FORM 10-K

Annual report pursuant to section 13 and 15(d)

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2022.

or

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from to

Commission File Number: 001-41358

ACLARION, INC.

(Exact name of registrant as specified in its charter)

Delaware	**47-3324725**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
8181 Arista Place, Suite 100 Broomfield, Colorado	**80021**
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code **(833) 275-2266**

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.00001 per share	ACON	The Nasdaq Stock Market LLC
Warrants, each exercisable for one share of Common Stock	ACONW	The Nasdaq Stock Market LLC

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

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

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

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

Large accelerated filer ☐	Accelerated filer ☐
Non-accelerated filer ☒	Smaller reporting company ☒
	Emerging Growth Company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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

As of June 30, 2022, the last business day of the registrant's most recently completed second fiscal quarter, the aggregate market value of the registrant's common stock held by non-affiliates of the registrant was approximately $5,019,673 based on a closing price of $0.9135 per share as quoted by the Nasdaq Capital Market as of such date. In determining the market value of non-affiliate common stock, shares of the registrant's common stock beneficially owned by officers, directors and affiliates have been excluded. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

As of February 27, 2023, 7,861,515 shares of the registrant's common stock, $0.0001 par value per share, were outstanding.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K, or Annual Report, contains forward-looking statements that involve risks and uncertainties. We make such forward-looking statements pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 and other federal securities laws. All statements other than statements of historical facts contained in this Annual Report are forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as “may”, “will”, “should”, “expects”, “intends”, “plans”, “anticipates”, “believes”, “estimates”, “predicts”, “potential”, “continue” or the negative of these terms or other comparable terminology.

Forward-looking statements are neither historical facts nor assurances of future performance, and are based only on our current beliefs, expectations and assumptions regarding the future of our business, future plans and strategies, projections, anticipated events and trends, the economy and other future conditions. Because forward-looking statements relate to the future, they are subject to inherent uncertainties, risks and changes in circumstances that are difficult to predict and many of which are outside of our control. Therefore, you should not rely on any of these forward-looking statements. Important factors that could cause our actual results and financial condition to differ materially from those indicated in the forward-looking statements include, among others, those set forth below in Part I, Item 1A, “Risk Factors” of this Annual Report.

These forward-looking statements speak only as of the date of this Form 10-K and are subject to business and economic risks. We do not undertake any obligation to update or revise the forward-looking statements to reflect events that occur or circumstances that exist after the date on which such statements were made, except to the extent required by law.

MARKET AND INDUSTRY DATA

Certain of the market data and other statistical information contained in this Annual Report, such as the size, growth and share of the services industry, are based on information from independent industry organizations and other third-party sources, industry publications, surveys and forecasts. The size of the market information referenced in this Annual Report is based on articles published in the Journal of the American Medical Association (“JAMA”). Some market data and statistical information contained in this Annual Report are also based on our management’s estimates and calculations, which we derived from our review and interpretation of the independent sources, our internal market and brand research and our knowledge of the industries in which we operate. While we believe that each of these studies and publications is reliable, neither we nor the underwriters have independently verified market or industry data from third-party sources and the Company is responsible for such disclosure. We also believe our internal company research is reliable and the definitions of our market and industry are appropriate, though neither this research nor these definitions have been verified by any independent source. Information that is based on estimates, forecasts, projections or similar methodologies is inherently subject to uncertainties, and actual events or circumstances may differ materially from events and circumstances that are assumed in this information.

Although we are not aware of any misstatements regarding the industry data that we present in this prospectus, our estimates involve risks and uncertainties and are subject to change based on various factors, including those discussed under “Risk Factors,” “Forward-

Looking Statements," and "Management's Discussion and Analysis of Financial Condition and Results of Operations" in this Annual Report.

Our company name was changed from "Nocimed, Inc.", to "Aclarion, Inc." on December 3, 2021. NOCIMED® -, NOCISCAN® - , NOCIGRAM®, NOCISCORE®™ -, NOCICALC™ - MRS NOCI+™ - NOCI-™ -, NOCImild™ -NOCIWEB™ - SI-SCORE™, VIRTUAL DISCOGRAM™ - and the Nocimed logo are our trademarks. All other service marks, trademarks and trade names appearing in this Annual Report are the property of their respective owners. We do not intend our use or display of other companies' trade names, trademarks or service marks to imply a relationship with, or endorsement or sponsorship of us by, these other companies. Solely for convenience, trademarks and tradenames referred to in this prospectus may appear without the ® or ™ symbols, but such references are not intended to indicate in any way that we will not assert, to the fullest extent under applicable law, our rights, or that the applicable owner will not assert its rights, to these trademarks and tradenames. Unless the context otherwise requires, we use the terms "Nocimed," "Company," "we," "us" and "our" in this prospectus to refer to Aclarion, Inc.

GLOSSARY

Unless otherwise indicated or the context otherwise requires, references in this Annual Report to the term:

"**AI**" means Artificial Intelligence.

"**Category I Codes**" means numeric codes that identify a procedure or service that is approved by the Food and Drug Administration (FDA), performed by healthcare professionals nationwide, and is proven and documented.

"**Category III Codes**" are CPT Category III codes that are a set of temporary codes assigned to emerging technologies, services, and procedures.

"**CE mark**" is an administrative marking with which a manufacturer or importer affirms its products are in conformity with European health, safety, and environmental protection standards for products sold within the European Economic Area (EEA).

"**Covered Entity**" is a health care provider or other person or entity who acquires and transmits private health information of patients, as covered under HIPAA and GDPR regulations (see e.g. 45 CFR §160.103).

"**CPT**" means "Current Procedural Terminology", and refers to a medical code set created and maintained by the American Medical Association ("AMA") and used by providers of healthcare services to bill insurance companies for their work. All new medical devices and services are required to secure CPT codes to receive payment from government and private commercial payers.

"**CT-Scan**" means a computerized tomography (CT) scan combines a series of X-ray images taken from different angles around the body and uses computer processing to create cross-sectional images (slices) of the bones, blood vessels and soft tissues inside the body. CT scan images provide more-detailed information than plain X-rays do.

"**Cures Act**" means the 21st Century Cures Act, signed into law on December 13, 2016, as Public Law No: 114-255.

"**Disc**" means an intervertebral disc which is made of a gel-like material (nucleus pulposus) surrounded by a thick fibrous ring (annulus fibrosus) is situated between the vertebral bodies of the spine.

"**DLBP**" means Discogenic Low Back Pain

"**DOC**" means "Declaration of Conformity," a document signed by us that declares that we have self-complied with applicable regulations for self-certifying our CE Marking for our products.

"**Fusion**" means "Spinal Fusion" which is surgery to permanently connect two or more vertebrae in the spine, eliminating motion between them.

"**GDPR**" means the General Data Protection Regulation in the EU, originally effective May 25, 2018 and implemented in all local privacy laws across the EU and EEA region, to protect a patient's personally identifiable information (PII) and regulate how it must be collected, stored, and used by others, and in certain situations applies concurrently with HIPAA requirements with respect to PII that is PHI for persons located in the EU and received by companies or other persons or entities in the US.

"**IRB**" means Institutional Review Board, which is typically an appointed board for reviewing and approving investigational clinical trials.

"**Indications for Use**" means the limited scope of the intended uses and related medical indications for appropriately using our products.

"**LBP**" means Lower Back Pain.

"**Labeling**" means the scope of intended "Indications for Use" that is identified with the commercial sale and use of our products.

"**Lumbar Spine**" means the five (5) lower vertebrae, L-1 to L-5.

"**MR**" means Magnetic Resonance.

"**MRI**" means Magnetic Resonance Imaging.

"**MRS**" means Magnetic Resonance Spectroscopy and is a type of pulse sequence used by MR scanners that, unlike MRI pulse sequences which generate images of tissue structures, generates a 'spectrum' with various peaks that represent different chemicals in the body tissue being examined, and which allows for the quantitative measurement of the relative amounts of those chemicals in the examined tissues.

"**Notified Body**" means an organization designated by an EU country to assess the conformity of certain products before being placed on the market, as is required for certain medical products.

"**NIH**" means the United States National Institutes of Health.

"**PD TEST**" means a Provocation Discogram test which is a diagnostic test meant to confirm or exclude the intervertebral disc(s) as a source of back pain. This technique involves puncture of the disc with a fine-gauge needle under fluoroscopic guidance and pressurization of the disc via the injection of contrast media.

"**PMA**" means Premarket Approval by the FDA.

"**QMS**" means Quality Management System, which is a formalized system that documents processes, procedures, and responsibilities for achieving quality policies and objectives, in particular to meet customer and regulatory requirements.

"**DICOM**" means an acronym for digital image communication, typically referring to standardized data architecture formats for managing, storing, and communicating or transferring MRI images and other associated data.

"**Disc**" means intervertebral disc that is located between two vertebral body bones of the spine, where it is bordered by superior and inferior disc end-plate structures, and comprises an inner disc nucleus between the two end-plates and that is a circumferentially surrounded by, and normally contained by, and outer disc annulus that is normally a fibrous collagen-based connective tissue structure.

"**Spectroscopy**" means the science of deriving and evaluating a multi-peak spectrum for a material and in which different molecular bonds representing different components of the material are represented by unique respective peaks at particular locations along the spectra, and with the different peaks typically reflecting different resonant frequencies of the different components when subjected to a pulsed magnetic field; and in our current product, relates to producing and evaluating spectra for the different chemical constituents of disc tissue as derived from MR pulse sequences applied to those tissues for that chemical analysis.

PART I

Item 1. Business

Overview

Aclarion is a healthcare technology company that leverages Magnetic Resonance Spectroscopy ("MRS"), and proprietary biomarkers to optimize clinical treatments. Aclarion's technology addresses the $134.5B U.S. low back and neck pain market, which according to a 2020 JAMA (Journal of the American Medical Association) article is now the most costly healthcare condition in the United States. The Company is currently utilizing Artificial Intelligence ("AI") to assist in quality control processes that flag spectroscopy data indicative of a poor MRS study. The use of AI in this application is early in its development cycle and is expected to evolve with further research and development. The Company is capturing in databases both the raw spectroscopy data and the post-processed spectral data from every Nociscan completed in order to utilize this data as future training data to teach a machine learning algorithms to associate MRS data with clinical outcomes. The use of AI in this application is aspirational and we intend this type of AI research and development to be an ongoing process applied not only to the various treatment paths associated with back pain, such as conservative therapies, regenerative and cell therapies and surgical intervention, but also to potentially expand into other clinical explorations involving the diagnosis of brain, breast and prostate tumors.

The Company, which has limited sales to date, is addressing the chronic low back pain market by initially focusing on improving the outcomes of surgical interventions to treat chronic discogenic low back pain. In this initial application, Aclarion technology is intended to assist surgeons in determining the optimal surgical procedure for a patient undergoing surgery for pain isolated to their lumbar spine (the "lumbar spine" is comprised of the five (5) lower vertebrae, L-1 to L-5). Through clinical studies we intend to extend the application of our technology beyond surgical decisioning to help with managing large segments of low back pain patients from the point of initial MRI through to episode resolution. We believe this will expand the use of our technology to supporting treatment decisions for chronic low back pain patients undergoing conservative therapies such as physical therapy or biologic and cell therapies aimed at regenerating the lumbar discs. We plan to expand the application of our technology beyond the lumbar spine to address neck pain populations in addition to low back pain populations. To expand the application of our technology for use in neck pain populations, we will need to overcome technical changes associated with securing adequate MRS data from the cervical disc, which is significantly smaller than the lumbar disc, and there can be no assurance the Company will be able to overcome these challenges.

The core technology Aclarion employs is MR Spectroscopy. The patient experience when undergoing an MRS exam is exactly like that of a standard MRI, with the exception of an additional 3-5 minutes for each disc undergoing a spectroscopy exam. Whereas a standard MRI produces a signal that is converted into anatomical images, an MRS produces a signal that is converted into a waveform that identifies the chemical composition of tissues. Just like with standard MRIs, the data from spectroscopy is useless without technologies that can process the data. Aclarion has developed proprietary signal processing software that transforms spectroscopy data into clear biomarkers. These biomarkers, which are exclusively licensed from the Regents of University of California, San Francisco ("UCSF"), are the key data inputs for our proprietary algorithms that, when applied, determine if an intervertebral disc is consistent with pain. Our patent portfolio includes 22 U.S. Patents, 17 Foreign Patents, 6 pending U.S. patent applications, and 7 pending Foreign patent applications, including patents and patent applications exclusively licensed from Regents of the University of California.

We believe one of the biggest issues driving the cost of treating low back and neck pain patients to the top of the list for healthcare spending is that there is no objective, cost effective and noninvasive diagnostics to reliably identify the source of a patient's pain. We believe the poor surgical outcomes for chronic DLBP are largely due to difficulties in reliably and accurately diagnosing the specific spinal discs that are causing pain. The current primary diagnostic standard is the MRI, which is useful for showing abnormal structures and tissue dehydration, but, we believe, cannot reliably identify specific discs that are causing pain. To diagnose specific discs that are causing pain, a needle-based Provocation Discogram test ("PD Test") has been developed. PD Tests have been shown to be highly accurate when performed properly. However, a PD Test is invasive, subjective, and unpleasant for the patient as the patient needs to be awake in order to tell the physician if the pain the physician is purposefully causing in the disc is the same as the pain the patient feels when they are experiencing a back pain episode. In addition, recent evidence has shown that the action of inserting a needle into a normal disc during a discogram procedure leads to an increased rate of degeneration in these previously normal discs. Based on the limitations and concerns of the PD Test, we believe there is a significant need for an objective, accurate, personalized, and noninvasive diagnostic test that can reliably determine if an individual disc is a pain generator. By providing physicians information about whether a disc has the

chemical and structural makeup consistent with pain or not, we believe the treatment plan for each patient will lead to more efficient and targeted care that, will in turn, result in lower costs and healthier patient outcomes.

Aclarion has taken the first steps to demonstrate the potential use of our technology in helping to improve the outcome of surgical intervention for discogenic low back pain patients by publishing a clinical study in the European Spine Journal in April 2019. The study illustrated that when all discs identified as consistent with pain by our technology were included in a surgical treatment, 97% of the patients met the criteria for "clinical improvement". This compared to only 54% of patients meeting the criteria for clinical improvement if a disc that our technology identified as consistent with pain, was not included in the surgical treatment.

The results of this clinical study led the CPT committee to approve four Category III codes for our technology in January 2021. The NIH also included our technology as one of the handful of technologies selected to participate in their $150 million Back Pain Consortium (BACPAC) Research Program, an NIH translational, patient-centered effort to address the need for effective and personalized therapies for chronic low back pain. In 2022, the NIH subsequently selected our technology to be included in their prospective randomized follow-on study that resulted from BACPAC. This new study is called Biomarkers for the Evaluation of Spinal Treatments (BEST) and is designed to evaluate several technologies that provide data about a patient to see if these technologies can identify subgroups of chronic LBP patients that do better with one of four treatments being evaluated in the study.

Evolving science coupled with the understanding of degenerative painful discs has suggested that lumbar discs may become painful due to certain chemical changes, which changes cannot be identified using standard lumbar MRI imaging. However, an application of MRI scanners called Magnetic Resonance Spectroscopy has been developed by manufacturers of MRI equipment. MRSs are different than MRIs. An MRI generates images of body structures, while an MRS analyzes the relative amounts of various chemicals in body tissues.

Aclarion has developed a software application called NOCISCAN® which uses the existing MRS capabilities of many commercially available scanners to non-invasively analyze the chemical makeup of intervertebral discs in the spine. The software post-processes the MRS exam data and detects the presence of chemical biomarkers that we, in conjunction with spine researchers at UCSF, have demonstrated to be associated with degenerative pain and structural integrity of the lumbar discs. After processing the MRS exam data, we send the ordering clinician a report that details how to interpret the results of the MRS exam. We believe these results help clinicians make quicker and more informed decisions about which lumbar discs are painful, and which are not. We believe the ordering clinician can use this information to determine the optimal treatment plan for an individual patient.

Because we believe that spectroscopy is not widely used for any clinical purposes today, there are practical limitations to the market opportunity that must be addressed. We believe the two biggest limitations may be the lack of deployment of spectroscopy software across the installed base of existing MRIs worldwide, and the fact that only certain MR scanner models are compatible with our technology. For compatible MRI sites that do not currently have spectroscopy software installed, the onetime cost of the software ranges from $25,000 to $50,000. Currently, our NOCISCAN platform is only compatible with certain MR scanner models provided by SIEMENS, of which there are an estimated 1,500 in the United States, and 4,320 worldwide. We plan to collaborate with other MRI scanner vendors, as well as SIEMENS, to establish compatibility with their respective scanners and MRS capabilities for use with our products. That may allow us to include discounted pricing on spectroscopy software for MRI sites interested in providing DLBP patients with the NOCISCAN offering.

The first application of Aclarion's technology is focused on improving surgical decision making when surgical intervention is being contemplated for patients with low back pain. The Company's first commercial product, which we have named "NOCISCAN", utilizes our proprietary biomarkers and algorithms to provide surgeons with information about which intervertebral discs are determined to be consistent with generating pain, and which are not. We believe that surgeons can use this information to better plan their surgical treatments and improve outcomes in their patients. In a clinical study published in the European Spine Journal in April 2019 it was shown that in patients where all discs identified as painful by NOCISCAN were included in the surgical treatment that 97% of those patients met the criteria for significant clinical improvement. This compared to only 54% of surgical patients meeting the criteria for significant clinical improvement when discs identified as painful by NOCISCAN were omitted from the surgical treatment, or discs identified as not painful by NOCISCAN were included in the treatment. Some authors of this study had a financial relationship with Aclarion, who sponsored the study.

Based on the results of this clinical study, the Company believes that use of NOCISCAN could become the standard protocol for assisting in the treatment plan of patients with low back pain undergoing surgical intervention. Utilizing the results of our European Spine Journal Study, we applied to the American Medical Association for CPT codes to begin the process of securing insurance coverage to pay for

NOCISCAN. On January 1, 2021, Category III CPT codes became effective. The Company is now executing its plan to commercialize NOCISCAN. See “Reimbursement” below.

The core technology underlying NOCISCAN is the use of MR spectroscopy to identify the chemical makeup of intervertebral discs with a focus on identifying specific proprietary biomarkers known to be correlated to pain and to the structural degradation of discs. We believe this technology, in combination with advanced machine learning and AI platforms, has the potential to not only become included in the standard of care for patients undergoing surgical intervention for low back pain, but to become a core data input for optimally managing entire segments of patients suffering from low back and neck pain.

Industry Overview

Low Back Pain

According to the Global Burden of Disease Study 2017, low back pain (LBP) is among the top three causes for years lived with disability. A 2020 JAMA (Journal of the American Medical Association) article established the cost of low back and neck pain at $134.5B in the U.S, making it the most costly healthcare condition in the United States, surpassing cardiac disease, diabetes and cancer.

Low back pain (LBP) can be caused by many different problems and abnormalities along and around the spine, other than DLBP, including conditions such as spondylolisthesis or instability of the vertebral bodies, vertebral body fractures, facet pathologies, central canal and foraminal stenosis, disc herniations, pars fracture, congenital abnormalities and tumors. Many of the causes of low back pain are readily detected by standard MRI imaging of the spine, which reveals clear structural abnormalities, i.e., fractures and tumors. However, in many cases the source of the pain is not clear. As a result, the success rates of surgical care for LBP ranges from 41 to 57%, with 5-16% early complication and reoperation rates also reported.

We believe that poor surgical outcomes for discogenic LBP are largely due to difficulties in reliably and accurately diagnosing the specific spinal discs that are causing pain. The current primary diagnostic standard, lumbar MRI, is useful for showing abnormal structures and tissue dehydration, but, we believe, cannot reliably identify specific discs that are causing pain. To diagnose specific discs that are causing pain, a needle-based Provocation Discogram test (“PD Test”) has been developed. A PD Test has been shown to be highly accurate when performed properly. However, a PD Test is invasive, subjective and unpleasant for the patient, as the patient is required to be awake in order to tell the physician if the pain the physician is purposefully causing in the disc is the same as the pain the patient feels when they are experiencing a back pain episode. In addition, recent evidence has shown that the action of inserting a needle into a normal disc during PD Test, leads to an increased rate of degeneration in these previously normal discs.

Due to the current lack of uniform acceptance of a diagnostic platform to safely and reliably diagnose the specific discs that cause DLBP, patients with DLBP are faced with the options of surgical intervention with a risk of a poor surgical outcomes, or, non-surgical treatment with powerful pain killing drugs, such as opiates and synthetic opiates. Those patients who choose surgery and have a poor surgical outcome with no surgical alternatives will be faced with the possibility of enduring disabling, intractable pain, and often extended dangerous pain medication use.

Diagnostic Imaging

Diagnostic imaging involves the use of non-invasive procedures to generate representations of internal anatomy and function that can be recorded on film or digitized for display on a video monitor. Diagnostic imaging procedures facilitate the early diagnosis and treatment of diseases and disorders and may reduce unnecessary invasive procedures, often minimizing the cost and amount of care for patients. Diagnostic imaging procedures include MRI, CT, PET, nuclear medicine, ultrasound, mammography, X-ray and fluoroscopy.

While X-ray remains the most commonly performed diagnostic imaging procedure, one of the fastest growing procedures is the MRI. The number of MRI scans performed annually in the United States continues to grow due to its wider acceptance by physicians and third party payers, an increasing number of applications for their use and a general increase in demand due to the aging population. MRI has long been a widely accepted diagnostic standard of care for spine and low back pain, including discogenic low back pain patients, which is the target medical condition for our diagnostic products.

Diagnostic Imaging Settings

Diagnostic imaging services are typically provided in one of the following settings:

Fixed-site, freestanding outpatient diagnostic facilities

These facilities range from single-modality to multi-modality facilities and are generally not owned by hospitals or clinics. These facilities depend upon physician referrals for their patients and generally (although not always) do not maintain dedicated, contractual relationships with hospitals or clinics. In fact, these facilities may compete with hospitals or clinics that have their own imaging systems to provide services to patients. These facilities bill third-party payers, such as managed care organizations, insurance companies, Medicare or Medicaid, and workers' compensation providers.

Hospitals

Many hospitals provide both inpatient and outpatient diagnostic imaging services, typically on site or at a dedicated center located on or nearby the hospital campus. These can be owned and operated by the hospital and provide imaging services to inpatients as ordered or outpatients through physician referrals. The hospital normally bills third-party payors such as managed care organizations, insurance companies, Medicare or Medicaid, and workers' compensation providers. We have entered into joint ventures with certain hospitals both provide and manage their diagnostic imaging services, allowing them to leverage our industry expertise.

Mobile Imaging

While many hospitals own or lease their own equipment, certain hospitals provide diagnostic imaging services by contracting with providers of mobile imaging services. Using specially designed trailers, mobile imaging service providers transport imaging equipment and provide services to hospitals and clinics on a part-time or full-time basis, thus allowing small to mid-size hospitals and clinics that do not have the patient demand to justify fixed on-site access to advanced diagnostic imaging technology. Diagnostic imaging providers contract directly with the hospital or clinic and are typically reimbursed directly by them. We do not provide mobile imaging services. The cloud-based software products and services we do provide, however, are compatible for use for post-processing data that may be acquired by certain MR scanners that are deployed in a mobile imaging setting and model.

Company History

Aclarion's technology was originally invented, and initially tested, via successful proof of concept by Aclarion co-Founder and head of our Scientific Advisory Board, Jeffrey Lotz, PhD, at the University of California San Francisco ("UCSF"). Early research, which was published in a major peer-reviewed journal in 2005, was premised upon a growing suspicion and interest that discs may become painful due to chemical changes, in particular elevated acidity related to hypoxia, that are not tested using a standard MRI. With that theory in mind, Dr. Lotz's initial study looked to identify chemical biomarkers for painful discs using MRS, which applies a pulsed magnetic field to tissues in order to vibrate the different chemicals in that tissue and generate a spectrum that allows for measuring those different chemicals based on their different peaks along that spectrum. NMR equipment was used to conduct MRS chemical analysis of painful discs that were surgically removed for DLBP fusion surgery versus normal, non-painful discs that were surgically removed from spinal deformity (i.e. scoliosis) patients for lumbar spine reconstruction. Those ex vivo 11T MRS spectral measurement results showed that all (n=9) of the painful discs were distinguished from all of the non-painful discs based on the highly repeatable (100%) differences in their ratios between lactic acid, a painful chemical resulting from hypoxia, and proteoglycan, a structural chemical of the disc that holds water for hydration. It was observed that with degenerative painful discs, proteoglycan reduces with the degeneration, and lactic acid elevates with the pain. Hence, the MRS-based test and identifiable structural and degenerative pain biomarkers were able to be identified.

This work became the subject of the first patent granted to the Regents of the University of California and exclusively licensed to Aclarion. Thereafter, a strategic collaboration with SIEMENS, a major MRI equipment manufacturer, was initiated and a clinical study, the Gornet Study, involving 73 surgical patients was published in the European Spine Journal, a major peer-reviewed publication (See "Clinical Evidence" below). Our NOCICALC and NOCOGRAM products were subsequently registered with the FDA, CE marked and launched in the US, EU, and UK markets through a customer pay model since insurance codes were not yet in existence.

License Agreement with the Regents of the University of California

On January 8, 2008, the Company entered into an Exclusive License Agreement which was amended and restated on December 9, 2014, (the "License Agreement") with the Regents of the University of California, and was further amended on March 31, 2017. The License Agreement encompassed certain intellectual property and patents covering inventions generally characterized as systems, materials, and methods to localize and evaluate pain and degenerative properties of tissue, molecular markers that differentiate painful from non-painful discs; and MR Spectroscopy System and Method for diagnosing painful and non-painful intervertebral discs.

Pursuant to the License Agreement, the Company obtained a worldwide, exclusive license to intellectual property including certain patent rights related to the patents and technology which the Company utilizes. Under the License Agreement, we agreed to pay a royalty fee of 4% (subject to reduction to a minimum of 2% of net sales, in the event the Company pays a royalty on revenues to a third party) of net sales of the licensed products or technology and 10% of gross revenues we may receive from possible sub-licensees, affiliates or joint venture partners. Additionally, we agreed to pay a minimum annual royalty fee of $50,000, accountable against actual earned royalties, plus other costs and expenses related to the prosecution of existing or future patents related to the technology, and certain additional one-time fees that were contingent upon the occurrence of certain defined milestones.

The License Agreement also provides that for so long as we pay patent prosecution costs, the Regents of the University of California will diligently prosecute and maintain the United States and foreign patents comprising the Patent Rights using counsel of its choice, and the UC Regents' counsel will take instructions only from The Regents of the University of California.

Upon completion of our April 2022 IPO, we were required to pay the Regents of the University of California a contingent one-time "Indexed Milestone Payment" of an amount of cash determined by multiplying the amount of shares outstanding at such time the Company raises $1 million in capital, by 3% and then multiplying the 3% number by the IPO price. On May 2, 2022, we paid the amount of $123,828 to satisfy the Indexed Milestone Payment obligation included within the license agreement.

The Regents of the University of California has the right to terminate the License Agreement upon advanced notice in the event of a default by us. The License Agreement will expire upon the expiration or abandonment of the last of the licensed patents. The patents subject to the License Agreement expire between 2025 and 2029.

We rely on this license, as well as other aspects of our own patented technology and intellectual property, in order to be able to use and sell various proprietary technologies that are material to our business, as well as technologies which we intend to use in our future commercial activities. Our rights to use these licensed technologies and the inventions claimed in the licensed patents, are subject to the continuation of, and our compliance with the terms of the license. The loss of this license would materially negatively affect our ability to pursue our business objectives and result in material harm to our business operations.

Transactions with NuVasive, Inc.

In 2015, NuVasive, Inc. ("NuVasive") purchased approximately $2.0 million of the Company's Series B preferred shares. NuVasive and the Company also entered into a marketing agreement pursuant to which NuVasive would be the exclusive, other than the Company, marketing provider for the Company's technology and NuVasive would receive a commission (the "Commission") of all sales of the technology made by NuVasive. In conjunction with the marketing agreement, the Company entered into a Right of First Offer ("ROFO") Agreement pursuant to which the Company agreed that in the event that the Company determined to enter into a sale event (defined to include a sale of 50% or more of the Company's outstanding voting securities, a sale of substantially all of the Company's assets, or a sale or exclusive license of substantially all of the Company's intellectual property) NuVasive would have the right to receive notice ("ROFO Notice"), and NuVasive would have a 60-day period to determine whether it wanted to acquire the Company on terms set forth in the ROFO Notice. The ROFO obligations will expire 42 months after the FDA issues its first regulatory clearance of a Company product or service. The ROFO obligations do not apply to any proposed sale event in which the acquisition price is $40 million or more.

In February 2020, NuVasive agreed to purchase $308,720 of convertible notes, convertible into Series B-1 preferred shares and in connection with such purchase, was issued a warrant to purchase 171,511 shares of common stock at an exercise price of $.18 per share.

In February 2020, NuVasive and the Company also entered into an amended and restated commission agreement (the "Commission Agreement"), pursuant to which the Company agreed to pay NuVasive a commission of 6% of certain revenues of the Company related to Aclarion's Nociscan technology through December 31, 2023, and issued to NuVasive the right to receive the Company's preferred shares subject to the terms of a $2 million "SAFE" (Simple Agreement for Future Equity). The SAFE provided that NuVasive would receive $2 million of capital stock if the Company would raise a minimum of $10.0 million of new capital on or before December 31, 2020, which was later extended to June 30, 2021. If the $10.0 million was not raised, the Company would issue to NuVasive 1,584,660 Series B-2 preferred shares. The $10.0 million was not raised and the Company issued 1,584,660 Series B-2 preferred shares to NuVasive in December 2021. In connection with the Commission Agreement, NuVasive agreed that: (i) NuVasive would cease to market the Company's technology, (ii) NuVasive would reduce their Commission to 6%, and (iii) Commissions to NuVasive would terminate on December 31, 2023. In December 2021, NuVasive's convertible notes were converted into Series B-3 preferred shares.

Products and Solutions

Aclarion has developed a software application called NOCISCAN®. The product uses the existing MRS capabilities of many commercially available scanners to non-invasively analyze the chemical makeup of intervertebral discs in the spine. The software post-processes the MRS exam data and detects the presence of chemical biomarkers that Aclarion, in conjunction with spine researchers at UCSF, have demonstrated to be associated with degenerative pain and structural integrity of the lumbar discs. After processing the MRS exam data, Aclarion sends the ordering clinician a report that details how to interpret the results of the MRS exam. We believe these results help clinicians make faster and more informed decisions about which lumbar discs are painful, and which are not. We believe the ordering clinician can then use this information to determine the optimal treatment plan for an individual patient.

NOCISCAN is entirely non-invasive and only briefly extends an otherwise standard MRI exam. The MRI scan is the most frequently used type of pulse sequence for operating Nuclear Magnetic Resonance (NMR) scanners. It uses a powerful magnet to apply a pulsed magnetic field to a patient, sensors to detect radio waves that emanate from the resonant vibrations of different chemicals in the body in response to that pulsed magnetic field and a computer to create detailed images of tissue structures in the patient based on those detected chemical signals. Because water and fat are the most prevalent chemicals in the body, standard MRI images are typically based on the different levels of water and fat between different tissues. MRS, however, is another type of pulse sequence that uses NMR scanners in a similar way as an MRI, but instead of using the chemical resonances to create an image, MRS creates a spectrum for a tissue with different peaks that represent many different chemicals, in addition to water and fat, in that tissue. The relative amounts of those chemicals can be calculated by measuring their respective spectral peaks. While MRS has been used previously for diagnosing certain cancers (e.g. brain, breast, prostate) by measuring unique chemical biomarkers for tumors, NOCISCAN uses MRS for measuring the relative levels of degenerative pain and structural integrity biomarkers in discs. The relative levels of degenerative pain and structural integrity biomarkers are derived through the use of proprietary post processing technologies.

The platform used to conduct a NOCISCAN involves: (i) an MRS exam of an intervertebral disc performed according to a proprietary protocol, (ii) a data transfer portal to securely transfer data from the MRS exam to Aclarion's cloud based post-processer technology, (iii) post-processor technology that identifies biomarker peaks and leverages calculation tables that evaluate a number of ratios of biomarker peaks, where pain biomarkers are in the numerator and structural biomarkers are in the denominator, and (iv) a final diagnostic report called a Nocigram that identifies discs as painful or not.

(a) NOCISCAN MRS Exam Protocol: We have developed a custom software protocol and technique for using commercially available MRS pulse sequences in scanning intervertebral discs which extends the time of a standard lumbar MRI exam by an average of about 30 minutes for 5 lumbar discs. The custom protocol is a proprietary series of settings and instructions for MRS to conduct the NOCISCAN exam to obtain optimal and reliable MRS data. This protocol is not a product sold by the Company. The software protocol was created by Aclarion for insertion within a pre-existing software file format and is downloaded onto the MRS by the MRS owner, for use within the MRS's operating system environment. Currently, our software protocol is compatible with only certain MRS models and

operating systems available from SIEMENS, as those SIEMENS models specifically provide for user-defined customizations available for running our custom pulse sequences on SIEMENS MRS equipment.

(b) Data Transfer: Data is routinely transferred from MR scanners to externally hosted cloud post-processors in many settings and applications, with an existing market of products and protocols for doing so. Aclarion provides MR imaging providers two options for data transfer: (1) a licensed proprietary imaging data transfer platform provided by AMBRA® Healthcare, and (2) NOCIWEB®, a custom developed web-interface developed and offered by Aclarion.

(c) The NOCISCAN Post-Processor Suite: This comprises the products that Aclarion currently markets and sells. The post-processor technology requires MRS exam data acquired only according to Aclarion's proprietary MRS exam protocols described in (a) above. The NOCISCAN Post-Processor Suite comprises of two software products that interact with each other:

- NOCICALC® receives the raw un-processed NOCISCAN MRS exam data and post-processes that raw data into final spectra, and performs various degenerative pain biomarker calculations from those spectra, for each disc examined. NOCICALC is Registered as a Class I Medical Device with the FDA.

- NOCIGRAM® further processes the NOCICALC results into individual NOCISCORES, on a 0-10 scale, that represent the different relative levels of degenerative pain biomarkers the various discs examined in the patient. High/low NOCISCORE ranges are also correlated to painful (indicated as "NOCI+" result) versus non-painful (indicated as a "NOCI-result). The NOCISCORE scale was developed according to a reference PD TEST that was used as a standard control in a peer reviewed clinical development trial for our technology. The post-processed MRS results are shown in an intuitive NOCIGRAM report with reference to certain MRI images of the related patient's lumbar spine. The NOCIGRAM report is provided to the physician to aide in the physician's diagnosis and treatment planning. NOCIGRAM is commercially available in the United States as "Clinical Decision Support Software" under the 21st Century Cures Act, and as such is not considered a medical device nor regulated by the FDA.

Advantages over current technology and procedures

NOCISCAN provides new information to help doctors better diagnose which intervertebral discs may contribute to patients back pain and thereby assist in treatment planning and potentially improve patient outcomes.

More specifically, current standards of care for the diagnostic workup of LBP include lumbar X-Ray and MRI and less prevalently, needle-based provocative discography testing (PD Tests). While lumbar X-Ray and MRI can show various pathologic structural abnormalities and degeneration and can be helpful for diagnosing certain non-discogenic sources of pain, these techniques are unreliable for identifying painful discs in LBP patients. The PD TEST is another test that typically follows MRI for the purpose of identifying painful discs. PD Tests have been shown to be highly accurate when performed properly, however, a PD Test is invasive, subjective and unpleasant for the patient as the patient needs to be awake in order to tell the physician if the pain the physician is purposefully causing in the disc is the same as the pain the patient feels when they are experiencing a back pain episode. In addition, recent evidence has shown that the action of inserting a needle into a normal disc during a discogram procedure leads to an increased rate of degeneration in these previously normal discs. We believe NOCISCAN advantages include: (a) enhancing the ability and value of otherwise standard lumbar MRI exams to, for the first time, reliably identify chemically painful discs causing DLBP; and (b) providing a "Virtual Discogram™" as an entirely non-invasive, objectively quantitative, pain-free, non-significant risk, and more widely adoptable alternative to needle-based PD exams (which share none of those advantages).

More specifically, NOCISCAN offers many specific advantages to the marketplace, from a diagnostic point of view, including:

1) Readily and widely adoptable;

2) Non-invasive;

3) Non-painful;

4) Nonsignificant risk to patients;

5) Objective, quantitative diagnostic information;

6) Enhances the diagnostic value of MR exams for painful disc diagnosis in DLBP patients;

7) Correlative to the modern standard and accurate technique of PD diagnostic exams for DLBP diagnosis - but without the invasive, painful, subjective, potentially harmful, and limited adoptability shortcomings of PD;

8) First and only known ability to non-invasively assess degenerative painful disc chemistry;

9) More informed ability to reliably diagnose painful vs. non-painful discs;

10) More informed ability to predict the potential for ASD to develop or advance in discs next to neighboring discs that are initial surgical targets;

11) More informed ability to reliably diagnose actual ASD in discs following a prior surgery in neighboring discs;

12) Potential for improved patient outcomes in DLBP patients resulting from more informed diagnostic acuity for painful vs. non-painful discs and related targeted treatment planning; and

13) The only known non-invasive disc chemistry measurement and monitoring tool to support clinical research, development, and evaluation of new therapies, e.g. injectable biologics/cell therapies, that have therapeutic mechanisms of action related to disc chemistry interactions and changes.

NOCISCAN incorporates many patented technologies and features that we believe provide several technical advantages to the MRS field in general. Prior applications of MRS, e.g. for brain, prostate, or breast cancer diagnosis encountered technical challenges related to acquiring reliably robust spectra for making accurate quantitative chemical measurements. These technical challenges resulted in poor sensitivity and specificity for prior MRS products addressing clinical applications. The novel features and advantages provided in the NOCISCAN platform are designed to address the technical and diagnostic challenges of MRS in the past. Accordingly, we believe Aclarion improvements do not only propose benefits for disc MRS, but potentially for other MRS applications more broadly. Improvements in processing raw MRS data incorporated in Aclarion IP are summarized below:

1) Introducing novel signal processing approaches for enhanced reliability of the underlying spectra and related chemical biomarker ‘peak’ measurements:

   a) increased signal noise ratio or “SNR” for more reliably identifying and measuring chemical peaks - in particular, by averaging spectra from multiple acquisitions using (i) only strong acquired signals and filtering out weak ones (“frame editing”), and (ii) a “smart” form of frequency shift correction to align multiple acquisitions for “coherent” averaging; and

   b) detecting spectral artifacts that might compromise the reliability of spectral peak measurements and related chemical measurements, and which can occasionally result from technical issues during MRS exams in the scanner (generally observed in <10% of discs), and then either: (i) correct for the artifact (e.g. patient motion artifact correction), or (ii) identify the compromised MRS acquisition as a technical failure and unable to perform reliable spectroscopic measurement (i.e., occasionally supplanting a risk for inaccurate diagnosis instead of a technical failure and indeterminate diagnostic result).

2) Basing diagnostic results on relative, normalized comparisons of the differences between chemical biomarkers for multiple different disc tissues in the same patient vs. assigning diagnostic thresholds for chemical measurements that are empirically derived from a separate clinical trial patient population and are not patient specific.

3) Evaluating only multi-chemical "degenerative pain" biomarkers that use ratios between spectral peaks for chemicals associated with (i) pain and (ii) structural degeneration, thus providing for: (a) a two-fold and bi-directional sensitivity in the combined biomarker from both the ratio's numerator (pain biomarker) and its denominator (structural degeneration biomarker), and (b) reduction of patient anatomy-dependent variables in the MRS data to thereby enhance the personalization of the data and increase the generalizability of the diagnostic algorithms across diverse populations.

4) Using multi-peak spectral ranges, representing multiple different painful acids, as a single pain biomarker used in the combined ratios for degenerative pain biomarkers (e.g. "LAAL" painful chemical biomarker range combining adjacent Lactic Acid and ALanine peaks, and "ALPA" combining Alanine, Lactic acid, and Propionic Acid peaks) – thereby removing the need for accurately differentiating each individual peak, and thus reducing the risk for inaccuracy in the spectral measurements and diagnostic interpretations.

Clinical Evidence

We have pursued a clinical study (the "Gornet Study") to demonstrate the benefits of our technology to surgeons, imaging centers, third party payers, and patients. Without strong clinical data in support of our technology to improve clinical outcomes, the opportunity to secure new reimbursement codes and change existing treatment pathways would be limited.

In a clinical study sponsored by us, and authored by, among others, a spine surgeon who has a financial interest in the Company. and published in the European Spine Journal in April 2019, it was shown that 97% of the treated patients met the criteria for significant clinical improvement, where all discs identified as painful by NOCISCAN were included in the surgical treatment. This compared to 54% of surgical patients achieving clinically significant improvement when discs identified as painful by NOCISCAN were omitted from the surgical treatment, or discs identified as not painful by NOCISCAN were included in the treatment. Some authors of this study had a financial relationship with Aclarion, who sponsored the study.

This clinical study included 139 chronic low back pain patients who collectively underwent a NOCISCAN exam across 623 lumbar discs. Seventy-three patients underwent surgical intervention, consisting of fusion or disc replacement, and reached six months follow up. Clinical improvement post surgically was evaluated using the industry standard Oswestry Disability Index (ODI), and the Visual Analog Scale (VAS). ODI evaluates patient disability on a scale of 1-100 with a higher score indicating less impairment. VAS evaluates subjective pain on a scale of 1-10 with a lower score indicating less pain. Significant clinical improvement in the study was defined as a 15-point improvement in ODI and a 2-point improvement in VAS. NOCISCAN data was not used in surgical decision making.

Post-operatively, patients were separated into various groups for analysis. One group consisted of patients where the surgical intervention included every disc that was identified by NOCISCAN as painful. This group consisted of 36 patients with 26 undergoing a one-level surgical procedure and 10 undergoing a two-level surgical procedure. 97% (35 of 36) of the patients in this category met the criteria for significant clinical improvement. The one failure in this group did meet the VAS requirement and missed the ODI cutoff of 15 by only one point.

In another group consisting of 13 patients, a disc identified as painful by NOCISCAN was not included in the surgical intervention. In this group only 54% (7 of 13) of patients met the criteria for clinically significant improvement.

We believe the results of this study indicates that using NOCISCAN data to help determine the appropriate level for surgical intervention will significantly improve the outcomes for patients undergoing spine surgery for back pain. However, the Gornet Study was a single (relatively small) clinical study at a single clinical center sponsored by us, and authored by, among others, a spine surgeon who has a financial interest in the Company, and there can be no assurance that the results of such study accurately support our conclusions related to the market opportunity of our products.

Market Opportunity

The current NOCISCAN product addresses the $10B that is spent in the U.S. on spine fusion procedures annually. Our early clinical evidence points to a marked improvement in surgical outcomes when discs identified as painful by our technology are included in the

surgical treatment. We believe this market is actionable now and a significant portion of the proceeds of our IPO will be directed towards commercializing this market opportunity.

As we continue our commercialization efforts, we plan to track patients through clinical registries in order to build on our early clinical evidence. We expect to use these registries to track NOCISCAN patients regardless of what treatment path they may follow. Through the date of this prospectus, NOCISCAN has only been evaluated in formal clinical studies for patients primarily undergoing surgical interventions for fusion or disc replacement. The Company plans on expanding clinical registries to capture patients undergoing surgical interventions for back pain that include all surgical interventions, not just fusion and disc replacement procedures. If we are able to correlate specific MRS findings to improved surgical outcomes for all spine surgeries, we believe this would expand the size of our market opportunity in the U.S. from what we believe is $10B, to an estimated $40B, inclusive of pre-surgical conservative therapy costs. However, there can be no assurance that we will be successful in marketing our products, regardless of the size of the estimated market.

Our ultimate objective for NOCISCAN is to address the entire low back and neck pain market which at $134.5B annually represents the largest amount of healthcare dollars spent to treat any disease. To address this market, our current algorithms will need to expand to include advanced machine learning techniques that incorporate multiple data inputs besides the chemical composition of discs. These additional inputs will all need to be correlated to clinical outcomes for treatments ranging from physical therapy to regenerative therapies, and surgical interventions. To further this process, we have been selected as a participant in a $150M NIH funded study (the NIH BACPAC Initiative") focused on evaluating the most promising data inputs for predicting the optimal treatment path for back pain patients and in the NIH's follow on BEST study to evaluate the clinical efficacy of using these data inputs for improving clinical results.

In addition to participation in external studies such as the NIH BACPAC and BEST initiatives, we expect to create our own internal data by adding patients undergoing conservative and regenerative treatment plans to our clinical registries correlating NOCISCAN results to outcomes in order to utilize AI to associate spectroscopy signals with the optimal treatment pathway. If we are successful in demonstrating the clinical effectiveness of these associations, we intend to expand our market opportunity to the management of entire segments of low back and neck pain patients, thereby, we believe, increasing the size of our addressable market. However, there can be no assurance that we will be successful in marketing our products, regardless of the size of the estimated market.

Although we believe that we are addressing a large U.S. and European market, there are practical limitations to the market opportunity that must be overcome by us. We believe the two biggest limitations are the lack of deployment of spectroscopy software across the install base of existing MRI's worldwide and the fact that only certain MR scanner models are compatible with our technology. For compatible MRI machines, that do not have spectroscopy hardware and software installed, the onetime cost of the hardware and software ranges from $25,000 to $50,000. Currently, our NOCISCAN platform is only compatible with certain MR scanner models provided by SIEMENS, of which there are an estimated 1,500 in the United States, and 4,320 worldwide. We plan to collaborate with other MRI scanner vendors to establish compatibility of their respective scanners and MRS capabilities for use with our products, to include discounted pricing on spectroscopy software for MRI sites interested in providing DLBP patients with the NOCISCAN offering.

Plan of Operation and Growth Strategies

Our primary near-term growth strategy is to secure payer contracts to cover our Category III CPT codes. We believe that with favorable payer coverage decisions comes the opportunity to more efficiently market to spine surgeons and imaging centers to adopt our technology.

The Company is currently generating the vast majority of its revenue directly from patients paying out of pocket. With the introduction of Category III CPT codes and the proceeds of our IPO, the Company is transitioning to full commercial operations.

In order to effectively commercialize, the initial plan is to gain the support of up to 10 leading spine surgeons who believe Nociscan technology will help them with surgical decisioning in their practices. The Company has announced 7 of the 10 KOL surgeons to date and has verbal commitments to fill the remaining three KOL targets. Key Opinion Leader (KOL) surgeons are leaders in their field and will be assisting the Company in generating important clinical data in support of Nociscan and using that data to help the Company in discussions with payers to secure positive payment decisions for our Category III CPT codes.

Based primarily on our KOL surgeons and the strength of physician engagement in markets, the Company is prioritizing the following markets:

1. NYC Metropolitan Area
2. San Francisco, CA
3. Chicago, IL
4. Phoenix, AZ
5. Miami, FL
6. Denver & Colorado Springs, CO
7. Detroit, MI
8. Indianapolis

Once a positive local payment decision is secured in a geographical area, we intend to place a market manager and a team of business development professionals into each market to focus on expanding physician support and securing favorable coverage decisions from additional payers in the market. The objective in each market is to expand the provider network to include additional imaging centers and surgeons so there is increasing geographical coverage. We believe increasing our footprint in each market will grow volume and revenue through increased pressure on payers to expand positive coverage decisions across all of the varied plans associated with each payer.

We believe the following strategies will contribute to growth in the prescription and use of NOCISCAN.

- Enhance our multi-tiered sales/marketing/branding campaign targeted at (i) referring physicians, (ii) MR imaging providers, (iii) DLBP patients, (iv) spine implant equipment suppliers, (v) injectable biologics and cell therapy providers, (vi) MR scanner vendors, (vii) third party payors, and (viii) employers, all to grow awareness and demand for NOCISCAN;
- Increase third party payer reimbursement coverage via reimbursement code utilization, payer negotiations, growing clinical evidence dossier via published registry studies and Randomized Control Trials ("RCT"), and converting temporary Category III CPT codes into permanent CPT Category I codes see "Third Party Reimbursement " below;
- Expand MR scanner compatibility to additional scanner models, including within the Siemens product lines and other manufacturers/vendors;
- Expand into international markets;

- Evolve the adaptations and positioning of our products to support new emerging technologies, and clinical trials, in particular for injectable biologic and cell therapies;
- Continue to conduct clinical trials, and publish clinical trial results in peer-reviewed journals in relevant fields to our business (e.g. MR/radiology, spine, and pain);
- Continue to engage and expand Key Opinion Leader ("KOL") advisory boards and specialty medical society support for supporting and driving awareness of our products and services to wider audiences of potential customers and other stakeholders; and
- Pursue additional applications of our technology, including other regions of the spine (e.g., thoracic, cervical), areas of the anatomy outside of the spine, and integrative use of our diagnostic platform with other diagnostic platforms and tests to potentially improve the management and outcomes of populations of low back and neck pain patients.

Strategic Relationships

Siemens

The NOCISCAN product suite is currently compatible for use only with certain MR scanner models and configurations provided by SIEMENS. We are not subject to any exclusivity agreement or obligations with SIEMENS, nor do we have any fee sharing, royalty, or

other exchange of moneys or payments between us and Siemens. The nexus for our focused relationship with Siemens resulted from our determination that Siemens scanner models were optimally positioned to support our product. We have had a collaborative relationship with Siemens since 2011.

On May 2, 2012, following a prior period of informal collaboration, we entered a Memorandum of Understanding ("MOU") with SIEMENS, under which SIEMENS agreed to support Aclarion's research and development of what later became the NOCISCAN product suite for compatible use with SIEMENS scanners. The MOU included the development of certain custom features and technical support that SIEMENS would make available to support the development effort by Aclarion. The relationship was non-exclusive. The MOU was replaced by a Strategic Collaboration Agreement for Phased Commercialization of the SIEMENS-compatible NOCISCAN Product of Aclarion, Inc. (the "SIEMENS Agreement") that we entered into with SIEMENS Healthcare GmbH on December 31, 2017. This agreement comprised a collaboration to identify, onboard and provide technical support for the SIEMENS-compatible NOCISCAN platform with early commercial users in the European Union, including a free trial period for those initial commercial users to activate and use the SIEMENS SVS pulse sequence option package that is required to be purchased by our customers in order to perform disc MRS according to the specifications for compatible use with our products. The SIEMENS Agreement also provided for plans for global joint marketing, potential business model/fee agreement and a potential integration of the NOCISCAN product suite into the SIEMENS Next Generation Frontier App Store model. While these plans have not yet been realized, the agreement still remains in effect through automatic extensions and we are in on-going dialogue and negotiations toward some, or possibly all, of these objectives. The Siemens Agreement is terminable.at any time by either party if such party is of the opinion that the goals of the Collaborative Agreement cannot be achieved for technical, economic and/or clinical reasons. If Siemens were to terminate its relationship with the Company, it would have a material adverse effect on our business. Further, there can be no assurance that there will be any joint marketing or that future financial arrangements between us and SIEMENs will be established, and even if established, that such agreements will be successful or profitable.

RadNet

Two of the Company's imaging centers that are fully operational to perform NOCISCAN's are owned by RadNet, Inc., ("RadNet") a leading provider of outpatient imaging centers in the United States. RadNet currently own 353 outpatient imaging centers across seven states. Larry Tannenbaum is one of our former board members and leads the radiology section of our Medical Advisory Board. The New York/New Jersey area is one of our top targets for early commercialization post IPO and we expect to leverage RadNet's extensive relationship with commercial payers to secure introductions that we believe will lead to early coverage decisions from payers in support of our growth plans. Although we have ambitions to grow the RadNet relationship, the current arrangement is limited to the flow of revenue between Aclarion and RadNet for the performance of an MRS exam by RadNet and the subsequent generation of a Nociscan report by Aclarion.

Reimbursement

Current Procedural Terminology or "CPT" codes are developed by the American Medical Association ("AMA") to describe a wide range of health care services provided by physicians, hospitals and other health care professionals. These codes are utilized to communicate with: other physicians, hospitals, and insurers for claims processing. There are three categories of CPT Codes: Category I, Category II, and Category III (also often referred to interchangeably as "Levels"):

- Category I CPT codes are used for reporting devices and drugs (including vaccines) required for the performance of a service or procedure, services or procedures performed by physicians and other health care providers, services or procedures performed intended for clinical use, services or procedures performed according to current medical practice, and services or procedures that meet CPT requirements. These codes are billable for reimbursement.

- Category II CPT Codes are used for reporting performance measures reducing the necessity for chart review and medical records abstraction.

- Category III CPT codes are used for reporting emerging technology in a number of capacities including services or procedures recently performed on humans, clinical trials and etc. These codes are temporary codes and must be accepted for placement in Level I by the CPT committee within five years, be renewed for another five more years, or be removed from the book.

Our NOCISCAN product suite was initially commercialized without existing CPT codes or other pathways for seeking reimbursement coverage from third party payers. Accordingly, to date, the commercial uses of our products have been principally paid for directly by patients or their spine surgery care provider. The first third party payer reimbursement occurred in May 2021 via the payment of a Workman's Compensation claim in Colorado.

Effective January 1, 2021, a previously retired Category I CPT Code 76390 for MR Spectroscopy was reinstated and reactivated by the Centers for Medicare and Medicaid Services ("CMS"). This resulted from our own direct efforts with CMS in hopes of achieving this result. In addition, also effective January 1, 2021, the AMA approved four new Category III CPT Codes for performing MRS exams specifically on intervertebral discs. More specifically, these codes were assigned respectively to: (i) determine and localize discogenic pain via SVS (0609T), (ii) transmit the MRS derived biomarker data for software analysis (0610T), (iii) post-process the biomarker data for algorithmic analysis to determine relative chemical differences between discs (0611T), and (iv) interpret and report those results. Ambulatory Payment Classification ("APC") pricing assignments were also made by CMS for three of these Level 1 T-codes, while the fourth (0612T) was not priced and left for us, or interpreting doctors, to negotiate payment pricing amounts with Medicare Administrative Contractors (MACs) and third-party payers. The creation, activation, and APC pricing assignment of these four new Level 3 codes was also the result of our Company directly pursuing and negotiating with the AMA toward these interim objectives. We intend to further explore APC assignments such as a New Technology APC to ensure our NOCISCAN product suite is assigned an APC that is appropriate in terms of clinical characteristics and resource costs.

The table below further explains these four new Level III CPT Codes:

CPT Code	Description
0609T	MRS, determination and localization of discogenic pain (cervical, thoracic, or lumbar); acquisition of single voxel data, per disc, in ≥3 discs
0610T	MRS, determination and localization of discogenic pain (cervical, thoracic, or lumbar); transmit biomarker data for software analysis
0611T	MRS, determination and localization of discogenic pain (cervical, thoracic, or lumbar); postprocessing for algorithmic analysis of biomarker data for determination of relative chemical differences between discs
0612T	MRS, determination and localization of discogenic pain (cervical, thoracic, or lumbar); interpretation and report

Due to a lack of operating capital, we have not yet begun to seek reimbursement coverage or promote or suggest our customers use these codes. However, we plan to use the proceeds of our IPO to hire the personnel and expend our financial resources do so. The Category III Codes become more valuable and useful upon being converted into Level I, when widespread reimbursement coverage is expected to be achievable. We plan to support conversion of codes from Category III to Category I by advancing multiple clinical studies and related peer-reviewed clinical publications intended to further support improved patient outcomes (such as success rates following DLBP surgeries), and various economic advantages to be achieved by incorporating the use of our NOCISCAN platform into the DLBP patient's healthcare journey. However, there can be no assurance that the Category III codes will be converted and replaced with corresponding Level I Codes, and if there is a delay in the conversion of the Codes to Level 1 or there is ultimately no conversion of Codes to Level I, our business will be materially adversely affected. Further, even if the Codes are converted to Level 1, there can be no assurance that we will be successful in increasing the use of our technology by patients and health care professionals.

Intellectual Property - Licenses, Patents and Trademarks

We rely on a combination of licenses, patents, trade secrets, copyrights and trademarks, as well as contractual protections to establish and protect our intellectual property rights. Our success depends in part on our ability to obtain and maintain intellectual property protection for our technology. We seek to protect our technology and any potential future technology related to our NOCISCAN platform through a variety of methods, including seeking and maintaining patents intended to cover current and future technology, their methods of use and processes, and any other inventions that are commercially important to the development of our business. We seek to obtain domestic and foreign patent protection which includes, in addition to filing and prosecuting patent applications in the United States, typically filing counterpart patent applications in additional countries where we believe such foreign filing is likely to be beneficial, including Europe, Australia, Canada, China, Japan, India and South Africa.

On December 9, 2014, the Company entered into an amended and restated exclusive license agreement (the "License Agreement") with the Regents of the University of California for certain inventions, generally characterized as systems, materials, and methods to localize and evaluate pain and degenerative properties of tissue, molecular markers that differentiate painful from non-painful discs; and MR Spectroscopy System and Method for diagnosing painful and non-painful intervertebral discs (collectively the "Invention").

Pursuant to the License Agreement, the Company obtained a royalty-bearing, worldwide, exclusive license to the Invention, including certain patent rights related to the patents and technology the Company uses. Under the agreement, we agreed to pay a royalty of 4% of net sales of the licensed products. Additionally, we agreed to pay a minimum annual royalty fee starting on the third anniversary of the effective date of the agreement, which escalates each anniversary and is currently $50,000. UCSF has the right to terminate the agreement upon advanced notice in the event of a default by us. The agreement will expire upon the expiration or abandonment of the last of the licensed patents. The U.S. patents subject to the agreement expire between 2026 and 2029, without considering any possible patent term adjustment or extensions and assuming payment of all appropriate maintenance, renewal, annuity, or other governmental fees.

As of December 31, 2022, our intellectual property portfolio has 22 issued patent and 6 pending patent applications in the U.S., and 17 patent grants and 7 pending patent applications outside the United States. The overall patent portfolio includes patents and patent applications that are (i) assigned exclusively to the Company, (ii) assigned exclusively to the Regents of the University of California but exclusively licensed to the Company, and (iii) assigned to both the Company and the Regents of the University of California (also exclusively licensed to the Company). Many of these patents relate to, inventions involved in, the Company's first product, the NOCISCAN product suite for post-processing disc MRS exam data. Others relate to potential enhancements of the NOCISCAN disc MRS exam (as conducted at the MR scanner) and also other alternative diagnostic approaches (e.g. molecular imaging and gene expression testing). Our portfolio of patents and patent applications, if issued, are expected to expire between January 30, 2026 and June 16, 2037 in the U.S., in each case without considering any possible patent term adjustments or extensions and assuming payment of all appropriate maintenance, renewal, annuity, or other governmental fees.

Our intellectual property portfolio includes four patent families (each reflecting multiple families, if based on different original applications), that relate to our NOCISCAN technology and/or to other potential future pipeline products.

The first patent family is directed to inventions for signal processing techniques to include leveraging artificial intelligence technologies for improving the quality, reliability, and accuracy of MRS-based chemical biomarker measurements and related diagnostic interpretations. Many of these patented inventions are included in our NOCICALC product under the NOCISCAN Suite and cover uses specifically for disc MRS, and for MRS in any other tissues. This first family includes 8 issued patents and 1 pending patent application assigned to the Company in the US, and 3 issued patents and 1 pending patent application outside the U.S. (Europe and Australia). All of these are assigned to the Company. The U.S. granted patents and pending patent applications, if issued, are expected to expire between October 14, 2029 and March 15, 2033, without considering any possible patent term adjustment or extensions and assuming payment of all appropriate maintenance, renewal, annuity, or other governmental fees.

The second patent family relates to inventions for novel diagnostic systems and methods for providing diagnostically useful information based on MRS-based chemical biomarkers. Many of these patented inventions are incorporated in our NOCIGRAM product and related diagnostic report under the NOCISCAN Suite and relate to uses specifically for discogenic pain, conditions related to discs more generally, and more broadly any degenerative pain-related diagnosis in any tissue. This family includes patents relating to diagnosing degenerative painful discs (and other tissues) using the primary degenerative pain biomarkers evaluated by our NOCIGRAM product. The second patent family includes 6 issued patents and 3 pending patent applications in the US, and 9 patent grants and 6 pending patent applications outside the U.S. (Europe, Australia, Canada, China, Japan, India, South Africa). These are either assigned to the Regents of the University of California or assigned to both the Regents of the University of California and the Company, in all cases with the UC's rights exclusively licensed to the Company. The U.S. granted patents and pending patent applications, if issued, are expected to expire between January 30, 2026 and June 16, 2037, without considering any possible patent term adjustment or extensions and assuming payment of all appropriate maintenance, renewal, annuity, or other governmental fees.

Our third patent family relates to inventions that enhance the efficiency and reliability of certain aspects related to conducting MRS exams at the MR scanner. This includes enhancing the efficiency and quality of NOCISCAN disc MRS exams and other applications of MRS in general. These patented inventions are not currently incorporated into our commercial products but are in the research and

development phase for potential pipeline products. This third patent family includes 3 issued US patents that are expected to expire on November 23, 2031, without considering any possible patent term adjustment or extensions and assuming payment of all appropriate maintenance, renewal, annuity, or other governmental fees. These patents are all assigned to the Company. This patent family also includes a pending U.S. patent application that relates to the use of Artificial Intelligence for enhancing MRS exams, which is in the research and development phase for potential pipeline products.

Our fourth patent family relates to inventions for other novel diagnostic systems and methods that represent potential future pipeline products, or otherwise provide potential exclusionary rights against related potential competitive threats. This includes patents related to discogenic pain diagnosis using molecular imaging and/or gene expression testing. The fourth patent family includes 4 issued patents and 1 pending patent application in the US, and 5 patent grants outside the U.S. (Europe, Canada, China). These patents are assigned to the Regents of the University of California and exclusively licensed to the Company (and in certain aspects, co-exclusively licensed under which the Company has exclusive rights to diagnostic aspects and another third-party licensee has limited exclusive rights to only certain treatment aspects). The U.S. granted patents and pending patent applications, if issued, are expected to expire between September 21, 2026 and May 29, 2029, without considering any possible patent term adjustment or extensions and assuming payment of all appropriate maintenance, renewal, annuity, or other governmental fees.

We cannot be sure that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications we may own or license in the future. We cannot be sure that any of our existing patents or any patents we may own or license in the future will be useful in protecting our technology. Please see "*Risk Factors — Risks Related to Our Intellectual Property*" for additional information on the risks associated with our intellectual property strategy and portfolio.

We continually assess and refine our intellectual property strategies to fortify our position. We file additional patent applications when our intellectual property strategy warrants such filings. We intend to pursue additional intellectual property protection to the extent that we believe it would be beneficial and cost-effective. Our ability to stop third parties from making, using, selling, offering to sell, importing or otherwise commercializing any of our patented inventions, either directly or indirectly, will depend in part on our success in obtaining, defending and enforcing patent claims that relate to our technology, inventions, and improvements. With respect to our intellectual property, we cannot provide any assurance that any of our current or future patent applications will result in the issuance of patents in any particular jurisdiction, or that any of our current or future issued patents will effectively protect any of our tests or technology from infringement or prevent others from commercializing infringing tests or technology. Even if our pending patent applications are granted as issued patents, those patents may be challenged, circumvented or invalidated by third parties. Consequently, we may not obtain or maintain adequate patent protection for any of our tests or technology.

In addition to our reliance on patent protection for our inventions and technology, we also rely on trade secrets, know-how, confidentiality agreements and continuing technological innovation to develop and maintain our competitive position. For example, some elements of our analytics techniques and processes, computational-biological algorithms and related processes and software are based on unpatented trade secrets and know-how that are not publicly disclosed. Although we take steps to protect our proprietary information and trade secrets, including through contractual means with our employees, advisors and consultants, these agreements may be breached, and we may not have adequate remedies for any breach. In addition, third parties may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose our technology. As a result, we may not be able to meaningfully protect our trade secrets. For further discussion of the risks relating to intellectual property, see the section titled "Risk factors — Risks Related to our Intellectual Property."

The Company holds the following trademarks for its previous corporate brand name as well as for its key products and brands ("®" designates registered trademark, "™" designates unregistered trademark under common law protection):

NOCIMED®Corporate brand name
NOCISCAN® - Primary data acquisition exam (procedure) and software-based post-processing suite (product)
NOCIGRAM® - Post-processed report, one of two products in the NOCISCAN product suite
NOCISCORE® - Feature of NOCIGRAM Report
NOCICALC™ - MRS spectral processor and biomarker calculator, one of two products in the NOCISCAN suite
NOCI+™ - Feature of NOCIGRAM Report
NOCI-™ - Feature of NOCIGRAM Report

NOCImild™ - Feature of NOCIGRAM Report
NOCIWEB™ - Web-hosted user interface
SI-SCORE™ - Feature of NOCIGRAM Report
VIRTUAL DISCOGRAM™ - Additional name associated with NOCIGRAM

With respect to involved meanings, the recurrent prefix term "NOCI" among these marks is derived from Latin origins for "*pain*" (e.g. nerves that report pain are called "*noci*ceptors")

Research and Development

Research and Development ("R&D") activities at Aclarion primarily explore the use of AI, our post-processing technologies and clinical registry data to expand the use of our technology.

The Company is researching the application of AI and machine learning platforms to analyze both the raw spectroscopy data and the post-processed signal to evaluate whether AI platforms can more efficiently and more effectively associate MRS data with clinical outcomes. We expect this type of AI research and development to be an ongoing process applied not only to the various treatment paths associated with back pain, i.e., conservative therapies, regenerative and cell therapies and surgical intervention, but to potentially expand into other clinical explorations involving the diagnosis of brain, breast and prostate tumors.

Clinical research at Aclarion includes the building of clinical registries that provide the data inputs required to train the AI models to improve the efficiency and effectiveness of our technology for surgical decisioning as well as extend the use of our technology for potentially optimizing the treatment of neck and low back pain through other interventions.

Clinical registries track the MRS results for each disc being evaluated and correlates the MRS signature of the disc to patient specific data such as MRI imaging, Oswestry Disability Index (ODI) and Visual Analog Scores (VAS). These methods are proven tools to assess low back pain, clinical treatments performed and to identify conservative therapies such as physical therapy and chiropractic intervention, regenerative and cell therapies or surgical interventions. By tracking specific treatments applied to each patient over time and correlating the effectiveness of those treatments to the MRS data of each disc, we expect to create a large repository of clinical data that can be used to train advanced machine learning algorithms that correlate MRS signatures from specific discs to improved outcomes from conservative and regenerative therapies.

Government Regulation

United States FDA.

In the United States, the FDA has broad regulatory powers with respect to pre-clinical and clinical testing of new medical devices and the designing, manufacturing, labeling, storage, record keeping, marketing, advertising, promotion, distribution, post-approval monitoring and reporting and import and export of medical devices. Unless an exemption applies, federal law and FDA regulations require that all new or significantly modified medical devices introduced into the market be preceded either by a pre-market notification clearance order under section 510(k) of the Federal Food, Drug and Cosmetic Act (FDCA), or an approved Denovo or pre-market approval (PMA) application. Under the FDCA, medical devices are classified into one of three classes—Class I, Class II or Class III—depending on the degree of risk associated with each medical device and the extent of control needed to provide reasonable assurances with respect to safety and effectiveness. Class I devices are those for which safety and effectiveness can be reasonably assured by adherence to a set of regulations, referred to as General Controls, which require compliance with the applicable portions of the FDA's Quality System Regulation (QSR) facility registration and product listing, reporting of adverse events and malfunctions and appropriate, truthful and non-misleading labeling, advertising and promotional materials. Some Class I devices, also called Class I reserved devices, also require premarket clearance by the FDA through the 510(k) premarket notification process described below. Most Class I products are exempt from the premarket notification requirements, and subject only to registration requirements (which the FDA does not typically review, thus determined and submitted solely by the applicant product owner).

Class II devices are those that are subject to the General Controls, as well as Special Controls as deemed necessary by the FDA, which can include performance standards, guidelines and post-market surveillance. Most Class II devices are subject to premarket review and

clearance by the FDA. Premarket review and clearance by the FDA for Class II devices is accomplished through the 510(k) premarket notification process. Under the 510(k) process, the manufacturer must submit to the FDA a premarket notification, demonstrating that the product for which clearance has been sought is substantially equivalent to a previously cleared 510(k) device or a device that was in commercial distribution before May 28, 1976 for which the FDA had not yet called for the submission of pre-market approval applications. To be substantially equivalent, the proposed device must have the same intended use as the predicate device, and either have the same technological characteristics as the predicate device or have different technological characteristics and not raise different questions of safety or effectiveness than the predicate device. Clinical data is sometimes required to support substantial equivalence.

After a 510(k) notice is submitted, the FDA determines whether to accept it for substantive review. If it lacks necessary information for substantive review, the FDA will refuse to accept the 510(k) notification. If it is accepted for filing, the FDA begins a substantive review. By statute, the FDA is required to complete its review of, and clear or deny, a 510(k) notification within 90 days of receiving the 510(k) notification. As a practical matter, clearance often takes longer, and clearance is never assured. Although many 510(k) premarket notifications are cleared without clinical data, the FDA may require further information, including clinical data, to make a determination regarding substantial equivalence, which may significantly prolong the review process. If the FDA agrees that the device is substantially equivalent, it will grant clearance to commercially market the device.

After a device receives 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a new or major change in its intended use, will require a new 510(k) clearance or, depending on the modification, could require a De Novo or PMA application. The FDA requires each manufacturer to make this determination initially, but the FDA can review any such decision and can disagree with a manufacturer's determination. If the FDA disagrees with a manufacturer's determination regarding whether a new premarket submission is required for the modification of an existing device, the FDA can require the manufacturer to cease marketing and/or recall the modified device until 510(k) clearance or approval of a De Novo or PMA application is obtained. If the FDA requires us to seek 510(k) clearance or approval of a De Novo or PMA application for any modifications to a previously cleared product, we may be required to cease marketing or recall the modified device until we obtain this clearance or approval. In addition, in these circumstances, we may be subject to significant regulatory fines or penalties for failure to submit the requisite PMA application(s). In addition, the FDA is currently evaluating the 510(k) process and may make substantial changes to industry requirements.

Class III devices include devices deemed by the FDA to pose the greatest risk such as life-supporting or life-sustaining devices, or implantable devices, in addition to those deemed not substantially equivalent following the 510(k) process. The safety and effectiveness of Class III devices cannot be reasonably assured solely by the General Controls and Special Controls described above. Therefore, these devices are subject to the PMA application process, which is generally more costly and time consuming than the 510(k) process.

In the event a device might be considered Class III due to lack of an equivalent predicate device, but which does not pose a significant risk to patients, it may be 'down-classified' to a relatively newer De Novo pathway for pre-market notification review and approval, which typically involves burdens and review cycle times between what are typical for 510(k) and PMA pathways. In addition to the above classifications and related FDA regulatory pathways in the United States, certain technologies that were previously considered medical devices have recently been reclassified and not considered a medical device, and thus not regulated by the FDA. On December 13, 2016 the 21st Century Cures Act ("Cures Act") was signed into law (Public Law 114-255, 130 STAT. 1033), and was designed to help accelerate medical product development and bring new innovations and advances to patients who need them faster and more efficiently. Section 3060 of the Cures Act was created as an amendment to section 520 of the Federal Food, Drug, and Cosmetic Act (FD&C Act), which addressed how medical devices are defined. This outlined software functions that would be exempt from FDA regulation, such as those used for administrative purposes, encouraging a healthy lifestyle, electronic health records, clinical laboratory test results and related information, and clinical decision tools.

In the United States, the NOCISCAN product suite is only partially regulated as a medical device by the FDA. The NOCICALC product is considered a Class I "exempt" medical device and is registered as such with the FDA under product Classification "Calculator/Data Processing Module, for Clinical Use," Product Code "JQP," Regulation Number 862.2100, and Registration Number 3015426626.

The process to determine whether a product can be considered a Class I "exempt" medical device consists of self-determining whether the product is adequately described by one of the existing categories classified by the FDA. In conjunction with our regulatory consultants, we determined that the product Classification "Calculator/Data Processing Module, for Clinical Use," adequately described our NOCICALC product.

In contrast, we believe the NOCIGRAM product is considered Clinical Decision Support software (CDS) under the 21st Century Cures Act and not a medical device. As such, we believe NOCIGRAM is not regulated by the FDA. Our conclusion that NOCISCAN would be considered Clinical Decision Support software ("CDS"), which under the 21st Century Cures Act' is not a device and therefore exempted from medical device regulation," is based upon the following analysis:

Under the Cures Act provision, a software product is not considered a device if it meets the following four elements:

- "[Not] intended to acquire, process, or analyze a medical image or a signal from an in vitro diagnostic device or a pattern or signal from a signal acquisition system;"
- "[I]ntended ... for the purpose of... displaying, analyzing, or printing medical information about a patient or other medical information (such as peer-reviewed clinical studies and clinical practice guidelines);"
- "[I]ntended ... for the purpose of... supporting or providing recommendations to a health care professional about prevention, diagnosis, or treatment of a disease or condition;" and
- "[I]ntended ... for the purpose of... enabling such health care professional to independently review the basis for such recommendations that such software presents so that it is not the intent that such health care professional rely primarily on any of such recommendations to make a clinical diagnosis or treatment decision regarding an individual patient."[4]

Since December 13, 2016, the FDA has issued draft guidance which provides further insight into the interpretation of the above four elements. The draft guidance, entitled "Clinical and Patient Decision Support Software" (Dec. 2017) ("Draft Guidance"), reviews section 520(o)(l)(E) of the FDC Act and provides additional clarity on each element.

With respect to the last element listed above, the Draft Guidance elaborates on what is meant by allowing health professionals to "independently" review the basis for recommendations such that the CDS software is not intended to be "primarily" relied upon in a diagnosis or treatment decision. To that end, according to the Draft Guidance, the user must be told: "(I) The purpose or intended use of the software function; (2) The intended user (e.g., ultrasound technicians, vascular surgeons); (3) The inputs used to generate the recommendation (e.g., patient age and gender); and (4) The rationale or support for the recommendation.

As described above, FDA will not regulate software that meets the four requirements in the Cures Act as a medical device. Although there are some ambiguities as to the meaning of the relevant statutory terms, we believe NOCIGRAM meets all four of these requirements.

First, the NOCIGRAM is not intended to acquire, process, or analyze a medical image or a signal from an in vitro diagnostic device or a pattern or signal from a signal acquisition system. Rather, it receives information from the NOCICALC, which separately performs such operations and produces a table of calculated disc chemistry ratio values for each disc examined. It is this table that the NOCIGRAM references in performing its analysis.

Second, NOCIGRAM is intended for the purpose of displaying, analyzing, or printing medical information about a patient or other medical information. The NOCISCORE Table and graphical plots provide medical information about the patient and analyze the data into classifications.

Third, NOCIGRAM is intended for the purpose of supporting or providing recommendations to a health care professional about prevention, diagnosis, or treatment of a disease or condition. The information generated by the product is intended to support recommendations on how to manage patients presenting with low back pain that may be discogenic in nature. It does this by providing additional disc chemistry-based information to be considered by the physician in combination with other available patient information.

The fourth element of the statute is also met by NOCIGRAM, although the requirements for this element are more involved than the other three elements. This element requires a means for the health care professional to independently review the basis for any recommendation to prevent primary reliance on the software. In its recent Draft Guidance, FDA provides four elements that can be used to determine whether the CDS software allows for independent review: whether it explains (1) the purpose or intended use; (2) the intended user; (3) the inputs used to generate the recommendation; and (4) the rationale for the recommendation.

The NOCIGRAM explains the purpose of the intended use. It instructs the user that it is intended to provide analyses of chemical ratio information obtained from the NOCICALC product, which was separately derived from data via an MRS device, for the purpose of supporting recommendations about diagnosing and/or treating patients with certain back conditions. This information is explained in the product labeling. The product labeling also explicitly states that the intended user is a professional medical healthcare provider trained and skilled in diagnosing and recommending treatment options for low back pain and related lumbar spine disorders. Thus, both the first and second elements set forth in the Draft Guidance are satisfied.

As to the third element, the inputs used to generate any calculations for the health care professional consist of the chemical ratio information obtained from the NOCICALC device, and also the adjustment and analysis factors (e.g. weighting and thresholding/ranges) for analyzing that disc chemistry data. The labeling for NOCIGRAM will describe the NOCICALC outputs as the source disc chemistry data, and will also reference the published clinical trial results (i.e. correlations to discogram results) and related adjustment and analysis factors. This satisfies the third element.

The fourth element requires that the health care professional is able to independently review the rationale for the CDS software recommendation. FDA's Draft Guidance indicates that the sources supporting a recommendation should, among other things, be publicly available. Tracking the statute, FDA suggests that clinical practice guidelines and published literature would fit this description. The Company intends to publish the various factors (i.e. weighting and thresholds) applied to adjusting and analyzing the various input chemical ratios, and the correlative analysis to the PD reference test (as well as certain related treatment outcomes), in medical literature in marketing NOCIGRAM. The user is informed of the medical literature in the instructions for use of NOCIGRAM.

Moreover, the physician-user will have three means to independently verify the results of the NOCIGRAM. First, the user can manually input the adjustment factors and thresholding of the ratios as custom inputs for the NOCICALC product to derive the same custom output results from NOCICALC as those results provided by NOCIGRAM. Second, the user can independently (apart from NOCICALC) perform these same factor-adjusted and threshold classifier calculations based on the values obtained from NOCICALC using the methods described in publicly available literature. Third, the user can further verify the NOCI+/- results of the NOCIGRAM, which are correlated to discogram as a reference test based on clinical trial data, by conducting a discogram on the same discs in the patient. This will either confirm or disprove the correlation of NOCI+/ - to discogram results in those particular discs in that specific patient. These three verification options sufficiently address the issue of a proprietary database or algorithm that is essentially a "black box" to users, creating primary reliance on the CDS software rather than aiding informed decision making.

However, although we believe the above analysis is reasonable, whenever a company self classifies, there is a risk that FDA could disagree with the classification. Accordingly, in that context, it is possible that FDA could potentially disagree that the NOCIGRAM falls under the CDS software exemption to the definition of a device and there can be no assurance that the FDA will agree with our conclusion and in the event the FDA does not agree, our business would be severely negatively impacted.

FDA clearance or approval, when granted, may entail limitations on the indicated uses for which a product may be marketed, and such product approvals, once granted, may be withdrawn if problems occur after initial marketing. Manufacturers of FDA-regulated products are subject to pervasive and continuing post-approval governmental regulation, including, but not limited to: (i) the registration and listing regulation, which requires manufacturers to register all manufacturing facilities and list all medical devices placed into commercial distribution, (ii) the QSR, which requires manufacturers, including third party manufacturers, to follow stringent design, validation, testing, production, control, supplier/contractor selection, complaint handling, documentation and other quality assurance procedures during the manufacturing process, (iii) labeling regulations and unique device identification requirements, (iv) advertising and promotion requirements, (v) restrictions on sale, distribution or use of a device, (vi) PMA annual reporting requirements, (vii) the FDA’s general

prohibition against promoting products for unapproved or "off-label" uses, (viii) the Medical Device Reporting (MDR) regulation, which requires that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to reoccur, (ix) medical device correction and removal reporting regulations, which require that manufacturers report to the FDA field corrections and product recalls or removals if undertaken to reduce a risk to health posed by the device or to remedy a violation of the FDCA that may present a risk to health; recall requirements, including a mandatory recall if there is a reasonable probability that the device would cause serious adverse health consequences or death; an order of repair, replacement or refund, (x) device tracking requirements, and (xi) post-approval study and post-market surveillance requirements. The FDA has also established a Unique Device Identification ("UDI") system that was phased in over a period of years. The UDI system requires manufacturers to mark certain medical devices distributed in the United States with unique device identifiers.

The FDA recently finalized its guidance for managing post-market cybersecurity for connected medical devices. This guidance places additional expectations on our technology to build in cybersecurity controls when we design and develop our devices to assure safe performance in the face of cyber threats. It is also incumbent on us to monitor third party software for new vulnerabilities and verify and validate any software updates or patches meant to address vulnerabilities.

Our facilities, records and manufacturing processes are subject to periodic unscheduled inspections by the FDA. Failure to comply with the applicable United States medical device regulatory requirements could result in, among other things, warning letters, untitled letters, fines, injunctions, consent decrees, civil penalties, unanticipated expenditures, repairs, replacements, refunds, recalls or seizures of products, operating restrictions, total or partial suspension of production, the FDA's refusal to issue certificates to foreign governments needed to export products for sale in other countries, the FDA's refusal to grant future premarket clearances or approvals, withdrawals or suspensions of current product clearances or approvals and criminal prosecution.

Coverage and Reimbursement.

Government and private sector initiatives to limit the growth of healthcare costs, including price regulation and competitive pricing, coverage and payment policies, comparative effectiveness therapies, technology assessments and managed care arrangements, are continuing in many countries where we do business, including the United States, Europe and Asia. As a result of these changes, the marketplace has placed increased emphasis on the delivery of more cost-effective medical therapies. In addition, because there is generally no separate reimbursement from third-party payers to our customers for many of our products, the additional costs associated with the use of our products can impact the profit margin of our customers. Accordingly, these various initiatives have created increased price sensitivity over healthcare products generally and may impact demand for our products and technologies.

Healthcare cost containment efforts have also prompted domestic hospitals and other customers of medical devices to consolidate into larger purchasing groups to enhance purchasing power, and this trend is expected to continue. The medical device industry has also experienced some consolidation, partly in order to offer a broader range of products to large purchasers. As a result, transactions with customers are larger, more complex and tend to involve more long-term contracts than in the past. These larger customers, due to their enhanced purchasing power, may attempt to increase the pressure on product pricing.

Significant healthcare reforms have had an impact on medical device manufacturer and hospital revenues. The Patient Protection and Affordable Care Act as amended by the Health Care and Education and Reconciliation Act of 2010, collectively referred to as the Affordable Care Act, is a sweeping measure designed to expand access to affordable health insurance, control healthcare spending and improve healthcare quality. Many states have also adopted or are considering changes in healthcare policies, in part due to state budgetary pressures. Ongoing uncertainty regarding implementation of certain aspects of the Affordable Care Act makes it difficult to predict the impact the Affordable Care Act or state law proposals may have on our business.

Other Healthcare Laws.

In addition to FDA restrictions on marketing and promotion of drugs and devices, other federal and state laws restrict our business practices. These laws include, without limitation, data privacy and security laws, anti-kickback and false claims laws, and transparency laws regarding payments or other items of value provided to healthcare providers.

As a participant in the healthcare industry, we are subject to extensive regulations protecting the privacy and security of patient health information that we receive, including the Health Insurance Portability and Accountability Act of 1996 (HIPAA), as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH), which was enacted as part of the American Recovery and Reinvestment Act of 2009. Among other things, these regulations impose extensive requirements for maintaining the privacy and security of individually identifiable health information, known as "protected health information." The HIPAA privacy regulations do not preempt state laws and regulations relating to personal information that may also apply to us. Our failure to comply with these regulations could expose us to civil and criminal sanctions.

The HIPAA provisions also created federal criminal statutes that prohibit among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payers, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. A person or entity does not need to have actual knowledge of the statutes or specific intent to violate them in order to have committed a violation. Also, many states have similar fraud and abuse statutes or regulations that may be broader in scope and may apply regardless of payer, in addition to items and services reimbursed under Medicaid and other state programs.

The federal Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, to induce or in return for the purchasing, leasing, ordering, or arranging for or recommending the purchase, lease or order of items or services for which payment may be made, in whole or in part, under Medicare, Medicaid or other federal healthcare programs. The term "remuneration" has been broadly interpreted to include anything of value. Although there are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, the exceptions and safe harbors are drawn narrowly. Further, a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act.

The federal False Claims Act prohibits, among other things, any person or entity from knowingly presenting, or causing to be presented, a false or fraudulent claim for payment or approval to the federal government, or knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government. A claim includes "any request or demand" for money or property presented to the U.S. Government. Medical device manufacturers have been held liable under these laws if they are deemed to cause the submission of false or fraudulent claims by, for example, providing customers with inaccurate billing or coding information.

These laws impact the kinds of financial arrangements we may have with potential users of our technology. They particularly impact how we structure our marketing, including discount practices, customer support, education and training programs, physician consulting, research grants and other service arrangements. If our operations are found to be in violation of any of the health regulatory laws described above or any other laws that apply to us, we may be subject to penalties, including potentially significant criminal and civil and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government healthcare programs, contractual damages, reputational harm, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

Additionally, there has been a trend towards increased federal and state regulation of payments and other transfers of value provided to healthcare professionals or entities. The federal Physician Payment Sunshine Act requires that certain device manufacturers track and report to the government information regarding payments and other transfers of value to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their family members. A manufacturer's failure to submit timely, accurately and completely the required information for all payments, transfers of value or ownership or investment interests may result in civil monetary penalties of up to an aggregate of $150,000 per year, and up to an aggregate of $1 million per year for "knowing failures." Certain states also mandate implementation of compliance programs, impose restrictions on device manufacturer marketing practices and/or require the tracking and reporting of gifts, compensation and other remuneration to healthcare professionals and entities.

We are subject to similar laws in foreign countries where we conduct business. For example, within the EU, the control of unlawful marketing activities is a matter of national law in each of the member states. The member states of the EU closely monitor perceived

unlawful marketing activity by companies. We could face civil, criminal, and administrative sanctions if any member state determines that we have breached our obligations under its national laws. Industry associations also closely monitor the activities of member companies. If these organizations or authorities name us as having breached our obligations under their regulations, rules or standards, our reputation would suffer and our business and financial condition could be adversely affected.

Other Foreign Healthcare Regulations

We are also subject to regulation in the foreign countries in which we manufacture and market our products. For example, the commercialization of certain products, including certain medical devices, in the EU is regulated under a system that presently requires all such products sold in the EU to bear the CE mark—an international symbol of adherence to quality assurance standards.

The International Medical Device Regulators Forum has implemented a global approach to auditing manufacturers of medical devices. This audit system, called the Medical Device Single Audit Program ("MDSAP"), provides for an annual audit of a medical device manufacturer by a certified body on behalf of various regulatory authorities. Current authorities participating in MDSAP include the Therapeutic Goods Administration of Australia, Brazil's Agencia Nacional de Vigilancia Sanitaria, Health Canada, Japan's Ministry of Health, Labour and Welfare, and the Japanese Pharmaceuticals and Medical Devices Agency and the FDA. It is expected that more regulatory authorities will participate in MDSAP in the future.

We, and other medical device manufacturers, are currently adjusting to major changes in the EU's decades-old regulatory framework which governs market access to the EU. The Medical Devices Regulation ("MDR") went into effect on May 26, 2021 and replaces the EU's prior Medical Device Directive (93/42/EEC).

Our NOCISCAN product suite is subject to these EU regulations, and is CE Marked via self-certification as a Class I medical device. However, this was secured prior to enactment of the MDR. Under the MDR, we expect to be considered a Class II medical device and subject to stricter requirements for pre-market review and certification for CE Marking by a Notified Body, including with respect to clinical data that must be submitted in support of our claimed indications and labeling. However, manufacturers of certain classes of currently approved medical devices will have a transition time to meet certain aspects of the new requirements under the MDR. A grace period until May 2024 is provided for Class I medical devices that were self-certified for CE Marking prior to the MDR conversion to become CE Mark certified as a Class II medical device by a Notified Body. We are still, however, required to continue monitoring and ensuring our on-going compliance with certain other provisions under the new MDR requirements with respect to post-market surveillance of our products, as of May 2021.

The MDR differs in several important ways from the EU's prior MDD directives for medical devices and active implantable medical devices. The most significant changes in the regulation include:

- The definition of medical devices covered under the MDR will be significantly expanded to include devices that may not have a medical intended purpose, such as colored contact lenses. Also included in the scope of the regulation are devices designed for the purpose of "prediction and prognosis" of a disease or other health condition;
- Device manufacturers will be required to identify at least one person within their organization who is ultimately responsible for all aspects of compliance with the requirements of the new MDR. The organization must document the specific qualifications of this individual relative to the required tasks;
- The MDR requires rigorous post-market oversight of medical devices;
- The MDR will allow the EU Commission or expert panels to publish "Common Specifications", such as requirements for technical documentation, risk management, or clinical evaluation, which devices shall be required to meet;
- Devices will be reclassified according to risk, contact, duration, and invasiveness;
- Systematic clinical evaluation will be required for Class IIa and Class IIb medical devices; and

- All currently approved devices must be recertified in accordance with the new MDR requirements.

Following Brexit, certain medical devices, including our products, are also required to meet the local regulatory requirements within the U.K., separate and apart from EU regulations that previously also covered commercial practices in the U.K. While our CE Mark still applies for the U.K., other U.K. requirements for regulatory monitoring and compliance must also be met. Our quality and regulatory compliance systems and practices are currently in the process of being updated for ensuring compliance with the applicable U.K. regulations.

General Data Protection Regulation

The implementation on May 25, 2018 of the General Data Protection Regulation ("GDPR"), a regulation in the EU on data protection and privacy for all individuals in the EU and the European Economic Area ("EEA"), applies to all enterprises, regardless of location, that are doing business in the EU or that collect and analyze data tied to EU and EEA residents. GDPR creates a range of new compliance obligations, including stringent technical and security controls surrounding the storage, use, and disclosure of personal information, and significantly increases financial penalties for noncompliance (including possible fines of up to 4% of global annual turnover for the preceding financial year or €20 million (whichever is higher) for the most serious infringements).

In July 2020, the European Commission invalidated the EU.-U.S. Privacy Shield framework, of which we were registrants. This has resulted in some uncertainty related to continuing obligations and future data transfer compliance obligations.

California Consumer Privacy Act

The California Consumer Privacy Act, "CCPA", became effective on January 1, 2020 along with a number of complex privacy regulations affecting the processing of personal information of California residents. If we fail to comply with the CCPA, we may be subject to significant financial penalties or adverse regulatory actions. In addition to the CCPA, the California legislature is exploring additional regulations to expand the scope and depth of the state's data protection controls.

Competition

In the diagnostic and connected care markets, competition is also based on a variety of factors including product performance, functionality, value and breadth of sales and service organization. We believe that currently, there is a scarcity of new diagnostic platforms on the market, or otherwise proposed and approaching the market, that are competitive with our products for our primary intended discogenic low back pain indication. Accordingly, our primary competition resides with the current diagnostic standards over which our products are intended to improve – in particular, X-ray, lumbar MRI, and provocation discography (PD). While we believe our products are positioned for synergistic use with lumbar MRI, and to enhance the diagnostic value of lumbar MR exams, the existing reliance on MRI as a standard of care for our indication, and other potential enhancements to those platforms and techniques, nonetheless also represent competition. To the extent these other platforms represent our primary competitors, they are mainly provided by large, well-capitalized companies with significant market share and resources. Our competitors have more established sales and marketing programs than we do and have greater name recognition. These competitors also have long operating histories and may have more established relationships with our potential customers. In addition to competing for market share, competitors may develop or acquire patents or other rights that may limit our ability to compete.

Competition could result in price reductions, reduced margins and loss of our potential market share. We believe that our NOCISCAN product suite is superior to currently known competition in this market as follows:

- We believe we are superior to standard lumbar MRI because:
    - Standard lumbar MRI only indicates structural defects, degeneration, and hydration, which have not been well correlated to identifying painful discs in DLBP patients, whereas our products have been highly correlated to pain as indicated by positive Provocation Discogram results in a clinical trial published in a major peer-reviewed spine journal;

- Standard lumbar MRI does not identify nor allow for measuring levels of acidic chemicals, such as lactic acid, that have been identified as a source of causing discs to become painful, and which we both identify and measure objectively and quantitatively; and
- Patient outcomes from surgeries following standard lumbar MRI diagnosis, but without the benefit of or following our diagnosis, have resulted in a much lower <60% success rate versus much higher >90% success rates shown for patient outcomes following surgeries that treat painful discs identified via our diagnostic products, as also demonstrated in the same published clinical trial referenced above.

- We believe we are superior to standard Provocation Discogram (PD) because:
  - PD is highly invasive, whereas our test is entirely non-invasive;
  - PD is painful by deliberate design, whereas our test is entirely pain-free;
  - PD has certain risks of harm, including certain reports of >1% risk of infection and increased risks of accelerating degeneration and/or herniation rates in discs after receiving needle injections form PD, whereas our test is non-significant risk and no more risky that standard lumbar MRI or other applications of MRS;

  - PD is subjective, based both on patient reporting of subjective pain and physician subjectivity in interpreting results, whereas our test is entirely objective; and
  - PD is often performed, for optimal reliability and accuracy, with a CT scan to evaluate the distribution of injected dye in and around the disc, which requires a second diagnostic imaging exam and additional related costs, and which also exposes the patient to radiation, whereas our test is only a single exam, is more cost effective, and is entirely radiation free.

Employees

As of January 1, 2023, we had 7 total employees, 2 of whom were engaged in full-time research and development activities, 1 engaged in strategy and business development, and 4 of whom were engaged in general administration. We believe that we maintain good relations with our employees.

Segment Information

We operate in a single operating segment and a single reporting segment. Operating segments are defined as components of an enterprise about which separate financial information is regularly evaluated by the chief operating decision maker function (which is fulfilled by our chief executive officer) in deciding how to allocate resources and in assessing performance. Our chief executive officer allocates resources and assesses performance based upon financial information at the level. Since we operate in one operating segment, all required financial segment information is presented in the financial statements.

Our corporate information

We were formed under the name Nocimed, LLC, a limited liability company in January 2008, under the laws of the State of Delaware. In February 2015, Nocimed, LLC was converted into Nocimed, Inc. a Delaware corporation. On December 3, 2021, we changed our name to Aclarion, Inc. Our principal executive offices are located at 8181 Arista Place, Suite 100, Broomfield, Colorado 80021. Our main telephone number is (833) 275-2266. Our internet website is www.aclarion.com. The information contained in or accessible from our website is not incorporated into this Annual Report, and you should not consider it part of this Annual Report. We have included our website address in this Annual Report solely as an inactive textual reference.

Implications of being an emerging growth company

We qualify as an "emerging growth company" as defined in the Jumpstart our Business Startups Act of 2012 (the "JOBS Act"). An emerging growth company may take advantage of specified reduced reporting and other burdens that are otherwise applicable generally to public companies. These provisions include:

- inclusion of only two years, as compared to three years, of audited financial statements in addition to any required unaudited interim financial statements with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure;

- an exemption from the auditor attestation requirement in the assessment of our internal control over financial reporting pursuant to the Sarbanes-Oxley Act of 2002 (the "Sarbanes-Oxley Act");

- an exemption from compliance with any new requirements adopted by the Public Company Accounting Oversight Board (the "PCAOB") requiring mandatory audit firm rotation;

- reduced disclosure about executive compensation arrangements; and

- an exemption from the requirement to seek non-binding advisory votes on executive compensation or golden parachute arrangements.

We may take advantage of these provisions until we are no longer an emerging growth company. We will remain an emerging growth company until the earliest of (1) the last day of the fiscal year (a) following the fifth anniversary of the completion of our IPO, (b) in which we have total annual gross revenue of at least $1.07 billion or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds $700 million as of the prior December 31st, and (2) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period.

We have taken advantage of the reduced reporting requirements in this Annual Report. Accordingly, the information contained herein may be different from the information you receive from other public companies that are not emerging growth companies.

The JOBS Act permits an emerging growth company such as us to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies until those standards would otherwise apply to private companies.

Available Information

Our internet address is www.aclarion.com. Our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to those reports can be found on our investor relations website, free of charge, as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. Information contained on our website is not incorporated by reference into this Form 10-K. The SEC maintains a public website, www.sec.gov, which includes information about and the filings of issuers that file electronically with the SEC.

Item 1A Risk Factors

Summary of Risk Factors

The following is a summary of the principal risks and uncertainties that could materially adversely affect our business, financial condition, or results of operations. You should read this summary together with the more detailed description of risk factors below under the heading "Risk Factors".

- We have a history of net losses, and we expect to continue to incur losses for the foreseeable future. If we do achieve profitability, we may not be able to sustain it;

- Our auditors have previously expressed substantial doubt about our ability to continue as a going concern, which may hinder our ability to obtain further financing;

- We believe our current cash resources will be sufficient to fund our current operating plans into April 2023. We have based these estimates, however, on assumptions that may prove to be wrong, and we could spend our available financial resources much faster than we currently expect and need to raise additional funds sooner than we anticipate. If we are unable to raise additional capital when needed or on acceptable terms, we would be forced to delay, reduce, or eliminate our technology development and commercialization efforts.

- We have identified a material weakness in our internal control over financial reporting. Failure to maintain effective internal controls could cause our investors to lose confidence in us and adversely affect the market price of our common stock. If our internal controls are not effective, we may not be able to accurately report our financial results or prevent fraud;

- The COVID-19 pandemic may have a material adverse effect on our business, financial condition and operating results, as well as on the operations and financial performance of our customers and suppliers. We are unable to predict the extent to which the pandemic and related restrictions will impact our business, operations, financial performance and the achievement of our strategic objectives;

- We currently rely on our technology for use in assisting doctors to diagnose chemically painful discs causing discogenic low back pain, as well for supporting other diagnoses, treatments, and research related to lumbar disc chemistry. If we are not successful in marketing and enhancing awareness of our technology, driving adoption across our current target population, increasing referrals, and expanding the population of eligible patients, our sales, business, financial condition and results of operations will be negatively affected;

- Currently, we can only market our product in the United States and certain countries observing CE mark regulations. Regulatory approvals that currently apply to our products include assessments where we determine the appropriate regulatory pathway for our products. Although we use regulatory consultants to assist in the self-registration processes and determinations, it is possible a regulator could disagree with our analysis. It is also possible that regulations relating to how we market our products may change. In addition, to maintain our ability to market our products under the approved regulations, we are required to adhere to multiple protocols in order to maintain regulatory approvals. The Company has failed to adequately follow protocols in the past and it is possible this may happen again in the future. If there is a change in our ability to market our products it may harm our sales, business, financial condition and results of operations;

- Our commercial success will depend on attaining significant market acceptance of our technology among patients, clinicians (primarily spine surgeons and pain management physicians) and imaging facilities, as well as increasing the number of patients who are prescribed for use of our diagnostic technology. If we are unable to successfully achieve substantial market acceptance and adoption of our technology, our sales, business, financial condition and results of operations would be harmed;

- Our commercial software products currently depend on compatible use with a limited number of MR scanners that are provided by one MR scanner vendor, SIEMENS, which limits our ability to address the total potential patient population that our products could otherwise address in commercial sales. There are risks related to the on-going compatibility, shortages, price fluctuations, and ability to grow the number of compatible MR scanner platforms that, if realized, could harm our sales, business, financial condition, and results of operations;

- If we are unable to obtain, maintain, protect, enforce and defend patent or other intellectual property protection for our technology, or if the scope of our patents and other intellectual property protections is not sufficiently broad, or as a result of our existing or any future out-licenses of our intellectual property, our competitors could develop and commercialize products similar to or competitive with our products and services, our ability to continue to commercialize our technology, or our other products and services, may be harmed.

- We may be unable to compete successfully with other available alternatives for diagnosing low back pain, including, in particular, identifying painful discs causing discogenic low back pain, which could harm our sales, business, financial condition and results of operations;

- If adequate reimbursement becomes unavailable for the procedures that use, or could use, our diagnostic technology, or becomes unavailable for providing other ongoing care for patients diagnosed with the assistance of our technology, it could diminish our sales, affect our ability to sell our technology profitably, or could otherwise harm our business, financial condition, and results of operations;

- Our collection, use, storage, disclosure, transfer and other processing of sensitive and personal information could give rise to significant costs, liabilities and other risks, including, as a result of investigations, inquiries, litigation, fines, legislative and regulatory action and negative press about our privacy and data protection practices, which may harm our business, financial conditions, results of operations;

- Our current product is supported by a single clinical study at a single clinical center involving one spine surgeon who has a financial interest in the Company. If we are unable to replicate the success of our initial clinical trial, the efficacy of our product may be in question and our sales, business, financial condition and results of operations will be harmed;

- To reach the full market potential of our product, we will need to leverage advanced machine learning and artificial intelligence technologies ("AI") to a larger degree than we do today. Introducing new technologies into our products require that we secure new regulatory approvals and demonstrate additional clinical success. If we are unable to secure regulatory approvals for our new products, or if they prove incapable of demonstrating clinical success, our market opportunity will be reduced and our sales, business, financial condition and results of operations may be harmed; and

- Our current product is dependent on certain processes that are not optimized to support the scaling of our technology. If we are not able to efficiently automate these processes, the Company will not be able to grow and our sales, business, financial condition and results of operations will be harmed.

Risk Factors.

This Annual Report on Form 10-K contains forward-looking information based on our current expectations. Because our business is subject to many risks and our actual results may differ materially from any forward-looking statements made by or on behalf of us, this section includes a discussion of important factors that could affect our business, operating results, financial condition and the trading price of our securities. This discussion should be read in conjunction with the other information in this Annual Report on Form 10-K, including our financial statements and the related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations. The occurrence of any of the events or developments described below could have a material adverse effect on our business, results of operations, financial condition, prospects and securities trading prices. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations.

Risks related to the Corona Virus and COVID-19 Pandemic

Our business is subject to risks arising from COVID-19 and other epidemic diseases.

The COVID-19 pandemic has presented substantial public health and economic challenges worldwide and is affecting our employees, patients, physicians and other healthcare providers, communities and business operations, as well as the U.S. and global economies and financial markets. A pandemic, including COVID-19, or other public health epidemic, poses the risk that we or our employees,

contractors, including our CROs, suppliers, collaborators and other partners may be prevented from conducting business activities for an indefinite period of time, including due to spread of the disease within these groups or due to shutdowns that may be requested or mandated by governmental authorities. International and U.S. governmental authorities in impacted regions are taking actions in an effort to slow the spread of COVID-19, including issuing varying forms of "stay-at-home" orders, and restricting business functions outside of one's home. To date we have not experienced material disruptions in our business operations. However, while it is not possible at this time to estimate the impact that COVID-19 could have on our business in the future, particularly as we advance our product development and marketing, the continued spread of COVID-19 and the measures taken by the governmental authorities, and any future epidemic disease outbreaks could: (i) disrupt our operations and the manufacture or shipment of MRIs and MRSs used with our products and in our research, preclinical studies and clinical trials (ii) delay, limit or prevent our employees and consultants from continuing research and development activities (iii) impede our clinical trial initiation and recruitment (iv) impede the ability of patients to continue in clinical trials, including the risk that participants enrolled in our clinical trials will contract COVID-19 or other epidemic disease while the clinical trials are ongoing, which could impact the results of clinical trials, and impede testing, monitoring, data collection and analysis and other related activities, any of which could delay our studies and clinical trials and increase our development costs, and have a material adverse effect on our business, financial condition and results of operations. The COVID-19 pandemic and any future epidemic disease could also potentially affect the business of the FDA or comparable foreign regulatory authorities, which could result in delays in meetings related to planned clinical trials. The COVID-19 pandemic and mitigation measures have had and may continue to have, and any future epidemic disease outbreak may have, an adverse impact on global economic conditions which could have an adverse effect on our business and financial condition, including impairing our ability to raise capital when needed. The extent to which the COVID-19 pandemic impacts our results will depend on future developments that are highly uncertain and cannot be predicted, including new information that may emerge concerning the severity of the virus and the actions to contain its impact.

Risks related to financial, operational, commercial and manufacturing matters

Our auditors have expressed substantial doubt about our ability to continue as a going concern, which may hinder our ability to obtain further financing.

Our past working capital deficiency, stockholders' deficit and recurring losses from operations raised substantial doubt about our ability to continue as a going concern. As a result, our independent registered public accounting firm included an explanatory paragraph in its report on our financial statements for the year ended December 31, 2022, with respect to this uncertainty. Our existing cash of approximately $1.5 million will only be sufficient to fund our current operating plans into the second quarter of 2023. If we are unable to raise capital when needed or on acceptable terms, we would be forced to delay, reduce, or eliminate our technology development and commercialization efforts.

We have incurred significant net losses since inception and anticipate that we will continue to incur net losses for the foreseeable future and may never achieve or maintain profitability.

Since our inception, we have incurred significant net losses. Our net losses were $7,605,542 and $4,950,290 for the years ended December 31, 2022, and 2021, respectively. As of December 31, 2022, we had an accumulated deficit of $39,907,101. To date, we have devoted our efforts toward securing financing, building and evolving our technology platform, and complying with regulatory requirements as well as initiating marketing efforts for our products. We expect to continue to incur significant expenses and operating losses for the foreseeable future. We anticipate that our expenses will increase substantially if, and as, we:

- hire and retain additional sales, accounting and finance, marketing and engineering personnel;
- build out our product pipeline;
- add operational, financial and management information systems and personnel; and
- maintain, expand, protect and enforce our intellectual property portfolio.

To become and remain profitable, we must enhance the marketing and commercial acceptance of our products. This will require us to be successful in a range of challenging activities, and our expenses will increase substantially as we bring these products to market.

We may never succeed in any or all of these activities and, even if we do, we may never generate revenue that is significant or large enough to achieve profitability. If we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would decrease the value of our company and could impair our ability to raise capital, develop new products, expand our business or continue our operations. A decline in the value of our company also could cause stockholders to lose all or part of their investment.

We have identified a material weakness in our internal control over financial reporting. Failure to maintain effective internal controls could cause our investors to lose confidence in us and adversely affect the market price of our common stock. If our internal controls are not effective, we may not be able to accurately report our financial results or prevent fraud.

Section 404 of the Sarbanes-Oxley Act of 2002, or Section 404, requires that we maintain internal control over financial reporting that meets applicable standards. We may err in the design or operation of our controls, and all internal control systems, no matter how well designed and operated, can provide only reasonable assurance that the objectives of the control system are met. Because there are inherent limitations in all control systems, there can be no assurance that all control issues have been or will be detected. If we are unable, or are perceived as unable, to produce reliable financial reports due to internal control deficiencies, investors could lose confidence in our reported financial information and operating results, which could result in a negative market reaction and a decrease in our stock price.

The Company will be required, pursuant to Section 404, to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting. Such report will not be required until our second annual report filed on Form 10-K. We will need to disclose any material weaknesses identified by our management in our internal control over financial reporting. As an "emerging growth company," we will avail ourselves of the exemption from the requirement that our independent registered public accounting firm attest to the effectiveness of our internal control over financial reporting under Section 404. However, we may no longer avail ourselves of this exemption when we cease to be an "emerging growth company." When our independent registered public accounting firm is required to undertake an assessment of our internal control over financial reporting, the cost of our compliance with Section 404 will correspondingly increase. Our compliance with applicable provisions of Section 404 will require that we incur substantial accounting expense and expend significant management time on compliance-related issues as we implement additional corporate governance practices and comply with reporting requirements. Moreover, if we are not able to comply with the requirements of Section 404 applicable to us in a timely manner, or if we or our independent registered public accounting firm identifies deficiencies in our internal control over financial reporting that are deemed to be material weaknesses, the market price of our stock could decline and we could be subject to sanctions or investigations by the U.S. Securities and Exchange Commission, or SEC, or other regulatory authorities, which would require additional financial and management resources.

If we continue to have material weaknesses in our internal control over financial reporting, if we are unable to comply with the requirements of Section 404 in a timely manner, if we are unable to assert that our internal control over financial reporting is effective, or if our independent registered public accounting firm is unable to express an opinion as to the effectiveness of our internal control over financial reporting, we may be late with the filing of our periodic reports, investors may lose confidence in the accuracy and completeness of our financial reports and the market price of our common stock could be negatively affected.

We will need additional funding, which may not be available on acceptable terms, or at all. Failure to obtain this capital when needed may force us to delay, limit or terminate our product development efforts or other operations.

We believe our current cash resources, approximately $1.5 million as of December 31, 2022, will be sufficient to fund our current operating plans into the second quarter of 2023. We expect our expenses to increase in connection with our ongoing activities, particularly as we continue to invest in sales, marketing and engineering resources and bring our products to market. Furthermore, since the closing of our IPO, we have incurred additional costs associated with operating as a public company. We will need additional funding to complete the development of our full product line and scale products with a demonstrated market fit.

Building and scaling technology products is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary user experience required to obtain market acceptance and achieve meaningful product sales. In addition, our product candidates, once developed, may not achieve commercial success. The majority of revenue will be derived from or based on

sales of software products that may not be commercially available for many years, if at all. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all.

Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our technologies and product candidates.

We may seek additional capital through a combination of public and private equity offerings, debt financings, strategic partnerships and alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a stockholder. The incurrence of indebtedness would result in increased fixed payment obligations and could involve restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. If we raise additional funds through strategic partnerships and alliances and licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, or our other product candidates, or grant licenses on terms unfavorable to us.

We are highly dependent on our senior management team and key personnel, and our business could be harmed if we are unable to attract and retain personnel necessary for our success.

We are highly dependent on our senior management and key personnel. Our success will depend on our ability to retain senior management and to attract and retain qualified personnel in the future, including sales and marketing professionals, engineers, scientists, clinical trial specialists and other highly skilled personnel and to integrate current and additional personnel in all departments. The loss of members of our senior management, marketing professionals, engineers, scientists and clinical trial specialists could result in delays in product development and harm our business.

Competition for skilled personnel in our market is intense and may limit our ability to hire and retain highly qualified personnel on acceptable terms, or at all. To induce valuable employees to remain at our company, in addition to salary and cash incentives, we have issued stock options that vest over time. The value to employees of stock options that vest over time may be significantly affected by fluctuations in our stock price that are beyond our control, and may at any time be insufficient to counteract more lucrative offers from other companies. Despite our efforts to retain valuable employees, members of our management and other key personnel may terminate their employment with us on short notice. Our employment arrangements with our employees provide for at-will employment, which means that any of our employees could leave our employment at any time, with or without notice. We also do not maintain “key man” insurance policies on the lives of these individuals or the lives of any of our other employees.

Our MR data post-processing products currently depend on compatible use with only a limited number of MR scanners that are provided only by one manufacturer of MR devices.

Our MR data post-processing software products are only compatible for post-processing disc MRS data acquired via certain scanner models and operating configurations provided only by one, third-party scanner vendor - SIEMENS. There are risks associated with our reliance on SIEMENS, and/or the MR service providers who own and operate the SIEMENS scanners, to maintain those scanners and their operating configurations in a manner that continues to support compatibility with our products. There are also risks that current compatible scanner platforms may become incompatible as a result of changes made to those scanners by SIEMENS, or by the scanner owner or related service provider, which would frustrate our ability to continue supporting that MR provider customer with our products. There are also risks that these SIEMENS scanners do not perform reliably as intended or expected in performing data acquisition exams as required by our post-processing products, which would also frustrate the ability for our products to perform as intended. There is also a risk that SIEMENS loses its install base of compatible MR Scanners due to cannibalization by other non-compatible replacement scanner sales or fails to grow its install base of those compatible scanners, which could adversely affect the number and locations of compatible scanners for our own market share and penetration. Manifestations of these risks becoming actually realized in the marketplace could harm our business, financial condition, and results of operations. We are not subject to any exclusivity agreement or obligations with SIEMENS, nor do we have any fee sharing, royalty, or other exchange of moneys or payments between us and Siemens. The nexus for our focused relationship with Siemens resulted from our determination that SIEMENS scanner models were optimally positioned to support our product. We have had a collaborative relationship with Siemens since 2011 and have been party to a Collaborative Agreement with

Siemens since October of 2017, The Collaborative Agreement is terminable.at any time by either party if such party is of the opinion that the goals of the Collaborative Agreement cannot be achieved for technical, economic and/or clinical reasons. If Siemens were to terminate its relationship with the Company, it would have a material adverse effect on our business.

If we are not successful in enhancing awareness of our technology, driving adoption across our current target population, increasing referrals from surgeons and clinicians, and expanding the population of eligible patients, our sales, business, financial condition and results of operations will be negatively affected.

Our business depends on our ability to successfully market our technology, which includes increasing the number of patients scanned with our technology, increasing adoption of our technology and driving utilization of our technology by surgeons and clinicians. Additionally, our technology is primarily recommended and implemented to provide advanced diagnosis and management of spine and back pain, in particular, for diagnosing painful discs causing discogenic low back pain. Therefore, we are dependent on widespread market adoption of our technology. While we intend to expand the population of patients we can provide with our diagnostic technology as well as increase the number of physicians, surgeons and clinicians that can prescribe technology, there can be no assurance that we will succeed.

The commercial success of our technology will continue to depend on a number of factors, including the following:

- the actual and perceived effectiveness, safety and reliability, and clinical benefit, of our technology, especially relative to alternative diagnostic systems and devices;
- the prevalence and severity of any adverse patient events involving the use of our technology;
- the degree to which physicians, surgeons and clinicians, patients and imaging centers adopt our technology;
- the continued effects of the COVID-19 pandemic;
- the availability, relative cost and perceived advantages and disadvantages of alternative technologies, or other diagnostic or treatment methods, for spine and back pain;
- the results of additional clinical and other studies relating to the health, safety, economic or other benefits of our technology;
- whether key thought leaders in the medical community accept that our clinical efficacy and safety results are sufficiently meaningful to influence their decision to adopt our technology over other spine and back pain diagnostics;
- the extent to which we are successful in educating physicians, surgeons, clinicians, patients, and imaging facilities about the appropriate (and inappropriate) uses and benefits of our technology;
- the strength of our marketing and distribution infrastructure, including our ability to drive adoption and utilization of our technology, as well as our ability to develop and maintain relationships with MRI manufacturers and imaging centers;
- our ability to obtain, maintain, protect, enforce and defend our intellectual property rights, in and to our technology;
- our ability to maintain compliance with all legal and regulatory requirements, including those applicable to our technology;
- our ability to maintain our contractual relationships with our vendors and component suppliers, including single-source vendors and suppliers through which we obtain critical components for (or compatible use with) our technology;
- the establishment and continued reimbursement coverage of and adequate payment for the use of our technology and
- our ability to continue to attract and retain key personnel.

If we fail to successfully market and sell our technology cost-effectively and maintain and expand our market share, our sales, business, financial condition and results of operations will be negatively affected.

Our commercial success will continue to depend on attaining significant market acceptance of our technology among physicians, surgeons, patients, clinicians and imaging facilities, and increasing the number of patients diagnosed by our technology.

Our commercial success will depend, in large part, on the further acceptance by surgeons, physicians, clinicians, patients and imaging facilities of our technology as safe, useful, cost-effective, and that it can increase the number of patients that are diagnosed. We cannot predict how quickly, or if at all, additional surgeons, physicians, clinicians, patients and imaging facilities will adopt our technology over competing diagnostic platforms for support in on-going care and treatment options that are expected to be supported by the intended diagnostic uses of our technology. For example, surgeons, other physicians, clinicians, patients, and imaging facilities may be reluctant

to use our technology due to familiarity with pre-existing diagnostic systems that are more established or an otherwise resistance to adopt new technologies or change current practices. Our ability to grow sales of our technology and drive market acceptance will depend on successfully educating surgeons, physicians, clinicians, patients and MR imaging facilities on the relative benefits of our Technology.

We may be unable to compete successfully with other diagnostic options for low back pain, or may be unable to continue providing value for supporting new treatments that may not need the diagnostic information our products provide.

The medical device industry is intensely competitive, subject to rapid change and significantly affected by new product introductions and other market activities of industry participants. Our current competition primarily resides with the diagnostic standards over which our products are intended to improve – in particular, X-ray, lumbar MRI, and PD. Our products are positioned for synergistic use with lumbar MRI, and to enhance the diagnostic value of lumbar MR exams. However, the existing reliance on lumbar MRI as a standard of care for our DLBP indication, and on PD in some medical practices, and the potential for other enhancements to those platforms and techniques, nonetheless also represents a competitive threat. To the extent that these other platforms represent our primary competitors, they are mainly provided by large, well-capitalized companies with significant market share and resources. Most of our competitors have more established sales and marketing programs than us and have greater name recognition. These competitors also have long operating histories and may have more established relationships with potential customers. Also, there can be no assurance that other companies or institutions will not succeed in developing or marketing devices and products that are more accurate, useful, effective or safer than our technology or that would render our technology obsolete or noncompetitive.

Adoption of our technology depends on positive clinical data as well as clinician acceptance of the data and our products, and negative clinical data or perceptions among these clinicians would harm our sales, business, financial condition, and results of operations.

The rate of adoption and sales of our products are heavily influenced by clinical data. We have published positive clinical data from an Institutional Review Board ("IRB"), approved more than 100 patient single center trial in a major peer-reviewed spine journal which showed both: (a) high diagnostic accuracy against provocation discography controls, and (b) much higher patient success outcomes for surgeries that treated discs identified as painful using our products, versus much lower success rates when discs diagnosed as painful with our products were left untreated. However, there can be no assurance that our clinical data will continue to be positive for our ongoing or future clinical studies. Additionally, there can be no assurance that future clinical studies, including those to continue demonstrating the diagnostic accuracy and value of our products in currently approved patient populations and those to support label retention and expansion for our products, will demonstrate diagnostic acuity or value. Unfavorable or inconsistent clinical data from ongoing or future clinical studies conducted by us, our competitors, or third parties, or the potential for negative interpretation of our clinical data by customers, competitors, patients, and regulators, or the potential for finding new or more frequent adverse events related to the use of our products could harm our sales, business, financial condition, and results of operations.

If adequate reimbursement is not available for the procedures implementing our technology, or for clinicians to provide ongoing care for patients diagnosed with our technology, it could diminish our sales or affect our ability to sell our technology.

Our ability to increase sales of our technology depends, in significant part, on the availability of adequate financial coverage and reimbursement from third-party payors, which include: (i) governmental payors such as the Medicare and Medicaid programs in the United States; (ii) private managed care organizations; and (iii) private health insurers. Third-party payers determine which services and treatments they will cover and establish reimbursement rates for those treatments. While we have secured certain reimbursement codes against which the use of our products can potentially be billed, we do not yet currently bill any third-party payers directly for our technology. The cost of our customers using our technology is currently being paid for by either: (i) billing patients to pay directly (ii) allocation at least in part against payments received by healthcare providers for other procedures conducted in association with the use of our technology, or (c) third-party payer reimbursement payments to a several of our customers for less than 10 patients through the date of this prospectus. A failure to obtain wide coverage and adequate reimbursement for using our technology in conducting our new diagnostic procedures, or for clinicians providing ongoing patient care based on or related to our diagnostic results could diminish our sales and affect our ability to sell our technology.

If adequate reimbursement for our temporary Category III CMS Code designation for our products cannot be obtained or we are not successful in obtaining conversion to permanent Category I codes at an adequate reimbursement level, it would diminish our sales and would affect our ability to market our technology.

On January 1, 2021, our Category III CPT Codes became effective (see "Business", "Reimbursement" above). Category III codes represent the first step in the reimbursement process (See "Business" "Reimbursement" above). The effectiveness of our Category III codes commenced a five-year period in which, in order to maintain our Category III status, we are required to demonstrate that the medical community needs ("Clinical Needs") the NOCISCAN product. Clinical Needs would be demonstrated to the CPT Committee based on the volume at which our Category III codes are billed by imaging centers and physicians. In addition to demonstrating that there is Clinical Needs, we also are required to show that NOCISCAN is clinically effective as indicated by patients having better outcomes when NOCISCAN reports are used to help guide surgical treatments. We expect to show clinical effectiveness through a combination of clinical registries and clinical studies that build upon our published clinical study the CPT committee used to create our Category III CPT codes. However, if we are not able to demonstrate Clinical Needs, nor that NOCISCAN is clinically effective, our revenue would be limited to a direct patient payment model, which will severely limit our ability to market our products and generate sufficient revenue to continue market our technology.

Further, for us to obtain a conversion from of our CPT codes from Category III to Category I, we will need to attract a significant larger number of surgeons and imaging centers to adopt our technology and thereby increase the volume of reimbursement claims data needed for the CPT committee to determine that our product is needed in the healthcare marketplace. In addition to generating clinical use volume, we will also need to demonstrate the ongoing clinical efficacy of our products to secure adequate reimbursement from payers. A failure to convert Category III codes to Category I codes will ultimately make us more dependent on a patient pay model which will significantly diminish our sales and affect our ability to market our technology.

Use of our technology requires appropriate training for proper use of our products, and inadequate training may lead to negative patient outcomes, which could harm our business, financial condition, and results of operations.

The successful use of our technology depends, in part, on the training and skill of referring doctors and other healthcare providers for appropriately prescribing our diagnostic exam for the correctly indicated patients and anatomy, and properly interpreting the results from using our product as indicated under our related IFUs. It also depends upon MR technicians and operators appropriately implementing and using our technology as indicated under our related IFUs. MR technicians and operators could also experience difficulty with the steps and techniques necessary to successfully implement and use our technology protocols. We cannot guarantee that all medical and MR technician professionals will have the necessary skills and training, according to our instructions for use, or will sufficiently comply with that training and instructions for use in order to properly prescribe and interpret the results of our diagnostic imaging platform. We cannot be certain that surgeons, other physicians, MRI technicians or operators, or other healthcare providers that use our technology will have received sufficient training or will continue to comply with that training in their on-going practice in using our technology. If physicians and surgeons utilize our technology incorrectly or, without adhering to or completing all relevant training according to our instructions, the utility and value of our diagnostic products and their related patient outcomes from on-going care following that diagnostic work-up may not be consistent with the outcomes achieved in our clinical studies or otherwise expected or desired by such care providers or the patients themselves. Adverse treatment outcomes that could potentially arise from improper or incorrect use of our technology may negatively impact the perception of patient benefit and safety of our technology, notwithstanding results from our clinical studies. These results could limit adoption of our technology, which would harm our sales, business, financial condition, and results of operations.

We expect to increase the size of our organization in the future, and we may experience difficulties in managing this growth. If we are unable to manage the anticipated growth of our business, our future revenue and operating results may be harmed.

As of February 1, 2023, we had 7 full-time employees, 1 full-time consultant, and 6 part-time consultants. As our sales and marketing strategies develop, and as we transition into operating as a public company, we expect to need additional managerial, operational, sales,

marketing, financial and other personnel. Future growth would impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, maintaining and motivating additional employees;
- managing our internal development efforts effectively, while complying with our contractual obligations to contractors and other third parties; and
- improving our operational, financial and management controls, reporting systems and procedures.

Our future financial performance and our ability to successfully market and sell our technology will depend, in part, on our ability to effectively manage any future growth, and our management may also have to divert a disproportionate amount of attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities.

We may not be able to achieve or maintain satisfactory pricing and margins for our NOCISCAN disc MRS diagnostic software products and related services, which could harm our business and results of operations.

Software products classified as medical devices have a history of price competition and we can give no assurance that we will be able to maintain satisfactory prices for our technology. The pricing of our technology could be impacted by several factors, including pressure to reduce prices by our customers due to a decline in the amount that third-party payers reimburse for diagnostic procedures using our technology or for clinicians providing ongoing patient care related to the diagnostic information we provide. A decline in the amount that third-party payers reimburse our customers for ongoing patient care could also make it difficult for us to maintain procedural volume without a corresponding reduction in prices for our products. If we are forced to lower the price we charge for our technology, our gross margins will decrease, which, will harm our ability to invest in and grow our business. If we are unable to maintain our prices or if our costs increase and we are unable to offset such increase with an increase in our prices, our margins would erode and could harm our business, financial condition, and results of operations.

Our results of operations may be harmed if we are unable to accurately forecast customer demand for our technology

Our ability to accurately forecast demand for our products could be negatively affected by many factors, including (i) our potential failure to accurately manage or execute our expansion strategy, (ii) new product introductions by competitors, (iii) an increase or decrease in customer demand for our products or for other competing products, (iv) our failure to accurately forecast customer adoption of new products, (v) unanticipated changes in general market conditions or regulatory matters, (vi) weakening of economic conditions or consumer confidence in future economic conditions, and (vii) the ongoing COVID-19 pandemic. Software processing capacity, data storage, and related computer hosting resources in excess of customer demand may result in financial write-downs or write-offs, which would cause our gross margin to be adversely affected and could impair the strength of our brand. Conversely, if we underestimate customer demand for our products, our technical and IT resource support team, software processing and storage resources, and computing architectures may not be able to support sufficient processing requirements to meet the demand for our products; and, this could result in lost sales and damage to our reputation and customer relationships. In addition, if we experience a significant increase in demand, additional computing and storage capacity and resources, and additional technical support personnel required to support the increased demand may not be available when required or on terms that are acceptable to us, or at all, which may negatively affect our sales, business, financial condition, and results of operations.

Risks related to government regulation and our industry

Our operations and technology are subject to pervasive and continuing FDA regulatory requirements, and failure to comply with these requirements could harm our business, financial condition and results of operations.

Before a regulated new medical device or service, or a new intended use for an existing device or service, can be marketed in the United States, a company must first receive either 510(k) clearance, or a PMA from the FDA, unless an exemption applies. In the 510(k) clearance process, before a device may be marketed, the FDA must determine that: (i) a proposed device is substantially equivalent to a legally-marketed predicate device, which includes a legal marketed device that has been previously cleared through the 510(k) process, (ii) was legally marketed prior to May 28, 1976 (pre-amendments device), (iii) was legally marketed pursuant to an approved PMA and later down-classified, or (iv) is covered by a classification regulation created through the de novo review process.

In the process of obtaining PMA approval, which the FDA could potentially require in the future for our products, the FDA must determine that a proposed device is safe and effective for its intended use based, in part, on extensive data, including, but not limited to, technical, preclinical, clinical study, manufacturing and labeling data. The PMA process is typically required for devices that are deemed to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices.

We believe that one of our products under the NOCISCAN Suite, NOCICALC, is a Class I 510(k)-exempt medical device, which only requires registration and no pre-market review with the FDA, and which we registered as such with the FDA. We also believe the other of our products in the suite, NOCIGRAM, is "Clinical Decision Support Software" under the 21st Century Cures Act and as such, is not considered a medical device, and thus is not regulated by the FDA. Accordingly, we believe that our current products do not require FDA clearance or approval under either 510(k) or PMA approval pathways. However, there can be no assurance that in the future, the FDA will not determine that PMA approval, de novo classification, or 510(k) clearance is required for our products. If the FDA were to make such a determination, we would not be able to sell or market our products without or until securing such approval or clearance and may be subject to potential fines and other penalties or remedial actions for illegally marketing or selling an unapproved medical device, which would affect our sales, business, financial condition, and results of operation.

If we are unable to expand the labeling claims for using our technology to include additional indications, our growth potential could be harmed.

We intend to seek expanded labeling claims for our technology in the future, including for example: (i) extending the intended indications for use to include disc MRS along the thoracic or cervical spine, (ii) incorporating certain MRI image post-processing along with MRS data post-processing, and (iii) real-time post-processing of MRS exam data during the exam itself via our software installed and operated within the MR scanner software environment (vs. our current products which are for cloud-hosted post-processing of MRS data that is transferred to us, following the MRS exams, via our own remote computing resources). If regulatory clearance or approval is required to expand the use of our technology, and which clearance and approval may require clinical trial results, we could incur substantial costs and the attention of management could be diverted throughout this process. However, there can be no assurance we will be able to obtain and maintain necessary clearance or approvals for additional uses of our technology, or even if obtained, that the broadened use of our technology would be accepted or adopted by intended users, thus limiting the growth potential of our business.

Our medical device products may be subject to recalls, which could divert managerial and financial resources, harm our reputation and our business.

The FDA has the authority to require the recall of medical device products in certain circumstances. A government mandated or voluntary product recall by us could occur because of device malfunctions or other adverse events, such as quality-related issues resulting from product operating malfunctions or defects. Any future recalls of our products could divert managerial and financial resources, harm our reputation and negatively impact our business.

If we initiate a correction or removal of certain of our products from the market to reduce a risk to health posed by the device, we would be required to submit a Correction and Removal report to the FDA and, in many cases, similar reports to other regulatory agencies. This report could be classified by the FDA as a device recall which could lead to increased scrutiny by the FDA and our customers regarding the quality and safety of our products. Furthermore, the submission of these reports could be used by competitors against us and could harm our reputation, which could cause customers to delay purchase decisions, cancel orders or decide not to purchase our products and could cause patients to lose trust in our technology.

We may experience difficulties outside the US in obtaining or maintaining regulatory clearance or approval, or exemptions therefrom, or in successfully gaining third-party reimbursement or marketing our technology, even if approved or otherwise legally marketed.

Our NOCISCAN product suite was initially commercialized as a Class I medical device under European Commission regulations. The process did not require pre-market submission, review, or certification by a Notified Body in order to be CE marked. A "Notified Body" is an organization designated by an EU country to assess the conformity of certain products before being placed on the market.

For commercialization outside the United States, in particular the European Union ("EU") and United Kingdom ("UK"), the Company, in conjunction with our regulatory consultants, determined NOCISCAN to be a Class I medical device, for which we secured a CE mark via self-certification. As such, we self-certified our product for the CE mark under a Declaration of Conformity ("DOC") filed by us as part of a dossier with a qualified EU Representative. Since self-certification was completed by the Company, the EU adopted Medical Device Regulation (EU) 2019/1020, known as MDR, that went into effect on July 16, 2021. Under these new regulations, we believe NOCISCAN to be considered a Class II(a) device that requires re-certification for CE mark by a Notified Body prior to May 2024. Notified Bodies carry out tasks related to conformity assessment procedures set out in the applicable legislation, when a third party is required. Class II(a) device certification is subject to additional requirements for approval beyond our existing submissions, including requiring pre-market review and CE mark approval by a Notified Body, and which may require submission and approval of supportive clinical data. We are currently seeking to identify, but have not yet engaged, a Notified Body for this purpose. The available number of Notified Bodies, and those engaging new company applicants, has been significantly reduced in recent years and the ability for conducting a Notified Body review and CE mark approval can typically take more than a year. Certain aspects of the new MDR also place new requirements on Class I medical devices that are not subject to the extended 2024 grace period and became effective as of May 2021. This applies to new required policies and practices for post-market surveillance of our products. While we are not currently compliant with these new requirements, we are in the process of updating our policies and practices and taking the corrective actions to achieve and maintain ongoing compliance. We believe the actions we are taking are sufficient to support the continuance of our commercial activities in the EU under our CE mark without adverse penalties or other consequences. However, there is a risk that one or more regulatory body or agency in the EU may determine otherwise, either with respect to our prior non-compliance that has since been corrected or with respect to the sufficiency of our corrective actions, and which could result in us incurring certain penalties or other consequences.

If we are unable to engage or receive CE mark approval from a Notified Body under the MDR by the May 2024 grace period deadline, or are determined to be non-compliant with MDR regulations not subject to the grace period and therefore applicable to us as of May 2021, we could lose our CE mark, and may become unable to continue promoting or selling our products for commercial use in the EU, UK, or other countries that relate their medical device regulations to a CE mark.

In conjunction with Brexit, medical devices in the UK are no longer governed by CE regulations. As such, the UK has introduced the UKCA marking system which largely follows the CE marking regulations to include permitting use of the same submissions for approval. The major difference post-Brexit is that CE marking is regulated by the EU and UKCA marking is regulated by the UK. The only practical implication to the Company is the requirement of a Notifying Body within both the EU and the UK. If the Company is successful in meeting all requirements of the CE mark under MDR set forth above, the company believes it will meet all requirements for UKCA marking. While we are not currently compliant with new requirements in the UK, we are in the process of updating our policies and practices and taking what we believe are corrective actions to achieve and maintain ongoing compliance in the UK. We believe our activities are sufficient to support the continuance of our commercial activities in the UK under our CE mark without adverse penalties or other consequences. However, there is a risk that one or more regulatory body or agency in the UK may determine otherwise, either with respect to our prior non-compliance that we believe has been corrected or with respect to the sufficiency of those corrective actions and which could result in us incurring certain penalties or other adverse consequences to our business. There can be no assurance that we can obtain a UKCA mark and if we are not able to secure a UKCA mark, we will lose our ability to conduct business in the UK.

Sales of our technology outside of the United States will be subject to foreign regulatory requirements governing clinical studies and marketing approval, as well as additional post-market requirements. We would incur substantial expenses in connection with any international expansion. Additional risks related to operating in foreign countries include:

- differing, and potential changes in, regulatory requirements in foreign countries, including with respect to data privacy and security;
- differing, and potential changes in, reimbursement regimes in foreign countries, including price controls;
- unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses or reduced revenue;
- difficulties staffing and managing foreign operations;
- workforce uncertainty in countries where labor unrest is more common than in the United States;

- potential liability under the U.S. Foreign Corrupt Practices Act of 1977, as amended, or the FCPA, or comparable foreign regulations;
- challenges enforcing our contractual and intellectual property rights as well as intellectual property theft or compulsory licensing, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States; and
- business interruptions resulting from geopolitical actions, including war and terrorism.

These and other risks associated with international operations that may harm our ability to attain or maintain profitable operations internationally, which would harm our growth potential.

Furthermore, there are foreign privacy laws and regulations that impose restrictions on the collection, use, storage, disclosure, transfer and other processing of personal data, including health information. For example, the European Union General Data Protection Regulation ("GDPR"), imposes stringent data protection requirements, including, for example, more robust disclosures to individuals, a strengthened individual data rights regime, shortened timelines for data breach notifications, limitations on retention of information, increased requirements pertaining to special categories of data, such as health data, and additional obligations regarding third-party processors in connection with the processing of the personal data. Our failure to comply with the GDPR or other applicable foreign privacy laws or regulations or significant changes in the laws and regulations restricting our ability to obtain or use required patient information could significantly impact our business and our future business plans.

If we fail to comply with fraud and abuse and other healthcare laws and regulations in the U.S. and internationally including those relating to kickbacks and false claims for reimbursement, we could face substantial penalties and our business, financial condition and results of operations could be harmed.

Healthcare providers play a primary role in the distribution, recommendation, ordering and purchasing of any of our products. Through our arrangements with healthcare professionals and hospital facilities, we are exposed to broadly applicable anti-fraud and abuse, anti-kickback, false claims and other healthcare laws and regulations that may constrain our business, our arrangements and relationships with customers, and how we market, sell and distribute our marketed medical devices. We have a compliance program, code of conduct and associated policies and procedures, but it is not always possible to identify and deter misconduct by our employees, contractors, and other third parties, including our customers, and the precautions we take to detect and prevent noncompliance may not be effective in protecting us from governmental investigations for failure to comply with applicable fraud and abuse or other healthcare laws and regulations.

In the United States, we are subject to various state and federal anti-fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute and federal civil False Claims Act, or the FCA. Our relationships with physicians, other health care professionals and hospitals are subject to scrutiny under these laws. There are also similar laws in other countries that we may become subject to if we expand internationally.

The laws that may affect our ability to operate include, among others:

- The Anti-Kickback Statute, which prohibits, among other things, knowingly and willingly soliciting, offering, receiving or paying remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward either the referral of an individual, or the purchase, order or recommendation of, items or services for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs;

- The federal civil and criminal false claims laws, including the FCA, and civil monetary penalties laws, which prohibits, among other things, persons or entities from knowingly presenting, or causing to be presented, a false or fraudulent claim for payment of government funds and knowingly making, using or causing to be made or used, a false record or statement to get a false claim paid or to avoid, decrease or conceal an obligation to pay money to the federal government;

- The Health Insurance Portability and Accountability Act of 1996, or HIPAA, which applies to our customers and some of their downstream vendors and contractors, imposes criminal and civil liability for, among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including

private third-party payers, or knowingly and willfully falsifying, concealing or covering up a material fact or making a materially false, fictitious or fraudulent statement or representation, or making or using any false writing or document knowing the same to contain any materially false, fictitious or fraudulent statement or entry in connection with the delivery of or payment for healthcare benefits, items or services;

- Various state laws governing the privacy and security of personal information, including the California Consumer Privacy Act ("CCPA"), which became effective on January 1, 2020, which regulates the processing of personal information of California residents and increases the privacy and security obligations of covered companies handling such personal information. The CCPA requires covered companies to, amongst other things, provide new and additional disclosures to California residents, and affords such residents new abilities to access their personal information and opt out of certain sales of personal information; and

- The federal Physician Payments Sunshine Act, also known as Open Payments, requires manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program to report annually, with certain exceptions to the Centers for Medicare and Medicaid Services, or CMS, information related to payments or other "transfers of value" made to certain physicians or other healthcare providers, as defined by such law, and teaching hospitals, and requires applicable manufacturers and group purchasing organizations to report annually to CMS ownership and investment interests held by physicians and their immediate family members.

State and federal regulatory and enforcement agencies continue to actively investigate violations of healthcare laws and regulations, and the U.S. Congress continues to strengthen the arsenal of enforcement tools. Enforcement agencies also continue to pursue novel theories of liability under these laws. In particular, government agencies have increased regulatory scrutiny and enforcement activity with respect to manufacturer reimbursement support activities and patient care programs, including bringing criminal charges or civil enforcement actions under the Anti-Kickback Statute, the FCA and HIPAA's healthcare fraud and privacy provisions.

Achieving and sustaining compliance with applicable federal and state anti-fraud and abuse laws may prove costly. If we, or our employees, are found to have violated any of the above laws we may be subjected to substantial criminal, civil and administrative penalties, including imprisonment, exclusion from participation in federal healthcare programs, such as Medicare and Medicaid, and significant fines, monetary penalties, forfeiture, disgorgement and damages, contractual damages, reputational harm, administrative burdens, diminished profits and future earnings and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our financial results. Any action or investigation against us for the violation of these healthcare fraud and abuse laws, even if successfully defended, could result in significant legal expenses and could divert our management's attention from the operation of our business. Companies settling FCA, Anti-Kickback Statute or civil monetary penalties law cases also may be required to enter into a Corporate Integrity Agreement with the OIG, in order to avoid exclusion from participation (which results in a loss of coverage for their products) in federal healthcare programs such as Medicare and Medicaid. Corporate Integrity Agreements typically impose substantial costs and operational burdens on companies to ensure compliance. Defending against any such actions can be detrimental to our reputation and brand and can otherwise be costly, time-consuming and may require significant personnel resources, and may harm our business, financial condition and results of operations.

We have financial relationships with certain physicians and health care providers, research investigators, and authors for our clinical or scientific publications that may be deemed a conflict of interest and may be subject to certain statutory or regulatory requirements, under which a failure to comply could lead to enforcement actions against us and other negative consequences for our business.

We have certain financial relationships with medical doctors and other healthcare providers who are investors and shareholders in our Company and/or paid consultants, clinical investigators, or speakers promoting our products and clinical results, some of whom are also our customers who pay us for patients receiving a NOCISCAN exam, or otherwise prescribe and get paid for interpreting a NOCISCAN exam. There are risks that one or more of these relationships may be determined to be a conflict of interest and be in violation of applicable laws, regulations, or guidelines, which could potentially subject us to significant fines or curtailment of our active commercial operations, and which could also potentially harm our reputation in the marketplace. If we are deemed to not comply with requirements governing the industry's relationships with physicians or there is an investigation into our compliance by the Office of the Inspector

General, the Department of Justice, states' attorney generals or other government agencies, it could harm our sales, business, financial condition, and results of operations.

Regulatory compliance is expensive, complex and uncertain, and a failure to comply could lead to enforcement actions against us and other negative consequences for our business.

The FDA, EU, and other foreign regulatory agencies or governing bodies, regulate certain of our products as medical devices. Complying with these regulations is costly, time-consuming, complex and uncertain. For instance, before a new medical device, or a new intended use for an existing device, can be marketed in the United States, a company must first submit and receive either 510(k) clearance, de novo approval, or approval of a PMA from the FDA, unless an exemption applies. FDA regulations and regulations of similar agencies are wide-ranging and include, among other things, oversight of:

- product design, development, manufacturing (including suppliers) and testing;
- laboratory, preclinical and clinical studies;
- product safety and effectiveness;
- product labeling;
- product storage and shipping;
- quality assurance policies, practices, and record keeping;
- pre-market clearance or approval;
- marketing, advertising and promotion;
- product sales and distribution;
- product changes;
- product recalls; and
- post-market surveillance and reporting of deaths, serious injuries, certain malfunctions, and related corrective actions.

Further, improvements of our existing technology, any potential new technology, and new indications for use of our current technology may be subject to extensive regulation, and we may require permission from regulatory agencies and ethics boards to conduct clinical studies, as well as clearance or approval from the FDA, or other such foreign regulatory agencies or governing bodies, prior to commercial sale. In order to commercialize and distribute our products in markets outside of the United States, it will require approval from, or otherwise meeting the requirements of, non-U.S. regulatory agencies.

The FDA and foreign regulatory bodies can delay, limit or deny clearance or approval (or otherwise a related "exemption") for a device for many reasons, including:

- our inability to demonstrate to the satisfaction of the FDA or the applicable regulatory entity or notified body that our products are safe or effective for their intended uses;
- disagreement of the FDA or the applicable foreign regulatory body with the design or implementation of our clinical studies or the interpretation of data from clinical studies, or with the regulatory classification or related pre-market regulatory pathway pursued by the Company for our products;
- adverse device effects experienced by participants in our clinical studies;
- the insufficiency of data from our preclinical studies and clinical studies to support clearance or approval, where required;
- our inability to demonstrate that the clinical and other benefits of our products outweigh the risks;
- failure of our manufacturing process or facilities to meet applicable requirements; and
- significant changes to the policies or regulations of the FDA or applicable foreign regulatory bodies that render our clinical data or regulatory classifications, pre-market review pathways, or related filings insufficient for approval or that otherwise prevent us from legally marketing our products.

Future clinical studies may be delayed, suspended or terminated for many reasons, including to support reimbursement coverage and certain potential label expansions for additional indications, which will increase our expenses and delay the time it takes to secure reimbursement coverage or support label expansion for additional indications.

We plan to continue to develop and execute clinical studies to support reimbursement coverage for using our products, label retention for our products, label expansion for our products into additional claims for diagnosing painful discs and improving patient outcomes and additional thoracic and cervical discogenic back pain patient populations. We may also develop and execute clinical studies for new products or for label expansion for our current products into patient populations suffering from other pain or tissue chemistry-mediated conditions. We may also develop modifications to our products, and conduct related clinical studies, related to expanding indications for post-processing data from other MRS applications in the body. We do not know whether future clinical studies will begin on time, will need to be redesigned, have an adequate number of patients enrolled or be completed on schedule, if at all. The commencement and completion of clinical studies to support label retention and expansion for additional indications or for new products may be delayed, suspended or terminated as a result of many factors, including:

- the delay or refusal of regulators or Institutional Review Boards, or IRBs, to authorize us to commence a clinical study at a prospective trial site;
- changes in regulatory requirements, policies and guidelines;
- delays or failure to reach agreement on acceptable terms with prospective clinical research organizations, or CROs, and clinical study sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- delays in patient enrollment and variability in the number and types of patients available for clinical studies, including due to COVID-19 or other disease outbreak, and delays in or the inability to monitor enrolled patients, including due to COVID-19 or other disease outbreak;
- the inability to recruit, enroll, or retain a sufficient number of patients;
- deviations by our CROs or clinical sites from the trial protocol or study discontinuation by participants, investigators, or study sites;
- safety or tolerability concerns that could cause us to suspend or terminate a trial if we find that the participants are being exposed to unacceptable health risks;
- regulators, Institutional Review Boards ("IRBs"), Ethics Committees or Data Safety Monitoring Boards requiring that we or our investigators or study sites suspend or terminate clinical studies for various reasons, including noncompliance with GCP or other regulatory requirements or safety concerns;
- lower than anticipated retention rates of patients and volunteers in clinical studies;
- failure of our CROs or clinical studies sites to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- delays relating to identifying and engaging with and adding new clinical study site that have access to compatible MR scanners for using our products; and
- exceeding budgeted costs.

In addition, if the FDA concludes that we have not adequately disclosed financial interests of our investigators or if our disclosed financial relationships with investigators result in a perceived or actual conflict of interest that may have affected the interpretation of a study, the integrity of the data generated at the applicable clinical study site or the utility of the clinical study itself, FDA may refuse to consider data from the study. This could result in the delay or rejection by the FDA. Any such delay or rejection could prevent us from supporting label retention and expansion for our products.

A failure to comply with governmental regulatory requirements would have a negative impact upon our business.

Failure to comply with applicable U.S. requirements regarding promoting, manufacturing, labeling, and establishing and complying with appropriate quality assurance policies, systems, and practices for our products may subject us to a variety of administrative or judicial actions and sanctions. We currently offer the NOCISCAN product suite via two interactive products, NOCICALC, which is listed with the FDA as a Class I, 510(k)-exempt product, and NOCIGRAM, a type of medical software that we have concluded is exempt from medical device regulation by the FDA pursuant to the 21st Century Cures Act. This product suite is also self-certified and CE Marked as a Class I medical device under MDD requirements, while we believe it is considered a Class II medical device and requiring Notified Body review and certification under newer MDR regulations (subject to a grace period until May 2024). These products are marketed and sold with certain labeling and related instructions for use and are promoted by various marketing and sales materials and related human interactions via our personnel and our target customers. We have also established, and operate under, certain quality assurance

systems, policies, and procedures under our QMS intended to be compliant with applicable requirements for all relevant territories and jurisdictions related to our commercial activities. In the event that our establishment, maintenance, marketing, promotion, labeling, or execution of these products, or these systems, policies, practices, or procedures, are determined to be inadequate or non-compliant with applicable regulatory requirements, such defect could result in certain potential enforcement actions or other adverse consequences, and our business would be negatively affected.

If we become subject to enforcement action by governmental regulatory agencies, our business would be negatively affected.

Our failure to comply with applicable regulatory requirements could result in enforcement action by the FDA or other governmental regulatory agencies, which enforcement actions may include the following:

- untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties;
- unanticipated expenditures to address or defend such actions;
- issuance of form 483s, or other compliance or enforcement notices, communications or correspondence from regulatory bodies;
- recall, detention or seizure of our products;
- operating restrictions or partial suspension or total shutdown of marketing, sales and production or offering of product-related services;
- refusing or delaying our requests for 510(k) clearance or de novo classification or PMA approval of new products or modified products;
- requiring products that we determined to be classified and listed with the FDA as a Class I, 510(k)-exempt medical device, or that we determined not to be a medical device and thus unregulated by the FDA, instead to be submitted for marketing authorization (510(k) clearance, de novo classification, or PMA approval);
- operating restrictions;
- withdrawing market authorizations that have already been granted;
- refusal to grant any export approval that might be required for our NOCISCAN product suite; or
- criminal prosecution

If any of these events were to occur, it would have a negative impact on our business, financial condition and results of operations.

If certain of our medical device products cause or contribute to a death or a serious injury or malfunction in certain ways, we will be required to report under applicable medical device reporting regulations, or MDRs, which can result in voluntary corrective actions or agency enforcement actions and harm our reputation, business, financial condition and results of operations.

FDA's Medical Device Reporting ("MDR") regulation requires, medical device manufacturers to report to the FDA information of which the manufacturer becomes aware that a device has or may have caused or contributed to a death or serious injury or has malfunctioned in a way that would likely cause or contribute to death or serious injury if the malfunction of the device or a similar device marketed by the manufacturer were to recur. If we fail to report events required to be reported to the FDA within the required timeframes, or at all, the FDA could take enforcement action and impose sanctions against us. Any such adverse event involving our products also could result in the need to take corrective and preventative actions, such as changes to design or manufacturing processes, corrections, removals, or recalls or customer notifications, or agency action, such as inspection or enforcement action. Risk of harm to patients, including without limitation serious injury or death, associated with using our products could also result in product liability actions against us. Any corrective action, whether voluntary or involuntary, as well as defending ourselves in a lawsuit, would be costly, distract management from operating our business, could be used by competitors against us, and may harm our reputation, business, financial condition and results of operations.

From time to time, we engage outside parties to perform services related to certain of our clinical studies. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to complete our clinical studies on our planned timelines, or at all, and may incur significant additional costs.

The FDA's investigational device exemption ("IDE") regulations impose requirements on the conduct of certain clinical investigations conducted with medical devices. The requirements depend on whether the study is considered to be exempt, a nonsignificant risk or a significant risk. In general, clinical investigations with medical devices, including those that are IDE exempt, must comply with

requirements for the protection of human subjects, which include review and approval by an institutional review board ("IRB") and informed consent of subject participants. Significant risk device studies also must submit an IDE to FDA for approval. The IDE regulations specify the responsibilities of sponsors and investigators to ensure compliance with IDE requirements, including compliance with Good Clinical Practice ("GCP") requirements. Failure to comply may result in FDA placing a temporary or permanent clinical hold on the study, issuance of warning letters, or other regulatory actions.

From time to time, we engage consultants to help design, monitor and analyze the results of certain clinical studies and trials that we sponsor. The consultants we engage may interact with clinical investigators to enroll patients in our clinical studies. We depend on these consultants and clinical investigators to conduct clinical studies and trials and monitor and analyze data from these studies and trials under the investigational plan and protocol for the study or trial and in compliance with applicable regulations and standards. We may face delays in, or be prevented from, completing our clinical studies if these parties do not perform their obligations in a timely, compliant or competent manner. Such roles, functions, and related risks, also apply to certain employees of the Company. If these third parties or employees do not successfully carry out their duties, comply with Good Clinical Practice (GCP) guidelines and other applicable requirements, or meet expected deadlines, or if the quality, completeness or accuracy of the data they obtain is compromised due to the failure to adhere to our clinical study protocols or for other reasons, our clinical studies or trials may need to be extended, delayed or terminated by us or be placed on clinical hold by FDA, or may otherwise prove to be unsuccessful, and we may have to conduct additional studies, which would significantly increase our costs.

Healthcare reform initiatives and other administrative and legislative proposals may harm our business, financial condition, results of operations and cash flows in our key markets.

There have been, and continue to be, proposals by the federal government, state governments, regulators and third-party payers to control or manage the increased costs of healthcare and, more generally, to reform the U.S. healthcare system. Certain of these proposals could limit the prices we are able to charge for our products or the coverage and reimbursement available for our products and could limit the acceptance and availability of our products. The adoption of proposals to control costs could harm our business, financial condition and results of operations.

There likely will continue to be legislative and regulatory proposals at the federal and state levels directed at containing or lowering the cost of healthcare. We cannot predict the initiatives that may be adopted in the future or their full impact. The continuing efforts of the government, insurance companies, managed care organizations and other payers of healthcare services to contain or reduce costs of healthcare may harm:

- our ability to set a price that we believe is fair for our products;
- our ability to generate revenue and achieve or maintain profitability; and
- the availability of capital.

Recently there has been heightened governmental scrutiny over the manner in which companies set prices for their marketed products, which has resulted in several U.S. Congressional inquiries and proposed and enacted federal legislation designed to bring transparency to product pricing and reduce the cost of products and services under government healthcare programs. Additionally, individual states in the United States have also increasingly passed legislation and implemented regulations designed to control product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures. Moreover, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what products to purchase and which suppliers will be included in their healthcare programs. Adoption of price controls and other cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures may prevent or limit our ability to generate revenue and attain profitability.

Various new healthcare reform proposals are emerging at the federal and state level. It is also possible that additional governmental action will be taken in response to the COVID-19 pandemic. Any new federal and state healthcare initiatives that may be adopted could limit the amounts that federal and state governments will pay for healthcare products and services, and could harm our business, financial condition and results of operations.

Our collection, use, storage, disclosure, transfer and other processing of sensitive and personal information could give rise to significant costs, liabilities and other risks, including as a result of investigations, inquiries, litigation, fines, legislative and regulatory action and negative press about our privacy and data protection practices, which may harm our business, financial conditions, results of operations and prospects.

In the course of our operations, we collect, use, store, disclose, transfer and otherwise process an increasing volume of sensitive, and personal information including detailed recordings of MRI and MRS results from patients as well as information from our employees and third parties with whom we conduct business. The collection, use, storage, disclosure, transfer and other processing of personal information is increasingly subject to a wide array of federal, state and foreign laws, rules, regulations, and standards regarding data privacy and security including comprehensive laws of broad application, such as the CCPA and the GDPR, that are intended to protect the privacy of personal information that is collected, used, stored, disclosed, transferred or otherwise processed in or from the governing jurisdiction. As we seek to expand our business, we are, and may increasingly become, subject to various laws, rules, regulations and standards, as well as contractual obligations, relating to data privacy and security in the jurisdictions in which we operate or in the jurisdictions where our patients may be. When conducting clinical studies, we face risks associated with collecting trial participants' data, especially health data, in a manner consistent with applicable laws and regulations, such as GCP guidelines or FDA human subject protection regulations.

In many cases, these laws, rules, regulations and standards apply not only to third-party transactions, but also to transfers of information between or among us, any of our affiliates and other parties with whom we conduct business. These laws, rules, regulations and standards may be interpreted and applied differently over time and from jurisdiction to jurisdiction, and it is possible that they will be interpreted and applied in ways that may harm our business, financial condition and results of operations. The regulatory framework for data privacy and security worldwide is continuously evolving and developing and, as a result, interpretation and implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future.

We are subject to many diverse laws and regulations relating to data privacy and security. In the United States, various federal and state regulators have adopted, or are considering adopting, laws and regulations concerning personal information and data security. Additionally, our customers may be subject to additional federal and state privacy and security laws, rules, regulations and standards, including HIPAA, that they may require us to comply with through contractual obligations. This patchwork of legislation and regulation may give rise to conflicts or differing views of personal privacy rights. For example, certain state laws may be more stringent or broader in scope, or offer greater individual rights, with respect to personal information than federal, foreign or other state laws, and such laws may differ from each other, all of which may complicate compliance efforts. Additionally, new privacy rules are being enacted in the United States and globally, and existing ones are being updated and strengthened. The CCPA regulates the processing of personal information of California residents and increases the privacy and security obligations of covered companies handling such personal information. The CCPA requires covered companies to, amongst other things, provide new and additional disclosures to California consumers and provide such consumers new data protection and privacy rights, including the ability to access their personal information and opt out of certain sales of personal information. The CCPA provides for civil penalties for violations, as well as a private right of action for certain data breaches that result in the loss of personal information. This private right of action may increase the likelihood of, and risks associated with, data breach litigation. The CCPA was amended in September 2018 and November 2019, and it is possible that further amendments will be enacted, but even in its current form it remains unclear how various provisions of the CCPA will be interpreted and enforced. Moreover, a new privacy law, the California Privacy Rights Act, ("CPRA") a consumer privacy ballot initiative that amends and expands the CCPA, was recently passed. The CPRA affords California residents significantly more control over their personal information, imposes heightened compliance obligations on covered companies, and establishes a new enforcement agency dedicated to consumer privacy. The CPRA's substantive provisions become effective January 1, 2023, and new regulations are expected to be introduced by July 1, 2022. While aspects of the CPRA and its interpretation remain to be determined in practice, they create further uncertainty and may result in additional costs and expenses in an effort to comply. Further, all 50 states have passed laws regulating the actions that a business must take if it experiences a data breach, such as prompt disclosure to affected customers. In addition to data breach notification laws, some states have enacted statutes and rules requiring businesses to reasonably protect certain types of personal information they hold or to otherwise comply with certain specified data security requirements for personal information. We are also subject to the supervisory and enforcement authority of the Federal Trade Commission with regard to the collection, use, sharing, and disclosure of certain data collected from or about individuals. State laws are changing rapidly and there is discussion in Congress of a new federal data protection and privacy law to which we would become subject if it is enacted. All of these evolving compliance and operational requirements impose significant costs that are likely to increase over time, may require us to modify our data processing practices and policies, divert resources

from other initiatives and projects, and could restrict the way products and services involving data are offered, all of which may harm our business, financial condition and results of operations.

In the event we expand our operations internationally, we may become subject to additional foreign data privacy and security laws, rules, regulations, requirements, and standards, which in the European Union, for instance, have been significantly reformed. On May 25, 2018, the General Data Protection Regulation ("GDPR") entered into force and became directly applicable in all European Union member states. The GDPR implements more stringent operational requirements than its predecessor legislation. For example, the GDPR requires companies to make more detailed disclosures to data subjects, requires disclosure of the legal basis on which companies can process personal data, makes it harder for companies to obtain valid consent for processing, requires the appointment of data protection officers when sensitive personal data, such as health data, is processed on a large scale, provides more robust rights for data subjects, introduces mandatory data breach notification through the European Union, imposes additional obligations on companies when contracting with service providers and requires companies to adopt appropriate privacy governance including policies, procedures, training and data audits. The GDPR permits data protection authorities to impose large penalties for violations of the GDPR, including potential fines of up to €20 million or four percent of annual global revenues, whichever is greater. The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. If we become subject to the GDPR and do not comply with our obligations under the GDPR, we could be exposed to significant fines. Compliance with the GDPR will be a rigorous and time-intensive process that may increase our cost of doing business or require us to change our business practices, and despite those efforts, there is a risk that we may be subject to fines and penalties, litigation, and reputational harm in connection with our European activities. In addition, we may be the subject of litigation or adverse publicity, which could negatively affect our business, financial condition and results of operations.

We expect that there will continue to be new proposed laws and regulations concerning data privacy and security, and we cannot yet determine the impact such future laws, rules, regulations and standards may have on our business. New laws, amendments to or re-interpretations of existing laws, regulations, standards and other obligations may require us to incur additional costs and restrict our business operations. Because the interpretation, scope, and application of laws, regulations, standards and other obligations relating to data privacy and security are still uncertain, it is possible that these laws, regulations, standards and other obligations may be interpreted and applied in a manner that is inconsistent with our data processing practices and policies or the features of our products and services. If so, in addition to the possibility of fines, lawsuits, regulatory investigations, public censure, other claims and penalties, and significant costs for remediation and damage to our reputation, we could be materially and adversely affected if legislation or regulations are expanded to require changes in our data processing practices and policies or if governing jurisdictions interpret or implement their legislation or regulations in ways that negatively impact our business, financial condition and results of operations. We may be unable to make such changes and modifications in a commercially reasonable manner, or at all. In addition to government regulation, privacy advocates and industry groups have and may in the future propose self-regulatory standards from time to time. These and other industry standards may legally or contractually apply to us, or we may elect to comply with such standards. Any inability to adequately address data privacy or security-related concerns, even if unfounded, or to comply with applicable laws, regulations, standards and other obligations relating to data privacy and security, could result in additional cost and liability to us, harm our reputation and brand, damage our relationships with consumers and harm our business, financial condition and results of operations.

We make public statements about our use and disclosure of personal information through our privacy policies, information provided on our website and press statements. Although we endeavor to comply with our public statements and documentation, we may at times fail to do so or be alleged to have failed to do so. The publication of our privacy policies and other statements that provide promises and assurances about data privacy and security can subject us to potential government or legal action if they are found to be deceptive, unfair or misrepresentative of our actual practices. Any concerns about our data privacy and security practices, even if unfounded, could damage the reputation of our business and harm our business, financial condition and results of operations.

Complying with these numerous, complex and often changing laws, rules, regulations, and standards is expensive and difficult. Any failure or perceived failure by us or our service providers to comply with our posted privacy policies or with any applicable or potentially applicable federal or state laws, rules, regulations, standards, certifications or orders relating to data privacy, security or consumer protection, or any compromise of security that results in the theft, unauthorized access, acquisition, use, disclosure, or misappropriation of personal information or other user data, could result in significant fines or penalties, negative publicity or proceedings or litigation by governmental agencies or consumers, including class action privacy litigation in certain jurisdictions, which would subject us to significant awards, penalties or judgments, one or all of which could require us to change our business practices or increase our costs

and could materially and adversely affect our business, financial condition and results of operations. In addition, if our practices are not consistent, or viewed as not consistent, with applicable legal and regulatory requirements, including changes in laws, regulations and standards or new interpretations or applications of existing laws, regulations and standards, we may also become subject to audits, inquiries, whistleblower complaints, adverse media coverage, investigations, criminal or civil sanctions, all of which may harm our business, financial condition and results of operations.

Our employees, independent contractors, consultants, commercial partners and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could harm our business, financial condition and results of operations.

We are exposed to the risk that our employees, independent contractors, consultants, commercial partners and vendors may engage in fraudulent or illegal activity. Misconduct by these parties could include intentional, reckless or negligent conduct or disclosure of unauthorized activities to us that violates: (i) the laws of the FDA and other similar state or foreign regulatory bodies, including those laws requiring the reporting of true, complete and accurate information to such regulators, (ii) manufacturing standards, (iii) healthcare fraud and abuse laws in the United States and similar foreign fraudulent misconduct laws, (iv) laws related to discrimination, harassment, or other conduct relating to a hostile work environment, or (v) laws that require the true, complete and accurate reporting of financial information or data. These laws may impact, among other things, future sales, marketing and education programs. In particular, the promotion, sales and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry, are subject to extensive laws designed to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing arrangements, discounting, marketing and promotion, structuring and commissions, certain customer incentive programs and other business arrangements generally. These laws also address the improper use of information obtained in the course of patient recruitment for clinical studies.

We have adopted a code of conduct, employee handbook, and compliance policies, but it is not always possible to identify and deter misconduct by our employees and other third parties, and the precautions we take to detect and prevent these activities may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could result in the imposition of significant fines or other sanctions, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, disgorgement, imprisonment, reporting and oversight obligations, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, diminished profits and future earnings and curtailment of operations, any of which could adversely affect our ability to operate our business and our results of operations. If any such actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could result in integrity issues, or a negative impact to our reputation or brand. Whether or not we are successful in defending against any such actions or investigations, we could incur substantial costs, including legal fees, and divert the attention of management in defending ourselves against any of these claims or investigations, which could harm our business, financial condition and results of operations.

Significant disruptions in our information technology systems, whether through breaches or failures of our technology, unauthorized access or otherwise, may result in both an adverse impact to our products, as well as the unauthorized use, disclosure, modification or misappropriation of patient personal information, the occurrence of fraudulent activity, or other data security-related incidents, all of which could have a material and adverse impact on our business, financial condition and results of operations.

We are increasingly dependent on complex information technology systems for the efficient functioning of our business, including the manufacture, distribution and maintenance of our products, as well as for accounting, data storage, compliance, purchasing and inventory management purposes. Further, our products collect, use, store, disclose, transfer, and otherwise process sensitive patient data, such as detailed recordings of MRIs to help clinicians make more informed treatment decisions and optimize their patients' care. These data are recorded by our technology and can be viewed by the physician during regular patient visits using the Physician Tablet or on demand through a secure website. We also collect, use, store, disclose, transfer, and otherwise process a growing volume of other personal information and confidential, proprietary and sensitive data, which may include procedure-based information and sensitive healthcare data, credit card, and other financial information, insurance information, and other potentially personally identifiable information. Our information technology systems or those of our service providers may be subject to computer viruses, phishing, social engineering, denial or degradation of service attacks, ransomware, malware attacks or other threats, cyberattacks, or dishonest acts by computer

hackers or terrorists, failures during the process of upgrading or replacing software, databases or components thereof, power outages, damage or interruption from fires or other natural disasters, hardware failures, telecommunication failures and user errors, among other malfunctions. Technological interruptions or threats would disrupt our operations, including the ability of our clinicians to use our products as intended to treat patients, the ability of patients to safely and securely upload their data using and into our products, as well as our ability to adequately manufacture our products, timely ship and track product orders, project inventory requirements, manage our supply chain and otherwise adequately service our customers. Additionally, any of these incidents could result in the theft, unauthorized access, acquisition, use, disclosure, modification, or misappropriation of personal information of patients that use our products, trial participants, employees, third parties with whom we conduct business, as well as other confidential, proprietary, and sensitive data, and can also result in fraudulent activity, system disruptions or shutdowns.

The occurrence of any actual or attempted breach, failure of security or fraudulent activity, the reporting of such an incident, whether accurate or not, or our failure to make adequate or timely disclosures to the public or law enforcement agencies following any such event, whether due to delayed discovery or a failure to follow existing protocols, could result in claims made against us or our service providers, which could result in state and/or federal litigation and related financial liabilities, as well as criminal penalties or civil liabilities, regulatory actions from state and/or federal governmental authorities, and significant fines, orders, sanctions, litigation and claims against us by consumers or third parties and related indemnification obligations. Actual or perceived security breaches or failures could also cause financial losses, increased costs, interruptions in the operations of our businesses, misappropriation of assets, significant damage to our brand and reputation with customers, patients, employees, and third parties with whom we do business, and result in adverse publicity, loss of consumer confidence, distraction to our management, and reduced sales and profits, any or all of which could harm our business, financial condition and results of operations.

Our technology is also subject to compromise from internal threats, such as theft, misuse, unauthorized access or other improper actions by employees, service providers and other third parties with otherwise legitimate access to our systems and website. Data security-related incidents and fraudulent activity are increasing in frequency and evolving in nature. We rely on a framework of security processes, procedures, tools, and controls designed to protect our information and assets but, given the unpredictability of the timing, nature and scope of data security-related incidents and fraudulent activity, there can be no assurance that any security procedures and controls that we or our service providers have implemented will be sufficient to prevent data security-related incidents or other fraudulent activity from occurring. Furthermore, because the methods of attack and deception change frequently, are increasingly complex and sophisticated, and can originate from a wide variety of sources, including third parties such as service providers and even nation-state actors, despite our reasonable efforts to ensure the integrity of our systems and website, it is possible that we may not be able to anticipate, detect, appropriately react and respond to, or implement effective preventative measures against, all security breaches and failures and fraudulent activity. In the event we experience significant disruptions, we may be unable to repair our systems in an efficient and timely manner.

We also face risks associated with security breaches affecting third parties with whom we are affiliated or otherwise conduct business. Due to applicable laws and regulations or contractual obligations, we may be held responsible for any breach, failure or fraudulent activity attributed to our service providers as they relate to the information we share with them. In addition, while we take precautions in selecting service providers, because we do not control our service providers and our ability to monitor their data security is limited, we cannot ensure the security measures they take will be sufficient to protect our information. Any of the foregoing could harm our business, financial condition and results of operations.

As data security-related threats continue to evolve, we may be required to expend significant additional resources to continue to modify or enhance our protective measures or to investigate and remediate any information security vulnerabilities, or to protect against, respond to and recover from any potential, attempted, or existing security breaches. In addition, our remediation efforts may not be successful. The inability to implement, maintain and upgrade adequate safeguards could have a material and adverse impact on our business, financial condition and results of operations. Moreover, there could be public announcements regarding any data security-related incidents and any steps we take to respond to or remediate such incidents, and if securities analysts or investors perceive these announcements to be negative, it could, among other things, have a substantial adverse effect on the price of our common stock. Any of the foregoing could harm our business, financial condition and results of operations.

We currently maintain a cybersecurity insurance policy and business interruption coverage in order to mitigate certain potential losses but this insurance is limited in amount, and we cannot be certain that such potential losses will not exceed our policy limits, or will cover all potential claims to which we are exposed and may not be adequate to indemnify us for all liability that may be imposed. Therefore, failure

to maintain or protect our information systems and data integrity effectively could harm our business, financial condition, and results of operations.

We face potential liability related to the privacy of health information we obtain.

We may maintain, use, and share sensitive health information that we receive directly from patients that use our technology, throughout the clinical study process, in the course of our research collaborations, and from healthcare providers in the course of using our products and systems. Most healthcare providers, including hospitals from which we obtain patient health information, are subject to privacy and security regulations promulgated under HIPAA, as amended by the HITECH, and also under GDPR. We believe that we are not currently classified or regulated under HIPAA or GDPR as a Covered Entity, but we believe we are considered and regulated as a Business Associate. Accordingly, we are subject to HIPAA and GDPR requirements or penalties as applied to Business Associates. However, in certain situations, any person may be prosecuted under HIPAA's criminal provisions either directly or under aiding-and-abetting or conspiracy principles. Consequently, depending on the facts and circumstances, we could face substantial criminal penalties if we knowingly receive, maintain, use, or transfer individually identifiable health information from a Covered Entity, as defined under HIPAA, that has not satisfied HIPAA's requirements for disclosure of individually identifiable health information. Furthermore, certain health privacy laws, data breach notification laws, consumer protection laws and genetic testing laws may apply directly to our operations or those of our collaborators and may impose restrictions on our collection, use and dissemination of individuals' health information As such, we may be subject to state laws requiring notification of affected individuals and state regulators in the event of a breach of personal information, including certain health information, which is a broader class of information than the health information protected by HIPAA. To the extent we engage in clinical studies and commercial uses of our products outside the United States, we may implicate foreign data privacy and security laws and regulations, including the GDPR and legislation of the European Union member states implementing it.

To the extent we do business in international markets now, and in the future, any failure by us or our third-party contractors to comply with the strict rules on the transfer of personal data from outside of the European Union, the United Kingdom, or other foreign country or territory into the United States in accordance with such laws and regulations may result in the imposition of criminal and administrative sanctions on such contractors, which could adversely affect our sales, business, financial condition, and results of operations.

Moreover, patients about whom we or our contractors or collaborators obtain or share health information, as well as the providers who share this information with us or whom we share this data with, may have statutory or contractual rights that limit our ability to use and disclose the information. We may be required to expend significant capital and other resources to ensure ongoing compliance with applicable privacy and data security laws. Potential claims alleging that we have violated individuals' privacy rights or breached our contractual obligations, even if we are not found liable, could be expensive and time consuming to defend and could result in adverse publicity that could negatively affect our business, financial condition and results of operations. If we or third-party contractors or consultants fail to comply with applicable federal, state or local regulatory requirements, we could be subject to a range of regulatory actions that could affect our or our contractors' ability to develop and commercialize our products and could harm or prevent sales of our technology, or could substantially increase the costs and expenses of developing, commercializing and marketing our products. Any threatened or actual government enforcement action could also generate adverse publicity and require that we devote substantial resources that could otherwise be used in other aspects of our business.

Additionally, data collection, privacy and security have become the subject of increasing public concern and changing preferences towards data collection, privacy and security could adversely affect patient willingness to consent to our collection of their health information. Patients may be reluctant or unwilling to consent to the collecting of their health information, and patients that have opted-in to the collection of their health information may revoke their consent at any time, including as a result of these concerns or as a result of changes to our data policies that we have implemented or may implement in the future. In particular, the success of our business depends in part on our ability to lawfully obtain health information from our patients. If patients choose not to consent to the collection of their health information as a result of these concerns, or our customers who transfer patient data to us via the use of our products refuse to do so due to concerns for data privacy or potential related liabilities, or our consent or data privacy protection and management policies or practices are found to be unlawful, this could negatively impact the growth potential for our business.

We have encountered potential customers in the EU who have been reluctant, and indeed refused, to become customers due to concerns about transferring of any private patient information from their practice in the EU into the United States. Certain such customers have

indicated their opinion that such a transfer is, on its face, non-compliant with GDPR requirements due to certain rights of the US Federal Government to seize such data from US domiciled companies or storage facilities. We may need to expand our operations to host at least one foreign instance of our cloud-based post-processing software products within a foreign country, such as within the European Union, in order to overcome such concerns and reach and engage more customers to grow our business in the related territory. If we are unable to sufficiently dissuade these concerns held by certain potential customers outside of the United States, or do not establish certain changes in our private patient health information data privacy practices, such as moving the hosting of EU-based information to an EU-based instance of our products and storage of related patient health information we receive via use of our products, our sales, business, financial condition, and results of operations could be harmed. We could also encounter delays if a clinical study is suspended or terminated by us, by the IRBs or the Ethics Committees of institutions at which such studies are being conducted, by the Data Safety Monitoring Board for such trial or by the FDA or other regulatory authorities. Such authorities may suspend or terminate a clinical study due to a number of factors, including failure to conduct the clinical study in accordance with regulatory requirements, including GC.

Risks related to our intellectual property

If we are unable to obtain, maintain, protect, enforce and defend patents or other intellectual property protection for our technology, or if the scope of our patents and other intellectual property protections is not sufficiently broad, or as a result of our existing or any future out-licenses of our intellectual property, our competitors could develop and commercialize products similar to or competitive with our products and services, our ability to continue to commercialize our technology, or our other products and services, may be harmed.

As with other medical device companies, our success depends, in large part, on our ability to obtain, maintain, protect, enforce and defend a proprietary position for our products and services, which will depend upon our success in obtaining and maintaining effective patent and other intellectual property protection in the United States and other countries into which we may expand our business in the future that relate to our technology and any other products, their manufacturing processes and their intended methods of use. Furthermore, our success will also depend on our ability to enforce and defend those patents, as well as our other intellectual property. In some cases, we may not be able to obtain patents relating to our products and services which are sufficient to prevent third parties, such as our competitors, from copying and competing with other products or services that are the same, similar, or otherwise competitive with our products and services. Or, our competitors may have rights under current or future out-licenses of our intellectual property which could result in our competitors developing and commercializing products similar to or competitive with our products and services. Any failure to obtain, maintain, protect, enforce or defend patent and other intellectual property protection with respect to our NOCISCAN product suite and related services, or other aspects of our business, could harm our business, competitive position, financial condition and results of operations.

Changes in the patent or other intellectual property laws, or their interpretation, in the United States and other countries may diminish our ability to protect our inventions or to obtain, maintain, protect, enforce, and defend our patents and other intellectual property rights, and could affect the value of our intellectual property or narrow the scope of our patents. Additionally, we cannot predict whether the patent applications we are currently pursuing will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient protection from competitors or other third parties.

The patent prosecution process is expensive, time-consuming and complex and we may not be able to file, prosecute, maintain, enforce or license all necessary or desirable patents or patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output in time to obtain patent protection in one, several, or all geographies. Although we enter into non-disclosure and confidentiality agreements with parties who have access to our confidential information or patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, suppliers, consultants, advisors and other third parties, any of these parties may breach the agreements and publicly disclose such confidential information or research and development output. If such unauthorized public disclosure occurs before a patent application is filed, it could compromise or diminish our ability to seek patent protection. Such third parties could also breach obligations with respect to limited uses of our confidential information, which may include (i) breaching restrictions against making or inventing improvements or modifications to, or derivations of, our confidential technologies, and (ii) further separately applying, on their own behalf, for patent protections for such improvements, modifications, or derivations. Such breaches may compromise our ability to obtain or enforce our own patent protections for such improvements, modifications, or derivations. In addition, our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our inventions and the prior art allow our inventions to be patentable over the prior art. Furthermore, the publication of discoveries in scientific literature often lags behind the

actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. As such, we cannot be certain that we were the first to make the inventions claimed in any of our patents or pending patent applications, or that we were the first to file for patent protection of such inventions. Moreover, in some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, relating to technology that we license from or license to third parties, including by way of our license from the Board of Regents of the University of California, and we are therefore reliant on our licensors or licensees. Therefore, these and any of our patents and patent applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. Furthermore, our license agreements may be terminated by the licensor. Defects of form in the preparation or filing of our patents or patent applications may exist, or may arise in the future, for example, with respect to proper priority claims, inventorship and the like, although we are unaware of any such defects that we believe are of importance. If we or any of our current or future licensors or licensees fail to obtain, maintain, protect, enforce or defend such patents and other intellectual property rights, such rights may be reduced or eliminated. If any of our current or future licensors or licensees are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised. If there are material defects in the form, preparation or prosecution of our patents or patent applications, such patents or applications may be invalid and/or unenforceable. Any of these outcomes could impair our ability to prevent competition from third parties, which may harm our business.

The strength of patent rights generally, and particularly the patent position of medical device companies, involves complex legal and scientific questions, can be uncertain, and has been the subject of much litigation in recent years. This uncertainty includes changes to the patent laws through either legislative action to change statutory patent law or court action that may reinterpret existing law or rules in ways affecting the scope or validity of issued patents. Our current or future patent applications may fail to result in issued patents in the United States or foreign countries with claims that cover our products, including our technology. Even if patents do successfully issue from our patent applications, third parties may challenge the validity, enforceability or scope of such patents, which may result in such patents being narrowed, invalidated or held unenforceable. Any successful challenge to our patents could deprive us of exclusive rights necessary for the successful commercialization of our products, including our NOCISCAN product suite. Furthermore, even if they are unchallenged, our patents may not adequately protect our technology or any other products we develop, provide exclusivity for these products or prevent others from designing around our claims. If the scope of any patent protection we obtain is not sufficiently broad, or if we lose any of our patent protection, our ability to prevent our competitors from commercializing similar or identical products could be adversely affected. If the breadth or strength of protection provided by the patents we hold or pursue with respect to our products is challenged, it could dissuade companies from collaborating with us to develop, or threaten our ability to commercialize, our technology.

Patents have a limited lifespan. In the United States, the natural expiration of a utility patent is generally 20 years after its effective filing date and the natural expiration of a design patent is generally 14 years after its issue date, unless the filing date occurred on or after May 13, 2015, in which case the natural expiration of a design patent is generally 15 years after its issue date. However, the actual protection afforded by a patent varies from country to country, and depends upon many factors, including the type of patent, the scope of its coverage, any terminal disclaimers filed or to be filed, overlap in claimed subject matter with other patents in the portfolio, the availability of regulatory-related extensions, the availability of legal remedies in a particular country and the validity and enforceability of the patent. Various extensions may be available; however, the life of a patent, and the protection it affords, is limited. Without patent protection for our technology, we may be open to competition. Further, if we encounter delays in our development efforts, the period of time during which we could market our technology under patent protection would be reduced and, given the amount of time required for the development, testing and regulatory review of planned or future technology and products, patents protecting such technology and products might expire before or shortly after such products are commercialized. For information regarding the expiration dates of patents in our patent portfolio, see “Business—Intellectual Property.” Our U.S. issued patents are expected to expire between January 3, 2026 and March 15, 2033, without taking into account all possible patent term adjustments, extensions, or abandonments, and assuming payment of all appropriate maintenance, renewal, annuity, and other governmental fees. As our patents expire, the scope of our patent protection will be reduced, which may reduce or eliminate any competitive advantage afforded by our patent portfolio. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

Moreover, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Even if patent applications licensed to us or assigned to us, currently or in the future, issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us, or otherwise provide us with any competitive advantage. Any patents assigned to us may be challenged, narrowed, circumvented or invalidated by third parties. Consequently, we do not know whether our NOCISCAN product suite or our other products will be

protectable or remain protected by valid and enforceable patents. Our competitors or other third parties may be able to circumvent our patents by developing similar or alternative products in a non-infringing manner, which could harm our business, financial condition and results of operations.

Some of our patents and patent applications may be co-owned or cross-licensed with third parties. If we give up, do not pursue, or are unable to obtain an exclusive license to any such third-party co-owners' or licensee's interest in such patents or patent applications, such co-owners or cross-licensees may be able to license or sub-license, respectively, their rights to other third parties, including our competitors, and our competitors could market competing products and technology. In addition, we may need the cooperation of any such co-owners or co-licensees of our patents in order to enforce such patents against third parties, and such cooperation may not be provided to us. Any of the foregoing could harm our sales, business, financial condition and results of operations.

We rely on a License from the Regents of the University of California, as well as other aspects of our own patented technology and intellectual property, in order to be able to use and sell various proprietary technologies that are material to our business, as well as technologies which we intend to use in our future commercial activities. Our rights to use these licensed technologies and the inventions claimed in the licensed patents, are subject to the continuation of, and our compliance with the terms of the license. The License provides that for so long as we pay patent prosecution costs, the Regents of the University of California will diligently prosecute and maintain the United States and foreign patents comprising the Patent Rights using counsel of its choice, and the UCSF Regents' counsel will take instructions only from The Regents of the University of California has the right to terminate the agreement upon advanced notice in the event of a default by us. The agreement will expire upon the expiration or abandonment of the last of the licensed patents. The patents subject to the agreement expire between 2025 and 2029. The loss of this license would materially negatively affect our ability to pursue our business objectives and result in material harm to our business operations.

We may not be successful in obtaining or maintaining necessary rights to any products or processes we may have or develop through acquisitions and in-licenses.

We may find it necessary or prudent to acquire, obtain, or maintain licenses to intellectual property or proprietary rights held by third parties that we may identify as necessary or important to our business operations. However, we may be unable to acquire, secure, or maintain such licenses to any intellectual property or proprietary rights from third parties that we identify as necessary for our technology or any future products we may develop. The acquisition or licensing of third-party intellectual property or proprietary rights is a competitive area, and our competitors may pursue strategies to acquire or license third party intellectual property or proprietary rights that we may consider attractive or necessary. Our competitors may have a competitive advantage over us due to their size, capital resources and greater development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to acquire or license third party intellectual property or proprietary rights on terms that would allow us to make an appropriate return on our investment or at all. We have an existing license with the Board of Regents of the University of California, and which covers multiple patents and patent applications for inventions that are incorporated into our products, and if we are unable to maintain this license, we may not be able to legally market or sell our current or future products, which would harm our sales, business, financial condition, and results of operations. If we are unable to successfully acquire or license third-party intellectual property or proprietary rights that we require for making, using, or selling our products or services, or to maintain the existing licenses to intellectual property rights we have, we may have to abandon the development, manufacturing, marketing, or selling of our related products that require those rights, which could harm our sales, business, financial condition, and results of operations.

Patents directing to our technology could be found invalid or unenforceable if challenged in court or before administrative bodies in the United States or abroad, which could harm our business, financial condition and results of operations.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patents may be challenged in the courts or patent offices in the United States and abroad. We may be subject to a third-party pre-issuance submission of prior art to the U.S. Patent and Trademark Office ("USPTO"), or become involved in opposition, derivation, revocation, reexamination, post-grant and inter partes review, or IPR, or interference proceedings or other similar proceedings challenging our patent rights. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate or render unenforceable, such patent rights, allow third parties to commercialize our products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. Moreover, we may have to participate in interference proceedings

declared by the USPTO to determine priority of invention or in post-grant challenge proceedings, such as oppositions in a foreign patent office, that challenge our priority of invention or other features of patentability with respect to our patents and patent applications. Such challenges may result in loss of patent rights, in loss of exclusivity, or in patent claims being narrowed, invalidated or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical products or limit the duration of the patent protection of our products. Such proceedings also may result in substantial cost and require significant time from our management, even if the eventual outcome is favorable to us.

In addition, if we initiate legal proceedings against a third party to enforce a patent relating to our products, the defendant could counterclaim that such patent is invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a false or misleading statement, or otherwise committed inequitable conduct, during prosecution. Defenses of these types of claims, regardless of their merit, would involve substantial litigation expense, would result in reputational harm, and would be a substantial diversion of employee resources from our business. Third parties may also raise claims challenging the validity or enforceability of our patents before administrative bodies in the United States or abroad, even outside the context of litigation, including through re-examination, post-grant review, IPR, interference proceedings, derivation proceedings and equivalent or similar proceedings in foreign jurisdictions (such as opposition proceedings). Such proceedings could result in the revocation of, cancellation of or amendment to our patents in such a way that they no longer relate to our products. The outcome for any particular patent following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. Moreover, potential third-party claims that are validated in a final ruling or determination regarding inequitable conduct with respect to securing or enforcing a patent could also potentially give rise to other adverse claims, which may include business torts or other causes of action regarding our enforcement of that patent, and could also potentially carry over and apply downstream to other patents that are related to (e.g. claim of priority) the instant patent. If a defendant or other third party were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and potentially all, of the patent protection for the patents raised in such a claim. Such a loss of patent protection would harm our sales, business, financial condition, and results of operations.

The medical device industry is characterized by patent litigation and in the future we could become subject to actual or threatened patent or other intellectual property litigation alleging our products or services infringe or misappropriate third party rights, which could be costly to address and defend, result in the diversion of management's time and efforts, require us to pay damages, or prevent us from making, using, or selling our existing or future products.

Patent litigation is prevalent in the medical device and diagnostic sectors. Our commercial success depends, in part, upon our ability and that of our suppliers to manufacture, market, sell, and use our proprietary technology without infringing, misappropriating or otherwise violating the intellectual property or proprietary rights of third parties. We may in the future become party to, or be threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to our products. Third parties may assert infringement claims against us based on existing or future intellectual property rights, regardless of merit. If we are found to infringe a third party's intellectual property rights, we could be required to incur costs to obtain a license from such third party to continue developing, making, using, or selling our products and services. We may also elect to enter into such a license in order to settle pending or threatened litigation. However, we may not be able to obtain any required license on commercially reasonable terms, or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies or methods licensed to us and could require us to pay significant royalties and other fees. We could be forced, including by court order, to cease commercializing the infringing product or service. In addition, we could be found liable for monetary damages, which may be significant. If we are found to have willfully infringed a third-party patent, we could be required to pay treble damages and attorneys' fees. A finding of infringement could prevent us from commercializing our planned products in commercially important territories or force us to cease some of our business operations, which could harm our business and cause brand and reputational harm. An adverse infringement determination in one territory where such a claim might be brought could also potentially carry over to influence other similarly adverse claims being brought, and/or adverse results of those additional claims, in other territories where we have or seek a commercial presence. We could also be forced to redesign or otherwise change those products or services that use or implicate the allegedly infringing intellectual property, which could be costly, disruptive and infeasible.

Many of our employees were previously employed at, and many of our current advisors and consultants are employed by, universities or other biotechnology, medical device, healthcare, or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, advisors and consultants do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we, or these employees, have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee's former employer. Furthermore, although these agreements may be difficult to enforce, we may in the future be subject to claims that these individuals are violating non-compete agreements with their former employers. These and other claims that we have misappropriated the confidential information or trade secrets of third parties can have a similar negative impact on our business, including with respect to the infringement claims discussed above.

Even if we are successful in defending against intellectual property claims, litigation or other legal proceedings relating to such claims, the claims and related defense may still cause us to incur significant expenses, cause reputational harm, and could distract our technical and management personnel from their normal responsibilities. If we fail in defending any such claims, in addition to paying monetary damages or other settlements, we may lose valuable intellectual property rights or personnel, which could harm our business, financial condition and results of operations. We could potentially be required, or be forced or choose among other options, to negotiate a settlement of third party infringement claims that may include cross-licensing of our own patent or other intellectual property rights with the third party bringing the initial adverse claim against us. This could result in our inability to protect our products and services as exclusively proprietary only to us, and allow the third party to compete against us, with respect to the inventions or technologies related to those out-licensed rights, and which could also diminish the value of our products, services, and overall business and company, and harm our sales, business, financial condition, and results of operations. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial negative impact on the price of our shares of common stock. Such litigation or proceedings could substantially increase our operating losses and reduce our resources available for development activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation of litigation or other intellectual property related proceedings could harm our business, financial condition and results of operations.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by government patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Obtaining and maintaining our patent protection depends on compliance with various procedural measures, document submissions, fee payments and other requirements imposed by government patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other government fees on patents and patent applications will be due to be paid to the USPTO and various government patent agencies outside of the United States over the lifetime of our patents and applications. The USPTO and various non-U.S. government agencies require compliance with several procedural, documentary, fee payment and other similar provisions during the patent application process. In some cases, an intentional lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. There are situations, however, in which non-compliance can result in the abandonment or lapse of the patent or patent application, resulting in a partial or complete loss of patent rights in the relevant jurisdiction. In such an event, potential competitors might be able to enter the market with similar or identical products or technology, which could harm our business, financial condition and results of operations. Certain legal or contractual requirements, and/or rights of others involved in our development or products, may permit the U.S. government to disclose our confidential information to third parties. To the extent any of our current or future intellectual property is generated through the use of U.S. government funding, the provisions of the Bayh-Dole Act may similarly apply. For example, the National Institute of Health and the Regents of the University of California have limited rights to use certain of our patents and patent applications for research. Any exercise by the government of any of the foregoing rights could harm our business, financial condition, results of operations and prospects.

If we fail to comply with our obligations in any current or future agreements under which we license intellectual property rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could lose license rights that are important to our business.

We are, and may become, party to license or collaboration agreements with third parties to advance our research or allow commercialization of our products. Such agreements may impose numerous obligations, such as development, diligence, payment, commercialization, funding, milestone, royalty, sublicensing, insurance, patent prosecution, enforcement and other obligations on us and may require us to meet development timelines, or to exercise certain efforts to develop and commercialize licensed products, in order to maintain the licenses. In spite of our best efforts, our licensors might conclude that we have materially breached such license agreements and might therefore terminate the license agreements, thereby removing or limiting our ability to develop and commercialize products and technologies covered by these license agreements.

We have an existing license with the Regents of the University of California which covers multiple patents and patent applications for inventions that are incorporated into our products. Any termination of this or other licenses could result in the loss of significant rights and could harm our ability to commercialize our products and competitors or other third parties may have the freedom to seek regulatory approval of, and to market, products identical to ours, at least to the extent of products and services that incorporate the features captured by those previously licensed patent rights and assuming our licensor permits such competitive activities, either passively or via further out licensing, under their remaining patent rights. If we lose our licensed patent rights, we may also be required to cease our development and commercialization of certain of our products. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

Disputes may also arise between us and our licensors regarding intellectual property subject to a license agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- whether and the extent to which our technology and processes infringe, misappropriate or otherwise violate intellectual property rights of the licensor that are not subject to the license agreement;
- our right to sublicense patent and other rights to third parties under collaborative development relationships;
- our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our products, and what activities satisfy those diligence obligations;
- the priority of invention of any patented technology; and
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our future licensors and us and our partners.

In addition, the agreements under which we may license intellectual property or technology from third parties are likely to be complex and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our sales, business, financial condition or results of operations. Moreover, if disputes over intellectual property that we may license prevent or impair our ability to maintain future license agreements on acceptable terms, we may be unable to successfully develop and commercialize the affected products, which could have a material adverse effect on our sales, business, financial conditions or results of operations.

Our existing license with the Regents of the University of California, in particular, includes both exclusive rights, as applied to certain aspects of their patent rights under the license, and partial-exclusive and co-exclusive rights as applied to certain other aspects of the Licensor's patent rights, under which we have rights for diagnostic-related patent claims. The balance of remaining rights for therapy-related claims are exclusively licensed to another third-party company. There are risks that the interpretation of which patent rights apply to us under our license, versus which patent rights apply to the other third-party company under their license, could be the subject of disagreement or dispute, the existence of which, and potential adverse result from which, could diminish the scope of rights we actually have. This could also be the subject of disagreement or dispute with respect to patent prosecution matters along the examination path of applications toward seeking issued patents. Any of the above could diminish, or prevent, our ability to commercialize all aspects of our products as intended, and which could result in harm to our sales, business, financial condition, or result of operations.

Our existing license also includes exclusive rights to certain patents which are co-owned by us and the Board of Regents of the University of California, in relation to inventions that have been determined to be jointly invented by separate but joint inventors that are under different obligation of assignment to us and them. If we fail to maintain and/or lose those license rights to one or more of these co-

owned patents and patent applications, others would have the ability to commercialize, or license the ability to commercialize, products or services covered by those patents competitively against us. This would result in us losing exclusive proprietary advantage with respect to technologies and methods relating to those patents, which could harm our sales, business, financial condition, and results of operations.

If we are unable to obtain patent term extension under the Hatch-Waxman Amendments, our business may be materially harmed.

Depending upon the timing, duration and specifics of FDA marketing approval of our products, one or more of the U.S. patents assigned or licensed to us may be eligible for limited patent term restoration under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years for a patent covering an approved product as compensation for effective patent term lost during product development and the FDA regulatory review process. However, even if, at the relevant time, we have an issued patent covering our product, we may not be granted an extension if we were, for example, to fail to exercise due diligence during the testing phase or regulatory review process, to fail to apply within applicable deadlines or prior to expiration of relevant patents or otherwise to fail to satisfy applicable requirements. Moreover, the time period of the extension or the scope of patent protection afforded could be less than we request. Only one patent per approved product can be extended, the extension cannot extend the total patent term beyond 14 years from approval and only those claims covering the approved product, a method for using it or a method for manufacturing it may be extended. If we are unable to obtain patent term extension or restoration or the term of any such extension is less than we request, the period during which we can enforce our patent rights for the applicable product will be shortened and our competitors may obtain approval of competing products following our patent expiration. As a result, our ability to generate revenues could be adversely affected. Further, if this occurs, our competitors may take advantage of our investment in development and studies by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case. If we do not have adequate patent protection or other exclusivity for our products, our business, financial condition or results of operations could be adversely affected.

We have limited foreign intellectual property rights and may not be able to protect our intellectual property and proprietary rights throughout the world, which could harm our business, financial condition and results of operations.

We have limited intellectual property rights outside the United States. Filing, prosecuting and defending patents on our products in all countries throughout the world would be prohibitively expensive, and the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection but enforcement is not as strong as in the United States. While we do not currently operate or sell our products outside of the United States, these products may compete with our products, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. Patent protection must ultimately be sought on a country-by-country basis, which is an expensive and time-consuming process with uncertain outcomes. Accordingly, we may choose not to seek patent protection in certain countries, and we will not have the benefit of patent protection in such countries, which may impede on our ability to grow outside of the United States.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our intellectual property and proprietary rights generally. Proceedings to enforce our intellectual property and proprietary rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, could put our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property and proprietary rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we are forced to grant a license

to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition and results of operations may be harmed.

Changes in U.S. patent laws, or patent laws in other countries and jurisdictions, could diminish the value of patents in general, thereby impairing our ability to protect our products.

Changes in either the patent laws or interpretation of the patent laws in the United States, or elsewhere, could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. Assuming that other requirements for patentability are met, prior to March 2013, in the United States, the first to invent the claimed invention was entitled to the patent, while outside the United States, generally the first to file a patent application was entitled to the patent. After March 2013, under the Leahy-Smith America Invents Act, or the America Invents Act, enacted in September 2011, the United States transitioned to a first inventor to file system in which, assuming that other requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party, who may have filed a patent application later, was the first to actually invent the claimed invention. A third party that files a patent application in the USPTO after March 2013, but before we filed a patent application for the same invention (as defined by claims), could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by such third party. This will require us to be cognizant of the time from invention to filing of a patent application. Since patent applications in the United States and most other countries are confidential for a period of time after filing or until issuance, we could continue incurring costs without being certain that we were the first to file any patent application related to our products or the first to invent any of the inventions claimed in our patents or patent applications.

The America Invents Act also includes a number of significant changes that affect the way patent applications are prosecuted and also may affect patent litigation. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including post-grant review, inter partes review and derivation proceedings. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in U.S. federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. Additionally, USPTO proceedings provide a venue for challenging the validity of patents at a cost must lower than district court litigation and on much faster timelines. This lower-cost, faster and potentially more potent tribunal for challenging patents could itself increase the likelihood that our own patents will be challenged. Therefore, the America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. In addition, future actions by the U.S. Congress, the federal courts and the USPTO could cause the laws and regulations governing patents to change in unpredictable ways. Any of the foregoing could harm our business, financial condition and results of operations.

In addition, recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the validity and enforceability of patents, once obtained. For example, after the filing of our earlier filed patent applications, from which we have received granted patents and also continue to prosecute additional patent applications under priority filing claims, certain laws and interpretation of those laws changed. This includes, in particular, new changes that diminish or make it more difficult to obtain, enforce, or defend as valid, claims related to medical diagnostics, any methods, and in particular any methods involving the human body or medical procedures. Our patent portfolio is principally related to medical diagnostic methods, which in many cases merge these multiple areas of patent laws that have since been changed. Some of our patents were issued prior to certain such changes in the laws occurring, which could potentially result in certain risks that the patents which were initially valid when granted, under the laws at that time, had become invalid due to the later changes in the laws. Moreover, some of our patents were granted after these changes in the laws, but these may still be subject to risk of challenge due to uncertainty in interpreting and applying these newer changes in the laws related to medical diagnostic methods to our issued patent claims. Depending on future actions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. We cannot predict how this and future decisions laws or regulations by the courts, the U.S. Congress or the USPTO may impact the value of our patents. Any similar adverse changes in the patent laws of other jurisdictions could also harm our business, financial condition, results of operations and prospects.

We may be subject to claims, including third-party claims of intellectual property infringement, misappropriation or other violations against us or our collaborators, challenging the ownership or inventorship of our intellectual property and, if unsuccessful in any of these proceedings, we may be required to obtain licenses from third parties, which may not be available on commercially reasonable terms, or at all, or to cease the development, manufacture and commercialization of one or more of our products.

The medical device industry is highly competitive and dynamic. Due to the focused research and development that is taking place by several companies, including us and our competitors in this field, the intellectual property landscape is in flux and it may remain uncertain in the future. As such, we may be subject to claims that current or former employees, collaborators or other third parties have an interest, either as an owner, co-owner, or otherwise, in our patents, trade secrets or other intellectual property as an inventor or co-inventor. Additionally, we could become subject to significant intellectual property-related litigation and proceedings relating to our or third-party intellectual property and proprietary rights. For example, we may have inventorship disputes arise from conflicting obligations of employees, consultants or others who are involved in developing our products, or could face third-party claims of intellectual property infringement, misappropriation or other violations, including by a licensor from whom we've licensed certain intellectual property. These risks apply to our existing license from the Regents of the University of California, both in relation to patent rights we co-own with them as a result of joint invention between our and their respective inventors, and in relation to co-existent license rights that we share with another third-party company in some of those patent rights, as further summarized above.

Litigation may be necessary to defend against these and other claims challenging inventorship of our patents, trade secrets or other intellectual property. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, intellectual property that is important to our products. If we were to lose exclusive ownership of such intellectual property, other owners may be able to license their rights to other third parties, including our competitors. We also may be required to obtain and maintain licenses from third parties, including parties involved in any such disputes. Such licenses may not be available on commercially reasonable terms, or at all, or may be non-exclusive. If we are unable to obtain and maintain such licenses, we may need to cease the development, manufacture and commercialization of one or more of our products. The loss of exclusivity or the narrowing of our patent claims could limit our ability to stop others from using or commercializing similar or identical technology and products. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. Any of the foregoing could harm our business, financial condition and results of operations.

Additionally, our commercial success depends, in part, on our and any potential future collaborators' ability to develop, manufacture, market and sell any products that we may develop and use our proprietary technologies without infringing, misappropriating or otherwise violating the patents and other intellectual property or proprietary rights of third parties. It is uncertain whether the issuance of any third-party patent would require us or any potential collaborators to alter our development or commercial strategies, obtain licenses or cease certain activities. The medical device industry is characterized by extensive litigation regarding patents and other intellectual property rights, as well as administrative proceedings for challenging patents, including interference, inter partes or post-grant review, derivation and reexamination proceedings before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions.

Third parties, including our competitors, may currently have patents or obtain patents in the future and claim that the manufacture, use or sale of our products infringes upon these patents. We have not conducted an extensive search of patents issued or assigned to other parties, including our competitors, and no assurance can be given that patents containing claims relating to our products, parts of our products, technology or methods do not exist, have not been filed or could not be filed or issued. In addition, because patent applications can take many years to issue and because publication schedules for pending patent applications vary by jurisdiction, there may be applications now pending of which we are unaware and which may result in issued patents which our current or future products infringe. Also, because the claims of published patent applications can change between publication and patent grant, there may be published patent applications that may ultimately issue with claims that we infringe. Unintentionally abandoned patents or applications can also be revived, so there may be recently revived patents or applications of which we are unaware. As the number of competitors in our market grows and the number of patents issued in this area increases, the possibility of patent infringement claims against us escalates. Moreover, we may face claims from non-practicing entities, or NPEs, which have no relevant product revenue and against whom our own patent portfolio may have no deterrent effect. Third parties may in the future claim that our products infringe or violate their patents or other intellectual property rights.

Defense of infringement claims, regardless of their merit or outcome, would involve substantial litigation expense and would be a substantial diversion of management and other employee resources from our business, and may impact our reputation. In the event of a successful claim of infringement against us, we may be enjoined from further developing or commercializing the infringing products and/or have to pay substantial damages for use of the asserted intellectual property, including treble damages and attorneys' fees were we found to willfully infringe such intellectual property. Claims that we have misappropriated the confidential information or trade secrets of third parties could harm our business, financial condition and results of operations. We also might have to redesign any our allegedly infringing products or technologies, which may be impossible or require substantial time and monetary expenditure.

Engaging in litigation, including to defend against third-party infringement claims is very expensive, particularly for a company of our size, and time-consuming. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a substantial negative impact on our common stock price. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of litigation or administrative proceedings more effectively than we can because of greater financial resources and more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings against us could impair our ability to compete in the marketplace. The occurrence of any of the foregoing could harm our business, financial condition and results of operations.

We may become involved in lawsuits to protect or enforce our patents and other intellectual property rights, which could be expensive, time-consuming and unsuccessful.

Competitors may infringe our patents, or the patents of any current or future licensing partners, or we may be required to defend against claims of infringement. Our ability to enforce our patent rights against competitors who infringe our patents depends on our ability to detect such infringement. It may be difficult to detect infringers who do not advertise the components or processes that are used in their products or services. Moreover, it may be difficult or impossible to obtain evidence of infringement in a competitor's or potential competitor's product. For example, many of our patents relate to methods and related computer processing architectures and structures for post-processing data. The use of these methods and structures may not be obvious or certain to assess, and may not be possible or at least may be challenging to reveal or confirm by reverse engineering, based on limited evidence that might be available to us, such as for example from only being able to observe the results of using those methods or architectures. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded if we were to prevail may not be commercially meaningful.

In addition, our patents or the patents of our licensing partners also may become involved in inventorship, priority or validity disputes. For example, although we try to ensure that our employees, consultants and advisors are not in breach of any past contractual obligations and do not use the proprietary information or know-how of others in the work that they do for us, we may in the future become subject to claims that we or these individuals have, inadvertently or otherwise, used or disclosed intellectual property, including trade secrets or other proprietary information, of their former university or employer. Additionally, we may be subject to claims from third parties challenging intellectual property rights we regard as our own, based on claims that our agreements with employees or consultants obligating them to assign intellectual property to us are ineffective or in conflict with prior or competing contractual obligations to assign inventions to a previous employer, or to another person or entity. Furthermore, while it is our policy to require all employees and contractors to execute agreements assigning relevant intellectual property to us, we may also be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own. These assignment agreements may not be self-executing or adequate in scope, and may be breached or challenged, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. We may not have adequate remedies for any such breaches, and such claims could harm our business, financial condition and results of operations.

To counter or defend against such claims can be expensive and time-consuming and it may be necessary or we may desire to enter into a license to settle any such claims; however, there can be no assurance that we would be able to obtain a license on commercially reasonable terms, if at all. In an infringement proceeding, a court may decide that our patent is invalid or unenforceable or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover such technology. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during litigation.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our management and other personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a substantial negative impact on our common stock price. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could harm our ability to compete in the marketplace, including ability to hire new employees or contract with independent sales representatives. Additionally, we may lose valuable intellectual property rights or personnel. Any of the foregoing could harm our business, financial condition and results of operations.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be harmed.

Our registered and unregistered trademarks or trade names may be challenged, infringed, circumvented, declared generic or determined to be violating or infringing on marks held by others. We may not be able to protect our rights to these trademarks and trade names, which we need to build or sustain name recognition among potential partners, customers and patients in our markets of interest. At times, competitors or other third parties may adopt trade names or trademarks similar to ours, thereby impeding our ability to continue to build brand identity and possibly leading to market confusion. In fact, a practice exists with international scope, and which may become manifest in a given case in any or only certain territories, in which certain third parties will deliberately secure or allege they own trademarks or tradenames that are specifically being first used by another party in order to extort license fees or damages in those territories in which the original user of the mark had not filed or perfected its rights to the mark. In addition, there could be potential trade name or trademark infringement, or dilution claims brought by owners of other trademarks. Over the long term, if we are unable to establish name recognition based on our trademarks, trade names, domain names or other intellectual property, then we may not be able to compete effectively, and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, trade secrets, domain names or other intellectual property may be ineffective, could result in substantial costs, diversion of resources, or adverse impact to our brand and could harm our sales, business, financial condition, and results of operations.

Intellectual property rights do not necessarily address all potential threats, and limitations in intellectual property rights could harm our business, financial condition and results of operations.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, may evolve, and may not adequately protect our business or permit us to maintain our competitive advantage. For example:

- others may be able to make products that are similar to our products or utilize similar technology but that are not covered by the claims of our patents or that incorporate certain technology in our products that is in the public domain;
- our intellectual property strategy may be limited, we may not seek protection for intellectual property that may ultimately become relevant to our business or our invention disclosure process may prove insufficient to encourage inventors to come forward with protectable intellectual property;
- we, or our current or future licensors or collaborators, might not have been the first to make the inventions related to the applicable issued patent or pending patent application assigned or licensed to us now or in the future;

- we, or our current or future licensors or collaborators, might not have been the first to file patent applications covering certain of our or their inventions;
- we, or our current or future licensors or collaborators, may fail to meet our obligations to the U.S. government regarding any future patents and patent applications funded by U.S. government grants, leading to the loss or unenforceability of patent rights;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our current or future pending patent applications will not lead to issued patents;
- it is possible that there are prior public disclosures that could invalidate our patents, or parts of our patents;
- it is possible that there are unpublished applications or patent applications maintained in secrecy that may later issue with claims related to our products or technology similar to ours;
- it is possible that our patents or patent applications omit individuals that should be listed as inventors or include individuals that should not be listed as inventors, which may cause these patents or patents issuing from these patent applications to be held invalid or unenforceable;
- issued patents that we hold rights to may be held invalid or unenforceable, including as a result of legal challenges by our competitors or other third parties;
- the claims of our patents or patent applications, if and when issued, may not cover our products or technologies;
- the laws of foreign countries may not protect our proprietary rights or the rights of current or future licensors or collaborators to the same extent as the laws of the United States;
- the inventors of our patents or patent applications may become involved with competitors, develop products or processes that design around our patents, or become hostile to us or the patents or patent applications on which they are named as inventors;
- our competitors or other third parties might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we have engaged in scientific collaborations in the past and will continue to do so in the future and our collaborators may develop adjacent or competing products that are outside the scope of our patents;
- we may not develop additional proprietary technologies that are patentable;
- our trade secrets may be misappropriated, without an ability to know or reverse engineer the misappropriation, or we may lose trade secret protections based on a failure to properly establish or maintain them;
- certain employees, consultants, or other collaborators may be engaged on terms that do not prevent them from inventing improvements, modifications, alterations, derivations of our technologies and methods, or otherwise from inventing alternative or new technologies or methods and pursuing them outside of and competitive with the company;
- the patents of others may harm our business; or
- we may choose not to file a patent in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property, and thereby potentially preventing us from continuing to use those related technologies or practice those related methods.

Any of the foregoing could harm our business, financial condition and results of operations.

If we are unable to protect the confidentiality of our other proprietary information, our business and competitive position may be harmed.

In addition to patent protection, we also rely on other proprietary rights, including protection of trade secrets, know-how and other confidential or proprietary information that is not patentable or that we elect not to patent. However, such information can be difficult to protect, and some courts, for instance, are less willing or unwilling to protect trade secrets. To maintain the confidentiality of our trade secrets and proprietary information, we rely heavily on confidentiality provisions that we have in contracts with our employees, consultants, collaborators, suppliers, customers, and others upon the commencement of their relationship with us. We cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets or proprietary technology and processes. Furthermore, we may not be able to prevent the unauthorized disclosure or use of our technical knowledge or other trade secrets by such third parties, despite the existence generally of these confidentiality restrictions. These contracts may not provide meaningful protection or equitable remedies for our trade secrets, know-how, or other proprietary information in the event of any unauthorized use, misappropriation, or disclosure of such trade secrets, know-how, or other proprietary information. There can be no

assurance that such third parties will not breach their agreements with us, that we will have adequate remedies for any breach, or that our trade secrets will not otherwise become known or independently developed by competitors. Despite the protections we do place on our intellectual property or other proprietary rights, monitoring unauthorized use and disclosure of our intellectual property is difficult, and we do not know whether the steps we have taken to protect our intellectual property or other proprietary rights have or will be adequate. Trade secret violations are often a matter of state law, and the criteria for protection of trade secrets can vary among different jurisdictions. In addition, the laws of many foreign countries will not protect our intellectual property or other proprietary rights to the same extent as the laws of the United States. Consequently, we may be unable to prevent our proprietary technology from being exploited abroad, which could affect our ability to expand to foreign markets or require costly efforts to protect our products.

We also license rights to use certain proprietary information and technology from third parties. The use of such proprietary information and technology is therefore subject to the obligations of the applicable license agreement between us and the owner. For example, the software we developed for our technology includes the use of open source software that is subject to the terms and conditions of the applicable open source software licenses that grant us permission to use such software. The owner of any such proprietary information or technology also might not enforce or otherwise protect its rights in the proprietary information or technology with the same vigilance that we would, which would allow competitors to use such proprietary information and technology without having to adhere to a license agreement with the owner.

To the extent our intellectual property or other proprietary information protection is incomplete, we are exposed to a greater risk of direct competition. A third party could, without authorization, copy or otherwise obtain and use our products or technology, or develop similar products or technology. Our competitors could purchase our products and attempt to reverse engineer or replicate some or all of the competitive advantages we derive from our development efforts or design around our protected products or technology. Our failure to secure, protect and enforce our intellectual property rights could substantially harm the value of our products, brand and business. The theft or unauthorized use or publication of our trade secrets and other confidential business information could reduce the differentiation of our products, substantially and adversely impact our sales and commercial operations and harm our business. Additionally, the value of our investment in development or business acquisitions could be reduced and third parties might make claims against us related to losses of their confidential or proprietary information. Any of the foregoing could materially and adversely affect our business, financial condition and results of operations.

Further, it is possible that others will independently develop the same or similar technology or product or otherwise obtain access to our unpatented technology, and in such cases, we could not assert any trade secret rights against such parties. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our trade secret rights and related confidentiality and nondisclosure provisions. If we fail to obtain or maintain trade secret protection, or if our competitors otherwise obtain our trade secrets or independently develop technology or products similar to and potentially competing with our products, our competitive market position could be materially and adversely affected. In addition, some courts are less willing or unwilling to protect trade secrets and agreement terms that address non-competition are difficult to enforce in many jurisdictions and might not be enforceable in certain cases.

We also seek to preserve the integrity and confidentiality of our data and other confidential information by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations, systems and tools, agreements or security measures may be breached, whereby detecting the disclosure or misappropriation of confidential information and enforcing a claim that a party illegally disclosed or misappropriated confidential information is difficult, expensive and time-consuming, and the outcome is unpredictable. Further, we may not be able to obtain adequate remedies for any breach.

Our inability to use software licensed from third parties, or our use of open source software under license terms that interfere with our proprietary rights, could disrupt our business.

Our products, including our technology and methods used, include the use of open source software that is subject to the terms and conditions of the applicable open source software licenses that grant us permission to use such software. Although we monitor our use of open source software, the terms of many open source licenses to which we are subject have not been interpreted by U.S. or foreign courts, and there is a risk that such licenses could be construed in a manner that imposes unanticipated conditions or restrictions on our ability to provide our technology to our customers. Moreover, we cannot ensure that we have not incorporated additional open source software in our products in a manner that is inconsistent with the terms of the applicable license or our current policies and procedures. In the future,

we could be required to seek licenses from third parties in order to continue offering our solutions, which licenses may not be available on terms that are acceptable to us, or at all. Claims related to our use of open source software could also result in litigation, require us to purchase costly licenses or require us to devote additional research and development resources to change the software underlying our technology, any of which would have a negative effect on our business, financial condition and operating results and may not be possible in a timely manner. We and our customers may also be subject to suits by parties claiming infringement due to the reliance by our products on certain open source software, and such litigation could be costly for us to defend or subject us to injunctions enjoining us from the sale of our products that contain open source software.

Alternatively, we may need to re-engineer our products or discontinue using portions of the functionality provided by our products. In addition, the terms of open source software licenses may require us to provide software that we develop using such software to others on unfavorable terms, such as by precluding us from charging license fees, requiring us to disclose our source code, requiring us to license certain of our own source code under the terms of the applicable open source license or requiring us to provide notice on our products using such code. Any such restriction on the use of our own software, or our inability to use open source or third-party software, could result in disruptions to our business or operations, or delays in our development of future products or enhancements of our existing products, such as our RNS System, which could impair our business.

Other risks facing our company

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit or halt the marketing and sale of our technology. The expense and potential unavailability of insurance coverage for liabilities resulting from our technology could harm our business and our ability to sell our technology

We face an inherent risk of product liability as a result of the marketing and sale of our technology. Although we have established internal procedures designed to minimize risks that may arise from quality issues, there can be no assurance that we will eliminate or mitigate occurrences of these issues and associated liabilities. Our products and services are diagnostic in nature and involve an exam that is non-invasive using other third-party MR scanner products and technologies. Those exams are also conducted by other third party MR service providers. The results of using our products are also intended to provide information to doctors that help them perform a diagnosis for their patient, using all other diagnostic information that is available to them. The downstream results from those diagnoses may also lead to certain treatments being performed, which are decided upon between that treating doctor and the patient (and related payers), and which are conducted by that treating doctor on the patient. We are not responsible for the performance of those MR scanners, nor for the performance of the MR service providers for conducting those patient exams using the MR scanners, nor for the final diagnosis performed by a doctor as assisted via the results of our products in combination with other available information, nor for the decisions and performance on conducting treatments or other on-going patient care, or the patient outcomes from that care, following the use of our diagnostic assistance product. However, there are risks that certain liability exposures or claims could be threatened or actually filed against us with respect to the performance or results of these other activities around and relating to, but not directly caused by, the use of our products, including with respect to the use of our products in the overall patient care regimen that might result in adverse patient outcomes. Even if we successfully defend any such allegation or claim, this could involve significant risk of liability exposure and significant cost and diversion of resources and focus.

If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit or halt commercialization of our products. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our technology;
- injury to our brand or reputation;
- initiation of investigations by regulators;
- costs to defend the related litigation;
- increased insurance premiums;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- regulatory investigations, product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;
- exhaustion of any available insurance and our capital resources; and

- the inability to market and sell our products.

We believe we have adequate product liability insurance, but it may not prove to be adequate to cover all liabilities that we may incur. Insurance coverage is increasingly expensive. We currently carry product liability insurance in the amount of $5 million in the aggregate. In the future, we may not be able to maintain or obtain insurance at a reasonable cost or in an amount adequate to satisfy any liability that may arise. Our insurance policy contains various exclusions, and we may be subject to a product liability claim for which we have no coverage. The potential inability to obtain sufficient product liability insurance at an acceptable cost to protect against product liability claims could prevent or inhibit the marketing and sale of products we may develop. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts, which would harm our business, financial condition and results of operations. In addition, any product liability claims brought against us, with or without merit, could increase our product liability insurance rates or prevent us from securing continuing coverage, harm our patient-focused brand, negatively impact our reputation in the industry, significantly increase our expenses and reduce product sales.

Some of our customers may also have difficulty in procuring or maintaining liability insurance to cover their operations, including their use of our products. Medical malpractice carriers are withdrawing coverage in certain states or substantially increasing premiums. If this trend continues or worsens, our customers may discontinue using our products and potential additional customers may opt against purchasing our products due to the cost or inability to procure insurance coverage.

The failure of third parties to meet their contractual, regulatory and other obligations could adversely affect our business.

We rely on licensors, suppliers, vendors, partners, consultants, and other third parties to research, develop, and partake in both the commercialization of our technology, as well as manage certain parts of our business. Using these third parties poses a number of risks, such as:

- they may not perform to our standards or legal requirements;
- they may not produce reliable results;
- they may not perform in a timely manner;
- they may not maintain confidentiality of our proprietary information;
- disputes may arise with respect to ownership of rights to products developed with our partners; and
- disagreements could cause delays in, or termination of, the research, development or commercialization of our products or result in litigation or arbitration.

If and as any of one or more of these identified parties might be replaced in the future by another party with whom we might engage or rely upon for similar technological or business purposes, or to the extent we may expand our business to involve and rely on still more additional parties for similar purposes as those listed (e.g. additional MR scanner vendors), similar risks would apply to those other parties.

Moreover, some third parties may be located in markets subject to political and social risk, corruption, infrastructure problems and natural disasters, in addition to country-specific privacy and data security risk given current legal and regulatory environments. Failure of third parties to meet their contractual, regulatory and other obligations may materially affect our business.

Litigation and other legal proceedings may harm our business.

From time to time in the future we may become involved in legal proceedings relating to patent and other intellectual property matters, product liability claims, employee matters, tort or contract claims, federal regulatory investigations, private rights of action, securities class action and other legal proceedings or investigations, which could have a negative impact on our reputation, business and financial condition and divert the attention of our management from the operation of our business.

Litigation is inherently unpredictable and can result in excessive or unanticipated verdicts, judgements, and/or injunctive relief that affect how we operate our business. We could incur judgments or enter into settlements of claims for monetary damages or for agreements to change the way we operate our business, or both. There may be an increase in the scope of these or other matters or there may be

additional lawsuits, claims, proceedings or investigations in the future, which could harm our business, financial condition and results of operations. Adverse publicity about regulatory or legal action against us, irrespective of outcome, could damage our reputation and brand image, undermine our customers' confidence and reduce long-term demand for our products, even if the regulatory or legal action is unfounded or not material to our operations.

Our stock price may be volatile, and the value of our common stock and IPO Warrants may decline.

The market price of our common stock and IPO Warrants may be highly volatile and may fluctuate or decline substantially as a result of a variety of factors, some of which are beyond our control or are related in complex ways, including:

- Actual or anticipated fluctuations in our financial condition and results of operations;
- Variance in our financial performance from expectations of securities analysts or investors;
- Changes in the coverage decisions, reimbursement or pricing of our technology;
- Changes in our projected operating and financial results;
- Changes in laws or regulations applicable to our technology;
- Announcements by us or our competitors of significant business developments, acquisitions, or new offerings;
- Publicity associated with issues related to our technology;
- Our involvement in regulatory investigations or litigation;
- Future sales of our common stock or other securities, by us or our stockholders, as well as the anticipation of lock-up releases;
- Changes in senior management or key personnel;
- The trading volume of our common stock;
- Changes in the anticipated future size and growth rate of our market;
- General economic, regulatory, and market conditions, including economic recessions or slowdowns;
- The impact of the COVID-19 pandemic;
- Changes in the structure of healthcare payment systems; and
- Developments or disputes concerning our intellectual property or other proprietary rights.

Broad market and industry fluctuations, as well as general economic, political, regulatory, and market conditions, may negatively impact the market price of our common stock. In addition, given the relatively small expected public float of shares of our common stock on the Nasdaq Capital Market, the trading market for our shares may be subject to increased volatility. In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us, because medical device companies have experienced significant stock price volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm our reputation and our business.

Our operating results may fluctuate across periods, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations or any guidance we may provide.

Our quarterly and annual operating results may fluctuate across periods, which makes it difficult for us to predict our future operating results. Accordingly, the results of any one quarter or period should not be relied upon as an indication of future performance. Our quarterly and annual operating results may fluctuate due to a variety of factors, many of which are outside of our control, including, but not limited to:

- The level of demand for our technology and any future technology, which may vary significantly from period to period;
- Expenditures that we may incur to acquire, develop or commercialize additional technology;
- The timing and cost of obtaining regulatory approvals or clearances to expand our indications and get future approvals of any future technology or features;
- Pricing pressures;
- Our ability to expand the geographic reach of our commercial efforts;

- The degree of competition in our industry and any change in the competitive landscape of our industry, including consolidation among our competitors or future partners;
- Coverage and reimbursement policies with respect to our technology, and potential future technology that compete with our products;
- The timing and success or failure of preclinical or clinical studies for expanding the indications of our technology or any future technology we develop or competing technology;
- Positive or negative coverage in the media or clinical publications of our technology or technology of our competitors or our industry;
- The impact of COVID-19 on procedure volume or otherwise;
- The timing and cost of, and level of investment in, research, development, licenses, regulatory approval, commercialization activities, acquisitions and other strategic transactions, or other significant events relating to our technology, which may change from time to time;
- The cost of developing our technology, which may vary depending on the terms of our agreements with third-party; and
- Future accounting pronouncements or changes in our accounting policies.

The cumulative effects of these factors could result in fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period-to-period basis may not be meaningful. Further, our historical results are not necessarily indicative of results expected for any future period, and quarterly results are not necessarily indicative of the results to be expected for the full year or any other period. Investors should not rely on our past results as an indication of our future performance.

This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our revenue or operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the market, it could harm our business, financial condition, and results or operations.

We will incur increased costs as a result of operating as a public company, and our management and board of directors will be required to devote substantial time to compliance with our public company responsibilities and corporate governance practices.

As a public company, we will incur significant legal, accounting and other expenses that we did not incur as a private company. We expect such expenses to further increase after we are no longer an emerging growth company. The Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of the Nasdaq Capital Market, and other applicable securities rules and regulations impose various requirements on public companies. Furthermore, most senior members of our management team as well as our board of directors do not have significant experience with operating a public company. As a result, our management, board of directors, and other personnel will have to devote a substantial amount of time to compliance with these requirements. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. We cannot predict or estimate the amount of additional costs we will incur as a public company or the timing of such costs.

Risks related to the ownership of our common stock and IPO Warrants

We are not currently in compliance with the minimum bid price rule of the Nasdaq Capital Market and a delisting could limit the liquidity of our stock, increase its volatility and hinder our ability to raise capital.

As reported in our Current Report on Form 8-K filed on December 23, 2022, on December 20, 2022 we received a written notice (the "Notice") from the Listing Qualifications Department of The Nasdaq Stock Market ("Nasdaq") indicating that the Company is not in compliance with the $1.00 Minimum Bid Price requirement set forth in Nasdaq Listing Rule 5550(a)(2) for continued listing on The Nasdaq Capital Market (the "Bid Price Requirement"). The Notice does not result in the immediate delisting of the Company's common stock from The Nasdaq Capital Market.

The Nasdaq Listing Rules require listed securities to maintain a minimum bid price of $1.00 per share and, based upon the closing bid price of the Company's common stock for the 30 consecutive business days for the period November 4 through December 19, 2022, the Company no longer meets this requirement.

The Notice indicated that the Company will be provided 180 calendar days in which to regain compliance. If at any time during this 180 calendar day period the bid price of the Company's common stock closes at or above $1.00 per share for a minimum of ten consecutive business days, the Nasdaq staff (the "Staff") will provide the Company with a written confirmation of compliance and the matter will be closed.

Alternatively, if the Company fails to regain compliance with Rule 5550(a)(2) prior to the expiration of the initial 180 calendar day period, the Company may be eligible for an additional 180 calendar day compliance period, provided (i) it meets the continued listing requirement for market value of publicly held shares and all other applicable requirements for initial listing on The Nasdaq Capital Market (except for the Bid Price Requirement) and (ii) it provides written notice to Nasdaq of its intention to cure this deficiency during the second compliance period by effecting a reverse stock split, if necessary. In the event the Company does not regain compliance with Rule 5550(a)(2) prior to the expiration of the initial 180 calendar day period, and if it appears to the Staff that the Company will not be able to cure the deficiency, or if the Company is not otherwise eligible, the Staff will provide the Company with written notification that its securities are subject to delisting from The Nasdaq Capital Market. At that time, the Company may appeal the delisting determination to a Hearings Panel.

If our common stock is delisted by Nasdaq, our common stock may be eligible for quotation on an over-the-counter quotation system or on the pink sheets. Upon any such delisting, our common stock would become subject to the regulations of the SEC relating to the market for penny stocks. A penny stock is any equity security not traded on a national securities exchange that has a market price of less than $5.00 per share. The regulations applicable to penny stocks may severely affect the market liquidity for our common stock and could limit the ability of shareholders to sell securities in the secondary market. In such a case, an investor may find it more difficult to dispose of or obtain accurate quotations as to the market value of our common stock, and there can be no assurance that our common stock will be eligible for trading or quotation on any alternative exchanges or markets.

Delisting from Nasdaq could adversely affect our ability to raise additional financing through public or private sales of equity securities, would significantly affect the ability of investors to trade our securities and would negatively affect the value and liquidity of our common stock. Delisting could also have other negative results, including the potential loss of confidence by employees, the loss of institutional investor interest and fewer business development opportunities.

Our executive officers, directors and principal stockholders will maintain the ability to control all matters submitted to our stockholders for approval.

Our executive officers, directors and stockholders who owned more than 5% of our outstanding common stock as of February 1, 2023, in the aggregate, beneficially own shares representing approximately 35% of our common stock upon completion of this offering. As a result, if these stockholders were to act together, they would be most likely be able to control or significantly influence all matters submitted to our stockholders for approval, as well as our management and affairs. For example, these persons, if they act together, would likely control the election of directors and approval of any merger, consolidation, or sale of all or substantially all of our assets. This concentration of voting power could delay or prevent an acquisition of our company on terms that other stockholders may desire or result in management of our company with which our public stockholders disagree.

A significant portion of our total outstanding shares are restricted from immediate resale but may be sold into the market in the near future, which could cause the market price of our common stock to drop significantly, even if our business is performing well.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that holders of a large number of shares intend to sell shares, could reduce the market price of our common stock.

You may experience additional dilution if our IPO Warrants are exercised.

If the holders of our IPO Warrants exercise their IPO Warrants, you will experience dilution at the time they exercise their IPO Warrants.

As part of our April 2022 IPO, we issued a warrant to the representative of our IPO underwriters that is exercisable for 173,200 shares of common stock (the "Representative's Warrant"). If the representative of the underwriters exercises the Representative's Warrant, you will experience additional dilution.

The price of our common stock and IPO Warrants may be volatile and fluctuate substantially, which could result in substantial losses for investors in our common stock and IPO Warrants.

Our common stock price and Warrant price are likely to be volatile. The stock market in general and the market for bio-technology companies in particular, has experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, you may not be able to sell your common stock at or above your investment price. The market price for our common stock may be influenced by many factors, including:

- the success of competitive products or technologies;
- regulatory or legal developments in the United States,
- the recruitment or departure of key personnel;
- the level of expenses related to any of our product candidates, and our commercialization efforts;
- actual or anticipated changes in our development timelines;
- our ability to raise additional capital;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our product candidates;
- significant lawsuits, including patent or stockholder litigation;
- variations in our financial results or those of companies that are perceived to be similar to us;
- general economic, industry and market conditions; and
- the other factors described in this “Risk Factors” section.

If our quarterly operating results fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. Furthermore, any quarterly fluctuations in our operating results may, in turn, cause the price of our stock to fluctuate substantially. We believe that quarterly comparisons of our financial results are not necessarily meaningful and should not be relied upon as an indication of our future performance.

In the past, following periods of volatility in the market price of a company’s securities, securities class-action litigation often has been instituted against that company. Such litigation, if instituted against us, could cause us to incur substantial costs to defend such claims and divert management’s attention and resources.

Because we do not expect to pay dividends for the foreseeable future, investors seeking cash dividends should not purchase shares of our common stock.

We have never declared or paid any cash dividends on our common stock. We currently intend to retain future earnings, if any, to finance the expansion of our business. As a result, we do not anticipate paying any cash dividends in the foreseeable future. Our payment of any future dividends will be at the discretion of our Board of Directors after taking into account various factors, including but not limited to our financial condition, operating results, cash needs, growth plans and the terms of any credit agreements that we may be a party to at the time. Accordingly, investors seeking cash dividends should not purchase our shares.

Warrants are speculative in nature.

Our IPO Warrants do not confer any rights of common stock ownership on their holders, such as voting rights or the right to receive dividends, but rather merely represent the right to acquire shares of our common stock at a fixed price for a limited period of time. Specifically, holders of the IPO Warrants may exercise their right to acquire the common stock and pay an exercise price of $4.35, prior to 5 years from the date of issuance, after which date any unexercised IPO Warrants will expire and have no further value. Moreover, the market value of the IPO Warrants is uncertain. There can be no assurance that the market price of the common stock will ever equal or exceed the exercise price of the IPO Warrants, and, consequently, whether it will ever be profitable for holders of the warrants to exercise the IPO Warrants.

If securities analysts do not publish research or reports about our business or if they publish negative evaluations of our stock, the price of our stock could decline.

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

We are an emerging growth company and a smaller reporting company, and our compliance with the reduced reporting and disclosure requirements applicable to emerging growth companies and smaller reporting companies could make our common stock and IPO Warrants less attractive to investors.

We are an emerging growth company, as defined in the JOBS Act, and we expect to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including the auditor attestation requirements of Section 404, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved and extended adoption period for accounting pronouncements.

Even after we no longer qualify as an emerging growth company, we may still qualify as a "smaller reporting company," which would allow us to continue to take advantage of many of the same exemptions from disclosure requirements, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act and reduced disclosure obligations regarding executive compensation in this prospectus and our periodic reports and proxy statements.

We cannot predict whether investors will find our common stock less attractive as a result of our reliance on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

We will remain an emerging growth company until the earliest of (i) the end of the fiscal year following the fifth anniversary of the completion of our IPO, (ii) the first fiscal year after our annual gross revenues exceed $1.07 billion, (iii) the date on which we have, during the immediately preceding three-year period, issued more than $1.00 billion in non-convertible debt securities, or (iv) the end of any fiscal year in which the market value of our common stock held by non-affiliates exceeds $700 million as of the end of the second quarter of that fiscal year.

Provisions in our corporate charter and our bylaws and under Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.

The anti-takeover provisions of the Delaware General Corporation Law (the "DGCL") may discourage, delay or prevent a change in control by prohibiting us from engaging in a business combination with an interested stockholder for a period of three years after the person becomes an interested stockholder, even if a change in control would be beneficial to our existing stockholders.

Provisions in our corporate charter and our bylaws discourage, delay or prevent a merger, acquisition or other change in control of us that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares.

These provisions also could limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our board of directors is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Among other things, these provisions:

- allow the authorized number of our directors to be changed only by resolution of our board of directors;
- limit the manner in which stockholders can remove directors from the board;
- establish advance notice requirements for stockholder proposals that can be acted on at stockholder meetings and nominations to our board of directors;
- require that stockholder actions must be effected at a duly called stockholder meeting and prohibit actions by our stockholders by written consent;
- limit who may call stockholder meetings;
- authorize our board of directors to issue preferred stock without stockholder approval, which could be used to institute a stockholder rights plan, or so-called "poison pill," that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our board of directors; and

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the DGCL, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware or, under certain circumstances, the federal district courts of the United States of America will be the exclusive forums for certain types of actions and proceedings that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, employees or agents.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware (or, if the Court of Chancery of the State of Delaware lacks subject matter jurisdiction, any state court located within the State of Delaware or, if all such state courts lack subject matter jurisdiction, the federal district court for the District of Delaware) is the sole and exclusive forum for the following types of actions or proceedings under Delaware statutory or common law for:

- any derivative action or proceeding brought on our behalf;
- any action asserting a breach of fiduciary duty;
- any action arising pursuant to the Delaware General Corporation Law, our amended and restated certificate of incorporation, or our amended and restated bylaws; and
- any action asserting a claim against us that is governed by the internal-affairs doctrine.

These provisions would not apply to suits brought to enforce a duty or liability created by the Exchange Act or any claim for which the federal district courts of the United States of America have exclusive jurisdiction. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims.

Our stockholders cannot waive compliance with the federal securities laws and the rules and regulations thereunder. Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock will be deemed to have notice of, and consented to, the provisions of our amended and restated certificate of incorporation described in the preceding sentences.

To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our amended and restated certificate of provides that the federal district courts of the United States will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions. In such instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of our amended and restated certificate of incorporation in effect upon the effectiveness of our IPO. This may require significant additional costs associated with resolving such action in other jurisdictions and there can be no assurance that the provisions will be enforced by a court in those other jurisdictions.

These exclusive forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers, or other employees, which may discourage lawsuits against us and our directors, officers and other employees. If a court were to find either exclusive-forum provision in our amended and restated certificate of incorporation in effect upon the effectiveness of our IPO to be inapplicable or unenforceable in an action, we may incur further significant additional costs associated with resolving the dispute in other jurisdictions, all of which could harm our business and financial condition.

Item 1B Unresolved Staff Comments

None.

Item 2 Properties

Our current office lease and sublease expired on June 30, 2022. The Company does not have any contractual obligations not otherwise on our balance sheet as of December 31, 2022.

Rent expense for the year ended December 31, 2022 and 2021 was $36,070 and $64,932, respectively. The Company entered into a subleasing agreement in 2021 and realized $26,340 and $48,400 of sublease income for the year ended December 31, 2022, and 2021. Both the lease and sublease are netted within the general & administrative line item in the Statements of Operations.

Item 3 Legal Proceedings

From time to time, we may be involved in litigation relating to claims arising out of our operations in the normal course of business. We are not currently a party to any material legal proceedings, the adverse outcome of which, in our management's opinion, individually or in the aggregate, could have a material adverse effect on the results of our operations or financial position. There are no material proceedings in which any of our directors, officers or affiliates or any registered or beneficial stockholder of more than 5% of our common stock is an adverse party or has a material interest adverse to our interest.

Item 4 Mine Safety Disclosures

None.

PART II

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

Our common stock has been traded on the Nasdaq Stock Market under the symbol "ACON" since our IPO on April 21, 2022. Our IPO Warrants have been traded on the Nasdaq Stock Market under the symbol "ACONW" since our IPO on April 21, 2022. As of February 24, 2023, there were approximately 153 holders of record of our common stock and 1 holder of record of our IPO Warrants. These numbers are based on the actual number of holders registered at such date and does not include holders whose shares are held in "street name" by brokers and other nominees.

Dividends

We have never paid any cash dividends on our common stock. We currently intend to retain all available funds and any future earnings for use in the operation of our business and do not anticipate paying any cash dividends on our common stock in the foreseeable future. Any future determination to declare dividends will be made at the discretion of our board of directors and will depend on our financial condition, operating results, capital requirements, general business conditions and other factors that our board of directors may deem relevant.

Recent Sales of Unregistered Securities

In connection with our IPO, on April 21, 2022 the Company effected a 1-for-7.47 reverse stock split (the "Reverse Stock Split") of its issued and outstanding common stock. All per share amounts and numbers of shares of common stock below reflect the Reverse Stock Split.

From January 1, 2019 through December 31, 2022, we sold and issued the following unregistered securities:

- During 2018 and early 2019, the Company conducted a financing consisting of Preferred B-1 shares, which accrued 6% interest. A total of $5,217,698 was raised in 2018 and $2,463,328 was raised in 2019.
- In February 2020, the Company issued to Nuvasive, Inc. a $2 million "SAFE" (Simple Agreement for Future Equity). In December 2021, the SAFE was converted into shares of Series B-2 Preferred Stock.
- In February 2020 and continuing through June 2021, the Company conducted a financing in the form of 6% convertible promissory notes due June 30, 2021. This financing raised $2,114,041 during 2020 and $814,000 during the first six months of 2021. In December 2021, all such notes were converted into shares of Series B-3 Preferred Stock.
- In connection with the above-referenced note financing, the Company also issued certain common stock warrants. Such warrants were net exercised immediately prior to our IPO, resulting in the issuance of 60,408 shares of common stock.
- In February 2021 and April 2020, the Company entered into two promissory notes (the "PPP Notes") evidencing an unsecured loan (the "Loan") in the amounts of $125,000 and $245,191 made to the Company under the Paycheck Protection Program (the "PPP"). The PPP was established under the CARES Act and is administered by the U.S. Small Business Administration.
- In June 2021, the Company issued $2.0 million of secured promissory notes that would mature at the earlier of the consummation of a qualified financing or May 31, 2022. These secured notes incorporated the following major attributes; interest on the secured notes accrues at 33%, and the accrued interest would automatically convert into the securities offered in a qualified financing, at a per security price equal to the offering price of the qualified financing multiplied by 0.30 (70% discount).

- In connection with our April 2022 IPO, all of our outstanding shares of our preferred stock were converted into 3,279,117 shares of common stock.
- In connection with our April 2022 IPO, all accrued dividends on our outstanding shares of preferred stock were converted into 984,429 shares of common stock.

- In connection with our April 2022 IPO, all accrued interest on our secured notes was converted into (i) 426,767 shares of common stock and (ii) 426,767 common stock warrants.

- From January 1, 2019, through April 2022, we granted to our consultants, employees, officers and directors options to purchase an aggregate of 2,151,694 shares of common stock at per share exercise prices ranging from $1.34 to $1.94 under our 2015 Stock Plan. Included in those totals were grants made during 2021 of options to purchase an aggregate of 1,905,581 shares of Common Stock at a per share exercise price of $1.94.

- From January 1, 2019, through April 2022, we issued an aggregate of 1,339 shares of Common Stock pursuant to the exercise of options by our consultants, employees, officers and directors.

- In November 2022, we issued 40,000 restricted shares of Common Stock to a vendor in partial payment of vendor fees.

These sales and issuances were deemed to be exempt from registration under the Securities Act in reliance upon Section 4(a)(2) of the Securities Act and/or Regulation D or Rule 701 promulgated thereunder, and did not involve any underwriters, underwriting discounts or commissions, or any public offering. The persons and entities who received such securities have represented their intention to acquire these securities for investment only and not with a view to or for sale in connection with any distribution thereof, and appropriate legends are be affixed to all share certificates issued. All recipients had adequate access through their relationship with us to information about us.

None of the foregoing transactions involved any underwriters, underwriting discounts or commissions, or any public offering, and we believe each transaction was exempt from the registration requirements of the Securities Act in reliance upon Section 4(2) of the Securities Act or Regulation D or Rule 701 promulgated under the Securities Act. Furthermore, we affixed appropriate legends to the share certificates and instruments issued in each foregoing transactions setting forth that the securities had not been registered and the applicable restrictions on transfer.

Use of Proceeds

On April 21, 2022, the registration statement (SEC Registration No. 333-262026) for our IPO was declared effective. There has been no material change in the planned use of proceeds from our IPO from that described in the related prospectus dated April 21, 2022, filed with the SEC pursuant to Rule 424(b)(4) under the Securities Act. As described in such IPO prospectus, we have used the IPO proceeds: (i) to retire all $2,000,000 of outstanding secured notes; (ii) to pay approximately $124,000 for a milestone license fee; (iii) to pay $458,000 of bonuses; (iv) to pay approximately $930,000 to reduce accounts payable; and (v) to pay ongoing operating expenses.

Issuer Purchases of Equity Securities

We did not repurchase any of our equity securities during the period covered by this Annual Report.

Item 6. [Reserved]

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

You should read the following discussion and analysis of our financial condition and results of operations in conjunction with the audited financial statements (prepared in accordance with accounting principles generally accepted in the United States ("U.S. GAAP")) and related notes included elsewhere in this Annual Report on Form 10-K (this "Form 10-K"). The following discussion contains forward-looking statements that are subject to risks and uncertainties. See "Special Note Regarding Forward-Looking Statements" for a discussion of the uncertainties, risks, and assumptions associated with those statements. Actual results could differ materially from those discussed in or implied by forward-looking statements as a result of various factors, including those discussed below and elsewhere in this Form 10-K, particularly in the section entitled "Risk Factors." Unless we state otherwise or the context otherwise requires, the terms "we," "us," "our" and the "Company" refer to Aclarion, Inc.

Overview

Aclarion is a healthcare technology company that leverages Magnetic Resonance Spectroscopy ("MRS"), proprietary signal processing techniques, biomarkers, and augmented intelligence algorithms to optimize clinical treatments. The Company is first addressing the chronic low back pain market with Nociscan, the first, evidence-supported, SaaS platform to noninvasively help physicians distinguish between painful and nonpainful discs in the lumbar spine. Through a cloud connection, Nociscan receives magnetic resonance spectroscopy (MRS) data from an MRI machine for each lumbar disc being evaluated. In the cloud, proprietary signal processing techniques extract and quantify chemical biomarkers demonstrated to be associated with disc pain. Biomarker data is entered into proprietary algorithms to indicate if a disc may be a source of pain. When used with other diagnostic tools, Nociscan provides critical insights into the location of a patient's low back pain, giving physicians clarity to optimize treatment strategies.

We have funded our operations with proceeds from the April 2022 IPO. Since inception we have incurred significant operating losses. As of December 31, 2022, we had an accumulated deficit of approximately $39.9 million. Our ability to generate product revenue sufficient to achieve profitability will depend heavily on the successful commercialization and continued development of our SaaS platform. We expect that our expenses and capital requirements will increase substantially in connection with our ongoing activities, particularly if and as we:

- identify and support Key Opinion Leader ("KOL") physicians and radiologists to help secure local payer coverage decisions and spine society support for our technology;
- expand the network of imaging centers and physicians using NOCISCAN in each market such that the technology is widely available to patients covered by payers;
- support surgeons, radiologists, Physical Medicine and Rehabilitation physicians, chiropractors, physical therapists, regenerative therapy physicians and medical device companies that address low back pain to initiate studies and report results;
- build and expand clinical trials and registries to provide real world evidence of better outcomes when using Nociscan to help determine which discs to treat;
- pursue value-based care contracts to share in the profits that result from the improved surgical outcomes we believe our technology enables in DLBP patients;
- hire additional business development, product management, operational and marketing personnel;
- add operational and general administrative personnel which will support our product development programs, commercialization efforts, and our transition to operating as a public company.

Our primary near-term growth strategy is to secure payer contracts (including insurance companies, self- insured employers, Medicare, Medicaid, workmen's compensation boards et. al.) to cover our Category III CPT codes. We believe that with favorable payer coverage, the Company has the opportunity to more efficiently engage physicians and imaging centers that will adopt our technology.

As a result, we may need substantial additional funding to support our continuing operations and pursue our growth strategy. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through the sale of equity, debt financings or other capital sources, which may include collaborations with other companies or other strategic transactions.

As of December 31, 2022, we had cash of approximately $1.5 million, which we believe will fund our operating expenses and capital expenditure requirements into the second quarter of 2023. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect. See "Liquidity and capital resources." To finance our operations beyond that point, we will need to raise additional capital, which cannot be assured. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back, or discontinue the commercialization or further development of our SaaS platform.

Corporate Information

We were formed under the name Nocimed, LLC, a limited liability company in January 2008, under the laws of the State of Delaware. In February 2015, Nocimed, LLC was converted into Nocimed, Inc. a Delaware corporation. On December 3, 2021, we changed our name to Aclarion, Inc. Our principal executive offices are located at 8181 Arista Place, Suite 100, Broomfield, Colorado 80021. Our main telephone number is (833) 275-2266. Our internet website is www.aclarion.com. The information contained in, or that can be accessed through, our website is not incorporated by reference and is not a part of this Annual Report on Form 10-K (this "Form 10-K").

Effect of COVID-19 Pandemic on business operations

The COVID-19 Pandemic is not currently impacting plans for marketing our products or our continuing development efforts, as all such activities have been conducted by us using remote work strategies. The Company cannot accurately predict the longer- term impact of the COVID-19 Pandemic on its business.

Results of operations

Operating activities:

The following table summarizes our results of operations for the twelve months ended December 31, 2022, and 2021.

	Year Ended December 31,		2021 to 2022
	2022	2021	$ Change
Revenue			
Revenue	$ 60,444	$ 60,292	$ 152
Cost of revenue	65,298	69,175	(3,877)
Net profit (loss)	(4,854)	(8,883)	4,029
Operating expenses:			
Sales and marketing	537,069	330,814	206,255
Research and development	1,088,778	787,850	300,928
General and administrative	4,467,815	1,825,491	2,642,324
Total operating expenses	6,093,662	2,944,155	3,149,507
Income (loss) from operations	(6,098,516)	(2,953,038)	(3,145,478)
Other income (expense):			
PPP loan forgiveness	–	373,511	(373,511)
Interest expense	(1,507,546)	(474,911)	(1,032,635)
Changes in fair value of redeemable preferred stock	–	(1,900,310)	1,900,310
Other, net	520	4,458	(3,938)
Total other income (expense)	(1,507,026)	(1,997,252)	490,226
Income (loss) before income taxes	(7,605,542)	(4,950,290)	(2,655,252)
Income tax provision	–	–	–
Net income (loss)	$ (7,605,542)	$ (4,950,290)	$ (2,655,252)
Dividends accrued for preferred stockholders	$ (415,523)	$ (1,005,598)	$ 590,075
Net income (loss) allocable to common stockholders	$ (8,021,064)	$ (5,955,888)	$ (2,065,177)
Net income (loss) per share allocable to common shareholders	$ (1.31)	$ (6.58)	$ 5.26
Weighted average shares of common stock outstanding, basic and diluted	6,105,569	905,685	5,199,884

Years ended December 31, 2022, and 2021

Total revenues. Total revenues for the year ended December 31, 2022, were $60,444, which was a small increase of $152 from $60,292 for the year ended December 31, 2021. Volumes and pricing were consistent in each year.

Cost of Revenue. Cost of Revenue is comprised of hosting and software costs, field support, UCSF royalty cost, NuVasive commission of 6%, partner fees (Radnet), and credit card fees. Total Cost of Revenue was $65,298 for the year ended December 31, 2022, compared to $69,175 for the year ended December 31, 2021, a decrease of 5.6%. This decrease was primarily due to a variation in commissions.

Sales and Marketing. Sales and marketing expenses were $537,069 for the year ended December 31, 2022, compared to $330,814 for the year ended December 31, 2021, an increase of $206,255 or 62.3%, This increase was driven primarily by additional investment in website and branding development, press releases, attendance at conferences, and Key Opinion Leader consulting fees.

Research and Development. Research and development expenses were $1,088,778 for the year ended December 31, 2022, compared to $787,850 for the year ended December 31, 2021, an increase of $300,928 or 38.2%. This increase was due to a $123,828 contract milestone payment to UCSF in April 2022, and increased utilization of independent service providers in the areas of clinical and reimbursement.

General and Administrative. General and administrative expenses were $4,467,815 for the year ended December 31, 2022, an increase of $2,642,324 or 144.7%, from $1,825,491 for the year ended December 31, 2021. The increase in general and administrative expenses was driven by increased compensation expense related to the vesting of the Executive Chairman's and executive's outstanding common stock options, increased compensation expense related to new management, director and executive chairman bonuses, and an increase in directors' and officers' liability insurance.

Interest Expense. Total Interest expense was $1,507,546 for the year ended December 31, 2022, an increase of $1,032,635, from the $474,911 for the year ended December 31, 2021. This increase was driven by the $1.3 million beneficial conversion rate charged to interest expense for the conversion of all accrued interest on the Company's outstanding secured promissory notes into common shares and common stock warrants in connection with the effectiveness of the IPO. There was a partial positive offset due to fewer months of accrued interest charges in 2022 related to both the secured promissory notes and convertible notes outstanding in 2021.

Changes in Fair Value of Redeemable Preferred Stock. In the year ended December 31, 2021, the Company recorded $1,900,310 of changes in the fair value of a B2 and B3 series preferred stock commitment prior to the issuance of those shares on December 3, 2021.

Other Net Expenses. During the year ended December 31, 2022, Other Net expenses were $520, which included bank interest, government fees, and realized exchange rate losses. During the year ended December 31, 2021, Other Net expenses of $4,458 (gain) included a $5,000 grant from the California Relief Program and cash rewards from credit card programs, offset in part by government fees and realized exchange rate losses.

Net income (loss). The Company experienced a net loss of $7,605,542 for the year ended December 31, 2022, compared to a net loss of $4,950,290 for the year ended December 31, 2021. In general, the year 2022 included higher compensation expenses and interest charges specific to the April 2022 IPO. During the year 2021 the Company had an approximate $1.9 million fair value adjustment (expense) related to the issuance of preferred stock.

Critical accounting policies and use of estimates

Our Management's Discussion and Analysis of Financial Condition and Results of Operations is based on our financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States. The preparation of our financial statements and related disclosures requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities, costs and expenses and the disclosure of contingent assets and liabilities in our financial statements. We base our estimates on historical experience, known trends and events and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates.

While our significant accounting policies are described in more detail in the notes to our financial statements, we believe that the following accounting policies are those most critical to the judgments and estimates used in the preparation of our financial statements.

Revenue Recognition

The Company derives its revenues from one source, the delivery of Nociscan reports to medical professionals. Revenues are recognized when a contract with a customer exists, and the control of the promised services are transferred to our customers. The amount of revenue

recognized reflects the consideration we expect to receive in exchange for those services. Substantially all our revenues are generated from contracts with customers in the United States.

Equity-based compensation

The Company accounts for stock-based awards in accordance with provisions of ASC Topic 718, *Compensation—Stock Compensation*, under which the Company recognizes the grant-date fair value of stock-based awards issued to employees and nonemployee board members as compensation expense on a straight-line basis over the vesting period of the award, while awards containing a performance condition are recognized as expense when the achievement of the performance criteria is considered probable. The Company uses the Black-Scholes option pricing model to determine the grant-date fair value of stock options. The Company adjusts expense for actual forfeitures in the periods they occur.

Until our April 2022 IPO, we were a private company with no active public market for our common equity. Therefore, we had periodically determined the overall value of our company and the estimated per share fair value of our common equity at their various dates using contemporaneous valuations performed in accordance with the guidance outlined in the American Institute of CPA's Practice Aid. Since a public trading market for our common stock has been established in connection with the completion of our IPO, the fair value of the Company's common stock underlying its equity awards is the quoted market price of the Company's common stock on the grant date.

Going Concern

The Company believes that cash on hand of approximately $1.5 million, as of December 31, 2022, will be sufficient to fund current operating plans into the second quarter of 2023. The Company has based these estimates, however, on assumptions that may prove to be wrong, and could spend available financial resources much faster than we currently expect. The Company will need to raise additional funds to continue funding our technology development and commercialization efforts over the following twelve months. Management has plans to secure such additional funding.

As a result of the Company's recurring losses from operations, and the need for additional financing to fund its operating and capital requirements, there is uncertainty regarding the Company's ability to maintain liquidity sufficient to operate its business effectively, which raises substantial doubt as to the Company's ability to continue as a going concern.

Liquidity and capital resources

Sources of liquidity

To date, we have financed our operations primarily through private placements of preferred shares and debt financing, PPP loans that were forgiven, and an initial public offering on April 21, 2022.

Through the year ended December 31, 2022, we raised an aggregate of $33,145,148 of gross proceeds from $19,319,098 of preferred and common stock, $2,928,541 from the sale of convertible notes, $2,000,000 from secured promissory notes payable, $370,191 of PPP loans that were forgiven, and net proceeds of $8,527,318 from the IPO, after underwriter compensation and deductions. As of December 31, 2022, we had cash, including $10,000 of restricted cash, of $1,482,806.

Cash flows

The following table summarizes our sources and uses of cash for each of the periods presented:

	Year Ended December 31,	
	2022	2021
Cash used in operating activities	$ (5,314,171)	$ (2,399,949)
Cash used in investing activities	(207,870)	(102,005)
Cash provided by financing activities	6,552,318	2,939,500

Net increase (decrease) in cash and cash equivalents	$ 1,030,276	$ 437,546

Operating activities

During the year ended December 31, 2022, net cash used in operating activities was $5,314,171. This use of cash consisted primarily of compensation and benefit expense, bonuses in connection with the completion of the IPO, a milestone payment to UCSF, directors' and officers' liability insurance, and pre-IPO marketing activities. During the twelve months ended December 31, 2021, operating activities used $2,399,949, consisting primarily of compensation and benefit expense, consulting, and professional fees.

Investing activities

During the year ended December 31, 2022, and 2021, investing activities used $207,870 and $102,005 of cash, respectively. These investing activities consisted almost entirely of patent and license maintenance.

Financing activities

During the year ended December 31, 2022, net cash provided by financing activities was $6,552,318, which included the net of $8,552,318 (net of underwriter compensation and deductions but excluding $25,000 pre-payment in 2021) of initial public offering proceeds and $2,000,000 repayment of promissory notes. During the year ended December 31, 2021, net cash provided by financing activities was $2,939,500, which included $2,000,000 from issuance of promissory notes, $814,500 from our sale of convertible notes and the issuance of a $125,000 PPP loan to the Company.

Funding requirements

Developing medical technology products is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate meaningful revenues. Accordingly, we may need to obtain substantial additional funds to achieve our business objectives.

Adequate additional funds may not be available to us on acceptable terms, or at all. To the extent that we raise additional capital through the sale of equity securities, current stockholders' ownership interests may be diluted. Any debt or preferred equity financing, if available, may involve agreements that include restrictive covenants that may limit our ability to take specific actions, such as incurring additional debt, making capital expenditures, or declaring dividends, which could adversely impact our ability to conduct our business, and may require the issuance of warrants, which could potentially dilute existing stockholders' ownership interests.

If we raise additional funds through licensing agreements and strategic collaborations with third parties, we may have to relinquish valuable rights to our technology, future revenue streams, research programs, or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds, we may be required to delay, limit, reduce and/or terminate development of our product candidates or any future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Contractual obligations and commitments

Our current office lease and sublease expired on June 30, 2022. The Company does not have any contractual obligations not otherwise on our balance sheet as of December 31, 2022.

Off-balance sheet arrangements

We did not have, during the periods presented, and we do not currently have any off-balance sheet arrangements as defined in the rules and regulations of the Securities and Exchange Commission ("SEC").

Recently issued accounting pronouncements

We have reviewed all recently issued standards and have determined that, other than as disclosed in Note 2 to our financial statements appearing at the end of this annual report, such standards will not have a material impact on our financial statements or do not otherwise apply to our operations.

Emerging growth company status

The JOBS Act permits an emerging growth company such as us to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies until those standards would otherwise apply to private companies. We have irrevocably elected to apply of this extended transition period and, as a result, we will not adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for public entities. Accordingly, our financial statements may not be comparable to other public companies that do not elect the extended transition period.

Item 7A. Quantitative and Qualitative Disclosures about Market Risk

Interest rate sensitivity

We had cash and cash equivalents totaling $1,482,806 as of December 31, 2022. These amounts are invested primarily in demand deposit accounts and money market funds. We consider all highly liquid debt instruments purchased with a maturity of three months or less and SEC-registered money market mutual funds to be cash equivalents. The primary objectives of our investing activities are capital preservation, meeting our liquidity needs and, with respect to investing client funds, generating interest income while maintaining the safety of principal. We do not enter into investments for trading or speculative purposes.

Our cash equivalents are subject to market risk due to changes in interest rates. The market value of fixed rate securities may be adversely affected due to a rise in interest rates, while floating rate securities may produce less income than expected if interest rates fall. Due in part to these factors, our future investment income may fall short of expectations due to changes in interest rates, or we may suffer losses in principal if we are forced to sell securities that decline in market value due to changes in interest rates.

Item 8. Financial Statements and Supplementary Data

Aclarion, Inc. **Page**
Financial Statements

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders
Aclarion, Inc.
Broomfield, Colorado

Opinion on the Financial Statements

We have audited the accompanying balance sheets of Aclarion, Inc. (the "Company") at December 31, 2022 and 2021, and the related statements of operations, changes in stockholders' equity (deficit) and cash flows for each of the years in the two-year period ended December 31, 2022, and the related notes (collectively referred to as the financial statements). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2022 and 2021, and the results of its operations and its cash flows for each of the years in the two-year period ended December 31, 2022, in conformity with accounting principles generally accepted in the United States of America.

Going Concern Uncertainty

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the financial statements, the Company has suffered recurring losses from operations and has a deficiency in shareholders' equity that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

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

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

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

Critical Audit Matters

The critical audit matters communicated below are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

Intangible Assets Impairment Assessments

As described in Notes 8 to the financial statements, the Company has intangible assets, mainly comprised of patents and license costs of approximately $1.2 million at December 31, 2022. No directly observable market inputs are available to measure the fair value to determine if the asset is recoverable. Therefore, an estimate is derived indirectly and is based on net present value techniques utilizing post-tax cash flows and discount rates. The estimates that management used in calculating the net present values depend on assumptions specific to the nature of the markets in which its product operates with regard to the amount and timing of projected future cash flows; long-term demand forecasts; actions of competitors, future tax and discount rates.

The principal considerations for our determination that performing procedures relating to the intangible assets impairment assessment is a critical audit matter are the significant judgment by management when developing the net present value of the intangible assets. This in turn led to a high degree of auditor judgment, subjectivity, and effort in performing procedures and evaluating management's significant assumptions related to the amount and timing of projected future cash flows and the discount rate.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the financial statements. These procedures included testing management's process for developing the fair value estimate; evaluating the appropriateness of the net present value techniques; testing the completeness and accuracy of underlying data used in the model; and evaluating the significant assumptions used by management, including the amount and timing of projected future cash flows and the discount rate. Evaluating management's assumptions related to the amount and timing of projected future cash flows and the discount rate involved evaluating whether the assumptions used by management were reasonable considering the current and past performance of the intangible assets, the consistency with external market and industry data, and whether these assumptions were consistent with evidence obtained in other areas of the audit.

/s/ Daszkal Bolton LLP

Daszkal Bolton LLP
We have served as the Company's auditor since 2021
Fort Lauderdale, Florida

February 27, 2023

Aclarion, Inc.
Balance Sheets
December 31, 2022 and 2021

	December 31, 2022	December 31, 2021
ASSETS		
Current assets:		
Cash and cash equivalents	$ 1,472,806	$ 432,530
Restricted cash	10,000	20,000
Accounts receivable, net	18,569	6,280
Deferred Compensation	291,331	–
Prepaids & other current assets	195,534	273,394
Total current assets	1,988,240	732,204
Non-current assets:		
Property and equipment, net	3,346	12,636

Intangible assets, net	1,214,374	1,144,625
Total non-current assets	1,217,720	1,157,261
Total assets	$ 3,205,961	$ 1,889,465
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	$ 462,202	$ 1,065,304
Accrued and other liabilities	610,765	696,582
Promissory note payable	–	2,000,000
Preferred dividends payable	–	3,856,898
Liability to issue equity	345,243	–
Total current liabilities	1,418,209	7,618,784
Commitments and contingencies (See Note 9)		
Redeemable preferred stock: (See Note 8)		
Series B-2 preferred stock - $0.0001 par value, 1,600,000 authorized and 1,584,660 shares issued and outstanding at December 31, 2021	–	16
Series B-3 preferred stock - $0.0001 par value, 4,300,000 authorized and 4,228,149 shares issued and outstanding at December 31, 2021	–	42
Additional paid-in capital - series B2 and B3 preferred Stock	–	7,102,229
Total mezzanine equity	–	7,102,287
Stockholders' equity (deficit)		
Series A preferred stock - $0.00001 par value, 6,247,695 authorized and 6,247,695 shares issued and outstanding at December 31, 2021	–	62
Series B preferred stock - $0.00001 par value, 5,180,814 authorized and 5,160,096 shares issued and outstanding at December 31, 2021	–	52
Series B-1 preferred stock - $0.00001 par value, 10,758,338 authorized and 7,274,404 shares issued and outstanding at December 31, 2021	–	73
Common stock - $0.00001 par value, 200,000,000 authorized and 7,861,515 and 905,685 shares issued and outstanding (see Note 1)	79	9
Additional paid-in capital	41,694,774	19,054,234
Accumulated deficit	(39,907,101)	(31,886,036)
Total stockholders' equity (deficit)	1,787,751	(12,831,606)
Total liabilities, mezzanine, and stockholders' equity (deficit)	$ 3,205,961	$ 1,889,465

See Accompanying Notes to Financial Statements

Aclarion, Inc.
Statements of Operations
For the Years Ended December 31, 2022, and 2021

	Year Ended December 31,	
	2022	**2021**
Revenue		
Revenue	$ 60,444	$ 60,292

Cost of revenue	65,298	69,175
Net profit (loss)	(4,854)	(8,883)
Operating expenses:		
Sales and marketing	537,069	330,814
Research and development	1,088,778	787,850
General and administrative	4,467,815	1,825,491
Total operating expenses	6,093,662	2,944,155
Income (loss) from operations	(6,098,516)	(2,953,038)
Other income (expense):		
PPP loan forgiveness	–	373,511
Interest expense	(1,507,546)	(474,911)
Changes in fair value of redeemable preferred stock	–	(1,900,310)
Other, net	520	4,458
Total other income (expense)	(1,507,026)	(1,997,252)
Income (loss) before income taxes	(7,605,542)	(4,950,290)
Income tax provision	–	–
Net income (loss)	$ (7,605,542)	$ (4,950,290)
Dividends accrued for preferred stockholders	$ (415,523)	$ (1,005,598)
Net income (loss) allocable to common stockholders	$ (8,021,064)	$ (5,955,888)
Net income (loss) per share allocable to common stockholders	$ (1.31)	$ (6.58)
Weighted average shares of common stock outstanding, basic and diluted	6,105,569	905,685

See Accompanying Notes to Financial Statements

Aclarion, Inc.
Statements of Changes in Stockholders' Equity (Deficit)
For the Years Ended December 31, 2022, and 2021

	Series A-1 Preferred Stock		Series A-2 Preferred Stock		Series A-3 Preferred Stock		Series A-4 Preferred Stock		Series B Preferred Stock	
	Shares	Value	Shares	Value	Shares	Value	Shares	Value	Shares	Value
Balance, December 31, 2020	1,777,630	$ 18	1,444,037	$ 14	935,296	$ 9	2,090,732	$ 21	5,160,096	$ 52
Issuance of warrants	–	–	–	–	–	–	–	–	–	–
Preferred stock dividend payable	–	–	–	–	–	–	–	–	–	–
Issuance of preferred shares *	–	–	–	–	–	–	–	–	–	–
Share-based compensation	–	–	–	–	–	–	–	–	–	–
Net income (loss)	–	–	–	–	–	–	–	–	–	–
Balance, December 31, 2021	1,777,630	$ 18	1,444,037	$ 14	935,296	$ 9	2,090,732	$ 21	5,160,096	$ 52
Balance, December 31, 2021	1,777,630	$ 18	1,444,037	$ 14	935,296	$ 9	2,090,732	$ 21	5,160,096	$ 52
Issuance of warrants	–	–	–	–	–	–	–	–	–	–
Exercise of convertible note warrants	–	–	–	–	–	–	–	–	–	–
Preferred stock dividend payable	–	–	–	–	–	–	–	–	–	–
Conversion of preferred stock to common stock	(1,777,630)	(18)	(1,444,037)	(14)	(935,296)	(9)	(2,090,732)	(21)	(5,160,096)	(52)

Conversion of accrued interest on promissory notes	–	–	–	–	–	–	–	–	–	–	–	–
Issuance of common stock and warrants related to IPO, net banker costs	–	–	–	–	–	–	–	–	–	–	–	–
IPO issuance costs	–	–	–	–	–	–	–	–	–	–	–	–
Issuance of preferred shares	–	–	–	–	–	–	–	–	–	–	–	–
Issuance of common shares	–	–	–	–	–	–	–	–	–	–	–	–
Share-based compensation	–	–	–	–	–	–	–	–	–	–	–	–
Net income (loss)	–	–	–	–	–	–	–	–	–	–	–	–
Balance, December 31, 2022	–	$ –	–	$ –	–	$ –	–	–	$ –	–	$ –	$ –

* Series B2 and B3 Preferred Stock amounts reflected in mezzanine equity

	Series B1 Preferred Stock		Series B2 Preferred Stock		Series B3 Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total
	Shares	Value	Shares	Value	Shares	Value	Shares	Value			
Balance, December 31, 2020	7,274,404	$ 73	–	$ –	–	$ –	905,685	$ 9	$ 18,846,352	$ (25,930,149)	$ (7,083,601)
Issuance of warrants	–	–	–	–	–	–	–	–	30,393	–	30,393
Preferred stock dividend payable	–	–	–	–	–	–	–	–	–	(1,005,597)	(1,005,597)
Issuance of preferred shares *	–	–	1,584,660	–	4,228,149	–	–	–	–	–	–
Share-based compensation	–	–	–	–	–	–	–	–	177,489	–	177,489
Net income (loss)	–	–	–	–	–	–	–	–	–	(4,950,290)	(4,950,290)
Balance, December 31, 2021	7,274,404	$ 73	1,584,660	$ –	4,228,149	$ –	905,685	$ 9	$ 19,054,234	$ (31,886,036)	$(12,831,606)
Balance, December 31, 2021	7,274,404	$ 73	1,584,660	$ –	4,228,149	$ –	905,685	$ 9	$ 19,054,234	$ (31,886,036)	$(12,831,606)
Issuance of warrants	–	–	–	–	–	–	–	–	1,280	–	1,280
Exercise of convertible note warrants	–	–	–	–	–	–	60,408	1	152,653	–	152,653
Preferred stock dividend payable	–	–	–	–	–	–	984,537	10	4,272,411	(415,523)	3,856,898
Conversion of preferred stock to common stock	(7,274,404)	(73)	(1,584,660)	–	(4,228,149)	–	3,279,117	33	7,102,441	–	7,102,287
Conversion of accrued interest on promissory notes	–	–	–	–	–	–	426,768	4	1,855,154	–	1,855,158
Issuance of common stock and warrants related to IPO, net banker costs	–	–	–	–	–	–	2,165,000	22	8,552,318	–	8,552,340
IPO issuance costs	–	–	–	–	–	–	–	–	(530,463)	–	(530,463)
Issuance of preferred shares	–	–	–	–	–	–	–	–	–	–	–
Issuance of common shares	–	–	–	–	–	–	40,000	–	102,000	–	102,000
Share-based compensation	–	–	–	–	–	–	–	–	1,132,747	–	1,132,747
Net income (loss)	–	–	–	–	–	–	–	–	–	(7,605,542)	(7,605,542)
Balance, December 31, 2022	–	$ –	–	$ –	–	$ –	7,861,515	$ 79	$ 41,694,774	$ (39,907,101)	$ 1,787,751

* Series B2 and B3 Preferred Stock amounts reflected in mezzanine equity

See Accompanying Notes to Financial Statements

Aclarion, Inc.
Statements of Cash Flows

For the Years Ended December 31, 2022, and 2021

	Year Ended December 31,	
	2022	**2021**
Cash flows from operating activities		
Net income (loss)	$ (7,605,542)	$ (4,950,290)
Adjustments to reconcile net income (loss) to net cash used in operation activities:		
Depreciation and amortization	193,621	186,388
Share-based compensation	1,186,659	177,489
Share-based vendor payments	102,000	–
Warrants issued as non- cash finance charge	–	30,393
Gain on forgiveness of PPP loans	–	(373,511)
Loss on disposal of furniture and equipment	3,789	–
Changes in fair value of redeemable preferred stock	–	1,900,310
Change in assets and liabilities		
Accounts receivable	(12,290)	16,222
Prepaids and other current assets	(267,383)	(210,765)
Accounts payable	(603,102)	199,604
Accrued and other liabilities	1,487,363	509,806
Accrued interest on promissory and convertible notes	200,712	114,404
Net cash (used in) operations	(5,314,171)	(2,399,949)
Investing Activities		
Proceeds from sale of furniture	1,000	–
Intangible assets - Patents	(208,870)	(102,005)
Net cash (used in) investing activities	(207,870)	(102,005)
Financing Activities		
Proceeds from issuance of PPP Loan	–	125,000
Proceeds from issuance of convertible notes	–	814,500
Proceeds from issuance of promissory notes	–	2,000,000
Repayment of promissory notes	(2,000,000)	–
Issuance of common stock and warrants related to IPO, net issuance costs	8,552,318	–
Net cash provided by financing activities	6,552,318	2,939,500
Net increase (decrease) in cash and cash equivalents	$ 1,030,276	$ 437,546
Cash, cash equivalents, and restricted cash, beginning of period	452,530	14,984
Cash, cash equivalents, and restricted cash, end of period	$ 1,482,806	$ 452,530
Non- cash activities		
Conversion of indebtedness to preferred equity commitment	–	5,201,977
Dividends accrued on preferred shares	415,523	1,005,598
Conversion of preferred stock to common stock	25,754,379	–
Conversion of preferred stock dividends to common stock	4,272,420	–
Conversion of accrued interest on promissory notes to common stock and warrants	1,856,438	–
Issuance of underwriter's warrants related to IPO	74,677	–
Changes in fair value of redeemable preferred stock	–	1,900,310
Liability to issue common shares	345,243	–

See Accompanying Notes to Financial Statements

Aclarion, Inc.
Notes to Financial Statements
For the Year Ended December 31, 2022

NOTE 1. THE COMPANY AND BASIS OF PRESENTATION

The Company

Aclarion, Inc., formerly Nocimed, Inc., (the "Company" or "Aclarion") is a healthcare technology company that leverages magnetic resonance spectroscopy ("MRS"), and a proprietary biomarker to optimize clinical treatments. The Company was formed in February 2015, is incorporated in Delaware, and has its principal place of business in Broomfield, Colorado.

Risks and Uncertainties

The Company is subject to various risks and uncertainties frequently encountered by companies in the early stages of development. Such risks and uncertainties include, but are not limited to, its limited operating history, competition from other companies, limited access to additional funds, dependence on key personnel, and management of potential rapid growth. To address these risks, the Company must, among other things, develop its customer base; implement and successfully execute its business and marketing strategy; develop follow-on products; provide superior customer service; and attract, retain, and motivate qualified personnel. There can be no guarantee that the Company will be successful in addressing these or other such risks.

The Company is also subject to risks and uncertainties as a result of the coronavirus disease ("COVID-19") pandemic. The pandemic continues to evolve and its impact on the Company's business will depend on several factors that are highly uncertain and unpredictable, including, the efficacy and adoption of vaccines, future resurgences of the virus and its variants, the imposition of governmental lockdowns, quarantine and physical distancing requirements, patient capacity at hospitals and healthcare systems, the duration and severity of healthcare worker shortages, and the willingness and ability of patients to seek care and treatment due to safety concerns or financial hardship. As such, given the dynamic nature of this situation, the Company cannot reasonably estimate the impacts of COVID-19 on our financial condition, results of operations or cash flows in the future. We are focused on navigating these recent challenges presented by COVID-19 and believe we are in a strong position to continue to sustain and grow our business.

Initial Public Offering

On April 21, 2022, the registration statement for our initial public offering ("IPO") was declared effective. In connection with the effectiveness of the IPO registration statement:

- we effected a 1-for-7.47 reverse stock split of our outstanding common stock;
- accordingly, all common share amounts and per share data presented in our condensed financial statements have been retrospectively adjusted to reflect the reverse stock split for all periods presented;
- we filed a restated Certificate of Incorporation with the State of Delaware and we adopted new restated Bylaws;
- certain outstanding common stock warrants were exercised on a net share basis for 60,408 common shares (451,245 pre-split shares);
- 24,495,004 (pre-split) outstanding shares of our preferred stock were converted into 3,279,117 post-split shares of common stock;
- all accrued dividends on our outstanding Series B, B-1, B-2 and B-3 preferred stock were converted to 984,429 post-split common shares; and
- all accrued interest on the Company's outstanding secured promissory notes was converted into (i) 426,768 post-split common shares and (ii) 426,768 post-split common stock warrants, with beneficial conversion rates charged to interest expense upon conversion.

On April 26, 2022, the Company completed its IPO of 2,165,000 units, at a public offering price of $4.35 per unit. Each unit consisted of (i) one share of common stock and (ii) one common stock warrant with an exercise price of $4.35 per share. Following the commencement of the IPO, the underwriters partially exercised their over-allotment option and purchased an additional 324,750 common stock warrants. After deducting underwriter's commissions and expenses, we received net proceeds of approximately $8.6 million and our common stock and warrants started trading on Nasdaq under the ticker symbols “ACON” and “ACONW”, respectively.

In connection with the IPO, we issued to the representative of the underwriters a common stock warrant for 173,200 shares with an exercise price of $5.44 per share. The representative's warrants are exercisable commencing October 26, 2022 and will expire on April 26, 2027.

On April 21, 2022, 1,204,819 outstanding common stock options previously awarded to the Company's Executive Chairman, Dr. Jeffrey Thramann, vested in connection with the completion of the IPO pursuant to the terms of such options. The exercise price of these options is $1.94 per share. The options have a 10-year term.

On April 21, 2022, in connection with the IPO, the Company’s 2022 Aclarion Equity Incentive Plan, or “2022 Plan”, became effective. Our board of directors has appointed the compensation committee of our board of directors as the committee under the 2022 Plan with the authority to administer the 2022 Plan. The aggregate number of our shares of common stock that may be issued or used for reference purposes under the 2022 Plan may not exceed 2,000,000 shares, subject to adjustments as described in the 2022 Plan.

On April 29, 2022, in connection with the IPO, a bonus was paid to David Neal and Brent Ness of $100,000 each. On May 13, 2022, in connection with the IPO, a bonus of $130,000 was paid to James Peacock.

On May 2, 2022, in connection with the IPO, the Company paid the University of California - San Francisco the amount of $123,828 to satisfy the Indexed Milestone Payment obligation included within the exclusive license agreement.

Reverse Stock Split

On April 21, 2022, the Company effected a 1-for-7.47 reverse stock split (the “Stock Split”) of its issued and outstanding common stock. As a result of the Stock Split, unless described otherwise, all references to common stock, options to purchase common stock, share data, per share data and related information contained in these financial statements have been retrospectively adjusted to reflect the effect of the Stock Split for all periods presented. In addition, any fractional shares that would otherwise be issued as a result of the Stock Split were rounded up to the nearest whole share. Further, the number of shares issuable and exercise prices of stock options and warrants have been retrospectively adjusted in these financial statements for all periods presented to reflect the Stock Split.

Basis of Presentation

The accompanying financial statements have been prepared in accordance with generally accepted accounting principles in the United States of America (“GAAP”).

NOTE 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosures of

contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

The financial statements include some amounts that are based on management's best estimates and judgments. The most significant estimates relate to depreciation, amortization, valuation of capital stock, and valuation of warrants and options to purchase shares of the Company's preferred and common stock. These estimates may be adjusted as more current information becomes available, and any adjustment could be significant.

Reclassifications

Certain accounts relating to the prior year have been reclassified to conform to the current period's presentation. These reclassifications had no effect on the net income or net assets as previously reported.

Valuation of Derivative Instruments

Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") 815-40, *Derivatives and Hedging: Contracts on an Entity's Own Equity*, addresses whether an equity-linked contract qualifies as equity in the entity's financial statements. Agreements where an entity has insufficient authorized and unissued shares to settle the contract generally are accounted for as a liability and marked to fair value through earnings each reporting period. The Company evaluates its financial instruments, to determine if such instruments are liabilities or contain features that qualify as embedded derivatives. For financial instruments that are accounted for as liabilities, the derivative instrument is initially recorded at its fair value and is then revalued at each reporting date, with changes in the fair value reported as charges or credits to income.

Fair Value Measurements

The carrying values of the Company's financial instruments including cash equivalents, restricted cash, accounts receivable and accounts payable, and notes payable are approximately equal to their respective fair values due to the relatively short-term nature of these instruments.

Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. Assets and liabilities recorded at fair value in the balance sheets are categorized based upon the level of judgment associated with the inputs used to measure their fair value. The fair value hierarchy distinguishes between (1) market participant assumptions developed based on market data obtained from independent sources (observable inputs), and (2) an entity's own assumptions about market participant assumptions developed based on the best information available in the circumstances (unobservable inputs). The fair value hierarchy consists of three broad levels, which gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1) and the lowest priority to unobservable inputs (Level 3).

Cash and Cash Equivalents

The Company considers all highly liquid instruments purchased with an original maturity of three months or less to be cash equivalents. The Company had no cash equivalents for all periods presented. The Company maintains cash deposits at several financial institutions, which are insured by the Federal Deposit Insurance Corporation up to $250,000. The Company's cash balance may at times exceed these limits. On December 31, 2022, and 2021, the Company had approximately $1,229,000 and $201,000, respectively, in excess of federally insured limits. The Company continually monitors its positions with, and the credit quality of, the financial institutions with which it invests. The Company maintains no international bank accounts. As of December 31, 2022, $10,000 of the Company's cash was restricted as collateral related to the credit card program offered by our bank.

Accounts Receivable, Less Allowance for Doubtful Accounts

The Company estimates an allowance for doubtful accounts based upon an evaluation of the current status of receivables, historical experience, and other factors as necessary. It is reasonably possible that the Company's estimate of the allowance for doubtful accounts will change. The allowance for doubtful accounts was $0 on December 31, 2022, and 2021.

Revenue Recognition

Revenues are recognized when a contract with a customer exists, and at that point in time when we have delivered a Nociscan report to our customer. Revenue is recognized in the amount that reflects the negotiated consideration expected to be received in exchange for those reports. Following the delivery of the report, the company has no ongoing obligations or services to provide to the customer. Customers pay no other upfront, licensing, or other fees. To date, our reports are not reimbursable under any third-party payment arrangements, The Company invoices its customers based on the billing schedules in its sales arrangements. Payment terms range generally from 30 to 90 days, from the date of invoice.

Geographic Locations & Segments

Approximately 9% and 11% of the Company's revenues were generated from contracts with customers outside the United States in the years ended December 31, 2022, and 2021, respectively. All invoices are billed in the currency of the customers and are recorded in US Dollars at the then spot rate, which automatically is converted to dollars upon receipt and deposited in the Company's bank. Differences between the amounts received and the amounts initially recorded are reflected in Other Income (Expense).

Segment Disclosure

The Company has a single operating and reporting segment, which is the delivery of Nociscan reports to our customers. The Company's Chief Executive Officer reviews financial information for purposes of making operating decisions and assessing financial performance.

Property and Equipment

Property and equipment are stated at cost and are depreciated using the straight-line method over the estimated useful lives of the related assets. Furniture and fixtures are depreciated over seven years. Computer and office equipment and computer software are depreciated over five years. Repairs and maintenance costs, which are not considered improvements and do not extend the useful life of the property and equipment, are expensed as incurred.

Impairment of Long-Lived Assets

The Company reviews long-lived assets, including intangible assets, property and equipment, for impairment whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable using pre-tax undiscounted cash flows. Impairment, if any, is measured as the amount by which the carrying value of a long-lived asset exceeds its fair value.

Sales and Marketing Expenses

The Company expenses the costs of sales and marketing its products and services as incurred. The primary drivers of cost have been employee payroll, website and branding development, press releases, attendance at various industry conferences, Key Opinion Leader consulting fees, and travel expenses.

Research and Development Costs

Costs related to research, design and development of products are charged to research and development expense as incurred. These costs include direct compensation, benefits, and other headcount related costs for research and development personnel; costs for materials used in research and development activities; costs for outside services and allocated portions of facilities and other corporate costs. The Company has entered into research and clinical study arrangements with selected hospitals, cancer treatment centers, academic institutions and research institutions worldwide. These agreements support the Company's internal research and development capabilities.

Liquidity, Capital Resources and Going Concern

The Company believes that the net proceeds from the April 2022 initial public offering will be sufficient to fund current operating plans into the second quarter of 2023. The Company has based these estimates, however, on assumptions that may prove to be wrong, and could spend available financial resources much faster than we currently expect. The Company will need to raise additional funds to continue funding our technology development. Management plans to secure such additional funding.

As a result of the Company's recurring losses from operations, and the need for additional financing to fund its operating and capital requirements, there is uncertainty regarding the Company's ability to maintain liquidity sufficient to operate its business effectively, which raises substantial doubt as to the Company's ability to continue as a going concern.

Share-Based Compensation

The Company accounts for stock-based awards in accordance with provisions of ASC Topic 718, *Compensation—Stock Compensation*, under which the Company recognizes the grant-date fair value of stock-based awards issued to employees and nonemployee board members as compensation expense on a straight-line basis over the vesting period of the award, while awards containing a performance condition are recognized as expense when the achievement of the performance criteria is considered probable. The Company uses the Black-Scholes option pricing model to determine the grant-date fair value of stock options. The Company estimates forfeitures that it expects will occur and adjusts expense for actual forfeitures in the periods they occur.

The exercise or strike price of each option is not less than 100% of the fair market value of the Common Stock subject to the option on the date the option is granted.

The Company issues restricted stock unit awards to non-employee consultants who are providing various services. The awards are valued at the market price on the date of the grant. The awards vest over the contract life and based on achievement of targeted performance milestones.

On occasion, the Company grants common stock, subject to vesting, to compensate vendors for services rendered.

Deferred Financing Costs

The Company capitalizes certain legal, accounting, and other fees and costs that are directly attributable to in-process equity financings as deferred offering costs until such financings are completed. Upon the completion of an equity financing, these costs are recorded as a reduction of additional paid-in capital of the related offering. Upon the completion of the IPO in April 2022, approximately $1.5 million of offering costs related to the IPO were reclassified to additional paid-in capital.

Emerging Growth Company Status

The Company is an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act"). Under the JOBS Act, emerging growth companies can delay the adoption of new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. The Company has elected to use this extended transition period for complying with certain new or revised accounting standards that have different effective dates for public and private companies.

Income Taxes

The Company is required to estimate its income taxes in each of the tax jurisdictions in which it operates prior to the completion and filing of tax returns for such periods. This process involves estimating actual current tax expense together with assessing temporary differences in the treatment of items for tax purposes versus financial accounting purposes that may create net deferred tax assets and liabilities. The Company accounts for income taxes under the asset and liability method, which requires, among other things, that deferred income taxes be provided for temporary differences between the tax bases of the Company's assets and liabilities and their financial statement reported amounts. In addition, deferred tax assets are recorded for the future benefit of utilizing net operating losses, research and development credit carryforwards and other deferred tax assets. The Company has not recorded an deferred tax asset because of the uncertainty that

the Company will be able to utilize any future benefits (see Liquidity, Capital Resources and Going Concern in Note 2). Generally, the Company is not subject to income tax examinations for periods prior to 2019.

NOTE 3. RECENT ACCOUNTING PRONOUNCEMENTS

In August 2020, the FASB issued ASU No. 2020-06, *Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging-Contracts in Entity's Own* Equity (Subtopic 815-40) ("ASU 2020-06"), which simplifies the accounting for convertible instruments. The guidance removes certain accounting models that separate the embedded conversion features from the host contract for convertible instruments. The guidance also modifies how certain convertible instruments, that may be settled in cash or shares, impact the calculation of diluted earnings per share. ASU 2020-06 allows for a modified or full retrospective method of transition. This update is effective for emerging growth companies following private company adoption dates in fiscal years beginning after December 15, 2023, including interim periods within those fiscal years, and early adoption is permitted. As of December 31, 2022, the Company has no debt with conversion features.

In February 2016, the FASB issued its new lease accounting guidance in ASU 2016-02, Leases (Topic 842). Under the new guidance, lessees will be required to recognize for all leases (with the exception of short-term leases) a lease liability, which is a lessee's obligation to make lease payments arising from a lease, measured on a discounted basis and a right-of-use asset, which is an asset that represents the lessee's right to use, or control the use of, a specified asset for the lease term. ASU 2016-02, as subsequently amended for various technical issues, is effective for emerging growth companies following private company adoption dates in fiscal years beginning after December 15, 2021, and interim periods within fiscal years beginning after December 15, 2022. The Company has adopted the new guidance, which did not have a material impact on its financial statements. The Company has no leases as of December 31, 2022.

NOTE 4. REVENUE

Contract Balances

The timing of revenue recognition, billings, and cash collections may result in trade, unbilled receivables, and deferred revenues on the balance sheets. At times, revenue recognition may occur before the billing, resulting in an unbilled receivable, which would represent a contract asset. The contract asset would be a component of accounts receivable and other assets for the current and non-current portions, respectively. In the event the Company receives advances or deposits from customers before revenue is recognized, this would result in a contract liability. In years ending December 31, 2022, and 2021, the Company invoiced as services were performed and did not invoice in advance, the company has no contract balances.

NOTE 5. SUPPLEMENTAL FINANCIAL INFORMATION

Balance Sheets

Accounts receivable, net

Accounts receivable, net consisted of the following:

	December 31,	
	2022	2021
Accounts receivable (1)	$ 18,569	$ 6,280
Less: Allowance for doubtful accounts	–	–
Accounts receivable, net	$ 18,569	$ 6,280

(1) Accounts receivable denominated in foreign currencies represent less than 15% of accounts receivable in all periods.

Accounts payable and accrued and other liabilities

	December 31,	
	2022	2021
Accounts payable	$ 457,558	$ 1,059,546
Credit cards payable	4,644	5,758
Accrued salaries and expenses	610,765	340,363
Accrued Interest	–	356,219
	$ 1,072,967	$ 1,761,886

Statements of Operations

Other expense, net consisted of the following:

	Year Ended December 31,	
Income/(Expense)	2022	2021
Bank Interest	$ 2,510	$ (1,568)
California Relief Program [1]	–	5,000
Taxes	(800)	(800)
Foreign Currency Gain (Loss)	(1,190)	(1,309)
Other	–	3,135
	$ 520	$ 4,458

1 The California Small Business COVID-19 Relief Grant Program (the "Program") provides micro grants ranging from $5,000 to $25,000 to eligible small businesses and nonprofits impacted by COVID-19 and the related health and safety restrictions.

NOTE 6. LEASES

Rent expense for the year ended December 31, 2022 and 2021 was $36,070 and $64,932, respectively. The Company entered into a subleasing agreement in 2021 and realized $26,340 and $48,400 of sublease income for the year ended December 31, 2022, and 2021. Both the lease and sublease are netted within the general & administrative line item in the Statements of Operations. Our current office lease and sublease expired on June 30, 2022.

NOTE 7: PROPERTY, PLANT, AND EQUIPMENT

Property and equipment are stated at cost and are depreciated using the straight-line method over the estimated useful lives of the related assets. Furniture and fixtures are depreciated over seven years. Computer and office equipment and computer software are depreciated over five years. Repairs and maintenance costs, which are not considered improvements and do not extend the useful life of the property and equipment, are expensed as incurred.

The Company’s property and equipment are as follows:

	December 31,	
	2022	2021
Furniture and fixtures	$ –	$ 7,700
Computer and office equipment	13,032	45,187
Software	42,150	42,150
Other Equipment	18,190	18,190

	73,372	113,227
Less: Accumulated depreciation	(70,026)	(100,591)
Property and equipment, net	$ 3,346	$ 12,636

Depreciation expense related to property and equipment were $4,500 and $12,981 for the years ended December 31, 2022 and 2021, respectively.

During 2022 the Company received proceeds of $1,000 from the sale of property and equipment.

Future depreciation and amortization of property, equipment, and software is as follows:

2023	$ 1,563
2024	1,187
2025	596
Total	$ 3,346

NOTE 8. INTANGIBLE ASSETS

The Company's intangible assets are as follows:

	December 31, 2022	December 31, 2021
Patents and licenses	$ 2,147,729	$ 1,938,858
UC royalty	200,000	150,000
Other	5,017	5,017
	2,352,746	2,093,875
Less: accumulated amortization	(1,138,372)	(949,250)
Intangible assets, net	$ 1,214,374	$ 1,144,625

Amortization expense related to purchased intangible assets was $189,121 and $176,390 for the years ended December 31, 2022, and 2021, respectively.

Patents and licenses costs are accounted for as intangible assets and amortized over the life of the patent or license agreement and charged to research and development. During the fourth quarter of 2022, the Company reviewed the remaining life of the patent portfolio and the mix of domestic and international patent filings and revised its estimated future amortization periods. The impact of this change of estimate over the three months ended December 31, 2022, was in increase in amortization of $3,128. Future amortization of patents and trademarks was impacted as follows:

2023	$ 15,312
2024	19,219
2025	21,910
2026	27,532
2027 and beyond	(87,101)
Total	$ 0

UC royalties are paid annually, amortized over twelve months, and charged to cost of revenue.

Patents and trademarks are reviewed at least annually for impairment. No impairment was recorded through December 31, 2022, and 2021, respectively.

Future amortization of intangible assets is as follows:

2023	$	158,114
2024		153,587
2025		153,587
2026		153,587
2027 and beyond		595,499
Total	$	1,214,374

NOTE 9. SHORT TERM NOTES AND CONVERTIBLE DEBT

Convertible Notes:

During the year ended December 31, 2021, and 2020, accredited investors purchased $814,500 and $1,598,488 of our convertible notes, respectively. In addition, the holders of the Company's short-term notes exchanged their notes for this issuance of convertible notes. The convertible notes accrued interest at 10.0% per year and were originally scheduled to mature on December 31, 2020, which the holders agreed to extend until September 30, 2021. While the convertible notes contained a provision to automatically convert into shares of common stock at a discount to the price in the next Qualified Financing, the Qualified Financing did not occur prior to the June 30, 2021 maturity date of the convertible notes. In accordance with the terms of the convertible notes, the principal plus accrued, but unpaid, interest on the convertible notes (aggregating to $3,201,977) was required to be automatically converted into 4,228,149 Series B-3 Preferred Shares. The Company did not have the Series B-3 preferred shares authorized for issuance, and the Company established a liability to issue these shares. This liability was adjusted to fair value until the B-3 preferred shares were authorized and issued December 3, 2021 (See Note 11: Stockholders' Equity).

NuVasive, Inc. Convertible Note and SAFE Agreement:

In February 2020, NuVasive and the Company renegotiated and amended their prior marketing agreement. In consideration of changing the marketing agreement, NuVasive and the Company entered into a $2.0 million Simple Agreement for Future Equity ("SAFE") agreement. The SAFE provided that NuVasive would receive $2 million of capital stock if the Company would raise a minimum of $10.0 million of new capital on or before December 31, 2020, which was later extended to June 30, 2021. If the $10.0 million was not raised, the Company would issue to NuVasive 1,584,660 Series B-2 preferred shares. The $10.0 million was not raised and the Company issued 1,584,660 Series B-2 preferred shares to NuVasive in December 2021.

The Company recorded the SAFE when issued at its fair value, which was measured at $2 million, as NuVasive was to receive a variable number of shares with an aggregate value of $2 million. The Company recorded the liability to issue the 1,584,660 Series B-2 preferred shares at its fair value of $2 million (a per-share value of $1.2621), based on third-party valuations at June 30, 2021, and marked the liability to fair value on September 30, 2021, and at the time the B-2 preferred shares were issued December 3, 2021.

In March 2020, the Company negotiated an additional investment agreement with NuVasive whereby NuVasive purchased $308,720 of convertible notes under the same terms as the existing holders of the Company's convertible notes.

In June 2021, NuVasive's convertible note principal plus accrued, but unpaid, interest was converted (in accordance with the terms of all of the convertible notes) into Series B-3 Preferred shares (see *Convertible Notes* above). The B-3 preferred shares were issued December 3, 2021.

As of December 31, 2021, there were no Convertible Notes payable and outstanding. There was no convertible note activity in the year ended December 31, 2022.

Cares Act Paycheck Protection Program Loan (PPP Loan)

In April 2020 and February 2021, the Company entered into two promissory notes evidencing an unsecured loan (the "Loans") in the amounts of $245,191 and $125,000, respectively, made to the Company under the Paycheck Protection Program (the "PPP"). The PPP was established under the CARES Act administered by the U.S. Small Business Administration.

The PPP promissory notes were to mature in March 2022 (2020 note) and January 2026 (2021 note) and bear interest at a rate of 1% per annum, payable monthly commencing in June 2019 and November 2020. The Loans could be prepaid by the Company at any time prior to maturity with no prepayment penalties. The proceeds from the Loans could only be used for payroll costs (including benefits), interest on mortgage obligations, rent, utilities and interest on certain other debt obligations.

The Loans contained customary events of default relating to, among other things, payment defaults, making materially false and misleading representations to the lender, or breaching the terms of the Loan documents. The occurrence of an event of default would result in an increase in the interest rate to 18% per annum and provide the lender with customary remedies, including the right to require immediate payment of all amounts owed under the promissory note.

Pursuant to the terms of the CARES Act and the PPP, the Company applied in February 2021 to the lender for forgiveness of the amount due on the Loans. In May 2021, the Company was notified that 100% of the first loan of $245,191 and related interest of $2,622 had been forgiven, and in August 2021 the Company was notified that 100% of the second loan of $125,000 and related interest of $698 had been forgiven. The amounts eligible for forgiveness was based on the amount of Loan proceeds used by the Company for the payment of certain covered costs, including payroll costs (including benefits), interest on mortgage obligations, rent and utilities, subject to certain limitations and reductions in accordance with the CARES Act and the PPP.

As of December 31, 2021, there was no outstanding PPP loan balance. There was no activity for PPP loans for the year ended December 31, 2022.

Secured Promissory Notes Payable

In June 2021, the Company issued $2.0 million of secured promissory notes that matured at the earlier of the consummation of a Qualified Financing or May 31, 2022. The secured promissory notes incorporated the following major attributes: secured by a lien and security interest on substantially all of the Company's assets; interest accrues at 33%; holder option to convert the accrued interest into the Company securities being offered in a Qualified Financing at 30% (i.e. 70% discount) of the price being paid by other investors in the Qualified Financing; and automatic conversion in the case of a Qualifying IPO of the accrued interest into the Company securities being offered in the Qualifying IPO at 30% (70% discount) of the price being paid by other investors in the Qualifying IPO. If the secured promissory notes remained outstanding after May 31, 2022, the Company had the option to extend the promissory notes upon the payment of an extension fee, which consisted of 150,000 warrants (20,080 warrants post-split) with a five-year term, to purchase shares of the Company's common stock at a price of $ 0.01 per share ($0.0747 post-split).

On April 21, 2022, the registration statement for our IPO was declared effective. In connection with the effectiveness of the IPO registration statement, all accrued interest on the Company's outstanding secured promissory notes was converted into (i) 426,768 post-split common shares and (ii) 426,768 post-split common stock warrants, with a $1,299,507 beneficial conversion rate charged to interest expense.

On April 27, 2022, the Company used $2 million of the IPO proceeds to retire all outstanding secured promissory notes.

NOTE 10. COMMITMENTS AND CONTINGENCIES

Royalty Agreement

The Company has an exclusive license agreement with the Regents of the University of California to make, use, sell and otherwise distribute products under certain of the Regents of the University of California's patents anywhere in the world. The Company is obligated to pay a minimum annual royalty of $50,000, and an earned royalty of 4% of net sales. The minimum annual royalty will be applied against the earned royalty due for the calendar year in which the minimum payment was made. The license agreements expire upon expiration of the patents and may be terminated earlier if the Company so elects. The U.S. licensed patents that are currently issued expire between 2026 and 2029, without considering any possible patent term adjustment or extensions and assuming payment of all appropriate maintenance, renewal, annuity, or other governmental fees. The Company recorded royalty costs of $50,000 for each of the years ended December 31, 2022, and 2021.

Additionally, the Company was obligated to make a cash Indexed Milestone Payment to the Regents of the University of California in the event of either a change of control or an IPO. This cash payment was calculated as follows: 28,532 post-split shares (213,313 pre-split shares) of Company common stock times the IPO price of $4.34. On May 2, 2022, in connection with the IPO, the Company paid the University of California - San Francisco the amount of $123,828 to satisfy the Indexed Milestone Payment obligation included within the exclusive license agreement.

Litigation

To date, the Company has not been involved in legal proceedings arising in the ordinary course of its business. If any legal proceeding occurs, the Company would record a provision for a loss when it believes that it is both probable that a loss has been incurred and the amount can be reasonably estimated, although litigation is inherently unpredictable and is subject to significant uncertainties, some of which are beyond the Company's control. Should any of these estimates and assumptions change or prove to have been incorrect, the Company could incur significant charges related to legal matters that could have a material impact on its results of operations, financial position and cash flows.

Stock Option Grant to our Executive Chairman

In September 2021, the Board of Directors approved a stock option grant of 1,204,819 post-split shares to Dr. Jeffrey Thramann, our Executive Chairman. These options were conditional, such that they vested only upon the occurrence of certain specified events, including an IPO, a next round financing, the merger of the Company with a SPAC, or the sale of the Company. The amount of stock options that would vest upon such specified events depended upon the terms and timing of the applicable event.

On April 21, 2022, 1,204,819 outstanding common stock options previously awarded to Dr. Jeffrey Thramann vested in connection with the completion of the IPO pursuant to the terms of such options. The exercise price of these options is $1.94 per share. The options have a 10-year term.

On September 15, 2022, the Board of Directors approved a stock option grant of an additional 185,285 common shares to Dr. Thramann. The exercise price of the options is $1.94 per share, they are fully vested, and they have a 10-year term.

NOTE 11. STOCKHOLDERS' EQUITY

The Company filed an Amended and Restated Certificate of Incorporation on April 21, 2022, as part of the IPO. The Company is authorized to issue two classes of stock to be designated, respectively, "Common Stock" and "Preferred Stock." The total number of shares which the Company is authorized to issue is two hundred twenty million (220,000,000) shares. Two hundred million (200,000,000) shares are authorized to be Common Stock, having a par value per share of $0.00001. Twenty million (20,000,000) shares are authorized to be Preferred Stock, having a par value per share of $0.00001.

Prior to the IPO, the Company had authorized two classes of shares. These classes included shares of common stock and preferred stock. There was one authorized series of shares of common stock and eight existing authorized series of preferred stock: Series A-1, A-2, A-3, A-4, B, B-1, B-2, and B-3.

The preferred shares converted to common shares on a 1:1 pre-split basis immediately prior to the Stock Split on April 21, 2022. Those common shares were adjusted to reflect the Stock Split as described in Note 1 Reverse Stock Split.

Preference Amounts	Issue Date	Total Face Value of Investment	Issue Purchase Price/Share
Series A-1 Preferred Stock	12/31/2014	$ 1,247,541	$ 0.70
Prior to its conversion to common shares, the Series A-1 had a 1x liquidation preference junior to B/B1 plus participation on an as-converted to common basis, which participation was capped at 3x, conversion into common stock at a ratio of 1:1, limited anti-dilution protection, and voting rights on an as-converted to common basis.			
Series A-2 Preferred Stock	12/31/2014	$ 1,114,797	$ 0.77
Prior to its conversion to common shares, the Series A-2 had a 1x liquidation preference junior to B/B1 plus participation on an as-converted to common basis, which participation was capped at 3x, conversion into common stock at a ratio of 1:1, limited anti-dilution protection, and voting rights on an as-converted to common basis.			
Series A-3 Preferred Stock	12/31/2014	$ 795,002	$ 0.85
Prior to its conversion to common shares, the Series A-3 had a 1x liquidation preference junior to B/B1 plus participation on an as-converted to common basis, which participation was capped at 3x, conversion into common stock at a ratio of 1:1, limited anti-dilution protection, and voting rights on an as-converted to common basis.			
Series A-4 Preferred Stock	12/31/2014	$ 1,965,288	$ 0.94
Prior to its conversion to common shares, the Series A-4 had a 1x liquidation preference junior to B/B1 plus participation on an as-converted to common basis, which participation was capped at 3x, conversion into common stock at a ratio of 1:1, limited anti-dilution protection, and voting rights on an as-converted to common basis.			
Series B Preferred Stock	12/5/2015	$ 5,013,579	$ 1.00
Prior to its conversion to common shares, the Series B had a 1x senior liquidation preference junior to B/B1 plus participation on an as-converted to common basis, which participation was capped at 3x, conversion into common stock at a ratio of 1:1, limited anti-dilution protection, and voting rights on an as-converted to common basis.			
The dividend rate is 6.0% Dividends are cumulative. Accrued and unpaid dividends are payable in shares of common stock in certain events (including an IPO) at the then current fair market value of the common stock.			
Series B-1 Preferred Stock	7/27/2017	$ 1,500,000	$ 1.26
	8/2/2018	$ 5,217,698	$ 1.26
	3/1/2019	$ 2,463,328	$ 1.26
Prior to its conversion to common shares, the Series B-1 had a 1x senior liquidation preference junior to B2/B3 plus participation on an as-converted to common basis, which participation was capped at 3x, conversion into common stock at a ratio of 1:1, limited anti-dilution protection, and voting rights on an as-converted to common basis.			
The dividend rate is 6.0%. Dividends are cumulative. Accrued and unpaid dividends are payable in shares of common stock in certain events (including an IPO) at the then current fair market value of the common stock.			

Preference Amounts	Issue Date	Total Face Value of Investment	Issue Purchase Price/Share
Series B-2 Preferred Stock	12/3/2021	$ 1,774,819	$ 1.12

Prior to its conversion to common shares, the Series B-2 has a 1x senior liquidation preference plus participation on an as-converted to common basis, which participation was capped at 3x, conversion into common stock at a ratio of 1:1, limited anti-dilution protection, and voting rights on an as-converted to common basis.					
The dividend rate is 6.0%. Dividends are cumulative. Accrued and unpaid dividends are payable in shares of common stock in certain events (including an IPO) at the then current fair market value of the common stock. Redemption is available by a majority vote of holders commencing after fifth anniversary from issuance, payable in three annual installments.					
Series B-3 Preferred Stock	12/3/2021	$	5,327,468	$	1.26
Prior to its conversion to common shares, the Series B-3 has a 2x senior liquidation preference, conversion into common stock at a ratio of 1:1, limited anti-dilution protection, and voting rights on an as-converted to common basis.					
The dividend rate is 6.0%. Dividends are cumulative. Accrued and unpaid dividends are payable in shares of common stock in certain events (including an IPO) at the then current fair market value of the common stock. Redemption is available by a majority vote of holders commencing after fifth anniversary from issuance, payable in three annual installments.					

Warrants

Warrants issued with Convertible Notes

During the years ended December 31, 2021, and 2020, the Company issued 17,286 and 58,846 warrants, respectively, to certain investors who participated over an agreed investment minimum amount in the purchase of our convertible notes. The value of the warrants was recorded as a debt discount and expensed based on the fair value. Just prior to the IPO, these common stock warrants were exercised on a net share basis for 60,408 common shares (451,245 pre-split shares). A loss on warrants exercised of $152,653 was recorded.

Warrants issued in connection with the IPO

In connection with the Company's IPO, all accrued interest on the Company's outstanding secured promissory notes were converted into (i) 426,768 post-split common shares and (ii) 426,768 post-split common stock warrants, with beneficial conversion rates charged to interest expense upon conversion. These warrants have an exercise price of $4.35 per share.

In the IPO, the Company sold 2,165,000 units, at a public offering price of $4.35 per unit. Each unit consisted of (i) one share of common stock and (ii) one common stock warrant ("IPO Warrant") with an exercise price of $4.35 per share. The common stock and the IPO Warrants were immediately separable and issued separately in the offering. The IPO Warrants are listed and tradeable on the NASDAQ stock market, immediately exercisable at the option of the holder, and expire five years from the date of issuance.

On April 22, 2022, the underwriters partially exercised their over-allotment option for an additional 324,750 IPO Warrants.

In connection with the IPO, we issued to the representative of the underwriters' common stock warrants for 173,200 shares with an exercise price of $5.44 per share. The representative's warrants are exercisable commencing October 26, 2022, and will expire on April 26, 2027.

The Company evaluated the terms of all warrants issued at the IPO and determined that they should be classified as equity instruments based upon accounting guidance provided in ASC 480, *Distinguishing Liabilities from Equity, and ASC 815, Derivatives and Hedging*. Since the Company determined that the warrants were equity classified, the Company recorded the proceeds from the IPO, net of issuance costs, within common stock at par value and the balance of proceeds to additional paid in capital.

As of December 31, 2022, 2,489,750 IPO Warrants, and 599,968 other common stock warrants, were outstanding.

NOTE 12. NET LOSS PER SHARE OF COMMON STOCK

Basic and diluted net loss per share is computed by dividing net loss attributable to stockholders by the weighted average number shares of common stock outstanding during the year. Potentially dilutive outstanding shares of common stock equivalents were excluded from the computation of diluted net loss per share for loss periods presented because including them would have been antidilutive.

A reconciliation of the numerator and denominator used in the calculation of basic and diluted net loss per share attributable to stockholders follows:

	December 31,	
	2022	2021
Numerator:		
Net loss used to compute basic and diluted loss per common share	$ (8,021,064)	$ (5,955,888)
Denominator:		
Weighted average shares used to compute basic and dilutive loss per share	6,105,569	905,685

The following outstanding potentially dilutive securities were excluded from the calculation of dilutive loss per share attributable to common stockholders because their impact would have been antidilutive for the period presented:

	December 31, 2022	December 31, 2021
Series A and B convertible preferred stock	819,779	2,565,809
Warrants	2,329,977	70,840
Restricted stock units	50,038	–
Stock options	2,481,816	985,283
	5,681,610	3,621,932

NOTE 13. STOCK-BASED COMPENSATION

2022 Aclarion Equity Incentive Plan

On April 21, 2022, in connection with the IPO, the Company's 2022 Aclarion Equity Incentive Plan, or "2022 Plan", went into effect. Our board of directors has appointed the compensation committee of our board of directors as the committee under the 2022 Plan with the authority to administer the 2022 Plan. The aggregate number of our shares of common stock that may be issued or used for reference purposes under the 2022 Plan is 2,000,000 shares, with an automatic increase on January 1st of each year, for a period of not more than ten years, commencing on January 1st of the year following the year in which the IPO Date occurs and ending on (and including) January 1, 2032, in an amount equal to 5% of the total number of shares of Capital Stock outstanding on December 31st of the preceding calendar year. Notwithstanding the foregoing, the Board may act prior to January 1st of a given year to provide that there will be no January 1st increase in shares for such year or that the increase in shares for such year will be a lesser number of shares of Common Stock than would otherwise occur pursuant to the preceding sentence.

Options granted under the 2022 Plan may be incentive stock options or non-statutory stock options, as determined by the administrator at the time of grant of an option. Restricted stock may also be granted under the 2022 Plan. The options vest in accordance with the grant terms and are exercisable for a period of up to 10 years from grant date.

The fair value of the options granted for the twelve months ended December 31, 2022, and December 31, 2021, respectively, were estimated at the date of grant using the Black-Scholes-Merton option pricing model with the following assumptions:

Risk-free interest rate (4/2022 – 8/2022)	1.99%
Risk-free interest rate (9/2022 – 12/2022)	3.67%
Dividend yield	–
Expected term	6-8 years

Expected volatility	66.35%

Nocimed, Inc. 2015 Stock Plan

The Company maintains the Nocimed, Inc. 2015 Stock Plan, or the "Existing Plan", under which the Company could grant 2,440,931 post-split shares or options of the Company to our employees, consultants, and other service providers. The Company has suspended the Existing Plan in connection with the IPO. No further awards will be granted under the Existing Plan, but awards granted prior to the suspension date will continue in accordance with their terms and the terms of the Existing Plan.

The fair value of the options granted for the twelve months ended December 31, 2022, and 2021, were estimated at the date of grant using the Black-Scholes-Merton option pricing model with the following assumptions:

Risk-free interest rate	1.99%
Dividend yield	–
Expected term	6-8 years
Expected volatility	25.00%

Determining Fair Value of Stock Options

The fair value of each grant of stock options was determined by the Company using the methods and assumptions discussed below. Each of these inputs is subjective and generally requires significant judgment to determine.

Valuation and Amortization Method —The Company estimates the fair value of its stock options using the Black-Scholes-Merton option-pricing model. This fair value is then amortized over the requisite service periods of the awards.

Expected Term—The Company estimates the expected term of stock option by taking the average of the vesting term and the contractual term of the option, as illustrated by the simplified method.

Expected Volatility—The expected volatility is derived from the Company's expectations of future market volatility over the expected term of the options.

Risk-Free Interest Rate—The risk-free interest rate is based on the U.S. Treasury yield curve on the date of grant.

Dividend Yield—The dividend yield assumption is based on the Company's history and expectation of no dividend payouts.

Stock Award Activity

A summary of option activity under the Company's equity incentive plans is as follows:

	Options Outstanding	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life (In Years)
Balance at December 31, 2021	2,255,672	$ 1.84	9.2
Options granted	533,349	$ 2.30	9.6
Options exercised	–		
Options forfeited/expired	(50,201)	$ 1.27	5.6
Balance at December 31, 2022	2,738,820	$ 1.94	8.4
Exercisable at December 31, 2022	2,169,088	$ 1.87	8.3

Vested and expected to vest at December 31, 2022	2,738,820	$	1.94	8.4

The aggregate intrinsic value in the table above of the unexercised options reflects the total pre-tax intrinsic value (the difference between the Nasdaq closing price on December 30, 2022, and the exercise price of the options that would have been received by option holders if all options exercisable had been exercised.

The aggregate intrinsic value of options outstanding at December 31, 2022 is $0. The aggregate intrinsic value of vested and exercisable options at December 31, 2022 is $0.

As of December 31, 2022, there was approximately $559,414 of total unrecognized compensation cost related to non-vested stock options, which is expected to be recognized over the next 33 months.

The Company adjusts expense for actual forfeitures in the periods they occur.

Restricted Stock Units

In 2022, the Company granted RSUs under the 2022 Plan that have a combination of time-based and performance-based vesting, contingent upon continued service with the Company. The Company granted certain consultants an aggregate of 481,915 RSUs.

RSU activity under the 2022 Plan was as follows for the year ended December 31, 2022:

	RSU's Outstanding		Weighted-Average Grant-Date Fair value per Unit
Nonvested as of December 31, 2021	–	$	–
Granted	481,915		0.82
Vested	(61,826)		0.87
Forfeited	–		–
Nonvested as of December 31, 2022	420,089	$	0.82

The grant date fair value for a RSU is the market price of the common stock on the date of grant. The total fair value of RSUs vested during 2022 was $53,912.

As of December 31, 2022, there was approximately $291,331 total unrecognized compensation cost related to non-vested RSUs, which is expected to be recognized over the next twelve months.

Common Stock Subject to Vesting

The Company entered into a contract for consulting services shortly after the completion of the IPO in April 2022. The contract included a fee payable in the form of 40,000 restricted common shares that vested over six months. The shares were issued in November 2022 after the shares vested. Stock-based vendor payments of $102,000 were recognized on the date of grant and recorded as general and administrative expense.

Stock-based Compensation Expense

The following table summarizes the total stock-based compensation expense included in the Company's statements of operations for the periods presented:

	December 31,	
	2022	2021
Sales and marketing	$ 57,299	$ 4,741
Research and development	(259)	23,604
General and administrative	1,129,619	149,144
	$ 1,186,659	$ 177,489

NOTE 14. SUBSEQUENT EVENTS

On February 16, 2023, the Company entered into a Securities Purchase Agreement (the "Purchase Agreement") with Jeffrey Thramann, the Company's Executive Chairman (the "Purchaser") pursuant to which it issued and sold one (1) share (the "Share") of the Company's newly designated Series A Preferred Stock, par value $0.00001 per share (the "Series A Preferred Stock"), to such Purchaser for an aggregate purchase price of $1,000.

The Share of Series A Preferred Stock will have 15,000,000 votes and will vote together with the outstanding shares of the Company's common stock as a single class exclusively with respect to any proposal to amend the Company's Certificate of Incorporation to effect a reverse stock split of the Company's common stock. The Share of Series A Preferred Stock will be voted, without action by the holder, on any such reverse stock split proposal in the same proportion as shares of common stock are voted on such proposal (excluding any common shares that are not voted). The Series A Preferred Stock otherwise has no voting rights, except as may otherwise be required by the General Corporation Law of the State of Delaware. The Share of Series A Preferred Stock is not convertible into, or exchangeable for, shares of any other class or series of stock or other securities of the Company. The Share of Series A Preferred Stock has no rights with respect to any distribution of assets of the Company, including upon a liquidation, bankruptcy, reorganization, merger, acquisition, sale, dissolution or winding up of the Company, whether voluntarily or involuntarily. The holder of the Share of Series A Preferred Stock will not be entitled to receive dividends of any kind.

The outstanding share of Preferred Stock shall be redeemed in whole, but not in part, at any time (i) if such redemption is ordered by the Board of Directors in its sole discretion or (ii) automatically upon the effectiveness of the amendment to the Certificate of Incorporation implementing a reverse stock split. Upon such redemption, the holder of the Series A Preferred Stock will receive consideration of $1,000.00 in cash.

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

None.

Item 9A. Controls and Procedures.

Attestation Report of the Registered Public Accounting Firm

This Annual Report on Form 10-K does not include an attestation report of our registered public accounting firm due to an exemption established by the JOBS Act for "emerging growth companies."

Annual Evaluation of Disclosure Controls and Procedures

We have adopted and maintain disclosure controls and procedures (as such term is defined in Exchange Act Rules 13a-15(e) and 15d-15(e) under the Exchange Act), that are designed to ensure that information required to be disclosed in our reports under the

Exchange Act, is recorded, processed, summarized and reported within the time periods required under the SEC's rules and forms and that the information is gathered and communicated to our management, including our Chief Executive Officer (Principal Executive Officer) and Chief Financial Officer (Principal Financial Officer), to allow for timely decisions regarding required disclosure.

As required by Exchange Act Rule 13a-15, our Chief Executive Officer and Chief Financial Officer carried out an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures pursuant to Exchange Act Rule 13a-15 as of the end of the period covered by this report. Based on the foregoing evaluation, our Chief Executive Officer and Chief Financial Officer concluded that due to our limited resources our disclosure controls and procedures are not effective in providing material information required to be included in our periodic SEC filings on a timely basis and to ensure that information required to be disclosed in our periodic SEC filings is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, to allow timely decisions regarding required disclosure about our internal control over financial reporting discussed below.

Management's Annual Report on Internal Control Over Financial Reporting

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

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2022. Based on that assessment, our management has determined that as of December 31, 2022, our internal control over financial reporting was not effective due to material weaknesses related to a limited segregation of duties due to our limited resources and the small number of employees. Management has determined that this control deficiency constitutes a material weakness which could result in material misstatements of significant accounts and disclosures that could result in a material misstatement to our interim or annual financial statements that would not be prevented or detected. In addition, due to limited staffing, we are not always able to detect minor errors or omissions in reporting.

This Annual Report does not include an attestation report of our independent registered public accounting firm regarding management's assessment of our internal control over financial reporting pursuant to temporary rules of the SEC.

Changes in Internal Control Over Financial Reporting

There were no changes to our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the quarter ended December 31, 2022 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

None

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

Not applicable.

PART III

Item 10. Directors, Executive Officers, and Corporate Governance

Executive officers and directors

Set forth below are the names, ages and positions of our executive officers and directors as of February 24, 2023.

Name	Age	Position(s) held	Served as a Director and/or Officer Since
Executive Officers			
Jeff Thramann, M.D.	58	Executive Chairman and Director	2020(1)
Brent Ness	56	Chief Executive Officer, President and Director	2021(2)
John Lorbiecki	60	Chief Financial Officer	2021(3)
Ryan Bond	51	Chief Strategy Officer	2021(4)
Non-Employee Directors			
Scott Breidbart, M.D.	67	Director	(5)
Steve Deitsch	51	Director	(5)
David Neal	51	Director	(6)
William Wesemann	66	Director	(6)
Amanda Williams	45	Director	(5)

(1) Dr. Thramann has been a director since 2020. He was appointed Executive Director as of March 2021, and became Executive Chairman as of April 21, 2022.
(2) Mr. Ness was appointed CEO and a director on September 15, 2021.
(3) Mr. Lorbiecki was appointed Chief Financial Officer on October 1, 2021.
(4) Mr. Bond was appointed Chief Strategy Officer on September 15, 2021.
(5) Ms. Williams, Mr. Deitsch, and Dr. Breidbart have been directors since April 21, 2022.
(6) Mr. Wesemann and Mr. Neal have been directors since 2016.

Executive Officers

Jeff Thramann, M.D., Executive Chairman and Director: Jeff Thramann has been a director since September, 2020. He was also an executive Director since March of 2021, which is an executive officer of the Company. He transitioned to Executive Chairman at the time of our April 2022 IPO. He oversees strategic initiatives, capitalization and governance at the company. This includes day-to-day involvement in working with senior management to establish the strategic vision of the Company, assist in KOL development, work with the Chief Executive Officer and Chief Financial Officer on financial plans, clinical reimbursement and product strategies, and assisting the Chief Executive Officer in recruitment and hiring of senior executives and the pursuit of business development activities. His responsibilities also include leading investor relations efforts, building the board of directors and leading board meetings. Dr. Thramann is currently the founder and Executive Chairman of Auddia Inc. (NASDAQ: AUUD), a technology company that is reinventing how

consumers interact with audio through an AI platform that enables unique consumer experiences across radio and podcast listening. Dr. Thramann founded Auddia Inc. in January 2012. In 2002, Dr. Thramann was the founder (and became the chairman) of Lanx, LLC ("Lanx"). Lanx was an innovative medical device company focused on the spinal implant market that created the interspinous process fusion space with the introduction of its patented Aspen product. Lanx was sold to Biomet, Inc., an international orthopedic conglomerate, in November, 2013. Concurrent with Lanx, in July, 2006 Dr. Thramann was the founder and chairman of ProNerve, LLC ("ProNerve"). ProNerve was a healthcare services company that provided monitoring of nerve function during high-risk surgical procedures affecting the brain and spinal cord. ProNerve was sold to Waud Capital Partners, a private equity firm, in 2012. Prior to ProNerve and concurrent with Lanx, Dr. Thramann was the founder and chairman of U.S. Radiosurgery (USR). USR is a healthcare services company that provides advanced radiosurgical treatments for tumors throughout the body. USR became the largest provider of robotic guided CyberKnife treatments of such tumors in the U.S. and was sold to Alliance Healthcare Services (NASDAQ: AIQ) in April, 2011. From July, 2001 through April, 2008, Dr. Thramann was the founder and senior partner of Boulder Neurosurgical Associates, a neurosurgical practice serving Boulder County, Colorado. Dr. Thramann is the named inventor on over 100 U.S. and international issued and pending patents. He completed his neurosurgical residency and complex spinal reconstruction fellowship at the Barrow Neurological Institute in Phoenix, AZ, in June, 2001. He is a graduate of Cornell University Medical College in New York City and earned his Bachelor of Science degree in electrical engineering management at the U. S. Military Academy in West Point, NY.

Brent Ness, Chief Executive Officer. Mr. Ness became our Chief Executive Officer on September 15, 2021. From December 2019 through April 2021, he was a consultant and then became President and Chief Commercial Officer of Cleerly, Inc., ("Cleerly"). Cleerly is a developer of an AI enabled non-invasive digital care pathway aimed at improving clinicians understanding of their patients' risk of sudden coronary death. At Cleerly, Mr. Ness co-led efforts to create a partnership with Canon, Inc. who co-markets Cleerly solutions as part of their offerings. From March 2016 to December 2019, Mr. Ness was the Chief Operating Officer of Mighty Oak Medical ("Mighty Oak") whose principal products progressed from pre-FDA clearance through an international full market launch of their platform called FIREFLY. FIREFLY is a 3D Printed patient specific solution that is intended to provide spine surgeons with a highly accurate alternative to navigation and robotic applications in the spinal navigation space. FIREFLY involves the use of CT scans as the core data upon which sophisticated pre-surgical plans are created along with guides and bone models. From 2014 through 2016, Mr. Ness was the Chief Commercial Officer of HeartFlow, Inc., ("Heartflow"). HeartFlow is a medical technology company that created and developed a non-invasive cardiac test enabling physicians to make more informed decisions for their patients with suspected coronary heart disease. Mr. Ness led the business from pre-FDA clearance through a global expansion of early adopter sites. Along with the senior leadership team at HeartFlow, he deployed a strong clinical evidence-based approach in the early launch of the SaaS platform to engage Key Opinion Leader Physicians and the third-party payer community. This resulted in the issuance of Category III CPT Codes and multiple private payer coverage decisions. From 2008 through 2013, he was President of ProNerve, LLC, ("ProNerve"). ProNerve is a provider of intraoperative neuromonitoring services which involves the use of a variety of electro-physiological monitoring procedures during spine and brain surgery, to allow early warning and avoidance of injury to nervous system structures. As President of ProNerve, Mr. Ness presided over a roll up of the highly fragmented Interoperative Nerve Monitoring Industry. From 2004 to 2008, Mr. Ness served as Vice President- Global Sales and Marketing for Medtronic Navigation, a division of Medtronic, Inc. Earlier in his career he was employed by GE Healthcare as Director of Corporate Accounts and for Philips North America as Vice President of Sales Operations, which companies are suppliers of diagnostic imaging equipment.

Mr. Ness currently serves as an advisor to Mighty Oak Medical, K2 Capital and Cleerly. Mr. Ness has a Bachelor's Degree in Marketing from the University of North Dakota and an MBA from the University of Colorado.

John Lorbiecki, Chief Financial Officer: Mr. Lorbiecki became our Chief Financial Officer on October 1, 2021. He has over 25 years of financial management and operational experience which includes serving as the divisional CFO for two business units within Medtronic, Inc. From January 2019 through October 1, 2021, Mr. Lorbiecki was a principal of Strategic Finance Solutions LLC, a financial consulting company. From April 2021 to October 2021, he also advised Fusion Robotics LLC through their merger with Integrity Implants Inc., now doing business as Accelus Inc. From January 2020 through April 2021, Mr. Lorbiecki held the lead finance role at Honeybee Robotics, an aerospace company that designs and builds advanced robotic systems. He led the financial dimensions of the strategic planning process, managed monthly project reviews to measure progress and ensure economic targets were met, and oversaw monthly accounting activities. From March 2017 through July 2018, he served as Chief Operating Officer at Colorado Therapeutics LLC, a medical startup focused on innovative biologic soft tissue repair products where he was instrumental in completing the relocation of the company headquarters and increasing manufacturing capacity. From 1991 through 2017 he was with Medtronic, among the largest medical device companies in the world. He led sales operations, including pricing and contracting, for the Cardiac Surgery Division, and moved through other business unit and corporate financial leadership roles. Mr. Lorbiecki has a Bachelor's Degree in Economics from the University of St. Thomas where he graduated magna cum laude and an MBA from the University of Chicago Booth School of Business.

Ryan Bond, Chief Strategy Officer: Commencing in September 2021, Mr. Bond has been our Chief Strategy Officer. From December 2018 to August 2021, he has been our Vice President, Business Development, where he led business development, sales and marketing including a limited commercial launch of Aclarion's cloud-based SaaS with early adopters in the US, EU, and UK, Mr. Bond coordinated multiple research trials sponsored by our customers, where Aclarion's proprietary, adjunctive diagnostic technology is employed. Mr. Bond was instrumental in working with reimbursement consultants to gain Category III CPT Codes for Aclarion with assigned APC rates and advocating to CMS for the removal of a long-standing non-coverage policy for magnetic resonance spectroscopy (MRS, CPT Code 76390). From November 2014 to September 2018 Mr. Bond was Director, Healthcare Solutions at NuVasive, a company in the global spine market. While at NuVasive, he led several strategic initiatives involving strategic partnerships, channel development, pricing, contracting, and sales training. From 2005 to 2014, Mr. Bond was with Accelero Health Partners ("Accelero"), a consulting firm focused on musculoskeletal service line development using a combination of strategic organizational development programs and a proprietary cloud-based business intelligence tool that discretely measured a cadre of clinical, functional, operational, and volume-based metrics, while simultaneously illustrating the interrelated cause-effect of each. In 2006, Accelero was acquired by Zimmer Holdings. Mr. Bond serves on an Advisory Board to the College of Business at Ohio University, where he earned a Bachelor's of Science Degree in Engineering from the Russ College of Engineering and Technology.

Non-employee directors

Scott Breidbart, M.D., Director: Dr. Scott Breidbart has been consulting in the healthcare industry since November 2021. Before that, he was the Chief Medical Officer of Affinity Health Plans from January 2018 until its purchase in November 2021. From October 2016 to January 2018, he was Chief Medical Officer of Solera Health and from October 2015 to September 2016, he was the Chief Clinical Officer of Emblem Health. From November 2008 to October 2015, Mr. Breidbart served as the Chief Medical Officer of Empire BlueCross BlueShield, and from May 1998 to August 2008 he had various roles in medical management for HealthNet. Dr. Breidbart practiced pediatric endocrinology for ten years on the faculty of New York Medical College. He is Board Certified in Pediatrics and Pediatric Endocrinology and is licensed to practice medicine in NY. He holds a BA in Mathematics from Yale, an MD from Columbia, and an MBA from Pace University.

Steve Deitsch, Director: Steve Deitsch is currently the CFO of Paradigm 28, a medical device company focused on surgical implants for the foot and ankle. Steve has extensive strategic, operational, and financial leadership experience at both publicly traded and privately held companies. From April 2017 to August 2019, Mr. Deitsch served as Senior Vice President and Chief Financial Officer of BioScrip, Inc., which is now part of Option Care Health, Inc. (NASDAQ: BIOS). From August 2015 to April 2017, Mr. Deitsch served as Executive Vice President, Chief Financial Officer and Corporate Secretary of Coalfire, Inc., a leading cyber-security firm owned by The Carlyle Group. Steve served as the Chief Financial Officer of the Zimmer Biomet Spine, Bone Healing, and Microfixation business from July 2014 to July 2015 and as Vice President Finance, Biomet Corporate Controller from February 2014 to July 2014. Mr. Deitsch was the Chief Financial Officer of Lanx from September 2009 until it was acquired by Biomet in October 2013. From 2002 to 2009, Mr. Deitsch also served in various senior financial leadership roles at Zimmer Holdings, Inc. (now part of Zimmer Biomet, Inc.), including Vice President Finance, Reconstructive and Operations, and Vice President Finance, Europe. Steve is a director of Green Sun Medical, a privately held medical device company, a position he has held since October 2017, and a director and audit committee chair of Auddia Inc. (NASDAQ: AUUD), since February of 2021. Mr. Deitsch holds a B.S. in Accounting from Ball State University and has an in-active CPA license.

David Neal, Director: Mr. Neal has been a director since September 2016. He is the founder and a current member of SC Capital 1 LLC which was formed in 2016. SC Capital 1 LLC is a securitized LLC formed to invest in breakthrough medical technologies and therapies. Also, from April 2015 to the present, he has been a partner of Frontier Wealth Enterprises, LLC a financial services firm providing advice-based financial services to high-net worth families. From 2000 to 2015, he held various positions with UBS, including Portfolio Manager and manager of a Regional Office in Wichita Kansas. He was on the Hutchinson Regional Medical Center board of directors for 9 years and currently is a member of the board of the Hutchinson Community Foundation. He holds a Bachelor of Sport Science degree from the University of Kansas and a Master of Management Science degree from the John Cook School of Business at Saint Louis University.

William (Bill) Wesemann, Director: Mr. Wesemann has been a director since 2016. Mr. Wesemann has been an independent businessman and investor since June 2002. Prior to 2002 his experience included serving in chief executive, sales leadership, and advisory roles at technology companies. Since 2004, he has been a director of LivePerson (Nasdaq: LPSN), a global technology company that develops conversational commerce and AI software. He is also a director of Stationhead, Inc. (commencing in 2019), a consumer social audio

platform; and a director of Mylio, Inc (commencing in 2013) a photo management company. Mr. Wesemann received a B.A. from Glassboro State College (Rowan University).

Amanda Williams, Director: Ms. Williams is currently the Senior Vice President of Clinical, Quality and Regulatory at ViewRay, Inc. (Nasdaq: "VRAY"), a healthcare company that integrates real time MRI imaging of tumors with the delivery of high dose radiation for improved treatment accuracy. She joined ViewRay in October of 2018 and brings 20 years of experience in the medical device space. From December, 2017, to September, 2018, she was the Head of Regulatory with the Image Guided Therapy Devices and Systems divisions of Philips. From July, 2010 to December, 2017 Ms. Sequira was the Senior Director (2010-2013) and Vice President (2013-2017) of Clinical and Regulatory with The Spectranetics Corp., (now part of Philips), and from 2003 to 2010 she was Manager, and then Director of Regulatory of AGA Medical Corp (now part of Abbott). Prior to these roles, she worked as a Regulatory Specialist with Vascular Solutions and as a Chemist with GE – Osmonics. In these positions, she worked on a diverse range of products, including cardiovascular treatment, implantable heart defect device, combination drug/device and large capital equipment (both imaging and treatment) devices. At Spectranetics, she led teams that completed multiple global randomized clinical studies. She holds a Master of Science in Regulatory from Northeastern University and a Bachelor of Science in Chemistry from the University of Minnesota.

Section 16(a) Beneficial Ownership Reporting Compliance

Following our IPO, Section 16(a) of the Exchange Act requires our directors, executive officers, and persons holding more than 10% of our common stock to report their initial ownership of the common stock and other equity securities and any changes in that ownership in reports that must be filed with the SEC. The SEC has designated specific deadlines for these reports, and we must identify in our Annual Report on Form 10-K those persons who did not file these reports when due.

Based solely on a review of reports furnished to us, or written representations from reporting persons, we believe all directors, executive officers, and 10% owners timely filed all reports regarding transactions in our securities required to be filed to date in 2022 by Section 16(a) under the Exchange Act, except that each of Mr. Lorbiecki, Mr. Bond, SC Capital and Nuvasive filed a late Form 3.

Election of Officers

Our executive officers are appointed by, and serve at the discretion of, our board of directors. There are no family relationships among any of our directors or executive officers.

Composition of the Board of Directors

Our board of directors currently consists of seven members. Four of our directors are independent within the meaning of the independent director guidelines of the Nasdaq Stock Market.

Each director's term continues until the election and qualification of his successor, or his earlier death, resignation or removal. Our restated certificate of incorporation and restated bylaws authorize only our board of directors to fill vacancies on our board of directors.

Board Leadership Structure and Role in Risk Oversight

Our corporate governance guidelines provide that unless the board chair is an independent director, the board shall appoint a Lead Independent Director. The Lead Independent Director chairs the executive sessions of the independent directors, coordinates the activities of the other independent directors and performs such other duties as deemed necessary by the board from time to time. Because our Executive Chairman Dr. Thramann is not independent, the board has appointed William Wesemann to serve as our Lead Independent Director.

Risk is inherent with every business, and how well a business manages risk can ultimately determine its success. We face a number of risks, including credit risk, interest rate risk, liquidity risk, operational risk, strategic risk and reputation risk. Management is responsible for the day-to-day management of risks we face, while the board, as a whole and through its committees, has responsibility for the oversight of risk management. In its risk oversight role, the board has the responsibility to satisfy itself that the risk management processes designed and implemented by management are adequate and functioning as designed. To do this, the board meets regularly with management to discuss strategy and the risks we face. In addition, the Audit Committee regularly monitors our enterprise risk, including financial risks, through reports from management. Senior management attends the board meetings and is available to address

any questions or concerns raised by the board on risk management and any other matters. The Lead Independent Director and the independent board members work together to provide strong, independent oversight of our management and affairs through the board's standing committees and, when necessary, executive sessions of the independent directors.

Director Independence

Under the rules of Nasdaq, independent directors must comprise a majority of a listed company's board of directors within a specified period following the completion of its IPO. In addition, the rules of Nasdaq require that, subject to specified exceptions, each member of a listed company's audit, compensation and nominating and governance committees be independent. Under the rules of Nasdaq, a director will only qualify as an "independent director" if, in the opinion of that company's board of directors, that person does not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director.

Audit committee members must also satisfy the independence criteria set forth in Rule 10A-3 under the Exchange Act. In order to be considered independent for purposes of Rule 10A-3, a member of an audit committee of a listed company may not, other than in his capacity as a member of the audit committee, the board of directors or any other board committee: (i) accept, directly or indirectly, any consulting, advisory or other compensatory fee from the listed company or any of its subsidiaries; or (ii) be an affiliated person of the listed company or any of its subsidiaries. We currently satisfy the audit committee independence requirements of Rule 10A-3. Additionally, compensation committee members must not have a relationship with us that is material to the director's ability to be independent from management in connection with the duties of a compensation committee member.

Our board of directors has undertaken a review of the independence of each director and considered whether each director has a material relationship with us that could compromise his ability to exercise independent judgment in carrying out his responsibilities. As a result of this review, our board of directors determined that all of our directors, except for Jeffrey Thramann, Brent Ness and David Neal are "independent directors" as defined under the applicable rules and regulations of the Securities and Exchange Commission, or SEC, and the listing requirements and rules of Nasdaq. In making these determinations, our board of directors reviewed and discussed information provided by the directors and us with regard to each director's business and personal activities and relationships as they may relate to us and our management.

Committees of our board of directors

Audit Committee

Our audit committee is comprised of Bill Wesemann, Scott Breidbart and Steve Deitsch, with Steve Deitsch serving as its chairman The composition of our audit committee meets the requirements for independence under the current Nasdaq and SEC rules and regulations. Each member of our audit committee is financially literate. In addition, our board of directors has determined that Stephen Deitsch is an "audit committee financial expert" as defined in Item 407(d)(5)(ii) of Regulation S-K promulgated under the Securities Act. This designation does not impose on Mr. Deitsch any duties, obligations or liabilities that are greater than are generally imposed on members of our audit committee and our board of directors. Our audit committee is directly responsible for, among other things:

- selecting and hiring our independent registered public accounting firm;
- the qualifications, independence and performance of our registered public accounting firm;
- the preparation of the audit committee report to be included in our annual proxy statement;
- our compliance with legal and regulatory requirements;
- our accounting and financial reporting processes, including our financial statement audits and the integrity of our financial statements; and
- reviewing and approving related-person transactions.

Compensation Committee

Our compensation committee is comprised of Amanda Williams, Scott Breidbart, and Bill Wesemann, with Mr. Wesemann serving as chairman. Each member of our compensation committee is a non-employee director, as defined by Rule 16b-3 promulgated under the Exchange Act and meets the requirements for independence under the current Nasdaq listing standards and SEC rules and regulations. Our compensation committee is responsible for, among other things:

- evaluating, recommending, approving and reviewing executive officer compensation arrangements, plans, policies and programs;
- evaluating and recommending non-employee director compensation arrangements for determination by our board of directors;
- administering our cash-based and equity-based compensation plans; and
- overseeing our compliance with regulatory requirements associated with the compensation of directors, officers and employees.

Nominating and Governance Committee

Our nominating and governance committee is comprised of Bill Wesemann, Scott Breidbart, and Amanda Williams, with Amanda Williams serving as its chairman. Each member of our nominating and governance committee meets the requirements for independence under the current Nasdaq listing standards. Our nominating and governance committee is responsible for, among other things:

- identifying, considering and recommending candidates for membership on our board of directors;
- overseeing the process of evaluating the performance of our board of directors; and
- advising our board of directors on other corporate governance matters.

Consideration of Director Nominees

Director Qualifications

There are no specific minimum qualifications that the Board requires to be met by a director nominee recommended for a position on our board, nor are there any specific qualities or skills that are necessary for one or more members of our board to possess, other than as are necessary to meet the requirements of the rules and regulations applicable to us. The Nominating and Governance Committee considers a potential director candidate's experience, areas of expertise and other factors relative to the overall composition of our board and its committees, including the following characteristics: experience, judgment, commitment (including having sufficient time to devote to the Company), skills, diversity, and expertise appropriate for the Company. In assessing potential directors, the Nominating and Governance Committee may consider the current needs of the board and the Company to maintain a balance of knowledge, experience and capability in various areas.

Stockholder Nominations

In accordance with our bylaws, a stockholder wishing to nominate a director for election at an annual meeting of stockholders must timely submit a written proposal of nomination to us at our executive offices. To be timely, a written proposal of nomination for an annual meeting of stockholders must be received at least 90 calendar days but no more than 120 calendar days before the first anniversary of the date on which we held our annual meeting of stockholders in the immediately preceding year; *provided*, *however*, that in the event that the date of the annual meeting is advanced or delayed more than 30 calendar days from the anniversary of the annual meeting of stockholders in the immediately preceding year, the written proposal must be received: (i) at least 90 calendar days but no more than 120 calendar days prior to the date of the annual meeting; or (ii) no more than 10 days after the date we first publicly announce the date of the annual meeting.

Each written proposal for a nominee must contain: (1) the name, age, business address and residence address of such nominee, (2) the principal occupation or employment of such nominee, (3) the class and number of shares of each class of capital stock of the Company which are owned of record and beneficially by such nominee, (4) the date or dates on which such shares were acquired and the investment intent of such acquisition, (5) a statement whether such nominee, if elected, intends to tender, promptly following such person's failure to receive the required vote for election or reelection at the next meeting at which such person would face election or re-election, an irrevocable resignation effective upon acceptance of such resignation by the board, and (6) such other information concerning such nominee as would be required to be disclosed in a proxy statement soliciting proxies for the election of such nominee as a director in an election contest (even if an election contest is not involved), or that is otherwise required to be disclosed pursuant to Section 14 of the 1934 Act and the rules and regulations promulgated thereunder (including such person's written consent to being named as a nominee and to serving as a director if elected).

A stockholder interested in submitting a nominee for election to the board should refer to our bylaws for additional requirements. Upon receipt of a written proposal of nomination meeting these requirements, the Nominating and Governance Committee of the Board will evaluate the nominee in accordance with its charter and the characteristics listed above.

Evaluating Nominees for Director

Our Nominating and Corporate Governance Committee considers director candidates that are suggested by members of the committee, other members of our Board, members of management, advisors and our stockholders who submit recommendations in accordance with the requirements set forth in our Bylaws, as described above. Our Board has in the past engaged a third-party search firm to identify potential candidates for consideration by the Nominating and Governance Committee and election to our Board. The Nominating and Corporate Governance Committee may, in the future, retain third-party search firms to identify Board candidates on terms and conditions acceptable to the Nominating and Corporate Governance Committee to assist in the process of identifying or evaluating director candidates. The Nominating and Corporate Governance Committee evaluates all nominees for director using the same approach whether they are recommended by stockholders or other sources. The Nominating and Corporate Governance Committee reviews candidates for director nominees in the context of the current composition of our Board and committees, the operating requirements of the Company and the long-term interests of our stockholders. In conducting this assessment, the Nominating and Corporate Governance Committee considers the director nominee's qualifications, diversity, skills and such other factors as it deems appropriate given the current needs of the Board, the committees and the Company, to maintain a balance of knowledge, experience, diversity and capability. In the case of incumbent directors whose terms of office are set to expire, the Nominating and Corporate Governance Committee reviews such directors' overall service to the Board, the committees and the Company during their term, including the number of meetings attended, level of participation, quality of performance and any other relationships and transactions that might impair such directors' independence. In the case of new director candidates, the Nominating and Corporate Governance Committee will also determine whether the nominee must be independent for Nasdaq purposes, which determination will be based upon applicable Nasdaq listing standards and applicable SEC rules and regulations. Although we do not have a formal diversity policy, when considering diversity in evaluating director nominees, the Nominating and Corporate Governance Committee focuses on whether the nominees can contribute varied perspectives, skills, experiences and expertise to the Board.

The Nominating and Corporate Governance Committee will evaluate the proposed director's candidacy, including proposed candidates recommended by stockholders, and recommend whether the Board should nominate the proposed director candidate for election by our stockholders.

Stockholder Communications with the Board

Any stockholder or interested party who desires to contact our board, or specific members of our board, may do so electronically by sending an email to our CFO at the following address: jlorbiecki@aclarion.com. Alternatively, a stockholder may contact our board, or specific members of our board, by writing to: Aclarion, Inc., 8181 Arista Place, Suite 100, Broomfield, Colorado, 80021, Attn: CFO. All such communications will be initially received and processed by the office of our CFO. Communications concerning accounting, audit, internal accounting controls and other financial matters will be referred to the Chair of the Audit Committee. Other matters will be referred to the board, the non-employee directors or individual directors, as appropriate.

The board has instructed the CFO to review all communications so received and to exercise his discretion not to forward to the board correspondence that is inappropriate such as business solicitations, frivolous communications and advertising, routine business matters and personal grievances. However, any director may at any time request the CFO to forward any and all communications received by the CFO but not forwarded to the directors.

Compensation committee interlocks and insider participation

None of the current members of our compensation committee has ever been an executive officer or employee of ours. None of our executive officers currently serves, or has served during the last completed fiscal year, on the compensation committee or board of directors of any other entity that has one or more executive officers serving as a member of our board of directors or compensation committee.

Code of Business Conduct and Ethics

Our board of directors has adopted a code of business conduct and ethics that applies to all of our employees, officers and directors, including our Chief Executive Officer and other executive and senior officers. The full text of our code of business conduct and ethics is posted on the investor relations section of our website. The reference to our website address in this Annual Report on Form 10-K does not include or incorporate by reference the information on our website into this Annual Report on Form 10-K. We intend to disclose future amendments to certain provisions of our code of business conduct and ethics, or waivers of these provisions, on our website or in public filings to the extent required by the applicable rules.

Number of Meetings

Since our current board took office at the time of our April 2022 IPO, the board held a total of four meetings in 2022. Our Audit Committee held five meetings, our Compensation Committee held two meetings, and our Nominating and Governance Committee held no meetings. Each director attended at least 75% of the aggregate of the total number of meetings of the board and the board committees on which he served.

Board Member Attendance at Annual Stockholder Meetings

Although we do not have a formal policy regarding director attendance at annual stockholder meetings, directors are encouraged to attend these annual meetings absent extenuating circumstances. We did not hold an annual meeting during 2022.

Non-Employee Director Compensation

Our non-employee directors began serving on our board following our April 2022 IPO. Accordingly, our current non-employee directors did not receive any cash or equity compensation from the Company for the year ended December 31, 2021.

Our Executive Chairman, Dr. Thramann, and our President and Chief Executive Officer, Mr. Ness, do not receive compensation for their services as a director.

Following our April 2022 IPO, our board of directors approved the following compensation for our non-employee directors in 2022. Our non-employee directors will receive annual cash compensation of (i) $25,000 for service on the board (ii) $15,000 for service as the Audit Committee chair, and (iii) $5,000 for service on each board committee. All cash payments will be made quarterly in arrears, and pro-rated for any partial quarters of service.

The following Director Compensation Table summarizes the compensation of each of our non-employee directors for services rendered to us during the year ended December 31, 2022:

In addition, each of our non-employee directors were granted an option to purchase 63,000 shares of our common stock following the closing of our IPO. Such stock options have an exercise price of $2.72, which was equal to the Company's closing stock price on the first trading day following our IPO. These grants will vest in 36 equal installments, subject to the director's continued service through each applicable vesting date.

The following Director Compensation Table summarizes the compensation of each of our non-employee directors for services rendered to us during the year ended December 31, 2022:

Name	Fees Earned or Paid in Cash ($)	Stock Awards ($)	Option Awards ($) (1)	All Other Compensation ($)	Total ($)
Scott Breidbart	27,582	-0-	104,218	-0-	131,800
Steve Deitsch	31,030	-0-	104,218	-0-	135,248
David Neal	17,239	-0-	-0-	100,000 (2)	117,239
William Wesemann	27,582	-0-	105,190	-0-	132,772
Amanda Williams	24,135	-0-	104,218	-0-	128,353

(1) Represents the grant date fair value of stock option awards computed in accordance with FASB ASC Topic 718, excluding the effect of estimated forfeitures. For information regarding assumptions underlying the valuation of equity awards, see Note 13 to our financial statements included in this Annual Report on Form 10-K.

(2) Reflects a cash bonus paid following the closing of our IPO.

Item 11. Executive Compensation

Executive Compensation Overview

As an "emerging growth company," we have opted to comply with the executive compensation disclosure rules applicable to "smaller reporting companies," as such term is defined in the rules promulgated under the Securities Act.

This section provides an overview of the compensation awarded to, earned by, or paid to each individual who served as our principal executive officer during our fiscal year 2022, and our next three most highly compensated executive officers in respect of their service to our company for fiscal year 2022. Our named executive officers, or the Named Executive Officers, for the year ended December 31, 2022, are:

- Jeffrey Thramann, Executive Chairman;
- Brent Ness, Chief Executive Officer;
- John Lorbiecki, Chief Financial Officer; and
- Ryan Bond, Chief Strategy Officer.

Summary Compensation Table Year Ended December 31, 2022

The following table contains information about the compensation paid to or earned by each of our Named Executive Officers during the two most recently completed fiscal years.

Name and Principal Position	Year	Salary ($)	Bonus ($)[1]	Stock Awards ($)	Option Awards ($)[2]	All Other Compensation ($)	Total ($)
Jeff Thramann, Executive Director	2022	300,000	–	–	252,369	–	552,369
	2021	250,000	–	–	672,603	–	922,603
Brent Ness, Chief Executive Officer	2022	300,000	100,000[3]	–	90,704	–	490,704
	2021	100,000	–	–	186,216	–	286,216
Ryan Bond, Chief Strategy Officer	2022	200,000	8,594	–	–	–	208,594
	2021	185,417	17,188[4]	–	3,983	–	206,588
John Lorbiecki, Chief Financial Officer	2022	225,000	28,125[5]	–	19,747	–	272,872
	2021	56,250	–	–	36,513	–	92,763

(1) The Company has a discretionary annual cash bonus program. As of the filing date of this annual report, the Company has not approved or paid any annual cash bonuses for the 2022 year.

(2) Represents the grant date fair value of stock option awards computed in accordance with FASB ASC Topic 718, excluding the effect of estimated forfeitures. For information regarding assumptions underlying the valuation of equity awards, see Note 13 to our financial statements included in this Annual Report on Form 10-K.

(3) Under the terms of his employment agreement, Mr. Ness received a bonus payment of $100,000 upon the IPO completed in April 2022.

(4) The Company implemented a cash bonus plan related to the temporary deferral of all employees' base salaries by 50% effective as of October 16, 2020. The cash bonus paid to Mr. Bond in 2021 was equal to 50% of the amount of the temporary salary deferral incurred by the employee during the same period.

(5) Under the terms of his employment agreement, Mr. Lorbiecki received a bonus payment of $28,125 upon the IPO completed in April 2022.

Employment Agreements

Dr. Jeff Thramann

On June 15, 2021, we entered into an employment agreement with Dr. Jeff Thramann. The employment agreement was retroactively made effective to March 1, 2021. The employment agreement provides that Dr. Thramann will:

- Receive a salary of $25,000 per month.;
- Be appointed as Executive Director (an executive officer position with the Company), as an "at will" employee, until the date of the IPO, at which time he transitioned from Executive Director to Executive Chairman, an executive officer of the Company.
- Be issued options (the "Thramann Options") to purchase 1,204,819 shares of common stock (the "Thramann Option Shares") of the Company subject to the terms and conditions set forth in the Company's equity incentive plan, at an exercise price of $1.94 per share. The options have a 10-year term. The vesting of the Thramann Options occurred on the date of the IPO, April 21, 2022.

Brent Ness

On September 15, 2021, we entered into an Employment Agreement with Brent Ness. The employment agreement provides that Mr. Ness would:

- Be appointed Chief Executive Officer of the Company.
- Receive an annual base salary of $300,000, plus an additional $100,000 if the Company completes an initial public offering and its securities are listed for trading on Nasdaq or the NYSE.
- Commencing in 2022, Mr. Ness will be eligible to receive, upon certain conditions, an annual incentive bonus up to 50% of Mr. Ness' base salary
- Mr. Ness' employment agreement is terminable 'at will' by the Company. If the Company terminates Mr. Ness' employment without cause or Mr. Ness terminates for good reason, he is entitled to receive twelve months of base salary, (ii) up to nine months of paid health insurance under COBRA, and (iii) any earned but unpaid bonus for a prior completed fiscal year.
- Be issued options to purchase 341,365 shares of common stock of the Company, subject to the terms and conditions set forth in the Company's equity incentive plan, at an exercise price of $1.94 per share. The stock options have a 10-year term. The stock options will vest in 48 equal installments on each monthly anniversary of the date of grant, such that the grant will become fully vested and exercisable on the four-year anniversary of the date of grant.

John Lorbiecki

On September 22, 2021, we entered into an Employment Agreement with John Lorbiecki. The employment agreement provides that Mr. Lorbiecki would:

- Be appointed Chief Financial Officer of the Company as an "at will" employee.
- Receive an annual base salary of $225,000.
- Commencing in 2022, Mr. Lorbiecki will be eligible to receive, upon certain conditions, an annual incentive bonus up to 50% of Mr. Lorbiecki's base salary.

- Mr. Lorbiecki's employment agreement is terminable 'at will' by the Company. If the Company terminates Mr. Lorbiecki's employment without cause or Mr. Lorbiecki terminates for good reason, he is entitled to receive twelve months of base salary, (ii) up to nine months of paid health insurance under COBRA, and (iii) any earned but unpaid bonus for a prior completed fiscal year.

- Be issued options to purchase 66,934 shares of common stock of the Company subject to the terms and conditions set forth in the Company's equity incentive plan, at an exercise price of $1.94 per share. The stock options have a 10-year term. The stock options will vest in 48 equal installments on each monthly anniversary of the date of grant, such that the grant will become fully vested and exercisable on the four-year anniversary of the date of grant.

Outstanding Equity Awards at December 31, 2022

The following table sets forth information regarding equity awards held by our Named Executive Officers as of December 31, 2022.

		Option Awards				Stock Awards	
Name	Grant Date	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price ($)	Option Expiration Date	Number of Shares or Units of Stock That Have Not Vested (#)	Market Value of Shares or Units That Have Not Vested ($)
Dr. Jeffrey Thramann	9/27/2021	1,204,819	–	$1.94	9/27/2031	–	–
	9/14/2022	185,285	–	$1.94	9/14/2032	–	–
Brent Ness	9/27/2021	106,677	234,689	$1.94	9/27/2031	–	–
	9/14/2022	23,619	51,963	$1.94	9/14/2032	–	–
Ryan Bond	2/19/2019	21,419	–	$1.34	2/19/2029	–	–
	9/4/2021	6,108	–	$1.94	9/4/2031	–	–
John Lorbiecki	9/27/2021	19,523	47,412	$1.94	9/27/2031	–	–
	9/14/2022	4,799	11,656	$1.94	9/14/2032	–	–

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

The following table sets forth information regarding the beneficial ownership of our common stock as of February 1, 2023 by (i) each person who beneficially owned more than 5% of our outstanding shares of common stock, (ii) each director, (iii) each Named Executive Officer and (iv) all of our directors and executive officers as a group. Unless otherwise indicated, the address of each executive officer and director is c/o listed below is c/o Aclarion, Inc., 8181 Arista Place, Suite 100, Broomfield, Colorado 80021.

The number of shares of common stock "beneficially owned" by each stockholder is determined under rules issued by the SEC regarding the beneficial ownership of securities. This information is not necessarily indicative of beneficial ownership for any other purpose. Under these rules, beneficial ownership of shares of our common stock includes (1) any shares as to which the person or entity has sole or shared voting power or investment power, and (2) any shares as to which the person or entity has the right to acquire beneficial ownership within 60 days after February 1, 2022.

The calculations set forth below are based upon 7,861,515 shares of common stock outstanding at February 1, 2022.

Unless otherwise indicated below, and subject to community property laws where applicable, to our knowledge, all persons named in the table have sole voting and investment power with respect to their shares of common stock.

Name of Beneficial Owner	Number of Shares Beneficially Owned (12)	Percentage of Shares Beneficially Owned
5% Stockholders:		
NuVasive Inc. (1)	1,126,495	14.3%
James Peacock (2)	515,162	6.4%
Clark Gunderson	439,876	5.6%
Richard Minicozzi (3)	405,429	4.9%
Executive Officers and Directors:		
Jeff Thramann (4)	1,390,104	15.0%
Brent Ness (5)	186,542	2.3%
John Lorbiecki (6)	53,675	0.7%
Ryan Bond (7)	68,527	0.9%
David Neal (8)	291,210	3.7%
William Wesemann (9)	93,026	1.2%
Amanda Williams (10)	19,250	0.2%
Stephen Deitsch (10)	19,250	0.2%
Scott Breidbart (10)	19,250	0.2%
All directors and executive officers as a group (9 persons)	2,140,834	22.1%

(1) The principal business address for NuVasive, Inc. is 7475 Lusk Boulevard, San Diego, California 92121.

(2) Mr. Peacock's individually owned beneficial shares includes 229,112 common shares and 157,535 vested stock options. Mr. Peacock also influences the voting shares of a related entity which holds 128,515 common shares.

(3) Mr. Minicozzi's beneficial ownership includes 405,429 common shares. Does not include 405,429 common stock warrants that are not currently exercisable due to a 4.9% ownership blocker provision.

(4) Represents outstanding stock options held by Dr. Thramann.

(5) Mr. Ness' beneficial ownership includes 20,500 common shares, 165,042 vested options, and 1,000 IPO Warrants, and excludes 251,906 unvested options.

(6) Mr. Lorbiecki's beneficial ownership includes 22,404 common shares and 31,271 vested options, and excludes 52,119 unvested options.

(7) Mr. Bond's beneficial ownership includes 20,000 common shares, 27,527 vested options, and 21,000 IPO Warrants.

(8) Mr, Neal's beneficial ownership includes 186,528 common shares, 34,400 IPO Warrants, and 70,282 vested options.

(9) Mr. Wesemann's beneficial ownership includes 52,736 common shares, 29,290 vested stock options, and 11,000 IPO Warrants, and excludes 43,750 unvested stock options.

(10) Includes 19,250 vested stock options and excludes 43,750 unvested stock options.

Securities Authorized for Issuance under Equity Compensation Plans

The following table provides certain information as of December 31, 2022, with respect to all of our equity compensation plans in effect on that date:

Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights	Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column (a))
	(a)	(b)	(c)
Equity Compensation Plans Approved by Stockholders (1)	3,220,735	$1.77	984,747
Equity Compensation Plans Not Approved by Stockholders	–	–	–
Total	3,220,735	$ 1.77	984,747

(1) Consists of (i) stock options granted under the Nocimed, Inc. 2015 Stock Plan and (ii) stock options and restricted stock units ("RSUs") granted under the Aclarion, Inc. 2022 Equity Incentive Plan, as amended. We ceased granting awards under the 2015 Plan upon the implementation of the 2022 Plan described below.

The Company's 2022 Equity Incentive Plan, which became effective upon the completion of our IPO in April 2022, serves as the successor equity incentive plan to the 2015 Plan.

The 2022 Equity Incentive Plan contains an "evergreen" provision, pursuant to which the number of shares of common stock reserved for issuance pursuant to awards under such plan shall be increased on the first day of each year beginning in 2023 and ending in 2032 equal to the lesser of (a) five percent (5%) of the shares of stock outstanding (on an as converted basis) on the last day of the immediately preceding fiscal year and (b) such smaller number of shares of stock as determined by our board of directors. On January 1, 2023, the Company had an additional 393,076 common shares added to the 2022 Equity Incentive Plan pursuant to the evergreen provision.

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

In addition to the executive officer and director compensation arrangements discussed above, below we describe transactions since January 1, 2019 to which we have been or will be a participant, in which the amount involved in the transaction exceeds or will exceed $120,000 and in which any of our directors, executive officers or beneficial holders of more than 5% of any class of our capital stock, or 5% security holders, or any immediate family member of, or person sharing the household with, any of these individuals, had or will have a direct or indirect material interest.

Commencing January 2020 and through the date of the filing of this annual report, we paid a total of $125,324 to the Regents of the University of California pursuant to our License Agreement with them Professor Jeffrey Lotz, PhD. who was a director of the Company prior to our IPO is a Director of the Company, is the Vice Chair of Orthopedic Research at UCSF. Dr. Lotz continues to serve as a member of our Scientific Advisory Board. We will continue to make payments to the Regents of the University of California for the duration of our License Agreement with UCSF (See "Business- License Agreement with the Regents of the University of California" above).

We have entered into a number of investment and commercial transactions with Nuvasive. See "Business – Transactions with Nuvasive."

Since January 2019, SC Capital 1 LLC and Clark Gunderson, M.D. have invested in (i) our Series B-1 preferred stock financing and (ii) our 6% convertible preferred note financing. Such investments were made on the same terms offered to other investors. David Neal, one of our directors, is the founder and a current member of SC Capital 1, LLC. Until December 2022, SC Capital 1 LLC owned more than 10% of our outstanding common shares.

On February 16, 2023, we entered into a securities purchase agreement with Jeffrey Thramann, our Executive Chairman pursuant to which we issued and sold one (1) share of the Company's newly designated Series A Preferred Stock for an aggregate purchase price of $1,000.

The share of Series A Preferred Stock will have 15,000,000 votes and will vote together with the outstanding shares of the Company's common stock as a single class exclusively with respect to any proposal to amend the Company's Certificate of Incorporation to effect a reverse stock split of the Company's common stock. The share of Series A Preferred Stock will be voted, without action by the holder, on any such reverse stock split proposal in the same proportion as shares of common stock are voted on such proposal (excluding any common shares that are not voted).

The Series A Preferred Stock otherwise has no voting rights, except as may otherwise be required by the General Corporation Law of the State of Delaware. The share of Series A Preferred Stock is not convertible into, or exchangeable for, shares of any other class or series of stock or other securities of the Company. The share of Series A Preferred Stock has no rights with respect to any distribution of assets of the Company, including upon a liquidation, bankruptcy, reorganization, merger, acquisition, sale, dissolution or winding up of the Company, whether voluntarily or involuntarily. The holder of the Share of Series A Preferred Stock will not be entitled to receive dividends of any kind. The share of Series A Preferred Stock shall be redeemed in whole, but not in part, at any time (i) if such redemption is ordered by our board in its sole discretion or (ii) automatically upon the effectiveness of the amendment to the Certificate of Incorporation implementing a reverse stock split. Upon such redemption, the holder of the Series A Preferred Stock will receive consideration of $1,000.00 in cash.

Policy for approval of related-person transactions

We have adopted a related-person transaction policy that requires audit committee review and approval of any transaction, arrangement or relationship in which we are a participant and one of our executive officers, directors, director nominees or each person whom we know to beneficially own more than 5% of our outstanding common stock (a "5% stockholder") (or their immediate family members), each of whom we refer to as a "related person," has a direct or indirect material interest.

Item 14. Principal Accountant Fees and Services

The firm of Daszkal Bolton LLP, independent registered public accounting firm, has been selected by the audit committee as auditors for Aclarion for the fiscal years ending December 31, 2021 and December 31, 2022. Daszkal Bolton LLP has served as the independent registered public accounting firm for the Company since 2021.

The audit committee is solely responsible for selecting Aclarion's independent registered public accounting firm and has appointed Daszkal Bolton LLP as auditors for Aclarion for the fiscal year ending December 31, 2022. Stockholder approval is not required to appoint Daszkal Bolton LLP as Aclarion's independent registered public accounting firm.

Independent Registered Public Accounting Firm Fees

The following is a summary and description of fees incurred by Daszkal Bolton LLP for the fiscal year ended December 31, 2021 and 2020:

	2022	2021
Audit fees[(1)]	$ 95,096	$ 70,000
Tax fees	–	–
All other fees[(2)]	27,886	–
Total fees	$ 122,982	$ 70,000

(1) Audit fees consist of fees for the audit of our annual financial statements and the review of our interim financial statements,

(2) Consists of services provided in connection with the registration statement for the IPO of our common stock, which was completed in April 2022.

Audit Committee Pre-approval Policy and Procedures

Our audit committee has adopted policies and procedures relating to the approval of all audit and non-audit services that are to be performed by our independent registered public accounting firm. This policy provides that we will not engage our independent registered public accounting firm to render audit or non-audit services unless the service is specifically approved in advance by our audit committee, or the engagement is entered into pursuant to the pre-approval procedure described below.

From time to time, our audit committee may pre-approve specified types of services that are expected to be provided to us by our independent registered public accounting firm during the next 12 months. Any such pre-approval details the particular service or type of services to be provided and is also generally subject to a maximum dollar amount.

PART IV

Item 15. Exhibits and Financial Statement Schedules

(a) 1. Financial Statements

For a list of the financial statements included herein, see Index to the Financial Statements on page 88 of this Annual Report, incorporated into this Item by reference.

2. Financial Statement Schedules

Financial statement schedules have been omitted because they are either not required or not applicable or the information is included in the financial statements or the notes thereto.

3. Exhibits

The exhibits required by Item 601 of Regulation S-K and Item 15(b) of this Annual Report are listed in the Exhibit Index below. The exhibits listed in the Exhibit Index are incorporated by reference herein.

Exhibit Number		Description of Document	Incorporated by reference from Form	Filing Date	Exhibit Number	Filed Herewith
1.1		Underwriting Agreement dated April 21, 2022	8-K	04-27-2022	1.1	
3.1		Certificate of Incorporation of the Company	8-K	04-27-2022	3.1	
3.2		Bylaws of the Company	8-K	04-27-2022	3.2	
3.3		Certificate of Designation of Series A Preferred Stock	8-K	02-17-2023	3.1	
4.1		Form of Common Stock Certificate	10-Q	06-06-2022	4.1	
4.2		Form of Public Warrant	8-K	04-27-2022	4.1	
4.3		Form of Representative's Common Stock Purchase Warrant	8-K	04-27-2022	4.2	
4.4		Description of Securities	10-Q	06-06-2022	4.4	
10.1	#	Employment Agreement of Jeff Thramann	S-1/A	03-23-2022	10.1	
10.2	#	Employment Agreement of Brent Ness	S-1/A	03-23-2022	10.2	
10.3	#	Employment Agreement of John Lorbiecki	S-1/A	03-23-2022	10.3	
10.4	#	Form of Aclarion, Inc. 2022 Equity Incentive Plan	S-1	01-06-2022	10.4	
10.5		Senior Secured Bridge Note	S-1/A	03-04-2022	10.5	
10.6		License Agreement with UCSF the Regents of the University of California	S-1	01-06-2022	10.6	
10.7		Amendment to UC License Agreement	S-1/A	03-04-2022	10.7	
10.8	**	NuVasive Amended and Restated Commission Agreement dated February 28, 2020	S-1/A	03-23-2022	10.8	

10.9	Amended and Restated Investor Rights Agreement dated July 27, 2017	S-1/A	03-23-2022	10.9	

10.10	First Amendment to Amended and Restated Investor Rights Agreement dated February 20, 2020	S-1/A	03-23-2022	10.10	
10.11	NuVasive SAFE (Simple Agreement for Future Equity) dated February 28, 2020	S-1/A	03-23-2022	10.11	
10.12	** Right of First Offer Agreement	S-1/A	03-23-2022	10.12	
10.13	First Amendment to Right of First Offer Agreement	S-1/A	03-23-2022	10.13	
10.14	Second Amendment to Right of First Offer Agreement	S-1/A	03-23-2022	10.14	
10.15	Convertible Note and Warrant Purchase Agreement	S-1/A	03-23-2022	10.16	
10.16	Warrant Agent Agreement dated April 21, 2022	8-K	04-27-2022	10.1	
10.17	Siemens Strategic Collaboration Agreement	S-1	01-06-2022	10.17	
10.18	# Aclarion, Inc. 2022 Equity Incentive Plan – Form of Option Grant Notice and Stock Option Agreement	S-1	01-06-2022	10.20	
10.19	# Aclarion, Inc. 2022 Equity Incentive Plan – Form of RSU Grant Notice and RSU Agreement	S-1	01-06-2022	10.21	
10.20	# Nocimed, Inc. 2015 Stock Plan	S-8	05-26-2022	99.4	
10.21	# Nocimed, Inc. 2015 Stock Plan – Form of Option Grant Notice and Stock Option Agreement	S-8	05-26-2022	99.5	
10.22	Securities Purchase Agreement dated February 16, 2023 between Aclarion, Inc. and Jeffrey Thramann	8-K	02-17-2023	10.1	
23.1	Consent of Daszkal Bolton LLP, Independent Registered Public Accounting Firm				X
24.1	Power of Attorney (Included on Signature Page)				X
31.1	Section 302 Certification by the Corporation's Chief Executive Officer				X
31.2	Section 302 Certification by the Corporation's Chief Financial Officer				X
32.1	Section 906 Certification by the Corporation's Chief Executive Officer				X
32.2	Section 906 Certification by the Corporation's Chief Financial Officer				X

101.INS	Inline XBRL Instance Document (the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document)
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (formatted in IXBRL, and included in exhibit 101).

# Indicates management contract or compensatory plan.

** Certain portions of the exhibit have been omitted pursuant to Rule 601(b)(10) of Regulation S-K. The omitted information is (i) not material and (ii) would likely cause competitive harm to the Company if publicly disclosed.

Item 16. Form 10-K Summary

Not applicable.

SIGNATURES

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

ACLARION, INC.

By: /s/ Brent Ness
Brent Ness
Chief Executive Officer

By: /s/ John Lorbiecki
John Lorbiecki
Chief Financial Officer

Date: February 27, 2023

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose individual signature appears below hereby authorizes and appoints each of Brent Ness and John Lorbiecki, with full power of substitution and re-substitution and full power to act without the other, as his or her true and lawful attorney-in-fact and agent to act in his or her name, place and stead and to execute in the name and on behalf of each person, individually and in each capacity stated below, and to file any and all amendments to this annual report on Form 10-K and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing, ratifying and confirming all that said attorneys-in-fact and agents or any of them or their or his substitute or substitutes may lawfully do or cause to be done by virtue thereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this report has been signed below by the following persons on behalf of the registrant and in the capacities indicated on the 27th day of February, 2023.

/s/ Jeffery Thamann, M.D. Jeffrey Thramann, M.D.	Executive Chairman and Director
/s/ Brent Ness Brent Ness	President, Chief Executive Officer and Director (Principal Executive Officer)
/s/ John Lorbiecki John Lorbiecki	Chief Financial Officer (Principal Financial and Accounting Officer)
/s/ Stephen Deitsch Stephen Deitsch	Director
/s/ David Neal David Neal	Director
/s/ Amanda Williams Amanda Williams	Director
/s/ Scott Breidbart, M.D. Scott Breidbart, M.D.	Director
/s/ William Wesemann William Wesemann	Director

EXHIBIT 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Aclarion, Inc.
Broomfield, Colorado

We hereby consent to the incorporation by reference in (i) the Registration Statement on Form S-1/A (File no. 333-262026) and (ii) the Registration Statement on Form S-8 (File no. 333-265220) of Aclarion, Inc., of our report dated February 27, 2023 relating to the financial statements at and for the years ended December 31, 2022 and 2021, which appear in this Annual Report on Form 10-K.

/s/ Daszkal Bolton LLP

Fort Lauderdale, Florida

February 27, 2023

EXHIBIT 31.1

CERTIFICATIONOF PRINCIPAL EXECUTIVE OFFICER
PURSUANTTORULES13a-14(a)OR15D-14(a)
UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF
THE SARBANES-OXLEY ACT OF 2002

I, Brent Ness, certify that:

1. I have reviewed this Annual Report on Form 10-K for the year ended December 31, 2022 of Aclarion, Inc.

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) (Paragraph omitted pursuant to SEC Release Nos. 33-8238/34-47986 and 33-8392/34-49313);

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting.

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

February 27, 2023

/s/ Brent Ness
Brent Ness
Chief Executive Officer
(Principal Executive Officer)

EXHIBIT 31.2

CERTIFICATIONOF PRINCIPAL FINANCIAL OFFICER
PURSUANTTORULES13a-14(a)OR15D-14(a)
UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF
THE SARBANES-OXLEY ACT OF 2002

I, John Lorbiecki, certify that:

1. I have reviewed this Annual Report on Form 10-K for the year ended December 31, 2022 of Aclarion, Inc.

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) (Paragraph omitted pursuant to SEC Release Nos. 33-8238/34-47986 and 33-8392/34-49313);

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting.

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

February 27, 2023

/s/ John Lorbiecki
John Lorbiecki
Chief Financial Officer
(Principal Financial and Accounting Officer)

EXHIBIT 32.1

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

In connection with the Annual Report of Aclarion, Inc. (the "Company") on Form 10-K, for the year ended December 31, 2022 as filed with the Securities and Exchange Commission, I, Brent Ness, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Annual Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

February 27, 2023

/s/ Brent Ness
Brent Ness
Chief Executive Officer
(Principal Executive Officer)

EXHIBIT 32.2

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

In connection with the Annual Report of Aclarion, Inc. (the "Company") on Form 10-K, for the year ended December 31, 2022 as filed with the Securities and Exchange Commission, I, John Lorbiecki, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Annual Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

February 27, 2023

/s/ John Lorbiecki
John Lorbiecki
Chief Financial Officer
(Principal Financial and Accounting Officer)

Cover - USD ($)	12 Months Ended		
	Dec. 31, 2022	Feb. 27, 2023	Jun. 30, 2022
Document Type	10-K		
Amendment Flag	false		
Document Annual Report	true		
Document Transition Report	false		
Document Period End Date	Dec. 31, 2022		
Document Fiscal Period Focus	FY		
Document Fiscal Year Focus	2022		
Current Fiscal Year End Date	--12-31		
Entity File Number	001-41358		
Entity Registrant Name	ACLARION, INC.		
Entity Central Index Key	0001635077		
Entity Tax Identification Number	47-3324725		
Entity Incorporation, State or Country Code	DE		
Entity Address, Address Line One	8181 Arista Place		
Entity Address, Address Line Two	Suite 100		
Entity Address, City or Town	Broomfield		
Entity Address, State or Province	CO		
Entity Address, Postal Zip Code	80021		
City Area Code	(833)		
Local Phone Number	275-2266		
Entity Well-known Seasoned Issuer	No		
Entity Voluntary Filers	No		
Entity Current Reporting Status	Yes		
Entity Interactive Data Current	Yes		
Entity Filer Category	Non-accelerated Filer		
Entity Small Business	true		
Entity Emerging Growth Company	true		
Elected Not To Use the Extended Transition Period	false		
Entity Shell Company	false		
Entity Public Float			$ 5,019,673
Entity Common Stock, Shares Outstanding		7,861,515	
Auditor Name	Daszkal Bolton LLP		
Auditor Location	Fort Lauderdale, Florida		
Auditor Firm ID	229		
Common Stock Par Value 0. 00001 Per Share [Member]			
Title of 12(b) Security	Common Stock, par value $0.00001 per share		
Trading Symbol	ACON		

Security Exchange Name	NASDAQ
Warrants Each Exercisable For One Share Of Common Stock [Member]	
Title of 12(b) Security	Warrants, each exercisable for one share of Common Stock
Trading Symbol	ACONW
Security Exchange Name	NASDAQ

Balance Sheets - USD ($)	Dec. 31, 2022	Dec. 31, 2021
Current assets:		
Cash and cash equivalents	$ 1,472,806	$ 432,530
Restricted cash	10,000	20,000
Accounts receivable, net	18,569	6,280
Deferred Compensation	291,331	0
Prepaids & other current assets	195,534	273,394
Total current assets	1,988,240	732,204
Non-current assets:		
Property and equipment, net	3,346	12,636
Intangible assets, net	1,214,374	1,144,625
Total non-current assets	1,217,720	1,157,261
Total assets	3,205,961	1,889,465
Current liabilities:		
Accounts payable	462,202	1,065,304
Accrued and other liabilities	610,765	696,582
Promissory note payable	0	2,000,000
Preferred dividends payable	0	3,856,898
Liability to issue equity	345,243	0
Total current liabilities	1,418,209	7,618,784
Redeemable preferred stock: (See Note 8)		
Additional paid-in capital - series B2 and B3 preferred Stock	0	7,102,229
Total mezzanine equity	0	7,102,287
Stockholders' equity (deficit)		
Common stock - $0.00001 par value, 200,000,000 authorized and 7,861,515 and 905,685 shares issued and outstanding (see Note 1)	79	9
Additional paid-in capital	41,694,774	19,054,234
Accumulated deficit	(39,907,101)	(31,886,036)
Total stockholders’ equity (deficit)	1,787,751	(12,831,606)
Total liabilities, mezzanine, and stockholders’ equity (deficit)	3,205,961	1,889,465
Series B 2 Preferred Stock [Member]		
Redeemable preferred stock: (See Note 8)		
Preferred Stock, Value, Issued	0	16
Series B 3 Preferred Stock [Member]		
Redeemable preferred stock: (See Note 8)		
Preferred Stock, Value, Issued	0	42
Series A Preferred Stock [Member]		
Redeemable preferred stock: (See Note 8)		
Preferred Stock, Value, Issued	0	62
Series B Preferred Stock [Member]		
Redeemable preferred stock: (See Note 8)		
Preferred Stock, Value, Issued	0	52

Series B 1 Preferred Stock [Member]		
Redeemable preferred stock: (See Note 8)		
Preferred Stock, Value, Issued	$ 0	$ 73

Balance Sheets (Parenthetical) - $ / shares	Dec. 31, 2022	Dec. 31, 2021
Preferred Stock, Par or Stated Value Per Share	$ 0.00001	
Preferred Stock, Shares Authorized	20,000,000	
Common Stock, Par or Stated Value Per Share	$ 0.00001	$ 0.00001
Common Stock, Shares Authorized	200,000,000	200,000,000
Common Stock, Shares, Issued	7,861,515	905,685
Common Stock, Shares, Outstanding	7,861,515	905,685
Series B 2 Preferred Stock [Member]		
Preferred Stock, Par or Stated Value Per Share		$ 0.0001
Preferred Stock, Shares Authorized		1,600,000
Preferred Stock, Shares Issued		1,584,660
Preferred Stock, Shares Outstanding		1,584,660
Series B 3 Preferred Stock [Member]		
Preferred Stock, Par or Stated Value Per Share		$ 0.0001
Preferred Stock, Shares Authorized		4,300,000
Preferred Stock, Shares Issued		4,228,149
Preferred Stock, Shares Outstanding		4,228,149
Series A Preferred Stock [Member]		
Preferred Stock, Par or Stated Value Per Share		$ 0.00001
Preferred Stock, Shares Authorized		6,247,695
Preferred Stock, Shares Issued		6,247,695
Preferred Stock, Shares Outstanding		6,247,695
Series B Preferred Stock [Member]		
Preferred Stock, Par or Stated Value Per Share		$ 0.00001
Preferred Stock, Shares Authorized		5,180,814
Preferred Stock, Shares Issued		5,160,096
Preferred Stock, Shares Outstanding		5,160,096
Series B 1 Preferred Stock [Member]		
Preferred Stock, Par or Stated Value Per Share		$ 0.00001
Preferred Stock, Shares Authorized		10,758,338
Preferred Stock, Shares Issued		7,274,404
Preferred Stock, Shares Outstanding		7,274,404

Statements of Operations - USD ($)	12 Months Ended Dec. 31, 2022	Dec. 31, 2021
Revenue		
Revenue	$ 60,444	$ 60,292
Cost of revenue	65,298	69,175
Net profit (loss)	(4,854)	(8,883)
Operating expenses:		
Sales and marketing	537,069	330,814
Research and development	1,088,778	787,850
General and administrative	4,467,815	1,825,491
Total operating expenses	6,093,662	2,944,155
Income (loss) from operations	(6,098,516)	(2,953,038)
Other income (expense):		
PPP loan forgiveness	0	373,511
Interest expense	(1,507,546)	(474,911)
Changes in fair value of redeemable preferred stock	0	(1,900,310)
Other, net	520	4,458
Total other income (expense)	(1,507,026)	(1,997,252)
Income (loss) before income taxes	(7,605,542)	(4,950,290)
Income tax provision	0	0
Net income (loss)	(7,605,542)	(4,950,290)
Dividends accrued for preferred stockholders	(415,523)	(1,005,598)
Net income (loss) allocable to common stockholders	$ (8,021,064)	$ (5,955,888)

Statements of Operations (Parenthetical) - $ / shares	12 Months Ended	
	Dec. 31, 2022	Dec. 31, 2021
Income Statement [Abstract]		
Earnings Per Share, Basic	$ (1.31)	$ (6.58)
Earnings Per Share, Diluted	$ (1.31)	$ (6.58)
Weighted Average Number of Shares Outstanding, Basic	6,105,569	905,685
Weighted Average Number of Shares Outstanding, Diluted	6,105,569	905,685

Statement of Changes in Stockholders' Equity (Deficit) - USD ($)	Series A 1 Preferred Stock [Member]	Series A 2 Preferred Stock [Member]	Series A 3 Preferred Stock [Member]	Series A 4 Preferred Stock [Member]	Preferred Stock Series B [Member]	Preferred Stock Series B 1 [Member]	Preferred Stock Series B 2 [Member]	Preferred Stock Series B 3 [Member]	Common Stock [Member]	Additional Paid-in Capital [Member]	Retained Earnings [Member]	Total
Beginning balance, value at Dec. 31, 2020	$ 18	$ 14	$ 9	$ 21	$ 52	$ 73	$ 0	$ 0	$ 9	$ 18,846,352	$ (25,930,149)	$ (7,083,601)
Shares, Outstanding, Beginning Balance at Dec. 31, 2020	1,777,630	1,444,037	935,296	2,090,732	5,160,096	7,274,404	0	0	905,685			
Issuance of warrants										30,393		30,393
Preferred stock dividend payable											(1,005,597)	(1,005,597)
Issuance of preferred shares												
Share-based compensation										177,489		177,489
Net income (loss)											(4,950,290)	(4,950,290)
Issuance of preferred shares, shares							1,584,660	4,228,149				
Ending balance, value at Dec. 31, 2021	$ 18	$ 14	$ 9	$ 21	$ 52	$ 73	$ 0	$ 0	$ 9	19,054,234	(31,886,036)	(12,831,606)
Shares, Outstanding, Ending Balance at Dec. 31, 2021	1,777,630	1,444,037	935,296	2,090,732	5,160,096	7,274,404	1,584,660	4,228,149	905,685			
Issuance of warrants										1,280		1,280
Exercise of convertible note warrants									$ 1	152,653		152,653
Exercise of convertible note warrants, shares									60,408			
Preferred stock dividend payable												
Preferred stock dividend payable, shares									984,537			
Conversion of preferred stock to common stock	$ (18)	$ (14)	$ (9)	$ (21)	$ (52)	$ (73)			$ 33	7,102,441		7,102,287
Conversion of preferred stock to common stock, shares	(1,777,630)	(1,444,037)	(935,296)	(2,090,732)	(5,160,096)	(7,274,404)	(1,584,660)	(4,228,149)	3,279,117			
Conversion of accrued interest on promissory notes									$ 4	1,855,154		1,855,158
Conversion of accrued interest on promissory notes, shares									426,768			
Issuance of common stock and warrants related to IPO, net banker costs									$ 22	8,552,318		8,552,340
Issuance of preferred shares												
Issuance of common shares										102,000		102,000
Issuance of common stock and warrants related to IPO, shares									2,165,000			
Share-based compensation										1,132,747		1,132,747
Net income (loss)											(7,605,542)	(7,605,542)
IPO issuance costs										(530,463)		(530,463)
Preferred stock dividend payable									$ 10	4,272,411	(415,523)	3,856,898
Issuance of common shares, shares									40,000			
Ending balance, value at Dec. 31, 2022	$ 0	$ 0	$ 0	$ 0	$ 0				$ 79	$ 41,694,774	$ (39,907,101)	$ 1,787,751
Shares, Outstanding, Ending Balance at Dec. 31, 2022	0	0	0	0	0				7,861,515			

Statements of Cash Flows - USD ($)	12 Months Ended	
	Dec. 31, 2022	Dec. 31, 2021
Cash flows from operating activities		
Net income (loss)	$ (7,605,542)	$ (4,950,290)
Adjustments to reconcile net income (loss) to net cash used in operation activities:		
Depreciation and amortization	193,621	186,388
Share-based compensation	1,186,659	177,489
Share-based vendor payments	102,000	
Warrants issued as non- cash finance charge	0	30,393
Gain on forgiveness of PPP loans	0	(373,511)
Loss on disposal of furniture and equipment	3,789	0
Changes in fair value of redeemable preferred stock	0	1,900,310
Change in assets and liabilities		
Accounts receivable	(12,290)	16,222
Prepaids and other current assets	(267,383)	(210,765)
Accounts payable	(603,102)	199,604
Accrued and other liabilities	1,487,363	509,806
Accrued interest on promissory and convertible notes	200,712	114,404
Net cash (used in) operations	(5,314,171)	(2,399,949)
Investing Activities		
Proceeds from sale of furniture	1,000	0
Intangible assets - Patents	(208,870)	(102,005)
Net cash (used in) investing activities	(207,870)	(102,005)
Financing Activities		
Proceeds from issuance of PPP Loan	0	125,000
Proceeds from issuance of convertible notes	0	814,500
Proceeds from issuance of promissory notes		2,000,000
Repayment of promissory notes	(2,000,000)	0
Issuance of common stock and warrants related to IPO, net issuance costs	8,552,318	0
Net cash provided by financing activities	6,552,318	2,939,500
Net increase (decrease) in cash and cash equivalents	1,030,276	437,546
Cash, cash equivalents, and restricted cash, beginning of period	452,530	14,984
Cash, cash equivalents, and restricted cash, end of period	1,482,806	452,530
Non- cash activities		
Conversion of indebtedness to preferred equity commitment	0	5,201,977
Dividends accrued on preferred shares	415,523	1,005,598
Conversion of preferred stock to common stock	25,754,379	0
Conversion of preferred stock dividends to common stock	4,272,420	0
Conversion of accrued interest on promissory notes to common stock and warrants	1,856,438	0
Issuance of underwriter's warrants related to IPO	74,677	0
Changes in fair value of redeemable preferred stock	0	1,900,310

Liability to issue common shares	$ 345,243	$ 0

THE COMPANY AND BASIS OF PRESENTATION	12 Months Ended
	Dec. 31, 2022
Organization, Consolidation and Presentation of Financial Statements [Abstract]	
THE COMPANY AND BASIS OF PRESENTATION	

NOTE 1. THE COMPANY AND BASIS OF PRESENTATION

The Company

Aclarion, Inc., formerly Nocimed, Inc., (the "Company" or "Aclarion") is a healthcare technology company that leverages magnetic resonance spectroscopy ("MRS"), and a proprietary biomarker to optimize clinical treatments. The Company was formed in February 2015, is incorporated in Delaware, and has its principal place of business in Broomfield, Colorado.

Risks and Uncertainties

The Company is subject to various risks and uncertainties frequently encountered by companies in the early stages of development. Such risks and uncertainties include, but are not limited to, its limited operating history, competition from other companies, limited access to additional funds, dependence on key personnel, and management of potential rapid growth. To address these risks, the Company must, among other things, develop its customer base; implement and successfully execute its business and marketing strategy; develop follow-on products; provide superior customer service; and attract, retain, and motivate qualified personnel. There can be no guarantee that the Company will be successful in addressing these or other such risks.

The Company is also subject to risks and uncertainties as a result of the coronavirus disease ("COVID-19") pandemic. The pandemic continues to evolve and its impact on the Company's business will depend on several factors that are highly uncertain and unpredictable, including, the efficacy and adoption of vaccines, future resurgences of the virus and its variants, the imposition of governmental lockdowns, quarantine and physical distancing requirements, patient capacity at hospitals and healthcare systems, the duration and severity of healthcare worker shortages, and the willingness and ability of patients to seek care and treatment due to safety concerns or financial hardship. As such, given the dynamic nature of this situation, the Company cannot reasonably estimate the impacts of COVID-19 on our financial condition, results of operations or cash flows in the future. We are focused on navigating these recent challenges presented by COVID-19 and believe we are in a strong position to continue to sustain and grow our business.

Initial Public Offering

On April 21, 2022, the registration statement for our initial public offering ("IPO") was declared effective. In connection with the effectiveness of the IPO registration statement:

- we effected a 1-for-7.47 reverse stock split of our outstanding common stock;
- accordingly, all common share amounts and per share data presented in our condensed financial statements have been retrospectively adjusted to reflect the reverse stock split for all periods presented;
- we filed a restated Certificate of Incorporation with the State of Delaware and we adopted new restated Bylaws;
- certain outstanding common stock warrants were exercised on a net share basis for 60,408 common shares (451,245 pre-split shares);

- 24,495,004 (pre-split) outstanding shares of our preferred stock were converted into 3,279,117 post-split shares of common stock;

- all accrued dividends on our outstanding Series B, B-1, B-2 and B-3 preferred stock were converted to 984,429 post-split common shares; and

- all accrued interest on the Company's outstanding secured promissory notes was converted into (i) 426,768 post-split common shares and (ii) 426,768 post-split common stock warrants, with beneficial conversion rates charged to interest expense upon conversion.

On April 26, 2022, the Company completed its IPO of 2,165,000 units, at a public offering price of $4.35 per unit. Each unit consisted of (i) one share of common stock and (ii) one common stock warrant with an exercise price of $4.35 per share. Following the commencement of the IPO, the underwriters partially exercised their over-allotment option and purchased an additional 324,750 common stock warrants. After deducting underwriter's commissions and expenses, we received net proceeds of approximately $8.6 million and our common stock and warrants started trading on Nasdaq under the ticker symbols “ACON” and “ACONW”, respectively.

In connection with the IPO, we issued to the representative of the underwriters a common stock warrant for 173,200 shares with an exercise price of $5.44 per share. The representative's warrants are exercisable commencing October 26, 2022 and will expire on April 26, 2027.

On April 21, 2022, 1,204,819 outstanding common stock options previously awarded to the Company's Executive Chairman, Dr. Jeffrey Thramann, vested in connection with the completion of the IPO pursuant to the terms of such options. The exercise price of these options is $1.94 per share. The options have a 10-year term.

On April 21, 2022, in connection with the IPO, the Company’s 2022 Aclarion Equity Incentive Plan, or “2022 Plan”, became effective. Our board of directors has appointed the compensation committee of our board of directors as the committee under the 2022 Plan with the authority to administer the 2022 Plan. The aggregate number of our shares of common stock that may be issued or used for reference purposes under the 2022 Plan may not exceed 2,000,000 shares, subject to adjustments as described in the 2022 Plan.

On April 29, 2022, in connection with the IPO, a bonus was paid to David Neal and Brent Ness of $100,000 each. On May 13, 2022, in connection with the IPO, a bonus of $130,000 was paid to James Peacock.

On May 2, 2022, in connection with the IPO, the Company paid the University of California - San Francisco the amount of $123,828 to satisfy the Indexed Milestone Payment obligation included within the exclusive license agreement.

Reverse Stock Split

On April 21, 2022, the Company effected a 1-for-7.47 reverse stock split (the “Stock Split”) of its issued and outstanding common stock. As a result of the Stock Split, unless described otherwise, all references to common stock, options to purchase common stock, share data, per share data and related information contained in these financial statements have been retrospectively adjusted to reflect the effect of the Stock Split for all periods presented. In addition, any fractional shares that would otherwise be issued as a result of the Stock Split were rounded up to the nearest whole share. Further, the number of shares issuable and exercise prices of stock options and warrants have been retrospectively adjusted in these financial statements for all periods presented to reflect the Stock Split.

Basis of Presentation

The accompanying financial statements have been prepared in accordance with generally accepted accounting principles in the United States of America (“GAAP”).

SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES	12 Months Ended
	Dec. 31, 2022
Accounting Policies [Abstract]	
SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES	

NOTE 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Use of Estimates

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

The financial statements include some amounts that are based on management's best estimates and judgments. The most significant estimates relate to depreciation, amortization, valuation of capital stock, and valuation of warrants and options to purchase shares of the Company's preferred and common stock. These estimates may be adjusted as more current information becomes available, and any adjustment could be significant.

Reclassifications

Certain accounts relating to the prior year have been reclassified to conform to the current period’s presentation. These reclassifications had no effect on the net income or net assets as previously reported.

Valuation of Derivative Instruments

Financial Accounting Standards Board (“FASB”) Accounting Standards Codification (“ASC”) 815-40, *Derivatives and Hedging: Contracts on an Entity’s Own Equity*, addresses whether an equity-linked contract qualifies as equity in the entity’s financial statements. Agreements where an entity has insufficient authorized and unissued shares to settle the contract generally are accounted for as a liability and marked to fair value through earnings each reporting period. The Company evaluates its financial instruments, to determine if such instruments are liabilities or contain features that qualify as embedded derivatives. For financial instruments that are accounted for as liabilities, the derivative instrument is initially recorded at its fair value and is then revalued at each reporting date, with changes in the fair value reported as charges or credits to income.

Fair Value Measurements

The carrying values of the Company’s financial instruments including cash equivalents, restricted cash, accounts receivable and accounts payable, and notes payable are approximately equal to their respective fair values due to the relatively short-term nature of these instruments.

Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. Assets and liabilities recorded at fair value in the balance sheets are categorized based upon the level of judgment associated with the inputs used to measure their fair value. The fair value hierarchy distinguishes between (1) market participant assumptions developed based on market data obtained from independent sources (observable inputs), and (2) an entity’s own assumptions about market participant assumptions developed based on the best information available in the circumstances (unobservable inputs). The fair value hierarchy consists of three broad levels, which gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1) and the lowest priority to unobservable inputs (Level 3).

Cash and Cash Equivalents

The Company considers all highly liquid instruments purchased with an original maturity of three months or less to be cash equivalents. The Company had no cash equivalents for all periods presented. The Company maintains cash deposits at several financial institutions, which are insured by the Federal Deposit Insurance Corporation up to $250,000. The Company's cash balance may at times exceed these limits. On December 31, 2022, and 2021, the Company had approximately $1,229,000 and $201,000, respectively, in excess of federally insured limits. The Company continually monitors its positions with, and the credit quality of, the financial institutions with which it invests. The Company maintains no international bank accounts. As of December 31, 2022, $10,000 of the Company's cash was restricted as collateral related to the credit card program offered by our bank.

Accounts Receivable, Less Allowance for Doubtful Accounts

The Company estimates an allowance for doubtful accounts based upon an evaluation of the current status of receivables, historical experience, and other factors as necessary. It is reasonably possible that the Company's estimate of the allowance for doubtful accounts will change. The allowance for doubtful accounts was $0 on December 31, 2022, and 2021.

Revenue Recognition

Revenues are recognized when a contract with a customer exists, and at that point in time when we have delivered a Nociscan report to our customer. Revenue is recognized in the amount that reflects the negotiated consideration expected to be received in exchange for those reports. Following the delivery of the report, the company has no ongoing obligations or services to provide to the customer. Customers pay no other upfront, licensing, or other fees. To date, our reports are not reimbursable under any third-party payment arrangements, The Company invoices its customers based on the billing schedules in its sales arrangements. Payment terms range generally from 30 to 90 days, from the date of invoice.

Geographic Locations & Segments

Approximately 9% and 11% of the Company's revenues were generated from contracts with customers outside the United States in the years ended December 31, 2022, and 2021, respectively. All invoices are billed in the currency of the customers and are recorded in US Dollars at the then spot rate, which automatically is converted to dollars upon receipt and deposited in the Company's bank. Differences between the amounts received and the amounts initially recorded are reflected in Other Income (Expense).

Segment Disclosure

The Company has a single operating and reporting segment, which is the delivery of Nociscan reports to our customers. The Company's Chief Executive Officer reviews financial information for purposes of making operating decisions and assessing financial performance.

Property and Equipment

Property and equipment are stated at cost and are depreciated using the straight-line method over the estimated useful lives of the related assets. Furniture and fixtures are depreciated over seven years. Computer and office equipment and computer software are depreciated over five years. Repairs and maintenance costs, which are not considered improvements and do not extend the useful life of the property and equipment, are expensed as incurred.

Impairment of Long-Lived Assets

The Company reviews long-lived assets, including intangible assets, property and equipment, for impairment whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable using pre-tax undiscounted cash flows.

Impairment, if any, is measured as the amount by which the carrying value of a long-lived asset exceeds its fair value.

Sales and Marketing Expenses

The Company expenses the costs of sales and marketing its products and services as incurred. The primary drivers of cost have been employee payroll, website and branding development, press releases, attendance at various industry conferences, Key Opinion Leader consulting fees, and travel expenses.

Research and Development Costs

Costs related to research, design and development of products are charged to research and development expense as incurred. These costs include direct compensation, benefits, and other headcount related costs for research and development personnel; costs for materials used in research and development activities; costs for outside services and allocated portions of facilities and other corporate costs. The Company has entered into research and clinical study arrangements with selected hospitals, cancer treatment centers, academic institutions and research institutions worldwide. These agreements support the Company's internal research and development capabilities.

Liquidity, Capital Resources and Going Concern

The Company believes that the net proceeds from the April 2022 initial public offering will be sufficient to fund current operating plans into the second quarter of 2023. The Company has based these estimates, however, on assumptions that may prove to be wrong, and could spend available financial resources much faster than we currently expect. The Company will need to raise additional funds to continue funding our technology development. Management plans to secure such additional funding.

As a result of the Company's recurring losses from operations, and the need for additional financing to fund its operating and capital requirements, there is uncertainty regarding the Company's ability to maintain liquidity sufficient to operate its business effectively, which raises substantial doubt as to the Company's ability to continue as a going concern.

Share-Based Compensation

The Company accounts for stock-based awards in accordance with provisions of ASC Topic 718, *Compensation—Stock Compensation*, under which the Company recognizes the grant-date fair value of stock-based awards issued to employees and nonemployee board members as compensation expense on a straight-line basis over the vesting period of the award, while awards containing a performance condition are recognized as expense when the achievement of the performance criteria is considered probable. The Company uses the Black-Scholes option pricing model to determine the grant-date fair value of stock options. The Company estimates forfeitures that it expects will occur and adjusts expense for actual forfeitures in the periods they occur.

The exercise or strike price of each option is not less than 100% of the fair market value of the Common Stock subject to the option on the date the option is granted.

The Company issues restricted stock unit awards to non-employee consultants who are providing various services. The awards are valued at the market price on the date of the grant. The awards vest over the contract life and based on achievement of targeted performance milestones.

On occasion, the Company grants common stock, subject to vesting, to compensate vendors for services rendered.

Deferred Financing Costs

The Company capitalizes certain legal, accounting, and other fees and costs that are directly attributable to in-process equity financings as deferred offering costs until such financings are completed. Upon the completion of an equity financing, these costs are recorded as a reduction of additional paid-in capital of the related offering. Upon the completion of the IPO in April 2022, approximately $1.5 million of offering costs related to the IPO were reclassified to additional paid-in capital.

Emerging Growth Company Status

The Company is an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act"). Under the JOBS Act, emerging growth companies can delay the adoption of new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. The Company has elected to use this extended transition period for complying with certain new or revised accounting standards that have different effective dates for public and private companies.

Income Taxes

The Company is required to estimate its income taxes in each of the tax jurisdictions in which it operates prior to the completion and filing of tax returns for such periods. This process involves estimating actual current tax expense together with assessing temporary differences in the treatment of items for tax purposes versus financial accounting purposes that may create net deferred tax assets and liabilities. The Company accounts for income taxes under the asset and liability method, which requires, among other things, that deferred income taxes be provided for temporary differences between the tax bases of the Company's assets and liabilities and their financial statement reported amounts. In addition, deferred tax assets are recorded for the future benefit of utilizing net operating losses, research and development credit carryforwards and other deferred tax assets. The Company has not recorded an deferred tax asset because of the uncertainty that the Company will be able to utilize any future benefits (see Liquidity, Capital Resources and Going Concern in Note 2). Generally, the Company is not subject to income tax examinations for periods prior to 2019.

RECENT ACCOUNTING PRONOUNCEMENTS	12 Months Ended Dec. 31, 2022
Accounting Changes and Error Corrections [Abstract]	
RECENT ACCOUNTING PRONOUNCEMENTS	

NOTE 3. RECENT ACCOUNTING PRONOUNCEMENTS

In August 2020, the FASB issued ASU No. 2020-06, *Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging-Contracts in Entity's Own* Equity (Subtopic 815-40) ("ASU 2020-06"), which simplifies the accounting for convertible instruments. The guidance removes certain accounting models that separate the embedded conversion features from the host contract for convertible instruments. The guidance also modifies how certain convertible instruments, that may be settled in cash or shares, impact the calculation of diluted earnings per share. ASU 2020-06 allows for a modified or full retrospective method of transition. This update is effective for emerging growth companies following private company adoption dates in fiscal years beginning after December 15, 2023, including interim periods within those fiscal years, and early adoption is permitted. As of December 31, 2022, the Company has no debt with conversion features.

In February 2016, the FASB issued its new lease accounting guidance in ASU 2016-02, Leases (Topic 842). Under the new guidance, lessees will be required to recognize for all leases (with the exception of short-term leases) a lease liability, which is a lessee's obligation to make lease payments arising from a lease, measured on a discounted basis and a right-of-use asset, which is an asset that represents the lessee's right to use, or control the use of, a specified asset for the lease term. ASU 2016-02, as subsequently amended for various technical issues, is effective for emerging growth companies following private company adoption dates in fiscal years beginning after December 15, 2021, and interim periods within fiscal years beginning after December 15, 2022. The Company has adopted the new guidance, which did not have a material impact on its financial statements. The Company has no leases as of December 31, 2022.

REVENUE	12 Months Ended Dec. 31, 2022
Revenue from Contract with Customer [Abstract]	
REVENUE	**NOTE 4. REVENUE**

Contract Balances

The timing of revenue recognition, billings, and cash collections may result in trade, unbilled receivables, and deferred revenues on the balance sheets. At times, revenue recognition may occur before the billing, resulting in an unbilled receivable, which would represent a contract asset. The contract asset would be a component of accounts receivable and other assets for the current and non-current portions, respectively. In the event the Company receives advances or deposits from customers before revenue is recognized, this would result in a contract liability. In years ending December 31, 2022, and 2021, the Company invoiced as services were performed and did not invoice in advance, the company has no contract balances.

SUPPLEMENTAL FINANCIAL INFORMATION

Organization, Consolidation and Presentation of Financial Statements [Abstract]

SUPPLEMENTAL FINANCIAL INFORMATION

12 Months Ended

Dec. 31, 2022

NOTE 5. SUPPLEMENTAL FINANCIAL INFORMATION

Balance Sheets

Accounts receivable, net

Accounts receivable, net consisted of the following:

	December 31,	
	2022	**2021**
Accounts receivable (1)	$ 18,569	$ 6,280
Less: Allowance for doubtful accounts	–	–
Accounts receivable, net	$ 18,569	$ 6,280

(1) Accounts receivable denominated in foreign currencies represent less than 15% of accounts receivable in all periods.

Accounts payable and accrued and other liabilities

	December 31,	
	2022	**2021**
Accounts payable	$ 457,558	$ 1,059,546
Credit cards payable	4,644	5,758
Accrued salaries and expenses	610,765	340,363
Accrued Interest	–	356,219
	$ 1,072,967	$ 1,761,886

Statements of Operations

Other expense, net consisted of the following:

	Year Ended December 31,	
Income/(Expense)	**2022**	**2021**
Bank Interest	$ 2,510	$ (1,568)
California Relief Program [1]	–	5,000
Taxes	(800)	(800)
Foreign Currency Gain (Loss)	(1,190)	(1,309)
Other	–	3,135
	$ 520	$ 4,458

1 The California Small Business COVID-19 Relief Grant Program (the "Program") provides micro grants ranging from $5,000 to $25,000 to eligible small businesses and nonprofits impacted by COVID-19 and the related health and safety restrictions.

LEASES

12 Months Ended
Dec. 31, 2022

Leases
LEASES

NOTE 6. LEASES

Rent expense for the year ended December 31, 2022 and 2021 was $36,070 and $64,932, respectively. The Company entered into a subleasing agreement in 2021 and realized $26,340 and $48,400 of sublease income for the year ended December 31, 2022, and 2021. Both the lease and sublease are netted within the general & administrative line item in the Statements of Operations. Our current office lease and sublease expired on June 30, 2022.

PROPERTY, PLANT, AND EQUIPMENT

12 Months Ended
Dec. 31, 2022

Property, Plant and Equipment [Abstract]

PROPERTY, PLANT, AND EQUIPMENT

NOTE 7: PROPERTY, PLANT, AND EQUIPMENT

Property and equipment are stated at cost and are depreciated using the straight-line method over the estimated useful lives of the related assets. Furniture and fixtures are depreciated over seven years. Computer and office equipment and computer software are depreciated over five years. Repairs and maintenance costs, which are not considered improvements and do not extend the useful life of the property and equipment, are expensed as incurred.

The Company's property and equipment are as follows:

	December 31,	
	2022	**2021**
Furniture and fixtures	$ –	$ 7,700
Computer and office equipment	13,032	45,187
Software	42,150	42,150
Other Equipment	18,190	18,190
	73,372	113,227
Less: Accumulated depreciation	(70,026)	(100,591)
Property and equipment, net	$ 3,346	$ 12,636

Depreciation expense related to property and equipment were $4,500 and $12,981 for the years ended December 31, 2022 and 2021, respectively.

During 2022 the Company received proceeds of $1,000 from the sale of property and equipment.

Future depreciation and amortization of property, equipment, and software is as follows:

2023	$ 1,563
2024	1,187
2025	596
Total	$ 3,346

INTANGIBLE ASSETS

12 Months Ended
Dec. 31, 2022

Goodwill and Intangible Assets Disclosure [Abstract]
INTANGIBLE ASSETS

NOTE 8. INTANGIBLE ASSETS

The Company's intangible assets are as follows:

	December 31, 2022	December 31, 2021
Patents and licenses	$ 2,147,729	$ 1,938,858
UC royalty	200,000	150,000
Other	5,017	5,017
	2,352,746	2,093,875
Less: accumulated amortization	(1,138,372)	(949,250)
Intangible assets, net	$ 1,214,374	$ 1,144,625

Amortization expense related to purchased intangible assets was $189,121 and $176,390 for the years ended December 31, 2022, and 2021, respectively.

Patents and licenses costs are accounted for as intangible assets and amortized over the life of the patent or license agreement and charged to research and development. During the fourth quarter of 2022, the Company reviewed the remaining life of the patent portfolio and the mix of domestic and international patent filings and revised its estimated future amortization periods. The impact of this change of estimate over the three months ended December 31, 2022, was in increase in amortization of $3,128. Future amortization of patents and trademarks was impacted as follows:

2023	$ 15,312
2024	19,219
2025	21,910
2026	27,532
2027 and beyond	(87,101)
Total	$ 0

UC royalties are paid annually, amortized over twelve months, and charged to cost of revenue.

Patents and trademarks are reviewed at least annually for impairment. No impairment was recorded through December 31, 2022, and 2021, respectively.

Future amortization of intangible assets is as follows:

2023	$ 158,114
2024	153,587
2025	153,587
2026	153,587
2027 and beyond	595,499
Total	$ 1,214,374

SHORT TERM NOTES AND CONVERTIBLE DEBT

Debt Disclosure [Abstract]

SHORT TERM NOTES AND CONVERTIBLE DEBT

12 Months Ended

Dec. 31, 2022

NOTE 9. SHORT TERM NOTES AND CONVERTIBLE DEBT

Convertible Notes:

During the year ended December 31, 2021, and 2020, accredited investors purchased $814,500 and $1,598,488 of our convertible notes, respectively. In addition, the holders of the Company's short-term notes exchanged their notes for this issuance of convertible notes. The convertible notes accrued interest at 10.0% per year and were originally scheduled to mature on December 31, 2020, which the holders agreed to extend until September 30, 2021. While the convertible notes contained a provision to automatically convert into shares of common stock at a discount to the price in the next Qualified Financing, the Qualified Financing did not occur prior to the June 30, 2021 maturity date of the convertible notes. In accordance with the terms of the convertible notes, the principal plus accrued, but unpaid, interest on the convertible notes (aggregating to $3,201,977) was required to be automatically converted into 4,228,149 Series B-3 Preferred Shares. The Company did not have the Series B-3 preferred shares authorized for issuance, and the Company established a liability to issue these shares. This liability was adjusted to fair value until the B-3 preferred shares were authorized and issued December 3, 2021 (See Note 11: Stockholders' Equity).

NuVasive, Inc. Convertible Note and SAFE Agreement:

In February 2020, NuVasive and the Company renegotiated and amended their prior marketing agreement. In consideration of changing the marketing agreement, NuVasive and the Company entered into a $2.0 million Simple Agreement for Future Equity ("SAFE") agreement. The SAFE provided that NuVasive would receive $2 million of capital stock if the Company would raise a minimum of $10.0 million of new capital on or before December 31, 2020, which was later extended to June 30, 2021. If the $10.0 million was not raised, the Company would issue to NuVasive 1,584,660 Series B-2 preferred shares. The $10.0 million was not raised and the Company issued 1,584,660 Series B-2 preferred shares to NuVasive in December 2021.

The Company recorded the SAFE when issued at its fair value, which was measured at $2 million, as NuVasive was to receive a variable number of shares with an aggregate value of $2 million. The Company recorded the liability to issue the 1,584,660 Series B-2 preferred shares at its fair value of $2 million (a per-share value of $1.2621), based on third-party valuations at June 30, 2021, and marked the liability to fair value on September 30, 2021, and at the time the B-2 preferred shares were issued December 3, 2021.

In March 2020, the Company negotiated an additional investment agreement with NuVasive whereby NuVasive purchased $308,720 of convertible notes under the same terms as the existing holders of the Company's convertible notes.

In June 2021, NuVasive's convertible note principal plus accrued, but unpaid, interest was converted (in accordance with the terms of all of the convertible notes) into Series B-3 Preferred shares (see *Convertible Notes* above). The B-3 preferred shares were issued December 3, 2021.

As of December 31, 2021, there were no Convertible Notes payable and outstanding. There was no convertible note activity in the year ended December 31, 2022.

Cares Act Paycheck Protection Program Loan (PPP Loan)

In April 2020 and February 2021, the Company entered into two promissory notes evidencing an unsecured loan (the "Loans") in the amounts of $245,191 and $125,000, respectively, made to the

Company under the Paycheck Protection Program (the "PPP"). The PPP was established under the CARES Act administered by the U.S. Small Business Administration.

The PPP promissory notes were to mature in March 2022 (2020 note) and January 2026 (2021 note) and bear interest at a rate of 1% per annum, payable monthly commencing in June 2019 and November 2020. The Loans could be prepaid by the Company at any time prior to maturity with no prepayment penalties. The proceeds from the Loans could only be used for payroll costs (including benefits), interest on mortgage obligations, rent, utilities and interest on certain other debt obligations.

The Loans contained customary events of default relating to, among other things, payment defaults, making materially false and misleading representations to the lender, or breaching the terms of the Loan documents. The occurrence of an event of default would result in an increase in the interest rate to 18% per annum and provide the lender with customary remedies, including the right to require immediate payment of all amounts owed under the promissory note.

Pursuant to the terms of the CARES Act and the PPP, the Company applied in February 2021 to the lender for forgiveness of the amount due on the Loans. In May 2021, the Company was notified that 100% of the first loan of $245,191 and related interest of $2,622 had been forgiven, and in August 2021 the Company was notified that 100% of the second loan of $125,000 and related interest of $698 had been forgiven. The amounts eligible for forgiveness was based on the amount of Loan proceeds used by the Company for the payment of certain covered costs, including payroll costs (including benefits), interest on mortgage obligations, rent and utilities, subject to certain limitations and reductions in accordance with the CARES Act and the PPP.

As of December 31, 2021, there was no outstanding PPP loan balance. There was no activity for PPP loans for the year ended December 31, 2022.

Secured Promissory Notes Payable

In June 2021, the Company issued $2.0 million of secured promissory notes that matured at the earlier of the consummation of a Qualified Financing or May 31, 2022. The secured promissory notes incorporated the following major attributes: secured by a lien and security interest on substantially all of the Company's assets; interest accrues at 33%; holder option to convert the accrued interest into the Company securities being offered in a Qualified Financing at 30% (i.e. 70% discount) of the price being paid by other investors in the Qualified Financing; and automatic conversion in the case of a Qualifying IPO of the accrued interest into the Company securities being offered in the Qualifying IPO at 30% (70% discount) of the price being paid by other investors in the Qualifying IPO. If the secured promissory notes remained outstanding after May 31, 2022, the Company had the option to extend the promissory notes upon the payment of an extension fee, which consisted of 150,000 warrants (20,080 warrants post-split) with a five-year term, to purchase shares of the Company's common stock at a price of $ 0.01 per share ($0.0747 post-split).

On April 21, 2022, the registration statement for our IPO was declared effective. In connection with the effectiveness of the IPO registration statement, all accrued interest on the Company's outstanding secured promissory notes was converted into (i) 426,768 post-split common shares and (ii) 426,768 post-split common stock warrants, with a $1,299,507 beneficial conversion rate charged to interest expense.

On April 27, 2022, the Company used $2 million of the IPO proceeds to retire all outstanding secured promissory notes.

COMMITMENTS AND CONTINGENCIES	12 Months Ended Dec. 31, 2022
Commitments and Contingencies Disclosure [Abstract]	
COMMITMENTS AND CONTINGENCIES	

NOTE 10. COMMITMENTS AND CONTINGENCIES

Royalty Agreement

The Company has an exclusive license agreement with the Regents of the University of California to make, use, sell and otherwise distribute products under certain of the Regents of the University of California's patents anywhere in the world. The Company is obligated to pay a minimum annual royalty of $50,000, and an earned royalty of 4% of net sales. The minimum annual royalty will be applied against the earned royalty due for the calendar year in which the minimum payment was made. The license agreements expire upon expiration of the patents and may be terminated earlier if the Company so elects. The U.S. licensed patents that are currently issued expire between 2026 and 2029, without considering any possible patent term adjustment or extensions and assuming payment of all appropriate maintenance, renewal, annuity, or other governmental fees. The Company recorded royalty costs of $50,000 for each of the years ended December 31, 2022, and 2021.

Additionally, the Company was obligated to make a cash Indexed Milestone Payment to the Regents of the University of California in the event of either a change of control or an IPO. This cash payment was calculated as follows: 28,532 post-split shares (213,313 pre-split shares) of Company common stock times the IPO price of $4.34. On May 2, 2022, in connection with the IPO, the Company paid the University of California - San Francisco the amount of $123,828 to satisfy the Indexed Milestone Payment obligation included within the exclusive license agreement.

Litigation

To date, the Company has not been involved in legal proceedings arising in the ordinary course of its business. If any legal proceeding occurs, the Company would record a provision for a loss when it believes that it is both probable that a loss has been incurred and the amount can be reasonably estimated, although litigation is inherently unpredictable and is subject to significant uncertainties, some of which are beyond the Company's control. Should any of these estimates and assumptions change or prove to have been incorrect, the Company could incur significant charges related to legal matters that could have a material impact on its results of operations, financial position and cash flows.

Stock Option Grant to our Executive Chairman

In September 2021, the Board of Directors approved a stock option grant of 1,204,819 post-split shares to Dr. Jeffrey Thramann, our Executive Chairman. These options were conditional, such that they vested only upon the occurrence of certain specified events, including an IPO, a next round financing, the merger of the Company with a SPAC, or the sale of the Company. The amount of stock options that would vest upon such specified events depended upon the terms and timing of the applicable event.

On April 21, 2022, 1,204,819 outstanding common stock options previously awarded to Dr. Jeffrey Thramann vested in connection with the completion of the IPO pursuant to the terms of such options. The exercise price of these options is $1.94 per share. The options have a 10-year term.

On September 15, 2022, the Board of Directors approved a stock option grant of an additional 185,285 common shares to Dr. Thramann. The exercise price of the options is $1.94 per share, they are fully vested, and they have a 10-year term.

STOCKHOLDERS' EQUITY	12 Months Ended Dec. 31, 2022
Equity [Abstract]	

STOCKHOLDERS' EQUITY

NOTE 11. STOCKHOLDERS' EQUITY

The Company filed an Amended and Restated Certificate of Incorporation on April 21, 2022, as part of the IPO. The Company is authorized to issue two classes of stock to be designated, respectively, "Common Stock" and "Preferred Stock." The total number of shares which the Company is authorized to issue is two hundred twenty million (220,000,000) shares. Two hundred million (200,000,000) shares are authorized to be Common Stock, having a par value per share of $0.00001. Twenty million (20,000,000) shares are authorized to be Preferred Stock, having a par value per share of $0.00001.

Prior to the IPO, the Company had authorized two classes of shares. These classes included shares of common stock and preferred stock. There was one authorized series of shares of common stock and eight existing authorized series of preferred stock: Series A-1, A-2, A-3, A-4, B, B-1, B-2, and B-3.

The preferred shares converted to common shares on a 1:1 pre-split basis immediately prior to the Stock Split on April 21, 2022. Those common shares were adjusted to reflect the Stock Split as described in Note 1 Reverse Stock Split.

Preference Amounts	Issue Date	Total Face Value of Investment	Issue Purchase Price/Share
Series A-1 Preferred Stock	12/31/2014	$ 1,247,541	$ 0.70
Prior to its conversion to common shares, the Series A-1 had a 1x liquidation preference junior to B/B1 plus participation on an as-converted to common basis, which participation was capped at 3x, conversion into common stock at a ratio of 1:1, limited anti-dilution protection, and voting rights on an as-converted to common basis.			
Series A-2 Preferred Stock	12/31/2014	$ 1,114,797	$ 0.77
Prior to its conversion to common shares, the Series A-2 had a 1x liquidation preference junior to B/B1 plus participation on an as-converted to common basis, which participation was capped at 3x, conversion into common stock at a ratio of 1:1, limited anti-dilution protection, and voting rights on an as-converted to common basis.			
Series A-3 Preferred Stock	12/31/2014	$ 795,002	$ 0.85
Prior to its conversion to common shares, the Series A-3 had a 1x liquidation preference junior to B/B1 plus participation on an as-converted to common basis, which participation was capped at 3x, conversion into common stock at a ratio of 1:1, limited anti-dilution protection, and voting rights on an as-converted to common basis.			
Series A-4 Preferred Stock	12/31/2014	$ 1,965,288	$ 0.94
Prior to its conversion to common shares, the Series A-4 had a 1x liquidation preference junior to B/B1 plus participation on an as-converted to common basis, which participation was capped at 3x, conversion into common stock at a ratio of 1:1, limited anti-dilution protection, and voting rights on an as-converted to common basis.			
Series B Preferred Stock	12/5/2015	$ 5,013,579	$ 1.00
Prior to its conversion to common shares, the Series B had a 1x senior liquidation preference junior to B/B1 plus participation on an as-converted to common basis, which participation was capped at 3x, conversion into common stock at a ratio of 1:1, limited anti-dilution protection, and voting rights on an as-converted to common basis.			

The dividend rate is 6.0% Dividends are cumulative. Accrued and unpaid dividends are payable in shares of common stock in certain events (including an IPO) at the then current fair market value of the common stock.

Series B-1 Preferred Stock	7/27/2017	$ 1,500,000	$ 1.26
	8/2/2018	$ 5,217,698	$ 1.26
	3/1/2019	$ 2,463,328	$ 1.26

Prior to its conversion to common shares, the Series B-1 had a 1x senior liquidation preference junior to B2/B3 plus participation on an as-converted to common basis, which participation was capped at 3x, conversion into common stock at a ratio of 1:1, limited anti-dilution protection, and voting rights on an as-converted to common basis.

The dividend rate is 6.0%. Dividends are cumulative. Accrued and unpaid dividends are payable in shares of common stock in certain events (including an IPO) at the then current fair market value of the common stock.

Preference Amounts	Issue Date	Total Face Value of Investment	Issue Purchase Price/Share
Series B-2 Preferred Stock	12/3/2021	$ 1,774,819	$ 1.12

Prior to its conversion to common shares, the Series B-2 has a 1x senior liquidation preference plus participation on an as-converted to common basis, which participation was capped at 3x, conversion into common stock at a ratio of 1:1, limited anti-dilution protection, and voting rights on an as-converted to common basis.

The dividend rate is 6.0%. Dividends are cumulative. Accrued and unpaid dividends are payable in shares of common stock in certain events (including an IPO) at the then current fair market value of the common stock. Redemption is available by a majority vote of holders commencing after fifth anniversary from issuance, payable in three annual installments.

Series B-3 Preferred Stock	12/3/2021	$ 5,327,468	$ 1.26

Prior to its conversion to common shares, the Series B-3 has a 2x senior liquidation preference, conversion into common stock at a ratio of 1:1, limited anti-dilution protection, and voting rights on an as-converted to common basis.

The dividend rate is 6.0%. Dividends are cumulative. Accrued and unpaid dividends are payable in shares of common stock in certain events (including an IPO) at the then current fair market value of the common stock. Redemption is available by a majority vote of holders commencing after fifth anniversary from issuance, payable in three annual installments.

Warrants

Warrants issued with Convertible Notes

During the years ended December 31, 2021, and 2020, the Company issued 17,286 and 58,846 warrants, respectively, to certain investors who participated over an agreed investment minimum amount in the purchase of our convertible notes. The value of the warrants was recorded as a debt discount and expensed based on the fair value. Just prior to the IPO, these common stock warrants were exercised on a net share basis for 60,408 common shares (451,245 pre-split shares). A loss on warrants exercised of $152,653 was recorded.

Warrants issued in connection with the IPO

In connection with the Company’s IPO, all accrued interest on the Company's outstanding secured promissory notes were converted into (i) 426,768 post-split common shares and (ii) 426,768 post-

split common stock warrants, with beneficial conversion rates charged to interest expense upon conversion. These warrants have an exercise price of $4.35 per share.

In the IPO, the Company sold 2,165,000 units, at a public offering price of $4.35 per unit. Each unit consisted of (i) one share of common stock and (ii) one common stock warrant ("IPO Warrant") with an exercise price of $4.35 per share. The common stock and the IPO Warrants were immediately separable and issued separately in the offering. The IPO Warrants are listed and tradeable on the NASDAQ stock market, immediately exercisable at the option of the holder, and expire five years from the date of issuance.

On April 22, 2022, the underwriters partially exercised their over-allotment option for an additional 324,750 IPO Warrants.

In connection with the IPO, we issued to the representative of the underwriters' common stock warrants for 173,200 shares with an exercise price of $5.44 per share. The representative's warrants are exercisable commencing October 26, 2022, and will expire on April 26, 2027.

The Company evaluated the terms of all warrants issued at the IPO and determined that they should be classified as equity instruments based upon accounting guidance provided in ASC 480, *Distinguishing Liabilities from Equity, and ASC 815, Derivatives and Hedging*. Since the Company determined that the warrants were equity classified, the Company recorded the proceeds from the IPO, net of issuance costs, within common stock at par value and the balance of proceeds to additional paid in capital.

As of December 31, 2022, 2,489,750 IPO Warrants, and 599,968 other common stock warrants, were outstanding.

NET LOSS PER SHARE OF COMMON STOCK	12 Months Ended Dec. 31, 2022
Earnings Per Share [Abstract]	
NET LOSS PER SHARE OF COMMON STOCK	

NOTE 12. NET LOSS PER SHARE OF COMMON STOCK

Basic and diluted net loss per share is computed by dividing net loss attributable to stockholders by the weighted average number shares of common stock outstanding during the year. Potentially dilutive outstanding shares of common stock equivalents were excluded from the computation of diluted net loss per share for loss periods presented because including them would have been antidilutive.

A reconciliation of the numerator and denominator used in the calculation of basic and diluted net loss per share attributable to stockholders follows:

	December 31,	
	2022	2021
Numerator:		
Net loss used to compute basic and diluted loss per common share	$ (8,021,064)	$ (5,955,888)
Denominator:		
Weighted average shares used to compute basic and dilutive loss per share	6,105,569	905,685

The following outstanding potentially dilutive securities were excluded from the calculation of dilutive loss per share attributable to common stockholders because their impact would have been antidilutive for the period presented:

	December 31, 2022	December 31, 2021
Series A and B convertible preferred stock	819,779	2,565,809
Warrants	2,329,977	70,840
Restricted stock units	50,038	–
Stock options	2,481,816	985,283
	5,681,610	3,621,932

STOCK-BASED COMPENSATION	12 Months Ended Dec. 31, 2022
Share-Based Payment Arrangement [Abstract]	
STOCK-BASED COMPENSATION	

NOTE 13. STOCK-BASED COMPENSATION

2022 Aclarion Equity Incentive Plan

On April 21, 2022, in connection with the IPO, the Company's 2022 Aclarion Equity Incentive Plan, or "2022 Plan", went into effect. Our board of directors has appointed the compensation committee of our board of directors as the committee under the 2022 Plan with the authority to administer the 2022 Plan. The aggregate number of our shares of common stock that may be issued or used for reference purposes under the 2022 Plan is 2,000,000 shares, with an automatic increase on January 1st of each year, for a period of not more than ten years, commencing on January 1st of the year following the year in which the IPO Date occurs and ending on (and including) January 1, 2032, in an amount equal to 5% of the total number of shares of Capital Stock outstanding on December 31st of the preceding calendar year. Notwithstanding the foregoing, the Board may act prior to January 1st of a given year to provide that there will be no January 1st increase in shares for such year or that the increase in shares for such year will be a lesser number of shares of Common Stock than would otherwise occur pursuant to the preceding sentence.

Options granted under the 2022 Plan may be incentive stock options or non-statutory stock options, as determined by the administrator at the time of grant of an option. Restricted stock may also be granted under the 2022 Plan. The options vest in accordance with the grant terms and are exercisable for a period of up to 10 years from grant date.

The fair value of the options granted for the twelve months ended December 31, 2022, and December 31, 2021, respectively, were estimated at the date of grant using the Black-Scholes-Merton option pricing model with the following assumptions:

Risk-free interest rate (4/2022 – 8/2022)	1.99%
Risk-free interest rate (9/2022 – 12/2022)	3.67%
Dividend yield	–
Expected term	6-8 years
Expected volatility	66.35%

Nocimed, Inc. 2015 Stock Plan

The Company maintains the Nocimed, Inc. 2015 Stock Plan, or the "Existing Plan", under which the Company could grant 2,440,931 post-split shares or options of the Company to our employees, consultants, and other service providers. The Company has suspended the Existing Plan in connection with the IPO. No further awards will be granted under the Existing Plan, but awards granted prior to the suspension date will continue in accordance with their terms and the terms of the Existing Plan.

The fair value of the options granted for the twelve months ended December 31, 2022, and 2021, were estimated at the date of grant using the Black-Scholes-Merton option pricing model with the following assumptions:

Risk-free interest rate	1.99%
Dividend yield	–
Expected term	6-8 years
Expected volatility	25.00%

Determining Fair Value of Stock Options

The fair value of each grant of stock options was determined by the Company using the methods and assumptions discussed below. Each of these inputs is subjective and generally requires significant judgment to determine.

Valuation and Amortization Method —The Company estimates the fair value of its stock options using the Black-Scholes-Merton option-pricing model. This fair value is then amortized over the requisite service periods of the awards.

Expected Term—The Company estimates the expected term of stock option by taking the average of the vesting term and the contractual term of the option, as illustrated by the simplified method.

Expected Volatility—The expected volatility is derived from the Company's expectations of future market volatility over the expected term of the options.

Risk-Free Interest Rate—The risk-free interest rate is based on the U.S. Treasury yield curve on the date of grant.

Dividend Yield—The dividend yield assumption is based on the Company's history and expectation of no dividend payouts.

Stock Award Activity

A summary of option activity under the Company's equity incentive plans is as follows:

	Options Outstanding	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life (In Years)
Balance at December 31, 2021	2,255,672	$ 1.84	9.2
Options granted	533,349	$ 2.30	9.6
Options exercised	–		
Options forfeited/expired	(50,201)	$ 1.27	5.6
Balance at December 31, 2022	2,738,820	$ 1.94	8.4
Exercisable at December 31, 2022	2,169,088	$ 1.87	8.3
Vested and expected to vest at December 31, 2022	2,738,820	$ 1.94	8.4

The aggregate intrinsic value in the table above of the unexercised options reflects the total pre-tax intrinsic value (the difference between the Nasdaq closing price on December 30, 2022, and the exercise price of the options that would have been received by option holders if all options exercisable had been exercised.

The aggregate intrinsic value of options outstanding at December 31, 2022 is $0. The aggregate intrinsic value of vested and exercisable options at December 31, 2022 is $0.

As of December 31, 2022, there was approximately $559,414 of total unrecognized compensation cost related to non-vested stock options, which is expected to be recognized over the next 33 months.

The Company adjusts expense for actual forfeitures in the periods they occur.

Restricted Stock Units

In 2022, the Company granted RSUs under the 2022 Plan that have a combination of time-based and performance-based vesting, contingent upon continued service with the Company. The Company granted certain consultants an aggregate of 481,915 RSUs.

RSU activity under the 2022 Plan was as follows for the year ended December 31, 2022:

	RSU's Outstanding	Weighted-Average Grant-Date Fair value per Unit
Nonvested as of December 31, 2021	–	$ –
Granted	481,915	0.82
Vested	(61,826)	0.87
Forfeited	–	–
Nonvested as of December 31, 2022	420,089	$ 0.82

The grant date fair value for a RSU is the market price of the common stock on the date of grant. The total fair value of RSUs vested during 2022 was $53,912.

As of December 31, 2022, there was approximately $291,331 total unrecognized compensation cost related to non-vested RSUs, which is expected to be recognized over the next twelve months.

Common Stock Subject to Vesting

The Company entered into a contract for consulting services shortly after the completion of the IPO in April 2022. The contract included a fee payable in the form of 40,000 restricted common shares that vested over six months. The shares were issued in November 2022 after the shares vested. Stock-based vendor payments of $102,000 were recognized on the date of grant and recorded as general and administrative expense.

Stock-based Compensation Expense

The following table summarizes the total stock-based compensation expense included in the Company's statements of operations for the periods presented:

	December 31,	
	2022	2021
Sales and marketing	$ 57,299	$ 4,741
Research and development	(259)	23,604
General and administrative	1,129,619	149,144
	$ 1,186,659	$ 177,489

SUBSEQUENT EVENTS	12 Months Ended Dec. 31, 2022
Subsequent Events [Abstract]	
SUBSEQUENT EVENTS	

NOTE 14. SUBSEQUENT EVENTS

On February 16, 2023, the Company entered into a Securities Purchase Agreement (the "Purchase Agreement") with Jeffrey Thramann, the Company's Executive Chairman (the "Purchaser") pursuant to which it issued and sold one (1) share (the "Share") of the Company's newly designated Series A Preferred Stock, par value $0.00001 per share (the "Series A Preferred Stock"), to such Purchaser for an aggregate purchase price of $1,000.

The Share of Series A Preferred Stock will have 15,000,000 votes and will vote together with the outstanding shares of the Company's common stock as a single class exclusively with respect to any proposal to amend the Company's Certificate of Incorporation to effect a reverse stock split of the Company's common stock. The Share of Series A Preferred Stock will be voted, without action by the holder, on any such reverse stock split proposal in the same proportion as shares of common stock are voted on such proposal (excluding any common shares that are not voted). The Series A Preferred Stock otherwise has no voting rights, except as may otherwise be required by the General Corporation Law of the State of Delaware. The Share of Series A Preferred Stock is not convertible into, or exchangeable for, shares of any other class or series of stock or other securities of the Company. The Share of Series A Preferred Stock has no rights with respect to any distribution of assets of the Company, including upon a liquidation, bankruptcy, reorganization, merger, acquisition, sale, dissolution or winding up of the Company, whether voluntarily or involuntarily. The holder of the Share of Series A Preferred Stock will not be entitled to receive dividends of any kind.

The outstanding share of Preferred Stock shall be redeemed in whole, but not in part, at any time (i) if such redemption is ordered by the Board of Directors in its sole discretion or (ii) automatically upon the effectiveness of the amendment to the Certificate of Incorporation implementing a reverse stock split. Upon such redemption, the holder of the Series A Preferred Stock will receive consideration of $1,000.00 in cash.

SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Policies)	12 Months Ended Dec. 31, 2022
Accounting Policies [Abstract]	
Use of Estimates	**Use of Estimates** The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosures of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates. The financial statements include some amounts that are based on management's best estimates and judgments. The most significant estimates relate to depreciation, amortization, valuation of capital stock, and valuation of warrants and options to purchase shares of the Company's preferred and common stock. These estimates may be adjusted as more current information becomes available, and any adjustment could be significant.
Reclassifications	**Reclassifications** Certain accounts relating to the prior year have been reclassified to conform to the current period's presentation. These reclassifications had no effect on the net income or net assets as previously reported.
Valuation of Derivative Instruments	**Valuation of Derivative Instruments** Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") 815-40, *Derivatives and Hedging: Contracts on an Entity's Own Equity*, addresses whether an equity-linked contract qualifies as equity in the entity's financial statements. Agreements where an entity has insufficient authorized and unissued shares to settle the contract generally are accounted for as a liability and marked to fair value through earnings each reporting period. The Company evaluates its financial instruments, to determine if such instruments are liabilities or contain features that qualify as embedded derivatives. For financial instruments that are accounted for as liabilities, the derivative instrument is initially recorded at its fair value and is then revalued at each reporting date, with changes in the fair value reported as charges or credits to income.
Fair Value Measurements	**Fair Value Measurements** The carrying values of the Company's financial instruments including cash equivalents, restricted cash, accounts receivable and accounts payable, and notes payable are approximately equal to their respective fair values due to the relatively short-term nature of these instruments. Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. Assets and liabilities recorded at fair value in the balance sheets are categorized based upon the level of judgment associated with the inputs used to measure their fair value. The fair value hierarchy distinguishes between (1) market participant assumptions developed based on market data obtained from independent sources (observable inputs), and (2) an entity's own assumptions about market participant assumptions developed based on the best information available in the circumstances (unobservable inputs). The fair value hierarchy consists of three broad levels, which gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1) and the lowest priority to unobservable inputs (Level 3).

Cash and Cash Equivalents

Cash and Cash Equivalents

The Company considers all highly liquid instruments purchased with an original maturity of three months or less to be cash equivalents. The Company had no cash equivalents for all periods presented. The Company maintains cash deposits at several financial institutions, which are insured by the Federal Deposit Insurance Corporation up to $250,000. The Company's cash balance may at times exceed these limits. On December 31, 2022, and 2021, the Company had approximately $1,229,000 and $201,000, respectively, in excess of federally insured limits. The Company continually monitors its positions with, and the credit quality of, the financial institutions with which it invests. The Company maintains no international bank accounts. As of December 31, 2022, $10,000 of the Company's cash was restricted as collateral related to the credit card program offered by our bank.

Accounts Receivable, Less Allowance for Doubtful Accounts

Accounts Receivable, Less Allowance for Doubtful Accounts

The Company estimates an allowance for doubtful accounts based upon an evaluation of the current status of receivables, historical experience, and other factors as necessary. It is reasonably possible that the Company's estimate of the allowance for doubtful accounts will change. The allowance for doubtful accounts was $0 on December 31, 2022, and 2021.

Revenue Recognition

Revenue Recognition

Revenues are recognized when a contract with a customer exists, and at that point in time when we have delivered a Nociscan report to our customer. Revenue is recognized in the amount that reflects the negotiated consideration expected to be received in exchange for those reports. Following the delivery of the report, the company has no ongoing obligations or services to provide to the customer. Customers pay no other upfront, licensing, or other fees. To date, our reports are not reimbursable under any third-party payment arrangements, The Company invoices its customers based on the billing schedules in its sales arrangements. Payment terms range generally from 30 to 90 days, from the date of invoice.

Geographic Locations & Segments

Geographic Locations & Segments

Approximately 9% and 11% of the Company's revenues were generated from contracts with customers outside the United States in the years ended December 31, 2022, and 2021, respectively. All invoices are billed in the currency of the customers and are recorded in US Dollars at the then spot rate, which automatically is converted to dollars upon receipt and deposited in the Company's bank. Differences between the amounts received and the amounts initially recorded are reflected in Other Income (Expense).

Segment Disclosure

Segment Disclosure

The Company has a single operating and reporting segment, which is the delivery of Nociscan reports to our customers. The Company's Chief Executive Officer reviews financial information for purposes of making operating decisions and assessing financial performance.

Property and Equipment

Property and Equipment

Property and equipment are stated at cost and are depreciated using the straight-line method over the estimated useful lives of the related assets. Furniture and fixtures are depreciated over seven years. Computer and office equipment and computer software are depreciated over five years. Repairs and maintenance costs, which are not considered improvements and do not extend the useful life of the property and equipment, are expensed as incurred.

Impairment of Long-Lived Assets

Impairment of Long-Lived Assets

The Company reviews long-lived assets, including intangible assets, property and equipment, for impairment whenever events or changes in business circumstances indicate that the carrying

amount of the assets may not be fully recoverable using pre-tax undiscounted cash flows. Impairment, if any, is measured as the amount by which the carrying value of a long-lived asset exceeds its fair value.

Sales and Marketing Expenses

Sales and Marketing Expenses

The Company expenses the costs of sales and marketing its products and services as incurred. The primary drivers of cost have been employee payroll, website and branding development, press releases, attendance at various industry conferences, Key Opinion Leader consulting fees, and travel expenses.

Research and Development Costs

Research and Development Costs

Costs related to research, design and development of products are charged to research and development expense as incurred. These costs include direct compensation, benefits, and other headcount related costs for research and development personnel; costs for materials used in research and development activities; costs for outside services and allocated portions of facilities and other corporate costs. The Company has entered into research and clinical study arrangements with selected hospitals, cancer treatment centers, academic institutions and research institutions worldwide. These agreements support the Company's internal research and development capabilities.

Liquidity, Capital Resources and Going Concern

Liquidity, Capital Resources and Going Concern

The Company believes that the net proceeds from the April 2022 initial public offering will be sufficient to fund current operating plans into the second quarter of 2023. The Company has based these estimates, however, on assumptions that may prove to be wrong, and could spend available financial resources much faster than we currently expect. The Company will need to raise additional funds to continue funding our technology development. Management plans to secure such additional funding.

As a result of the Company's recurring losses from operations, and the need for additional financing to fund its operating and capital requirements, there is uncertainty regarding the Company's ability to maintain liquidity sufficient to operate its business effectively, which raises substantial doubt as to the Company's ability to continue as a going concern.

Share-Based Compensation

Share-Based Compensation

The Company accounts for stock-based awards in accordance with provisions of ASC Topic 718, *Compensation—Stock Compensation*, under which the Company recognizes the grant-date fair value of stock-based awards issued to employees and nonemployee board members as compensation expense on a straight-line basis over the vesting period of the award, while awards containing a performance condition are recognized as expense when the achievement of the performance criteria is considered probable. The Company uses the Black-Scholes option pricing model to determine the grant-date fair value of stock options. The Company estimates forfeitures that it expects will occur and adjusts expense for actual forfeitures in the periods they occur.

The exercise or strike price of each option is not less than 100% of the fair market value of the Common Stock subject to the option on the date the option is granted.

The Company issues restricted stock unit awards to non-employee consultants who are providing various services. The awards are valued at the market price on the date of the grant. The awards vest over the contract life and based on achievement of targeted performance milestones.

On occasion, the Company grants common stock, subject to vesting, to compensate vendors for services rendered.

Deferred Financing Costs

Deferred Financing Costs

The Company capitalizes certain legal, accounting, and other fees and costs that are directly attributable to in-process equity financings as deferred offering costs until such financings are completed. Upon the completion of an equity financing, these costs are recorded as a reduction of additional paid-in capital of the related offering. Upon the completion of the IPO in April 2022, approximately $1.5 million of offering costs related to the IPO were reclassified to additional paid-in capital.

Emerging Growth Company Status

Emerging Growth Company Status

The Company is an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act"). Under the JOBS Act, emerging growth companies can delay the adoption of new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. The Company has elected to use this extended transition period for complying with certain new or revised accounting standards that have different effective dates for public and private companies.

Income Taxes

Income Taxes

The Company is required to estimate its income taxes in each of the tax jurisdictions in which it operates prior to the completion and filing of tax returns for such periods. This process involves estimating actual current tax expense together with assessing temporary differences in the treatment of items for tax purposes versus financial accounting purposes that may create net deferred tax assets and liabilities. The Company accounts for income taxes under the asset and liability method, which requires, among other things, that deferred income taxes be provided for temporary differences between the tax bases of the Company's assets and liabilities and their financial statement reported amounts. In addition, deferred tax assets are recorded for the future benefit of utilizing net operating losses, research and development credit carryforwards and other deferred tax assets. The Company has not recorded an deferred tax asset because of the uncertainty that the Company will be able to utilize any future benefits (see Liquidity, Capital Resources and Going Concern in Note 2). Generally, the Company is not subject to income tax examinations for periods prior to 2019.

SUPPLEMENTAL FINANCIAL INFORMATION (Tables)

12 Months Ended

Dec. 31, 2022

Organization, Consolidation and Presentation of Financial Statements [Abstract]

Schedule of accounts receivable

	December 31,	
	2022	**2021**
Accounts receivable (1)	$ 18,569	$ 6,280
Less: Allowance for doubtful accounts	–	–
Accounts receivable, net	$ 18,569	$ 6,280

(1) Accounts receivable denominated in foreign currencies represent less than 15% of accounts receivable in all periods.

Schedule of accrued and other liabilities

	December 31,	
	2022	**2021**
Accounts payable	$ 457,558	$ 1,059,546
Credit cards payable	4,644	5,758
Accrued salaries and expenses	610,765	340,363
Accrued Interest	–	356,219
	$ 1,072,967	$ 1,761,886

Schedule of other expense

	Year Ended December 31,	
Income/(Expense)	**2022**	**2021**
Bank Interest	$ 2,510	$ (1,568)
California Relief Program [1]	–	5,000
Taxes	(800)	(800)
Foreign Currency Gain (Loss)	(1,190)	(1,309)
Other	–	3,135
	$ 520	$ 4,458

1 The California Small Business COVID-19 Relief Grant Program (the "Program") provides micro grants ranging from $5,000 to $25,000 to eligible small businesses and nonprofits impacted by COVID-19 and the related health and safety restrictions.

PROPERTY, PLANT, AND EQUIPMENT (Tables)	12 Months Ended Dec. 31, 2022

Property, Plant and Equipment [Abstract]

Schedule of property and equipment

	December 31, 2022	December 31, 2021
Furniture and fixtures	$ –	$ 7,700
Computer and office equipment	13,032	45,187
Software	42,150	42,150
Other Equipment	18,190	18,190
	73,372	113,227
Less: Accumulated depreciation	(70,026)	(100,591)
Property and equipment, net	$ 3,346	$ 12,636

Schedule of future depreciation of property and equipment

2023	$ 1,563
2024	1,187
2025	596
Total	$ 3,346

INTANGIBLE ASSETS
(Tables)

12 Months Ended
Dec. 31, 2022

Finite-Lived Intangible Assets [Line Items]

Intangible Assets

	December 31, 2022	December 31, 2021
Patents and licenses	$ 2,147,729	$1,938,858
UC royalty	200,000	150,000
Other	5,017	5,017
	2,352,746	2,093,875
Less: accumulated amortization	(1,138,372)	(949,250)
Intangible assets, net	$ 1,214,374	$1,144,625

Patents And Licenses [Member]

Finite-Lived Intangible Assets [Line Items]

Schedule of future amortization

2023	$ 15,312
2024	19,219
2025	21,910
2026	27,532
2027 and beyond	(87,101)
Total	$ 0

U C Royalty [Member]

Finite-Lived Intangible Assets [Line Items]

Schedule of future amortization

2023	$ 158,114
2024	153,587
2025	153,587
2026	153,587
2027 and beyond	595,499
Total	$1,214,374

NET LOSS PER SHARE OF COMMON STOCK (Tables)

12 Months Ended Dec. 31, 2022

Earnings Per Share [Abstract]

Reconciliation of loss per share

	December 31,	
	2022	**2021**
Numerator:		
Net loss used to compute basic and diluted loss per common share	$(8,021,064)	$(5,955,888)
Denominator:		
Weighted average shares used to compute basic and dilutive loss per share	6,105,569	905,685

Schedule of anti dilutive securities excluded from computation of earnings per share

	December 31, 2022	**December 31, 2021**
Series A and B convertible preferred stock	819,779	2,565,809
Warrants	2,329,977	70,840
Restricted stock units	50,038	–
Stock options	2,481,816	985,283
	5,681,610	3,621,932

STOCK-BASED COMPENSATION (Tables)

12 Months Ended Dec. 31, 2022

Share-Based Compensation Arrangement by Share-Based Payment Award [Line Items]

Assumptions used for valuation

Risk-free interest rate (4/2022 – 8/2022)	1.99%
Risk-free interest rate (9/2022 – 12/2022)	3.67%
Dividend yield	–
Expected term	6-8 years
Expected volatility	66.35%

Schedule of option activity

	Options Outstanding	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life (In Years)
Balance at December 31, 2021	2,255,672	$ 1.84	9.2
Options granted	533,349	$ 2.30	9.6
Options exercised	–		
Options forfeited/expired	(50,201)	$ 1.27	5.6
Balance at December 31, 2022	2,738,820	$ 1.94	8.4
Exercisable at December 31, 2022	2,169,088	$ 1.87	8.3
Vested and expected to vest at December 31, 2022	2,738,820	$ 1.94	8.4

Schedule of restricted stock unit, activity

	RSU's Outstanding	Weighted-Average Grant-Date Fair value per Unit
Nonvested as of December 31, 2021	–	$ –
Granted	481,915	0.82
Vested	(61,826)	0.87
Forfeited	–	–
Nonvested as of December 31, 2022	420,089	$ 0.82

Schedule of stock-based compensation expense

	December 31, 2022	December 31, 2021
Sales and marketing	$ 57,299	$ 4,741
Research and development	(259)	23,604
General and administrative	1,129,619	149,144
	$ 1,186,659	$ 177,489

Nocimed 2015 Stock Plan [Member]

Share-Based Compensation Arrangement by Share-Based Payment Award [Line Items]

Assumptions used for valuation

Risk-free interest rate	1.99%
Dividend yield	–
Expected term	6-8 years
Expected volatility	25.00%

THE COMPANY AND BASIS OF PRESENTATION (Details Narrative) - USD ($)	May 13, 2022	May 02, 2022	Apr. 29, 2022	Apr. 26, 2022	Apr. 26, 2022	Apr. 21, 2022	12 Months Ended	
							Dec. 31, 2022	Dec. 31, 2021
Collaborative Arrangement and Arrangement Other than Collaborative [Line Items]								
Proceeds from Issuance or Sale of Equity							$ 8,552,318	$ 0
Stockholders' Equity, Reverse Stock Split						1-for-7.47 reverse stock split		
Aclarion Equity Incentive Plan 2022 [Member]								
Collaborative Arrangement and Arrangement Other than Collaborative [Line Items]								
Share-Based Compensation Arrangement by Share-Based Payment Award, Number of Shares Authorized						2,000,000		
Executive Chairman [Member]								
Collaborative Arrangement and Arrangement Other than Collaborative [Line Items]								
Share-Based Compensation Arrangement by Share-Based Payment Award, Options, Vested, Number of Shares						1,204,819		
IPO [Member] | David Neal [Member]								
Collaborative Arrangement and Arrangement Other than Collaborative [Line Items]								
Labor and Related Expense			$ 100,000					
IPO [Member] | Brent Ness [Member]								
Collaborative Arrangement and Arrangement Other than Collaborative [Line Items]								
Labor and Related Expense			$ 100,000					
IPO [Member] | James Peacock [Member]								
Collaborative Arrangement and Arrangement Other than Collaborative [Line Items]								

Labor and Related Expense	$ 130,000			
IPO [Member] | UCSF [Member] | Indexed Milestone Payment Obligation [Member]				
Collaborative Arrangement and Arrangement Other than Collaborative [Line Items]				
Payments for Other Operating Activities	$ 123,828			
Preferred Stock [Member] | Pre Split Shares [Member]				
Collaborative Arrangement and Arrangement Other than Collaborative [Line Items]				
Conversion of Stock, Shares Converted				24,495,004
Warrants [Member] | IPO [Member] | Underwriters [Member]				
Collaborative Arrangement and Arrangement Other than Collaborative [Line Items]				
Class of Warrant or Right, Number of Securities Called by Each Warrant or Right		173,200	173,200	
Warrants and Rights Outstanding, Maturity Date		Apr. 26, 2027	Apr. 26, 2027	
Unit Of Common Stock And Warrant [Member] | IPO [Member]				
Collaborative Arrangement and Arrangement Other than Collaborative [Line Items]				
Stock Issued During Period, Shares, New Issues		2,165,000	2,165,000	
Proceeds from Issuance or Sale of Equity			$ 8,600,000	
Common Stock Warrants [Member] | IPO [Member] | Underwriters [Member]				
Collaborative Arrangement and Arrangement Other than Collaborative [Line Items]				
Stock Issued During Period, Shares, New Issues			324,750	
Warrants Converted Into Common Stock [Member] | Common Stock [Member] | Post Split Shares [Member]				

Collaborative Arrangement and Arrangement Other than Collaborative [Line Items]	
Conversion of Stock, Shares Issued	60,408
Preferred Stock Converted To Common Stock [Member] | Common Stock [Member] | Post Split Shares [Member]	
Collaborative Arrangement and Arrangement Other than Collaborative [Line Items]	
Conversion of Stock, Shares Issued	3,279,117
Dividends Converted To Common Stock [Member] | Common Stock [Member] | Post Split Shares [Member]	
Collaborative Arrangement and Arrangement Other than Collaborative [Line Items]	
Conversion of Stock, Shares Issued	984,429
Interest Converted To Common Stock [Member] | Common Stock [Member] | Post Split Shares [Member]	
Collaborative Arrangement and Arrangement Other than Collaborative [Line Items]	
Conversion of Stock, Shares Issued	426,768
Interest Converted To Warrants [Member] | Warrants [Member] | Post Split Shares [Member]	
Collaborative Arrangement and Arrangement Other than Collaborative [Line Items]	
Conversion of Stock, Shares Issued	426,768

SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Details Narrative) - USD ($)	12 Months Ended		
	Dec. 31, 2022	Dec. 31, 2021	Apr. 30, 2022
Product Information [Line Items]			
Cash Equivalents, at Carrying Value	$ 0	$ 0	
Cash, Uninsured Amount	1,229,000	201,000	
Restricted Cash	10,000	20,000	
Accounts Receivable, Allowance for Credit Loss	$ 0	$ 0	
Deferred Offering Costs			$ 1,500,000
Revenue, Segment Benchmark [Member] | Customer Concentration Risk [Member] | Customers Outside The U S [Member]			
Product Information [Line Items]			
Revenues from contracts with customers	9.00%	11.00%	

SUPPLEMENTAL FINANCIAL INFORMATION (Details - Accounts receivable) - USD ($)	Dec. 31, 2022	Dec. 31, 2021
Accounts, Notes, Loans and Financing Receivable [Line Items]		
Allowance for doubtful accounts	$ 0	$ 0
Accounts receivable, net	18,569	6,280
Accounts Receivable [Member]		
Accounts, Notes, Loans and Financing Receivable [Line Items]		
Accounts receivable gross	$ 18,569	$ 6,280

SUPPLEMENTAL FINANCIAL INFORMATION (Details - Accounts payable) - USD ($)	Dec. 31, 2022	Dec. 31, 2021
Organization, Consolidation and Presentation of Financial Statements [Abstract]		
Accounts payable	$ 457,558	$ 1,059,546
Credit cards payable	4,644	5,758
Accrued salaries and expenses	610,765	340,363
Accrued Interest	0	356,219
Accrued and other liabilities	$ 1,072,967	$ 1,761,886

SUPPLEMENTAL FINANCIAL INFORMATION (Details - Other expense) - USD ($)		12 Months Ended	
		Dec. 31, 2022	Dec. 31, 2021
Other income expenses		$ 520	$ 4,458
Bank Interest [Member]			
Other income expenses		2,510	(1,568)
California Relief Program [Member]			
Other income expenses	[1]	0	5,000
Taxes [Member]			
Other income expenses		(800)	(800)
Exchange Gain Loss [Member]			
Other income expenses		(1,190)	(1,309)
Other [Member]			
Other income expenses		$ 0	$ 3,135

[1] The California Small Business COVID-19 Relief Grant Program (the "Program") provides micro grants ranging from $5,000 to $25,000 to eligible small businesses and nonprofits impacted by COVID-19 and the related health and safety restrictions.

LEASES (Details Narrative) - USD ($)	9 Months Ended Sep. 30, 2021	12 Months Ended Dec. 31, 2022	Dec. 31, 2021
Leases			
Operating Lease, Expense		$ 36,070	$ 64,932
Operating Leases, Income Statement, Sublease Revenue	$ 48,400	$ 26,340	

PROPERTY, PLANT, AND EQUIPMENT (Details - property and equipment) - USD ($)	Dec. 31, 2022	Dec. 31, 2021
Property, Plant and Equipment [Line Items]		
Property, plant and equipment, gross	$ 73,372	$ 113,227
Accumulated depreciation	(70,026)	(100,591)
Property, plant and equipment, net	3,346	12,636
Furniture and Fixtures [Member]		
Property, Plant and Equipment [Line Items]		
Property, plant and equipment, gross	0	7,700
Computer And Office Equipment [Member]		
Property, Plant and Equipment [Line Items]		
Property, plant and equipment, gross	13,032	45,187
Software Development [Member]		
Property, Plant and Equipment [Line Items]		
Property, plant and equipment, gross	42,150	42,150
Other Equipment [Member]		
Property, Plant and Equipment [Line Items]		
Property, plant and equipment, gross	$ 18,190	$ 18,190

PROPERTY, PLANT, AND EQUIPMENT (Details - future depreciation) - USD ($)	Dec. 31, 2022	Dec. 31, 2021
Property, Plant and Equipment [Abstract]		
2023	$ 1,563	
2024	1,187	
2025	596	
Total	$ 3,346	$ 12,636

PROPERTY, PLANT, AND EQUIPMENT (Details Narrative) - USD ($)	12 Months Ended	
	Dec. 31, 2022	Dec. 31, 2021
Property, Plant and Equipment [Abstract]		
Depreciation expense	$ 4,500	$ 12,981
Sale of property and equipment	$ 1,000	

INTANGIBLE ASSETS (Details) - USD ($)	Dec. 31, 2022	Dec. 31, 2021
Finite-Lived Intangible Assets [Line Items]		
Total intangible assets gross	$ 2,352,746	$ 2,093,875
Less: accumulated amortization	1,138,372	949,250
Intangible assets, net	1,214,374	1,144,625
Patents And Licenses [Member]		
Finite-Lived Intangible Assets [Line Items]		
Total intangible assets gross	2,147,729	1,938,858
U C Royalty [Member]		
Finite-Lived Intangible Assets [Line Items]		
Total intangible assets gross	200,000	150,000
Other Intangible Assets [Member]		
Finite-Lived Intangible Assets [Line Items]		
Total intangible assets gross	$ 5,017	$ 5,017

INTANGIBLE ASSETS (Details - future amortization)	Dec. 31, 2022 USD ($)
Patents And Licenses [Member]	
Finite-Lived Intangible Assets [Line Items]	
2023	$ 15,312
2024	19,219
2025	21,910
2026	27,532
2027 and beyond	(87,101)
Total	0
Patents And Trademarks [Member]	
Finite-Lived Intangible Assets [Line Items]	
2023	158,114
2024	153,587
2025	153,587
2026	153,587
Total	1,214,374
2027 and beyond	$ 595,499

INTANGIBLE ASSETS (Details Narrative) - USD ($)	12 Months Ended	
	Dec. 31, 2022	Dec. 31, 2021
Goodwill and Intangible Assets Disclosure [Abstract]		
Amortization expense	$ 189,121	$ 176,390
Impairment of Intangible Assets, Finite-Lived	$ 0	$ 0

SHORT TERM NOTES AND CONVERTIBLE DEBT (Details Narrative) - USD ($)	1 Months Ended					12 Months Ended						
	Apr. 30, 2022	Apr. 21, 2022	Dec. 31, 2021	Aug. 31, 2021	May 31, 2021	Dec. 31, 2022	Dec. 31, 2021	Jun. 30, 2021	Feb. 28, 2021	Dec. 31, 2020	Apr. 30, 2020	Mar. 31, 2020
Debt Instrument [Line Items]												
Repayments of Notes Payable						$ 2,000,000	$ (0)					
Interest Converted To Common Stock [Member]												
Debt Instrument [Line Items]												
Adjustments to Additional Paid in Capital, Convertible Debt with Conversion Feature		$ 1,299,507										
Common Stock [Member] | Post Split Shares [Member] | Interest Converted To Common Stock [Member]												
Debt Instrument [Line Items]												
Debt Conversion, Converted Instrument, Shares Issued		426,768										
Warrants [Member] | Post Split Shares [Member] | Interest Converted To Common Stock [Member]												
Debt Instrument [Line Items]												
Debt Conversion, Converted Instrument, Shares Issued		426,768										
Qualified Financing [Member]												
Debt Instrument [Line Items]												
Notes Payable								$ 2,000,000.0				
Repayments of Notes Payable	$ 2,000,000											
PPP Loan [Member]												
Debt Instrument [Line Items]												
Notes Payable											$ 245,191	
Debt Instrument, Decrease, Forgiveness					$ 245,191							
Interest forgiven					$ 2,622							
PPP Loan [Member]												
Debt Instrument [Line Items]												
Notes Payable									$ 125,000			
Debt Instrument, Decrease, Forgiveness				$ 125,000								
Interest forgiven				$ 698								
Accredited Investors [Member]												
Debt Instrument [Line Items]												
Convertible Notes Payable			$ 814,500				$ 814,500			$ 1,598,488		

Accredited Investors [Member] | Convertible Notes Payable [Member]			
Debt Instrument [Line Items]			
Debt Instrument, Interest Rate, Stated Percentage	10.00%	10.00%	
Interest Payable	$ 3,201,977	$ 3,201,977	
NuVasive [Member]			
Debt Instrument [Line Items]			
Convertible Notes Payable			$ 308,720
NuVasive [Member] | SAFE Agreement [Member]			
Debt Instrument [Line Items]			
Stock issued for SAFE Agreement, shares	1,584,660		
Stock issued for SAFE Agreement, value	$ 2,000,000		

COMMITMENTS AND CONTINGENCIES (Details Narrative) - USD ($)			1 Months Ended		12 Months Ended	
	May 02, 2022	Apr. 21, 2022	Sep. 15, 2022	Sep. 30, 2021	Dec. 31, 2022	Dec. 31, 2021
Collaborative Arrangement and Arrangement Other than Collaborative [Line Items]						
Stock option grants, shares					533,349	
Exercise price			$ 1.94			
Stock options contractual term			10 years		8 years 4 months 24 days	
Board Of Directors [Member]						
Collaborative Arrangement and Arrangement Other than Collaborative [Line Items]						
Stock option grants, shares			185,285			
Regents Of The University Of California [Member]						
Collaborative Arrangement and Arrangement Other than Collaborative [Line Items]						
Minimum annual royalty payment					$ 50,000	
Royalty Expense					$ 50,000	$ 50,000
UCSF [Member] | IPO [Member] | Indexed Milestone Payment Obligation [Member]						
Collaborative Arrangement and Arrangement Other than Collaborative [Line Items]						
Payments for Other Operating Activities	$ 123,828					
Executive Chairman [Member]						
Collaborative Arrangement and Arrangement Other than Collaborative [Line Items]						
Stock option grants, shares				1,204,819		
Share-Based Compensation Arrangement by Share-Based Payment Award, Options, Vested, Number of Shares		1,204,819				

STOCKHOLDERS' EQUITY (Details Narrative) - USD ($)	Apr. 26, 2022	Apr. 26, 2022	Dec. 03, 2021	Mar. 01, 2019	Aug. 02, 2018	Jul. 27, 2017	Dec. 05, 2015	Dec. 31, 2014	3 Months Ended Mar. 31, 2022	12 Months Ended Dec. 31, 2022	Dec. 31, 2021	Dec. 31, 2020
Class of Stock [Line Items]												
Common Stock, Shares Authorized										200,000,000	200,000,000	
Common Stock, Par or Stated Value Per Share										$ 0.00001	$ 0.00001	
Preferred Stock, Shares Authorized										20,000,000		
Preferred Stock, Par or Stated Value Per Share										$ 0.00001		
Warrant [Member]												
Class of Stock [Line Items]												
Class of Warrant or Right, Outstanding										2,489,750		
Common Stock [Member]												
Class of Stock [Line Items]												
Stock Issued During Period, Shares, New Issues										40,000		
Class of Warrant or Right, Outstanding										599,968		
Warrants Converted To Common Stock [Member]												
Class of Stock [Line Items]												
Conversion of Stock, Shares Issued									60,408			
Warrants Issued For Convertible Notes [Member]												
Class of Stock [Line Items]												
[custom:WarrantsIssuedShares]											17,286	58,846
Warrants Issued With Convertible Notes [Member]												
Class of Stock [Line Items]												
Loss on warrants exercised									$ 152,653			
Preferred Stock Series A 1 [Member]												
Class of Stock [Line Items]												
Issuance date								Dec. 31, 2014				
Preferred Stock, Value, Issued								$ 1,247,541				
Shares Issued, Price Per Share								$ 0.70				
Preferred Stock Series A 2 [Member]												
Class of Stock [Line Items]												
Issuance date								Dec. 31, 2014				
Preferred Stock, Value, Issued								$ 1,114,797				
Shares Issued, Price Per Share								$ 0.77				
Preferred Stock Series A 3 [Member]												
Class of Stock [Line Items]												
Issuance date								Dec. 31, 2014				
Preferred Stock, Value, Issued								$ 795,002				
Shares Issued, Price Per Share								$ 0.85				

Preferred Stock Series A 4 [Member]								
Class of Stock [Line Items]								
Issuance date						Dec. 31, 2014		
Preferred Stock, Value, Issued						$ 1,965,288		
Shares Issued, Price Per Share						$ 0.94		
Series B Preferred Stock [Member]								
Class of Stock [Line Items]								
Preferred Stock, Shares Authorized								5,180,814
Preferred Stock, Par or Stated Value Per Share								$ 0.00001
Issuance date					Dec. 05, 2015			
Preferred Stock, Value, Issued					$ 5,013,579		$ 0	$ 52
Shares Issued, Price Per Share					$ 1.00			
Series B 1 Preferred Stock [Member]								
Class of Stock [Line Items]								
Preferred Stock, Shares Authorized								10,758,338
Preferred Stock, Par or Stated Value Per Share								$ 0.00001
Issuance date			Mar. 01, 2019	Aug. 02, 2018	Jul. 27, 2017			
Preferred Stock, Value, Issued			$ 2,463,328	$ 5,217,698	$ 1,500,000		0	$ 73
Shares Issued, Price Per Share			$ 1.26	$ 1.26	$ 1.26			
Series B 2 Preferred Stock [Member]								
Class of Stock [Line Items]								
Preferred Stock, Shares Authorized								1,600,000
Preferred Stock, Par or Stated Value Per Share								$ 0.0001
Issuance date		Dec. 03, 2021						
Preferred Stock, Value, Issued		$ 1,774,819					0	$ 16
Shares Issued, Price Per Share		$ 1.12						
Series B 3 Preferred Stock [Member]								
Class of Stock [Line Items]								
Preferred Stock, Shares Authorized								4,300,000
Preferred Stock, Par or Stated Value Per Share								$ 0.0001
Issuance date		Dec. 03, 2021						
Preferred Stock, Value, Issued		$ 5,327,468					$ 0	$ 42
Shares Issued, Price Per Share		$ 1.26						
Unit Of Common Stock And Warrant [Member] | IPO [Member]								
Class of Stock [Line Items]								
Stock Issued During Period, Shares, New Issues	2,165,000	2,165,000						

IPO Warrants [Member] | IPO [Member] | Underwriters [Member]		
Class of Stock [Line Items]		
Stock Issued During Period, Shares, New Issues	324,750	
Warrants [Member] | IPO [Member] | Underwriters [Member]		
Class of Stock [Line Items]		
Class of Warrant or Right, Number of Securities Called by Each Warrant or Right	173,200	173,200
Class of Warrant or Right, Exercise Price of Warrants or Rights	$ 5.44	$ 5.44
Warrants and Rights Outstanding, Maturity Date	Apr. 26, 2027	Apr. 26, 2027

NET LOSS PER SHARE OF COMMON STOCK (Details) - USD ($)	12 Months Ended	
	Dec. 31, 2022	Dec. 31, 2021
Earnings Per Share [Abstract]		
Net loss used to compute basic and diluted loss per common share	$ (8,021,064)	$ (5,955,888)
Weighted Average Number of Shares Outstanding, Basic	6,105,569	905,685
Weighted Average Number of Shares Outstanding, Diluted	6,105,569	905,685

NET LOSS PER SHARE OF COMMON STOCK (Details - dilutive securities) - shares	12 Months Ended	
	Dec. 31, 2022	Dec. 31, 2021
Antidilutive Securities Excluded from Computation of Earnings Per Share [Line Items]		
Antidilutive shares	5,681,610	3,621,932
Series A And B Convertible Preferred Stock [Member]		
Antidilutive Securities Excluded from Computation of Earnings Per Share [Line Items]		
Antidilutive shares	819,779	2,565,809
Warrants [Member]		
Antidilutive Securities Excluded from Computation of Earnings Per Share [Line Items]		
Antidilutive shares	2,329,977	70,840
Restricted Stock Units [Member]		
Antidilutive Securities Excluded from Computation of Earnings Per Share [Line Items]		
Antidilutive shares	50,038	0
Stock Options [Member]		
Antidilutive Securities Excluded from Computation of Earnings Per Share [Line Items]		
Antidilutive shares	2,481,816	985,283

STOCK-BASED COMPENSATION (Details - Assumptions used for valuation)	1 Months Ended Sep. 30, 2022	5 Months Ended Aug. 31, 2022	12 Months Ended Dec. 31, 2022
Aclarion Equity Incentive Plan 2022 [Member]			
Share-Based Compensation Arrangement by Share-Based Payment Award [Line Items]			
Share-Based Compensation Arrangement by Share-Based Payment Award, Fair Value Assumptions, Risk Free Interest Rate	3.67%	1.99%	
Share-Based Compensation Arrangement by Share-Based Payment Award, Fair Value Assumptions, Expected Dividend Rate			0.00%
Share-Based Compensation Arrangement by Share-Based Payment Award, Fair Value Assumptions, Expected Term, Simplified Method			6-8 years
Share-Based Compensation Arrangement by Share-Based Payment Award, Fair Value Assumptions, Expected Volatility Rate			66.35%
Nocimed 2015 Stock Plan [Member]			
Share-Based Compensation Arrangement by Share-Based Payment Award [Line Items]			
Share-Based Compensation Arrangement by Share-Based Payment Award, Fair Value Assumptions, Risk Free Interest Rate			1.99%
Share-Based Compensation Arrangement by Share-Based Payment Award, Fair Value Assumptions, Expected Dividend Rate			0.00%
Share-Based Compensation Arrangement by Share-Based Payment Award, Fair Value Assumptions, Expected Term, Simplified Method			6-8 years
Share-Based Compensation Arrangement by Share-Based Payment Award, Fair Value Assumptions, Expected Volatility Rate			25.00%

STOCK-BASED COMPENSATION (Details - Option activity) - USD ($)	1 Months Ended	12 Months Ended	
	Sep. 15, 2022	Dec. 31, 2022	Dec. 31, 2021
Share-Based Payment Arrangement [Abstract]			
Share-Based Compensation Arrangement by Share-Based Payment Award, Options, Outstanding, Number, Beginning Balance		2,255,672	
Share-Based Compensation Arrangement by Share-Based Payment Award, Options, Outstanding, Weighted Average Exercise Price, Beginning Balance		$ 1.84	
Share-Based Compensation Arrangement by Share-Based Payment Award, Options, Outstanding, Weighted Average Remaining Contractual Term		8 years 4 months 24 days	9 years 2 months 12 days
Share-Based Compensation Arrangement by Share-Based Payment Award, Options, Grants in Period, Net of Forfeitures		533,349	
Share-Based Compensation Arrangement by Share-Based Payment Award, Options, Outstanding, Weighted Average Exercise Price, Beginning Balance		$ 2.30	
Share-Based Compensation Arrangement by Share-Based Payment Award, Options, Outstanding, Weighted Average Remaining Contractual Term, Options Granted			9 years 7 months 6 days
Share-Based Compensation Arrangement by Share-Based Payment Award, Options, Grants in Period, Net of Forfeitures		$ 0	
Share-Based Compensation Arrangement by Share-Based Payment Award, Options, Expirations in Period		(50,201)	
Share-Based Compensation Arrangement by Share-Based Payment Award, Options, Outstanding, Weighted Average Exercise Price, Beginning Balance			
Share-Based Compensation Arrangement by Share-Based Payment Award, Options, Outstanding, Weighted Average Remaining Contractual Term, Options Forfeited			5 years 7 months 6 days
Share-Based Compensation Arrangement by Share-Based Payment Award, Options, Outstanding, Number, Ending Balance		2,738,820	2,255,672
Share-Based Compensation Arrangement by Share-Based Payment Award, Options, Outstanding, Weighted Average Exercise Price, Ending Balance		$ 1.94	$ 1.84
Share-Based Compensation Arrangement by Share-Based Payment Award, Options, Exercisable, Number		2,169,088	
Share-Based Compensation Arrangement by Share-Based Payment Award, Options, Exercisable, Weighted Average Exercise Price		$ 1.87	
Share-Based Compensation Arrangement by Share-Based Payment Award, Options, Exercisable Weighted Average Remaining Contractual Term		8 years 3 months 18 days	
Options outstanding, vested and expected to vest		2,738,820	
Weighted average exercise price vested and expected to vest		$ 1.94	
Share-Based Compensation Arrangement by Share-Based Payment Award, Options, Vested And Expected to Vest Weighted Average Remaining Contractual Term	10 years	8 years 4 months 24 days	

STOCK-BASED COMPENSATION (Details - RSU activity)	12 Months Ended Dec. 31, 2022 $ / shares shares
Share-Based Payment Arrangement [Abstract]	
Number of shares outstanding, beginning | shares	0
Weighted average grant date fair value, beginning | $ / shares	$ 0
Number of shares granted | shares	481,915
Weighted average grant date fair value, granted | $ / shares	$ 0.82
Number of shares vested | shares	(61,826)
Weighted average grant date fair value, vested | $ / shares	$ 0.87
Number of shares forfeited | shares	0
Weighted average grant date fair value, forfeited | $ / shares	$ 0
Number of shares outstanding, ending | shares	420,089
Weighted average grant date fair value, ending | $ / shares	$ 0.82

STOCK-BASED COMPENSATION (Details - Share based compensation) - USD ($)	12 Months Ended	
	Dec. 31, 2022	Dec. 31, 2021
Share-Based Payment Arrangement, Expensed and Capitalized, Amount [Line Items]		
General and administrative	$ 1,186,659	$ 177,489
Sales And Marketing [Member]		
Share-Based Payment Arrangement, Expensed and Capitalized, Amount [Line Items]		
General and administrative	57,299	4,741
Research And Development [Member]		
Share-Based Payment Arrangement, Expensed and Capitalized, Amount [Line Items]		
General and administrative	(259)	23,604
General And Administrative [Member]		
Share-Based Payment Arrangement, Expensed and Capitalized, Amount [Line Items]		
General and administrative	$ 1,129,619	$ 149,144

STOCK-BASED COMPENSATION (Details Narrative) - USD ($)	12 Months Ended	
	Dec. 31, 2022	Apr. 21, 2022
Share-Based Compensation Arrangement by Share-Based Payment Award [Line Items]		
Intrinsic value options exercised	$ 0	
Unrecognized compensation cost	$ 559,414	
Share-Based Compensation Arrangement by Share-Based Payment Award, Equity Instruments Other than Options, Grants in Period	481,915	
Fair value of restricted stock unit	$ 53,912	
Number of share granted	40,000	
Stock based compensation expense	$ 102,000	
Restricted Stock Units (RSUs) [Member]		
Share-Based Compensation Arrangement by Share-Based Payment Award [Line Items]		
Share-Based Compensation Arrangement by Share-Based Payment Award, Equity Instruments Other than Options, Grants in Period	481,915	
Restricted Stock [Member]		
Share-Based Compensation Arrangement by Share-Based Payment Award [Line Items]		
Unrecognized compensation cost	$ 291,331	
Options Held [Member]		
Share-Based Compensation Arrangement by Share-Based Payment Award [Line Items]		
Intrinsic value options exercised	$ 0	
Aclarion Equity Incentive Plan 2022 [Member]		
Share-Based Compensation Arrangement by Share-Based Payment Award [Line Items]		
Share-Based Compensation Arrangement by Share-Based Payment Award, Number of Shares Authorized		2,000,000

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  "http://aclarion.com/role/ShortTermNotesAndConvertibleDebtDetailsNarrative",
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    "label": "Audited Annual Financial Statements"
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    "label": "Document Accounting Standard"
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    "label": "Document Fiscal Year Focus"
   }
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  "en-us": {
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    "label": "Document Transition Report"
   }
  }
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   "role": {
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    "label": "Document Type"
   }
  }
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 "xbrltype": "submissionTypeItemType"
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"dei_DocumentsIncorporatedByReferenceTextBlock": {
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 "lang": {
  "en-us": {
   "role": {
    "documentation": "Documents incorporated by reference.",
    "label": "Documents Incorporated by Reference [Text Block]"
   }
  }
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 "localname": "DocumentsIncorporatedByReferenceTextBlock",
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    "label": "Entity Address, Address Line One"
   }
  }
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 "xbrltype": "normalizedStringItemType"
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    "documentation": "Address Line 2 such as Street or Suite number",
    "label": "Entity Address, Address Line Two"
   }
  }
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 "xbrltype": "normalizedStringItemType"
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"dei_EntityAddressAddressLine3": {
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  "en-us": {
   "role": {
    "documentation": "Address Line 3 such as an Office Park",
    "label": "Entity Address, Address Line Three"
   }
  }
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 "xbrltype": "normalizedStringItemType"
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"dei_EntityAddressCityOrTown": {
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    "documentation": "Name of the City or Town",
    "label": "Entity Address, City or Town"
   }
  }
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 "xbrltype": "normalizedStringItemType"
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  "en-us": {
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    "label": "Entity Address, Country"
   }
  }
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    "label": "Entity Address, Postal Zip Code"
   }
  }
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    "documentation": "Name of the state or province.",
    "label": "Entity Address, State or Province"
   }
  }
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 "xbrltype": "stateOrProvinceItemType"
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"dei_EntityBankruptcyProceedingsReportingCurrent": {
 "auth_ref": [
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 "lang": {
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   "role": {
    "documentation": "For registrants involved in bankruptcy proceedings during the preceding five years, the value Yes indicates that the registrant has filed all documents and reports required to be filed by Section 12, 13 or 15(d) of the Securities Exchange Act of 1934 subsequent to the distribution of securities under a plan confirmed by a court; the value No indicates the registrant has not.  Registrants not involved in bankruptcy proceedings during the preceding five years should not report this element.",
    "label": "Entity Bankruptcy Proceedings, Reporting Current"
   }
  }
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    "documentation": "A unique 10-digit SEC-issued value to identify entities that have filed disclosures with the SEC. It is commonly abbreviated as CIK.",
    "label": "Entity Central Index Key"
   }
  }
 },
 "localname": "EntityCentralIndexKey",
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   "role": {
    "documentation": "Indicate number of shares or other units outstanding of each of registrant's classes of capital or common stock or other ownership interests, if and as stated on cover of related periodic report. Where multiple classes or units exist define each class/interest by adding class of stock items such as Common Class A [Member], Common Class B [Member] or Partnership Interest [Member] onto the Instrument [Domain] of the Entity Listings, Instrument.",
    "label": "Entity Common Stock, Shares Outstanding"
   }
  }
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 "xbrltype": "sharesItemType"
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  "en-us": {
   "role": {
    "documentation": "Indicate 'Yes' or 'No' whether registrants (1) have filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that registrants were required to file such reports), and (2) have been subject to such filing requirements for the past 90 days. This information should be based on the registrant's current or most recent filing containing the related disclosure.",
    "label": "Entity Current Reporting Status"
   }
  }
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 "localname": "EntityCurrentReportingStatus",
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    "label": "Entity Emerging Growth Company"
   }
  }
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   "role": {
    "documentation": "Indicate if an emerging growth company has elected not to use the extended transition period for complying with any new or revised financial accounting standards.",
    "label": "Elected Not To Use the Extended Transition Period"
   }
  }
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 "localname": "EntityExTransitionPeriod",
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 "xbrltype": "booleanItemType"
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  "en-us": {
   "role": {
    "documentation": "Commission file number. The field allows up to 17 characters. The prefix may contain 1-3 digits, the sequence number may contain 1-8 digits, the optional suffix may contain 1-4 characters, and the fields are separated with a hyphen.",
    "label": "Entity File Number"
   }
  }
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 "localname": "EntityFileNumber",
 "nsuri": "http://xbrl.sec.gov/dei/2022",
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 ],
 "xbrltype": "fileNumberItemType"
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"dei_EntityFilerCategory": {
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 ],
 "lang": {
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   "role": {
    "documentation": "Indicate whether the registrant is one of the following: Large Accelerated Filer, Accelerated Filer, Non-accelerated Filer. Definitions of these categories are stated in Rule 12b-2 of the Exchange Act. This information should be based on the registrant's current or most recent filing containing the related disclosure.",
    "label": "Entity Filer Category"
   }
  }
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 "localname": "EntityFilerCategory",
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 ],
 "xbrltype": "filerCategoryItemType"
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 "lang": {
  "en-us": {
   "role": {
    "documentation": "Two-character EDGAR code representing the state or country of incorporation.",
    "label": "Entity Incorporation, State or Country Code"
   }
  }
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 ],
 "xbrltype": "edgarStateCountryItemType"
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 ],
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   "role": {
    "documentation": "Boolean flag that is true when the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit such files).",
    "label": "Entity Interactive Data Current"
   }
  }
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 "localname": "EntityInteractiveDataCurrent",
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 "lang": {
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    "label": "Entity Primary SIC Number"
   }
  }
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 "xbrltype": "sicNumberItemType"
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"dei_EntityPublicFloat": {
 "auth_ref": [],
 "crdr": "credit",
 "lang": {
  "en-us": {
   "role": {
    "documentation": "The aggregate market value of the voting and non-voting common equity held by non-affiliates computed by reference to the price at which the common equity was last sold, or the average bid and asked price of such common equity, as of the last business day of the registrant's most recently completed second fiscal quarter.",
    "label": "Entity Public Float"
   }
  }
 },
 "localname": "EntityPublicFloat",
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 ],
 "xbrltype": "monetaryItemType"
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"dei_EntityRegistrantName": {
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 ],
 "lang": {
  "en-us": {
   "role": {
    "documentation": "The exact name of the entity filing the report as specified in its charter, which is required by forms filed with the SEC.",
    "label": "Entity Registrant Name"
   }
  }
 },
 "localname": "EntityRegistrantName",
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 ],
 "xbrltype": "normalizedStringItemType"
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"dei_EntityShellCompany": {
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 ],
 "lang": {
  "en-us": {
   "role": {
    "documentation": "Boolean flag that is true when the registrant is a shell company as defined in Rule 12b-2 of the Exchange Act.",
    "label": "Entity Shell Company"
   }
  }
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 "localname": "EntityShellCompany",
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  "http://aclarion.com/role/Cover"
 ],
 "xbrltype": "booleanItemType"
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"dei_EntitySmallBusiness": {
 "auth_ref": [
  "r515"
 ],
 "lang": {
  "en-us": {
   "role": {
    "documentation": "Indicates that the company is a Smaller Reporting Company (SRC).",
    "label": "Entity Small Business"
   }
  }
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 "localname": "EntitySmallBusiness",
 "nsuri": "http://xbrl.sec.gov/dei/2022",
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 "xbrltype": "booleanItemType"
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"dei_EntityTaxIdentificationNumber": {
 "auth_ref": [
  "r515"
 ],
 "lang": {
  "en-us": {
   "role": {
    "documentation": "The Tax Identification Number (TIN), also known as an Employer Identification Number (EIN), is a unique 9-digit value assigned by the IRS.",
    "label": "Entity Tax Identification Number"
   }
  }
 },
 "localname": "EntityTaxIdentificationNumber",
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 "lang": {
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   "role": {
    "documentation": "Indicate 'Yes' or 'No' if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act.",
    "label": "Entity Voluntary Filers"
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    }
   }
  },
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  "presentation": [
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  "xbrltype": "yesNoItemType"
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 "dei_EntityWellKnownSeasonedIssuer": {
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  ],
  "lang": {
   "en-us": {
    "role": {
     "documentation": "Indicate 'Yes' or 'No' if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Is used on Form Type: 10-K, 10-Q, 8-K, 20-F, 6-K, 10-K/A, 10-Q/A, 20-F/A, 6-K/A, N-CSR, N-Q, N-1A.",
     "label": "Entity Well-known Seasoned Issuer"
    }
   }
  },
  "localname": "EntityWellKnownSeasonedIssuer",
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  "xbrltype": "yesNoItemType"
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  "lang": {
   "en-us": {
    "role": {
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     "label": "Extension"
    }
   }
  },
  "localname": "Extension",
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  ],
  "xbrltype": "normalizedStringItemType"
 },
 "dei_LocalPhoneNumber": {
  "auth_ref": [],
  "lang": {
   "en-us": {
    "role": {
     "documentation": "Local phone number for entity.",
     "label": "Local Phone Number"
    }
   }
  },
  "localname": "LocalPhoneNumber",
  "nsuri": "http://xbrl.sec.gov/dei/2022",
  "presentation": [
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  ],
  "xbrltype": "normalizedStringItemType"
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 "dei_NoTradingSymbolFlag": {
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     "label": "No Trading Symbol Flag"
    }
   }
  },
  "localname": "NoTradingSymbolFlag",
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  ],
  "xbrltype": "trueItemType"
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 "dei_OtherReportingStandardItemNumber": {
  "auth_ref": [
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  "lang": {
   "en-us": {
    "role": {
     "documentation": "\"Item 17\" or \"Item 18\" specified when the basis of accounting is neither US GAAP nor IFRS.",
     "label": "Other Reporting Standard Item Number"
    }
   }
  },
  "localname": "OtherReportingStandardItemNumber",
  "nsuri": "http://xbrl.sec.gov/dei/2022",
  "presentation": [
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  ],
  "xbrltype": "otherReportingStandardItemNumberItemType"
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 "dei_PreCommencementIssuerTenderOffer": {
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  "lang": {
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    "role": {
     "documentation": "Boolean flag that is true when the Form 8-K filing is intended to satisfy the filing obligation of the registrant as pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act.",
     "label": "Pre-commencement Issuer Tender Offer"
    }
   }
  },
  "localname": "PreCommencementIssuerTenderOffer",
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  ],
  "xbrltype": "booleanItemType"
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  "lang": {
   "en-us": {
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     "documentation": "Boolean flag that is true when the Form 8-K filing is intended to satisfy the filing obligation of the registrant as pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act.",
     "label": "Pre-commencement Tender Offer"
    }
   }
  },
  "localname": "PreCommencementTenderOffer",
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  "xbrltype": "booleanItemType"
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  "lang": {
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     "label": "Title of 12(b) Security"
    }
   }
  },
  "localname": "Security12bTitle",
  "nsuri": "http://xbrl.sec.gov/dei/2022",
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  ],
  "xbrltype": "securityTitleItemType"
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 "dei_Security12gTitle": {
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  ],
  "lang": {
   "en-us": {
    "role": {
     "documentation": "Title of a 12(g) registered security.",
     "label": "Title of 12(g) Security"
    }
   }
  },
  "localname": "Security12gTitle",
  "nsuri": "http://xbrl.sec.gov/dei/2022",
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  ],
  "xbrltype": "securityTitleItemType"
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  "auth_ref": [
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  ],
  "lang": {
   "en-us": {
    "role": {
     "documentation": "Name of the Exchange on which a security is registered.",
     "label": "Security Exchange Name"
    }
   }
  },
  "localname": "SecurityExchangeName",
  "nsuri": "http://xbrl.sec.gov/dei/2022",
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  ],
  "xbrltype": "edgarExchangeCodeItemType"
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 "dei_SecurityReportingObligation": {
  "auth_ref": [
   "r522"
  ],
  "lang": {
   "en-us": {
    "role": {
     "documentation": "15(d), indicating whether the security has a reporting obligation under that section of the Exchange Act.",
     "label": "Security Reporting Obligation"
    }
   }
  },
  "localname": "SecurityReportingObligation",
  "nsuri": "http://xbrl.sec.gov/dei/2022",
  "presentation": [
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  ],
  "xbrltype": "securityReportingObligationItemType"
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 "dei_SolicitingMaterial": {
  "auth_ref": [
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  "lang": {
   "en-us": {
    "role": {
     "documentation": "Boolean flag that is true when the Form 8-K filing is intended to satisfy the filing obligation of the registrant as soliciting material pursuant to Rule 14a-12 under the Exchange Act.",
     "label": "Soliciting Material"
    }
   }
  },
  "localname": "SolicitingMaterial",
  "nsuri": "http://xbrl.sec.gov/dei/2022",
  "presentation": [
   "http://aclarion.com/role/Cover"
  ],
  "xbrltype": "booleanItemType"
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 "dei_TradingSymbol": {
  "auth_ref": [],
  "lang": {
   "en-us": {
    "role": {
     "documentation": "Trading symbol of an instrument as listed on an exchange.",
     "label": "Trading Symbol"
    }
   }
  },
  "localname": "TradingSymbol",
  "nsuri": "http://xbrl.sec.gov/dei/2022",
  "presentation": [
   "http://aclarion.com/role/Cover"
  ],
  "xbrltype": "tradingSymbolItemType"
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 "dei_WrittenCommunications": {
  "auth_ref": [
   "r531"
  ],
  "lang": {
   "en-us": {
    "role": {
     "documentation": "Boolean flag that is true when the Form 8-K filing is intended to satisfy the filing obligation of the registrant as written communications pursuant to Rule 425 under the Securities Act.",
     "label": "Written Communications"
    }
   }
  },
  "localname": "WrittenCommunications",
  "nsuri": "http://xbrl.sec.gov/dei/2022",
  "presentation": [
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  "xbrltype": "booleanItemType"
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 "srt_CounterpartyNameAxis": {
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   "r284",
   "r310",
   "r485",
   "r487"
  ],
  "lang": {
   "en-us": {
    "role": {
     "label": "Counterparty Name [Axis]"
    }
   }
  },
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   "http://aclarion.com/role/CompanyAndBasisOfPresentationDetailsNarrative",
   "http://aclarion.com/role/ShortTermNotesAndConvertibleDebtDetailsNarrative",
   "http://aclarion.com/role/StockholdersEquityDetailsNarrative"
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  "xbrltype": "stringItemType"
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 "srt_MajorCustomersAxis": {
  "auth_ref": [
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   "http://aclarion.com/role/ShortTermNotesAndConvertibleDebtDetailsNarrative",
   "http://aclarion.com/role/StockholdersEquityDetailsNarrative"
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     "verboseLabel": "Accounts payable"
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  "lang": {
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     "label": "Accounts receivable gross"
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     "label": "Accounts Receivable [Member]"
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   "weight": 1.0
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    "label": "Accrued and other liabilities"
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    "label": "Adjustments to Additional Paid in Capital, Convertible Debt with Conversion Feature"
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    "label": "ASSETS"
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"us-gaap_AssetsCurrent": {
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    "label": "Assets, Current",
    "totalLabel": "Total current assets"
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   "totalLabel": "Total non-current assets"
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"lang": {
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   "label": "Award Type [Axis]"
  }
 }
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"localname": "AwardTypeAxis",
"nsuri": "http://fasb.org/us-gaap/2022",
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 "http://aclarion.com/role/Stock-basedCompensationDetailsNarrative"
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"xbrltype": "stringItemType"
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"us-gaap_CashAndCashEquivalentsAtCarryingValue": {
"auth_ref": [
 "r37",
 "r145",
 "r483"
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  "parentTag": "us-gaap_AssetsCurrent",
  "weight": 1.0
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  }
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 "r38"
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"lang": {
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  "role": {
   "documentation": "Disclosure of accounting policy for cash and cash equivalents, including the policy for determining which items are treated as cash equivalents. Other information that may be disclosed includes (1) the nature of any restrictions on the entity's use of its cash and cash equivalents, (2) whether the entity's cash and cash equivalents are insured or expose the entity to credit risk, (3) the classification of any negative balance accounts (overdrafts), and (4) the carrying basis of cash equivalents (for example, at cost) and whether the carrying amount of cash equivalents approximates fair value.",
   "label": "Cash and Cash Equivalents"
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"auth_ref": [
 "r31",
 "r37",
 "r41"
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"crdr": "debit",
"lang": {
 "en-us": {
  "role": {
   "documentation": "Amount of cash and cash equivalents, and cash and cash equivalents restricted to withdrawal or usage. Excludes amount for disposal group and discontinued operations. Cash includes, but is not limited to, currency on hand, demand deposits with banks or financial institutions, and other accounts with general characteristics of demand deposits. Cash equivalents include, but are not limited to, short-term, highly liquid investments that are both readily convertible to known amounts of cash and so near their maturity that they present insignificant risk of changes in value because of changes in interest rates.",
   "label": "Cash, Cash Equivalents, Restricted Cash, and Restricted Cash Equivalents",
   "periodEndLabel": "Cash, cash equivalents, and restricted cash, end of period",
   "periodStartLabel": "Cash, cash equivalents, and restricted cash, beginning of period"
  }
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 "http://aclarion.com/role/StatementsOfCashFlows"
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"us-gaap_CashCashEquivalentsRestrictedCashAndRestrictedCashEquivalentsPeriodIncreaseDecreaseExcludingExchangeRateEffect": {
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 "r111"
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  "weight": null
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"crdr": "debit",
"lang": {
 "en-us": {
  "role": {
   "documentation": "Amount of increase (decrease) in cash and cash equivalents, and cash and cash equivalents restricted to withdrawal or usage; excluding effect from exchange rate change. Cash includes, but is not limited to, currency on hand, demand deposits with banks or financial institutions, and other accounts with general characteristics of demand deposits. Cash equivalents include, but are not limited to, short-term, highly liquid investments that are both readily convertible to known amounts of cash and so near their maturity that they present insignificant risk of changes in value because of changes in interest rates.",
   "label": "Cash, Cash Equivalents, Restricted Cash, and Restricted Cash Equivalents, Period Increase (Decrease), Excluding Exchange Rate Effect",
   "totalLabel": "Net increase (decrease) in cash and cash equivalents"
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"localname": "CashCashEquivalentsRestrictedCashAndRestrictedCashEquivalentsPeriodIncreaseDecreaseExcludingExchangeRateEffect",
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"crdr": "debit",
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 "en-us": {
  "role": {
   "documentation": "Amount of short-term, highly liquid investments that are both readily convertible to known amounts of cash and so near their maturity that they present insignificant risk of changes in value because of changes in interest rates. Excludes cash and cash equivalents within disposal group and discontinued operation.",
   "label": "Cash Equivalents, at Carrying Value"
  }
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"presentation": [
 "http://aclarion.com/role/SummaryOfSignificantAccountingPoliciesDetailsNarrative"
],
"xbrltype": "monetaryItemType"
},
"us-gaap_CashUninsuredAmount": {
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"crdr": "debit",
"lang": {
 "en-us": {
  "role": {
   "documentation": "The amount of cash as of the balance sheet date that is not insured by the Federal Deposit Insurance Corporation.",
   "label": "Cash, Uninsured Amount"
  }
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"localname": "CashUninsuredAmount",
"nsuri": "http://fasb.org/us-gaap/2022",
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],
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"lang": {
 "en-us": {
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   "documentation": "Share of stock differentiated by the voting rights the holder receives. Examples include, but are not limited to, common stock, redeemable preferred stock, nonredeemable preferred stock, and convertible stock."
  }
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 "http://aclarion.com/role/BalanceSheetsParenthetical",
 "http://aclarion.com/role/CompanyAndBasisOfPresentationDetailsNarrative",
 "http://aclarion.com/role/Cover",
 "http://aclarion.com/role/ShortTermNotesAndConvertibleDebtDetailsNarrative",
 "http://aclarion.com/role/StockholdersEquityDetailsNarrative"
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"xbrltype": "domainItemType"
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"us-gaap_ClassOfStockLineItems": {
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  }
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"xbrltype": "stringItemType"
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"us-gaap_ClassOfWarrantOrRightExercisePriceOfWarrantsOrRights1": {
"auth_ref": [
 "r324"
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"lang": {
 "en-us": {
  "role": {
   "documentation": "Exercise price per share or per unit of warrants or rights outstanding.",
   "label": "Class of Warrant or Right, Exercise Price of Warrants or Rights"
  }
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},
"localname": "ClassOfWarrantOrRightExercisePriceOfWarrantsOrRights1",
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"xbrltype": "perShareItemType"
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"us-gaap_ClassOfWarrantOrRightNumberOfSecuritiesCalledByEachWarrantOrRight": {
"auth_ref": [],
"lang": {
 "en-us": {
  "role": {
   "documentation": "Number of securities into which each warrant or right may be converted. For example, but not limited to, each warrant may be converted into two shares.",
   "label": "Class of Warrant or Right, Number of Securities Called by Each Warrant or Right"
  }
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 "http://aclarion.com/role/StockholdersEquityDetailsNarrative"
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"us-gaap_ClassOfWarrantOrRightOutstanding": {
"auth_ref": [],
"lang": {
 "en-us": {
  "role": {
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   "label": "Class of Warrant or Right, Outstanding"
  }
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"xbrltype": "sharesItemType"
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  }
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 "http://aclarion.com/role/CompanyAndBasisOfPresentationDetailsNarrative"
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"xbrltype": "stringItemType"
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"crdr": "credit",
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   "documentation": "Represents the caption on the face of the balance sheet to indicate that the entity has entered into (1) purchase or supply arrangements that will require expending a portion of its resources to meet the terms thereof, and (2) is exposed to potential losses or, less frequently, gains, arising from (a) possible claims against a company's resources due to future performance under contract terms, and (b) possible losses or likely gains from uncertainties that will ultimately be resolved when one or more future events that are deemed likely to occur do occur or fail to occur.",
   "label": "Commitments and contingencies (See Note 9)"
  }
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 "en-us": {
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  }
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"auth_ref": [
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 "r270",
 "r271",
 "r478",
 "r546"
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"lang": {
 "en-us": {
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   "label": "COMMITMENTS AND CONTINGENCIES"
  }
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 "r547",
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 "r549"
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"lang": {
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  "role": {
   "documentation": "Stock that is subordinate to all other stock of the issuer.",
   "label": "Common Stock [Member]"
  }
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 "http://aclarion.com/role/ShortTermNotesAndConvertibleDebtDetailsNarrative",
 "http://aclarion.com/role/StatementOfChangesInStockholdersEquityDeficit",
 "http://aclarion.com/role/StockholdersEquityDetailsNarrative"
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"xbrltype": "domainItemType"
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"lang": {
 "en-us": {
  "role": {
   "documentation": "Face amount or stated value per share of common stock.",
   "label": "Common Stock, Par or Stated Value Per Share"
  }
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"localname": "CommonStockParOrStatedValuePerShare",
"nsuri": "http://fasb.org/us-gaap/2022",
"presentation": [
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 "http://aclarion.com/role/StockholdersEquityDetailsNarrative"
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"xbrltype": "perShareItemType"
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"us-gaap_CommonStockSharesAuthorized": {
"auth_ref": [
 "r4"
],
"lang": {
 "en-us": {
  "role": {
   "documentation": "The maximum number of common shares permitted to be issued by an entity's charter and bylaws.",
   "label": "Common Stock, Shares Authorized"
  }
 }
},
"localname": "CommonStockSharesAuthorized",
"nsuri": "http://fasb.org/us-gaap/2022",
"presentation": [
 "http://aclarion.com/role/BalanceSheetsParenthetical",
 "http://aclarion.com/role/StockholdersEquityDetailsNarrative"
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"xbrltype": "sharesItemType"
},
"us-gaap_CommonStockSharesIssued": {
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"lang": {
 "en-us": {
  "role": {
   "documentation": "Total number of common shares of an entity that have been sold or granted to shareholders (includes common shares that were issued, repurchased and remain in the treasury). These shares represent capital invested by the firm's shareholders and owners, and may be all or only a portion of the number of shares authorized. Shares issued include shares outstanding and shares held in the treasury.",
   "label": "Common Stock, Shares, Issued"
  }
 }
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"localname": "CommonStockSharesIssued",
"nsuri": "http://fasb.org/us-gaap/2022",
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 "http://aclarion.com/role/BalanceSheetsParenthetical"
],
"xbrltype": "sharesItemType"
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"us-gaap_CommonStockSharesOutstanding": {
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 "r4",
 "r77"
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"lang": {
 "en-us": {
  "role": {
   "documentation": "Number of shares of common stock outstanding. Common stock represent the ownership interest in a corporation.",
   "label": "Common Stock, Shares, Outstanding"
  }
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"localname": "CommonStockSharesOutstanding",
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],
"xbrltype": "sharesItemType"
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"us-gaap_CommonStockValue": {
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 "r512"
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"calculation": {
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  "weight": 1.0
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"crdr": "credit",
"lang": {
 "en-us": {
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   "documentation": "Aggregate par or stated value of issued nonredeemable common stock (or common stock redeemable solely at the option of the issuer). This item includes treasury stock repurchased by the entity. Note: elements for number of nonredeemable common shares, par value and other disclosure concepts are in another section within stockholders' equity.",
   "label": "Common stock - $0.00001 par value, 200,000,000 authorized and 7,841,515 and 905,685 shares issued and outstanding (see Note 1)"
  }
 }
},
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"nsuri": "http://fasb.org/us-gaap/2022",
"presentation": [
 "http://aclarion.com/role/BalanceSheets"
],
"xbrltype": "monetaryItemType"
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"us-gaap_CompensationRelatedCostsPolicyTextBlock": {
"auth_ref": [
 "r97"
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"lang": {
 "en-us": {
  "role": {
   "documentation": "Disclosure of accounting policy for salaries, bonuses, incentive awards, postretirement and postemployment benefits granted to employees, including equity-based arrangements; discloses methodologies for measurement, and the bases for recognizing related assets and liabilities and recognizing and reporting compensation expense.",
   "label": "Share-Based Compensation"
  }
 }
},
"localname": "CompensationRelatedCostsPolicyTextBlock",
"nsuri": "http://fasb.org/us-gaap/2022",
"presentation": [
 "http://aclarion.com/role/SummaryOfSignificantAccountingPoliciesPolicies"
],
"xbrltype": "textBlockItemType"
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"us-gaap_ConcentrationRiskBenchmarkDomain": {
"auth_ref": [
 "r47",
 "r48",
 "r109",
 "r110",
 "r240",
 "r477"
],

"lang": {
"en-us": {
"role": {
"documentation": "The denominator in a calculation of a disclosed concentration risk percentage."
}
}
},
"localname": "ConcentrationRiskBenchmarkDomain",
"nsuri": "http://fasb.org/us-gaap/2022",
"presentation": [
"http://aclarion.com/role/SummaryOfSignificantAccountingPoliciesDetailsNarrative"
],
"xbrltype": "domainItemType"
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"us-gaap_ConcentrationRiskByBenchmarkAxis": {
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"r48",
"r109",
"r110",
"r240",
"r476",
"r477"
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"en-us": {
"role": {
"documentation": "Information by benchmark of concentration risk.",
"label": "Concentration Risk Benchmark [Axis]"
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"localname": "ConcentrationRiskByBenchmarkAxis",
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"xbrltype": "stringItemType"
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"auth_ref": [
"r47",
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"r110",
"r240",
"r477",
"r610"
],
"lang": {
"en-us": {
"role": {
"documentation": "Information by type of concentration risk, for example, but not limited to, asset, liability, net assets, geographic, customer, employees, supplier, lender.",
"label": "Concentration Risk Type [Axis]"
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"label": "Revenues from contracts with customers"
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"http://aclarion.com/role/StockholdersEquityDetailsNarrative"
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"label": "SHORT TERM NOTES AND CONVERTIBLE DEBT"
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"label": "Debt Instrument, Decrease, Forgiveness"
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"label": "Debt Instrument, Interest Rate, Stated Percentage"
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"label": "Debt Instrument [Line Items]"
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"label": "Schedule of Long-Term Debt Instruments [Table]"
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"label": "Deferred Offering Costs"
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"label": "Depreciation expense"
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      "@context": "file:///schema/v1.0/jsonld/context.jsonld",
      "@id": "fin:GrossFairValueOfDerivativeLiabilities",
      "@type": [
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        "owl:Class"
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      "rdfs:comment": "The fair value of derivative contracts in a liability position, before the effect of master netting arrangements with counterparties.",
      "rdfs:label": "Gross Fair Value of Derivative Liabilities"
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    {
      "@context": "file:///schema/v1.0/jsonld/context.jsonld",
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        "owl:Class"
      ],
      "rdfs:comment": "The fair value of derivative contracts in a liability position, before the effect of master netting arrangements with counterparties.",
      "rdfs:label": "Gross Fair Value of Derivative Liabilities"
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    {
      "@context": "file:///schema/v1.0/jsonld/context.jsonld",
      "@id": "fin:NetFairValueOfDerivatives",
      "@type": [
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      "rdfs:comment": "The net fair value of derivatives after the effect of master netting arrangements with counterparties, presented on the balance sheet.",
      "rdfs:label": "Net Fair Value of Derivatives"
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    {
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      "@id": "fin:NetFairValueOfDerivatives",
      "@type": [
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      ],
      "rdfs:comment": "The net fair value of derivatives after the effect of master netting arrangements with counterparties, presented on the balance sheet.",
      "rdfs:label": "Net Fair Value of Derivatives"
    },
    {
      "@context": "file:///schema/v1.0/jsonld/context.jsonld",
      "@id": "fin:DerivativeCollateralObligationToReturnCash",
      "@type": [
        "rdfs:Class",
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      "rdfs:comment": "The obligation to return cash collateral received from counterparties under master netting arrangements.",
      "rdfs:label": "Derivative Collateral Obligation to Return Cash"
    },
    {
      "@context": "file:///schema/v1.0/jsonld/context.jsonld",
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      "@type": [
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        "owl:Class"
      ],
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      "rdfs:label": "Derivative Collateral Obligation to Return Cash"
    },
    {
      "@context": "file:///schema/v1.0/jsonld/context.jsonld",
      "@id": "fin:RightToReclaimCash",
      "@type": [
        "rdfs:Class",
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      ],
      "rdfs:comment": "Equity instrument.",
      "rdfs:label": "Right to Reclaim Cash"
    },
    {
      "@context": "file:///schema/v1.0/jsonld/context.jsonld",
      "@id": "fin:RightToReclaimCash",
      "@type": [
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        "owl:Class"
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      "rdfs:comment": "Equity instrument.",
      "rdfs:label": "Right to Reclaim Cash"
    },
    {
      "@context": "file:///schema/v1.0/jsonld/context.jsonld",
      "@id": "fin:OrdinaryShares",
      "@type": [
        "rdfs:Class",
        "owl:Class"
      ],
      "rdfs:comment": "Components of equity are the parts of the total equity balance including that which is allocated to common, preferred, treasury stock, retained earnings, etc.",
      "rdfs:label": "Ordinary Shares"
    },
    {
      "@context": "file:///schema/v1.0/jsonld/context.jsonld",
      "@id": "fin:OrdinaryShares",
      "@type": [
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        "owl:Class"
      ],
      "rdfs:comment": "Components of equity are the parts of the total equity balance including that which is allocated to common, preferred, treasury stock, retained earnings, etc.",
      "rdfs:label": "Ordinary Shares"
    },
    {
      "@context": "file:///schema/v1.0/jsonld/context.jsonld",
      "@id": "fin:AccountingPolicyForFairValueMeasurementOfFinancialAndNonFinancialAssetsLiabilitiesAndInstrumentsClassifiedInShareholdersEquity",
      "@type": [
        "rdfs:Class",
        "owl:Class"
      ],
      "rdfs:comment": "Disclosure of accounting policy for fair value measurements of financial and non-financial assets, liabilities and instruments classified in shareholders' equity. Disclosures include, but are not limited to, how an entity has managed a group of financial assets and liabilities on the basis of its net exposure measures the fair value of those assets and liabilities.",
      "rdfs:label": "Fair Value Measurement"
    },
    {
      "@context": "file:///schema/v1.0/jsonld/context.jsonld",
      "@id": "fin:AccountingPolicyForFairValueMeasurementOfFinancialAndNonFinancialAssetsLiabilitiesAndInstrumentsClassifiedInShareholdersEquity",
      "@type": [
        "rdfs:Class",
        "owl:Class"
      ],
      "rdfs:comment": "Disclosure of accounting policy for fair value measurements of financial and non-financial assets, liabilities and instruments classified in shareholders' equity. Disclosures include, but are not limited to, how an entity has managed a group of financial assets and liabilities on the basis of its net exposure measures the fair value of those assets and liabilities.",
      "rdfs:label": "Fair Value Measurement"
    },
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      "@context": "file:///schema/v1.0/jsonld/context.jsonld",
      "@id": "fin:ScheduleOfFairValueMeasurementOfAssetsAndLiabilities",
      "@type": [
        "rdfs:Class",
        "owl:Class"
      ],
      "rdfs:comment": "Table disclosing fair value measurements of assets and liabilities.",
      "rdfs:label": "Schedule of Fair Value Measurement"
    },
    {
      "@context": "file:///schema/v1.0/jsonld/context.jsonld",
      "@id": "fin:ScheduleOfFairValueMeasurementOfAssetsAndLiabilities",
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        "owl:Class"
      ],
      "rdfs:comment": "Table disclosing fair value measurements of assets and liabilities.",
      "rdfs:label": "Schedule of Fair Value Measurement"
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      "@context": "file:///schema/v1.0/jsonld/context.jsonld",
      "@id": "fin:FairValueInputsLevel1",
      "@type": [
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        "owl:Class"
      ],
      "rdfs:comment": "Unadjusted quoted prices in active markets for identical assets or liabilities that the entity has the ability to access at the measurement date.",
      "rdfs:label": "Fair Value, Inputs, Level 1"
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    {
      "@context": "file:///schema/v1.0/jsonld/context.jsonld",
      "@id": "fin:FairValueInputsLevel1",
      "@type": [
        "rdfs:Class",
        "owl:Class"
      ],
      "rdfs:comment": "Unadjusted quoted prices in active markets for identical assets or liabilities that the entity has the ability to access at the measurement date.",
      "rdfs:label": "Fair Value, Inputs, Level 1"
    },
    {
      "@context": "file:///schema/v1.0/jsonld/context.jsonld",
      "@id": "fin:FairValueInputsLevel2",
      "@type": [
        "rdfs:Class",
        "owl:Class"
      ],
      "rdfs:comment": "Inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly or indirectly.",
      "rdfs:label": "Fair Value, Inputs, Level 2"
    },
    {
      "@context": "file:///schema/v1.0/jsonld/context.jsonld",
      "@id": "fin:FairValueInputsLevel2",
      "@type": [
        "rdfs:Class",
        "owl:Class"
      ],
      "rdfs:comment": "Inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly or indirectly.",
      "rdfs:label": "Fair Value, Inputs, Level 2"
    },
    {
      "@context": "file:///schema/v1.0/jsonld/context.jsonld",
      "@id": "fin:FairValueInputsLevel3",
      "@type": [
        "rdfs:Class",
        "owl:Class"
      ],
      "rdfs:comment": "Unobservable inputs for the asset or liability, reflecting the reporting entity's own assumptions about the assumptions that market participants would use in pricing the asset or liability.",
      "rdfs:label": "Fair Value, Inputs, Level 3"
    },
    {
      "@context": "file:///schema/v1.0/jsonld/context.jsonld",
      "@id": "fin:FairValueInputsLevel3",
      "@type": [
        "rdfs:Class",
        "owl:Class"
      ],
      "rdfs:comment": "Unobservable inputs for the asset or liability, reflecting the reporting entity's own assumptions about the assumptions that market participants would use in pricing the asset or liability.",
      "rdfs:label": "Fair Value, Inputs, Level 3"
    },
    {
      "@context": "file:///schema/v1.0/jsonld/context.jsonld",
      "@id": "fin:ValuationTechniqueDiscountedCashFlow",
      "@type": [
        "rdfs:Class",
        "owl:Class"
      ],
      "rdfs:comment": "Valuation technique based on discounting estimated future cash flows to present value using a discount rate that reflects current market assessments of the time value of money and risk.",
      "rdfs:label": "Valuation Technique, Discounted Cash Flow"
    },
    {
      "@context": "file:///schema/v1.0/jsonld/context.jsonld",
      "@id": "fin:ValuationTechniqueDiscountedCashFlow",
      "@type": [
        "rdfs:Class",
        "owl:Class"
      ],
      "rdfs:comment": "Valuation technique based on discounting estimated future cash flows to present value using a discount rate that reflects current market assessments of the time value of money and risk.",
      "rdfs:label": "Valuation Technique, Discounted Cash Flow"
    },
    {
      "@context": "file:///schema/v1.0/jsonld/context.jsonld",
      "@id": "fin:ValuationTechniqueOptionPricingModel",
      "@type": [
        "rdfs:Class",
        "owl:Class"
      ],
      "rdfs:comment": "Valuation technique using option pricing models to estimate fair value, incorporating assumptions about volatility, interest rates, and time to expiration.",
      "rdfs:label": "Valuation Technique, Option Pricing Model"
    },
    {
      "@context": "file:///schema/v1.0/jsonld/context.jsonld",
      "@id": "fin:ValuationTechniqueOptionPricingModel",
      "@type": [
        "rdfs:Class",
        "owl:Class"
      ],
      "rdfs:comment": "Valuation technique using option pricing models to estimate fair value, incorporating assumptions about volatility, interest rates, and time to expiration.",
      "rdfs:label": "Valuation Technique, Option Pricing Model"
    },
    {
      "@context": "file:///schema/v1.0/jsonld/context.jsonld",
      "@id": "fin:ValuationTechniqueMarketApproach",
      "@type": [
        "rdfs:Class",
        "owl:Class"
      ],
      "rdfs:comment": "Valuation technique using prices and other relevant information generated by market transactions for identical or comparable assets or liabilities.",
      "rdfs:label": "Valuation Technique, Market Approach"
    },
    {
      "@context": "file:///schema/v1.0/jsonld/context.jsonld",
      "@id": "fin:ValuationTechniqueMarketApproach",
      "@type": [
        "rdfs:Class",
        "owl:Class"
      ],
      "rdfs:comment": "Valuation technique using prices and other relevant information generated by market transactions for identical or comparable assets or liabilities.",
      "rdfs:label": "Valuation Technique, Market Approach"
    },
    {
      "@context": "file:///schema/v1.0/jsonld/context.jsonld",
      "@id": "fin:ValuationTechniqueCostApproach",
      "@type": [
        "rdfs:Class",
        "owl:Class"
      ],
      "rdfs:comment": "Valuation technique based on the amount required to replace the service capacity of an asset, adjusted for obsolescence.",
      "rdfs:label": "Valuation Technique, Cost Approach"
    },
    {
      "@context": "file:///schema/v1.0/jsonld/context.jsonld",
      "@id": "fin:ValuationTechniqueCostApproach",
      "@type": [
        "rdfs:Class",
        "owl:Class"
      ],
      "rdfs:comment": "Valuation technique based on the amount required to replace the service capacity of an asset, adjusted for obsolescence.",
      "rdfs:label": "Valuation Technique, Cost Approach"
    },
    {
      "@context": "file:///schema/v1.0/jsonld/context.jsonld",
      "@id": "fin:FinancialInstrumentsOwnedAtFairValue",
      "@type": [
        "rdfs:Class",
        "owl:Class"
      ],
      "rdfs:comment": "Aggregate amount of financial instruments owned, at fair value.",
      "rdfs:label": "Financial Instruments Owned, at Fair Value"
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    {
      "@context": "file:///schema/v1.0/jsonld/context.jsonld",
      "@id": "fin:FinancialInstrumentsOwnedAtFairValue",
      "@type": [
        "rdfs:Class",
        "owl:Class"
      ],
      "rdfs:comment": "Aggregate amount of financial instruments owned, at fair value.",
      "rdfs:label": "Financial Instruments Owned, at Fair Value"
    },
    {
      "@context": "file:///schema/v1.0/jsonld/context.jsonld",
      "@id": "fin:FinancialInstrumentsOwnedAtFairValueParenthetical",
      "@type": [
        "rdfs:Class",
        "owl:Class"
      ],
      "rdfs:comment": "Parenthetical disclosure for financial instruments owned, at fair value.",
      "rdfs:label": "Financial Instruments Owned, at Fair Value, Parenthetical"
    },
    {
      "@context": "file:///schema/v1.0/jsonld/context.jsonld",
      "@id": "fin:FinancialInstrumentsOwnedAtFairValueParenthetical",
      "@type": [
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        "owl:Class"
      ],
      "rdfs:comment": "Parenthetical disclosure for financial instruments owned, at fair value.",
      "rdfs:label": "Financial Instruments Owned, at Fair Value, Parenthetical"
    },
    {
      "@context": "file:///schema/v1.0/jsonld/context.jsonld",
      "@id": "fin:FinancialInstrumentsOwnedAtFairValueShares",
      "@type": [
        "rdfs:Class",
        "owl:Class"
      ],
      "rdfs:comment": "Number of shares or units held in financial instruments owned, at fair value.",
      "rdfs:label": "Financial Instruments Owned, at Fair Value, Shares"
    },
    {
      "@context": "file:///schema/v1.0/jsonld/context.jsonld",
      "@id": "fin:FinancialInstrumentsOwnedAtFairValueShares",
      "@type": [
        "rdfs:Class",
        "owl:Class"
      ],
      "rdfs:comment": "Number of shares or units held in financial instruments owned, at fair value.",
      "rdfs:label": "Financial Instruments Owned, at Fair Value, Shares"
    },
    {
      "@context": "file:///schema/v1.0/jsonld/context.jsonld",
      "@id": "fin:FinancialInstrumentsOwnedAtFairValuePercentOfNetAssets",
      "@type": [
        "rdfs:Class",
        "owl:Class"
      ],
      "rdfs:comment": "Percentage of net assets represented by financial instruments owned, at fair value.",
      "rdfs:label": "Financial Instruments Owned, at Fair Value, Percent of Net Assets"
    },
    {
      "@context": "file:///schema/v1.0/jsonld/context.jsonld",
      "@id": "fin:FinancialInstrumentsOwnedAtFairValuePercentOfNetAssets",
      "@type": [
        "rdfs:Class",
        "owl:Class"
      ],
      "rdfs:comment": "Percentage of net assets represented by financial instruments owned, at fair value.",
      "rdfs:label": "Financial Instruments Owned, at Fair Value, Percent of Net Assets"
    },
    {
      "@context": "file:///schema/v1.0/jsonld/context.jsonld",
      "@id": "fin:FinancialInstrumentsOwnedAtFairValueLineItems",
      "@type": [
        "rdfs:Class",
        "owl:Class"
      ],
      "rdfs:comment": "Line items representing financial instruments owned, at fair value.",
      "rdfs:label": "Financial Instruments Owned, at Fair Value [Line Items]"
    },
    {
      "@context": "file:///schema/v1.0/jsonld/context.jsonld",
      "@id": "fin:FinancialInstrumentsOwnedAtFairValueLineItems",
      "@type": [
        "rdfs:Class",
        "owl:Class"
      ],
      "rdfs:comment": "Line items representing financial instruments owned, at fair value.",
      "rdfs:label": "Financial Instruments Owned, at Fair Value [Line Items]"
    }
  ]
}
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"rule": "dec/1",
"type": {
  "choice": [
    {
      "documentation": "Sum of the carrying amounts of all intangible assets, excluding goodwill, as of the balance sheet date, net of accumulated amortization and impairment charges.",
      "type": "monetary_intangible_assets_net"
    }
  ]
},

"concept": "FinancialStatementLiabilitiesAndEquityAbstract",
"base": "http://fhem.org/sw-gaap/ifrs",
"absolute": "http://xbrlsite.com/xbrl/monetaryUnit",

"datatype": "monetaryItemType",
"xbrltype": "monetaryItemType",
"balance": "credit",
"period_type": "instant",
"nillable": true,
"abstract": true,
"substitutionGroup": "xbrldt:hypercubeItem",

"rule": "num/1",
"type": {
  "choice": [
    {
      "documentation": "Amount of the cost of borrowed funds accounted for as interest expense.",
      "type": "interest_expense"
    }
  ]
},

"concept": "InterestExpense",
"base": "http://fhem.org/sw-gaap/ifrs",
"absolute": "http://xbrlsite.com/xbrl/monetaryUnit",

"datatype": "monetaryItemType",
"xbrltype": "monetaryItemType",
"balance": "credit",
"period_type": "instant",
"nillable": true,
"abstract": true,
"substitutionGroup": "xbrldt:hypercubeItem",

"rule": "num/1",
"type": {
  "choice": [
    {
      "documentation": "Carrying value as of the balance sheet date of (accrued) interest payable on all forms of debt, including trade payables, that has been invoiced and is unpaid. Used to reflect the current portion of the liabilities (due within one year or within the normal operating cycle if longer).",
      "type": "monetary_accounts_payable_and_accrued_liabilities_and_other_liabilities_current"
    }
  ]
},

"concept": "LiabilitiesAndEquity",
"base": "http://fhem.org/sw-gaap/ifrs",
"absolute": "http://xbrlsite.com/xbrl/monetaryUnit",

"datatype": "monetaryItemType",
"xbrltype": "monetaryItemType",
"balance": "credit",
"period_type": "instant",
"nillable": true,
"abstract": true,
"substitutionGroup": "xbrldt:hypercubeItem",

"rule": "num/1",
"type": {
  "choice": [
    {
      "documentation": "Amount of interest payable on debt, including, but not limited to, trade payables.",
      "type": "InterestPayableCurrent"
    }
  ]
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"concept": "InterestPayableCurrentAndNoncurrent",
"base": "http://fhem.org/sw-gaap/ifrs",
"absolute": "http://xbrlsite.com/xbrl/monetaryUnit",

"datatype": "monetaryItemType",
"xbrltype": "monetaryItemType",
"balance": "credit",
"period_type": "instant",
"nillable": true,
"abstract": true,
"substitutionGroup": "xbrldt:hypercubeItem",

"rule": "num/1",
"type": {
  "choice": [
    {
      "documentation": "Carrying value as of the balance sheet date of (accrued) interest payable on all forms of debt, including trade payables, that has been invoiced and is unpaid. Used to reflect the current portion of the liabilities (due within one year or within the normal operating cycle if longer).",
      "type": "InterestPayableCurrent"
    }
  ]
},

"concept": "InterestPayableCurrent",
"base": "http://fhem.org/sw-gaap/ifrs",
"absolute": "http://xbrlsite.com/xbrl/monetaryUnit",

"datatype": "monetaryItemType",
"xbrltype": "monetaryItemType",
"balance": "credit",
"period_type": "instant",
"nillable": true,
"abstract": true,
"substitutionGroup": "xbrldt:hypercubeItem",

"rule": "num/1",
"type": {
  "choice": [
    {
      "documentation": "Total value of unsecured compensation granted to nonemployees as payment for services rendered or acknowledged claims.",
      "type": "NonemployeeCompensationPayable"
    }
  ]
},

"concept": "AccountsPayableAndAccruedLiabilitiesCurrent",
"base": "http://fhem.org/sw-gaap/ifrs",
"absolute": "http://xbrlsite.com/xbrl/monetaryUnit",

"datatype": "monetaryItemType",
"xbrltype": "monetaryItemType",
"balance": "credit",
"period_type": "instant",
"nillable": true,
"abstract": true,
"substitutionGroup": "xbrldt:hypercubeItem",

"rule": "num/1",
"type": {
  "choice": [
    {
      "documentation": "Amount of expenses for salary, wage, profit sharing, incentive and equity-based compensation; and other employee benefits.",
      "type": "wages_and_salaries_expense"
    }
  ]
},

"concept": "EmployeeBenefitsAndShareBasedCompensation",
"base": "http://fhem.org/sw-gaap/ifrs",
"absolute": "http://xbrlsite.com/xbrl/monetaryUnit",

"datatype": "monetaryItemType",
"xbrltype": "monetaryItemType",
"balance": "debit",
"period_type": "duration",
"nillable": true,
"abstract": true,
"substitutionGroup": "xbrldt:hypercubeItem",

"rule": "num/1",
"type": {
  "choice": [
    {
      "documentation": "The entire disclosure for operating leases of lessee. Includes, but is not limited to, description of operating lease and maturity analysis of operating lease liability.",
      "type": "Leases"
    }
  ]
},

"concept": "LeaseObligationsDisclosureBlock",
"base": "http://fhem.org/sw-gaap/ifrs",
"absolute": "http://xbrlsite.com/xbrl/lease",

"datatype": "textBlockItemType",
"xbrltype": "textBlockItemType",
"nillable": true,
"abstract": true,
"substitutionGroup": "xbrldt:hypercubeItem",

"rule": "num/1",
"type": {
  "choice": [
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      "documentation": "Amount of all liabilities and equity (today, including the portion of equity attributable to noncontrolling interests, if any).",
      "type": "LiabilitiesAndEquity"
    }
  ]
},

"concept": "FinancialStatementLiabilitiesAndEquityAbstract",
"base": "http://fhem.org/sw-gaap/ifrs",
"absolute": "http://xbrlsite.com/xbrl/monetaryUnit",

"datatype": "monetaryItemType",
"xbrltype": "monetaryItemType",
"balance": "credit",
"period_type": "instant",
"nillable": true,
"abstract": true,
"substitutionGroup": "xbrldt:hypercubeItem",

"rule": "token/1",
"type": {
  "choice": [
    {
      "token": "LIABILITIES AND STOCKHOLDERS' EQUITY (DEPRECATED)"
    }
  ]
},

"concept": "LiabilitiesAndStockholdersEquityDeprecated",
"base": "http://fhem.org/sw-gaap/ifrs",
"absolute": "http://xbrlsite.com/xbrl/monetaryUnit",

"datatype": "monetaryItemType",
"xbrltype": "monetaryItemType",
"balance": "credit",
"period_type": "instant",
"nillable": true,
"abstract": true,
"substitutionGroup": "xbrldt:hypercubeItem",

"rule": "num/1",
"type": {
  "choice": [
    {
      "documentation": "Total obligations incurred as part of normal operations that are expected to be paid during the following twelve months or within one business cycle, if longer.",
      "type": "AccruedLiabilities_Current"
    }
  ]
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"concept": "AccruedLiabilitiesCurrent",
"base": "http://fhem.org/sw-gaap/ifrs",
"absolute": "http://xbrlsite.com/xbrl/monetaryUnit",

"datatype": "monetaryItemType",
"xbrltype": "monetaryItemType",
"balance": "credit",
"period_type": "instant",
"nillable": true,
"abstract": true,
"substitutionGroup": "xbrldt:hypercubeItem",

"rule": "num/1",
"type": {
  "choice": [
    {
      "documentation": "Accrued liabilities.",
      "type": "Accrued_Liabilities"
    }
  ]
},

"concept": "AccruedLiabilities",
"base": "http://fhem.org/sw-gaap/ifrs",
"absolute": "http://xbrlsite.com/xbrl/monetaryUnit",

"datatype": "monetaryItemType",
"xbrltype": "monetaryItemType",
"balance": "credit",
"period_type": "instant",
"nillable": true,
"abstract": true,
"substitutionGroup": "xbrldt:hypercubeItem",

"rule": "num/1",
"type": {
  "choice": [
    {
      "documentation": "Reference to type of long-term debt.",
      "type": "LongTermDebtTypes"
    }
  ]
},

"concept": "LongTermDebtTypes",
"base": "http://fhem.org/sw-gaap/ifrs",
"absolute": "http://xbrlsite.com/xbrl/debt/LongTermDebtClassesAxis",
"http://xbrlsite.com/xbrl/debt/LongTermDebtClassesAxis",

"datatype": "monetaryItemType",
"xbrltype": "monetaryItemType",
"balance": "credit",
"period_type": "instant",
"nillable": true,
"abstract": true,
"substitutionGroup": "xbrldt:hypercubeItem",

"rule": "num/1",
"type": {
  "choice": [
    {
      "documentation": "Type of long-term debt arrangement, such as notes, line of credit, commercial paper, bond-based financing, project financing, terms of credit financing. These are debt arrangements that ordinarily replaced repayment more than twelve months after issuance or greater than the normal operating cycle of the company, if longer."
    }
  ]
},

"concept": "LongTermDebtTypeAxis",
"base": "http://fhem.org/sw-gaap/ifrs",
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"concept": "NetCashProvidedByUsedInFinancingActivities",
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"concept": "NetCashInflowOutflowFromFinancingActivities",
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      "type": "Net_cash_provided_by_used_in_investing_activities"
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      "type": "Net_cash_provided_by_used_in_operating_activities"
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"concept": "NetCashProvidedByUsedInOperatingActivities",
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      "type": "Net_income_loss"
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"concept": "NetIncomeLoss",
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"http://xbrlsite.com/xbrl/profitloss/ProfitLossAttributableToParentAxis",
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      "type": "Net_income_loss_available_to_common_stockholders_basic"
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"concept": "NetIncomeLossAvailableToCommonStockholdersBasic",
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"label": "RECENT ACCOUNTING PRONOUNCEMENTS"
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"label": "Nonmonetary Transaction Type [Axis]"
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"http://aclarion.com/role/ShortTermNotesAndConvertibleDebtDetailsNarrative"
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"label": "Nonoperating Income (Expense)",
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"label": "Promissory note payable"
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"documentation": "Generally recurring costs associated with normal operations except for the portion of these expenses which can be clearly related to production and included in cost of sales or services. Includes selling, general and administrative expense.",
"label": "Operating Expenses",
"totalLabel": "Total operating expenses"
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"label": "Operating Income (Loss)",
"totalLabel": "Income (loss) from operations"
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"us-gaap_OperatingLeaseExpense": {
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"en-us": {
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"documentation": "Amount of operating lease expense. Excludes sublease income.",
"label": "Operating Lease, Expense"
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"localname": "OperatingLeaseExpense",
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"en-us": {
"role": {
"documentation": "The amount of revenue recognized for the period under subleasing arrangements.",
"label": "Operating Leases, Income Statement, Sublease Revenue"
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"localname": "OperatingLeasesIncomeStatementSubleaseRevenue",
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"documentation": "Contracts conveying rights, but not obligations, to buy or sell a specific commodity, or financial or equity instrument, at a specified price during a specified period (an American option) or at a specified date (a European option) which were purchased or otherwise acquired, excluding options written (for which a premium was received).",
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"label": "THE COMPANY AND BASIS OF PRESENTATION"
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"localname": "OrganizationConsolidationAndPresentationOfFinancialStatementsDisclosureTextBlock",
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"en-us": {
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"label": "Other, net",
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"label": "Payments for Other Operating Activities"
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}
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"localname": "PaymentsForOtherOperatingActivities",
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"http://aclarion.com/role/CompanyAndBasisOfPresentationDetailsNarrative"
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"en-us": {
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"documentation": "The cash outflow to acquire asset without physical form usually arising from contractual or other legal rights, excluding goodwill.",
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"label": "Plan Name [Axis]"
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"http://aclarion.com/role/Stock-basedCompensationDetails-AssumptionsUsedForValuation",
"http://aclarion.com/role/Stock-basedCompensationDetailsNarrative",
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   "weight": -1.0
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    "label": "Preferred Stock Dividends and Other Adjustments",
    "negatedLabel": "Dividends accrued for preferred stockholders"
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  }
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    "documentation": "Preferred shares may provide a preferential dividend to the dividend on common stock and may take precedence over common stock in the event of a liquidation. Preferred shares typically represent an ownership interest in the company.",
    "label": "Preferred Stock [Member]"
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  }
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    "label": "Preferred Stock, Par or Stated Value Per Share"
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  "en-us": {
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    "label": "Preferred Stock, Shares Authorized"
   }
  }
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 "localname": "PreferredStockSharesAuthorized",
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  "http://aclarion.com/role/BalanceSheetsParenthetical",
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"us-gaap_PreferredStockSharesIssued": {
 "auth_ref": [
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 "lang": {
  "en-us": {
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  }
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    "label": "Preferred Stock, Shares Outstanding"
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  }
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  }
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    "label": "Prepaids & other current assets"
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    "label": "Reclassifications"
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  }
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    "label": "Proceeds from issuance of convertible notes"
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    "verboseLabel": "Proceeds from Issuance or Sale of Equity"
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  "http://aclarion.com/role/StatementsOfCashFlows"
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    "totalLabel": "Income (loss) before income taxes"
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  "r465",
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    "terseLabel": "Total",
    "verboseLabel": "Property, plant and equipment, net"
   }
  }
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  "http://aclarion.com/role/PropertyPlantAndEquipmentDetails-FutureDepreciation",
  "http://aclarion.com/role/PropertyPlantAndEquipmentDetails-PropertyAndEquipment"
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  "r480"

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"label": "Schedule of property and equipment"
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"lang": {
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}
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    "label": "Collaborative Arrangement and Arrangement Other than Collaborative [Table]"
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    "http://xbrl.fasb.org/us-gaap/2024/elts/us-gaap-2024-01-31.xsd"
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        "label": "Schedule of share-based compensation by expense"
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          "label": "Earnings per share"
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            "label": "Share-based Payment Arrangement, Expensed and Capitalized, Amount [Table]"
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        {
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            "http://xbrl.fasb.org/us-gaap/2024/elts/us-gaap-2024-01-31.xsd"
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                "label": "Schedule of Assets Leased to Others by Major Class [Table]"
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                  "label": "Schedule of other expense"
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