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

FORM C-AR

UNDER THE SECURITIES ACT OF 1933

(Mark one.)

- ☐ Form C: Offering Statement
- ☐ Form C-U: Progress Update
- ☐ Form C/A: Amendment to Offering Statement
  - ☐ Check box if Amendment is material and investors must reconfirm within five business days.
- ☑ Form C-AR: Annual Report
- ☐ Form C-AR/A: Amendment to Annual Report
- ☐ Form C-TR: Termination of Reporting

Name of issuer
Kneevoice, Inc.

Legal status of issuer

Form
Corporation

Jurisdiction of Incorporation/Organization
Delaware

Date of organization
June 17, 2016

Physical address of issuer
1626 Montana Avenue, #155, Santa Monica, CA 90403

Website of issuer
www.KneeVoice.com

Current number of employees
7

	Most recent fiscal year-end	Prior fiscal year-end
Total Assets	$98,091.21	$392,115.81
Cash & Cash Equivalents	$16,487.97	$320,039.29
Accounts Receivable	$0.00	$0.00
Short-term Debt	$356,359.12	$197,717.92
Long-term Debt	$0.00	$0.00
Revenues/Sales	$0.00	$0.00
Cost of Goods Sold	$0.00	$0.00
Taxes Paid	$5,632.31	$815.00
Net Income	-$613,754.34	-$751,695.91

April 23, 2024

FORM C-AR

Kneevoice, Inc.

This Form C-AR (including the cover page and all exhibits attached hereto, the "Form C-AR) is being furnished by Kneevoice, Inc., a Delaware Corporation (the "Company," as well as references to "we," "us," or "our") for the sole purpose of providing certain information about the Company as required by the Securities and Exchange Commission ("SEC").

No federal or state securities commission or regulatory authority has passed upon the accuracy or adequacy of this document. The U.S. Securities and Exchange Commission does not pass upon the accuracy or completeness of any disclosure document or literature. The Company is filing this Form C-AR pursuant to Regulation CF (§ 227.100 et seq.) which requires that it must file a report with the Commission annually and post the report on its website at www.KneeVoice.com no later than 120 days after the end of each fiscal year covered by the report. The Company may terminate its reporting obligations in the future in accordance with Rule 202(b) of Regulation CF (§ 227.202(b)) by 1) being required to file reports under Section 13(a) or Section 15(d) of the Exchange Act of 1934, as amended, 2) filing at least one annual report pursuant to Regulation CF and having fewer than 300 holders of record, 3) filing annual reports for three years pursuant to Regulation CF and having assets equal to or less than $10,000,000, 4) the repurchase of all the Securities sold pursuant to Regulation CF by the Company or another party, or 5) the liquidation or dissolution of the Company.

The date of this Form C-AR is April 23, 2024.

THIS FORM C-AR DOES NOT CONSTITUTE AN OFFER TO PURCHASE OR SELL SECURITIES.

Forward Looking Statement Disclosure

This Form C-AR and any documents incorporated by reference herein or therein contain forward-looking statements and are subject to risks and uncertainties. All statements other than statements of historical fact or relating to present facts or current conditions included in this Form C-AR are forward-looking statements. Forward-looking statements give the Company's

current reasonable expectations and projections relating to its financial condition, results of operations, plans, objectives, future performance and business. You can identify forward-looking statements by the fact that they do not relate strictly to historical or current facts. These statements may include words such as "anticipate," "estimate," "expect," "project," "plan," "intend," "believe," "may," "should," "can have," "likely" and other words and terms of similar meaning in connection with any discussion of the timing or nature of future operating or financial performance or other events.

The forward-looking statements contained in this Form C-AR and any documents incorporated by reference herein or therein are based on reasonable assumptions the Company has made in light of its industry experience, perceptions of historical trends, current conditions, expected future developments and other factors it believes are appropriate under the circumstances. As you read and consider this Form C-AR, you should understand that these statements are not guarantees of performance or results. They involve risks, uncertainties (many of which are beyond the Company's control) and assumptions. Although the Company believes that these forward-looking statements are based on reasonable assumptions, you should be aware that many factors could affect its actual operating and financial performance and cause its performance to differ materially from the performance anticipated in the forward-looking statements. Should one or more of these risks or uncertainties materialize or should any of these assumptions prove incorrect or change, the Company's actual operating and financial performance may vary in material respects from the performance projected in these forward-looking statements.

Any forward-looking statement made by the Company in this Form C-AR or any documents incorporated by reference herein or therein speaks only as of the date of this Form C-AR. Factors or events that could cause our actual operating and financial performance to differ may emerge from time to time, and it is not possible for the Company to predict all of them. The Company undertakes no obligation to update any forward-looking statement, whether as a result of new information, future developments or otherwise, except as may be required by law.

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About this Form C-AR

You should rely only on the information contained in this Form C-AR. We have not authorized anyone to provide you with information different from that contained in this Form C-AR. You should assume that the information contained in this Form C-AR is accurate only as of the date of this Form C-AR, regardless of the time of delivery of this Form C-AR. Our business, financial condition, results of operations, and prospects may have changed since that date.
Statements contained herein as to the content of any agreements or other document are summaries and, therefore, are necessarily selective and incomplete and are qualified in their entirety by the actual agreements or other documents.

SUMMARY

The following summary is qualified in its entirety by more detailed information that may appear elsewhere in this Form C-AR and the Exhibits hereto.

Kneevoice, Inc. (the "Company") is a Delaware Corporation, formed on June 17, 2016.

The Company is located at 1626 Montana Avenue, #155, Santa Monica, CA 90403.

The Company's website is www.KneeVoice.com.

The information available on or through our website is not a part of this Form C-AR.

The Business

KneeVoice is a MedTech company that has developed a simple, quick and noninvasive diagnostic platform presently applied to orthopedic medicine engineered to provide diagnosis of cartilage damage in the patellofemoral joint (knee joint). The platform is intended to be used in the diagnostic process, as well as in the follow-up and treatment outcome monitoring phases of recovery. This platform is designed to be used by orthopedic and sports medicine clinicians, physical therapists, trainers, and individuals monitoring their own performance. This is a first-of-its-kind platform that offers advanced technology applied to the orthopedic practice, with intellectual property protection covering the data capture and analysis methods used in diagnostic testing.

RISK FACTORS

Risks Related to the Company's Business and Industry

We have a limited operating history upon which you can evaluate our performance, and accordingly, our prospects must be considered in light of the risks that any new company encounters.
Although we were formed under the laws of the State of California in 2015 and reincorporated into the State of Delaware in June 2016, when we began operations. Accordingly, we have a very 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 a new enterprise. The likelihood of our creation of a viable business must be considered in light of the problems, expenses, difficulties, complications, and delays frequently encountered in connection with the

inception of a business, operation in a competitive industry, and the continued development of advertising, promotions, and a corresponding client base. We anticipate that our operating expenses will increase for the near future. There can be no assurances that we will ever operate profitably. You should consider our business, operations and prospects in light of the risks, expenses and challenges faced as an early-stage company.

The development and commercialization of our products is highly competitive.
We face competition with respect to any products that we may seek to develop or commercialize in the future. Our competitors include major companies worldwide. Many of our competitors have significantly greater financial, technical and human resources than we have and superior expertise in research and development and marketing approved products and thus may be better equipped than us to develop and commercialize products. These competitors also compete with us in recruiting and retaining qualified personnel and acquiring technologies. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. Accordingly, our competitors may commercialize products more rapidly or effectively than we are able to, which would adversely affect our competitive position, the likelihood that our products will achieve initial market acceptance and our ability to generate meaningful additional revenues from our products.

We depend on third-party service providers and outsource providers for a variety of services, and we outsource a number of our non-core functions and operations.
In certain instances, we rely on single or limited-service providers and outsourcing vendors around the world because the relationship is advantageous due to quality, price, or lack of alternative sources. If production or service was interrupted and we were not able to find alternate third-party providers, we could experience disruptions in manufacturing and operations including product shortages, higher freight costs and re-engineering costs. If outsourcing services are interrupted or not performed or the performance is poor, this could impact our ability to process, record and report transactions with our customers and other constituents. Such interruptions in the provision of supplies and/or services could result in our inability to meet customer demand, damage our reputation and customer relationships and adversely affect our business.

We depend on third party providers, suppliers and licensors to supply some of the hardware, software and operational support necessary to provide some of our services.
We obtain these materials from a limited number of vendors, some of which do not have a long operating history, or which may not be able to continue to supply the equipment and services we desire. Some of our hardware, software and operational support vendors represent our sole source of supply or have, either through contract or as a result of intellectual property rights, a position of some exclusivity. If demand exceeds these vendors' capacity or if these vendors experience operating or financial difficulties or are otherwise unable to provide the equipment or services we need in a timely manner, at our specifications and at reasonable prices, our ability to provide some services might be materially adversely affected, or the need to procure or develop alternative sources of the affected materials or services might delay our ability to serve our customers. These events could materially and adversely affect our ability to retain and attract customers, and have a material negative impact on our operations, business, financial results and financial condition.

We may implement new lines of business or offer new products and services within existing lines of business.

There are substantial risks and uncertainties associated with these efforts, particularly in instances where the markets are not fully developed. In developing and marketing new lines of business and/or new products and services, we may invest significant time and resources. Initial timetables for the introduction and development of new lines of business and/or new products or services may not be achieved, and price and profitability targets may not prove feasible. We may not be successful in introducing new products and services in response to industry trends or developments in technology, or those new products may not achieve market acceptance. As a result, we could lose business, be forced to price products and services on less advantageous terms to retain or attract clients or be subject to cost increases. As a result, our business, financial condition or results of operations may be adversely affected.

The use of individually identifiable data by our business, our business associates and third parties is regulated at the state, federal and international levels.

Costs associated with information security - such as investment in technology, the costs of compliance with consumer protection laws and costs resulting from consumer fraud - could cause our business and results of operations to suffer materially. Additionally, the success of our online operations depends upon the secure transmission of confidential information over public networks, including the use of cashless payments. The intentional or negligent actions of employees, business associates or third parties may undermine our security measures. As a result, unauthorized parties may obtain access to our data systems and misappropriate confidential data. There can be no assurance that advances in computer capabilities, new discoveries in the field of cryptography or other developments will prevent the compromise of our customer transaction processing capabilities and personal data. If any such compromise of our security or the security of information residing with our business associates or third parties were to occur, it could have a material adverse effect on our reputation, operating results and financial condition. Any compromise of our data security may materially increase the costs we incur to protect against such breaches and could subject us to additional legal risk.

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

We collect and store sensitive data, including intellectual property, our proprietary business information and that of our customers, suppliers and business partners, and personally identifiable information of our customers and employees, in our data centers and on our networks. The secure processing, maintenance and transmission 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 could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, and regulatory penalties, disrupt our operations and the services we provide to customers, and damage our reputation, and cause a loss of confidence in our products and services, which could adversely affect our business/operating margins, revenues and competitive position. The secure processing, maintenance and transm1ss1on of this information is critical to our operations and business strategy, and we may devote significant resources to protecting our information. The expenses associated with protecting our information through these steps could reduce our operating margins.

Our success depends on the experience and skill of our board of directors, executive officers and key employees.

In particular, we are dependent on Gustavo De Greiff, Felipe Rigby, and Dr. Carlos Leal who are our CEO - founder since 2016, CTO - Founder since start 2016, Chief Medical Officer - Founder since start 2016 and Chief Marketing Officer of the Company, respectively. We have entered into or intend to enter into employment agreements with Gustavo De Greiff, Felipe Rigby and Dr. Carlos Leal, although there can be no assurance that we will be able to or that they will continue to be employed by the Company for a particular period of time. The loss of any of Gustavo De Greiff, Felipe Rigby, and Dr. Carlos Leal or any member of our board of directors or any of our executive officers could harm our business, financial condition, cash flow and results of operations.

In order for us to compete and grow, we must attract, recruit, retain and develop the necessary personnel who have the needed experience.

Recruiting and retaining highly qualified personnel is critical to our success. These demands may require us to hire additional personnel and will require our existing management personnel to develop additional expertise. We face intense competition for personnel. The failure to attract and retain personnel or to develop such expertise could delay or halt the development and commercialization of our product candidates. If we experience difficulties in hiring and retaining personnel in key positions, we could suffer from delays in product development, loss of customers and sales and diversion of management resources, which could adversely affect operating results. Our consultants and advisors may be employed by third parties and may have commitments under consulting or advisory contracts with third parties that may limit their availability to us.

We rely on various intellectual property rights, including patents and trademarks in order to operate our business.

Such intellectual property rights, however, may not be sufficiently broad or otherwise may not provide us a significant competitive advantage. In addition, the steps that we have taken to maintain and protect our intellectual property may not prevent it from being challenged, invalidated, circumvented or designed around, particularly in countries where intellectual property rights are not highly developed or protected. In some circumstances, enforcement may not be available to us because an infringer has a dominant intellectual property position or for other business reasons, or countries may require compulsory licensing of our intellectual property. Our failure to obtain or maintain intellectual property rights that convey competitive advantage, adequately protect our intellectual property or detect or prevent circumvention or unauthorized use of such property, could adversely impact our competitive position and results of operations. We also rely on nondisclosure and noncompetition agreements with employees, consultants and other parties to protect, in part, trade secrets and other proprietary rights. There can be no assurance that these agreements will adequately protect our trade secrets and other proprietary rights and will not be breached, that we will have adequate remedies for any breach, that others will not independently develop substantially equivalent proprietary information or that third parties will not otherwise gain access to our trade secrets or other proprietary rights. As we expand our business, protecting our intellectual property will become increasingly important. The protective steps we have taken may be inadequate to deter our competitors from using our proprietary information. In order to protect or enforce our patent rights, we may be required to initiate litigation against third parties, such as infringement lawsuits. Also, these third parties

may assert claims against us with or without provocation. These lawsuits could be expensive, take significant time and could divert management's attention from other business concerns. The law relating to the scope and validity of claims in the technology field in which we operate is still evolving and, consequently, intellectual property positions in our industry are generally uncertain. We cannot assure you that we will prevail in any of these potential suits or that the damages or other remedies awarded, if any, would be commercially valuable.

From time to time, third parties may claim that one or more of our products or services infringe their intellectual property rights.

Any dispute or litigation regarding patents or other intellectual property could be costly and time-consuming due to the complexity of our technology and the uncertainty of intellectual property litigation and could divert our management and key personnel from our business operations. A claim of intellectual property infringement could force us to enter into a costly or restrictive license agreement, which might not be available under acceptable terms or at all, could require us to redesign our products, which would be costly and time-consuming, and/or could subject us to an injunction against development and sale of certain of our products or services. We may have to pay substantial damages, including damages for past infringement if it is ultimately determined that our products infringe on a third party's proprietary right. Even if these claims are without merit, defending a lawsuit takes significant time, may be expensive and may divert management's attention from other business concerns. Any public announcements related to litigation or interference proceedings initiated or threatened against us could cause our business to be harmed. Our intellectual property portfolio may not be useful in asserting a counterclaim, or negotiating a license, in response to a claim of intellectual property infringement. In certain of our businesses, we rely on third party intellectual property licenses, and we cannot ensure that these licenses will be available to us in the future on favorable terms or at all.

Our business is substantially dependent upon awareness and market acceptance of our platform and brand.

Our business depends on acceptance by both our primary end users, including orthopedic and sports medicine clinicians, physical therapists, trainers and individuals who are monitoring performance, as well as the businesses that we work with of our platform that has the potential to provide incremental sales growth. We believe that the success of our business will also be substantially dependent upon acceptance of our brand. Accordingly, any failure of our brand to maintain or increase acceptance or market penetration would likely have a material adverse effect on our business, operations and financial results.

Reductions in future sales of our platfon11 or usage will have an adverse effect on our profitability and ability to generate cash to fund our business plan.

The following factors, among others, could affect continued market acceptance and profitability of our platform and brand:

- the introduction of competitive products;
- the level and effectiveness of our sales and marketing efforts;
- any unfavorable publicity regarding our platform or similar services;

• any unfavorable publicity regarding our brand;

• litigation or threats of litigation with respect to our platform;

• any changes in government policies and practices related to our platform and markets; and

• regulatory developments affecting the marketing or use of our platform.

Adverse developments with respect to the sale or market acceptance of our platform would significantly reduce our sales and profitability and have a material adverse effect on our ability to maintain profitability and achieve our business plan.

Although dependent on certain key personnel, the Company does not have any key man life insurance policies on any such people.

We are dependent on Gustavo De Greiff, Felipe Rigby, and Dr. Carlos Leal in order to conduct its operations and execute our business plan, however, we have not purchased any insurance policies with respect to those individuals in the event of their death or disability. Therefore, if any of Gustavo De Greiff, Felipe Rigby, or Dr. Carlos Leal die or become disabled, we will not receive any compensation to assist with such person's absence. The loss of such persons could negatively affect us and our operations.

We have not prepared any audited financial statements.

Our independent accountant has reviewed our financial statements; however, our financial statements have not been audited and therefore have not been subject to the more rigorous review required by an audit. Accordingly, you have no audited financial information regarding our capitalization or assets or liabilities on which to make your investment decision. If you feel the information provided is insufficient, you should not invest in our Company.

We are subject to income taxes as well as non-income-based taxes, such as payroll, sales, use, value-added, net worth, property and goods and services taxes, in the U.S.

Significant judgment is required in determining our provision for income taxes and other tax liabilities. In the ordinary course of our business, there are many transactions and calculations where the ultimate tax determination is uncertain. Although we believe that our tax estimates are reasonable: (i) there is no assurance that the final determination of tax audits or tax disputes will not be different from what is reflected in our income tax provisions, expense amounts for non-income based taxes and accruals and (ii) any material differences could have an adverse effect on our financial position and results of operations in the period or periods for which determination is made.

We are not subject to Sar banes-Oxley regulations and lack the financial controls and safeguards required of public companies.

We do not have the internal infrastructure necessary, and are not required, to complete an attestation about our financial controls that would be required under Section 404 of the Sarbanes-Oxley Act of 2002. There can be no assurance that there are no significant deficiencies or

material weaknesses in the quality of our financial controls. We expect to incur additional expenses and diversion of management's time if and when it becomes necessary to perform the system and process evaluation, testing and remediation required in order to comply with the management certification and auditor attestation requirements.

We have indicated that we have engaged in certain transactions with related persons.
Please see the section of this Memorandum entitled "Transactions with Related Persons and Conflicts of Interest" for further details.

Our business operations may be materially adversely affected by a pandemic such as the Coronavirus (COVID-19) outbreak.
In December 2019, a novel strain of coronavirus was reported to have surfaced in Wuhan, China, which spread throughout other parts of the world, including the United States. On January 30, 2020, the World Health Organization declared the outbreak of the coronavirus disease (COVID-19) a "Public Health Emergency of International Concern." On January 31, 2020, U.S. Health and Human Services Secretary Alex M. Azar II declared a public health emergency for the United States to aid the U.S. healthcare community in responding to COVID-19, and on March 11, 2020, the World Health Organization characterized the outbreak as a "pandemic." COVID-19 resulted in a widespread health crisis that adversely affected the economies and financial markets worldwide. Our business could be materially and adversely affected. The extent to which COVID- 19 impacts our business will depend on future developments, which are highly uncertain and cannot be predicted, including new information which may emerge concerning the severity of COVID-19 and the actions to contain COVID-19 or treat its impact, among others. If the disruptions posed by COVID-19 or other matters of global concern continue for an extended period of time, our operations may be materially adversely affected.

We face risks related to health epidemics and other outbreaks, which could significantly disrupt our operations and could have a material adverse impact on us.
The outbreak of pandemics and epidemics could materially and adversely affect our business, financial condition, and results of operations. If a pandemic occurs in areas in which we have material operations or sales, our business activities originating from affected areas, including sales, materials, and supply chain related activities, could be adversely affected. Disruptive activities could include the temporary closure of facilities used in our supply chain processes, restrictions on the export or shipment of products necessary to run our business, business closures in impacted areas, and restrictions on our employees' or consultants' ability to travel and to meet with customers, vendors or other business relationships. The extent to which a pandemic or other health outbreak impacts our results will depend on future developments, which are highly uncertain and cannot be predicted, including new information which may emerge concerning the severity of a virus and the actions to contain it or treat its impact, among others. Pandemics can also result in social, economic, and labor instability which may adversely impact our business. If our employees or employees of any of our vendors, suppliers or customers become ill or are quarantined and in either or both events are therefore unable to work, our operations could be subject to disruption. The extent to which a pandemic affects our results will depend on future developments that are highly uncertain and cannot be predicted.

Certain provisions of the Health Care Reform Lmv could affect us adversely.
The Patient Protection and Affordable Care Act as amended by the Health Care and Education

Reconciliation Act (the Healthcare Reform Law), each enacted in March 2010, generally known as the Health Care Reform Law, significantly expand health insurance coverage to uninsured Americans and changes the way health care is financed by both governmental and private payers. Additionally, further federal and state proposals for health care reform are likely. Such regulation could have a negative effect on our business, financial condition, and results of operations.

The Health Care Reform Law 2.3% excise tax on domestic sales of medical devices by manufacturers and importers beginning in 2013 may adversely affect sales and cost of goods sold.

For example, (i) where we purchase medical devices from third-party manufacturers, the manufacturers may increase their prices to cover their payment of the excise tax and our costs to purchase such medical devices may therefore increase and (ii) where we manufacture medical devices or are the importer of record, our cost of goods sold have increased because we are subject to paying the excise tax.

Political, economic and regulatory influences are subjecting the healthcare industry to potential fundamental changes that could substantially affect our results of operations.

Government and private sector initiatives to limit the growth of healthcare costs, including price regulation, competitive pricing, coverage and payment policies, comparative effectiveness of therapies, technology assessments and alternative payment models, are continuing in many countries where we do business, including the U.S. These changes are causing the marketplace to put increased emphasis on the delivery of more cost-effective treatments. As a U.S. headquartered Company with significant sales in the U.S., this healthcare reform legislation will materially impact/is impacting us. Certain provisions of the legislation will not be effective for a number of years, and it is unclear what the full impact of the legislation will be. Provisions of this legislation, including Medicare provisions aimed at improving quality and decreasing costs, comparative effectiveness research, an independent payment advisory board, and pilot programs to evaluate alternative payment methodologies, could meaningfully change the way healthcare is developed and delivered, and may adversely affect our business and results of operations. Further, we cannot predict what healthcare programs and regulations will be ultimately implemented at the federal or state level, or the effect of any future legislation or regulation in the U.S. or internationally. However, any changes that lower reimbursements for our products, reduce medical procedure volumes or increase cost containment pressures on us or other participants in the healthcare industry could adversely affect our business and results of operations.

Changes to governmen.t health care programs that reduce payments under Medicare and Medicaid may negatively impact payments from commercial third-party payers.

The Healthcare Reform Law will result in increased state legislative and regulatory changes in order for states to comply with new federal mandates, such as the requirement to establish or participate in Exchanges and to participate in grants and other incentive opportunities. In its June 28, 2012 ruling, the U.S. Supreme Court struck down the portion of the Health Reform Law that would have allowed the Department of Health and Human Services to penalize states that do not implement the Medicaid expansion provisions with the loss of existing federal Medicaid funding. Thus, states may opt not to implement the expansion. In some cases, commercial third-party payors rely on all or portions of Medicare payment systems to determine payment rates. Current or future health care reform and deficit reduction efforts, changes in laws or regulations regarding government health care programs, other changes in the administration of government

health care programs and changes to commercial third-party payers in response to health care reform and other changes to governn1ent health care programs could have a material, adverse effect on our financial position and results of operations.

Privacy laws and regulations could restrict our ability or the ability of our customers to obtain, use or disseminate patient information or could require us to incur significant additional costs to re-design our products.

State, federal and foreign laws, such as the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA), regulate the confidentiality of sensitive personal information and the circumstances under which such information may be released. These and future laws could have an adverse impact on our results of operations. Other health information standards, such as regulations under HIPAA, establish standards regarding electronic health data transmissions and transaction code set rules for specified electronic transactions, for example transactions involving claims submissions to third party payors. These also continue to evolve and are often unclear and difficult to apply. In addition, under the federal Health Information Technology for Economic and Clinical Health Act (HITECH Act), which was passed in 2009, many businesses that were previously only indirectly subject to federal HIPPA privacy and security rules became directly subject to such rules because the businesses serve as "business associates" to our customers. On January 17, 2013, the Office for Civil Rights of the Department of Health and Human Services released a final rule implementing the HITECH Act and making certain other changes to HIPAA privacy and security requirements. Compliance has increased the requirements applicable to some of our businesses. Failure to maintain the confidentiality of sensitive personal information in accordance with the applicable regulatory requirements, or to abide by electronic health data transmission standards, could expose us to breach of contract claims, fines and penalties, costs for remediation and harm to our reputation.

The healthcare industry is highly regulated.

We are subject to regulation in the U.S. at both the federal and state level and in foreign countries. In addition, the U.S. federal and state governments have allocated greater resources to the enforcement of these laws. If we fail to comply with these regulatory requirements, or if allegations are made that we failed to comply, our results of operations and financial condition could be adversely affected.

Products that we manufacture, source, distribute or market are required to comply with regulatory requirements.

To lawfully operate our businesses, we are required to hold permits, licenses and other regulatory approvals from, and to comply with operating and security standards of, governmental bodies.
Failure to maintain or renew necessary permits, licenses or approvals, or noncompliance or concerns over noncompliance may result in suspension of our ability to distribute, import or manufacture products, product recalls or seizures, or criminal and civil sanctions and could have an adverse effect on our results of operations and financial condition.

The manufacture, distribution, marketing and use of our products are subject to extensive regulation and increased scrutiny by the Food and Drug Administration (FDA) and other regulatory authorities globally.

Any new product must undergo lengthy and rigorous testing and other extensive, costly and time-consuming procedures mandated by FDA and foreign regulatory authorities. Changes to

current products may be subject to vigorous review, including additional 5 l0(k) and other regulatory submissions, and approvals are not certain. Our facilities must be approved and licensed prior to production and remain subject to inspection from time to time thereafter. Failure to comply with the requirements of FDA or other regulatory authorities, including a failed inspection or a failure in our adverse event reporting system, could result in adverse inspection reports, warning letters, product recalls or seizures, monetary sanctions, injunctions to halt the manufacture and distribution of products, civil or criminal sanctions, refusal of a government to grant approvals or licenses, restrictions on operations or withdrawal of existing approvals and licenses. Any of these actions could cause a loss of customer confidence in us and our products, which could adversely affect our sales and results of operations.

The sales, marketing and pricing of products and relationships that pharmaceutical and medical device companies have with healthcare providers are under increased scrutiny by federal, state and foreign government agencies.

Compliance with the Anti-Kickback Statute, False Claims Act, Food, Drug and Cosmetic Act (including as these laws relate to off-label promotion of products) and other healthcare related laws, as well as competition, data and patient privacy and export and import laws is under increased focus by the agencies charged with overseeing such activities, including FDA, Office of Inspector General (OIG), Department of Justice (DOJ) and the Federal Trade Commission. The DOJ and the Securities and Exchange Commission have also increased their focus on the enforcement of the U.S. Foreign Corrupt Practices Act (FCPA), particularly as it relates to the conduct of pharmaceutical companies.

Federal and State Laws Pertaining to Healthcare Fraud and Abuse Could Adversely Affect Our Business.

We are subject to various federal and state laws targeting fraud and abuse in the healthcare industry, including anti-kickback laws, false claims laws, laws constraining the sales, marketing and other promotional activities of manufacturers of medical devices by limiting the kinds of financial arrangements we may enter into with physicians, hospitals, laboratories and other potential purchasers of medical devices, laws requiring the reporting of certain transactions between us and healthcare professionals and HIPAA, as amended by HITECH, which governs the conduct of certain electronic healthcare transactions and protects security and privacy of protected health information. Violations of these laws are punishable by criminal or civil sanctions, including substantial fines, imprisonment and exclusion from participation in government healthcare programs such as Medicare and Medicaid. Many of the existing requirements are new and have not been definitively interpreted by state authorities or courts, and available guidance is limited. Unless and until we are in full compliance with these laws, we could face enforcement action and fines and other penalties, and could receive adverse publicity, all of which could materially harm our business. In addition, changes in or evolving interpretations of these laws, regulations, or administrative or judicial interpretations, may require us to change our business practices or subject our business practices to legal challenges, which could have a material adverse effect on our business, financial condition and results of operations.

The commercial success of our products will depend in part upon the level of reimbursement we receive from third parties for the cost of our products to users.

The commercial success of any product will depend, in part, on the extent to which reimbursement for the costs of our products and related treatments will be available from third-

party payors such as government health administration authorities, private health insurers, managed care programs, and other organizations. Adequate third-party insurance coverage may not be available for us to establish and maintain price levels that are sufficient for us to continue our business or for realization of an appropriate return on investment in product development.

If we are unable to educate physicians on the safe and effective use of our products, we may be unable to achieve our expected growth.

An important part of our sales process includes the education of physicians on the safe and effective use of our products. There is a learning process for physicians to become proficient in the use of our products and it typically takes several procedures for a physician to become comfortable using the product If a physician experiences difficulties during an initial procedure or otherwise, that physician may be less likely to continue to use our product, or to recommend it to other physicians. It is critical to the success of our commercialization efforts to educate physicians on the proper use of the product, and to provide them with adequate product support during clinical procedures. It is important for our growth that these physicians advocate for the benefits of our products in the broader marketplace. If physicians are not properly trained, they may misuse or ineffectively use our products. This may also result in unsatisfactory patient outcomes, patient injuries, negative publicity or lawsuits against us, any of which could have an adverse effect on our business.

The design, manufacture and marketing of the medical devices we produce entail an inherent risk of product liability claims.

Manufacturing and marketing of our commercial products, and clinical testing of our products under development, may expose us to product liability and other tort claims. Although we have, and intend to maintain, liability insurance, the coverage limits of our insurance policies may not be adequate and one or more successful claims brought against us may have a material adverse effect on our business and results of operations. There are a number of factors that could result in an unsafe condition or injury to, or death of, a patient with respect to these or other products which we manufacture or sell, including component failures, manufacturing flaws, design defects or inadequate disclosure of product-related risks or product-related information. Product liability claims may be brought by individuals or by groups seeking to represent a class. The outcome of litigation, particularly class action lawsuits, is difficult to assess or quantify. Plaintiffs in these types of lawsuits often seek recovery of very large or indeterminate amounts, and the magnitude of the potential loss relating to such lawsuits may remain unknown for substantial periods of time. Any costs (the material components of which are settlements, judgments, legal fees and other related defense costs) not covered under our previously issued product liability insurance policies and existing reserves could have a material adverse effect on our revenues, financial position and cash flows. Additionally, product liability claims could negatively affect our reputation, continued product sales, and our ability to obtain and maintain regulatory approval for our products.

We depend on fewer suppliers for our products and therefore we may be less able to negotiate price terms with suppliers.

In recent years, pharmaceutical suppliers have been subject to increasing consolidation. As a result, a small number of very large companies control a significant share of the market. Many healthcare organizations also have consolidated to create larger healthcare enterprises with greater market power. If this consolidation trend continues, it could reduce the size of our target

market and give the resulting enterprises greater bargaining power, which may lead to a decrease in the prices for our products and services.

If third-party payors do not provide adequate coverage and reimbursement for the use of our products, our revenues will be negatively impacted.

Our success in marketing our products depend in large part on whether U.S. and international government health administrative authorities, private health insurers and other organizations will adequately cover and reimburse customers for the cost of our products. In the United States, a third-party payor's decision to provide coverage for our products does not imply that an adequate reimbursement rate will be obtained. Further, one third-party payor's decision to cover our products does not assure that other payors will also provide coverage for the products or provide coverage at an adequate reimbursement rate. Reimbursement systems in international markets vary significantly by country and by region within some countries, and reimbursement approvals must be obtained on a country-by-country basis. In many international markets, a product must be approved for reimbursement before it can be approved for sale in that country. Further, many international markets have government-managed healthcare systems that control reimbursement for new devices and procedures. In most markets there are private insurance systems as well as government-managed systems. If sufficient coverage and reimbursement is not available for our current or future products, in either the United States or internationally, the demand for our products and our revenues will be adversely affected.

We may in the future be subject to various U.S. federal and state laws pertaining to health care fraud and abuse, including anti-kickback, self-referral, false claims and fraud laws, and any violations by us of such laws could result in fines or other penalties.

If one or more of our product candidates is approved, we will likely be subject to the various U.S. federal and state laws intended to prevent health care fraud and abuse. The federal anti-kickback statute prohibits the offer, receipt, or payment of remuneration in exchange for or to induce the referral of patients or the use of products or services that would be paid for in whole or part by Medicare, Medicaid or other federal health care programs. Remuneration has been broadly defined to include anything of value, including cash, improper discounts, and free or reduced-price items and services. Many states have similar laws that apply to their state health care programs as well as private payors. Violations of the anti-kickback laws can result in exclusion from federal health care programs and substantial civil and criminal penalties. The False Claims Act (FCA) imposes liability on persons who, among other things, present or cause to be presented false or fraudulent claims for payment by a federal health care program. The FCA has been used to prosecute persons submitting claims for payment that are inaccurate or fraudulent, that are for services not provided as claimed, or for services that are not medically necessary. The FCA includes a whistleblower provision that allows individuals to bring actions on behalf of the federal government and share a portion of the recovery of successful claims. If our marketing or other arrangements were determined to violate the FCA or anti-kickback or relate laws, then our revenue could be adversely affected, which would likely harm our business, financial condition, and results of operations. State and federal authorities have aggressively targeted medical technology companies for alleged violations of these anti-fraud statutes, based on improper research or consulting contracts with doctors, certain marketing arrangements that rely on volume-based pricing, off-label marketing schemes, and other improper promotional practices. Companies targeted in such prosecutions have paid substantial fines in the hundreds of millions of dollars or more, have been forced to implement extensive corrective action plans or Corporate Integrity Agreements, and have often become subject to consent decrees severely restricting the manner in which they conduct their business. If we become the target of such an

investigation or prosecution based on our contractual relationships with providers or institutions, or our marketing and promotional practices, we could face similar sanctions, which would materially harm our business.

If we are found to have violated laws protecting the privacy or security of patient health information, we could be subject to civil or criminal penalties, which could increase our liabilities and harm our reputation or our business.

There are a number of U.S. federal and state laws and foreign laws protecting the privacy and security of individually identifiable health information, or "protected health information" including patient records, and restricting the use and disclosure of that protected health information that we are subject to. In the United States, the U.S. Department of Health and Human Services promulgated health information privacy and security rules under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and then significantly strengthened and broadened the applicability of HIPAA under the Health Information Technology for Economic and Clinical Health Act (HITECH, together HIPAA). HIPAA applies to health care providers engaging in certain standard transactions electronically; health plans and health care clearing houses. These entities are referred to as "covered entities." Certain HIPAA provisions also apply to "business associates" of covered entities, or third-party providers of services to covered entities that involve the use or disclosure of protected health information. HIPAA ’s privacy rules protect medical records and protected health information in all forms by limiting its use and disclosure, giving individuals the right to access, amend and seek accounting of their own health information and limiting, in some circumstances, the use and disclosure of protected health information to the minimum amount reasonably necessary to accomplish the intended purpose of the use or disclosure. HIPAA ’s security standards require both covered entities and business associates to implement administrative, physical and technical security measures to maintain the security of protected health information in electronic form. Covered entities and business associates must conduct initial and ongoing risk assessments to ensure the ongoing effectiveness of security measures and maintain a written information security plan. We are a covered entity and as such, we must comply with HIPAA and ensure that all aspects of our operations comply with relevant HIPAA standards. We are subject to random audit by federal authorities, and enforcement by both state and federal regulators. We are also subject to investigation in response to complaints. If we are found to be in violation of the HIPAA requirements, we could be subject to civil or criminal penalties as well as fines, which could increase our liabilities and harm our reputation or our business. Beyond HIPAA, most states have adopted data security laws protecting the personal data of state residents. Personal data subject to protection typically includes name coupled with social security number, state-issued identification number, or financial account number. Most states require specific, technical security measures for the protection of all personal data, including employee data, and impose their own breach notification requirements in the event of a loss of personal data. State data security laws generally overlap and apply simultaneously with HIPAA. Non-U.S. privacy protection requirements such as the European Union’s Data Protection Directive governing the processing of personal data, may be stricter than the U.S. law and violation would impose similar or more severe penalties. These laws could create liability for us or increase our cost of doing business, and any failure to comply could result in harm to our reputation, and potentially fines and penalties.

We may not be able to conduct clinical trials necessary to commercialize and sell our proposed products and formulations.

In order to conduct clinical trials that are necessary to obtain approval by the FDA to market our

product, it is necessary to receive clearance from the FDA to conduct such clinical trials. The FDA can halt clinical trials at any time for safety reasons or because we or our clinical investigators do not follow the FDA's requirements for conducting clinical trials. If we are unable to receive clearance to conduct clinical trials or the trials are halted by the FDA, we would not be able to achieve any revenue from such product as it is illegal to sell a medical device for human use without FDA approval. Moreover, it is our stated intention to attempt to avail ourselves of the FDA's Fast Track approval procedure, which we believe is less costly and time consuming. If this approval pathway is not available to us with respect to a particular formulation or product, or at all, the time and cost associated with developing and commercializing such formulations or products may be prohibitive and our business strategy would be materially and adversely affected.

Our long-term viability and growth will depend upon successful clinical trials.

Product development is very expensive and involves a high degree of risk. Only a small number of research and development programs result in the commercialization of a product. Success in preclinical work or early-stage clinical trials does not ensure that later stage or larger scale clinical trials will be successful. Conducting clinical trials is a complex, time-consuming and expensive process. Our ability to complete our clinical trials in a timely fashion depends in large part on a number of key factors including protocol design, regulatory and institutional review board approval, the rate of patient enrollment in clinical trials, and compliance with extensive current Good Clinical Practices. We have opened clinical sites and are enrolling patients in a number of countries where our experience is more limited, and we are in most cases using the services of third-party clinical trial providers. If we fail to adequately manage the design, execution and regulatory aspects of our large, complex and diverse clinical trials, our studies and ultimately our regulatory approvals may be delayed, or we may fail to gain approval for our product candidates. Clinical trials may indicate that our product candidates have harmful side effects or raise other safety concerns that may significantly reduce the likelihood of regulatory approval, result in significant restrictions on use and safety warnings in any approved label, adversely affect placement within the treatment paradigm, or otherwise significantly diminish the commercial potential of the product candidate. Also, positive results in a registrational trial may not be replicated in any subsequent confirmatory trials. Even if later stage clinical trials are successful, regulatory authorities may disagree with our view of the data or require additional studies, and may fail to approve or delay approval of our product candidates or may grant marketing approval that is more restricted than anticipated, including indications for a narrower patient population than expected and the imposition of safety monitoring or educational requirements or risk evaluation and mitigation strategies.

Our research and development efforts may not succeed in developing commercially successful products and technologies, which may limit our ability to achieve profitability.

We must continue to explore opportunities that may lead to new products and technologies. To accomplish this, we must commit substantial efforts, funds, and other resources to research and development. A high rate of failure is inherent in the research and development of new products and technologies. Any such expenditures that we make will be made without any assurance that our efforts will be successful. Failure can occur at any point in the process, including after significant funds have been invested. Regardless of whether our clinical trials are deemed to be successful, promising new product candidates may fail to reach the market or may only have limited commercial success because of efficacy or safety concerns, failure to achieve positive clinical outcomes, inability to obtain necessary regulatory approvals or satisfy regulatory criteria, limited scope of approved uses, excessive costs to manufacture, the failure to establish or

maintain intellectual property rights, or infringement of the intellectual property rights of others. Even if we successfully develop new products or enhancements, they may be quickly rendered obsolete by changing customer preferences, changing industry standards, or competitors' innovations. Innovations may not be quickly accepted in the marketplace because of, among other things, entrenched patterns of clinical practice or uncertainty over third-party reimbursement. We cannot state with certainty when or whether any of our products under development will be launched, whether we will be able to develop, license, or otherwise acquire certain products, or whether any products will be commercially successful. Failure to launch successful new products or new indications for existing products may cause our products to become obsolete, which may limit our ability to achieve profitability.

Even if we are able to obtain regulatory approvals for our new pharmaceutical products, generic or branded, the success of those products is dependent upon market acceptance.
Levels of market acceptance for our new products could be in1pacted by several factors, including but not limited to: (i) the availability of alternative products from our competitors, (ii) the price of our products relative to that of our competitors, (iii) the timing of our market entry, (iv) the ability to market our products effectively to the retail level and (v) the acceptance of our products by government and private entities. Some of these factors are not within our control. Additionally, continuing studies of the proper utilization, safety and efficacy of pharmaceutical products are being conducted by the industry, government agencies and others. Such studies, which increasingly employ sophisticated methods and techniques, can call into question the utilization, safety and efficacy of previously marketed products. In some cases, studies have resulted, and may in the future result, in the discontinuance of product marketing or other risk management programs such as the need for a patient registry. These situations, should they occur, could have a material adverse effect on our profitability, business, financial position and results of operations.

We rely on a third-party to manufacture our hardware products, which enables us to certain risks.
We contract with a third-party manufacturer to produce our hardware products in accordance with our specifications and standards. This manufacturer's facilities are subject to the risk of catastrophic loss due to, among other things, earthquake, fire, flood, terrorism or other natural or man-made disasters, as well as occurrence of significant equipment failures. If any of its facilities were to experience a catastrophic loss, it would be expected to disrupt our operations and damage relationships with our customers, among other negative consequences. We cannot guarantee a relationship with this particular manufacturer will remain in the future. The cessation of our relationship, either voluntary or involuntary, could have negative adverse effects on our operations and financial condition. We will continue to assess our reliance on this particular manufacturer and explore additional providers of our hardware products. In addition, the occurrence of manufacturing-related compliance issues could require subsequent withdrawal of our products' potential approval from the FDA. Any delay, interruption or cessation of production by our third-party manufacturers or strategic partners of our commercial products or product candidates, or their respective materials and components, as a result of any of the above factors or otherwise, may limit our ability to meet demand for commercial products and/or delay future clinical trials, either of which could have a material adverse effect on our business, results of operations and financial condition.

We could experience difficulties and delays in the manufacturing, distribution and sale of our products.

Our product supply and related patient access could be negatively impacted by, among other things: (i) product seizures or recalls or forced closings of manufacturing plants; (ii) disruption in supply chain continuity including from natural or man-made disasters at one of our facilities or a a critical supplier, as well as our failure or the failure of any of our suppliers to comply with Current Good Manufacturing Practices and other applicable regulations or quality assurance guidelines that could lead to manufacturing shutdowns, product shortages or delays in product manufacturing; (iii) manufacturing, quality assurance/quality control, supply problems or governmental approval delays; (iv) the failure of a sole source or single source supplier to provide us with the necessary raw materials, supplies or finished goods within a reasonable timeframe; (v) the failure of a third-party manufacturer to supply us with bulk active or finished product on time; (vi) construction or regulatory approval delays for new facilities or the expansion of existing facilities, including those intended to support future demand for our biologics products; (vii) the failure to meet new and emerging regulations requiring products to be tracked throughout the distribution channels using unique identifiers to verify their authenticity in the supply chain; and (viii) other manufacturing or distribution issues, including limits to manufacturing capacity due to regulatory requirements, and changes in the types of products produced, such as biologics, physical limitations or other business interruptions, any of which could have a negative effect on our business and results of operations.

Increased concerns over the safety of our products may result in negative publicity or increased regulatory controls on our products.

The Company's reputation is the foundation of our relationships with physicians, patients and other customers. If we are unable to effectively manage real or perceived issues, which could negatively impact sentiments toward the Company, our business could suffer. Pharmaceuticals and medical devices are perceived to be dangerous products and our customers may have a number of concerns about the safety of our products whether or not such concerns have a basis in generally accepted science or peer-reviewed scientific research. These concerns may be increased by negative publicity, even if the publicity is inaccurate. In addition, government investigations related to the use of our products, but not the efficacy of the products themselves, may cause reputational harm to the Company. Negative publicity could also result in an increased number of product liability claims, whether or not these claims have a basis in scientific fact. We are also subject to adverse event reporting regulations that require us to report to the FDA or similar bodies in other countries if our products are associated with a death or serious injury, even if there is no available evidence of a causal relationship between the adverse event and the product. Such reports may be publicly released by the FDA and other authorities. Furthermore, any adverse publicity associated with adverse events for our products, and related post-marketing actions, could cause consumers to seek alternatives to our products, and thereby cause our sales to decline, even if our products are ultimately determined not to have been the primary cause of the adverse event.

Pharmaceutical products can develop unexpected safety or efficacy concerns, which could have a material adverse effect on our business.

Pharmaceutical products receive regulatory approval based on data obtained in controlled clinical trials of limited duration. After approval, the products are used for longer periods of time by much larger numbers of patients; we and others (including regulatory agencies and private payers) collect extensive information on the efficacy and safety of our marketed products by continuously monitoring the use of our products in the marketplace. In addition, we or others

may conduct post-marketing clinical studies on efficacy and safety of our marketed products. New safety or efficacy data from market surveillance, post-marketing clinical studies or general use may result in product label changes, product recalls, withdrawals, or declining sales, as well as product liability, consumer fraud and/or other claims, including potential civil or criminal governmental actions.

Product labeling changes for our marketed products could result in a negative impact on revenues.

We or regulatory authorities may need to change the labeling for any pharmaceutical product, including after a product has been marketed for several years. These changes are often the result of additional data from post-marketing studies, head-to-head trials, adverse events reports, studies that identify biomarkers (objective characteristics that can indicate a particular response to a product or therapy) or other studies or post-marketing experience that produce important additional information about a product. New information added to a product's label can affect its risk-benefit profile, leading to potential recalls, withdrawals, or declining revenue, as well as product liability claims. Sometimes additional information from these studies identifies a portion of the patient population that may be non-responsive to a medicine or would be at higher risk of adverse reactions and labeling changes based on such studies may limit the patient population. The studies providing such additional information may be sponsored by us, but they could also be sponsored by competitors, insurance companies, government: institutions, managed care organizations, scientists, investigators, or other interested parties. While additional safety and efficacy information from such studies assist us and healthcare providers in identifying the best patient population for each product, it can also negatively impact our revenues due to inventory returns and a more limited patient population going forward. Additionally, certain study results, especially from head-to-head trials, could affect a product's formulary listing, which could also adversely affect our revenues.

We are dependent on our collaborative agreements for the development of products and business development, which exposes us to the risk of reliance on the viability of third parties.

In conducting our research and development activities, we currently rely, and will in the future rely, on collaborative agreements with third parties such as manufacturers, contract research organizations, commercial partners, universities, governmental agencies and not-for-profit organizations for both strategic and financial resources. The loss of, or failure to perform by us or our partners under, any applicable agreements or arrangements, or our failure to secure additional agreements for other products in development, would substantially disrupt or delay our research and development and commercialization activities. Any such loss would likely increase our expenses and materially harm our business, financial condition and results of operation.

We extensively outsource our clinical trial activities and usually perform only a small portion of the start-up activities in-house.

We rely on independent third-party contract research organizations (CROs) to perform most of our clinical studies, including document preparation, site identification, screening and preparation, pre-study visits, training, program management and bioanalytical analysis. Many important aspects of the services performed for us by the CROs are out of our direct control. If there is any dispute or disruption in our relationship with our CROs, our clinical trials may be delayed. Moreover, in our regulatory submissions, we rely on the quality and validity of the clinical work performed by third-party CROs. If any of our CROs' processes, methodologies or

results were determined to be invalid or inadequate, our own clinical data and results and related regulatory approvals could be adversely impacted.

Limited reimbursement or insurance coverage of our approved products, if any, by third party payors may render our products less attractive to patients and healthcare providers.

Market acceptance and sales of any approved products will depend significantly on reimbursement or coverage of our products by third party payors and may be affected by existing and future healthcare reform measures or the prices of related products for which third party reimbursement applies. Coverage and reimbursement by a third party payor may depend upon a number of factors, including the third party payor's determination that use of a product is: a covered benefit under its health plan; safe, effective and medically necessary; Limited reimbursement or insurance coverage of our approved products, if any, by third party payors may render our products less attractive to patients and healthcare providers. Market acceptance and sales of any approved products will depend significantly on reimbursement or coverage of our products by third party payors and may be affected by existing and future healthcare reform measures or the prices of related products for which third party reimbursement applies. Coverage and reimbursement by a third party payor may depend upon a number of factors, including the third party payor's determination that use of a product is: a covered benefit under its health plan; safe, effective and medically necessary; Limited reimbursement or insurance coverage of our approved products, if any, by third party payors may render our products less attractive to patients and healthcare providers. Market acceptance and sales of any approved products will depend significantly on reimbursement or coverage of our products by third party payors and may be affected by existing and future healthcare reform measures or the prices of related products for which third party reimbursement applies. Coverage and reimbursement by a third party payor may depend upon a number of factors, including the third party payor's determination that use of a product is: a covered benefit under its health plan; safe, effective and medically necessary; appropriate for the specific patient; cost-effective and neither experimental nor investigational. Obtaining coverage and reimbursement approval for a product from a government or other third party payor is a time consuming and costly process that could require us to provide supporting scientific, clinical and cost-effectiveness data for the use of our products to the payor, which we may not be able to provide. Furthermore, the reimbursement policies of third party payors may significantly change in a manner that renders our clinical data insufficient for adequate reimbursement or otherwise limits the successful marketing of our products. Even if we obtain coverage for our product candidates, third party payors may not establish adequate reimbursement amounts, which may reduce the demand for, or the price of, our products. If reimbursement is not available or is available only to limited levels, we may not be able to commercialize certain of our products. Publication of discounts by third party payors or authorities may lead to further pressure on the prices or reimbursement levels within the country of publication and other countries. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unacceptable levels, we or our partner may elect not to commercialize our products, and our business and financial condition could be adversely affected.

If we are unable to negotiate and maintain satisfactory arrangements with group purchasing organizations with respect to the purchase of our products, our business could be adversely affected.

Our ability to sell our products to hospitals in the United States depends in part on our relationships with group purchasing organizations, or GPOs. Many existing and potential customers for our products become members of GPOs. GPOs negotiate pricing arrangements and

contracts, sometimes on an exclusive basis, with medical supply manufacturers and distributors. These negotiated prices are then made available to a GPO's affiliated hospitals and other members. If we are not one of the providers selected by a GPO, affiliated hospitals and other members may be less likely to purchase our products, and if the GPO has negotiated a strict sole source, market share compliance or bundling contract for another manufacturer's products, we may be precluded from making sales to members of the GPO for the duration of the contractual arrangement Our failure to renew contracts with GPOs may cause us to lose market share and could have a material adverse effect on our sales, financial condition and results of operations. We cannot assure you that we will be able to renew these contracts at the current or substantially similar terms. If we are unable to keep our relationships and develop new relationships with GPOs, our competitive position may suffer.

Increased pricing pressure and other restrictions in the U.S. and abroad from managed care organizations, institutional Investors, and government agencies and programs, among others, could negatively affect our revenues and profit margins.

Our products continue to be subject to increasing pressures from market access, pricing and rebates and other restrictions in the U.S., the EU and other regions around the world, including from (i) rules and practices of managed care organizations and institutional and governmental Investors; (ii) judicial decisions and governmental laws and regulations for Medicare, Medicaid and U.S. healthcare reform, including the 2010 Patient Protection and Affordable Care Act; (iii) the potential impact of pharmaceutical reimbursement, Medicare Part D Formularies and product pricing in general; (iv) delays in gaining reimbursement; (v) governn1ent price erosion mechanisms across Europe and in other countries, resulting in deflation for pharmaceutical product pricing; (vi) collection delays in government-funded public hospitals outside the U.S. (vii) the impact on pricing from parallel trade across borders; (viii) other developments in technology and/or industry practices that could impact the reimbursement policies and practices of third-party payers; and (ix) limited or blocked market access due to real or perceived differences in value propositions for our products compared to competing products.

The illegal importation of counterfeit products and medical device products from countries where government price controls or other mark.et dynamics result in lower prices may adversely affect our sales and profitability in the U.S. and other countries in which we operate.

Foreign imports are illegal under current U.S. law, with the sole exception of limited quantities of prescription drugs imported for personal use. However, the volume of illegal imports continues to rise as the ability of patients and other customers to obtain these lower priced imports has grown significantly. In addition, U.S. policy makers may expand consumers' ability to import lower priced versions of our products and competing products from Canada, where there are government price controls. Any future legislation or regulations that increase consumer access to lower priced medicines from outside the U.S. may lower the prices we receive for our products, which could adversely impact our revenues.

The shares of Series Seed Preferred Stock will not be freely tradable until one year from the initial purchase date.

Although the shares of Series Seed Preferred Stock may be tradable under federal securities law, state securities regulations may apply, and each Purchaser should consult with his or her attorney. You should be aware of the long-term nature of this investment. There is not now and likely will not be a public market for our shares of Series Seed Preferred Stock. Because our shares of

Series Seed Preferred Stock have not been registered under the Securities Act of 1933, as amended (the "Securities Act') or under the securities laws of any state or non-United States jurisdiction, our shares of Series Seed Preferred Stock have transfer restrictions and cannot be resold in the United States except pursuant to Rule 501 of Regulation CF. It is not currently contemplated that registration under the Securities Act or other securities laws will be effected. Limitations on the transfer of the shares of Series Seed Preferred Stock may also adversely affect the price that you might be able to obtain for the shares of Series Seed Preferred Stock in a private sale. Purchasers should be aware of the long-term nature of their investment in the Company. Each Purchaser in this Offering will be required to represent that it is purchasing the Securities for its own account, for investment purposes and not with a view to resale or distribution thereof.

Neither the Offering nor the Securities have been registered under federal or state securities laws, leading to an absence of certain regulation applicable to the Company.

No governmental agency has reviewed or passed upon this Offering, the Company or any Securities of the Company. The Company also has relied on exemptions from securities registration requirements under applicable state securities laws. Investors in the Company, therefore, will not receive any of the benefits that such registration would otherwise provide. Prospective investors must therefore assess the adequacy of disclosure and the fairness of the terms of this Offering on their own or in conjunction with their personal advisors.

No Guarantee of Return on Investment

There is no assurance that a Purchaser will realize a return on its investment or that it will not lose its entire investment For this reason, each Purchaser should read the Form CIA and all Exhibits carefully and should consult with its own attorney and business advisor prior to making any investment decision.

A majority of the Company is owned by a small number of owners.

Prior to the Offering the Company's current owners of20% or more beneficially own up to 73.02% of the Company. Subject to any fiduciary duties owed to our other owners or investors under Delaware law, these owners may be able to exercise significant influence over matters requiring owner approval, including the election of directors or managers and approval of significant Company transactions, and will have significant control over the Company's management and policies. Some of these persons may have interests that are different from yours. For example, these owners may support proposals and actions with which you may disagree. The concentration of ownership could delay or prevent a change in control of the Company or otherwise discourage a potential acquirer from attempting to obtain control of the Company, which in turn could reduce the price potential investors are willing to pay for the Company. In addition, these owners could use their voting influence to maintain the Company's existing management, delay or prevent changes in control of the Company, or support or reject other management and board proposals that are subject to owner approval.

Affiliates of the Company, including officers, directors and existing shareholders of the Company, may invest in this Offering and their funds will be counted toward the Company achieving the Minimum Amount.

There is no restriction on affiliates of the Company, including its officers, directors and existing shareholders, investing in the Offering. As a result, it is possible that if the Company has raised some funds, but not reached the Minimum Amount, affiliates can contribute the balance so that

there will be a closing. The Minimum Amount is typically intended to be a protection for investors and gives investors' confidence that other investors, along with them, are sufficiently interested in the Offering and the Company and its prospects to make an investment of at least the Minimum Amount. By permitting affiliates to invest in the offering and make up any shortfall between what non-affiliate investors have invested and the Minimum Amount, this protection is largely eliminated. Investors should be aware that no funds other than their own and those of affiliates investing along with them may be invested in this Offering.

Purchasers will grant a proxy to vote their Securities to the Intermediary or its affiliate, and, thus, will not have the right to vote on any matters submitted to a vote of the stockholders of the Company. By granting this proxy you are giving up your right to vote on important matters, including significant corporate actions like mergers, amendments to our certificate of incorporation, a liquidation of our company and the election of our directors.

By signing an irrevocable proxy in connection with the purchase of the Securities, you will grant a proxy to the Intermediary or its affiliate to vote the Securities on all matters coming before the shareholders for a vote. The Intermediary does not have any fiduciary duty to you to vote shares in a manner that is in your best interests. Accordingly, the Intermediary may vote its proxy in a manner that may not be in the best interests of you as a shareholder. For example, the Intermediary may vote the proxy in favor of an amendment to our charter that adversely affects the rights of the holders of your class of securities in order to allow for a new investment to occur where the new investor requires senior rights.

There is no present market for the Securities, and we have arbitrarily set the price.

We have arbitrarily set the price of the Securities with reference to the general status of the securities market and other relevant factors. The Offering price for the Securities should not be considered an indication of the actual value of the Securities and is not based on our net worth or prior earnings. We cannot assure you that the Securities could be resold by you at the Offering price or at any other price.

Your ownership of the shares of Series Seed Preferred Stock will be subject to dilution.

If the Company conducts subsequent offerings of Series Seed Preferred Stock or Securities convertible into Series Seed Preferred Stock, issues shares pursuant to a compensation or distribution reinvestment plan or otherwise issues additional shares, investors who purchase shares in this Offering who do not participate in those other stock issuances will experience dilution in their percentage ownership of the Company's outstanding shares. Furthermore, shareholders may experience a dilution in the value of their shares depending on the terms and pricing of any future share issuances (including the shares being sold in this Offering) and the value of the Company's assets at the time of issuance.

The Securities will be equity interests in the Company and will not constitute indebtedness.

The Securities will rank junior to all existing and future indebtedness and other non-equity claims on the Company with respect to assets available to satisfy claims on the Company, including in a Liquidation of the Company. Additionally, unlike indebtedness, for which principal and interest would customarily be payable on specified due dates, there will be no specified payments of dividends with respect to the Securities. Dividends are payable only if, when and as authorized and declared by the Company and depend on, among other matters, the Company's historical and projected results of operations, liquidity, cash flows, capital levels,

financial condition, debt service requirements and other cash needs, financing covenants, applicable state law, federal and state regulatory prohibitions and other restrictions and any other factors the Company's board of directors deems relevant at the time. In addition, the terms of the Securities will not limit the amount of debt or other obligations the Company may incur in the future. Accordingly, the Company may incur substantial amounts of additional debt and other obligations that will rank senior to the Securities.

There can be no assurance that we will ever provide liquidity to Purchasers through either a sale of the Company or a registration of the Securities.

There can be no assurance that any form of merger, combination, or sale of the Company will take place, or that any merger, combination, or sale would provide liquidity for Purchasers. Furthermore, we may be unable to register the Securities for resale by Purchasers for legal, commercial, regulatory, market-related or other reasons. In the event that we are unable to effect a registration, Purchasers could be unable to sell their Securities unless an exemption from registration is available.

The Company does not anticipate paying any cash dividends for the foreseeable future.

The Company currently intends to retain future earnings, if any, for the foreseeable future, to repay indebtedness and to support its business. The Company does not intend in the foreseeable future to pay any dividends to holders of its shares of Series Seed Preferred Stock.

The Company has the right to conduct multiple closings during the Offering.

If the Company meets certain terms and conditions an intermediate close of the Offering can occur, which will allow the Company to draw down on a portion of the proceeds of the offering committed and captured during the relevant period. The Company may choose to continue the Offering thereafter. Purchasers should be mindful that this means they can make multiple investment commitments in the offering, which may be subject to different cancellation rights. For example, if an intermediate close occurs and later a material change occurs as the Offering continues, Purchasers previously closed upon will not have the right to re-confirm their investment as it will be deemed completed.

The Company has the right to extend the Offering deadline.

The Company may extend the Offering deadline beyond what is currently stated herein. This means that your investment may continue to be held in escrow while the Company attempts to raise the Minimum Amount even after the Offering deadline stated herein is reached. Your investment will not be accruing interest during this time and will simply be held until such time as the new Offering deadline is reached without the Company receiving the Minimum Amount, at which time it will be returned to you without interest or deduction, or the Company receives the Minimum Amount, at which time it will be released to the Company to be used as set forth herein. Upon or shortly after release of such funds to the Company, the Securities will be issued and distributed to you.

The Company has the right to end the Offering early.

The Company may also end the Offering early~ if the Offering reaches its target Offering amount after 30-calendar days but before the deadline, the Company can end the Offering with five business days' notice. This means your failure to participate in the Offering in a timely

manner, may prevent you from being able to participate - it also means the Company may limit the amount of capital it can raise during the Offering by ending it early.

In addition to the risks listed above, businesses are often subject to risks not foreseen or fully appreciated by the management.
It is not possible to foresee all risks that may affect us. Moreover, the Company cannot predict whether the Company will successfully effectuate the Company's current business plan. Each prospective Purchaser is encouraged to carefully analyze the risks and merits of an investment in the Securities and should take into consideration when making such analysis, among other, the Risk Factors discussed above.

THE SECURITIES OFFERED INVOLVE A HIGHDEGREE OF RISK AND MAY RESULT IN THE LOSS OF YOUR ENTIRE INVESTMENT. ANY PERSON CONSIDERING THE PURCHASE OF THESE SECURITIES SHOULD BE AWARE OF THESE AND OTHER FACTORS SET FORTH IN THIS FORM C AND SHOULD CONSULT WITH HIS OR HER LEGAL, TAX AND FINANCIAL ADVISORS PRIOR TO MAKING AN INVESTMENT IN THE SECURITIES. THE SECURITIES SHOULD ONLY BE PURCHASED BY PERSONS WHO CAN AFFORD TO LOSE ALL OF THEIR INVESTMENT.

In addition to the risks listed above, businesses are often subject to risks not foreseen or fully appreciated by the management. It is not possible to foresee all risks that may affect us. Moreover, the Company cannot predict whether the Company will successfully effectuate the Company's current business plan. Each prospective Purchaser is encouraged to carefully analyze the risks and merits of an investment in the Securities and should take into consideration when making such analysis, among other, the Risk Factors discussed above.

BUSINESS

Description of the Business

KneeVoice is a MedTech company that has developed a simple, quick and noninvasive diagnostic platform presently applied to orthopedic medicine engineered to provide diagnosis of cartilage damage in the patellofemoral joint (knee joint). The platform is intended to be used in the diagnostic process, as well as in the follow-up and treatment outcome monitoring phases of recovery. This platform is designed to be used by orthopedic and sports medicine clinicians, physical therapists, trainers, and individuals monitoring their own performance. This is a first-of-its-kind platform that offers advanced technology applied to the orthopedic practice, with intellectual property protection covering the data capture and analysis methods used in diagnostic testing.

Business Plan

B2B distribution channel overview:
• Licensing and/or distribution agreements with big pharma companies involved in orthopedics.
• Direct sales to orthopedic centers, general practitioners, and physical therapists.

D2C distribution channel overview:

• Selling directly to consumers for day-to-day monitoring of knee health and to encourage everyone to understand the health effects of osteoarthritis with the goal of preventing early cartilage deterioration

Software-as-a-Service licensing stream from both distribution channels.

History of the Business

The Company's Products and/or Services

Product / Service	Description	Current Market
KneeVoice Diagnostic Device: Cartilage Auscultation System	KneeVoice is simple, quick, and non-invasive. It is intended to be used as the only office diagnostic tool for the orthopedic surgeon. The device is designed to provide precise information of cartilage damage in the diagnostic process, as well as in the follow-up and treatment outcome monitoring of patients.	Proof of concept being utilized for medical trials, testing and validation within the U.S.

KneeVoice Diagnostic Device: The KneeVoice Diagnostic Device is simple, quick to use and noninvasive. It is being designed to be the only office diagnostic tool for the orthopedic surgeon that can provide precise information of cartilage damage in the diagnostic process, as well as in the follow-up and treatment outcome monitoring of patients. The KneeVoice Diagnostic Device is intended to be used by orthopedic and sports medicine clinicians, as well as physical therapists, trainers and individuals to monitor cartilage degradation from sports-related activities. The Company anticipates medical device certification and introducing it to various markets with the proceeds of this Offering.

KneeVoice Wearable: KneeVoice Wearable is intended to be worn around the knee and uses acoustic signals and telemetry data to assess tissue and joint condition. Paired with a mobile app, Knee Voice Wearable is being designed to provide the user with information to maintain healthy knees. Used as a monitor device after intervention and by individuals monitoring performance Knee Voice Wearable is also intended to be used by physical therapists. The Company also intends for the product to be used by sports teams, performance training and as a claim's compliance instrument The Company anticipates introducing it to various markets with the proceeds of this Offering.

Competition

We are not aware of direct competitors· however, clinicians and surgeons currently use MRIs and ultrasound devices to understand the level of cartilage degradation in the knee. Some well-known MRI and ultrasound device manufacturers include GE Healthcare, Butterfly, Philips, and Siemens Healthineers. We anticipate focusing on the following issues: • Diagnostics: Precise and

dynamic diagnosis of PF cartilage damage cannot be obtained with high specificity or sensitivity with X-rays, CT scans or MRI. We aim to give a precise and easy-to-read assessment of PF Cartilage damage. • Interpretation: The analysis of patellofemoral osteoarthritis (PFOA) data is usually done by specialists different from the treating physician (radiologists among others). We plan on providing the specialist the opportunity to personally and directly assess in his office or practice the cartilage damage score and repeat it on every medical visit. With a device that is noninvasive, pain free and without exposure to damaging or toxic elements. Costs Problem: Monitoring PF cartilage damage requires expensive diagnostic tools such as MRI or CT scans. KneeVoice aims to provide active, dynamic and real-time information at a very low cost.

Customer Base

We have not yet sold any products, however, anticipate our initial customers to be orthopedic surgeons and other clinicians. We expect orthopedic centers, general practitioners, physical therapists and individuals to be our core customer base when both products are fully developed.

Intellectual Property

Patents

Application or Registration #	Title	Description	File Date	Grant Date	Country
USA 10448919	Assessing joint condition using acoustic sensors	A new, non-invasive tool for cartilage assessment, exercise and sports management, and prevention of osteoarthritis is provided. In various embodiments, cartable condition is assessed using audible signals from joints. Assessment test results are used to provide feedback regarding joint stress and friction that is related to physiological or pathological loads. Data obtained from audible signals are processed to provide an index that can be interpreted by a used or third parties. The index is useful as a baseline for	February 2, 0008	October 22, 2019	USA

		exercise practices, training routines, wellness programs, or rehabilitation protocols.			

EP3386393	Assessing joint condition using acoustic sensors	A new, non-invasive tool for cartilage assessment, exercise and sports management, and prevention of osteoarthritis is provided. In various embodiments, cartable condition is assessed using audible signals from joints. Assessment test results are used to provide feedback regarding joint stress and friction that is related to physiological or pathological loads. Data obtained from audible signals are processed to provide an index that can be interpreted by a used or third parties. The index is useful as a baseline for exercise practices, training routines, wellness	July 12, 2016	May 5, 2021	EUROPE and UK

		programs, or rehabilitation protocols.			

D874488	Display screen or portion thereof with graphical user interface	Description: The file of this patent contains at least one drawing executed in color. Copies of this patent with color drawing(s) will be provided by the Office upon request and payment of the necessary fee. FIG. 1 is a front view of an embodiment of a display screen or portion thereof with graphical used interface; FIG. 2 is a front view of an embodiment of a display screen or portion thereof with graphical user interface; FIG. 3 is a front view of an embodiment of a display screen or potion thereof with graphical user interface; FIG. 4 is a	November 21, 2017	February 4, 2020	USA

		front view of an embodiment of a display screen or potion thereof with graphical user interface; FIG. 5 is a front view of an embodiment of a display screen or potion thereof with graphical user interface; FIG. 6 is a front view of an embodiment of a display screen or potion thereof with graphical user interface; FIG. 7 is a front view of an embodiment of a display screen or potion thereof with graphical user interface; FIG. 8 is a front view of an embodiment of a display screen or potion thereof with graphical user interface; and FIG. 9 is a			

		front view of an embodiment of a display screen or potion thereof with graphical user interface. The broken lines showing the display screen or potion thereof form no part of the claimed design.			
D806730	Display screen or portion thereof with graphical user interface	The ornamental design for a display screen or portion thereof with graphical user interface, as shown and described. FIG. 1 is a front view of an embodiment of a display screen or portion thereof with graphical user interface; FIG. 2 is a front view of an embodiment of a display screen or portion thereof with graphical user interface;	January 5, 2016	January 2, 2018	USA

		FIG. 3 is a front view of an embodiment of a display screen or portion thereof with graphical user interface; FIG. 4 is a front view of an embodiment of a display screen or portion thereof with graphical user interface; FIG. 5 is a front view of an embodiment of a display screen or portion thereof with graphical user interface. The broken lines in the figures represent environmental structure and form no part of the claimed design.			

Trademarks

Application or Registration #	Goods / Services	Mark	File Date	Registration Date	Country
5387151	Apparatus for assessing	KNEEVOICE	October 13, 2015	January 23, 2018	USA

	tissue and joint health				

Governmental/Regulatory Approval and Compliance

Our business has been and will continue to be subject to the Food and Drug Administration (FDA) and various other U.S. laws and regulations. Failure to comply with these laws and regulations could subject us to administrative and legal proceedings and actions by these various governmental bodies. The KneeVoice Diagnostic Device is being built under FDA certifiable manufacturing rules. We have filed a pre-submission to the FDA on January 14, 2022. The KneeVoice Wearable does not require FDA clearance.

Litigation

There are no existing legal suits pending, or to the Company's knowledge, threatened, against the Company.

Other

The Company's principal address is 1626 Montana Avenue, #155, Santa Monica, CA 90403

DIRECTORS, OFFICERS, AND EMPLOYEES

Directors

The directors or managers (and any persons occupying a similar status or performing a similar function) of the Company are listed below along with all positions and offices held at the Company and their principal occupation and employment responsibilities for the past three (3) years and their educational background and qualifications.

Name

Gustavo De Greiff

All positions and offices held with the Company and date such position(s) was held with start and ending dates

June 2016 to present; Oversee company operations, strategy and financing.

Principal occupation and employment responsibilities during at least the last three (3) years with start and ending dates

VP of Business Development, LATM of Ubicquia LLC; February 2016 - 2022 • Identify, cultivate, and negotiate markets through LATM • Maintain full financial and P&L responsibility for the region and function as a liaison between the fireman local projects, with a focus on regulatory framework, channel development, marketing, brand promotion, and budgeting.

Name

Dr. Carlos Leal

All positions and offices held with the Company and date such position(s) was held with start and ending dates

Chief Medical Officer, Co-Founder, June 2016 to present; Leads the scientific and medical testing trials.

Principal occupation and employment responsibilities during at least the last three (3) years with start and ending dates

Professor, Universidad El Bosque, 1992 - Present; • Associate Professor of the Postgraduate course in Orthopedics and Traumatology • Member of the Board of Directors of El Bosque University Physician, Lufthansa; January 2011 - Present; • Physician for Lufthansa, Colombia President, HISPAMEF; June 2018 - Present; Director, Fenway Medical; November 2008 - Present

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Name

Felipe Rigby

All positions and offices held with the Company and date such position(s) was held with start and ending dates

CTO, Co-Founder, Director, June 2016 to present; Manage the tech stack, including software and product development.

Principal occupation and employment responsibilities during at least the last three (3) years with start and ending dates

CTO and Founder of Restowiz; March 2020 - Present • Creating a digital-first solution for restaurant management • Leading and shaping the tech stack for its global customers CTO of Sansa Advertising; September 2017 - March 2020 • Overseeing the technology transformation of Sansa’s clients • Developing growth marketing solutions for clients, focusing on client acquisition or partnership expansion opportunities

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Officers of the Company

The officers of the Company are listed below along with all positions and offices held at the Company and their principal occupation and employment responsibilities for the past three (3) years and their educational background and qualifications. The term officer means a president, vice president, secretary, treasurer or principal financial officer, comptroller, or principal accounting officer, and any person(s) routinely performing similar functions.

Name

Gustavo De Greiff

All positions and offices held with the Company and date such position(s) was held with start and ending dates

June 2016 to present; Oversee company operations, strategy and financing.

Principal occupation and employment responsibilities during at least the last three (3) years with start and ending dates

VP of Business Development, LATM of Ubicquia LLC; February 2016 - 2022 • Identify, cultivate, and negotiate markets through LATM • Maintain full financial and P&L responsibility for the region and function as a liaison between the fireman local projects, with a focus on regulatory framework, channel development, marketing, brand promotion, and budgeting.

Name

Dr. Carlos Leal

All positions and offices held with the Company and date such position(s) was held with start and ending dates

Chief Medical Officer, Co-Founder, June 2016 to present; Leads the scientific and medical testing trials.

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Name

Felipe Rigby

All positions and offices held with the Company and date such position(s) was held with start and ending dates

CTO, Co-Founder, Director, June 2016 to present; Manage the tech stack, including software and product development.

Principal occupation and employment responsibilities during at least the last three (3) years with start and ending dates

CTO and Founder of Restowiz; March 2020 - Present • Creating a digital-first solution for restaurant management • Leading and shaping the tech stack for its global customers CTO of Sansa Advertising; September 2017 - March 2020 • Overseeing the technology transformation of Sansa's clients • Developing growth marketing solutions for clients, focusing on client acquisition or partnership expansion opportunities

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Indemnification

Indemnification is authorized by the Company to directors, officers or controlling persons acting in their professional capacity pursuant to Delaware law. Indemnification includes expenses such as attorney's fees and, in certain circumstances, judgments, fines and settlement amounts actually paid or incurred in connection with actual or threatened actions, suits or proceedings involving such person, except in certain circumstances where a person is adjudged to be guilty of gross negligence or willful misconduct, unless a court of competent jurisdiction determines that such indemnification is fair and reasonable under the circumstances.

Employees

The Company currently has 7 employees.

The Company has the following employment/labor agreements in place:

Employee	Description	Effective Date	Termination Date
Dilson Beltran	Independent Contractor	June 3, 2019	
Mauricio Porras	Independent Contractor	June 1, 2019	
Andres Alegria	Independent Contractor	March 1, 2021	

CAPITALIZATION AND OWNERSHIP

Capitalization

The Company has issued the following outstanding securities:

Type of security	Common Stock
Amount outstanding	361,243
Voting Rights	One vote per share
Anti-Dilution Rights	N/A
How this Security may limit, dilute or qualify the Notes/Bonds issued pursuant to Regulation CF	N/A
Other Material Terms or information.	N/A

The Company has reserved the following securities for issuance upon exercise or conversion:

Type of security	Preferred Stock
Amount outstanding	
Voting Rights	Holders of Series Seed Preferred Stock are entitled to vote on all matters submitted to a vote of our stockholders as a single class with the holders of Common Stock. So long as at least 50% of the original number of Series Seed Preferred Stock is outstanding, specific matters submitted to a vote of the stockholders require the approval of the holders of a majority of outstanding Series Seed Preferred Stock voting as a separate class. These matters include any vote to: • alter the rights, powers or privileges of the Series Seed Preferred Stock set forth in the Restated Certificate, as then in effect, in a way that adversely affects the Series Seed Preferred Stock; or • create any new class or series of capital stock having rights, powers or privileges set forth in the certificate of incorporation, as then in effect, that are senior to Series Seed Preferred Stock unless the Company offers the Series Seed Preferred Stock the right to convert or exchange their Series Seed Preferred Stock into capital stock of the Company having such senior rights, powers or privileges.
Anti-Dilution Rights	
How this Security may limit, dilute or qualify the Notes/Bonds issued pursuant to Regulation CF	
Percentage ownership of the Company by the holders of such Securities (assuming conversion prior to the Offering if convertible securities).	

The Company has the following debt outstanding:

Type of debt	Accounts Payable
Name of creditor	Third-party manufacturing and professional services firms
Amount outstanding	$131,013.00
Interest rate and payment schedule	The Company shall repay its creditors within a reasonable time period from receiving an invoice.
Amortization schedule	N/A
Describe any collateral or security	None.
Maturity date	
Other material terms	N/A

Type of debt	Convertible Notes
Name of creditor	
Amount outstanding	$175,000.00
Interest rate and payment schedule	
Amortization schedule	
Describe any collateral or security	
Maturity date	
Other material terms	

The total amount of outstanding debt of the company is $306,013.00.

The Company has conducted the following prior Securities offerings in the past three years:

Security Type	Number Sold	Money Raised	Use of Proceeds	Offering Date	Exemption from Registration Used or Public Offering
Common Stock	63,213	$1,275,638.34	Commercial device design and development	November 15, 2021	Rule 506(b)
Preferred Stock			Intermediary Fees, Wearable Product Development, Software Costs, Wearable Product Inventory, Diagnostic Device Product Inventory, Marketing, Legal and Certifications, Company Overhead	March 29, 2022	Regulation CF

Ownership

A majority of the company is owned by few people. Those persons are: Dr. Carlos Leal, Felipe Rigby and Gustavo de Greiff.

The beneficial owners of 20% percent or more of the Company’s outstanding voting equity securities, calculated on the basis of voting power, are listed below along with the amount they own.

Name	Percentage Owned
Dr. Carlos Leal	24.3%
Felipe Rigby	24.3%
Gustavo de Greiff	24.3%

FINANCIAL INFORMATION

Please see the financial information listed on the cover page of this Form C-AR and attached hereto in addition to the following information. Financial statements are attached hereto as Exhibit A.

Operations

The year 2022 was notable because we dedicated to prototype development.

From the funds raised in 2021 we contracted a design company Karten:Design and a manufacturing company to bring our idea to life.

Both achievements companies delivered on the contract and in November 2022 Kneevoice was awarded Most Fundable company by Pepperdine University Competition.

Financially by the end of 2022 the company had only two months runway with only $16,000 in the bank.

Liquidity and Capital Resources

On November 15, 2021, the Company conducted an offering pursuant to Rule 506(b) and raised $1,275,638.34.

On March 29, 2022 the Company conducted an offering pursuant to Regulation CF and raised $170.619.52.

The Company does not have any additional sources of capital other than the proceeds from the Regulation CF Offering.

Capital Expenditures and Other Obligations

The Company intends to make the following material capital expenditures in the future:
The Company intends to make the following material capital expenditures in the future: Knee Voice contracted design and manufacturing of its devices.

Material Changes and Other Information

We closed a seed round in November 2021 by issuing shares of our common stock, par value $0.0001 per share (the "Common Stock’) which allowed the Company to proceed with design and manufacturing. The total amount raised was approximately $1.2 million.

Trends and Uncertainties

The financial statements are an important part of this Form C-AR and should be reviewed in their entirety. The financial statements of the Company are attached hereto as Exhibit A.

Restrictions on Transfer
Any Securities sold pursuant to Regulation CF being offered may not be transferred by any Investor of such Securities during the one-year holding period beginning when the Securities

were issued, unless such Securities were transferred: 1) to the Company, 2) to an accredited investor, as defined by Rule 501(d) of Regulation D of the Securities Act of 1933, as amended, 3) as part of an Offering registered with the SEC or 4) to a member of the family of the Investor or the equivalent, to a trust controlled by the Investor, to a trust created for the benefit of a family member of the Investor or the equivalent, or in connection with the death or divorce of the Investor or other similar circumstances. "Member of the family" as used herein means a child, stepchild, grandchild, parent, stepparent, grandparent, spouse or spousal equivalent, sibling, mother/father/daughter/son/sister/brother-in-law, and includes adoptive relationships. Remember that although you may legally be able to transfer the Securities, you may not be able to find another party willing to purchase them.

TRANSACTIONS WITH RELATED PERSONS AND CONFLICTS OF INTEREST

Related Person Transactions

From time to time the Company may engage in transactions with related persons. Related persons are defined as any director or officer of the Company; any person who is the beneficial owner of ten percent (10%) or more of the Company's outstanding voting equity securities, calculated on the basis of voting power; any promoter of the Company; any immediate family member of any of the foregoing persons or an entity controlled by any such person or persons.

The Company has engaged in the following transactions with related persons:

None.

Conflicts of Interest

To the best of our knowledge the Company has not engaged in any transactions or relationships, which may give rise to a conflict of interest with the Company, its operations or its security holders.

OTHER INFORMATION

The Company has not failed to comply with the ongoing reporting requirements of Regulation CF § 227.202 in the past.

The Company is not subject to any Bad Actor Disqualifications under any relevant U.S. securities laws. The Co-Issuer is not subject to any Bad Actor Disqualifications under any relevant U.S. securities laws.

SIGNATURE

Pursuant to the requirements of Sections 4(a)(6) and 4A of the Securities Act of 1933 and Regulation Crowdfunding (§ 227.100 et seq.), the issuer certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form C-AR and has duly caused this Form to be signed on its behalf by the duly authorized undersigned.

The issuer also certifies that the attached financial statements are true and complete in all material respects.

/s/Gustavo De Greiff
(Signature)

Gustavo De Greiff
(Name)

CEO, Co-Founder, Director
(Title)

Pursuant to the requirements of Sections 4(a)(6) and 4A of the Securities Act of 1933 and Regulation Crowdfunding (§ 227.100 et seq.), this Form C-AR has been signed by the following persons in the capacities and on the dates indicated.

/s/Gustavo De Greiff
(Signature)

Gustavo De Greiff
(Name)

CEO, Co-Founder, Director,
(Title)

(Date)

Instructions.

1. The form shall be signed by the issuer, its principal executive officer or officers, its principal financial officer, its controller or principal accounting officer and at least a majority of the board of directors or persons performing similar functions.

2. The name of each person signing the form shall be typed or printed beneath the signature.

Intentional misstatements or omissions of facts constitute federal criminal violations. See 18 U.S.C. 1001.

EXHIBITS

Exhibit A Financial Statements

EXHIBIT A

Financial Statements

Knee Voice Inc.

Profit and Loss

January - December 2021

	TOTAL
Income	
Total Income	
GROSS PROFIT	**$0.00**
Expenses	
Advertising	3,500.00
Bank Charges	112.80
EXPENSE REIMBURSEMENT	7,708.28
EXTERNAL Consulting	6,860.00
FDA CONSULTANTS	3,063.75
Interest Paid	4,366.00
Lawyers - Patents & Corporate	34,841.87
Legal & Professional Fees	1,500.00
Lodging	712.85
Meals and Entertainment	50.00
MEDICAL & INSURANCE CODES	20,500.00
Office Expenses	199.00
Profesional Fees - Programer	4,940.09
Professional fees - Product Manager	4,082.27
Promotional	342.96
PROTOTYPE DESIGN	55,200.00
Prototype Engineering	430,278.00
KARTEN DESIGN FINAL DESIGN	168,000.00
Total Prototype Engineering	**598,278.00**
Prototype Parts and equipment	218.30
Shipping - Samples & Documents	607.44
Shipping and Cargo	429.60
Taxes & Licenses	815.00
Transport and Auto	465.27
Travel	1,756.92
Travel Meals	1,145.51
Total Expenses	**$751,695.91**
NET OPERATING INCOME	**$ -751,695.91**
NET INCOME	**$ -751,695.91**

Knee Voice Inc.

Balance Sheet

As of December 31, 2021

	TOTAL
ASSETS	
Current Assets	
Bank Accounts	
BOFA 2019	320,129.09
Business Advantage Chk (6298)	-89.80
CITY NATIONAL	0.00
Total Bank Accounts	**$320,039.29**
Other Current Assets	
Uncategorized Asset	12.00
Total Other Current Assets	**$12.00**
Total Current Assets	**$320,051.29**
Other Assets	
IP - PATENTS	72,064.52
Total Other Assets	**$72,064.52**
TOTAL ASSETS	**$392,115.81**
LIABILITIES AND EQUITY	
Liabilities	
Current Liabilities	
Accounts Payable	
Accounts Payable	91,713.88
Total Accounts Payable	**$91,713.88**
Other Current Liabilities	
Deferred COMPENSATION	106,004.04
Dr. Esteban Santos/conv. note	0.00
FUTURE-VIBE LOAN	0.00
Philippe Chutczer FV-AD/Convertable loan	0.00
Total Other Current Liabilities	**$106,004.04**
Total Current Liabilities	**$197,717.92**
Total Liabilities	**$197,717.92**
Equity	
Equity Contribution Dr. Leal	77,500.00
Equity Contribution Felipe Rigby	78,000.00
Equity Contribution Gustavo de Greiff	78,000.00
PRE-Inc Investements	160,068.00
Retained Earnings	-690,873.60
SEED ROUND	1,243,399.40
Net Income	-751,695.91
Total Equity	**$194,397.89**
TOTAL LIABILITIES AND EQUITY	**$392,115.81**

Knee Voice Inc.

Profit and Loss

January - December 2022

	TOTAL
Income	
Total Income	
GROSS PROFIT	**$0.00**
Expenses	
Accounting Services	5,568.00
Advertising	9,463.64
Bank Charges	98.00
Dues & Subscriptions	23.96
EXTERNAL Consulting	16,338.73
FDA CONSULTANTS	2,958.75
Group-Meals	1,081.02
Hosting and Technology	1,128.67
Lawyers - Patents & Corporate	36,645.53
Legal & Professional Fees	12,529.73
Meals and Entertainment	521.42
Office Expenses	1,136.65
Profesional Fees - Programer	37,055.00
Professional fees - Product Manager	14,220.00
PROFESSIONAL FEES FDA	22,912.50
Promotional	14,472.93
PROTOTYPE DESIGN	3,412.50
Prototype Engineering	325,476.23
KARTEN DESIGN FINAL DESIGN	75,761.19
Total Prototype Engineering	**401,237.42**
Prototype Parts and equipment	169.99
Servers and Technology	256.99
Shipping - Samples & Documents	575.91
Shipping and Cargo	1,452.69
Supplies	66.15
Taxes & Licenses	5,632.31
Transport and Auto	1,896.07
Travel	5,755.77
Travel Meals	3,458.29
Uncategorized Expense	13,685.72
Total Expenses	**$613,754.34**
NET OPERATING INCOME	**$ -613,754.34**
NET INCOME	**$ -613,754.34**

Knee Voice Inc.

Balance Sheet

As of December 31, 2022

	TOTAL
ASSETS	
Current Assets	
Bank Accounts	
BOFA 2019	16,577.77
Business Advantage Chk (6298)	-89.80
CITY NATIONAL	0.00
Total Bank Accounts	**$16,487.97**
Other Current Assets	
Inventory Asset	3,528.86
Uncategorized Asset	12.00
Total Other Current Assets	**$3,540.86**
Total Current Assets	**$20,028.83**
Other Assets	
IP - PATENTS	78,062.38
Total Other Assets	**$78,062.38**
TOTAL ASSETS	**$98,091.21**
LIABILITIES AND EQUITY	
Liabilities	
Current Liabilities	
Accounts Payable	
Accounts Payable	122,976.50
Total Accounts Payable	**$122,976.50**
Credit Cards	
AMEX 91009	2,378.58
Total Credit Cards	**$2,378.58**
Other Current Liabilities	
Deferred COMPENSATION	106,004.04
Dr. Esteban Santos/conv. note	0.00
Felipe Rigby/Convertable Note	62,500.00
FUTURE-VIBE LOAN	0.00
Gustavo de Greiff/Convertable Loan	62,500.00
Philippe Chutczer FV-AD/Convertable loan	0.00
Total Other Current Liabilities	**$231,004.04**
Total Current Liabilities	**$356,359.12**
Total Liabilities	**$356,359.12**
Equity	
Equity Contribution Dr. Leal	77,500.00
Equity Contribution Felipe Rigby	78,000.00
Equity Contribution Gustavo de Greiff	78,000.00
MICROVENTURES SEED ROUND	161,088.54

Knee Voice Inc.

Balance Sheet

As of December 31, 2022

	TOTAL
PRE-Inc Investements	160,068.00
Retained Earnings	-1,442,569.51
SEED ROUND	1,243,399.40
Net Income	-613,754.34
Total Equity	**$ -258,267.91**
TOTAL LIABILITIES AND EQUITY	**$98,091.21**