the United States and some foreign jurisdictions, there have been a number of legislative and regulatory proposals to change the health care system in ways that could affect our ability to sell our products profitably.

For example, in March 2010, President Obama signed the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or the PPACA. This law will substantially change the way healthcare is financed by both government health plans and private insurers, and significantly impact the pharmaceutical industry. The PPACA contains a number of provisions that are expected to impact our business and operations in ways that may negatively affect our potential revenues in the future. For example, the PPACA imposes a non-deductible excise tax on pharmaceutical manufacturers or importers that sell branded prescription drugs to U.S. government programs which we believe will increase the cost of our products. In addition, as part of the PPACA's provisions closing a funding gap that currently exists in the Medicare Part D prescription drug program (commonly known as the "donut hole"), we will be required to provide a discount on branded prescription drugs equal to 50% of the government-negotiated price, for

drugs provided to certain beneficiaries who fall within the donut hole. Similarly, PPACA increases the level of Medicaid rebates payable by manufacturers of brand-name drugs from 15.1% to 23.1% and requires collection of rebates for drugs paid by Medicaid managed care organizations. The PPACA also includes significant changes to the 340B drug discount program including expansion of the list of eligible covered entities that may purchase drugs under the program. At the same time, the expansion in eligibility for health insurance benefits created under PPACA is expected to increase the number of patients with insurance coverage who may receive our products. While it is too early to predict all the specific effects the PPACA or any future healthcare reform legislation will have on our business, they could have a material adverse effect on our business and financial condition.

Congress periodically adopts legislation like the PPACA and the Medicare Prescription Drug, Improvement and Modernization Act of 2003, that modifies Medicare reimbursement and coverage policies pertaining to prescription drugs. Implementation of these laws is subject to ongoing revision through regulatory and sub regulatory policies. Congress also may consider additional changes to Medicare policies, potentially including Medicare prescription drug policies, as part of ongoing budget negotiations. While the scope of any such legislation is uncertain at this time, there can be no assurances that future legislation or regulations will not decrease the coverage and price that we may receive for our proposed products. Other third-party payers are increasingly challenging the prices charged for medical products and services. It will be time consuming and expensive for us to go through the process of seeking coverage and reimbursement from Medicare and private payors. Our proposed products may not be considered cost-effective, and coverage and reimbursement may not be available or sufficient to allow us to sell our proposed products on a profitable basis. Further federal and state proposals and health care reforms are likely which could limit the prices that can be charged for the product candidate that we develop and may further limit our commercial opportunities. Our results of operations could be materially adversely affected by proposed healthcare reforms, by the Medicare prescription drug coverage legislation, by the possible effect of such current or future legislation on amounts that private insurers will pay and by other health care reforms that may be enacted or adopted in the future.

In September 2007, the Food and Drug Administration Amendments Act of 2007 was enacted, giving the FDA enhanced post-marketing authority, including the authority to require post-marketing studies and clinical trials, labeling changes based on new safety information, and compliance with risk evaluations and mitigation strategies approved by the FDA. The FDA's exercise of this authority could result in delays or increased costs during product development, clinical trials and regulatory review, increased costs to assure compliance with post-approval regulatory requirements, and potential restrictions on the sale and/or distribution of approved products.

Security breaches and other disruptions could compromise our information and expose us to liability, which would cause our business and reputation to suffer.

In the ordinary course of our business, we collect and store sensitive data, including intellectual property, our proprietary business information and that of our suppliers and business partners, as well as personally identifiable information of clinical trial participants and employees. Similarly, our business partners and third-party providers possess certain of our sensitive data. The secure maintenance of this information is critical to our operations and business strategy. Despite our security measures, our information technology and infrastructure may be vulnerable to attacks by hackers or breached due to employee error, malfeasance or other disruptions. Any such breach could compromise our networks and the information stored there could be accessed, publicly disclosed, lost or stolen. Any such access, disclosure or other loss of information, including our data being breached at our business partners or third-party providers, could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, disrupt our operations, and damage our reputation which could adversely affect our business.

Our clinical activities involve the handling of hazardous materials, and we must comply with environmental laws and regulations, which can be expensive and restrict how we do business.

Our clinical activities involve the controlled storage, use and disposal of hazardous materials. We are subject to federal, state, city and local environmental, health and safety laws and regulations governing, among other matters, the use, manufacture, storage, handling and disposal of these hazardous materials. We cannot eliminate the risk of accidental contamination or injury from these materials. In the event of an accident or if we fail to comply with such laws and regulations, local, city, state or federal authorities may curtail the use of these materials and interrupt our business operations or impose sanctions, such as fines, and we could be held liable for any resulting damages or liabilities. We do not currently maintain hazardous materials insurance coverage.

Risks Related to Our Common Stock

Management identified material weaknesses in our internal controls, and failure to remediate it or any future ineffectiveness of internal controls could have a material adverse effect on the Company's business and the price of its common stock.

Our management determined that our disclosure controls and procedures and internal controls were ineffective as of December 31, 2017 and 2016 and if they continue to be ineffective could result in material misstatements in our financial statements.

Management continues to review our internal control systems, processes and procedures for compliance with the requirements of a smaller reporting company under Section 404 of the Sarbanes-Oxley Act. Such a review resulted in identification of material weaknesses in our internal controls and a conclusion that our disclosure controls and procedures and internal control over financial reporting

("ICFR") were ineffective as of the end of the period covered by this Report.

A "material weakness" is a deficiency, or a combination of deficiencies, in ICFR, such that there is a reasonable possibility that a material misstatement of the company's annual or interim financial statements will not be prevented or detected on a timely basis. We plan to take measures to remediate these deficiencies, such as providing additional training to our accounting staff in US GAAP. However, the implementation of these measures may not fully address the control deficiencies in our ICFR. Our failure to address any control deficiency could result in inaccuracies in our financial statements and could also impair our ability to comply with applicable financial reporting requirements and related regulatory filings on a timely basis. Moreover, effective ICFR is important to prevent fraud. As a result, our business, financial condition, results of operations and prospects, as well as the trading price of our shares, may be negatively impacted by a failure to accurately report financial results.

The material weaknesses and other matters impacting the Company's internal controls may cause it to be unable to report its financial information on a timely basis and thereby subject it to adverse regulatory consequences, including sanctions by the SEC or violations of applicable stock exchange or quotation service listing rules. There could also be a negative reaction in the financial markets due to a loss of investor confidence in the Company and the reliability of its financial statements. Confidence in the reliability of the Company's financial statements may suffer due to the Company's reporting of material weaknesses in its internal controls over financial reporting. This could materially adversely affect the Company and lead to a decline in the price of its common stock.

If we continue to fail to comply with the rules under the Sarbanes-Oxley Act of 2002 related to disclosure controls and procedures, or, if we discover material weaknesses and other deficiencies in our internal control and accounting procedures, our stock price could decline significantly and raising capital could be more difficult.

If we fail to comply with the rules under the Sarbanes-Oxley Act of 2002 related to disclosure controls and procedures, or, if we discover additional material weaknesses and other deficiencies in our internal control and accounting procedures, our stock price could decline significantly and raising capital could be more difficult. Moreover, effective internal controls are necessary for us to produce reliable financial reports and are important to helping prevent financial fraud. If we cannot provide reliable financial reports or prevent fraud, our business and operating results could be harmed, investors could lose confidence in our reported financial information, and the trading price of our common stock could drop significantly. In addition, we cannot be certain that additional material weaknesses or significant deficiencies in our internal controls will not be discovered in the future.

Our common stock price could continue to be volatile and you could lose the value of your investment.

Our stock price has been volatile and has fluctuated significantly in the past. The market price of our common stock could continue to be volatile and could fluctuate widely in price in response to various factors, many of which are beyond our control, including: technological innovations or new products and services by us or our competitors; additions or departures of key personnel; sales of our common stock; our ability to integrate operations, technology, products and services; our ability to execute our business plan; operating results below expectations; loss of any strategic relationships; industry developments; economic and other external factors; and period-to-period fluctuations in our financial results. Because we have a very limited operating history with no revenues to date, you may consider any one of these factors to be material. Our stock price may fluctuate widely as a result of any of the above. In addition, the securities markets have from time to time experienced significant price and volume fluctuations that are unrelated to the operating performance of particular companies. These market fluctuations may also materially and adversely affect the market price of our common stock. Your investment in our stock could lose some or all of its value.

Stockholders may have difficulty reselling their shares of common stock if we fail to stay listed on the OTCQB.

The Company's common stock was historically quoted on the OTCQB, the middle tier of the OTC Marketplace, under the ticker symbol "GBSX." Companies trading on the OTCQB generally must be reporting issuers under Section 12 of the Securities Exchange Act of 1934, as amended, and must be current in their reports under Section 13, in order to maintain price quotation privileges on the OTCQB. However, due to the fact the Company failed to file this Annual Report with the U.S. Securities and Exchange Commission by the April 15, 2014 extended deadline, the Company's common stock was moved from the OTCQB to the OTC Pink tier, the bottom tier of the OTC Markets. Now that our registration statement on Form 10 is effective and we have returned to reporting compliance under the Exchange Act, our common stock quotation has been restored to the OTCQB. If we fail to remain current in our annual and quarterly periodic reports with the SEC, our common stock quotation will be returned to the OTC Pink tier. Trading in stock quoted on the OTC Pink tier is often thin and characterized by wide fluctuations in trading prices, due to many factors that may have little to do with an issuer's operations or business prospects. Such volatility of trading of our common stock could depress the market price of our common stock for reasons unrelated to operating performance and result in investors having difficulty reselling any shares of our common stock.

The application of the "penny stock" rules could adversely affect the market price of our common stock and increase your transaction costs to sell those shares.

The Securities and Exchange Commission adopted Rule 15g-9 which generally defines "penny stock" to be any equity security that has a market price (as defined) less than $5.00 per share or an exercise price of less than $5.00 per share, subject to certain exceptions. If

the trading price of our common stock falls below $5.00 per share, the open-market trading of our common stock is subject to the penny stock rules, which imposes additional sales practice requirements on broker-dealers who sell to persons other than established customers and "accredited investors". The term accredited investor" refers generally to institutions with assets in excess of $5,000,000 or individuals with a net worth in excess of $1,000,000 or annual income exceeding $200,000 or $300,000 jointly with their spouse. The penny stock rules require a broker-dealer, prior to a transaction in a penny stock not otherwise exempt from the rules, to deliver a standardized risk disclosure document in a form prepared by the SEC, which provides information about penny stocks and the nature and level of risks in the penny stock market. The broker-dealer also must provide the customer with current bid and offer quotations for the penny stock, the compensation of the broker-dealer and its salesperson in the transaction and monthly account statements showing the market value of each penny stock held in the customer's account. The bid and offer quotations, and the broker-dealer and salesperson compensation information, must be given to the customer orally or in writing prior to effecting the transaction and must be given to the customer in writing before or with the customer's confirmation. In addition, the penny stock rules require that prior to a transaction in a penny stock not otherwise exempt from these 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 level of trading activity in the secondary market for the stock that is subject to these penny stock rules. Consequently, these penny stock rules may affect the ability of broker-dealers to trade our securities. We believe the penny stock rules discourage investor interest in and limit the marketability of our common stock.

FINRA sales practice requirements may also limit a stockholder's ability to buy and sell our common stock.

In addition to the "penny stock" rules described above, FINRA adopted rules that require that in recommending an investment to a customer, a broker-dealer must have reasonable grounds for believing that the investment is suitable for that customer. Prior to recommending speculative low priced securities to their non-institutional customers, broker-dealers must make reasonable efforts to obtain information about the customer's financial status, tax status, investment objectives and other information. Under interpretations of these rules, FINRA believes that there is a high probability that speculative low priced securities will not be suitable for at least some customers. FINRA requirements make it more difficult for broker-dealers to recommend that their customers buy our common stock, which may limit your ability to buy and sell our stock and have an adverse effect on the market for our shares.

Stockholders should have no expectation of any dividends.

The holders of our common stock are entitled to receive dividends when, as and if declared by the Board of Directors out of funds legally available therefore. To date, we have not declared or paid any cash dividends. The Board of Directors does not intend to declare any dividends in the foreseeable future, but instead intends to retain all earnings, if any, for use in our business operations.

Certain provisions in our certificate of incorporation and by-laws, and of Nevada law, may prevent or delay an acquisition of our company, which could decrease the trading price of our common stock.

Our certificate of incorporation, by-laws and Nevada law contain provisions that are intended to deter coercive takeover practices and inadequate takeover bids by making such practices or bids unacceptably expensive to the raider and to encourage prospective acquirers to negotiate with our board of directors rather than to attempt a hostile takeover. These provisions include, among others:

- the inability of our stockholders to call a special meeting;
- rules regarding how stockholders may present proposals or nominate directors for election at stockholder meetings;
- the right of our board to issue preferred stock without stockholder approval;
- the ability of our directors, and not stockholders, to fill vacancies on our board of directors.

Future sales and issuances of our common stock or rights to purchase common stock pursuant to our equity incentive plan could result in additional dilution of the percentage ownership of our stockholders and could cause our share price to fall.

We expect that significant additional capital will be needed in the future to continue our planned operations, including expanding research and development, funding clinical trials, purchasing of capital equipment, hiring new personnel, commercializing our products, and continuing activities as an operating public company. To the extent we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution. We may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities or other equity securities in more than one transaction, investors may be materially diluted by subsequent sales. Such sales may also result in material dilution to our existing stockholders, and new investors could gain rights superior to our existing stockholders.

We are an "emerging growth company" and as a result of our reduced disclosure requirements applicable to emerging growth companies, our common stock may be less attractive to investors.

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, and we intend to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not "emerging growth companies" including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. We could remain an "emerging growth company" until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the completion of our initial public offering in February 2014, (b) in which we have total annual gross revenue of at least $1.0 billion, or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeded $700.0 million as of the prior December 31st, and (2) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period. We cannot predict whether investors will find our common stock less attractive because we will rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards, and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

We may be at risk of securities class action litigation.

We may be at risk of securities class action litigation. In the past, life sciences, biotechnology and pharmaceutical companies have experienced significant stock price volatility, particularly when associated with binary events such as clinical trials and product approvals. If we face such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business and results in a decline in the market price of our common stock.

If securities or industry analysts do not publish research or reports about our business, or if they change their recommendations regarding our stock adversely, our stock price and trading volume could decline.

The trading market for our common stock will be influenced by the research and reports that industry or securities analysts publish about us or our business. We do not currently have and may never obtain research coverage by industry or financial analysts. If no or few analysts commence coverage of us, the trading price of our stock would likely decrease. Even if we do obtain analyst coverage, if one or more of the analysts who cover us downgrade our stock, our stock price would likely decline. If one or more of these analysts cease coverage of our company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

The Company does not own or rent any properties. Our principal executive office is located at 109 Ambersweet Way, #401 Davenport, Florida 33897 and our telephone number is (732) 723-7395.

Item 3. Legal Proceedings

We know of no material, active or pending legal proceedings against our Company, nor are we involved as a plaintiff in any material proceeding or pending litigation. There are no proceedings in which any of our directors, officers or affiliates, or any registered or beneficial shareholder, is an adverse party or has a material interest adverse to our interest.

Item 4. Mine Safety Disclosure

Not applicable.

PART II

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

Market Information

We were incorporated in Nevada on March 20, 2007 as SWAV Enterprises Ltd. ("SWAV"). On September 16, 2010, SWAV changed its name to GBS Enterprises Incorporated. On October 14, 2010, the trading symbol of the Company's Common Stock on the OTC

Market was changed from SWAV to GBSX and on July 27, 2018, the trading symbol of the Company's Common Stock was changed again to "MRZM."

Description of Common Stock

We are authorized to issue 75,000,000 shares, par value $0.001 per share, of Common Stock, of which 20,163,939 shares were issued and outstanding as of April 15, 2020. Holders of Common Stock are entitled to one vote per share on each matter submitted to a vote at any meeting of stockholders. Shares of Common Stock do not carry cumulative voting rights and, therefore, holders of a majority of the outstanding shares of Common Stock will be able to elect the entire Board of Directors, and, if they do so, minority stockholders would not be able to elect any members to the Board of Directors. Our Board of Directors has authority, without action by the stockholders, to issue all or any portion of the authorized but unissued shares of Common Stock, which would reduce the percentage ownership of the stockholders and which may dilute the book value of the Common Stock. Stockholders have no pre-emptive rights to acquire additional shares of Common Stock. The Common Stock is not subject to redemption and carries no subscription or conversion rights. In the event of liquidation, the shares of Common Stock are entitled to share equally in corporate assets after satisfaction of all liabilities. The shares of Common Stock, when issued, will be fully paid and non-assessable.

Holders of Common Stock are entitled to receive dividends as the Board of Directors may from time to time declare out of funds legally available for the payment of dividends. We have not paid dividends on Common Stock and do not anticipate that we will pay dividends in the foreseeable future.

All shares of Common Stock now outstanding are duly authorized, fully paid and non-assessable.

Preferred Stock

The Company is currently authorized to issue up to 25,000,000 "blank check" shares of Preferred Stock with all designations, rights and privileges as the Company's Board of Directors may decide, from time to time, without stockholder approval. As of March 6, 2019, there are no shares of Preferred Stock issued or outstanding.

On April 4, 2018 the Board of Directors agreed to create, and issued, 1,000 shares of Series A Non-Convertible Preferred Stock to Mr. Nicholas P. DeVito immediately prior to the resignations of Mr. Ott, Mr. Moore, and Mr. Shihadah. The Series A Non-Convertible Preferred Stock represented eighty percent (80%) of all of the votes entitled to be voted at any annual or special meeting of the shareholders of the Company or action by written consent of the shareholders. Mr. DeVito surrendered the 1,000 shares of Series A Non-Convertible Preferred Stock in exchange for 1,500,000 shares of Common Stock on September 13, 2018.

Transfer Agent

Action Stock Transfer Corporation
2469 E. Fort Union Blvd., Suite 214
Salt Lake City, UT 84121

Telephone: (801) 274-1088
Fax: (801) 274-1099
Email: justblank2000@yahoo.com
Website: www.actionstocktransfer.com

Holders

As of April 15,2020, 2020, we had 163 record holders of our Common Stock (not including beneficial owners who hold shares at broker/dealers in "street name").

Dividend Policy

While there are no restrictions that limit our ability to pay dividends, we have not paid, and do not currently intend to pay cash dividends on our Common Stock in the foreseeable future. Our policy is to retain all earnings, if any, to provide funds for the operation and expansion of our business. The declaration of dividends, if any, will be subject to the discretion of our Board of Directors, which may consider such factors as our results of operations, financial condition, capital needs and acquisition strategy, among others.

Issuer Purchases of Equity Securities

None

Item 6. Selected Financial Data.

Not applicable

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

The following discussion and analysis should be read in conjunction with our audited financial statements and the notes to those financial statements that are included elsewhere in this Annual Report on Form 10-K. Our discussion includes forward-looking statements based upon current expectations that involve risks and uncertainties, such as our plans, objectives, expectations and intentions. Actual results and the timing of events could differ materially from those anticipated in these forward-looking statements as a result of a number of factors, including those set forth under the "Risk Factors", "Cautionary Notice Regarding Forward-Looking Statements" and "Description of Business" sections and elsewhere in this annual report. We use words such as "anticipate," "estimate," "plan," "project," "continuing," "ongoing," "expect," "believe," "intend," "may," "will," "should," "could," "predict," and similar expressions to identify forward-looking statements. Although we believe the expectations expressed in these forward-looking statements are based on reasonable assumptions within the bound of our knowledge of our business, our actual results could differ materially from those discussed in these statements. Factors that could contribute to such differences include, but are not limited to, those discussed in the Risk Factors" section of this Annual Report. We undertake no obligation to update publicly any forward-looking statements for any reason even if new information becomes available or other events occur in the future. Except as required by applicable law, including the securities laws of the United States, we do not intend to update any of the forward-looking statements to conform these statements to actual results. Readers are urged to carefully review and consider the various disclosures made throughout the entirety of this annual report, which attempt to advise interested parties of the risks and factors that may affect our business, financial condition, results of operations, and prospects.

Overview

Marizyme, Inc., a Nevada corporation formerly known as GBS Enterprises Incorporated, conducted its primary business through its minority owned subsidiary, GBS Software AG, or GROUP, a German-based public-company whose stock trades on the Frankfurt Exchange. GROUP's software and consulting business was focused on serving IBM's Lotus Notes and Domino market. On March 21, 2018, GBS formed a wholly owned subsidiary named Marizyme, Inc., a Nevada Corporation and merged it with GBS Enterprises and renamed the Company Marizyme. The Company effectively spun off its legacy software business with the distribution of the shares of X-Assets to the Company's stockholders on September 5, 2018, as discussed elsewhere in this Annual Report.

Marizyme currently is focused on bringing early stage biotechnology assets to market and on September 12, 2018, consummated an asset purchase agreement with ACB Holding AB, Reg. No. 559119-5762, a Swedish corporation.

The Company's Common Stock is currently quoted on the OTC Markets' QB tier under the symbol "MRZM." We may also examine our options with respect to the listing of our Common Stock on the Nasdaq Stock market or the NYSE.

Products and Services

GBS had grown by consolidating the fragmented Lotus Software market through the acquisition of companies with complementary product, technology or services offerings. GBS had developed its software and service business to service and support GBS's expanding Lotus customer base. Historically, we had achieved growth by acquiring underperforming companies with complimentary operations and leveraging GROUP's expertise to turnaround and integrate these companies. This legacy business was spun off on September 5, 2018.

Marizyme is now focused on the life sciences business and no longer intends to operate a software products and services business. Marizyme's intentions for developing its new biotechnology focused products are discussed in detail in its Plan of Operation set forth below.

Change in Financial Condition

Results of Operations

Fiscal Year Ended December 31, 2019 compared to Fiscal Year Ended December 31, 2018

Revenues

For the fiscal year ended December 31, 2019, total revenue decreased to $-0- from $20,187 at December 31, 2018. The Company generated revenue from professional services rendered.

Cost of Goods Sold

For the fiscal year ended December 31, 2019, the Company's Cost of Goods Sold decreased to $-0- from $20,074 at December 31,

2018. Cost of Goods Sold consists of Cost for Services, Cost for Third-Party Products and Cost for Software Licenses.

Operating Expenses

For the fiscal year ended December 31, 2019, the Company's Operating Expense increased to $977,075 from $120,387 for the fiscal year ended December 31, 2018. The Company's operating expenses for these periods consist of administrative expenses relating to legal, accounting, insurance and consulting services provided to the Company. These increases were primarily the result of rising administrative costs for professional services related to our required public company filings.

General Expenses

For the fiscal year ended December 31, 2019, general expenses decreased to $110,964 from $126,855 for the fiscal year ended December 31, 2018. General expenses consisted of office supplies, registration fees and travel.

Net Other Income (Expense)

For the fiscal year ended December 31, 2019, the Company experienced Net Other Expense of $-0- compared to Net Other Expense of $1,614 for the fiscal year ended December 31, 2018.

Liquidity & Capital Resources

At December 31, 2019, we had $90 in cash, compared to $104 at December 31, 2018. At December 31, 2019, our accumulated stockholders' deficit was $30,190,519 compared to $29,922,542 at December 31, 2018. There is substantial doubt as to our ability to continue as a going concern.

The Company's cash flow depended on the timely and successful market entry of its strategic offerings. Future cash flows are expected to be very small as the company continues its strategic focus on life sciences and biotechnology.

Especially for strategic offerings for paradigm shifting technologies, the management's budget plan is based on a series of assumptions regarding regulatory approval, market acceptance, readiness and pricing. While management's assumptions are based on market research, assumptions bear the risk of being incorrect and may result in a delay in projects, delays in regulatory approvals and consequently a delay or a reduction in the related strategic offerings. In case these delays have an impact on the Company's liquidity and therefore its ability to support its operations with the necessary cash flow, the Company depends on its ability to generate cash flow from other resources, such as debt financing from related or independent resources or equity financing from existing stockholders or through the stock market.

During the entire fiscal years 2018 and 2019 the Company sought other strategic assets in the biotechnology space. The Company expects to access internal and external sources for financing future projects. These sources may provide the necessary funds to support the working capital needs of the Company. There can be no assurances, however, that the Company will be able to obtain additional funds from these or any other sources or that such funds will be sufficient to permit the Company to implement its intended business strategy. In the event the Company is not able to generate sufficient additional funds, management will postpone or discontinue some or all of its product development operations until sufficient financing becomes available. Management believes, in accordance with the above-mentioned statement, the Company will need to raise money to support its planned operations for the current fiscal period.

Plan of Operations

We believe our cash balance as reported in our financial statements is not sufficient to fund our growth plan for any period of time. In order to fully implement our plan of operations for the next 12-month period, we will need to raise a significant amount of capital through multiple future offerings. The discussion below is based on the assumption that we will be able to raise significant capital in the first half of 2020. We will need to raise $10 million to fund operations for the next 12 months and complete the acquisition of assets from Somah, including $700,000 for governance and administrative purposes. After the next 12-month period, we most likely will need to raise additional financing. We do not currently have any arrangements for any such financing and there can be no assurances that we will be able to raise the required capital on acceptable terms, if at all. The discussion below revises and updates our plan of operation set forth in our Form 10, Amendment No. 2, filed with the SEC on November 19, 2018.

We have generated minimal revenues to date and, although we expect to raise significant capital in the future, there can be no assurances that we will be successful in these endeavors. We believe that the actions presently being taken to further implement our business plan and generate revenues will provide the opportunity for us to develop into a successful business operation.

During the next four quarters or 12 months, we expect to engage in the following business development activities:

2020Q2
- Asset Acquisition – Complete the acquisition of the Somah assets.
- Capital Raise – $10 million target (2019Q2)

Staffing/Hiring – Marizyme plans to hire a permanent CEO with life sciences background and a permanent CFO. To that end, on February 17, 2020, we entered into an employment agreement with Ralph Makar pursuant to which Mr. Makar agreed to become the Company's President and Chief Executive Officer effective on or about April 1, 2020, subject to our obtaining director and officer liability insurance.

2020Q3
- Marketing Campaign Initiation – Marizyme will begin plans to distribute Somah products in Europe and South America.
- Regulatory – If the acquisition of the Somah assets closes, Marizyme intends to submit a Pre-IND to the FDA for the DuraGraft product. Because the closing of the Somah asset acquisition is contingent on our raising $10 million, there can be no assurances that we will be able to raise these funds, close the transaction or proceed with the planned FDA filings.
- Dental – Marizyme plans to finalize a formulation for a Krillase based dental application. If successful, we plan to seek a manufacturing and licensing partner for distribution in various regions around the world.

2020Q4
- Staffing/Hiring – Marizyme will need to hire or contract additional human resources to effectively achieve our operational plans including in the areas of clinical, manufacturing and testing.
- Wound Healing – We plan to leverage our relationships in Europe and South America to commercialize our Krillase wound healing application for manufacture and distribution in those regions.

2021Q1
- FDA Submission – Marizyme plans to file an Investigational Drug Application or IND for the Krillase based MB102 stroke indication.

The 12-month operational plan detailed above is based on the following additional assumptions:

- That we will be able to replicate and scale the manufacturing process for DuraGraft.
- Based on the previous European clinical trials, the FDA will allow us clinically to test DuraGraft in the U.S.
- Markets are stable enough to raise the necessary capital to complete our operational plan.

We can provide no assurances, however, that we will be able to successfully raise sufficient funds in the next six months or longer to begin to execute these plans, to reach or to develop, offer and generate revenues from any of our designated business activities and development actions. Also, we cannot assure you that we will be able to raise additional capital or debt as and when needed on acceptable terms if at all.

Additional Cash Requirements

We expect to incur additional administrative expenses during the next 12 months. We estimate that we will need the following amounts during the next 12 months to cover these administrative expenses:

Category	**Estimated Amount**
Salaries, Fees	$ 3,500,000
Legal	100,000
Accounting	100,000
OTC Listing Fees	50,000
Professional Fees	600,000
Clinical Trials	2,000,000
Marketing and Distribution	2,450,000
IP extensions and reserves	1,200,000
TOTAL	$10,000,000

This capital will be used to build out our corporate infrastructure, to provide for the payment of advisory and accounting services, legal, and anticipated up-listing fees for the NYSE Markets or Nasdaq Capital Market, if we choose to pursue one of those markets. However, there can be no assurance that we will qualify for uplisting to either exchange or that our application, if we submit one, will be approved.

Additional capital may also be required to perform further testing and trials to bring our assets to market.

We may raise these funds through equity financing, debt financing, or other sources, which may result in further dilution in the equity ownership of our Common Stock. There is no assurance that we will be able to maintain operations at a level sufficient for investors to obtain a return on their investment in our Common Stock, or that we will be able to raise sufficient capital required to implement our business plan on acceptable terms, if at all. Even if we are successful in raising sufficient capital to implement our business plan, we will, most likely, continue to be unprofitable for the foreseeable future.

CRITICAL ACCOUNTING POLICIES AND ESTIMATES

Assumptions and Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosures of contingent assets and liabilities at the date of financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates. The areas where critical estimates were made that have significant importance to the financial statements are as follows:

i. Impairment testing on intangibles and assets. As noted in more detail below, these areas involve numerous estimates as to expected cash flows, expected rates of return and other factors that are difficult to determine and are often out of the Company's direct control.

ii. Valuation of deferred tax credits. The Company provides an allowance for tax recoveries arising from the application of losses carried forward. An allowance is provided where management has determined that it is less than likely that the loss will be applied and income taxes recovered.

Segment Reporting

The Financial Accounting Standards Board ("FASB") authoritative guidance regarding segment reporting establishes standards for the way that public business enterprises report information about operating segments in annual financial statements and requires that those enterprises report selected information about operating segments in interim financial reports. It also establishes standards for related disclosures about products and services, geographic areas and major customers. Up until December 31, 2016, the Company operated in only one segment – the development and maintenance of computer software programs and support products. Going forward, the company focused exclusively on establishing a new business model and only managed its minority stake in GROUP. Upon the purchase of the Krillase patents, the Company changed its focus to life sciences industry.

Comprehensive Income (Loss)

The Company adopted the FASB Accounting Standards Codification topic ("ASC") 220, "Reporting Comprehensive Income", which establishes standards for the reporting and display of comprehensive income and its components in the financial statements. Comprehensive income consists of net income and other gains and losses affecting stockholder's equity that are excluded from net income, such as unrealized gains and losses on investments available for sale, foreign currency translation gains and losses and minimum pension liability. With the sale of the GROUP assets all other accumulated comprehensive income was eliminated.

Net Income per Common Share

FASB Codification topic ("ASC") 260, Earnings per share, requires dual presentation of basic and diluted earnings per share (EPS) with a reconciliation of the numerator and denominator of the EPS computations. Basic earnings per share amounts are based on the weighted average shares of Common Stock outstanding. If applicable, diluted earnings per share would assume the conversion, exercise or issuance of all potential Common Stock instruments such as options, warrants and convertible securities, unless the effect is to reduce a loss or increase earnings per share. Diluted net income (loss) per share on the potential exercise of the equity-based financial instruments is not presented where anti-dilutive. Accordingly, although the diluted weighted average number of Common Stock outstanding is disclosed on the statements of operation, the calculated net loss per share is the same for bother basic and diluted as both are based on the basic weighted average of Common Stock outstanding. There were no adjustments required to net income for the period presented in the computation of diluted earnings per share.

Financial Instruments

Financial instruments consist of cash, accounts, assets held for sale, accounts payable and accrued liabilities, due to related parties, liabilities held for sale, loans payable and loans and notes payable to related parties. Financial assets and liabilities are measured upon first recognition and reviewed at the financial statement date. Changes in fair value are recognized through profit and loss. Unless

otherwise noted, it is management's opinion that the Company is not exposed to significant interest or credit risks arising from these financial instruments.

Currency Risk

We use the US dollar as our reporting currency.

Fair Value Measurements

The Company follows FASB Codification topic (ASC") 820, Fair Value Measurements and Disclosures, for all financial instruments and non-financial instruments accounted for at fair value on a recurring basis. This new accounting standard establishes a single definition of fair value and a framework for measuring fair value, sets out a fair value hierarchy to be used to classify the source of information used in fair value measurement and expands disclosures about fair value measurements required under other accounting pronouncements. It does not change existing guidance as to whether or not an instrument is carried at fair value. The Company defines fair value as the price that would be received from selling an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. When determining the fair value measurements for assets and liabilities, which are required to be recorded at fair value, the Company considers the principal or most advantageous market in which the Company would transact and the market-based risk measurements or assumptions that market participants would use in pricing the asset or liability, such as inherent risk, transfer restrictions and credit risk.

The Company has adopted (ASC") 825, Financial Instruments, which allows companies to choose to measure eligible financial instruments and certain other items at fair value that are not required to be measured at fair value. The Company has not elected the fair value option for any eligible financial instruments.

Cash and cash equivalents

The Company considers all highly liquid instruments with a maturity of three months or less at the time of issuance to be cash equivalents. The Company did not have any cash equivalents in any of the years included herein.

Intangible Assets

Intangible assets represent the cost of purchasing patents through the issuance of Common Stock. Under ASC Topic 805-50, "Business Combinations, Related Issues", cost is based on the fair value of the consideration given or the fair value of the assets acquired, whichever is more clearly evident and, thus, more reliably measured. The Company determined that the consideration given, the value of shares issues, was the more reliably measured.

The Company amortizes intangible assets with a limited useful life to the estimated residual book value in accordance with ASC Topic 350-30, "Intangibles -Other Than Goodwill. In addition, in special circumstances according to ASC 350-30, a recoverability test is performed and, if applicable, unscheduled amortization is considered.

Amortization starts once the assets is expected to contribute to the future cash flows, which has not happened.

Revenue Recognition

Effective January 1, 2018, the Company adopted ASC, Topic 606, "Revenue from Contracts with Customers", using the modified retrospective transition method as permissible for all contracts not yet completed as of January 1, 2018. This standard applies to all contracts with customers, except for contracts that are within the scope of other standards, such as leases, insurance, collaboration arrangements and financial instruments.

Under Topic 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration that the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of Topic 606, the entity performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. The Company only applies the five-step model to contracts when it is probable that the entity will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer.

Assets and Liabilities Held-for-Sale

The Company classifies assets and liabilities as held-for-sale when the following conditions are met: (1) management has committed to a plan to sell, (2) the assets are available for immediate sale in their present condition, (3) the Company has initiated an active program to identify a buyer, (4) it is probable that a sale will occur within one year, (5) the assets are actively marketed for sale at a reasonable

price in relation to their current fair value, and (6) there is a low likelihood of significant changes to the plan or that the plan will be withdrawn. If all of the criteria are met as of the balance sheet date, the assets are presented separately in the balance sheet as held-for-sale at the lower of the carrying amount or fair value less costs to sell. The assets are then no longer depreciated or amortized while classified as held-for-sale.

Other Provisions

According to FASB ASC 450 Contingencies, provisions are made whenever there is a current obligation to third parties resulting from a past event which is likely in the future to lead to an outflow of resources and of which the amount can be reliably estimated. Provisions not already resulting in an outflow of resources in the following year are recognized at their discounted settlement amount on the financial statement date. The discount taken is based on market interest rates. The settlement amount also includes the expected cost increases. Provisions are not set off against contribution claims. If the amended estimate leads to a reduction of the obligatory amount, the provision is proportionally reversed and the earnings are recognized in other operating earnings.

Deferred Taxes

Income taxes are provided in accordance with FASB Codification topic 740, Accounting for Income Taxes. A deferred tax asset or liability is recorded for all temporary differences between financial and tax reporting and net operating loss-carry forwards.

Deferred tax assets are reduced by a valuation allowance when, in the opinion of management, it is more likely than not that, some portion or all of the deferred tax asset will not be realized. Deferred tax assets and liabilities are adjusted for the effect of changes in tax laws and rates on the date of enactment.

Recent Accounting Pronouncements

The Company adopts new pronouncements relating to generally accepted accounting principles applicable to the Company as of their effective date. Management does not believe that any pronouncement not yet effective but recently issued would, if adopted, have a material effect on the accompanying financial statements. During the two years presented by the accompanying financial statements, there have been new principles adopted that have affected their presentation.

Off - Balance Sheet Arrangements

We have not entered into any other financial guarantees or other commitments to guarantee the payment obligations of any third parties. We have not entered into any derivative contracts that are indexed to our shares and classified as shareholder's equity or that are not reflected in our audited financial statements. Furthermore, we do not have any retained or contingent interest in assets transferred to an entity that serves as credit, liquidity or market risk support to such entity. We do not have any variable interest in any entity that provides financing, liquidity, market risk or credit support to us or engages in leasing, hedging or research and development services with us.

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

Nor applicable

Item 8. Financial Statements and Supplementary Data

Our audited financial statements and related financial statement schedule, together with the report of independent registered public accounting firm, appear at pages F-1 through F-12 of this Annual Report on Form 10-K for the year ended December 31, 2018.

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

Not applicable.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

As of December 31, 2019, our management, with the participation of our interim Chief Executive Officer (principal executive officer) and interim Chief Financial Officer (principal financial and accounting officer), Nicholas P. DeVito, evaluated the effectiveness of our disclosure controls and procedures pursuant to Rule 13a-15(b) promulgated under the Securities Exchange Act. Based on that evaluation, our interim Chief Executive Officer and interim Chief Financial Officer concluded that, as of December 31, 2019, our disclosure controls and procedures were not effective in ensuring that the information required to be disclosed in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, including ensuring that such material information is accumulated and communicated to our management, including our Chief Executive

Officer and our Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

Management's Annual Report on Internal Control over Financial Reporting (ICFR)

Our management is responsible for establishing and maintaining adequate internal control over financial reporting ("ICFR"), as such term is defined in Rule 13a-15(f) of the Exchange Act. ICFR refers to the process designed by, or under the supervision of, our Interim Chief Executive Officer and Chief Financial Officer, and effected by our Board of Directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles ("GAAP"), and includes those policies and procedures that:

(i) Pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the Company;
(ii) Provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with GAAP, and that receipts and expenditures of the Company are being made only in accordance with authorizations of management and directors of the Company; and
(iii) Provide reasonable assurance regarding prevention or timely detection of an unauthorized acquisition, use or disposition of the Company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, ICFR 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.

A material weakness is a deficiency, or a combination of deficiencies, in ICFR, such that there is a reasonable possibility that a material misstatement of annual or interim financial statements will not be prevented or detected on a timely basis.

Management has evaluated the effectiveness of the Company's ICFR as of December 31, 2019. Management based its assessment on the framework set forth in COSO's Internal Control – Integrated Framework (1992) in conjunction with SEC Release No. 33-8810 entitled "Commission Guidance Regarding Management's Report on Internal Control Over Financial Reporting Under Section 13(a) or 15(d) of the Securities and Exchange Commission" (17 CFR PART 241; Effective June 27, 2007).

Because of the material weaknesses described below, management concluded that the Company's ICFR was not effective as of December 31, 2019:

- The Company's lack of sufficient accounting personnel with the requisite knowledge of GAAP and the financial reporting requirements of the SEC.
- Lack of segregation of duties of internal accounting and SEC reporting departments.

We plan to take measures to remediate these deficiencies, such as hiring additional qualified personnel and providing additional training to our accounting staff in US GAAP. However, the implementation of these measures may not fully address the control deficiencies in our ICFR. Our failure to address any control deficiency could result in inaccuracies in our financial statements and could also impair our ability to comply with applicable financial reporting requirements and related regulatory filings on a timely basis. Moreover, effective ICFR is important to prevent fraud. As a result, our business, financial condition, results of operations and prospects, as well as the trading price of our shares, may be negatively impacted by a failure to accurately report financial results.

The material weaknesses and other matters impacting the Company's internal controls may cause it to be unable to report its financial information on a timely basis and thereby subject it to adverse regulatory consequences, including sanctions by the SEC or violations of applicable stock exchange or quotation service listing rules. There could also be a negative reaction in the financial markets due to a loss of investor confidence in the Company and the reliability of its financial statements. Confidence in the reliability of the Company's financial statements may suffer due to the Company's reporting of material weaknesses in its internal controls over financial reporting. This could materially adversely affect the Company and lead to a decline in the price of its Common Stock.

Changes in Internal Control Over Financial Reporting (ICFR)

During the fourth quarter ended December 31, 2019, there were no changes in our ICFR that have materially affected, or are reasonably likely to materially affect, our ICFR.

This annual report does not include an attestation report of our registered public accounting firm regarding ICFR. Management's report was not subject to attestation by our registered public accounting firm pursuant to temporary rules of the SEC that permit us to provide only management's report in this annual report.

Item 9B. Other Information.

Subsequent Events:

There are no subsequent events to report.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

The table below sets forth the names, title and ages of our current directors and executive officers. Directors hold office until the next annual meeting of the stockholders or until their successors have been elected and qualified. Executive officers serve at the pleasure of the Board and may be removed with or without cause at any time, subject to contractual obligations between the executive officer and the Company, if any.

Name	Age	Position and Offices Held	Dates in Position or Office
Nicholas DeVito	57	Interim Chief Executive Officer and Interim Chief Accounting Officer	July 13, 2019, present
James Sapirstein	58	*Executive Chairman*	December 10, 2018, present
Terry Brostowin	60	*Director*	December 14, 2018, present

Business Experience*:*

Nicholas P. DeVito. Mr. DeVito our interim Chief Executive officer and interim Chief Financial officer, has 33 years of experience in finance, engineering and operations in a variety of industries including oil & gas, telecommunications, alternative energy, manufacturing and consumer products. Most recently he served as Sr. Director of Cloud Services at Synchronoss Technologies, Chief Operating Officer for Xtreme Oil & Gas (OTCBB:XTOG) successfully reorganizing the company and completing the filings to begin public trading. Mr. DeVito has served as VP of Business Development and as CEO of several subsidiaries in Tellium (NASDAQ:ZHNE), a highly successful telecommunications equipment manufacturer that sold optical switching products and completed an IPO. He consulted to several public and private companies acting to improve operations and grow sales. Finally, he spent 14 years at AT&T and Bell Laboratories. He has a BSEE and MSEE from Columbia University and an MBA in Management from New York University.

Key Attributes, Experience and Skills: Mr. DeVito brings his financial, operational and acquisition experience to the Board along with his leadership and investor relations skills. He has the ability to establish the vision and manage the execution of business plans, growth goals, creating value for shareholders, and achieving a successful exit.

James Sapirstein. James Sapirstein, our Executive Chairman, has served over thirty-five years in the pharmaceutical industry. He has been part of almost two dozen drug product launches and specifically either led or has been a key member of several HIV product launches into different new classes of therapeutics at the time.

He began his career in 1984 with Eli Lilly in Sales, moving to Hoffmann-LaRoche in 1987, where he served for almost a decade as part of its commercial teams in the US and abroad, rising to become a Product Director. He joined Bristol Myers Squibb as the Director of International Marketing in the Infectious Diseases group in 1996. While at BMS, he worked on several important HIV/AIDS projects including Secure the Future.

Mr. Sapirstein started his career in smaller biotech companies when he later joined Gilead Sciences, Inc. (GILD) in order to lead the Global Marketing team in its launch of Viread (tenofovir). In 2002, he accepted the position of Executive Vice President, Metabolic and Endocrinology, for Serono Laboratories. Later, in 2006, he became the founding CEO of Tobira Therapeutics, then a private company. In 2012, Mr. Sapirstein became the CEO of Alliqua Biomedical at Alliqua, Inc. Thereafter, he served as CEO of Contravir Pharmaceuticals from March 2014 until October 2018. All of these are publicly listed companies. Mr. Sapirstein has raised over $120 Million dollars in venture capital and public capital markets financing in his various engagements as CEO. He was named as a Finalist for Ernst &Young Entrepreneur of the Year award in 2015 as well as in 2016. He is currently CEO of AzurRx BioPharma working in Cystic Fibrosis since October 2019.

Mr. Sapirstein holds board positions on Enochian Biosciences (ENOB), RespireRx Pharmaceuticals (RSPI), Nanoviricides (NNVC) and Leading Biosciences. He is the Chairman of the Board for BioNJ, an association of biopharma industries in New Jersey. In addition, he is a Board Director for BIO, the leading Biopharma Industries Organization promoting public policy and networking in the healthcare space, where he sits on both the Health Section and Emerging Companies Section Governing Boards.

Mr. Sapirstein received an MBA from Fairleigh Dickinson University in 1997, and a BS (Pharmacy) from Rutgers University in 1984.

Terry Brostowin. Mr. Brostowin, a Director, is an accomplished attorney admitted to the Federal Court in both the Eastern and Southern districts of New York. He has extensive expertise in contracts, and commercial litigation. Mr. Brostowin has advised the New York City Mayor's office on judicial appointments and was a compliance specialist ensuring agencies followed court ordered activities and ensured the financial integrity of the Financial Systems Division accounting and budgetary systems. Mr. Brostowin has been affiliated with the law firm Brostowin & Associates, PC, since 2009. From 2002 to 2009, Mr. Brostowin was affiliated with the law firm Conway & Brostowin, LLC.

Family Relationships

There are no family relationships between or among any of our current directors, executive officers or persons nominated or charged by the Company to become directors or executive officers. There are no family relationships among our executive officers and directors and the executive officers and directors of our direct and indirect subsidiaries.

Involvement in Certain Legal Proceedings

None of the directors or executive officers has, during the past ten years:

(a) Had any bankruptcy petition filed by or against any business of which such person was a general partner or executive officer either at the time of the bankruptcy or within two years prior to that time;

(b) Been convicted in a criminal proceeding or subject to a pending criminal proceeding;

(c) Been subject to any order, judgment, or decree, not subsequently reversed, suspended or vacated, of any court of competent jurisdiction, permanently or temporarily enjoining, barring, suspending or otherwise limiting his involvement in any type of business, securities, futures, commodities or banking activities; or

(d) Been found by a court of competent jurisdiction (in a civil action), the SEC or the Commodity Futures Trading Commission to have violated a federal or state securities or commodities law, and the judgment has not been reversed, suspended, or vacated.

Code of Conduct

We have not adopted a Code of Conduct.

Changes in Officers and Directors

Mr. DeVito was appointed interim Chief Executive Officer and interim Chief Financial Officer on July 13, 2019.

On February 17, 2020, we entered into an employment agreement with Ralph Makar pursuant to which Mr. Makar agreed to become the Company's President and Chief Executive Officer effective on or about April 1, 2020, subject to the Company's obtaining director and officer liability insurance. Upon Mr. Makar's taking office as our Chief Executive officer, Mr. DeVito will resign from his position as our Interim Chief Executive Officer.

Compliance with Section 16(a) of the Securities Exchange Act of 1934

Section 16(a) of the Exchange Act requires our executive officers and directors and persons who own more than 10% of a registered class of our equity securities to file with the SEC initial statements of beneficial ownership, reports of changes in ownership and annual reports concerning their ownership of our Common Stock and other equity securities, on Forms 3, 4 and 5 respectively. Executive officers, directors and greater than 10% shareholders are required by the SEC regulations to furnish us with copies of all Section 16(a) reports that they file.

Based solely on our review, our officers and directors and one of our 10% stockholders failed to file their Section 16(a) forms on a timely basis for 2019.

Item 11. Executive Compensation

EXECUTIVE COMPENSATION

The following table sets forth all plan and non-plan compensation for the last two completed fiscal years paid to all individuals who served as the Company's principal executive officer or acting in similar capacity during the last completed fiscal year, regardless of compensation level, and other individuals as required by Item 402(m)(2) of Regulation S-K. We refer to all of these individuals collectively as our "named executive officers."

SUMMARY COMPENSATION TABLE

Name and Principal Position	Year Ended December 31,	Salary and Fees ($)	Bonus ($)	Total ($)
Michael K. Handley				
--*Chief Executive Officer*	2019	-	-	-
	2018	-	-	-
Nicholas P. DeVito				
-- *interim CEO and interim CFO* (2)	2019	-	-	-
	2018	40,000	-	-

(1) Mr. Handley was appointed Chief Executive Officer on September 14, 2018 and resigned from that position on March 28, 2019.

(2) Mr. DeVito served as Chief Executive Officer from May 7, 2018 to September 14, 2018. He was then appointed the interim Chief Executive Officer and interim Chief Financial Officer on July 13, 2019 following the resignation of Michael Handley.

Outstanding Equity Awards at Fiscal Year-End

On December 6, 2018 we issued an option to purchase 125,000 shares of Common Stock at $1.50 per share vesting over 12 months to James Sapirstein.

On December 6, 2018, we also issued an option to purchase 140,000 shares of Common Stock at $1.50 per share vesting over 12 months to Terry Brostowin.

On July 13, 2019 we issued an option to purchase 600,000 shares of Common Stock at $1.01 per share vesting over 24 months to Nicholas DeVito.

On July 13, 2019 we issued an option to purchase 1,100,000 shares of Common Stock at $1.01 per share vesting over 24 months to James Sapirstein.

On July 13, 2019 we issued an option to purchase 250,000 shares of Common Stock at $1.01 per share vesting over 24 months to Terry Brostowin.

Employment Agreements, Termination of Employment and Change-in-Control Arrangements with our Executive Officers

No one has an executive compensation agreement as of December 31, 2019.

Compensation of Directors

Except as indicated below, no fees have been accrued and none have been paid to the Company's directors who are not also "named executive officers." Only non-executive directors are entitled to receive any compensation for services rendered by them as directors.

Director Agreements

General

Our directors may receive equity in the form of options at fair market value for their service to the Board. We do not intend to pay cash compensation to any other director besides Mr. Sapirstein (see below).

James Sapirstein

Mr. Sapirstein receives $75,000 in cash compensation per annum for service on the Board as compensation effective December 6, 2018. He also received options to purchase 125,000 shares of the Company's Common Stock, at an exercise price equal to $1.50 per share, for service on the Board through the one-year anniversary of his December 6, 2018 start date. Mr. Sapirstein has waived his cash compensation fees indefinitely. All of these options are fully vested. On July 13, 2019 we issued an option to purchase 1,100,000 shares of Common Stock at $1.01 per share vesting over 24 months to James Sapirstein.

Terry Brostowin

Mr. Brostowin received options to purchase 140,000 shares of the Company's Common Stock, at an exercise price equal to $1.50 per share, for service on the Board through the one year anniversary of his start date on December 6, 2018, of which 80,000 were fully vested as of the date of grant, and the remaining 60,000 vest monthly over the course of the 12-month period beginning on December 6, 2018. He is not receiving any cash compensation for his service to the Board. On July 13, 2019 we issued an option to purchase 250,000 shares of Common Stock at $1.01 per share vesting over 24 months to Terry Brostowin.

Term of Office

Each of our directors is elected to hold office for a one year term or until his successor is elected and qualified.

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

The following table sets forth certain information regarding our Common Stock beneficially owned as of March 6, 2020, for (i) each stockholder known to be the beneficial owner of 5% or more of our outstanding Common Stock, (ii) each executive officer and director, and (iii) all executive officers and directors as a group. In general, a person is deemed to be a beneficial owner of a security if that person has or shares the power to vote or direct the voting of such security, or the power to dispose or to direct the disposition of such security. A person is also deemed to be a beneficial owner of any securities of which the person has the right to acquire beneficial ownership within 60 days. Shares of Common Stock subject to options, warrants or convertible securities exercisable or convertible within 60 days are deemed outstanding for computing the percentage of the person or entity holding such options, warrants or convertible securities but are not deemed outstanding for computing the percentage of any other person. Percentages are determined based on 20,163,939 shares of Common Stock of the Company issued and outstanding plus 1,085,000 vested options as of April 15, 2020. To the best of our knowledge, subject to community and marital property laws, all persons named have sole voting and investment power with respect to such shares, except as otherwise noted.

With respect to the 16.89 million shares of Common Stock issued to certain shareholders of ACB Holdings AB as a result of the asset acquisition that closed on September 12, 2018, any such shareholder who received 5% or more of our outstanding Common Stock in that asset acquisition has been included in the table below.

	Common Stock	
Name and Address of Beneficial Owner (1)	**Amount and Nature of Beneficial Ownership**	**Percent of Class Beneficially Owned (2)**
Officers and Directors		
Nicholas DeVito -Interim Chief Executive Officer and CFO	1,220,000 (3)	6.0%
James Sapirstein (4) -Executive Chairman	665,000	3.2%
Terry Brostowin (5) -Director	250,000	1.2%
All Officers and Directors as a group *(3 persons)*	2,135,000	10.0%
5% Stockholders		
Donna Maresca 1436 Mickelson Ct, Champions Gate, FL 33896, USA	1,965,000 (6)	9.6%
ESC Holding, LLC 1 Channel Drive # 1706, Monmouth Beach NJ 07750 (7)	2,555,640	12.7%

Name and Address of Beneficial Owner (1)	Common Stock	
	Amount and Nature of Beneficial Ownership	Percent of Class Beneficially Owned (2)
Marine Bio SpA Huérfanos 1160, Oficina 1101, Santiago, Chile (8)	2,416,548	12.0%
Inversiones DaVinci Limitada El Retiro 5101, Vitacura, Santiago, Chile (9)	1,461,961	7.3%
Rieux Enterprise Corp. E.A. Creque Building, Main Street, Road Town, Tortola, British Virgin Island (10)	1,072,560	5.3%

* Less than 1%.

(1) Unless otherwise indicated, the address of the named beneficial owner is c/o Marizyme, Inc. 109 Ambersweet Way, #401 Davenport, FL 33897

(2) Based on 20,163,939 shares of Common Stock outstanding as of April 15, 2020.

(3) Consists of 900,000 shares of Common Stock and options vesting within 60 days to purchase 320,000 shares of Common Stock. Does not include options to purchase 280,000 shares of Common Stock which do not vest within 60 days.

(4) Consists of 5,000 shares of common stock and options vesting within 60 days to purchase 660,000 shares of Common Stock. Does not include options to purchase 565,000 shares of Common Stock which do not vest within 60 days.

(5) Consists of an options vesting within 60 days to purchase 250,000 shares of Common Stock. Does not include options to purchase 140,000 shares of Common Stock which do not vest within 60 days.

(6) Includes 55,000 shares of Common Stock owned directly, 1,700,000 shares of Common Stock owned by a trust over which Donna Maresca, the wife of Frank Maresca, has voting and dispositive control and options vesting within 60 days to purchase 210,000 shares of Common Stock. Does not include options to purchase 540,000 shares of Common Stock which do not vest within 60 days.

(7) Emmanuelle Schleipfer-Conley has voting and dispositive control over ESC Holding LLC.

(8) Max Rutman has voting and dispositive control over Marine Bio SpA.

(9) Ricardo Majluf has voting and dispositive control over Inversiones DaVinci Limitada.

(10) Neva Sherille Dasent has voting and dispositive control over Rieux Enterprise Corp.

Item 13. Certain Relationships and Related Transactions, and Director Independence

Certain Relationships and Related Transactions

Independent Directors

The Board has determined that Messrs. Sapirstein and Brostowin each qualify as an "independent director" as defined by Section 10A(m)(3)(ii) of the Exchange Act and Rule 5065(a)(2) of the NASDAQ Marketplace Rules.

Item 14. Principal Accounting Fees and Services

K. R. Margetson Ltd., Chartered Accountant ("K.R. Margetson") is the Company's independent public accountant who has audited the fiscal years ended December 31, 2019 and December 31, 2018. The aggregate fees billed for the two most recently completed fiscal years ended December 31, 2019 and December 31, 2018 for professional services rendered by K.R. Margetson were as follows:

	2019	2018
Audit Fees and Audit Related Fees	$ 9,000	$ 9,000
Tax Fees	-	0
All Other Fees	-	0
Total	$ 9,000	$ 9,000

Policy on Pre-Approval by the Board of Services Performed by Independent Auditors

We do not use K.R. Margetson for financial information system design and implementation. These services, which include designing or implementing a system that aggregates source data underlying the financial statements or generates K.R. Margetson to provide compliance outsourcing services.

The Company's Board pre-approved all services provided by our independent auditors. All of the above services and fees were reviewed and approved by the Board of Directors either before or after the respective services were rendered.

The Board of Directors has considered the nature and amount of fees billed by K.R. Margetson and believes that the provision of services for activities unrelated to the audit is compatible with maintaining our independence.

PART IV

Item 15. Exhibits, Financial Statement Schedules

Exhibit No.:	Description:	Filed an Exhibit to the following Company SEC Filing and Incorporated by Reference herein:
2.1	Agreement and Plan of Merger between GBS Enterprises Incorporated and Marizyme, Inc.	Form 10 (File No. 000-53223) filed on September 12, 2018
3.1.1	Articles of Incorporation	Form SB-2 (File No: 333-146748) filed January 14, 2008
3.1.2	Certificate of Amendment to Articles of Incorporation, effective September 6, 2010	Form 10-K filed July 16, 2012
3.1.3	Certificate of Amendment to Articles of Incorporation, effective November 22, 2010	Form 10-K/A filed July 15, 2011
3.1.4	Certificate of Amendment to the Articles of Incorporation regarding 1-for-29 Reverse Stock Split filed March 20, 2018	Form 10 (File No. 000-53223) filed on September 12, 2018
3.1.5	Articles of Merger between Marizyme, Inc. and GBS Enterprises Incorporated filed May 19, 2018	Form 10 (File No. 000-53223) filed on September 12, 2018
3.1.6	Series A Non-Convertible Preferred Certificate of Designation filed May 11, 2018	Form 10 (File No. 000-53223) filed on September 12, 2018
3.2	Bylaws	Form SB-2 (File No: 333-146748) filed January 14, 2008
10.1	Asset Purchase Agreement, dated September 12, 2018 between ACB Holding AB, Reg. No. 559119-5762 and Marizyme, Inc.	Form 10 (File No. 000-53223) filed on September 12, 2018
10.2	Assignment Agreement of Patent Applications (Antarctic Krill), dated September 12, 2018, between ACB Holding AB, Reg. No. 559119-5762 and Marizyme, Inc.	Form 10 (File No. 000-53223) filed on September 12, 2018
10.3	Assignment Agreement of Patent Applications (Enzymatic), dated September 12, 2018, between ACB Holding AB, Reg. No. 559119-5762 and Marizyme, Inc.	Form 10 (File No. 000-53223) filed on September 12, 2018
10.4	Assignment Agreement of Patent Applications (Thrombosis), dated September 12, 2018, between ACB Holding AB, Reg. No. 559119-5762 and Marizyme, Inc.	Form 10 (File No. 000-53223) filed on September 12, 2018
10.5	Patent Purchase and Assignment Agreement, dated September 12, 2018, between ACB Holding AB, Reg. No. 559119-5762 and Marizyme, Inc.	Form 10 (File No. 000-53223) filed on September 12, 2018
10.6	Director Agreement with James Sapirstein dated December 6, 2018	Form 10-K (File No. 000-53223) filed on March 3, 2019
10.7	Director Agreement with James Sapirstein dated December 6, 2018	Form 10-K (File No. 000-53223) filed on March 3, 2019
10.8	Distribution Agreement dated November 7, 2019 by and between the Registrant and Somahlutions, LLC	Form 10-Q (File No. 000-53223) filed on November 13, 2019
10.9	Asset Purchase Agreement by and among the Registrant and Somahlution, LLC et al	Form 8-K (File No. 000-53223) filed on December 19, 2019
10.10	Employment Agreement by and between the Registrant and Mr. Ralph Makar dated February 2, 2020	Form 8-K (File No. 000-53223) filed on February 25, 2020
21	List of Subsidiaries (None)	Form 10 (File No. 000-53223) filed on September 12, 2018
31.1/31.2	Rule 13(a)-14(a)/15(d)-14(a) Certification of Principal Executive, Financial and Accounting Officer	Filed herewith.
32.1/32.2	Section 1350 Certification of Principal Executive, Financial and Accounting Officer	Filed herewith.

SIGNATURES

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

MARIZYME, INC.

By: */s/ Nicholas P. DeVito*
Nicholas P. DeVito
Interim Chief Executive Officer and Director
(Interim Principal Executive Officer)
(Interim Principal Financial and Accounting Officer)

Date: April 15, 2020

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

Signature:	**Title:**	**Date:**
/s/ James Sapirstein James Sapirstein	Executive Chairman of the Board of Directors,	April 15, 2020

Signature:	**Title:**	**Date:**
/s/ Terry Brostowin Terry Brostowin	Director,	April 15, 2020

CERTIFICATION PURSUANT TO 18 U.S.C. SS 1350, AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Nicholas P. DeVito, certify that:

1. I have reviewed this Annual Report on Form 10-K for the fiscal year ended December 31, 2019 of Marizyme, Inc. (the "registrant");
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) 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, if any, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
    (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
    (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
    (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
    (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
    (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: April 15, 2020

/s/ *Nicholas P. DeVito*

Nicholas P. DeVito

Interim Chief Executive Officer
(Interim Principal Executive and Financial and Accounting Officer)

Exhibit 32.1/32.2

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

I, Nicholas P. DeVito, hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the *Sarbanes-Oxley Act of 2002,* that:

(1) the Annual Report on Form 10-K of Marizyme, Inc. for the fiscal year ended December 31, 2019 (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 Marizyme, Inc.

Date: April 15, 2020

/s/ *Nicholas P. DeVito*
Nicholas P. DeVito
Interim Chief Executive Officer
(Interim Principal Executive and Financial and Accounting Officer)

Financial Pages Contents

K. R. MARGETSON LTD. *Chartered Professional Accountant*

1 **#210, 905 West Pender Street** **Tel: 604.641.4450**

2 **Vancouver BC V6C 1L6** **Fax: 1.855.603.3228**
Canada

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of
Marizyme, Inc.:

Opinion on the financial statements

I have audited the accompanying balance sheets of Marizyme, Inc. as of December 31, 2019 and 2018 and the related statements of operations, stockholders' equity and cash flows for each of the two years then ended and the related notes (collectively referred to as the "financial statements'). In my opinion, the financial statements present fairly, in all material respects, the financial position of the Company as at December 31, 2019 and 2018 and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2019 in conformity with accounting principles generally accepted in the United States of America.

Basis for opinion

These financial statements are the responsibility of the Company's management. My responsibility is to express an opinion on these financial statements based on my audits. My company is a public accounting firm registered with the Public Company Accounting Oversight Board ("PCAOB") and is 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.

I conducted my audits in accordance with the standards of the PCAOB. Those standards require that I plan and perform an audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. My 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. My audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. I believe that my audits provide a reasonable basis for my opinion.

The accompanying financial statements have been prepared using accounting principles generally accepted in the United States of America assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has incurred operating losses since inception, which raises substantial doubt about its ability to continue as a going concern. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ K. R. MARGETSON LTD

Chartered Professional Accountant

I have served as the Company's auditor since 2007

Vancouver, Canada

DATE

MARIZYME, INC.
BALANCE SHEETS
As Of December 31, 2019 and 2018

	2019 $	2018 $
ASSETS		
Current Assets:		
Cash	90	104
Prepaid Expenses	-	20,000
Total Current Assets	90	20,104
Long Term Assets:		
Intangible Assets – Note 4	28,613,000	28,600,000
TOTAL ASSETS	28,613,090	28,620,104
LIABILITIES		
Current Liabilities:		
Accounts Payable and Accrued Liabilities	270,218	42,780
Total Liabilities	270,218	42,780
STOCKHOLDERS' EQUITY		
Capital Stock - Note 6		
Authorized:		
75,000,000 common shares of $.001 par value each		
25,000,000 preferred shares of $.001 par value each		
Issued and outstanding:		
19,858,939 shares of common stock		
(19,740,302 shares at December 31, 2018)	19,859	19,740
Donated Capital	41,422	41,422
Additional Paid-in Capital	59,278,172	58,454,704
Treasury Stock	(16,000)	(16,000)
Accumulated Deficit	(30,980,581)	(29,922,542)
Total Stockholders' Equity	28,342,872	28,577,324
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	28,613,090	28,620,104

Note 1 – Going concern assumption

MARIZYME, INC.
STATEMENT OF OPERATIONS
For the Years Ended December 21, 2019 and 2018

	31-Dec 2019 $	
Total Revenue	-	
Total Cost of Goods Sold	-	
Gross Profit	-	
Expenses:		
Operating Expenses	947,075	
General and Administrative	110,964	
Total Expenses	1,058,039	
Net Operating Loss	(1,058,039)	(247
Other Income	-	
Other Expenses	-	(4,61
Net Loss and Comprehensive Loss for the year	(1,058,039)	(248
Net Loss per share, basic and diluted	(0.05)	(0.04
Weighted average number of shares		
of common stock outstanding,		
basic and diluted	19,805,959	

MARIZYME, INC.
STATEMENTS OF STOCKHOLDERS' EQUITY
For the Years ended December 31, 2019 and 2018

	Common Stock		Preferred Stock		Additional Paid in	Donated	Treasury	Accumulated	
	Shares	Amount	Shares	Amount	Capital	Capital	Stock	Deficit	Equity
	#	$	#	$	$	$	$	$	$
Balance, December 31, 2017	1,101,074	1,101	-	-	29,793,728	41,422	(16,000)	(27,653,439)	2,166,812
Preferred shares issued	-	-	1,000	1	-	-	-	-	1
Stock dividend issued to X-Assets, Inc	-	-	-	-	-	-	-	(2,020,360)	(2,020,360)
Common stock exchange for preferred shares	1,500,000	1,500	(1,000)	(1)	2,319,930	-	-	-	2,321,429
Common stock issued for intangible assets	6,980,000	16,980	-	-	26,261,591	-	-	-	26,278,571
Common stock issued on conversion of note	159,228	159	-	-	79,455	-	-	-	79,614
Net loss and comprehensive loss for the year ended December 31, 2018	-	-	-	-	-	-	-	(248,743)	(248,743)
Balance, December 31, 2018	19,740,302	19,740	-	-	58,454,704	41,422	(16,000)	(29,922,542)	28,577,324
Common shares issued	118,637	119	-	-	124,881	-	-	-	125,000
Stock-based compensation	-	-	-	-	698,587	-	-	-	698,587
Net loss and comprehensive loss for the year ended December 31, 2019	-	-	-	-	-	-	-	(1,058,039)	(1,058,039)
Balance, December 31, 2019	19,858,939	19,859	-	-	59,278,172	41,422	(16,000)	(30,980,581)	28,342,872

MARIZYME, INC.
STATEMENT OF CASH FLOWS
For the Years ended December 31, 2019 and 2018

	2019 $	2018 $
Cash Flow from Operating Activities:		
Net Loss for the year	(1,058,039)	(248,743)
Adjustments to reconcile Net Loss to		
to Net Cash used by operations:		
Stock-based compensation	698,587	-
Debt for consulting fees forgiven	30,000	-
Interest eliminated on note conversion	-	4,614
Preferred stock issued for consulting expense	-	1
Changes in assets and liabilities:		
Prepaid Expenses	20,000	6,668
Accounts Payable and Accrued Liabilities	197,438	18,557
Net Cash used by Operating Activities	(112,014)	(218,903)
Cash Flow from Investing Activities:		
Patents	(13,000)	-
Re-organization	-	(1,386)
Net Cash used by Investing Activities	(13,000)	(1,386)
Cash Flow from Financing Activities:		
Shares issued for cash	125,000	-
Preferred stock issued for consulting expense	-	75,000
Related party transactions	-	93,785
Net Cash provided by Financing Activities	125,000	168,785
Net cash decrease for year	(14)	(51,504)
Cash - Beginning of the year	104	51,608
Cash - End of year	90	104

Supplementary information

Interest	-	4 614
Taxes paid	-	-
Value of shares issued for patents rights and technology	-	28,600,000
Debt converted into shares	-	79,455

MARIZYME, INC.
NOTES TO THE FINANCIAL STATEMENTS
DECEMBER 31, 2019 AND 2018

Note 1 COMPANY AND BACKGROUND

Overview

Marizyme, Inc., a Nevada corporation formerly known as GBS Enterprises Incorporated (the "Company," "Marizyme", "GBS," "GBSX," "MRZM,", "we," "us," "our" or similar expressions), conducted its primary business through its majority owned subsidiary, GBS Software AG ("GROUP"), a German-based public-company.

By December 31, 2016, we sold the controlling interest in GROUP and other subsidiaries, keeping only a minority interest in GROUP. On March 21, 2018, we formed a wholly-owned subsidiary named Marizyme, Inc., a Nevada corporation, and merged with it, effectively changing the Company's name to Marizyme, Inc. On June 1, 2018, we exchanged the shares of GROUP and all the intercompany assets and liabilities for 100% of the shares of X-Assets Enterprises, Inc, a Nevada Corporation. As part of a type-D business restructuring on September 5, 2018, we then distributed the X-Assets shares to our own shareholders on a 1 for 1 basis.

Marizyme refocused on the life sciences and seeks technologies to acquire.

On September 12, 2018 we consummated an asset acquisition with ACB Holding AB, Reg. No. 559119-5762, a Swedish corporation to acquire all right, title and interest in their Krillase technology in exchange for 16.98 Million shares of Common Stock. Krillase is a naturally occurring enzyme that acts to break protein bonds and has applications in dental care, wound healing and thrombosis.

The Company's common stock, $0.001 par value per share (the "Common Stock") is currently quoted on the OTC Markets under the ticker symbol "MRZM."

Historically, we grew our operations by acquiring companies which have developed software and specialized services for the Lotus Notes and Domino market. These products and services may no longer remain in use. New technologies, especially in the areas of Cloud Computing and Mobile applications, have grown in popularity due to the potential cost savings and operational efficiencies they can offer. The associated software and consulting offerings were no longer needed.

These financial statements have been prepared in accordance with generally accepted principles applicable to a going concern, which assumes that the Company will be able to meet its obligations and continue its operations for its next twelve months. Realization values may be substantially different from carrying values as shown and these financial statements do not give effect to adjustments that would be necessary to the carrying values and classifications of assets and liabilities should the Company be unable to continue as a going concern. At December 31, 2018, the Company had not yet achieved profitable operations and had accumulated losses of $30,980,581 since its inception, all of which casts substantial doubt about the Company's ability to continue as a going concern. The Company's ability to continue as a going concern is dependent upon its ability to generate future profitable operations and/or to obtain the necessary financing to meet its obligations and repay its liabilities arising from normal business operations when they come due. Management is in the process of executing a strategy based upon a new strategic direction in the life sciences space. We have several technologies in the commercialization phase and in development. We are seeking acquisitions of biotechnology assets in support of this direction. There can be no assurances that management will be successful in executing this strategy.

Note 2 ACCOUNTING POLICIES

The financial statements and accompanying notes are prepared in accordance with accounting principles generally accepted in the United States of America, the more significant of which are as follows:

Assumptions and Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosures of contingent assets and liabilities at the date of financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates. The areas where critical estimates were made that have significant importance

to the financial statements are as follows:

i. Impairment testing on intangibles assets. As noted in more detail below, these areas involve numerous estimates as to expected cash flows and other factors that are difficult to determine and are often out of the Company's direct control.

ii. Valuation of deferred tax credits. The Company provides an allowance for tax recoveries arising from the application of losses carried forward. An allowance is provided where management has determined that it is less than likely that the loss will be applied and income taxes recovered.

Segment Reporting

The Financial Accounting Standards Board ("FASB") authoritative guidance regarding segment reporting establishes standards for the way that public business enterprises report information about operating segments in annual financial statements and requires that those enterprises report selected information about operating segments in interim financial reports. It also establishes standards for related disclosures about products and services, geographic areas and major customers. Up until December 31, 2016, the Company operated in only one segment – the development and maintenance of computer software programs and support products. Going forward, the company focused exclusively on establishing a new business model and only managed its minority stake in GROUP. Upon the purchase of the Krillase patents and technology, the Company changed its focus to life sciences industry.

Comprehensive Income (Loss)

The Company adopted the FASB Accounting Standards Codification topic ("ASC") 220, "Reporting Comprehensive Income", which establishes standards for the reporting and display of comprehensive income and its components in the financial statements. Comprehensive income consists of net income and other gains and losses affecting stockholder's equity that are excluded from net income, such as unrealized gains and losses on investments available for sale, foreign currency translation gains and losses and minimum pension liability. With the sale of the GROUP assets all other accumulated comprehensive income was eliminated.

Net Income per Common Share

ASC 260, "Earnings per share", requires dual presentation of basic and diluted earnings per share (EPS) with a reconciliation of the numerator and denominator of the EPS computations. Basic earnings per share amounts are based on the weighted average shares of Common Stock outstanding. If applicable, diluted earnings per share would assume the conversion, exercise or issuance of all potential Common Stock instruments such as options, warrants and convertible securities, unless the effect is to reduce a loss or increase earnings per share. Diluted net income (loss) per share on the potential exercise of the equity-based financial instruments is not presented where anti-dilutive. Accordingly, although the diluted weighted average number of Common Stock outstanding is disclosed on the statements of operation, the calculated net loss per share is the same for both the basic and diluted as both are based on the basic weighted average of Common Stock outstanding. There were no adjustments required to net income for the period presented in the computation of diluted earnings per share.

Financial Instruments

Financial instruments consist of cash, accounts payable and accrued liabilities. Financial assets and liabilities are measured upon first recognition and reviewed at the financial statement date. Changes in fair value are recognized through profit and loss. Unless otherwise noted, it is management's opinion that the Company is not exposed to significant interest or credit risks arising from these financial instruments.

Currency Risk

We use the US dollar as our reporting currency, which is our functional currency. December 31, 2019, we held no funds in foreign currencies, nor had any receivables or payables in foreign currencies.

Fair Value Measurements

The Company follows ASC 820, "Fair Value Measurements and Disclosures", for all financial instruments and non-financial instruments accounted for at fair value on a recurring basis. This accounting standard establishes a single definition of fair value and a framework for measuring fair value, sets out a fair value hierarchy to be used to classify the source of information used in fair value measurement and expands disclosures about fair value measurements required under other accounting pronouncements. It does not change existing guidance as to whether or not an instrument is carried at fair value. The Company defines fair value as the price that would be received

from selling an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. When determining the fair value measurements for assets and liabilities, which are required to be recorded at fair value, the Company considers the principal or most advantageous market in which the Company would transact and the market-based risk measurements or assumptions that market participants would use in pricing the asset or liability, such as inherent risk, transfer restrictions and credit risk.

The Company has adopted ASC 825, Financial Instruments, which allows companies to choose to measure eligible financial instruments and certain other items at fair value that are not required to be measured at fair value. The Company has not elected the fair value option for any eligible financial instruments.

Cash and cash equivalents

The Company considers all highly liquid instruments with a maturity of three months or less at the time of issuance to be cash equivalents. The Company did not have any cash equivalents in any of the years included herein.

Intangible Assets

Intangible assets represent the cost of patents, either purchased or applied for. For patents that were purchased through the issuance of Common Stock, the Company follows ASC Topic 805-50, "Business Combinations, Related Issues", wherein cost is based on the fair value of the consideration given or the fair value of the assets acquired, whichever is more clearly evident and, thus, more reliably measured. The Company determined that the consideration given, the value of shares issued, was the more reliably measured.

The Company amortizes intangible assets with a limited useful life to the estimated residual book value in accordance with ASC Topic 350-30, "Intangibles - Other Than Goodwill. In addition, in special circumstances according to ASC 350-30, a recoverability test is performed and, if applicable, unscheduled amortization is considered.

Amortization starts once the assets are expected to contribute to the future cash flows, which has not happened.

Revenue Recognition

Effective January 1, 2018, the Company adopted ASC, Topic 606, "Revenue from Contracts with Customers", using the modified retrospective transition method as permissible for all contracts not yet completed as of January 1, 2018. This standard applies to all contracts with customers, except for contracts that are within the scope of other standards, such as leases, insurance, collaboration arrangements and financial instruments.

Under Topic 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration that the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of Topic 606, the entity performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. The Company only applies the five-step model to contracts when it is probable that the entity will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer.

Foreign Currency Balances and Transactions

The Company's functional currency is US dollars. Foreign currency balances are translated into US dollars as follows:

Monetary assets and liabilities are translated at the year-end exchange rates. Non-monetary assets are translated at the rate of exchange in effect at their acquisition, unless such assets are carried at market or nominal value, in which case they ae translated at the year-end exchange rate. Revenue and expense items are translated at the average exchange rate for the period. Foreign exchange gains and losses are included in operations.

Other Provisions

According to FASB ASC 450 "Contingencies", provisions are made whenever there is a current obligation to third parties resulting from a past event which is likely in the future to lead to an outflow of resources and of which the amount can be reliably estimated. Provisions not already resulting in an outflow of resources in the following year are recognized at their discounted settlement amount on the financial statement date. The discount taken is based on market interest rates. The settlement amount also includes the expected cost increases. Provisions are not set off against contribution claims. If the amended estimate leads to a reduction of the obligatory

amount, the provision is proportionally reversed and the earnings are recognized in other operating earnings.

Deferred Taxes

Income taxes are provided in accordance with FASB Codification topic 740, "Accounting for Income Taxes". A deferred tax asset or liability is recorded for all temporary differences between financial and tax reporting and net operating loss-carry forwards.

Deferred tax assets are reduced by a valuation allowance when, in the opinion of management, it is more likely than not that, that some portion or all of the deferred tax asset will not be realized. Deferred tax assets and liabilities are adjusted for the effect of changes in tax laws and rates on the date of enactment.

Stock-based compensation

The Company grants stock-based compensation to directors and officers as an element of compensation. The fair value of the awards is recognized over the vesting period as stock-based compensation expense and additional paid in capital. The fair value of stock-based compensation is determined using the Black-Scholes option pricing model at the time of the grant. At each reporting date prior to vesting, the cumulative expense representing the extent to which the vesting period has expired and management best estimate of the awards that are ultimately expected to vest is computed. The movement in cumulative expense is recognized in the statement of operations with a corresponding entry within equity, against additional paid in capital. No expense is recognized for awards that do not ultimately vest.

Recent Accounting Pronouncements

The Company adopts new pronouncements relating to generally accepted accounting principles applicable to the Company as of their effective date. Management does not believe that any pronouncement not yet effective but recently issued would, if adopted, have a material effect on the accompanying financial statements. During the two years presented by the accompanying financial statements, there have not been new principles adopted that have affected their presentation.

Note 3 RE-ORAGANIZATION

On May 4, 2018 Marizyme signed an Assignment and Assumption Agreement with X-Assets Enterprises, Inc, a Nevada Corporation ("X-Assets"). We agreed to transfer assets and liabilities to X-Assets on June 1, 2018. To reflect that transaction, we identified those assets and liabilities on our December 31, 2017 Balance Sheet as Assets Held for Sale and Liabilities Held for Sale.

The assets included an account receivable valued at $130,766 and the GROUP shares valued at $2,610,440. The investment represented 23.9% of the outstanding shares of GROUP. The value was determined using the net book equity per share. The liabilities included a current payable valued at $628,447.

On June 1, 2018 all of the Assets and Liabilities Held for Sale were exchanged for 1,101,174 shares of X-Assets.

On September 5, 2018, we distributed all our shares of X-Assets – reflecting 100% of the shares of this subsidiary - to all of the stockholders of Marizyme on a 1 for 1 basis. As a result of the distribution, on June 30, 2018 this asset has $0 value to Marizyme. Its original value was determined by net equity, values not in the public domain, and there was no impairment required.

Note 4 INTANGIBLE ASSETS

On September 12, 2018 we consummated an asset acquisition with ACB Holding AB, Reg. No. 559119-5762, a Swedish corporation to acquire all right, title and interest in their Krillase technology in exchange for 16.98 million shares of Common Stock. Krillase is a naturally occurring enzyme that acts to break protein bonds and has applications in dental care, wound healing and thrombosis. The transaction was recorded at the fair value of the shares, which was calculated as $28,600,000. No amortization has been recorded as the assets are not yet in a position to produce cash flows.

During 2019, we incurred legal and filing fees of $13,000 associated with a patent application for pharmaceutical compositions and methods for the treatment of thrombosis. The patent is pending.

Note 5 CONVERTIBLE NOTE PAYABLE

On July 7, 2018 the Company issued a convertible note for $75,000. The note accrued interest at 12% interest, calculated monthly, due January 3, 2019 and convertible into Common Stock at the discretion of the noteholder at $0.50 per share.

On December 30, 2018, the noteholder converted the principal and interest owing of $79,614 into 159,228 shares of Common Stock.

Note 6 CAPITAL STOCK

The Company has authorized capital of 75,000,000 shares of Common Stock and 25,000,000 shares of "blank check" preferred stock, each with a par value of $0.001. On July 27, 2018 we completed a 1:29 reverse split of our Common Stock resulting in a total of 1,101,074 shares of Common Stock outstanding. As of December 31, 2019, there were 19,858,939 shares of Common Stock outstanding.

The following transactions in the Company's capital stock were completed in the year ended December 31, 2019:

On June 12, 2019, the Company issued 90,910 share units at $1.10 each for gross proceeds of $100,000 and it issued 27,727 share units at $0.9016 for gross proceeds of $25,000. Each unit consist of one share of common stock and one warrant, which allows the holder to purchase one common share of capital stock for a period of three years at a price of $3.00 per share.

The following transactions in the Company's capital stock were completed in the year ended December 31, 2018:

On May 14, 2018, 1,000 shares of preferred stock was issued to the CEO for services valued at $1. The preferred stock had voting rights of 80% at shareholder meetings.

On July 27, 2018, the Company completed a reverse stock split of 1 new share for 29 shares of the Company's issued and outstanding Common Stock. These financial statements give retroactive effect to this transaction.

On September 12, 2018, 16,980,000 common shares were issued to acquire patents and all rights, title and interest in Krillase technology and 1,500,000 shares were issued to the CEO in exchange for the 1,000 shares of preferred stock.

On December 30, 2018, 159,228 shares of Common Stock were issued on conversion of convertible debt of $79,614.

Options

The following stock options were granted during the past two years:

i) 265,000 options were granted to directors effective December 6, 2018. The options allowed the recipient to purchase shares at a price of $1.50 for a period of 10 years. The options vested in one year from the date of the grant and during the year, $330,651 was recorded as stock-based compensation, based on the inputs noted below.

ii) On July 13, 2019, 2,450,000 options were granted to an officer, directors and a consultant. The options granted the recipient to purchased shares at a price of $1.01 for a period of 10 years. 200,000 options vested at grant. The remaining options vest at the rate of 90,000 options per month. During the year, $367,936 was recorded as stock- based compensation, based on the inputs noted below.

The following weighted average inputs were used in calculating stock-based compensation for the 2019 year: term – 10 years; volatility – 203.45%; risk-free interest rate – 1.98%; dividend rate – nil.

As at December 31, 2019, the number of option outstanding and exercisable are as follows:

	# of options	# of options	Remaining

Exercise price	outstanding	exercisable	life
$1.50	265,000	265,000	8.94 yrs.
$1.01	2,450,000	740,000	9.54 yrs.
$1.06 *	2,715,000	1,005,000	9.48 yrs *

* weighted averages

Warrants

On June 12, 2019 as part of a financing, the Company issued Warrants to purchase 113,637 shares at a strike price of $3 for a period of three years. All these warrants are still outstanding as at December 31, 2019.

Note 7 COMMITMENTS

On September 14, 2018, the Company signed a 3-year employment agreement with its CEO, Mr Handley, with a base salary of $490,000 and bonuses of up to 55% of his base salary at the sole discretion of the Board of Directors. His base salary shall not accrue or be paid unless and until the company raises at least $2,000,000 dollars in financing. If the company raises $2,000,000 then Mr. Handley is eligible to receive 20% of his unpaid base salary up to a value of $98,000 maximum. If the company raises more than $5,000,000 then Mr. Handley is eligible to receive his unpaid base salary up to a value of $240,000 maximum. No bonuses will be paid if the company raises any money.

Mr. Handley is eligible to receive options to purchase up to 250,000 shares of the Company's Common Stock for each of the following milestones at a strike price of $0.01 upon the shares trading at a weighted average value during a period of 60 days equal to or greater than each of the following milestones: $7.50 per share, $15.00 per share, $30.00 per share, and $50.00 per share.

The Company may terminate Mr. Handley With Cause upon 15 days written notice and is not eligible for severance payment from the Company except for previously unpaid base salary or expense reimbursements. If the Company terminates Mr. Handley's employment Without Cause within 12 months since the execution of the agreement he shall be entitled to unpaid base salary plus 3 months of base salary severance. If the Company terminates Mr. Handley's employment Without Cause after 12 months since the execution of the agreement, he shall be entitled to unpaid base salary plus 6 months of base salary severance and his options shall be automatically vested.

Mr. Handley resigned from all positions at the Company on March 13, 2019 and the Company has no further obligations to him.

On October 15, 2018 the Company signed a consulting agreement with NCAL, LLC for services related to advising the Board of Directors. NCAL, LLC receives $10,000 per month through December 2019 and the contract can be terminated with payment in full due to NCAL, LLC. On July 13, 2019, NCAL agreed to terminate this agreement with no cash payments due or received.

On July 13, 2019 the Company signed a consulting agreement with an individual to advise the Board of Directors. The individual receives $30,000 per month through July 13, 2022 and received an option to purchase 500,000 shares of Common Stock at a strike price of $1.01which vest monthly through July 13, 2021. These options are included in the Note 6 options above.

On November 7, 2019 the Company signed a 5 year exclusive distribution agreement with Somahlutions, LLC to distribute their DuraGraft products in Europe, South America and other territories.

On December 16, 2019, Marizyme signed a definitive agreement to purchase all the assets of Somahlutions and its related companies subject to raising $10 Million.

Note 8 LEGAL PROCEEDINGS

We are not subject to any legal proceeding nor are we aware of any potential legal matters.

Note 9 INCOME TAXES

Income tax recover differs from that which would be expected from applying the effective tax rates to the net loss as follows:

		2019		2018
Net loss for the year	$	(1,058,039)	$	(248,743)
Statutory and effective future rate		21%		21%
Income tax recovery at effective rate	$	(222,188)	$	(52,236)
Permanent difference		146,703		-
Tax benefit not recognized		74,485		52,236
Income tax recovery recognized	$	-	$	-

As at December 31, 2019 and 2018, the tax effect of the temporary timing differences that give rise to significant components of deferred tax asset are noted below.

		2019		2018
Tax loss carried forward	$	27,552,000	$	27,193,000
Deferred tax assets	$	5,785,000	$	5,710,000
Valuation allowance		(5,785,000)		(5,710,000)
Deferred taxes recognized	$	-	$	-

Approximately $26,944,000 in tax losses will expire between 2030 and 2038. $608,195 in losses have no expiry date.

Note 10 SUBSEQUENT EVENTS

On January 9, 2020 the Company issued 125,000 shares of Common Stock and an option to purchase 250,000 shares of Common Stock at a strike price of $1.01 vesting monthly by November 9, 2020 to an individual.