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Employer Identification Number) Â 8181 Arista Place, Suite100Broomfield, Colorado 80021(833) 275-2266(Address, including zip code,and telephone number, including area code, of registrantâ€™s principal executive offices)Â John LorbieckiChief Financial OfficerAclarion, Inc.8181 Arista Place, Suite100Broomfield, Colorado 80021(833) 275-2266(Name, address, includingzip code, and telephone number, including area code, of agent for service)Â Copies to:Â Â Â Ralph V. De Martino, Esq. James H. Carroll, Esq. Â Marc E. Rivera, Esq. Carroll Legal LLC Â ArentFox Schiff LLP 1449 Wynkoop Street, Suite 507 Â 1717 K Street NW Denver, COÂ Â 80202 Â Washington, D.C. 20006 (303) 888-4859 Â (202) 724-6848 Â Approximate date of commencement of proposed sale to the public:As soon as practicable after the effective date of this Registration Statement.Â If any of the securitiesbeing registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act, checkthe following box.Â Â â˜’Â If this Form is filedto register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list theSecurities Act registration statement number of the earlier effective registration statement for the same offering.Â Â â˜Â If this Form is a post-effectiveamendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statementnumber of the earlier effective registration statement for the same offering.Â Â â˜Â If this Form is a post-effectiveamendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statementnumber of the earlier effective registration statement for the same offering. â˜Â Indicate by check markwhether the registrant is a large accelerated filer, an accelerated filer, aÂ non-acceleratedÂ filer, a smaller reporting companyor an emerging growth company. See the definitions of â€œlarge accelerated filer,â€ â€œaccelerated filer,â€ â€œsmallerreporting company,â€ and â€œemerging growth companyâ€ in Rule 12b-2 of the Exchange Act:Â LargeÂ acceleratedÂ filer Â â˜Â AcceleratedÂ filer Â â˜ Non-accelerated filer Â â˜’ Â SmallerÂ reportingÂ company Â â˜’ Â Â Â Â EmergingÂ growthÂ company Â â˜’ Â If an emerging growth company, indicate by checkmark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accountingstandards provided pursuant to Section 7(a)(2)(B) of the Securities Act.Â Â â˜Â The Registrant herebyamends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall filea further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section8(a) of the Securities Act of 1933, as amended, or until this Registration Statement shall become effective on such date as the Securitiesand Exchange Commission, acting pursuant to said SectionÂ 8(a), may determine.Â Â Â Â Â Â Â Â The informationcontained in this preliminary prospectus is not complete and may be changed. We may not sell these securities until the registration statementfiled with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell these securities andwe are not soliciting offers to buy these securities in any jurisdiction where the offer or sale is not permitted.Â Â SUBJECT TO COMPLETION,DATED DECEMBER [__], 2024Â PRELIMINARY PROSPECTUSÂ ACLARION, INC.Â Up to [***] Â Shares of Common StockUp to [***] Pre-Funded Warrants to Purchase[***] Shares of Common StockUp to [***] Series A Common Warrants to Purchaseup to [***] Shares of Common StockUp to [***] Series B Common Warrants to Purchaseup to [***] Shares of Common StockUp to [***] Shares of Common Stock Underlyingthe Pre-Funded Warrants, Series A Common Warrants, and Series B Common WarrantsÂ We are offering [***] shares of our common stock,par value $0.00001 per share (the â€œCommon Stockâ€) together with Series A common warrants to purchase up to [***] shares ofCommon Stock (the â€œSeries A Common Warrantsâ€) and Series B common warrants to purchase up to [***] shares of Common Stock(the â€œSeries B Common Warrantsâ€ and together with the Series A Warrants, the â€œCommon Warrantsâ€). Each share ofour Common Stock or a Pre-Funded Warrant (defined below) in lieu thereof, is being sold together with a Series A Common Warrant to purchaseone share of our Common Stock and a Series B Common Warrant to purchase one share of our Common Stock. The shares of Common Stock andCommon Warrants are immediately separable and will be issued separately in this offering but must be purchased together in this offering.The assumed combined public offering price for each share of Common Stock and accompanying Common Warrants is $[***], which is equal tothe closing price of our Common Stock on the Nasdaq Capital Market on December [***], 2024 (the â€œOffering Priceâ€). Each SeriesA Common Warrant will have an exercise price per share of $[***] and will be exercisable beginning on the date on which Stockholder Approval(as defined below) is received and deemed effective (the â€œInitial Exercise Dateâ€ or the â€œStockholder Approval Dateâ€).The Series A Warrants will expire on the five-year anniversary of the Initial Exercise Date. The Series B Warrants will have an exerciseprice per share of $[***] and will be exercisable beginning on the Initial Exercise Date. The Series B Warrants will expire on the twoand one-half year anniversary of the Initial Exercise Date.Â Because a purchaserâ€™s purchase of sharesof Common Stock in this offering could otherwise result in the purchaser, together with its affiliates and certain related parties, beneficiallyowning more than 4.99% (or at the election of the purchaser, 9.99%) of our outstanding Common Stock immediately following consummationof this offering, we are offering to the purchasers pre-funded warrants to purchase up to [***] shares of Common Stock (the â€œPre-FundedWarrantsâ€) in lieu of shares of Common Stock. Each Pre-Funded Warrant will be exercisable for one share of our Common Stock. Thepurchase price of each Pre-Funded Warrant is $[***], which is equal to the price per share at which the shares of Common Stock are beingsold to the public in this offering, minus $0.001 per share, and the exercise price of each Pre-

Funded Warrant will be $0.001 per share.For each Pre-Funded Warrant that we sell, the number of shares of our Common Stock offered will be decreased on a one-for-one basis. Thisoffering also relates to the shares of Common Stock issuable upon exercise of the Common Warrants (the â€œCommon Warrant Sharesâ€),and the shares of Common Stock issuable upon exercise of the Pre-Funded Warrants (the â€œPre-Funded Warrant Sharesâ€).Â The issuance of Common Warrant Shares upon exerciseof the Common Warrants is subject to stockholder approval under applicable rules and regulations of The Nasdaq Stock Market LLC (â€œNasdaqâ€)(â€œStockholder Approvalâ€ and the date on which Stockholder Approval is received and deemed effective, the â€œStockholderApproval Dateâ€). We intend to hold a meeting to obtain Stockholder Approval as soon as reasonably practicable following the closingof this offering.Â Our Common Stock is listed on the Nasdaq CapitalMarket under the symbol â€œACON.â€ On December [***], 2024, the closing price for our Common Stock, as reported on the NasdaqCapital Market, was $[***] per share. Our IPO Warrants offered in connection with our April 2022 initial public offering are quoted onthe Nasdaq Capital Market under the symbol â€œACONW.â€ The last reported sale price of our IPO Warrants on the Nasdaq CapitalMarket on December [***], 2024 was $[***] per IPO Warrant. All share, Common Warrant and Pre-Funded Warrant numbers are based on an assumedcombined public offering price of $[***] per share and the accompanying Common Warrants and $[***] per Pre-Funded Warrant and the accompanyingCommon Warrants, based on the closing price of the Companyâ€™s Common Stock on December [***], 2024 as reported on the Nasdaq CapitalMarket. The actual combined public offering price per share of Common Stock and accompanying Common Warrants, and per Pre-Funded Warrantand accompanying Common Warrants, will be fixed for the duration of this offering and will be determined between us and purchasers basedon market conditions at the time of pricing, and may be at a discount to the then current market price of our Common Stock. The recentmarket price used throughout this prospectus may not be indicative of the actual combined public offering price. The actual combined publicoffering price may be based upon a number of factors, including our history and our prospects, the industry in which we operate, our pastand present operating results, the previous experience of our executive officers and the general condition of the securities markets atthe time of this offering. There is no established public trading market for the Common Warrants or Pre-Funded Warrants, and we do notexpect a market for the Common Warrants or the Pre-Funded Warrants to develop. We do not intend to list the Common Warrants or Pre-FundedWarrants on the Nasdaq Capital Market, any other national securities exchange or any other trading system. Without an active trading market,the liquidity of the Common Warrants and the Pre-Funded Warrants will be limited. We anticipate that the shares of our Common Stock tobe issued upon exercise of the Common Warrants and the Pre- Funded Warrants will trade on The Nasdaq Capital Market.Â Â Â Â iÂ Â Â Â We have received deficiency letters from Nasdaqthat we are not in compliance with Nasdaqâ€™s (i)Â minimum bid price requirement of at least $1.00 per share (the â€œBid PriceRequirementâ€) and (ii) requirement to have at least $2,500,000 in stockholdersâ€™ equity (the â€œStockholdersâ€™ EquityRequirementâ€).Â On April 8, 2024, we received a written notice(the â€œBid Price Noticeâ€) from the Listing Qualifications Department of The Nasdaq Stock Market (â€œNasdaqâ€) indicatingthat the Company was not in compliance with the $1.00 minimum bid price requirement set forth in Nasdaq Listing Rule 5550(a)(2) for continuedlisting on The Nasdaq Capital Market (the â€œBid Price Requirementâ€).Â The Bid Price Notice did not result in the immediatedelisting of the Companyâ€™s Common Stock from The Nasdaq Capital Market.Â The Nasdaq Listing Rules require listed securitiesto maintain a minimum bid price of $1.00 per share and, based upon the closing bid price of the Companyâ€™s Common Stock for the 30consecutive business days for the period ending April 5, 2024, the Company no longer met this requirement.Â The Notice indicated that the Company will beprovided 180 calendar days (or until October 7, 2024) in which to regain compliance. We did not regain compliance with Rule 5550(a)(2)prior to the expiration of the initial 180 calendar day period on October 7, 2024. On October 8, 2024, we received from the Nasdaq staff(the â€œStaffâ€) written notification that our securities are subject to delisting from the Nasdaq Capital Market. We had anappeal hearing on October 10, 2024 before a Nasdaq hearings panel (the â€œPanelâ€) appeal the delisting notice from the Staff.While the appeal process is pending, the suspension of trading of our Common Stock will be stayed. Our Common Stock will continue to tradeon Nasdaq until the hearing process concludes and the Panel issues a written decision. The Panel has granted the Company an extensionuntil January 31, 2025 to demonstrate compliance with the Bid Price Requirement.Â At the Companyâ€™s special stockholdersâ€™meeting on September 23, 2024, the Companyâ€™s stockholders approved a proposal to grant discretionary authority to our board of directorsto (i) amend our certificate of incorporation to combine outstanding shares of our Common Stock into a lesser number of outstanding shares,or a â€œreverse stock split,â€ at a specific ratio within a range of one-for-five (1-for-5) to a maximum of a one-for-fifty (1-for-50split, with the exact ratio to be determined by our board of directors in its sole discretion; and (ii) effect the reverse stock split,if at all, within one year of the date the proposal was approved by stockholders. At the Companyâ€™s annual stockholdersâ€™ meetingon December 31, 2024, the Companyâ€™s stockholders will vote on a separate proposal to grant discretionary authority to our boardof directors to (i) amend our certificate of incorporation to combine outstanding shares of our Common Stock into a lesser number of outstandingshares, or a â€œreverse stock split,â€ at a specific ratio within a range of one-for-five (1-for-5) to a maximum of a one-for-fourhundred (1-for-400 split, with the exact ratio to be determined by our board of directors in its sole discretion; and (ii) effect thereverse stock split, if at all, within one year of the date the proposal was approved by stockholders.Â The Company intends to implement a reverse stocksplit in the near future in order to assist with the Companyâ€™s compliance with Nasdaqâ€™s Bid Price Requirement.Â On August 22, 2024, the Company received a letterfrom Nasdaq indicating that that the Company was not in compliance with the requirement to have at least $2,500,000 in stockholdersâ€™equity (the â€œStockholdersâ€™ Equity Requirementâ€). In its quarterly report on Form 10-Q for the period ended June 30,2024, the Company reported stockholdersâ€™ equity of $1,642,177, and, as a result, did not satisfy Listing Rule 5550(b)(1).Â Accordingly, the Staff determined to delist ourCommon Stock from Nasdaq. Nasdaqâ€™s letter provided the Company until August 29, 2024 to request an appeal of this determination.The Company requested a hearing before the Panel to appeal the delisting notice from the Staff. The hearing request stays any suspensionor delisting action pending the conclusion of the hearing process and the expiration of any additional extension period granted by thePanel following the hearing.Â We had an appeal hearing on October 10, 2024 beforethe Panel to appeal the delisting notice from the Staff. The Panel granted the Company an extension until January 31, 2025 to demonstratecompliance with the Stockholders' Equity Requirement. While the appeal process is pending, the suspension of trading of the Companyâ€™sCommon Stock will be stayed. Our Common Stock will continue to trade on Nasdaq until the hearing process concludes and the Panel issuesits final written determination.Â On November 14, 2024, the Company filed a QuarterlyReport on Form 10-Q for the nine months ending September 30, 2024, and reported stockholdersâ€™ equity of $2,509,785.Â Â Â Â iiÂ Â Â The Company intends to take all reasonable measuresavailable to maintain compliance under the Nasdaq Listing Rules and remain listed on

Nasdaq.Â The Panel has the right to reconsider the termsof this exception based on any event, condition or circumstance that exists or develops that would, in the opinion of the Panel, makecontinued listing of the Companyâ€™s securities on Nasdaq inadvisable or unwarranted. There can be no assurances that the Companywill maintain compliance with the Stockholders' Equity Requirement, or that the Company will maintain its listing on the Nasdaq CapitalMarket. See â€œRisk Factors â€“ Risks related to our Nasdaq listing.â€Â Except as otherwise indicated, all share and pershare information in this prospectus does not give effect to the reverse stock split of the Companyâ€™s outstanding Common Stock,which will be effected at a ratio of 1-for-[***] shares as of 5:00 pm Eastern Time on [***], 2025, trading for which will begin as of9:30 am Eastern Time on [***], 2025.Â Â Â Per Share of Common Stock and AccompanyingCommon Warrants Â Â Per Pre- Funded Warrant and AccompanyingCommon Warrants Â Â Total Â Public Offering price Â $ Â Â Â $ Â Â Â $ Â Â Underwriting discounts and commissions(1) Â $ Â Â Â $ Â Â Â $ Â Â Proceeds to us, before expenses(2) Â $ Â Â Â $ Â Â Â $ Â Â Â (1) See â€œUnderwritingâ€ for a description of the compensation payable to the underwriter. Â Â (2) The amount of offering proceeds to us presented in this table does not give effect to any exercise of the Common Warrants or the Pre-Funded Warrants. Â We have granted the underwriter an option to purchaseup to an additional shares of our securities from us at the public offering price, less underwriting discounts and commissions, within30 days from the date of this prospectus supplement. See â€œUnderwritingâ€ for more information.Â Investing in our securities involves a highdegree of risk. Before buying any shares, you should carefully read the discussion of material risks of investing in our securities inâ€œRisk Factorsâ€ beginning on page 20 of this prospectus. Â We may amend or supplementthis prospectus from time to time by filing amendments or supplements as required. You should read the entire prospectus and any amendmentsor supplements carefully before you make your investment decision.Â Neither the Securitiesand Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed on the adequacyor accuracy of this prospectus. Any representation to the contrary is a criminal offense.Â The delivery to the purchasers of the shares ofCommon Stock, Pre-Funded Warrants, and Common Warrants in this offering is expected to be made on or about [***], 202 [***], subject tosatisfaction of certain customary closing conditions.Â Sole Book-Running ManagerÂ Dawson James Securities,Inc.Â The date of this prospectus is [***] , 202[***]Â Â Â Â Â iiiÂ Â Â TABLE OF CONTENTSÂ Â Page Prospectus Summary 1 Information Regarding Forward-Looking Statements 16 The Offering 17 Risk Factors 20 Market and Industry Data 66 Use of Proceeds 67 Dividend Policy 68 Capitalization 68 Dilution 68 Market Price of and Dividends on Common Equity and Related Stockholder Matters 71 Managementâ€™s Discussion and Analysis of Financial Condition and Results of Operations 72 Business 82 Management, Governance, Director Compensation, Executive Compensation 110 Certain Relationships and Related Party Transactions 121 Principal Stockholders 122 Description of Capital Stock 123 Description of Securities We Are Offering 128 Underwriting 137 Legal Matters 141 Experts 141 Change in Accountants 141 Where You Can Find More Information 141 Index to Financial Statements F-1 Â Â Â Â ivÂ Â Â Neither we nor the underwriter has authorizedanyone to provide any information or to make any representations other than those contained in or incorporated by reference in this prospectusor in any free writing prospectus prepared by or on behalf of us or to which we have referred you. We and the underwriter take no responsibilityfor, and can provide no assurance as to the reliability of, any other information that others may give you. This prospectus is an offerto sell only the securities offered hereby, but only under circumstances and in jurisdictions where it is lawful to do so. The informationcontained in or incorporated by reference in this prospectus or in any applicable free writing prospectus is current only as of its date,regardless of its time of delivery or any sale of shares of our Common Stock. Our business, financial condition, results of operationsand prospects may have changed since that date.Â To the extent thereis a conflict between the information contained in this prospectus, on the one hand, and the information contained in any document incorporatedby reference filed with the Securities and Exchange Commission, or the SEC, before the date of this prospectus, on the other hand, youshould rely on the information in this prospectus. If any statement in a document incorporated by reference is inconsistent with a statementin another document incorporated by reference having a later date, the statement in the document having the late date modifies or supersedesthe earlier statement.Â No action is beingtaken in any jurisdiction outside the United States to permit a public offering of our Common Stock or possession or distribution of thisprospectus in that jurisdiction. Persons who come into possession of this prospectus in jurisdictions outside the United States are requiredto inform themselves about and to observe any restrictions as to this public offering and the distribution of this prospectus applicableto that jurisdiction.Â Unless otherwise indicated,information contained in this prospectus concerning our industry and the markets in which we operate, including our general expectationsand market position, market opportunity and market share, is based on information from our own management estimates and research, as wellas from industry and general publications and research, surveys and studies conducted by third-parties. Management estimates are derivedfrom publicly available information, our knowledge of our industry and assumptions based on such information and knowledge, which we believeto be reasonable. Our management estimates have not been verified by any independent source, and we have not independently verified anythird-party information. In addition, assumptions and estimates of our and our industryâ€™s future performance are necessarily subjectto a high degree of uncertainty and risk due to a variety of factors, including those described in â€œRiskFactors.â€ These and other factors could cause our future performance to differ materially from our assumptions and estimates.See â€œRisk Factorsâ€ and â€œInformation RegardingForward-Looking Statements.â€Â We further note thatthe representations, warranties and covenants made by us in any agreement that is filed as an exhibit to the registration statement ofwhich this prospectus is a part were made solely for the benefit of the parties to such agreement, including, in some cases, for the purposeof allocating risk among the parties to such agreements, and should not be deemed to be a representation, warranty or covenant to you.Moreover, such representations, warranties or covenants were accurate only as of the date when made. Accordingly, such representations,warranties and covenants should not be relied on as accurately representing the current state of our affairs.Â We may also provide aprospectus supplement or post-effective amendment to the registration statement to add information to, or update or change informationcontained in, this prospectus. You should read both this prospectus and any applicable prospectus supplement or post-effective amendmentto the registration statement together with the additional information to which we refer you in the sections of this prospectus entitledâ€œWhere You Can Find More Information.â€Â Our company name waschanged from â€œNocimed, Inc.â€, to â€œAclarion, Inc.â€ on December 3, 2021. NOCIMEDâ„¢ -, NOCISCANÂ® -, NOCIGRAMâ„¢, NOCISCOREâ„¢ -, NOCICALCâ„¢ - MRS NOCI+â„¢ - NOCI-â„¢ -, NOCImildâ„¢ -NOCIWEBâ„¢ - SI-SCOREâ„¢, VIRTUALDISCOGRAMâ„¢ - and the Nocimed logo are our trademarks. All other service marks, trademarks and trade names appearing in this prospectusare the property of their respective owners. We do not intend our use or display of other companiesâ€™ trade names, trademarks orservice marks to imply a relationship with, or endorsement or sponsorship of us by, these

other companies. Solely for convenience, trademarksand tradenames referred to in this prospectus may appear without the Â® orâ„¢ symbols, but such references are not intended toindicate in any way that we will not assert, to the fullest extent under applicable law, our rights, or that the applicable owner willnot assert its rights, to these trademarks and tradenames.Â Â Â vÂ Â Â GLOSSARYÂ Unless otherwise indicated or the context otherwise requires, referencesin this prospectus to the term:Â â€œAIâ€ means Artificial IntelligenceÂ â€œCategory I Codesâ€ means numericcodes that identify a procedure or service that is approved by the Food and Drug Administration (FDA), performed by healthcare professionalsnationwide, and is proven and documented.Â â€œCategory III Codesâ€ are CPT Category III codesthat are a set of temporary codes assigned to emerging technologies, services, and procedures.Â â€œCE markâ€ is an administrativemarking with which a manufacturer or importer affirms its products are in conformity with European health, safety, and environmental protectionstandards for products sold within the European Economic Area (EEA).Â "Covered Entityâ€ is a healthcare provider or other person or entity who acquires and transmits private health information of patients, as covered under HIPAA andGDPR regulations (see e.g. 45 CFR Â§160.103).Â â€œCPTâ€ means â€œCurrentProcedural Terminologyâ€, and refers to a medical code set created and maintained by the American Medical Association (â€œAMAâ€)and used by providers of healthcare services to bill insurance companies for their work. All new medical devices and services are requiredto secure CPT codes to receive payment from government and private commercial payers.Â â€œCT-Scanâ€ means a computerizedtomography (CT) scan combines a series of X-ray images taken from different angles around the body and uses computer processing to createcross-sectional images (slices) of the bones, blood vessels and soft tissues inside the body. CT scan images provide more-detailed informationthan plain X-rays do.Â â€œCures Actâ€ means the 21st Century CuresAct, signed into law on December 13, 2016, as Public Law No: 114-255.Â â€œDICOMâ€ means an acronym for digital image communication,typically referring to standardized data architecture formats for managing, storing, and communicating or transferring MRI images andother associated data.Â â€œDiscâ€ means an intervertebraldisc which is made of a gel-like material (nucleus pulposus) surrounded by a thick fibrous ring (annulus fibrosus) is situated betweenthe vertebral bodies of the spine.Â â€œDLBPâ€ means Discogenic Low Back PainÂ â€œDOCâ€ means â€œDeclarationof Conformity,â€ a document signed by us that declares that we have self-complied with applicable regulations for self-certifyingour CE Marking for our products.Â â€œFusionâ€ means â€œSpinalFusionâ€ which is surgery to permanently connect two or more vertebrae in the spine, eliminating motion between them.Â â€œGDPRâ€ means the General DataProtection 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 patientâ€™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 andreceived by companies or other persons or entities in the US.Â Â â€œIRBâ€ means Institutional ReviewBoard, which is typically an appointed board for reviewing and approving investigational clinical trials.Â â€œIndications for Useâ€ meansthe limited scope of the intended uses and related medical indications for appropriately using our products.Â â€œLBPâ€ means Lower Back Pain.Â Â Â viÂ Â Â â€œLabelingâ€ means the scopeof intended â€œIndications for Useâ€ that is identified with the commercial sale and use of our products.Â â€œLumbar Spineâ€ means the five(5) lower vertebrae, L-1 to L-5.Â â€œMRâ€ means Magnetic Resonance.Â â€œMRIâ€ means Magnetic Resonance Imaging.Â â€œMRSâ€ means Magnetic ResonanceSpectroscopy and is a type of pulse sequence used by MR scanners that, unlike MRI pulse sequences which generate images of tissue structures,generates a â€˜spectrumâ€™ with various peaks that represent different chemicals in the body tissue being examined, and whichallows for the quantitative measurement of the relative amounts of those chemicals in the examined tissues.Â â€œNotified Bodyâ€ means an organizationdesignated by an EU country to assess the conformity of certain products before being placed on the market, as is required for certainmedical products.Â â€œNIHâ€ means the United StatesNational Institutes of Health.Â â€œPD TESTâ€ means a ProvocationDiscogram test which is a diagnostic test meant to confirm or exclude the intervertebral disc(s) as a source of back pain. This techniqueinvolves puncture of the disc with a fine-gauge needle under fluoroscopic guidance and pressurization of the disc via the injection ofcontrast media.Â â€œPMAâ€ means Premarket Approval by the FDA.Â "QMSâ€ means QualityManagement System, which is a formalized system that documents processes, procedures, and responsibilities for achieving quality policiesand objectives, in particular to meet customer and regulatory requirements.Â â€œDICOMâ€ means an acronymfor digital image communication, typically referring to standardized data architecture formats for managing, storing, and communicatingor transferring MRI images and other associated data.Â â€œDiscâ€ means intervertebraldisc 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.Â â€œSpectroscopyâ€ means the scienceof deriving and evaluating a multi-peak spectrum for a material and in which different molecular bonds representing different componentsof the material are represented by unique respective peaks at particular locations along the spectra, and with the different peaks typicallyreflecting 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 sequencesapplied to those tissues for that chemical analysis.Â Â Â viiÂ Â Â PROSPECTUS SUMMARYÂ The following summaryhighlights information contained elsewhere in this prospectus and in documents incorporated by reference. This summary is not completeand may not contain all the information you should consider before investing in our Common Stock. You should read this entire prospectusand the documents incorporated by reference in this prospectus carefully, especially the risks of investing in our Common Stock discussedunder the heading â€œRisk Factors,â€ and our financial statements and related notes incorporatedby reference in this prospectus before making an investment decision. This prospectus includes forward-looking statements that involverisks and uncertainties. See â€œInformation Regarding Forward-Looking Statements.â€ Â The Company was originallyformed in Delaware as Nocimed, LLC in January 2008. Nocimed, LLC was converted to Nocimed, Inc., a Delaware corporation in February 2015.The name of the Company was changed from â€œNocimed, Inc.â€ to â€œAclarion, Inc.â€ on December 3, 2021. In this prospectus,unless the context otherwise requires, the terms â€œAclarion, Inc.,â€ â€œAclarionâ€, â€œNocimed, Inc.â€ theâ€œCompany,â€ â€œwe,â€ â€œusâ€ and â€œourâ€ refer, prior to the name change discussed herein, to Nocimed,Inc., and after the name change, to Aclarion, Inc.Â This prospectus includestrademarks, service marks and trade names owned by us or other companies. All trademarks, service marks and trade names included in thisprospectus are the property of their respective owners.Â Except as otherwisenoted, all information in this prospectus reflects and assumes (i) no sale of Pre-Funded Warrants in this offering, which, if sold, wouldreduce the number of shares of Common Stock that we are offering on a one-for-one basis and (ii) no exercise of the Common

Warrants issuedin this offering.Â All share and per share information in this prospectushave not been adjusted to reflect a 1-for-[***] reverse stock split of our Common Stock which will be effected at a ratio of 1-for-[***]shares as of 5:00 pm Eastern Time on [***], 2025, trading for which will begin as of 9:30 am Eastern Time on [***], 2025.Â OverviewÂ Aclarion is a healthcaretechnology company that leverages Magnetic Resonance Spectroscopy (â€œMRSâ€), and a proprietary biomarker to optimize clinicaltreatments. Aclarionâ€™s technology addresses the $134.5B U.S. low back and neck pain market, which according to a 2020 JAMA (Journalof the American Medical Association) article is now the most costly healthcare condition in the United States. The Company is currentlyutilizing Artificial Intelligence (â€œAIâ€) to assist in quality control processes that flag spectroscopy data indicative ofa poor MRS study. The use of AI in this application is early in its development cycle and is expected to evolve with further researchand development. The Company is also researching the application of AI and machine learning platforms to analyze both the raw spectroscopydata and the post-processed signal to evaluate whether AI platforms can more efficiently and more effectively associate MRS data withclinical outcomes. The use of AI in this application is aspirational and we intend this type of AI research and development to be an ongoingprocess applied not only to the various treatment paths associated with back pain, such as conservative therapies, regenerative and celltherapies and surgical intervention, but also to potentially expand into other clinical explorations involving the diagnosis of brain,breast and prostate tumors.Â The Company, which haslimited sales to date, is addressing this market by initially focusing on improving the outcomes of surgical interventions to treat lowback pain. In this initial application, Aclarion technology is intended to assist surgeons in determining the optimal surgical procedurefor a patient undergoing surgery for pain isolated to their lumbar spine (the â€œlumbar spineâ€ is comprised of the five (5)lower vertebrae, L-1 to L-5). We then intend to add additional applications of our technology targeting the management of large segmentsof low back pain patients from the point of initial Magnetic Resonance Imaging (â€œMRIâ€) through to episode resolution. We believethis will expand the use of our technology to low back pain patients undergoing conservative therapies such as physical therapy or biologicand cell therapies aimed at regenerating the lumbar discs. We plan to expand the application of our technology beyond the lumbar spineto address neck pain populations in addition to low back pain populations. To expand the application of our technology for use in neckpain populations, we will need to overcome technical changes associated with securing adequate MRS data from the cervical disc, whichis significantly smaller than the lumbar disc, and there can be no assurance the Company will be able to overcome these challenges.Â The core technology Aclarionemploys is MRS. The patient experience when undergoing an MRS exam is exactly like that of a standard MRI, with the exception of an additional3-5 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 standardMRIâ€™s, the data from spectroscopy is useless without technologies that can process the data. Aclarion has developed proprietarysignal processing software that transforms spectroscopy data into clear biomarkers. These biomarkers, which are exclusively licensed fromthe Regents of University of California, San Francisco (â€œUCSFâ€), 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 licensedfrom Regents of the University of California.Â Â Â 1Â Â Â We believe one of thebiggest issues driving the cost of treating low back and neck pain patients to the top of the list for healthcare spending is that thereis no objective, cost effective and noninvasive diagnostics to reliably identify the source of a patientâ€™s pain. We believe thepoor surgical outcomes for Discogenic Low Back Pain (â€œDLBPâ€) are largely due to difficulties in reliably and accurately diagnosingthe specific spinal discs that are causing pain. The current primary diagnostic standard is the MRI, which is useful for showing abnormalstructures and tissue dehydration, but, we believe, cannot reliably identify specific discs that are causing pain. To diagnose specificdiscs that are causing pain, a needle-based Provocation Discogram test (â€œPD Testâ€) has been developed. PD Tests have beenshown to be highly accurate when performed properly. However, a PD Test is invasive, subjective and unpleasant for the patient as thepatient needs to be awake in order to tell the physician if the pain the physician is purposefully causing in the disc is the same asthe pain the patient feels when they are experiencing a back pain episode. In addition, recent evidence has shown that the action of insertinga 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, personalizedand noninvasive diagnostic test that can reliably determine if an individual disc is a pain generator. By providing physicians informationabout whether a disc has the chemical and structural makeup consistent with pain or not, we believe the treatment plan for each patientwill lead to more efficient and targeted care that, will in turn, result in lower costs and healthier patient outcomes.Â Aclarion has taken thefirst steps to demonstrate the potential use of our technology in helping to improve the outcome of surgical intervention for DLBP patientsby publishing a clinical study (Gornet et al) in the European Spine Journal in April 2019. The study illustrated that when all discs identifiedas consistent with pain by our technology were included in a surgical treatment, 97% of the patients met the criteria for â€œclinicalimprovementâ€. This compared to only 54% of patients meeting the criteria for clinical improvement if a disc that our technologyidentified as consistent with pain, was not included in the surgical treatment.Â The results of this clinicalstudy led the CPT committee to approve four Category III codes for our technology in January 2021. The NIH also included our technologyas one of the handful of technologies selected to participate in their $150 million Back Pain Consortium (BACPAC) Research Program, anNIH translational, patient-centered effort to address the need for effective and personalized therapies for chronic low back pain.Â In April 2023, Aclarionadvanced the evidence of our technology with a peer-reviewed journal article detailing the Gornet 2-year outcomes, published in the EuropeanSpine Journal. The 2-year outcomes were durable with 1-year outcomes previously published in 2019. At 2-years follow-up, 85% of patientsimproved when disc(s) identified as consistent with pain by our technology were included in a surgical treatment, compared to only 63%of patients when disc(s) identified as consistent with pain were not treated or disc(s) identified as consistent without pain were treated.Â Aclarion SolutionÂ Evolving science coupledwith 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 Magnetic Resonance Spectroscopyhas been developed by manufacturers of MRI equipment. MRSs are different than MRIs. An MRI generates images of body structures, whilean MRS analyzes the relative amounts of various chemicals in body tissues.Â Aclarion has developeda software application called NOCISCAN-LSÂ® which uses the existing MRS capabilities of many commercially available scanners to non-invasivelyanalyze the chemical makeup of intervertebral discs in the spine. The software post-processes the MRS exam

data and detects the presenceof chemical biomarkers that we, in conjunction with spine researchers at UCSF, have demonstrated to be associated with degenerative painand structural integrity of the lumbar discs. After processing the MRS exam data, we send the ordering clinician a report that detailshow to interpret the results of the MRS exam. We believe these results help clinicians make quicker and more informed decisions aboutwhich lumbar discs are painful, and which are not. We believe the ordering clinician can use this information to determine the optimaltreatment plan for an individual patient.Â Â Â 2Â Â Â NOCISCAN is entirelynon-invasive and only briefly extends an otherwise standard MRI exam. The MRI scan is the most frequently used type of pulse sequencefor operating Nuclear Magnetic Resonance (NMR) scanners. It uses a powerful magnet to apply a pulsed magnetic field to a patient, sensorsto detect radio waves that emanate from the resonant vibrations of different chemicals in the body in response to that pulsed magneticfield and a computer to create detailed images of tissue structures in the patient based on those detected chemical signals. Because waterand fat are the most prevalent chemicals in the body, standard MRI images are typically based on the different levels of water and fatbetween different tissues. MRS, however, is another type of pulse sequence that uses NMR scanners in a similar way as an MRI, but insteadof using the chemical resonances to create an image, MRS creates a spectrum for a tissue with different peaks that represent many differentchemicals, in addition to water and fat, in that tissue. The relative amounts of those chemicals can be calculated by measuring theirrespective spectral peaks. While MRS has been used previously for diagnosing certain cancers (e.g. brain, breast, prostate) by measuringunique chemical biomarkers for tumors, NOCISCAN uses MRS for measuring the relative levels of degenerative pain and structural integritybiomarkers in discs. The relative levels of degenerative pain and structural integrity biomarkers are derived through the use of proprietarypost processing technologies.Â The platform used toconduct a NOCISCAN involves: (i) an MRS exam of an intervertebral disc performed according to a proprietary protocol, (ii) a data transferportal to securely transfer data from the MRS exam to Aclarionâ€™s cloud based post-processer technology, (iii) post-processor technologythat identifies biomarker peaks and leverages calculation tables that evaluate a number of ratios of biomarker peaks, where pain biomarkersare in the numerator and structural biomarkers are in the denominator, and (iv) a final diagnostic report called a Nocigram that identifiesdiscs as painful or not.Â NOCISCAN MRS ExamProtocol.Â We have developed a customsoftware protocol and technique for using commercially available MRS pulse sequences in scanning intervertebral discs which extends thetime of a standard lumbar MRI exam by an average of about 30 minutes for 5 lumbar discs. The custom protocol is a proprietary series ofsettings and instructions for MRS to conduct the NOCISCAN exam to obtain optimal and reliable MRS data. This protocol is not a productsold by the Company. The software protocol was created by Aclarion for insertion within a pre-existing software file format and is downloadedonto the MRS by the MRS owner, for use within the MRSâ€™s operating system environment. Currently, our software protocol is compatiblewith only certain MRS models and operating systems available from SIEMENS, as those SIEMENS models specifically provide for user-definedcustomizations available for running our custom pulse sequences on SIEMENS MRS equipment.Â Data Transfer.Â Data is routinely transferredfrom MR scanners to externally hosted cloud post-processors in many settings and applications, with an existing market of products andprotocols for doing so. Aclarion provides MR imaging providers two options for data transfer: (1) a licensed proprietary imaging datatransfer platform provided by AMBRAÂ® Health, and (2) NOCIWEBÂ®, a custom developed web-interface developed and offered by Aclarion.Â NOCISCAN-LS Post-ProcessorSuite.Â The NOCISCAN-LS PostProcessor Suite is comprised of the products that Aclarion currently markets and sells. The post-processor technology requires MRS examdata acquired only according to Aclarionâ€™s proprietary MRS exam protocols. The Suite is comprised of two software products thatinteract with each other:Â Â Â· NOCICALC-LSÂ® receives the raw un-processed NOCISCAN-LS 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-LS is Registered as a Class I Medical Device with the FDA. Â Â Â Â Â· NOCIGRAMÂ® further processes the NOCICALC-LS 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 â€œNOCI+â€ result) versus non-painful (indicated as a â€œNOCI-â€œ 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-LS report with reference to certain MRI images of the related patientâ€™s lumbar spine. The NOCIGRAM-LS report is provided to the physician to aid in the physicianâ€™s diagnosis and treatment planning. NOCIGRAM is commercially available in the United States as â€œClinical Decision Support Softwareâ€ under the 21st Century Cures Act, and as such is not considered a medical device nor regulated by the FDA. Â Â Â 3Â Â Â Clinical EvidenceÂ We have pursued a clinicalstudy (the â€œGornet Studyâ€) 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 reimbursementcodes and change existing treatment pathways would be limited.Â In a clinical study sponsoredby us, and authored by, among others, a spine surgeon who has a financial interest in the Company. and published in the European SpineJournal in April 2019, it was shown that 97% of the treated patients met the criteria for significant clinical improvement, where alldiscs identified as painful by NOCISCAN-LS were included in the surgical treatment. This compared to 54% of surgical patients achievingclinically significant improvement when discs identified as painful by NOCISCAN-LS were omitted from the surgical treatment, or discsidentified as not painful by NOCISCAN-LS were included in the treatment. Some authors of this study had a financial relationship withAclarion, who sponsored the study.Â This clinical study included139 chronic low back pain patients who collectively underwent a NOCISCAN-LS exam across 623 lumbar discs. Seventy-three patients underwentsurgical intervention, consisting of fusion or disc replacement, and reached six months follow up. Clinical improvement post surgicallywas evaluated using the industry standard Oswestry Disability Index (â€œODIâ€), and the Visual Analog Scale (â€œVASâ€).ODI evaluates patient disability on a scale of 1-100 with a higher score indicating less impairment. VAS evaluates subjective pain ona scale of 1-10 with a lower score indicating less pain. Significant clinical improvement in the study was defined as a 15-point improvementin ODI and a 2-point improvement in VAS. NOCISCAN-LS data was not used in surgical decision making.Â Post-operatively, patientswere separated into various groups for analysis. One group consisted of patients where the surgical intervention included every disc thatwas identified by NOCISCAN-LS as painful. This group consisted of 36 patients with 26 undergoing a one-level surgical procedure and 10undergoing 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.Â In another group consistingof 13 patients, a disc identified as painful by NOCISCAN-LS was not included in the surgical intervention. In this group only 54% (7 of13) of patients met the criteria for clinically

significant improvement.Â In April 2023, Aclarionadvanced the evidence of our technology with a peer-reviewed journal article detailing the Gornet 2-year outcomes, published in the EuropeanSpine Journal. The 2-year outcomes were durable with 1-year outcomes previously published in 2019. At 2-years follow-up, 85% of patientsimproved when disc(s) identified as consistent with pain by our technology were included in a surgical treatment, compared to only 63%of patients when disc(s) identified as consistent with pain were not treated or disc(s) identified as consistent without pain were treated.Â We believe the resultsof this study indicate that using NOCISCAN-LS data to help determine the appropriate level for surgical intervention will significantlyimprove the outcomes for patients undergoing spine surgery for back pain. However, the Gornet Study was a single, relatively small, clinicalstudy at a single clinical center sponsored by us, and authored by, among others, a spine surgeon who has a financial interest in theCompany, and there can be no assurance that the results of such study accurately support our conclusions related to the market opportunityof our products.Â Competitive LandscapeÂ We believe our main competitionfor diagnosing disc pain are the PD Test and SPECT â€“ CT.Â Since MRIs are consideredthe current standard for lumbar imaging, â€œSPECT â€“ CTâ€ requires an MRI, a CT-Scan, and an injection of a radioactivedye followed by a period of time for circulation of the dye. We believe the radioactive dye that is injected is aimed at binding to inflammatorymarkers that make the inflammation markers visible to the CT-Scan. However, we believe the inflammation markers have not been shown tospecifically correlate with pain. Because of the extra cost, time and radiation exposure when compared to MRS and our belief that SPECTâ€“ CT does not bind to specific known pain biomarkers, we do not believe that SPECT â€“ CT will play a major role in diagnosingDLBP.Â Â Â 4Â Â Â As set forth above, aPD Test has many issues. We believe the most significant issue impacting the future use of the PD Test is the growing evidence that thePD Test causes long term harm to the patient by accelerating degeneration of the normal control discs that are a required component ofthe PD Test. We believe this issue will create significant hesitation for spine surgeons to use a PD Test which will leave them, and otherclinicians, with a void in information about whether a disc is painful.Â We believe the advantagesNOCISCAN-LS delivers against this competitive landscape to address the needs of the marketplace are significant and include the following:Â Â Â· Published clinical trial indicating improved surgical outcomes when surgically treated discs were identified as consistent with pain by our technology; Â Â Â Â Â· Noninvasive study that is delivered with minimal risk and no pain; Â Â Â Â Â· Objective results that are quantifiable; Â Â Â Â Â· Core technology that identifies biomarkers shown to be linked to pain and structural integrity of intervertebral discs; Â Â Â Â Â· Software product that leverages the ubiquitous install base of compatible MRI scanners so that no new hardware is required; and Â Â Â Â Â· Potential diagnostic to evaluate the efficacy of regenerative therapies to treat degenerative discs with conservative measures such as PT, chiropractic interventions, steroid injections, etc., to impact outcomes. Â Because of the advantagesof Aclarionâ€™s solution as well as the issues associated with the limited availability of alternatives for patients and clinicians,we believe NOCISCAN-LS can become the standard of care in diagnosing DLBP prior to a surgical intervention. We will continue to expandclinical registries and data in support of the efficacy of our product.Â Intellectual PropertyÂ PatentsÂ Aclarion has an intellectualproperty portfolio consisting of 22 U.S. Patents, 17 Foreign Patents, 6 pending U.S. patent applications, and 7 pending Foreign patentapplications. This portfolio includes patents assigned to Aclarion and patents exclusively licensed from the Regents of the Universityof California. Many of the patents in our patent portfolio relate to aspects of our NOCISCAN-LS product suite and the related disc MRSexam itself, as well as to broader applications of our technologies to other applications for MRS. We may expand our portfolio into alternativeapproaches for pain diagnosis, in particular DLBP diagnosis, such as including using labeled molecular antibodies for imaging localizedpain. The Company is not aware of any third-party intellectual property rights that might threaten or prevent our ability to market productsor services without infringing such third-party intellectual property rights.Â TrademarksÂ The Company holds multiple trademarks for itsprevious corporate brand name as well as for its key products and brands (â€œÂ®â€ designates registered trademark, â€œâ„¢â€designates unregistered trademark under common law protection). With respect to involved meanings, the recurrent prefix term â€œNOCIâ€is derived from Latin origins for â€œpainâ€ e.g. nerves that report pain are called â€œnociceptors. These marks include:NOCIMEDÂ®, NOCISCANÂ®, NOCIGRAMÂ®, NOCISCOREÂ®, NOCICALCâ„¢, NOCI+â„¢, NOCI-â„¢, NOCImildâ„¢, NOCIWEBâ„¢,SI-SCOREâ„¢, VIRTUAL DISCOGRAMâ„¢.Â Â Â Â 5Â Â Â Market OpportunityÂ The current NOCISCAN-LSproduct addresses the $10 billion that is spent in the U.S. on spine fusion procedures annually. Our early clinical evidence points toa marked improvement in surgical outcomes when discs identified as consistent with pain by our technology are included in the surgicaltreatment. We believe this market is actionable now, and a significant portion of the proceeds of this offering will be directed towardscommercializing this market opportunity. However, our early clinical evidence is supported by a single (relatively small) clinical studyat 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 ourproducts (See â€œClinical Evidenceâ€ above.)Â As the commercializationprocess progresses, Aclarion plans to track patients through clinical registries in order to build on our early clinical evidence. Weexpect to use these registries to track NOCISCAN-LS patients regardless of what treatment path they may follow. Presently, NOCISCAN-LShas 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 includes allsurgical interventions, not just fusion and disc replacement procedures. We believe that if we are able to correlate specific MRS findingsto improved surgical outcomes for all spine surgeries, this will expand the size of the market opportunity in the U.S. from $10 billionto roughly $40 billion, inclusive of pre-surgical conservative therapy costs. However, there can be no assurance that we will be ableto correlate specific MRS findings on all spine surgeries, or even if we do, that we would be successful in expanding our market to allspine surgeries.Â Our objective for NOCISCAN-LSis to address the entire low back and neck pain market which at $134.5 billion annually, represents the largest amount of healthcare dollarsspent to treat any disease. To address this market, our current algorithms will need to expand to include advanced machine learning techniquesthat incorporate multiple data inputs in addition to the chemical composition of discs. These additional inputs will need to be correlatedto clinical outcomes for treatments ranging from physical therapy to regenerative therapies to surgical interventions. This process isalready underway as we have been selected as a participant in a $150 million, NIH funded study (the â€œStudyâ€), which is focusedon evaluating the most promising data inputs for predicting the optimal treatment path for back pain patients. The Study will cover anumber of protocols for the treatment of LBP, including NOCISCAN-LS. We will derive no revenue from the Study, but all results will beavailable to us.Â In addition to participationin major external studies such as the NIH BACPAC initiative, we expect to create our own internal data by adding patients undergoing conservativeand regenerative treatment plans to our clinical

registries, and then correlating NOCISCAN-LS results to outcomes in order to leverageAI to associate spectroscopy signals with the optimal treatment pathway. If our internal data demonstrates what we believe to be clinicaleffectiveness of our technology, we intend to expand our marketing opportunity to the management of all low back and neck pain patients,thereby increasing our potential market to $134.5 billion in the United States. However, there can be no assurance that our internal datawill demonstrate the clinical effectiveness of our technology on all back and neck pain patients, or even if we do, that we will be successfulin marketing our technology to such patients.Â Current Market LimitationÂ Because we believe thatspectroscopy is not widely used for any clinical purposes today, there are practical limitations to the market opportunity that must beaddressed. We believe the two biggest limitations may be the lack of deployment of spectroscopy software across the installed base ofexisting MRIs worldwide, and the fact that only certain MR scanner models are compatible with our technology. For compatible MRI sitesthat do not currently have spectroscopy software installed, the onetime cost of the software ranges from $25,000 to $50,000. Currently,our NOCISCAN-LS platform is only compatible with certain MRI scanner models provided by SIEMENS, of which there are an estimated 1,500in the United States, and 4,320 worldwide. We plan to collaborate with other MRI scanner vendors, as well as SIEMENS, to establish compatibilitywith their respective scanners and MRS capabilities for use with our products. That allows us to include discounted pricing on spectroscopysoftware for MRI sites interested in providing DLBP patients with the Nociscan-LS offering.Â Â Â 6Â Â Â Reimbursement by ThirdParty PayersÂ â€œCurrent ProceduralTerminologyâ€, more commonly known as CPTÂ® (â€œCPTâ€), refers to a medical code set created and maintained by the AmericanMedical Association (â€œAMAâ€) and used by providers of healthcare services to bill insurance companies for their work. All newmedical devices and services are required to secure CPT codes to receive payment from government and private commercial payers.Â Based on the strengthof the improvement in surgical outcomes from the Gornet study (see â€œOverviewâ€, â€œClinical Evidenceâ€ above), weapplied to the CPT committee for Category III codes to cover Nociscan reimbursement. On January 1, 2021, Category III CPT Codes becameeffective. CPT code 609T was established to cover payment to the imaging center and CPT code 611T was established to cover payment tous for the use of NOCISCAN-LS.Â Category III codes representthe first step in the reimbursement process. It also starts a five-year period in which we are required to demonstrate that the medicalcommunity needs (â€œClinical Needsâ€) the NOCISCAN-LS product. Clinical Needs would be demonstrated to the CPT Committee basedon the volume at which our codes are billed by imaging centers and physicians. In addition to demonstrating that there is a Clinical Need,we also are required to show that NOCISCAN-LS is clinically effective as indicated by patients having better outcomes when NOCISCAN-LSreports are used to help guide surgical treatments. We expect to show clinical effectiveness through a combination of clinical registriesand clinical studies that build upon our published clinical study the CPT committee used to create our Category III CPT codes. There canbe no assurance that we will be able to demonstrate Clinical Needs, and if we do not, our business would be adversely affected.Â In addition to the coreCPT codes that provide payment to the imaging center and to us, the AMA has approved two additional Category III codes. The first is CPTcode 610T which covers the process of transmitting the raw spectroscopy biomarker data from the MRI scanner to our software for analysis.This code is for payment to the imaging center and is bundled with CPT code 609T, which means the code can be billed but no additionalpayments beyond 609T will be made by government payers. Although additional payment by commercial payers is possible, we believe it isunlikely. The second is CPT code 612T, which is billed by the ordering physician and paid to the ordering physician for interpreting thereport.Â The 611T Code is thesole Code under which we will derive revenue.Â Regulatory FilingsÂ The NOCISCAN-LS Post-ProcessorSuite consists of two software products that interact with each other, NOCICALC-LSÂ® and NOCIGRAM-LSÂ®.Â NOCICALC-LS receivesand processes the acquired disc MRS data to calculate levels of degenerative pain biomarkers. In conjunction with our regulatory consultants,we determined NOCICALC-LS to be a â€œClass I 510(k)-exemptâ€ medical device subject only to registration listing requirementswith no pre-market review required by the FDA for clearance or approval. As such, in accordance with FDA regulations, NOCICALC-LS is registeredwith the FDA as an exempt Class I device.Â The process to determinewhether a product can be considered a Class I â€œexemptâ€ medical device consists of self-determining whether the product isadequately described by one of the existing categories classified by the FDA. In consultation with our regulatory consultants, we determinedthat the product Classification â€œCalculator/Data Processing Module, for Clinical Use,â€ adequately described our NOCICALC-LSproduct. Our registration filing is available for review at this link; Establishment Registration and Device Listing (fda.gov).Â We believe NOCIGRAM isnot considered a medical device as it meets the exclusion criteria of the 21st Century Cures Act for Clinical Support Software. Underthe Cures Act provision, a software product is not considered a device if it meets the following four elements:Â Â Â· 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; Â Â Â Â Â· Intended 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); Â Â Â Â Â· Intended for the purpose of supporting or providing recommendations to a health care professional about prevention, diagnosis, or treatment of a disease or condition; and Â Â Â Â Â· Intended 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. Â Â Â 7Â Â Â Management has evaluatedNOCIGRAM-LS against these four elements and believes NOCIGRAM meets each of the four criteria.Â However, although webelieve our 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-LS falls under the CDS software exemptionto 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 doesnot agree, our business would be severely negatively impacted.Â For commercializationoutside the United States, in particular the European Union (â€œEUâ€) and United Kingdom (â€œUKâ€), the Company, inconjunction 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 (â€œDOCâ€) under the Medical DeviceDirective (MDD) EU 93/42/ECC filed by us as part of a dossier with a qualified EU Representative. Since self-certification was completedby the Company, the EU adopted Medical Device Regulation (EU) 2017/745, known as MDR, that went into effect on July 16, 2021. Under thesenew regulations, we believe NOCISCAN to be considered a Class II(a) device that requires re-certification for CE mark by a Notified Body.The MDR was amended with EU 2023/607 to extend the validity of the MDD self certified CE mark to December 31, 2028 under specific conditions.The first step was to make an application to a Notified Body by May 26, 2024. Notified Bodies carry out tasks related to conformity assessmentprocedures set out in the applicable

legislation, when a third party is required. Class II(a) device certification is subject to additionalrequirements 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 have engaged TUV SUD as our Notified Body for this purposeand have made the application prior to the May 26, 2024 deadline. The next step to allow the extension of the MDD CE mark is to have asigned agreement with the Notified Body by Sept. 26, 2024. This agreement is in process. The final step is to obtain a MDR CE mark byDec. 31, 2028. Certain aspects of the new MDR also place new requirements on all medical devices related to quality management systemand post-market surveillance of our products. Consistent with the aforementioned, we are currently in compliance with the updated requirementsof QMS and post-market surveillance from the MDR. We believe the actions we are taking are sufficient to support the continuance of ourcommercial activities in the EU under our CE mark without adverse penalties or other consequences.Â 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 largelyfollows the CE marking regulations to include permitting use of the same submissions for approval. The major difference post-Brexit isthat CE marking is regulated by the EU and UKCA marking is regulated by the UK MHRA. MHRA has announced it will accept CE marks extendedunder EU 2023/607 until July 2025. At that time, the company will need to transition to the new UK Medical Device Regulation. At thistime, the UK Medical Device Regulation is undergoing change, but it appears that they may follow the device classification rules as theMDD rather than the MDR. If that is the case, we will be able to self-certify in the UK. Consistent with the aforementioned, we maintainongoing compliance in the UK. We believe our activities are sufficient to support the continuance of our commercial activities in theUK under our CE mark without adverse penalties or other consequences. The Company expects to meet all requirements for UKCA marking.Â CommercializationÂ The issuance of CategoryIII codes and satisfaction of regulatory requirements for marketing starts the commercialization phase which will be the primary use ofproceeds from this offering. The commercialization process in support of moving temporary Category III codes to permanent Category I codesconsists of the following key activities:Â Â Â· Identifying and supporting Key Opinion Leader (â€œKOLâ€) spine surgeons and radiologists to help secure local payer coverage decisions and surgical society support for our technology; Â Â· Expanding the network of imaging centers and surgeons using NOCISCAN-LS in each market such that the technology is widely available to patients covered by payers; Â Â· Supporting surgeons, radiologists, Physical Medicine and Rehabilitation physicians, physical therapists, regenerative therapy physicians and medical device companies that address low back pain to initiate studies and report results; Â Â· Building and expanding clinical registries to provide real world evidence of better outcomes when using Nociscan to help determine which discs to treat; and Â Â· Pursuing value-based care contracts to share in the profits that result from the improved surgical outcomes we believe our technology enables in DLBP patients. Â Â Â 8Â Â Â Our primary near-termgrowth strategy is to secure payer contracts (including insurance companies, self- insured employers, Medicare, Medicaid, workmenâ€™scompensation boards et. al.) to cover our Category III CPT codes. We believe that with favorable payer coverage, the Company has the opportunityto more efficiently engage spine surgeons and imaging centers that will adopt our technology.Â The Company currentlygenerates the vast majority of its revenue directly from patients paying out of pocket.Â In order to effectivelycommercialize our technology, the Company has completed its initial plan to gain the support of up to ten leading spine surgeons as KeyOpinion Leaders (KOL) who believe Nociscan technology will help them with surgical decisions in their practices. These KOL surgeons areleaders in their field and will be assisting the Company in generating important clinical data in support of Nociscan, and using thatdata to help the Company in discussions with payers to secure positive payment decisions for our Category III CPT codes.Â Based primarily on ourKOL surgeons and the strength of physician engagement in markets, the Company is prioritizing the following markets:Â Â 1. NYC Metropolitan Area Â 2. San Francisco, CA Â 3. Chicago, IL Â 4. Phoenix, AZ Â 5. Miami, FL Â 6. Denver and Colorado Springs, CO Â 7. Detroit, MI Â 8. Indianapolis Â Once a positive localpayment decision is secured in a geographical area, we intend to place a market manager and a team of business development professionalsinto 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 increasinggeographical coverage. We believe increasing our footprint in each market will grow volume and revenue through increased pressure on payersto expand positive coverage decisions across all of the varied plans associated with each payer.Â Recent DevelopmentsÂ Initial Payer CoverageDecisionsÂ In June and July 2024,the Company announced initial payer coverages of Nociscan by AXA and Aviva in London, UK in conjunction with The London Clinic, one ofthe UKâ€™s largest and most renowned independent hospitals. AXA and Aviva is each a leading provider of private medical insurancein the UK. In August 2024 the Company announced their third payer coverage of Nociscan by Vitality in London, UK in conjunction with TheLondon Clinic. With the addition of coverage by Vitality, payer coverage for Nociscan is now available from three major private medicalinsurance groups in the UK, a global healthcare market with more than nine million residents.Â Publication ofGornet StudyÂ As discussed above, inApril 2019, the initial results of the clinical Gornet Study were published in the European Spine journal. We have pursued the GornetStudy to demonstrate the benefits of our technology to surgeons, imaging centers, third party payers, and patients.Â On April 24, 2023, theCompany announced the publication in the European Spine Journal of two-year durability data as a follow up to the initial Gornet Study.Â The multi-year, singlesite clinical trial comprised 78 patients who received surgery for DLBP following standard clinical work-up including MRI and provocativediscography. Nociscan was performed on all patients but was not available in the surgical decision-making process. The patient outcomeswere evaluated using the Oswestry Disability Index (ODI) scoring scale (100 points), a common clinical outcomes measure for low back pain,where surgical success was defined using an industry-standard improvement of 15 points or more between surgeries that were concordantversus discordant with Nociscan results. Surgical success rates at 2 years illustrates a 22 percentage point improvement between the twogroups. The results suggest that Nociscan provides valuable new information that can help physicians successfully treat DLBP.Â Both clinical studieswere study sponsored by us. The principal author of these studies is a spine surgeon who has a financial interest in the Company. Otherauthors of these studies also have a financial relationship with Aclarion.Â Â Â 9Â Â Â White Lion EquityLine AgreementÂ On October 9, 2023, the Company entered into anequity line common stock purchase agreement (the â€œEquity Line Purchase Agreementâ€) and a related registration rights agreementwith White Lion Capital, LLC (â€œWhite Lionâ€). Pursuant to the Equity Line Agreement, the Company has the right, but not theobligation to require White Lion to purchase, from time to time, up to $10,000,000 in aggregate gross purchase price of newly issued sharesof the Companyâ€™s Common Stock, subject to certain limitations and conditions set forth in the Equity Line Purchase Agreement.Â On November 27, 2024, the Company and White Lionentered into an amendment to the Equity Line Purchase Agreement that (subject to

stockholder approval) among other things, extended theexpiration date of the Equity Line Purchase Agreement from December 31, 2024 to December 31, 2025.Â If the foregoing amendment is approved by stockholders,it is anticipated that the Company may sell shares of Common Stock to White Lion from time-to-time over a sales period that expires December31, 2025. The number of shares ultimately offered for sale to White Lion under the Equity Line Purchase Agreement is dependent upon thenumber of shares we elect to sell to White Lion under the Equity Line Purchase Agreement. The actual number of shares of Common Stockthat are sold to White Lion may depend based on a number of factors, including the market price of our Common Stock during the time thatthe Equity Line Purchase Agreement in is effect. The actual gross proceeds the Company may derive from the Equity Line Purchase Agreementmay be less than $10.0Â million, which may impact our future liquidity. Because the price per share of each share sold to White Lionwill fluctuate during the sales period, it is not currently possible to predict the number of shares that will be sold or the actual grossproceeds to be raised in connection with those sales, if any.Â The Company currently has effective registrationstatements to register for resale by White Lion 22,500,000 shares of Common Stock. White Lion may ultimately purchase all or some of theseshares. After White Lion has acquired shares under the Equity Line Purchase Agreement, it may sell all, some or none of those shares.Sales to the Selling Securityholder by us pursuant to the Equity Line Purchase Agreement may result in substantial dilution to the interestsof other holders of our Common Stock.Â The sale of a substantial number of shares toWhite Lion, or anticipation of such sales, could make it more difficult for us to sell equity or equity-related securities in the futureat a time and at a price that we might otherwise desire. The number of shares of our Common Stock ultimately offered for resale by WhiteLion is dependent upon the number of shares of Common Stock issued to White Lion pursuant to the Equity Line Purchase Agreement. Dependingon a variety of factors, including market liquidity of our Common Stock, the issuance of shares to White Lion may cause the trading priceof our Common Stock to decline.Â In consideration for the commitments of WhiteLion under the original Equity Line Purchase Agreement, as described above, the Company issued to White Lion 187,500 pre-split shares(11,719 post-split) of Common Stock as commitment shares, having a value of $75,000 based upon the closing sale price of the Common Stockon October 6, 2023. In consideration for the commitments of White Lion under the amendment as described above, the Company issued to WhiteLion 560,915 shares of Common Stock as commitment shares, having a value of $100,000 based upon the Nasdaq minimum price closing saleprice of the Common Stock determined as of November 27, 2024.Â Alphatec Strategic PartnershipÂ On January 8, 2024, we announced that we had executeda strategic partnership agreement solidifying our previously signed non-binding letter of intent with ATEC Spine, Inc., the wholly ownedoperating subsidiary of Alphatec Holdings, Inc. (â€œATECâ€). ATEC is a medical device company dedicated to revolutionizing theapproach to spine surgery through clinical distinction.Â The agreement contemplates a multi-step strategicpartnership. Under the agreement, ATEC and Aclarion will work together to identify Key Opinion Leader (KOL) surgeons to evaluate our Nociscantechnology. Feedback from these surgeons will inform clinical evaluations designed to assess the utility of Nociscan in conjunction withEOS imaging, the foundation of ATECâ€™s AlphaInformatiX platform. Assuming positive synergies, ATEC and Aclarion will co-market Nociscanin targeted markets. In exchange for select access to ATECâ€™s surgeon network for the evaluation and advancement of Nociscan, Aclarionwill provide ATEC with certain exclusive distribution rights to include Nociscan as part of an integrated procedural solution.Â Nasdaq Bid PriceNoticeÂ On April 8, 2024, wereceived a written notice (the â€œBid Price Noticeâ€) from the Listing Qualifications Department of The Nasdaq Stock Market (â€œNasdaqâ€)indicating that the Company was 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 â€œBid Price Requirementâ€).Â Â Â 10Â Â Â The Bid Price Notice did not result in the immediatedelisting of the Companyâ€™s Common Stock from The Nasdaq Capital Market.Â The Nasdaq Listing Rules require listed securitiesto maintain a minimum bid price of $1.00 per share and, based upon the closing bid price of the Companyâ€™s Common Stock for the 30consecutive business days for the period ending April 5, 2024, the Company no longer met this requirement.Â The Notice indicated that the Company will beprovided 180 calendar days (or until October 7, 2024) in which to regain compliance. We did not regain compliance with Rule 5550(a)(2)prior to the expiration of the initial 180 calendar day period on October 7, 2024. On October 8, 2024, we received from the Nasdaq staff(the â€œStaffâ€) written notification that our securities are subject to delisting from the Nasdaq Capital Market. We had anappeal hearing on October 10, 2024 before a Nasdaq hearings panel (the â€œPanelâ€) appeal the delisting notice from the Staff.While the appeal process is pending, the suspension of trading of our Common Stock will be stayed. Our Common Stock will continue to tradeon Nasdaq until the hearing process concludes and the Panel issues a written decision. The Panel has granted the Company an extensionuntil January 31, 2025 to demonstrate compliance with the Bid Price Requirement.Â At the Companyâ€™s special stockholdersâ€™meeting on September 23, 2024, the Companyâ€™s stockholders approved a proposal to grant discretionary authority to our board of directorsto (i) amend our certificate of incorporation to combine outstanding shares of our Common Stock into a lesser number of outstanding shares,or a â€œreverse stock split,â€ at a specific ratio within a range of one-for-five (1-for-5) to a maximum of a one-for-fifty (1-for-50)split, with the exact ratio to be determined by our board of directors in its sole discretion; and (ii) effect the reverse stock split,if at all, within one year of the date the proposal was approved by stockholders. At the Companyâ€™s annual stockholdersâ€™ meetingon December 31, 2024, the Companyâ€™s stockholders will vote on a separate proposal to grant discretionary authority to our boardof directors to (i) amend our certificate of incorporation to combine outstanding shares of our Common Stock into a lesser number of outstandingshares, or a â€œreverse stock split,â€ at a specific ratio within a range of one-for-five (1-for-5) to a maximum of a one-for-fourhundred (1-for-400) split, with the exact ratio to be determined by our board of directors in its sole discretion; and (ii) effect thereverse stock split, if at all, within one year of the date the proposal was approved by stockholders. The Company intends to implementa reverse stock split in the near future in order to assist with the Companyâ€™s compliance with Nasdaqâ€™s Bid Price Requirement.Â The Company intends to monitor the closing bidprice of its Common Stock and is considering its options to regain compliance with the Bid Price Requirement.Â Nasdaq StockholderEquity NoticeÂ On August 22, 2024, the Company received a letterfrom Nasdaq indicating that that the Company was not in compliance with the requirement to have at least $2,500,000 in stockholdersâ€™equity (the â€œStockholdersâ€™ Equity Requirementâ€). In its quarterly report on Form 10-Q for the period ended June 30,2024, the Company reported stockholdersâ€™ equity of $1,642,177, and, as a result, did not satisfy Listing Rule 5550(b)(1).Â Accordingly, the Staff determined to delist ourCommon Stock from Nasdaq. Nasdaqâ€™s letter provided the Company until August 29, 2024 to request an appeal of this determination.The Company requested a hearing before the Panel to appeal the delisting notice from the Staff. The hearing request stays any suspensionor delisting action pending the conclusion of the hearing process and the expiration of any additional extension period granted by thePanel following the hearing.Â We had an appeal hearing on October 10, 2024 beforethe

Panel to appeal the delisting notice from the Staff. The Panel granted the Company an extension until January 31, 2025 to demonstratecompliance with the Stockholders' Equity Requirement. While the appeal process is pending, the suspension of trading of the Companyâ€™sCommon Stock will be stayed. Our Common Stock will continue to trade on Nasdaq until the hearing process concludes and the Panel issuesits final written determination.Â Â Â Â Â 11Â Â Â On November 14, 2024, the Company filed a QuarterlyReport on Form 10-Q for the nine months ending September 30, 2024, and reported stockholdersâ€™ equity of $2,509,785.Â The Company intends to take all reasonable measuresavailable to maintain compliance under the Nasdaq Listing Rules and remain listed on Nasdaq.Â Going Concern OpinionÂ Our working capital deficiency,stockholdersâ€™ deficit, and recurring losses from operations raise 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 dated February 20, 2024,on our financial statements for the year ended December 31, 2023, with respect to this uncertainty. Our ability to continue as a goingconcern will require us to obtain additional funding.Â As of September 30, 2024, we had cash of approximately$1.3 million. We believe our cash on hand will be sufficient to fund current operating plans into December 2024. The Company has basedthese estimates, however, on assumptions that may prove to be wrong, and could spend available financial resources much faster than wecurrently expect. The Company will need to raise additional funds to continue funding our technology development and commercializationefforts over the following twelve months. Management has plans to secure such additional funding.Â As a result of the Companyâ€™s recurring lossesfrom operations, and the need for additional financing to fund its operating and capital requirements, there is uncertainty regardingthe Companyâ€™s ability to maintain liquidity sufficient to operate its business effectively, which raises substantial doubt as tothe Companyâ€™s ability to continue as a going concern.Â Assuming the receipt of the maximum amount ofnet proceeds from this offering, we believe our cash resources would be sufficient to fund our current operating plans into the [***]quarter of 2025. We have based these estimates, however, on assumptions that may prove to be wrong, and we could spend our available financialresources much faster than we currently expect and need to raise additional funds sooner than we anticipate. If we are unable to raiseadditional capital when needed or on acceptable terms, we would be forced to delay, reduce, or eliminate our technology development andcommercialization efforts.Â Exchange AgreementsÂ In May, September and November 2023 the Company issued $2,594,118 aggregateprincipal amount of unsecured non-convertible notes to certain accredited investors.Â Between January 22 andJanuary 29, 2024, the Company entered into a series of exchange agreements (the â€œExchange Agreementsâ€) with the accreditedinvestors to exchange principal and accrued interest on these notes for shares of Common Stock. Pursuant to the Exchange Agreements, theCompany issued an aggregate of 644,142 shares of Common Stock in exchange for $1,519,779 principal and accrued interest on the notes.Following these exchanges, the remaining outstanding balance of principal and interest on the notes was $1,145,037.Â On August 14, 2024, the Company entered into anexchange agreement (the â€œExchange Agreementâ€) with the accredited investors to exchange $930,052 of principal and accruedinterest on the September 2023 Notes for 930 shares of newly issued Series B convertible preferred stock (â€œSeries B Preferred Stockâ€)at a purchase price of $1,000 per share. The Series B Preferred Stock is convertible into Common Stock at an initial conversion price(â€œConversion Priceâ€) of $0.234 per share.Â Series C PreferredStock FinancingÂ On September 30, 2024,the Company entered into a securities purchase agreement with accredited investors for a convertible preferred stock and warrants financing.The Company has received $1,000,000 of gross proceeds in connection with the closing of this financing. The Company issued 1,000 sharesof Series C convertible preferred stock (â€œSeries C Preferred Stockâ€) at a purchase price of $1,000 per share of Series C PreferredStock. The Series C Preferred Stock is convertible into Common Stock at an initial conversion price (â€œConversion Priceâ€) of$0.1759 per share of Common Stock. The Company also issued warrants exercisable for 5,685,049 shares of Common Stock with a 5.5 year termand an initial exercise price of $0.1759 per share.Â Â Â Â 12Â Â Â Summary of Risk FactorsÂ Investing in oursecurities involves a high degree of risk. You should carefully consider the risks described in â€œRiskFactorsâ€ beginning on page 20 before making a decision to invest in our common stock. If any of these risks actuallyoccurs, our business, financial condition, results of operations and prospects would likely be materially, adversely affected. Inthat event, the trading price of our common stock could decline, and you could lose part or all of your investment. Below is asummary of some of the principal risks we face:Â Â Â· We are not currently in compliance with the minimum stockholdersâ€™ equity 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. Â Â Â Â Â· 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. Â Â Â Â Â· We, as well as the auditors of our financial statements, have previously expressed substantial doubt about our ability to continue as a going concern, which may hinder our ability to obtain further financing; have previously expressed substantial doubt about our ability to continue as a going concern, which may hinder our ability to obtain further financing. Â Â Â Â Â· Following the receipt of the net proceeds from this offering, we believe our cash resources would be sufficient to fund our current operating plans into the first quarter of 2025. 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. Â Â Â Â Â· We have identified material weaknesses 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. Â Â Â Â Â· 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. Â Â Â Â Â· 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. Â Â Â Â Â· 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. Â Â Â Â Â· 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. Â Â Â 13Â Â Â Â Â Â Â Â Â· 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. Â Â Â Â Â· 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. Â Â Â Â Â· 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. Â Â Â Â Â· 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. Â Â Â Â Â· 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. Â Â Â Â Â· To reach the full market potential of our product, we will need to leverage advanced machine learning and artificial intelligence technologies (â€œAIâ€) 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. Â Â Â Â Â· 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. Â Â Â Â Â· We may fail to continue to meet the listing standards of The Nasdaq Capital Market whether or not this offering occurs. Even if this offering occurs, this offering could cause our stock price to fall, which could result in us being delisted from The Nasdaq Capital Market. Failure to maintain the listing of our Common Stock with a U.S. national securities exchange could adversely effect the liquidity of our Common Stock. Â Implications of Beingan Emerging Growth Company and a Smaller Reporting CompanyÂ We qualify as an â€œemerging growth companyâ€as defined in the Jumpstart our Business Startups Act of 2012 (the â€œJOBS Actâ€). An emerging growth company may take advantageof specified reduced reporting and other burdens that are otherwise applicable generally to public companies. These provisions include:Â Â Â· 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 â€œManagementâ€™s Discussion and Analysis of Financial Condition and Results of Operationsâ€ disclosure; Â Â Â Â Â· 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 â€œSarbanes-Oxley Actâ€);Â Â Â 14Â Â Â Â Â Â Â Â Â· an exemption from compliance with any new requirements adopted by the Public Company Accounting Oversight Board (the â€œPCAOBâ€) requiring mandatory audit firm rotation; Â Â Â Â Â· reduced disclosure about executive compensation arrangements; and Â Â Â Â Â· an exemption from the requirement to seek non-binding advisory votes on executive compensation or golden parachute arrangements. Â We may take advantageof 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 April 2022 IPO, (b) in which we havetotal annual gross revenue of at least $1.235 billion or (c) in which we are deemed to be a large accelerated filer, which means the marketvalue of our Common Stock that is held by non-affiliates exceeds $700 million as of the prior December 31st, and (2) the date on whichwe have issued more than $1.0 billion in non-convertible debt during the prior three-year period.Â We have taken advantageof the reduced reporting requirements in this prospectus and in the documents incorporated by reference into this prospectus. Accordingly,the information contained herein may be different from the information you receive from other public companies that are not emerging growthcompanies.Â The JOBS Act permitsan emerging growth company such as us to take advantage of an extended transition period to comply with new or revised accounting standardsapplicable to public companies until those standards would otherwise apply to private companies.Â We are also a â€œsmallerreporting companyâ€ meaning that the market value of our stock held by non-affiliates is less than $700 million and our annual revenuewas less than $100 million during the most recently completed fiscal year. We may continue to be a smaller reporting company if either(i) the market value of our stock held by non-affiliates is less than $250 million or (ii) our annual revenue was less than $100 millionduring the most recently completed fiscal year and the market value of our stock held by non-affiliates is less than $700 million. Ifwe are a smaller reporting company at the time we cease to be an emerging growth company, we may continue to rely on exemptions from certaindisclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company we may chooseto present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K and, similar to emerginggrowth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation.Â Our Corporate InformationÂ We were formed underthe 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 principalexecutive 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 incorporatedby reference and is not a part of this prospectus.Â Â Â 15Â Â Â INFORMATION REGARDINGFORWARD-LOOKING STATEMENTSÂ This prospectus and thedocuments incorporated by reference in this prospectus include forward-looking statements, which involve risks and uncertainties. Theseforward-looking statements can be identified by the use of forward-looking terminology, including the terms â€œbelieve,â€ â€œestimate,â€â€œproject,â€ â€œanticipate,â€ â€œexpect,â€ â€œseek,â€ â€œpredict,â€ â€œcontinue,â€â€œpossible,â€ â€œintend,â€ â€œmay,â€ â€œmight,â€ â€œwill,â€ â€œcould,â€ wouldâ€or â€œshouldâ€ or, in each case, their negative, or other variations or comparable terminology. These forward-looking statementsinclude all matters that are not historical facts. They appear in a number of places throughout this prospectus and the documents incorporatedby reference in this prospectus, and include statements regarding our intentions, beliefs or current expectations concerning, among otherthings, our product candidates, research and development, commercialization objectives, prospects, strategies, the industry in which weoperate and potential collaborations. We derive many of our forward-looking statements from our operating budgets and forecasts, whichare based upon many detailed assumptions. While we believe that our assumptions are reasonable, we caution that it is very difficult topredict the impact of known factors, and, of course, it is impossible for us to anticipate all factors that could affect our actual results.Forward-looking statements should not be read as a guarantee of future performance or results and may not be accurate indications of whensuch performance or results will be achieved. In light of these risks and uncertainties, the forward-looking events and circumstancesdiscussed in this prospectus may not occur and actual results could differ materially from those anticipated or implied in the forward-lookingstatements.Â Forward-looking statementsspeak only as of the date of this prospectus. You should not put undue reliance on any forward-looking statements. We assume no obligationto update forward-looking statements to reflect actual results, changes in assumptions or changes in other factors affecting forward-lookinginformation, except to the extent required by applicable laws. If we update one or more forward-looking statements, no inference shouldbe drawn that we will make additional updates with respect to those or other forward-looking statements.Â You should read thisprospectus, the documents incorporated by reference in this prospectus, and the documents that we reference in this prospectus and havefiled with the SEC as exhibits to the registration statement of which this prospectus is a part with the understanding that our actualfuture results, levels of activity, performance and events and circumstances may be materially different from what we expect. All forward-lookingstatements are based upon information available to us on the date of this prospectus.Â By their nature, forward-lookingstatements involve risks and uncertainties because they relate to events and depend on circumstances that may or may not occur in thefuture. We caution you that forward-looking statements are not guarantees of future performance and that our actual results of operations,financial condition, business and prospects may differ materially from those made in or suggested by the forward-looking statements containedin this prospectus. In addition, even if our results of operations, financial condition, business and prospects are consistent with theforward-looking statements contained (or incorporated by reference) in this prospectus, those results may not be indicative of resultsin subsequent periods.Â Forward-looking statementsnecessarily involve risks and uncertainties, and our actual results could differ materially from those anticipated in the forward-lookingstatements due to a number of factors, including those set forth below under â€œRisk Factorsâ€ and elsewhere in this prospectus.The factors set forth below under â€œRisk Factorsâ€ and other cautionary statements made in this prospectus should be read andunderstood as being applicable to all related forward-looking statements wherever they appear in this prospectus. The forward-lookingstatements contained in this prospectus represent our judgment as of the date of this prospectus. We caution readers not to place unduereliance on such statements. Except as required by law, we undertake no obligation to update publicly any forward-looking statements forany reason, even if new information becomes available or other events occur in the future. All subsequent written and oral forward-lookingstatements attributable to us or persons acting on our behalf are expressly qualified in their entirety by the cautionary statements containedabove and throughout this prospectus.Â You should read thisprospectus, the documents incorporated by reference in this prospectus, and the documents that we reference in this prospectus and havefiled as exhibits to the registration statement of which this prospectus is a part completely and with the understanding that our actualfuture results may be materially different from what we expect. We qualify all of our forward-looking statements by these cautionary statements.Â Â Â Â 16Â Â Â THE OFFERINGÂ Common Stock Offered by Us: [***] shares of our Common Stock. The assumedcombined public offering price for each share of Common Stock and accompanying Common Warrants is $[***], based on the closing priceof the Companyâ€™s Common Stock on [***], 2024, as reported on the Nasdaq Capital Market.Â We are also registering up to [***] shares of Common Stock issuableupon exercise of the Common Warrants, and Pre-Funded Warrants. Â Â Pre-Funded Warrants Offered by Us: We are also offering to those purchasers, if any, whose purchase of the Common Stock in this offering would result in the purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% (or at the election of the purchaser, 9.99%) of our outstanding Common Stock immediately following consummation of this offering, the opportunity to purchase, if they so choose, Pre-Funded Warrants in lieu of the Common Stock that would otherwise result in ownership in excess of 4.99% (or 9.99% as applicable) of our Common Stock. Â The purchase price of each Pre-Funded Warrant and accompanying Common Warrant will equal the price per share of Common Stock and accompanying Common Warrant being sold to the public in this offering, minus $0.001, and the exercise price of each Pre-Funded Warrant will be $0.001 per share. Â Each Pre-Funded Warrant will be immediately exercisable and may be exercised at any time until exercised in full. There is no expiration date for the Pre-Funded Warrants. There is no established trading market for the Pre-Funded Warrants, and we do not expect a market to develop. We do not intend to apply for a listing for the Pre-Funded Warrants on any securities exchange or other nationally recognized trading system. Without an active trading market, the liquidity of the Pre-Funded Warrants will be limited. Â To better understand the terms of the Pre-Funded Warrants, you should carefully read the â€œDescription of Securities We Are Offeringâ€ section of this prospectus. Â Â Series A Common Warrants Offered by Us: Each share of our Common Stock and each Pre-Funded Warrant to purchase one share of our Common Stock is being sold together with a Series A Common Warrant to purchase one share of our Common Stock. Each Series A Common Warrant will have an exercise price of $[***] per share, will be exercisable at any time beginning on the Stockholder Approval Date (the â€œInitial Exercise Dateâ€) and will expire on the five year anniversary of the Initial Exercise Date.Â The shares of Common Stock and Pre-Funded Warrants, and the accompanying Common Warrants, as the case may be, can only be purchased together in this offering but will be issued separately. Â This prospectus also relates to the offering of the shares of Common Stock issuable upon exercise of the Common Warrants. Because we will issue a Series A Common Warrant for each share of Common Stock and for each Pre-Funded Warrant sold in this offering, the number of Series A Common Warrants sold in this offering will not change as a result of a change in the mix of the shares of our Common Stock and

Pre-Funded Warrants sold.Â Â Â Â 17Â Â Â Â Series B Common Warrants Offered by Us: Each share of our Common Stock and each Pre-FundedWarrant to purchase one share of our Common Stock is being sold together with a Series B Common Warrant to purchase one share of our CommonStock. Each Series B Common Warrant will have an exercise price of $[***] per share, will be exercisable at any time beginning on theInitial Exercise Date and will expire on the two and one-half (2.5) year anniversary of the Initial Exercise Date.Â The shares of Common Stock and Pre-Funded Warrants, and the accompanying Common Warrants, as the case may be, can only be purchased together in this offering but will be issued separately. Â This prospectus also relates to the offering of the shares of Common Stock issuable upon exercise of the Series B Common Warrants. Because we will issue a Series B Common Warrant for each share of Common Stock and for each Pre-Funded Warrant sold in this offering, the number of Common Warrants sold in this offering will not change as a result of a change in the mix of the shares of our Common Stock and Pre-Funded Warrants sold. Â Â Â Shares of Common Stock Outstanding Prior to this Offering: 10,431,159 shares as of November 14, 2024 Â Â Shares of Common Stock Outstanding After this Offering(1): [***] shares of Common Stock, assuming no sale of any Pre-Funded Warrantsand no exercise of the Common Warrants being offered in this offering. To the extent that Pre-Funded Warrants are sold, the number ofshares of Common Stock sold in this offering will be reduced on a one-for-one basis. Â Â Use of Proceeds: We estimate that the net proceeds of thisoffering based upon an assumed combined public offering price of $[***] per share and accompanying Common Warrant, which was the closingprice of our Common Stock on the Nasdaq Capital Market on [***], 2024, after deducting underwriting discounts and commissions and estimatedoffering expenses payable by us, will be approximately $[***] million, assuming no exercise of the Common Warrants. We will receive additionalproceeds from the Common Warrants and minimal proceeds from Pre-Funded Warrants (collectively, the â€œWarrantsâ€) to the extentsuch Warrants are exercisable for cash once exercisable.Â We intend to use the net proceeds from this offering, together with our existing cash, to redeem all outstanding shares of our Series B Preferred Stock and Series C Preferred Stock, each at a redemption price per share equal to $1,000 plus all accrued but unpaid dividends on each such share, with the remaining net proceeds to be used to build out the product platforms, expand our sales and marketing efforts, and for general and administration expenses and other general corporate purposes. See â€œUse of Proceeds.â€Â Â Â Â Â Â Â 18Â Â Â Â Lock-Up Agreements: We, and each of our officers and directors have agreed, subject to certainexceptions, not to sell, offer, agree to sell, contract to sell, hypothecate, pledge, grant any option to purchase, make any short saleof, or otherwise dispose of or hedge, directly or indirectly, any shares of our capital stock or any securities convertible into or exercisableor exchangeable for shares of capital stock, for a period of [***] ([***]) days after the date of this prospectus, without the prior writtenconsent of Dawson James Securities, Inc. See â€œUnderwritingâ€ for additional information. Â Â Dividend Policy: We currently intend to retain any future earnings and do not anticipate paying cash dividends in the foreseeable future. Any future determination to pay cash dividends will be at the discretion of our board of directors and will depend upon our financial condition, operating results, capital requirements, any contractual restrictions and such other factors as our board of directors may deem appropriate. Â Â Risk Factors: Investing in our securities involves significant risks. See â€œRisk Factorsâ€ on page 20 of this prospectus and under similar headings in the documents incorporated by reference into this prospectus for a discussion of the factors you should carefully consider before deciding to invest in our securities. Â Â Nasdaq Capital Market Symbol: Common Stock â€œACONâ€. IPO Warrants â€œACONWâ€. Â We do not intend to apply for the listing of the Common Warrants, or the Pre-Funded Warrants, on any national securities exchange or other trading system. Without an active trading market, the liquidity of the Warrants will be limited. Â Â Transfer Agent and Registrar: VStock Transfer, LLC Â The number of shares outstanding after this offeringis based on 10,431,159 shares of our Common Stock outstanding as of November 14, 2024, and excludes:Â Â Â· 136,123 shares of our Common Stock issuable upon the exercise of outstanding stock options granted under our 2015 Stock Plan, Â Â· 33,334 shares of our Common Stock issuable upon the exercise of outstanding stock options granted under our 2022 Stock Plan, Â Â· 130,093 shares of our Common Stock reserved for future grant under our 2022 Stock Plan, Â Â· 10,350,000 shares of our Common Stock issuable upon the exercise of our outstanding February 2024 public offering warrants, Â Â· 5,685,049 shares of our Common Stock issuable upon the exercise of our outstanding September 2024 warrants, Â Â· 155,610 shares of Common Stock issuable upon the exercise of our outstanding IPO Warrants, Â Â· 551,815 shares of Common Stock issuable upon the exercise of outstanding privately placed warrants, Â Â· 10,825 shares of Common Stock reserved for issuance upon the exercise of an outstanding IPO underwriter representative common stock warrant. Â Â· approximately 3,974,581 shares of Common Stock which may be issued upon conversion of our outstanding Series B Convertible Preferred Stock at the current conversion price of $0.234, Â Â· approximately 5,685,049 shares of Common Stock which may be issued upon conversion of our outstanding Series C Convertible Preferred Stock at the current conversion price of $0.1759, and Â Â· up to $6.8 million worth of Common Stock that may be sold in the future by us to White Lion from time to time pursuant to the Equity Line Purchase Agreement. Â Â Â Â 19Â Â Â RISK FACTORSÂ Risk Factors.Â Investing in our securities involves a highdegree of risk. You should carefully consider the risks and uncertainties described below, together with the other information containedin this prospectus, before making a decision to invest in our securities. If any of the following events occur, our business, financialcondition and operating results may be materially adversely affected. In that event, the trading price of our securities could decline,and you could lose all or part of your investment. The risks included here are not exhaustive or exclusive. Other sections of this prospectusmay include additional factors which could adversely affect our business, results of operations and financial performance. We operatein a very competitive and rapidly changing environment. New risk factors emerge from time to time, and it is not possible for managementto predict all such risk factors, nor can it assess the impact of all such risk factors on our business or the extent to which any factor,or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements.Â Risks Relating tothis OfferingÂ You will experience immediate dilution as aresult of this offering and may experience additional dilution in the future.Â The public offering pricefor the Common Stock offered hereby will be substantially higher than the net tangible book value per share of our Common Stock immediatelyafter this offering. If you purchase Common Stock in this offering, you will incur substantial and immediate dilution in the net tangiblebook value of your investment. Net tangible book value per share represents the amount of total tangible assets less total liabilities,divided by the number of shares of our Common Stock then outstanding. To the extent that options that are currently outstanding are exercised,there will be further dilution to your investment. We may also issue additional Common Stock, options and other securities in the futurethat may result in further dilution of your shares of our Common Stock.Â Except as otherwiseprovided in the Warrants, holders of Warrants issued in this offering will have no rights as stockholders of our shares of Common Stockuntil such holders exercise their Warrants.Â The Warrants offeredin this offering do not confer any rights of Common Stock ownership on their holders, such as voting rights, but

rather merely representthe right to acquire Common Stock at a fixed price. Specifically, a holder of a Pre-Funded Warrant may exercise the right to acquire CommonStock and pay a nominal exercise price of $0.001 at any time, a holder of a Series A Common Warrant may exercise the right to acquireCommon Stock and pay an exercise price of $[***] beginning on the Initial Exercise Date, and a holder of a Series B Common Warrant mayexercise the right to acquire Common Stock and pay an exercise price of $[***] beginning on the Initial Exercise Date. Upon exercise ofthe Warrants, the holders thereof will be entitled to exercise the rights of a holder of shares of Common Stock only as to matters forwhich the record date occurs after the exercise date.Â Â Â Â Â Â Â 20Â Â Â Future sales of our Common Stock, or the perceptionthat such sales may occur, could depress the trading price of our Common Stock.Â After the completion of this offering, weexpect to have [***] shares of our Common Stock outstanding, which may be resold in the public market immediately after thisoffering. We, each of our officers and directors have signed lock-up agreements for a period of [***] days following the date ofthis prospectus, subject to specified exceptions. See â€œUnderwriting.â€Â The underwriter may, in its sole discretion andwithout notice, release all or any portion of the shares of our Common Stock subject to lock-up agreements. As restrictions on resaleend, the market price of our Common Stock could drop significantly if the holders of these shares of our Common Stock sell them or areperceived by the market as intending to sell them. These factors could also make it more difficult for us to raise additional funds throughfuture offerings of our Common Stock or other securities.Â We have broad discretion in the use of thenet proceeds we receive from this offering and may not use them effectively.Â Our management will have broad discretion in theapplication of the net proceeds we receive in this offering, including for any of the purposes described in the section entitled â€œUseof Proceeds,â€ and you will not have the opportunity as part of your investment decision to assess whether our management is usingthe net proceeds appropriately. Because of the number and variability of factors that will determine our use of our net proceeds fromthis offering, their ultimate use may vary substantially from their currently intended use. The failure by our management to apply thesefunds effectively could result in financial losses that could have a material adverse effect on our business and cause the price of ourCommon Stock to decline. Pending their use, we may invest our net proceeds from this offering in short-term, investment-grade, interest-bearingsecurities. These investments may not yield a favorable return to our stockholders.Â There is no publicmarket for the Pre-Funded Warrants or Common Warrants in this offering.Â There is no establishedpublic trading market for the Pre-Funded Warrants or Common Warrants, and we do not expect a market to develop. In addition, we do notintend to apply for listing of the Pre-Funded Warrants or Common Warrants on any securities exchange or recognized trading system.Â Absence of a publictrading market for the Pre-Funded Warrants or Common Warrants may limit your ability to resell the Pre-Funded Warrants or Common Warrants.Â There is no establishedtrading market for the Pre-Funded Warrants or Common Warrants to be issued pursuant to this offering, and they will not be listed fortrading on Nasdaq or any other securities exchange or market, and the Pre-Funded Warrants or Common Warrants may not be widely distributed.Purchasers of the Pre-Funded Warrants or Common Warrants may be unable to resell the Pre-Funded Warrants or Common Warrants or sell themonly at an unfavorable price for an extended period of time, if at all.Â Â Â Â Â 21Â Â Â The market price ofour Common Stock may never exceed the exercise price of the Common Warrants issued in connection with this offering.Â The Common Warrants beingissued in connection with this offering become exercisable upon issuance and will expire five years from the date of issuance. The marketprice of our Common Stock may never exceed the exercise price of the Common Warrants prior to their date of expiration. Any Warrants notexercised by their date of expiration will expire worthless and we will be under no further obligation to the Warrant holder.Â We have a limitednumber of authorized shares of common stock available for issuance and will need to seek stockholder approval to amend our charter toeither effect an increase in our authorized shares of common stock or a reverse split. The issuance of additional securities if we obtainthe required amendment approval will cause investors to experience dilution.Â Following this offering,there will only be minimal authorized but unissued or reserved shares of our common stock. We do not have a sufficient number of authorizedshares to permit exercise of the Common Warrants or to undertake the additional equity financing that we will need to fund developmentof our product pipeline. We have agreed to seek stockholder approval of an amendment to our certificate of incorporation to effect anincrease in our authorized shares of common stock or a reverse split in an amount sufficient to permit the exercise in full of the CommonWarrants offered hereby, which if approved will provide us with additional available shares. If we do not receive the requisite stockholderapproval to enable us to issue equity in the future, our operations will likely be materially adversely impacted. There are risks associatedwith effecting a reverse split, including a decline in the market price of our common stock and the possibility of certain stockholdersowning â€œodd lotsâ€ of less than 100 shares, which may be more difficult to sell, or require greater transaction costs per shareto sell, than shares in â€œround lotsâ€ of even multiples of 100 shares. In addition, because holders of our common stock haveno preemptive rights to purchase or subscribe for any unissued stock of our company, the availability of a greater number of authorizedshares, whether as a result of a reverse split or an increase in the authorized number, could result in additional dilution to our existingstockholders.Â Risks related to our Nasdaq listingÂ We are not currently in compliance with the$1.00 minimum bid price requirement of the Nasdaq Capital Market and a delisting could limit the liquidity of our stock, increase itsvolatility, and hinder our ability to raise capital.Â On April 8, 2024, we received a written notice(the â€œBid Price Noticeâ€) from the Listing Qualifications Department of The Nasdaq Stock Market (â€œNasdaqâ€) indicatingthat the Company was not in compliance with the $1.00 Minimum Bid Price requirement set forth in Nasdaq Listing Rule 5550(a)(2) for continuedlisting on The Nasdaq Capital Market (the â€œBid Price Requirementâ€).Â The Bid Price Notice did not result in the immediatedelisting of the Companyâ€™s Common Stock from The Nasdaq Capital Market.Â The Nasdaq Listing Rules require listed securitiesto maintain a minimum bid price of $1.00 per share and, based upon the closing bid price of the Companyâ€™s Common Stock for the 30consecutive business days for the period ending April 5, 2024, the Company no longer met this requirement.Â The Notice indicated that the Company will beprovided 180 calendar days (or until October 7, 2024) in which to regain compliance. We did not regain compliance with Rule 5550(a)(2)prior to the expiration of the initial 180 calendar day period on October 7, 2024. On October 8, 2024, we received from the Nasdaq staff(the â€œStaffâ€) written notification that our securities are subject to delisting from the Nasdaq Capital Market. We had anappeal hearing on October 10, 2024 before a Nasdaq hearings panel (the â€œPanelâ€) appeal the delisting notice from the Staff.While the appeal process is pending, the suspension of trading of our Common Stock will be stayed. Our Common Stock will continue to tradeon Nasdaq until the hearing process concludes and the Panel issues a written decision. The Panel has granted the Company an extensionuntil January 31, 2025 to demonstrate compliance with the Bid Price Requirement.Â Â Â Â 22Â Â Â At the Companyâ€™s special stockholdersâ€™meeting on September 23, 2024, the Companyâ€™s stockholders approved a proposal to grant discretionary authority to our board of directorsto (i) amend our certificate of incorporation to combine outstanding

shares of our Common Stock into a lesser number of outstanding shares,or a â€œreverse stock split,â€ at a specific ratio within a range of one-for-five (1-for-5) to a maximum of a one-for-fifty (1-for-50)split, with the exact ratio to be determined by our board of directors in its sole discretion; and (ii) effect the reverse stock split,if at all, within one year of the date the proposal was approved by stockholders. The Company intends to implement a reverse stock splitin the near future in order to assist with the Companyâ€™s compliance with Nasdaqâ€™s Bid Price Requirement. At the Companyâ€™sannual stockholdersâ€™ meeting on December 31, 2024, the Companyâ€™s stockholders will consider approval of a separate proposalto grant discretionary authority to our board of directors to (i) amend our certificate of incorporation to combine outstanding sharesof our Common Stock into a lesser number of outstanding shares, or a â€œreverse stock split,â€ at a specific ratio within a rangeof one-for-five (1-for-5) to a maximum of a one-for-four hundred (1-for-400) split, with the exact ratio to be determined by our boardof directors in its sole discretion; and (ii) effect the reverse stock split, if at all, within one year of the date the proposal wasapproved by stockholders.Â The Company intends to implement a reverse stocksplit in the near future in order to assist with the Companyâ€™s compliance with Nasdaqâ€™s Bid Price RequirementÂ On August 22, 2024, the Company received a letterfrom Nasdaq indicating that that the Company was not in compliance with the requirement to have at least $2,500,000 in stockholdersâ€™equity (the â€œStockholdersâ€™ Equity Requirementâ€). In its quarterly report on Form 10-Q for the period ended June 30,2024, the Company reported stockholdersâ€™ equity of $1,642,177, and, as a result, did not satisfy Listing Rule 5550(b)(1).Â Accordingly, the Staff determined to delist ourCommon Stock from Nasdaq. Nasdaqâ€™s letter provided the Company until August 29, 2024 to request an appeal of this determination.The Company requested a hearing before the Panel to appeal the delisting notice from the Staff. The hearing request stays any suspensionor delisting action pending the conclusion of the hearing process and the expiration of any additional extension period granted by thePanel following the hearing.Â We had an appeal hearing on October 10, 2024 beforethe Panel to appeal the delisting notice from the Staff. The Panel granted the Company an extension until January 31, 2025 to demonstratecompliance with the Stockholders' Equity Requirement. While the appeal process is pending, the suspension of trading of the Companyâ€™sCommon Stock will be stayed. Our Common Stock will continue to trade on Nasdaq until the hearing process concludes and the Panel issuesits final written determination.Â On November 14, 2024, the Company filed a QuarterlyReport on Form 10-Q for the nine months ending September 30, 2024, and reported stockholdersâ€™ equity of $2,509,785.Â The Panel has the right to reconsider the termsof this exception based on any event, condition or circumstance that exists or develops that would, in the opinion of the Panel, makecontinued listing of the Companyâ€™s securities on Nasdaq inadvisable or unwarranted.Â There can be no assurances that the Company willbe able to maintain its listing on the Nasdaq Capital Market.Â If our Common Stock isdelisted by Nasdaq, our Common Stock may be eligible for quotation on an over-the-counter quotation system or on the pink sheets. Uponany such delisting, our Common Stock would become subject to the regulations of the SEC relating to the market for penny stocks. A pennystock is any equity security not traded on a national securities exchange that has a market price of less than $5.00 per share. The regulationsapplicable to penny stocks may severely affect the market liquidity for our Common Stock and could limit the ability of shareholders tosell securities in the secondary market. In such a case, an investor may find it more difficult to dispose of or obtain accurate quotationsas to the market value of our Common Stock, and there can be no assurance that our Common Stock will be eligible for trading or quotationon any alternative exchanges or markets.Â Delisting from Nasdaqcould adversely affect our ability to raise additional financing through public or private sales of equity securities, would significantlyaffect the ability of investors to trade our securities and would negatively affect the value and liquidity of our Common Stock. Delistingcould also have other negative results, including the potential loss of confidence by employees, the loss of institutional investor interestand fewer business development opportunities.Â Â Â Â 23Â Â Â Risks related to financial, operational, commercial and manufacturingmattersÂ The auditors of ourDecember 31, 2023 and 2022 financial statements have expressed substantial doubt about our ability to continue as a going concern, whichmay hinder our ability to obtain further financing.Â Our past working capital deficiency, stockholdersâ€™deficit and recurring losses from operations raised substantial doubt about our ability to continue as a going concern. As a result, ourindependent registered public accounting firm included an explanatory paragraph in its report on our financial statements for the yearended December 31, 2023, with respect to this uncertainty. Our existing cash will only be sufficient to fund current operating plans intoDecember 2024. If we are unable to raise capital when needed or on acceptable terms, we would be forced to delay, reduce, or eliminateour technology development and commercialization efforts.Â We have incurred significantnet losses since inception and anticipate that we will continue to incur net losses for the foreseeable future and may never achieve ormaintain profitability.Â Since our inception, we have incurred significantnet losses. Our net losses were $4,911,374 and $7,068,593 for the years ended DecemberÂ 31, 2023, and 2022, respectively. As of September30, 2024, we had an accumulated deficit of $49,272,739. To date, we have devoted our efforts toward securing financing, building and evolvingour technology platform, and complying with regulatory requirements as well as initiating marketing efforts for our products. We expectto continue to incur significant expenses and operating losses for the foreseeable future. We anticipate that our expenses will increasesubstantially if, and as, we:Â Â Â· hire and retain additional sales, accounting and finance, marketing and engineering personnel; Â Â Â Â Â· build out our product pipeline; Â Â Â Â Â· add operational, financial and management information systems and personnel; and Â Â Â Â Â· maintain, expand, protect and enforce our intellectual property portfolio. Â To become and remain profitable, we must enhancethe marketing and commercial acceptance of our products. This will require us to be successful in a range of challenging activities, andour expenses will increase substantially as we bring these products to market. We may never succeed in any or all of these activitiesand, 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 wouldddecrease the value of our company and could impair our ability to raise capital, develop new products, expand our business or continueour operations. A decline in the value of our company also could cause stockholders to lose all or part of their investment.Â Â Â Â Â 24Â Â Â We have identified a material weakness in ourinternal control over financial reporting. Failure to maintain effective internal controls could cause our investors to lose confidencein us and adversely affect the market price of our Common Stock. If our internal controls are not effective, we may not be able to accuratelyreport our financial results or prevent fraud.Â 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 thedesign or operation of our controls, and all internal control systems, no matter how well designed and operated, can provide only reasonableassurance that the objectives of the control system are met. Because there are inherent limitations in all control systems, there canbe no assurance that all control issues have been or will be detected. If we

are unable, or are perceived as unable, to produce reliablefinancial reports due to internal control deficiencies, investors could lose confidence in our reported financial information and operatingresults, which could result in a negative market reaction and a decrease in our stock price.Â The Company will be required, pursuant to Section404, to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting. Suchreport will not be required until our second annual report filed on Form 10-K. We will need to disclose any material weaknesses identifiedby our management in our internal control over financial reporting. As an â€œemerging growth company,â€ we will avail ourselvesof the exemption from the requirement that our independent registered public accounting firm attest to the effectiveness of our internalcontrol over financial reporting under Section 404. However, we may no longer avail ourselves of this exemption when we cease to be anâ€œemerging growth company.â€ When our independent registered public accounting firm is required to undertake an assessment ofour internal control over financial reporting, the cost of our compliance with Section 404 will correspondingly increase. Our compliancewith applicable provisions of Section 404 will require that we incur substantial accounting expense and expend significant managementtime 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 registeredpublic 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 ExchangeCommission, or SEC, or other regulatory authorities, which would require additional financial and management resources.Â If we continue to have material weaknesses inour internal control over financial reporting, if we are unable to comply with the requirements of Section 404 in a timely manner, ifwe are unable to assert that our internal control over financial reporting is effective, or if our independent registered public accountingfirm is unable to express an opinion as to the effectiveness of our internal control over financial reporting, we may be late with thefiling of our periodic reports, investors may lose confidence in the accuracy and completeness of our financial reports and the marketprice of our Common Stock could be negatively affected.Â We will need additionalfunding, 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.Â We believe our current cash resources will besufficient to fund current operating plans into the third quarter of 2024, approaching our final maturity repayment of our unsecured non-convertiblenote, which is due in September 2024. We expect our expenses to increase in connection with our ongoing activities, particularly as wecontinue to invest in sales, marketing and engineering resources and bring our products to market. Furthermore, since the closing of ourIPO, we have incurred additional costs associated with operating as a public company. We will need additional funding to complete thedevelopment of our full product line and scale products with a demonstrated market fit.Â Building and scalingtechnology products is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessaryuser 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 becommercially available for many years, if at all. Accordingly, we will need to continue to rely on additional financing to achieve ourbusiness objectives. Adequate additional financing may not be available to us on acceptable terms, or at all.Â Â Â Â 25Â Â Â Raising additionalcapital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our technologiesand product candidates.Â We may seek additionalcapital through a combination of public and private equity offerings, debt financings, strategic partnerships and alliances and licensingarrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownershipinterest 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 limitationson our ability to incur additional debt, limitations on our ability to acquire or license intellectual property rights and other operatingrestrictions that could adversely impact our ability to conduct our business. If we raise additional funds through strategic partnershipsand alliances and licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, or our otherproduct candidates, or grant licenses on terms unfavorable to us.Â We are highly dependent on our senior managementteam and key personnel, and our business could be harmed if we are unable to attract and retain personnel necessary for our success.Â We are highly dependent on our senior managementand key personnel. Our success will depend on our ability to retain senior management and to attract and retain qualified personnel inthe future, including sales and marketing professionals, engineers, scientists, clinical trial specialists and other highly skilled personneland 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.Â Competition for skilled personnel in our marketis intense and may limit our ability to hire and retain highly qualified personnel on acceptable terms, or at all. To induce valuableemployees to remain at our company, in addition to salary and cash incentives, we have issued stock options that vest over time. The valueto employees of stock options that vest over time may be significantly affected by fluctuations in our stock price that are beyond ourcontrol, and may at any time be insufficient to counteract more lucrative offers from other companies. Despite our efforts to retain valuableemployees, members of our management and other key personnel may terminate their employment with us on short notice. Our employment arrangementswith our employees provide for at-will employment, which means that any of our employees could leave our employment at any time, withor without notice. We also do not maintain â€œkey manâ€ insurance policies on the lives of these individuals or the lives ofany of our other employees.Â Our MR data post-processing products currentlydepend on compatible use with only a limited number of MR scanners that are provided only by one manufacturer of MR devices.Â Our MR data post-processing software productsare only compatible for post-processing disc MRS data acquired via certain scanner models and operating configurations provided only byone, third-party scanner vendor - SIEMENS. There are risks associated with our reliance on SIEMENS, and/or the MR service providers whoown and operate the SIEMENS scanners, to maintain those scanners and their operating configurations in a manner that continues to supportcompatibility with our products. There are also risks that current compatible scanner platforms may become incompatible as a result ofchanges made to those scanners by SIEMENS, or by the scanner owner or related service provider, which would frustrate our ability to continuesupporting that MR provider customer with our products. There are also risks that these SIEMENS scanners do not perform reliably as intendedor expected in performing data acquisition exams as required by our post-processing products, which would also frustrate the ability forour products to perform as intended. There is also a risk that SIEMENS loses its install base of compatible MR

Scanners due to cannibalizationby other non-compatible replacement scanner sales or fails to grow its install base of those compatible scanners, which could adverselyaffect the number and locations of compatible scanners for our own market share and penetration. Manifestations of these risks becomingactually realized in the marketplace could harm our business, financial condition, and results of operations. We are not subject to anyexclusivity agreement or obligations with SIEMENS, nor do we have any fee sharing, royalty, or other exchange of moneys or payments betweenus and Siemens. The nexus for our focused relationship with Siemens resulted from our determination that SIEMENS scanner models were optimallypositioned to support our product. We have had a collaborative relationship with Siemens since 2011 and have been party to a CollaborativeAgreement with Siemens since October of 2017, The Collaborative Agreement is terminable.at any time by either party if such party is ofthe opinion that the goals of the Collaborative Agreement cannot be achieved for technical, economic and/or clinical reasons. If Siemenswere to terminate its relationship with the Company, it would have a material adverse effect on our business.Â Â Â Â 26Â Â Â If we are not successful in enhancing awarenessof our technology, driving adoption across our current target population, increasing referrals from surgeons and clinicians, and expandingthe population of eligible patients, our sales, business, financial condition and results of operations will be negatively affected.Â Our business depends on our ability to successfullymarket our technology, which includes increasing the number of patients scanned with our technology, increasing adoption of our technologyand driving utilization of our technology by surgeons and clinicians. Additionally, our technology is primarily recommended and implementedto provide advanced diagnosis and management of spine and back pain, in particular, for diagnosing painful discs causing discogenic lowback pain. Therefore, we are dependent on widespread market adoption of our technology. While we intend to expand the population of patientswe can provide with our diagnostic technology as well as increase the number of physicians, surgeons and clinicians that can prescribetechnology, there can be no assurance that we will succeed.Â The commercial success ofour technology will continue to depend on a number of factors, including the following:Â Â Â· the actual and perceived effectiveness, safety and reliability, and clinical benefit, of our technology, especially relative to alternative diagnostic systems and devices; Â Â· the prevalence and severity of any adverse patient events involving the use of our technology; Â Â· the degree to which physicians, surgeons and clinicians, patients and imaging centers adopt our technology; Â Â· the availability, relative cost and perceived advantages and disadvantages of alternative technologies, or other diagnostic or treatment methods, for spine and back pain; Â Â· the results of additional clinical and other studies relating to the health, safety, economic or other benefits of our technology; Â Â· 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; Â Â· 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; Â Â· 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; Â Â· our ability to obtain, maintain, protect, enforce and defend our intellectual property rights, in and to our technology; Â Â· our ability to maintain compliance with all legal and regulatory requirements, including those applicable to our technology; Â Â· 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; Â Â· the establishment and continued reimbursement coverage of and adequate payment for the use of our technology and Â Â· our ability to continue to attract and retain key personnel. Â Â If we fail to successfully market and sell ourtechnology cost-effectively and maintain and expand our market share, our sales, business, financial condition and results of operationswill be negatively affected.Â Our commercial success will continue to dependon 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. Â 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-goingcare 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-existingdiagnostic systems that are more established or an otherwise resistance to adopt new technologies or change current practices. Our abilityto grow sales of our technology and drive market acceptance will depend on successfully educating surgeons, physicians, clinicians, patientsand MR imaging facilities on the relative benefits of our Technology.Â Â Â 27Â Â Â We may be unable to compete successfully withother diagnostic options for low back pain, or may be unable to continue providing value for supporting new treatments that may not needthe diagnostic information our products provide.Â 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 â€“ 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 lumbarMR 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 extentthat these other platforms represent our primary competitors, they are mainly provided by large, well-capitalized companies with significantmarket 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, therecan be no assurance that other companies or institutions will not succeed in developing or marketing devices and products that are moreaccurate, useful, effective or safer than our technology or that would render our technology obsolete or noncompetitive.Â Adoption of our technology depends on positiveclinical data as well as clinician acceptance of the data and our products, and negative clinical data or perceptions among these clinicianswould harm our sales, business, financial condition, and results of operations.Â The rate of adoption and sales of our productsare heavily influenced by clinical data. We have published positive clinical data from an Institutional Review Board (â€œIRBâ€),approved more than 100 patient single center trial in a major peer-reviewed spine journal which showed both: (a) high diagnostic accuracyagainst provocation discography controls, and (b) much higher patient success outcomes for surgeries that treated discs identified aspainful 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 ofour products in currently approved patient populations and those to support label retention and expansion for our products, will demonstratediagnostic 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, financialcondition, and results of operations.Â If adequate reimbursement is not availablefor 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.Â Our ability to increase sales of our technologydepends, 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 reimbursementrates for those treatments. While we have secured certain reimbursement codes against which the use of our products can potentially bebilled, we do not yet currently bill any third-party payers directly for our technology. The cost of our customers using our technologyis currently being paid for by either: (i) billing patients to pay directly (ii) allocation at least in part against payments receivedby healthcare providers for other procedures conducted in association with the use of our technology, or (c) third-party payer reimbursementpayments to a several of our customers for less than 10 patients through the date of this prospectus. A failure to obtain wide coverageand adequate reimbursement for using our technology in conducting our new diagnostic procedures, or for clinicians providing ongoing patientcare based on or related to our diagnostic results could diminish our sales and affect our ability to sell our technology.Â Â Â Â 28Â Â Â If adequate reimbursement for our temporaryCategory III CMS Code designation for our products cannot be obtained or we are not successful in obtaining conversion to permanent CategoryI codes at an adequate reimbursement level, it would diminish our sales and would affect our ability to market our technology.Â On January 1, 2021, our Category III CPT Codesbecame effective. Category III codes represent the first step in the reimbursement process. The effectiveness of our Category III codescommenced a five-year period in which, in order to maintain our Category III status, we are required to demonstrate that the medical communityneeds (â€œClinical Needsâ€) the NOCISCAN product. Clinical Needs would be demonstrated to the CPT Committee based on the volumeat 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 reportsare used to help guide surgical treatments. We expect to show clinical effectiveness through a combination of clinical registries andclinical studies that build upon our published clinical study the CPT committee used to create our Category III CPT codes. However, ifwe are not able to demonstrate Clinical Needs, nor that NOCISCAN is clinically effective, our revenue would be limited to a direct patientpayment model, which will severely limit our ability to market our products and generate sufficient revenue to continue market our technology.Â Further, for us to obtain a conversion from ofour CPT codes from Category III to Category I, we will need to attract a significant larger number of surgeons and imaging centers toadopt our technology and thereby increase the volume of reimbursement claims data needed for the CPT committee to determine that our productis needed in the healthcare marketplace. In addition to generating clinical use volume, we will also need to demonstrate the ongoing clinicalefficacy of our products to secure adequate reimbursement from payers. A failure to convert Category III codes to Category I codes willultimately make us more dependent on a patient pay model which will significantly diminish our sales and affect our ability to marketour technology.Â Use of our technology requires appropriatetraining 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.Â 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 examfor the correctly indicated patients and anatomy, and properly interpreting the results from using our product as indicated under ourrelated IFUs. It also depends upon MR technicians and operators appropriately implementing and using our technology as indicated underour related IFUs. MR technicians and operators could also experience difficulty with the steps and techniques necessary to successfullyimplement and use our technology protocols. We cannot guarantee that all medical and MR technician professionals will have the necessaryskills and training, according to our instructions for use, or will sufficiently comply with that training and instructions for use inorder 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 continueto comply with that training in their on-going practice in using our technology. If physicians and surgeons utilize our technology incorrectlyor, without adhering to or completing all relevant training according to our instructions, the utility and value of our diagnostic productsand their related patient outcomes from on-going care following that diagnostic work-up may not be consistent with the outcomes achievedin our clinical studies or otherwise expected or desired by such care providers or the patients themselves. Adverse treatment outcomesthat could potentially arise from improper or incorrect use of our technology may negatively impact the perception of patient benefitand 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.Â We expect to increase the size of our organizationin 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.Â As of November 14, 2024 we had 5 full-time employees,2 part-time employees, 1 full-time consultant, and 3 part-time consultants. As our sales and marketing strategies develop, and as we transitioninto 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:Â Â Â· identifying, recruiting, integrating, maintaining and motivating additional employees; Â Â· managing our internal development efforts effectively, while complying with our contractual obligations to contractors and other third parties; and Â Â· improving our operational, financial and management controls, reporting systems and procedures. Â Â Â 29Â Â Â Our future financial performance and our abilityto successfully market and sell our technology will depend, in part, on our ability to effectively manage any future growth, and our managementmay also have to divert a disproportionate amount of attention away from day-to-day activities in order to devote a substantial amountof time to managing these growth activities.Â We may not be able to achieve or maintain satisfactorypricing and margins for our NOCISCAN disc MRS diagnostic software products and related services, which could harm our business and resultsof operations.Â Software products classified as medical

deviceshave 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 declinein the amount that third-party payers reimburse for diagnostic procedures using our technology or for clinicians providing ongoing patientcare related to the diagnostic information we provide. A decline in the amount that third-party payers reimburse our customers for ongoingpatient 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 investin 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 withan increase in our prices, our margins would erode and could harm our business, financial condition, and results of operations.Â Our results of operations may be harmed ifwe are unable to accurately forecast customer demand for our technologyÂ Our ability to accurately forecast demand forour products could be negatively affected by many factors, including (i) our potential failure to accurately manage or execute our expansionstrategy, (ii) new product introductions by competitors, (iii) an increase or decrease in customer demand for our products or for othercompeting products, (iv) our failure to accurately forecast customer adoption of new products, (v) unanticipated changes in general marketconditions or regulatory matters and (vi) weakening of economic conditions or consumer confidence in future economic conditions. Softwareprocessing capacity, data storage, and related computer hosting resources in excess of customer demand may result in financial write-downsor write-offs, which would cause our gross margin to be adversely affected and could impair the strength of our brand. Conversely, ifwe 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, thiscould result in lost sales and damage to our reputation and customer relationships. In addition, if we experience a significant increasein demand, additional computing and storage capacity and resources, and additional technical support personnel required to support theincreased demand may not be available when required or on terms that are acceptable to us, or at all, which may negatively affect oursales, business, financial condition, and results of operations.Â Risks related to government regulation andour industryÂ Our operations and technology are subject topervasive and continuing FDA regulatory requirements, and failure to comply with these requirements could harm our business, financialcondition and results of operations.Â 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 FDAmust determine that: (i) a proposed device is substantially equivalent to a legally-marketed predicate device, which includes a legalmarketed device that has been previously cleared through the 510(k) process, (ii) was legally marketed prior to May 28, 1976 (pre-amendmentsdevice), (iii) was legally marketed pursuant to an approved PMA and later down-classified, or (iv) is covered by a classification regulationcreated through the de novo review process.Â In the process of obtaining PMA approval, whichthe FDA could potentially require in the future for our products, the FDA must determine that a proposed device is safe and effectivefor its intended use based, in part, on extensive data, including, but not limited to, technical, preclinical, clinical study, manufacturingand 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.Â Â Â 30Â Â Â We believe that one of our products under theNOCISCAN Suite, NOCICALC, is a Class I 510(k)-exempt medical device, which only requires registration and no pre-market review with theFDA, and which we registered as such with the FDA. We also believe the other of our products in the suite, NOCIGRAM, is â€œClinicalDecision Support Softwareâ€ under the 21st Century Cures Act and as such, is not considered a medical device, and thusis 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 novoclassification, or 510(k) clearance is required for our products. If the FDA were to make such a determination, we would not be able tosell or market our products without or until securing such approval or clearance and may be subject to potential fines and other penaltiesor remedial actions for illegally marketing or selling an unapproved medical device, which would affect our sales, business, financialcondition, and results of operation.Â If we are unable to expand the labeling claimsfor using our technology to include additional indications, our growth potential could be harmed.Â We intend to seek expanded labeling claims forour technology in the future, including for example: (i) extending the intended indications for use to include disc MRS along the thoracicor cervical spine, (ii) incorporating certain MRI image post-processing along with MRS data post-processing, and (iii) real-time post-processingof MRS exam data during the exam itself via our software installed and operated within the MR scanner software environment (vs. our currentproducts which are for cloud-hosted post-processing of MRS data that is transferred to us, following the MRS exams, via our own remotecomputing resources). If regulatory clearance or approval is required to expand the use of our technology, and which clearance and approvalmay require clinical trial results, we could incur substantial costs and the attention of management could be diverted throughout thisprocess. However, there can be no assurance we will be able to obtain and maintain necessary clearance or approvals for additional usesof our technology, or even if obtained, that the broadened use of our technology would be accepted or adopted by intended users, thuslimiting the growth potential of our business.Â Our medical device products may be subjectto recalls, which could divert managerial and financial resources, harm our reputation and our business.Â The FDA has the authority to require the recallof medical device products in certain circumstances. A government mandated or voluntary product recall by us could occur because of devicemalfunctions or other adverse events, such as quality-related issues resulting from product operating malfunctions or defects. Any futurerecalls of our products could divert managerial and financial resources, harm our reputation and negatively impact our business.Â If we initiate a correction or removal of certainof our products from the market to reduce a risk to health posed by the device, we would be required to submit a Correction and Removalreport to the FDA and, in many cases, similar reports to other regulatory agencies. This report could be classified by the FDA as a devicerecall 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 todelay purchase decisions, cancel orders or decide not to purchase our products and could cause patients to lose trust in our technology.Â We may experience difficulties outside theUS in obtaining or maintaining regulatory clearance or approval, or exemptions therefrom, or in successfully gaining third-party reimbursementor marketing our technology, even if approved or otherwise legally marketed. Â Our NOCISCAN product suite was initially commercializedas a Class I medical device under European Commission regulations. The process did not require pre-market submission, review, or certificationby a Notified Body

in order to be CE marked. A â€œNotified Bodyâ€ is an organization designated by an EU country to assess theconformity of certain products before being placed on the market.Â Â Â 31Â Â Â For commercialization outside the United States,in particular the European Union (â€œEUâ€) and United Kingdom (â€œUKâ€), the Company, in conjunction with our regulatoryconsultants, determined NOCISCAN to be a Class I medical device, for which we secured a CE mark via self-certification. As such, we self-certifiedour product for the CE mark under a Declaration of Continuity (â€œDOCâ€) under the Medical Device Directive (MDD) EU 93/42/ECCfiled by us as part of a dossier with a qualified EU Representative. Since self-certification was completed by the Company, the EU adoptedMedical Device Regulation (EU) 2017/745, known as MDR, that went into effect on July 16, 2021. Under these new regulations, we believeNOCISCAN to be considered a Class II(a) device that requires re-certification for CE mark by a Notified Body. The MDR was amended withEU 2023/607 to extend the validity of the MDD self- certified CE mark to December 31, 2028 under specific conditions. The first step wasto make an application to a Notified Body by May 26, 2024. Notified Bodies carry out tasks related to conformity assessment proceduresset out in the applicable legislation, when a third party is required. Class II(a) device certification is subject to additional requirementsfor approval beyond our existing submissions, including requiring pre-market review and CE mark approval by a Notified Body, and whichmay require submission and approval of supportive clinical data. We have engaged TUV SUD as our Notified Body for this purpose and havemade the application prior to the May 26, 2024 deadline. The next step to allow the extension of the MDD CE mark is to have a signed agreementwith the Notified Body by Sept. 26, 2024. This agreement is in process. The final step is to obtain a MDR CE mark by Dec. 31, 2028. Certainaspects of the new MDR also place new requirements on all medical devices related to quality management system and post-market surveillanceof our products. Consistent with the aforementioned, We are currently in compliance with the updated requirements of QMS and post-marketsurveillance from the MDR. We believe the actions we are taking are sufficient to support the continuance of our commercial activitiesin the EU under our CE mark without adverse penalties or other consequences. However, there is a risk that one or more regulatory bodyor agency in the EU may determine otherwise, either with respect to our prior non-compliance that has since been corrected or with respectto the sufficiency of our corrective actions, and which could result in us incurring certain penalties or other consequences.Â If we are unable to receive CE mark approval froma Notified Body under the MDR by the December 31, 2028 grace period deadline, or are determined to be non-compliant with MDR regulationsnot subject to the grace period and therefore applicable to us as of December 31, 2028, we could lose our CE mark, and may become unableto continue promoting or selling our products for commercial use in the EU, UK, or other countries that relate their medical device regulationsto a CE mark.Â Â In conjunction with Brexit, medical devices inthe UK are no longer governed by CE regulations. As such, the UK has introduced the UKCA marking system which largely follows the CE markingregulations to include permitting use of the same submissions for approval. The major difference post-Brexit is that CE marking is regulatedby the EU and UKCA marking is regulated by the UK MHRA. MHRA has announced it will accept CE marks extended under EU 2023/607 until July2025. At that time, the company will need to transition to the new UK Medical Device Regulation. At this time, the UK Medical Device Regulationis undergoing change, but it appears that they may follow the device classification rules as the MDD rather than the MDR. If that is thecase, we will be able to self-certify in the UK. Consistent with the aforementioned, we maintain ongoing compliance in the UK. We believeour activities are sufficient to support the continuance of our commercial activities in the UK under our CE mark without adverse penaltiesor other consequences. However, there is a risk that one or more regulatory body or agency in the UK may determine otherwise, either withrespect to our prior non-compliance that we believe has been corrected or with respect to the sufficiency of those corrective actionsand which could result in us incurring certain penalties or other adverse consequences to our business. There can be no assurance thatwe 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.Â Sales of our technology outside of the UnitedStates will be subject to foreign regulatory requirements governing clinical studies and marketing approval, as well as additional post-marketrequirements. We would incur substantial expenses in connection with any international expansion. Additional risks related to operatingin foreign countries include:Â Â Â· differing, and potential changes in, regulatory requirements in foreign countries, including with respect to data privacy and security; Â Â· differing, and potential changes in, reimbursement regimes in foreign countries, including price controls; Â Â· unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements; Â Â· economic weakness, including inflation, or political instability in particular foreign economies and markets; Â Â· compliance with tax, employment, immigration and labor laws for employees living or traveling abroad; Â Â· foreign taxes, including withholding of payroll taxes;Â Â Â 32Â Â Â Â Â· foreign currency fluctuations, which could result in increased operating expenses or reduced revenue; Â Â· difficulties staffing and managing foreign operations; Â Â· workforce uncertainty in countries where labor unrest is more common than in the United States; Â Â· potential liability under the U.S. Foreign Corrupt Practices Act of 1977, as amended, or the FCPA, or comparable foreign regulations; Â Â· 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 Â Â· business interruptions resulting from geopolitical actions, including war and terrorism. Â These and other risks associated with internationaloperations that may harm our ability to attain or maintain profitable operations internationally, which would harm our growth potential.Â Furthermore, there are foreign privacy laws andregulations that impose restrictions on the collection, use, storage, disclosure, transfer and other processing of personal data, includinghealth information. For example, the European Union General Data Protection Regulation (â€œGDPRâ€), imposes stringent data protectionrequirements, including, for example, more robust disclosures to individuals, a strengthened individual data rights regime, shortenedtimelines for data breach notifications, limitations on retention of information, increased requirements pertaining to special categoriesof data, such as health data, and additional obligations regarding third-party processors in connection with the processing of the personaldata. Our failure to comply with the GDPR or other applicable foreign privacy laws or regulations or significant changes in the laws andregulations restricting our ability to obtain or use required patient information could significantly impact our business and our futurebusiness plans.Â If we fail to comply with fraud and abuse andother 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.Â Healthcare providers play a primary role in thedistribution, recommendation, ordering and purchasing of any of our products. Through our arrangements with healthcare professionals andhospital facilities, we are exposed to broadly applicable anti-fraud and abuse, anti-kickback, false claims and other healthcare lawsand regulations that may constrain our business, our arrangements and relationships with customers, and how we market, sell and distributeour marketed medical devices. We have a

compliance program, code of conduct and associated policies and procedures, but it is not alwayspossible to identify and deter misconduct by our employees, contractors, and other third parties, including our customers, and the precautionswe take to detect and prevent noncompliance may not be effective in protecting us from governmental investigations for failure to complywith applicable fraud and abuse or other healthcare laws and regulations.Â In the United States, we are subject to variousstate and federal anti-fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute and federal civil FalseClaims Act, or the FCA. Our relationships with physicians, other health care professionals and hospitals are subject to scrutiny underthese laws. There are also similar laws in other countries that we may become subject to if we expand internationally.Â The laws that may affect our ability to operateinclude, among others:Â Â Â· 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; Â Â Â Â Â· 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; Â Â Â Â Â Â 33Â Â Â Â Â· 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; Â Â Â Â Â· Various state laws governing the privacy and security of personal information, including the California Consumer Privacy Act (â€œCCPA"), 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 Â Â Â Â Â· 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 Childrenâ€™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 â€œtransfers of valueâ€ 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. Â State and federal regulatory and enforcement agenciescontinue to actively investigate violations of healthcare laws and regulations, and the U.S. Congress continues to strengthen the arsenalof enforcement tools. Enforcement agencies also continue to pursue novel theories of liability under these laws. In particular, governmentagencies have increased regulatory scrutiny and enforcement activity with respect to manufacturer reimbursement support activities andpatient care programs, including bringing criminal charges or civil enforcement actions under the Anti-Kickback Statute, the FCA and HIPAAâ€™shealthcare fraud and privacy provisions.Â Achieving and sustaining compliance with applicablefederal and state anti-fraud and abuse laws may prove costly. If we, or our employees, are found to have violated any of the above lawswe may be subjected to substantial criminal, civil and administrative penalties, including imprisonment, exclusion from participationin federal healthcare programs, such as Medicare and Medicaid, and significant fines, monetary penalties, forfeiture, disgorgement anddamages, contractual damages, reputational harm, administrative burdens, diminished profits and future earnings and the curtailment orrestructuring of our operations, any of which could adversely affect our ability to operate our business and our financial results. Anyaction or investigation against us for the violation of these healthcare fraud and abuse laws, even if successfully defended, could resultin significant legal expenses and could divert our managementâ€™s attention from the operation of our business. Companies settlingFCA, Anti-Kickback Statute or civil monetary penalties law cases also may be required to enter into a Corporate Integrity Agreement withthe OIG, in order to avoid exclusion from participation (which results in a loss of coverage for their products) in federal healthcareprograms such as Medicare and Medicaid. Corporate Integrity Agreements typically impose substantial costs and operational burdens on companiesto ensure compliance. Defending against any such actions can be detrimental to our reputation and brand and can otherwise be costly, time-consumingand may require significant personnel resources, and may harm our business, financial condition and results of operations.Â We have financial relationships with certainphysicians and health care providers, research investigators, and authors for our clinical or scientific publications that may be deemeda conflict of interest and may be subject to certain statutory or regulatory requirements, under which a failure to comply could leadto enforcement actions against us and other negative consequences for our business.Â We have certain financial relationships with medicaldoctors 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 NOCISCANexam, or otherwise prescribe and get paid for interpreting a NOCISCAN exam. There are risks that one or more of these relationships maybe determined to be a conflict of interest and be in violation of applicable laws, regulations, or guidelines, which could potentiallysubject us to significant fines or curtailment of our active commercial operations, and which could also potentially harm our reputationin the marketplace. If we are deemed to not comply with requirements governing the industryâ€™s relationships with physicians or thereis an investigation into our compliance by the Office of the Inspector General, the Department of Justice, statesâ€™ attorney generalsor other government agencies, it could harm our sales, business, financial condition, and results of operations.Â Â Â 34Â Â Â Regulatory compliance is expensive, complexand uncertain, and a failure to comply could lead to enforcement actions against us and other negative consequences for our business.Â The FDA, EU, and other foreign regulatory agenciesor 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 theUnited States, a company must first submit and receive either 510(k) clearance, de novo approval, or approval of a PMA from the FDA, unlessan exemption applies. FDA regulations and regulations of similar agencies are wide-ranging

and include, among other things, oversightof:Â Â Â· product design, development, manufacturing (including suppliers) and testing; Â Â· laboratory, preclinical and clinical studies; Â Â· product safety and effectiveness; Â Â· product labeling; Â Â· product storage and shipping; Â Â· quality assurance policies, practices, and record keeping; Â Â· pre-market clearance or approval; Â Â· marketing, advertising and promotion; Â Â· product sales and distribution; Â Â· product changes; Â Â· product recalls; and Â Â· post-market surveillance and reporting of deaths, serious injuries, certain malfunctions, and related corrective actions. Â 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 mayrequire 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 ourproducts in markets outside of the United States, it will require approval from, or otherwise meeting the requirements of, non-U.S. regulatoryagencies.Â The FDA and foreign regulatory bodies can delay,limit or deny clearance or approval (or otherwise a related â€œexemptionâ€) for a device for many reasons, including:Â Â Â· 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; Â Â· 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; Â Â· adverse device effects experienced by participants in our clinical studies; Â Â· the insufficiency of data from our preclinical studies and clinical studies to support clearance or approval, where required; Â Â· our inability to demonstrate that the clinical and other benefits of our products outweigh the risks; Â Â· failure of our manufacturing process or facilities to meet applicable requirements; and Â Â· 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. Â Â Â Â 35Â Â Â Future clinical studies may be delayed, suspendedor 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 additionalindications.Â We plan to continue to develop and execute clinicalstudies to support reimbursement coverage for using our products, label retention for our products, label expansion for our products intoadditional claims for diagnosing painful discs and improving patient outcomes and additional thoracic and cervical discogenic back painpatient populations. We may also develop and execute clinical studies for new products or for label expansion for our current productsinto 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 enrolledor be completed on schedule, if at all. The commencement and completion of clinical studies to support label retention and expansion foradditional indications or for new products may be delayed, suspended or terminated as a result of many factors, including:Â Â Â· 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; Â Â· changes in regulatory requirements, policies and guidelines; Â Â· 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; Â Â· 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; Â Â· the inability to recruit, enroll, or retain a sufficient number of patients; Â Â· deviations by our CROs or clinical sites from the trial protocol or study discontinuation by participants, investigators, or study sites; Â Â· 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; Â Â· regulators, Institutional Review Boards (â€œIRBsâ€), 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; Â Â· lower than anticipated retention rates of patients and volunteers in clinical studies; Â Â· 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; Â Â· 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 Â Â· exceeding budgeted costs. Â In addition, if the FDA concludes that we havenot adequately disclosed financial interests of our investigators or if our disclosed financial relationships with investigators resultin a perceived or actual conflict of interest that may have affected the interpretation of a study, the integrity of the data generatedat the applicable clinical study site or the utility of the clinical study itself, FDA may refuse to consider data from the study. Thiscould result in the delay or rejection by the FDA. Any such delay or rejection could prevent us from supporting label retention and expansionfor our products.Â Â Â Â 36Â Â Â Â A failure to comply with governmental regulatoryrequirements would have a negative impact upon our business.Â Failure to comply with applicable U.S. requirementsregarding promoting, manufacturing, labeling, and establishing and complying with appropriate quality assurance policies, systems, andpractices for our products may subject us to a variety of administrative or judicial actions and sanctions. We currently offer the NOCISCANproduct 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 21stCentury Cures Act. This product suite is also self-certified and CE Marked as a Class I medical device under MDD requirements, while webelieve it is considered a Class II medical device and requiring Notified Body review and certification under newer MDR regulations (subjectto a grace period until May 2024). These products are marketed and sold with certain labeling and related instructions for use and arepromoted by various marketing and sales materials and related human interactions via our personnel and our target customers. We have alsoestablished, and operate under, certain quality assurance systems, policies, and procedures under our QMS intended to be compliant withapplicable 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, aredetermined to be inadequate or non-compliant with applicable regulatory requirements, such defect could result in certain potential enforcementactions or other adverse consequences, and our business would be negatively affected.Â If we become subject to enforcement actionby governmental regulatory agencies, our business would be negatively affected. Â Our failure to comply with applicable regulatoryrequirements could result in enforcement action by the FDA

or other governmental regulatory agencies, which enforcement actions may includethe following:Â Â Â· untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties; Â Â· unanticipated expenditures to address or defend such actions; Â Â· issuance of form 483s, or other compliance or enforcement notices, communications or correspondence from regulatory bodies; Â Â· recall, detention or seizure of our products; Â Â· operating restrictions or partial suspension or total shutdown of marketing, sales and production or offering of product-related services; Â Â· refusing or delaying our requests for 510(k) clearance or de novo classification or PMA approval of new products or modified products; Â Â· 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); Â Â· operating restrictions; Â Â· withdrawing market authorizations that have already been granted; Â Â· refusal to grant any export approval that might be required for our NOCISCAN product suite; or Â Â· criminal prosecution Â If any of these events were to occur, it wouldhave a negative impact on our business, financial condition and results of operations.Â If certain of our medical device products causeor contribute to a death or a serious injury or malfunction in certain ways, we will be required to report under applicable medical devicereporting 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.Â FDAâ€™s Medical Device Reporting (â€œMDRâ€)regulation requires, medical device manufacturers to report to the FDA information of which the manufacturer becomes aware that a devicehas or may have caused or contributed to a death or serious injury or has malfunctioned in a way that would likely cause or contributeto death or serious injury if the malfunction of the device or a similar device marketed by the manufacturer were to recur. If we failto report events required to be reported to the FDA within the required timeframes, or at all, the FDA could take enforcement action andimpose sanctions against us. Any such adverse event involving our products also could result in the need to take corrective and preventativeactions, such as changes to design or manufacturing processes, corrections, removals, or recalls or customer notifications, or agencyaction, such as inspection or enforcement action. Risk of harm to patients, including without limitation serious injury or death, associatedwith 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 competitorsagainst us, and may harm our reputation, business, financial condition and results of operations.Â Â Â 37Â Â Â From time to time, we engage outside partiesto perform services related to certain of our clinical studies. If these third parties do not successfully carry out their contractualduties or meet expected deadlines, we may not be able to complete our clinical studies on our planned timelines, or at all, and may incursignificant additional costs.Â The FDAâ€™s investigational device exemption(â€œIDEâ€) 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, clinicalinvestigations 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 (â€œIRBâ€) and informed consent of subject participants. Significantrisk device studies also must submit an IDE to FDA for approval. The IDE regulations specify the responsibilities of sponsors and investigatorsto ensure compliance with IDE requirements, including compliance with Good Clinical Practice (â€œGCPâ€) requirements. Failureto comply may result in FDA placing a temporary or permanent clinical hold on the study, issuance of warning letters, or other regulatoryactions.Â From time to time, we engage consultants to helpdesign, monitor and analyze the results of certain clinical studies and trials that we sponsor. The consultants we engage may interactwith clinical investigators to enroll patients in our clinical studies. We depend on these consultants and clinical investigators to conductclinical studies and trials and monitor and analyze data from these studies and trials under the investigational plan and protocol forthe study or trial and in compliance with applicable regulations and standards. We may face delays in, or be prevented from, completingour 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 theirduties, 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 otherreasons, our clinical studies or trials may need to be extended, delayed or terminated by us or be placed on clinical hold by FDA, ormay otherwise prove to be unsuccessful, and we may have to conduct additional studies, which would significantly increase our costs.Â Healthcare reform initiatives and other administrativeand legislative proposals may harm our business, financial condition, results of operations and cash flows in our key markets.Â There have been, and continue to be, proposalsby the federal government, state governments, regulators and third-party payers to control or manage the increased costs of healthcareand, more generally, to reform the U.S. healthcare system. Certain of these proposals could limit the prices we are able to charge forour 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.Â There likely will continue to be legislative andregulatory proposals at the federal and state levels directed at containing or lowering the cost of healthcare. We cannot predict theinitiatives that may be adopted in the future or their full impact. The continuing efforts of the government, insurance companies, managedcare organizations and other payers of healthcare services to contain or reduce costs of healthcare may harm:Â Â Â· our ability to set a price that we believe is fair for our products; Â Â· our ability to generate revenue and achieve or maintain profitability; and Â Â· the availability of capital. Â Recently there has been heightened governmentalscrutiny over the manner in which companies set prices for their marketed products, which has resulted in several U.S. Congressional inquiriesand proposed and enacted federal legislation designed to bring transparency to product pricing and reduce the cost of products and servicesunder government healthcare programs. Additionally, individual states in the United States have also increasingly passed legislation andimplemented regulations designed to control product pricing, including price or patient reimbursement constraints, discounts, restrictionson certain product access and marketing cost disclosure and transparency measures. Moreover, regional healthcare authorities and individualhospitals are increasingly using bidding procedures to determine what products to purchase and which suppliers will be included in theirhealthcare programs. Adoption of price controls and other cost-containment measures, and adoption of more restrictive policies in jurisdictionswith existing controls and measures may prevent or limit our ability to generate revenue and attain profitability.Â Â Â 38Â Â Â Various new healthcare reform proposals are emergingat the federal and state level. Any new federal and state healthcare initiatives that may be adopted could limit the amounts that federaland state governments will pay for

healthcare products and services, and could harm our business, financial condition and results of operations.Â Our collection, use, storage, disclosure, transferand other processing of sensitive and personal information could give rise to significant costs, liabilities and other risks, includingas a result of investigations, inquiries, litigation, fines, legislative and regulatory action and negative press about our privacy anddata protection practices, which may harm our business, financial conditions, results of operations and prospects.Â 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 recordingsof 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, stateand 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 increasinglybecome, subject to various laws, rules, regulations and standards, as well as contractual obligations, relating to data privacy and securityin the jurisdictions in which we operate or in the jurisdictions where our patients may be. When conducting clinical studies, we facerisks associated with collecting trial participantsâ€™ data, especially health data, in a manner consistent with applicable laws andregulations, such as GCP guidelines or FDA human subject protection regulations.Â In many cases, these laws, rules, regulationsand standards apply not only to third-party transactions, but also to transfers of information between or among us, any of our affiliatesand other parties with whom we conduct business. These laws, rules, regulations and standards may be interpreted and applied differentlyover time and from jurisdiction to jurisdiction, and it is possible that they will be interpreted and applied in ways that may harm ourbusiness, financial condition and results of operations. The regulatory framework for data privacy and security worldwide is continuouslyevolving and developing and, as a result, interpretation and implementation standards and enforcement practices are likely to remain uncertainfor the foreseeable future.Â We are subject to many diverse laws and regulationsrelating 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 federaland state privacy and security laws, rules, regulations and standards, including HIPAA, that they may require us to comply with throughcontractual obligations. This patchwork of legislation and regulation may give rise to conflicts or differing views of personal privacyrights. For example, certain state laws may be more stringent or broader in scope, or offer greater individual rights, with respect topersonal information than federal, foreign or other state laws, and such laws may differ from each other, all of which may complicatecompliance efforts. Additionally, new privacy rules are being enacted in the United States and globally, and existing ones are being updatedand strengthened. The CCPA regulates the processing of personal information of California residents and increases the privacy and securityobligations of covered companies handling such personal information. The CCPA requires covered companies to, amongst other things, providenew and additional disclosures to California consumers and provide such consumers new data protection and privacy rights, including theability to access their personal information and opt out of certain sales of personal information. The CCPA provides for civil penaltiesfor violations, as well as a private right of action for certain data breaches that result in the loss of personal information. This privateright of action may increase the likelihood of, and risks associated with, data breach litigation. The CCPA was amended in September 2018and November 2019, and it is possible that further amendments will be enacted, but even in its current form it remains unclear how variousprovisions of the CCPA will be interpreted and enforced. Moreover, a new privacy law, the California Privacy Rights Act, (â€œCPRAâ€)a consumer privacy ballot initiative that amends and expands the CCPA, was recently passed. The CPRA affords California residents significantlymore control over their personal information, imposes heightened compliance obligations on covered companies, and establishes a new enforcementagency dedicated to consumer privacy. The CPRAâ€™s substantive provisions become effective January 1, 2023, and new regulations areexpected to be introduced by July 1, 2022. While aspects of the CPRA and its interpretation remain to be determined in practice, theycreate further uncertainty and may result in additional costs and expenses in an effort to comply. Further, all 50 states have passedlaws 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 certaintypes 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 Congressof a new federal data protection and privacy law to which we would become subject if it is enacted. All of these evolving compliance andoperational requirements impose significant costs that are likely to increase over time, may require us to modify our data processingpractices and policies, divert resources from other initiatives and projects, and could restrict the way products and services involvingdata are offered, all of which may harm our business, financial condition and results of operations.Â Â Â 39Â Â Â 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 inthe European Union, for instance, have been significantly reformed. On May 25, 2018, the General Data Protection Regulation (â€œGDPRâ€)entered into force and became directly applicable in all European Union member states. The GDPR implements more stringent operationalrequirements 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 consentfor processing, requires the appointment of data protection officers when sensitive personal data, such as health data, is processed ona 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 privacygovernance including policies, procedures, training and data audits. The GDPR permits data protection authorities to impose large penaltiesfor violations of the GDPR, including potential fines of up to â‚¬20 million or four percent of annual global revenues, whichever isgreater. The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisoryauthorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. If we become subject tothe GDPR and do not comply with our obligations under the GDPR, we could be exposed to significant fines. Compliance with the GDPR willbe 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 connectionwith our European activities. In addition, we may be the subject of litigation or adverse publicity, which could negatively affect ourbusiness, financial condition and results of operations.Â We expect that there will continue to be new proposedlaws and regulations concerning data privacy and security, and we cannot yet determine the impact such future laws, rules, regulationsand standards may have on our business. New laws, amendments to or re-interpretations of existing laws, regulations, standards and otherobligations may require us to incur additional costs and restrict our business operations. Because the interpretation, scope, and applicationof laws, regulations, standards and other obligations relating to data privacy and security are still uncertain, it is possible that theselaws, regulations, standards and other obligations may be interpreted and applied in a manner that is inconsistent with our data processingpractices and policies or the features of our products and services. If so, in addition to the possibility of fines, lawsuits, regulatoryinvestigations, public censure, other claims and penalties, and significant costs for remediation and damage to our reputation, we couldbe materially and adversely affected if legislation or regulations are expanded to require changes in our data processing practices andpolicies 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-regulatorystandards from time to time. These and other industry standards may legally or contractually apply to us, or we may elect to comply withsuch standards. Any inability to adequately address data privacy or security-related concerns, even if unfounded, or to comply with applicablelaws, regulations, standards and other obligations relating to data privacy and security, could result in additional cost and liabilityto us, harm our reputation and brand, damage our relationships with consumers and harm our business, financial condition and results ofoperations.Â We make public statements about our use and disclosureof personal information through our privacy policies, information provided on our website and press statements. Although we endeavor tocomply with our public statements and documentation, we may at times fail to do so or be alleged to have failed to do so. The publicationof our privacy policies and other statements that provide promises and assurances about data privacy and security can subject us to potentialgovernment or legal action if they are found to be deceptive, unfair or misrepresentative of our actual practices. Any concerns aboutour data privacy and security practices, even if unfounded, could damage the reputation of our business and harm our business, financialcondition and results of operations.Â Complying with these numerous, complex and oftenchanging laws, rules, regulations, and standards is expensive and difficult. Any failure or perceived failure by us or our service providersto 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 resultsin the theft, unauthorized access, acquisition, use, disclosure, or misappropriation of personal information or other user data, couldresult in significant fines or penalties, negative publicity or proceedings or litigation by governmental agencies or consumers, includingclass action privacy litigation in certain jurisdictions, which would subject us to significant awards, penalties or judgments, one orall 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 applicablelegal and regulatory requirements, including changes in laws, regulations and standards or new interpretations or applications of existinglaws, 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.Â Â Â 40Â Â Â Our employees, independent contractors, consultants,commercial partners and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standardsand requirements, which could harm our business, financial condition and results of operations.Â 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 theseparties could include intentional, reckless or negligent conduct or disclosure of unauthorized activities to us that violates: (i) thelaws of the FDA and other similar state or foreign regulatory bodies, including those laws requiring the reporting of true, complete andaccurate information to such regulators, (ii) manufacturing standards, (iii) healthcare fraud and abuse laws in the United States andsimilar foreign fraudulent misconduct laws, (iv) laws related to discrimination, harassment, or other conduct relating to a hostile workenvironment, 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 itemsand 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 arrangementsgenerally. These laws also address the improper use of information obtained in the course of patient recruitment for clinical studies.Â 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, andthe precautions we take to detect and prevent these activities may not be effective in controlling unknown or unmanaged risks or lossesor in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with suchlaws 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 andadministrative penalties, damages, monetary fines, disgorgement, imprisonment, reporting and oversight obligations, possible exclusionfrom participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, diminished profits and future earningsand 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 actionscould result in integrity issues, or a negative impact to our reputation or brand. Whether or not we are successful in defending againstany such actions or investigations, we could incur substantial costs, including legal fees, and divert the attention of management indefending ourselves against any of these claims or investigations, which could harm our business, financial condition and results of operations.Â Significant disruptions in our informationtechnology systems, whether through breaches or failures of our technology, unauthorized access or otherwise, may result in both an adverseimpact 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 impacton our business, financial condition and results of operations.Â We are increasingly dependent on

complex informationtechnology 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 moreinformed treatment decisions and optimize their patientsâ€™ care. These data are recorded by our technology and can be viewed by thephysician 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 besubject to computer viruses, phishing, social engineering, denial or degradation of service attacks, ransomware, malware attacks or otherthreats, 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, telecommunicationfailures and user errors, among other malfunctions. Technological interruptions or threats would disrupt our operations, including theability of our clinicians to use our products as intended to treat patients, the ability of patients to safely and securely upload theirdata 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 incidentscould result in the theft, unauthorized access, acquisition, use, disclosure, modification, or misappropriation of personal informationof 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.Â Â Â 41Â Â Â 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 adequateor timely disclosures to the public or law enforcement agencies following any such event, whether due to delayed discovery or a failureto follow existing protocols, could result in claims made against us or our service providers, which could result in state and/or federallitigation and related financial liabilities, as well as criminal penalties or civil liabilities, regulatory actions from state and/orfederal governmental authorities, and significant fines, orders, sanctions, litigation and claims against us by consumers or third partiesand related indemnification obligations. Actual or perceived security breaches or failures could also cause financial losses, increasedcosts, interruptions in the operations of our businesses, misappropriation of assets, significant damage to our brand and reputation withcustomers, 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 resultsof operations.Â Our technology is also subject to compromise frominternal threats, such as theft, misuse, unauthorized access or other improper actions by employees, service providers and other thirdparties with otherwise legitimate access to our systems and website. Data security-related incidents and fraudulent activity are increasingin frequency and evolving in nature. We rely on a framework of security processes, procedures, tools, and controls designed to protectour information and assets but, given the unpredictability of the timing, nature and scope of data security-related incidents and fraudulentactivity, there can be no assurance that any security procedures and controls that we or our service providers have implemented will besufficient to prevent data security-related incidents or other fraudulent activity from occurring. Furthermore, because the methods ofattack 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 integrityof our systems and website, it is possible that we may not be able to anticipate, detect, appropriately react and respond to, or implementeffective preventative measures against, all security breaches and failures and fraudulent activity. In the event we experience significantdisruptions, we may be unable to repair our systems in an efficient and timely manner.Â We also face risks associated with security breachesaffecting third parties with whom we are affiliated or otherwise conduct business. Due to applicable laws and regulations or contractualobligations, we may be held responsible for any breach, failure or fraudulent activity attributed to our service providers as they relateto the information we share with them. In addition, while we take precautions in selecting service providers, because we do not controlour service providers and our ability to monitor their data security is limited, we cannot ensure the security measures they take willbe sufficient to protect our information. Any of the foregoing could harm our business, financial condition and results of operations.Â 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 investigateand remediate any information security vulnerabilities, or to protect against, respond to and recover from any potential, attempted, orexisting security breaches. In addition, our remediation efforts may not be successful. The inability to implement, maintain and upgradeadequate 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 suchincidents, and if securities analysts or investors perceive these announcements to be negative, it could, among other things, have a substantialadverse effect on the price of our Common Stock. Any of the foregoing could harm our business, financial condition and results of operations.Â We currently maintain a cybersecurity insurancepolicy and business interruption coverage in order to mitigate certain potential losses but this insurance is limited in amount, and wecannot be certain that such potential losses will not exceed our policy limits, or will cover all potential claims to which we are exposedand may not be adequate to indemnify us for all liability that may be imposed. Therefore, failure to maintain or protect our informationsystems and data integrity effectively could harm our business, financial condition, and results of operations.Â Â Â Â 42Â Â Â We face potential liability related to theprivacy of health information we obtain.Â We may maintain, use, and share sensitive healthinformation that we receive directly from patients that use our technology, throughout the clinical study process, in the course of ourresearch collaborations, and from healthcare providers in the course of using our products and systems. Most healthcare providers, includinghospitals from which we obtain patient health information, are subject to privacy and security regulations promulgated under HIPAA, asamended by the HITECH, and also under GDPR. We believe that we are not currently classified or regulated under HIPAA or GDPR as a CoveredEntity, but we believe we are considered and regulated as a Business Associate. Accordingly, we are subject to HIPAA and GDPR requirementsor penalties as applied to Business Associates. However, in certain situations, any person may be prosecuted under HIPAAâ€™s criminalprovisions 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 informationfrom a Covered Entity, as defined under HIPAA, that has not satisfied HIPAAâ€™s requirements for disclosure of individually identifiablehealth information. Furthermore, certain health privacy laws, data breach notification laws, consumer protection laws and genetic testinglaws may apply directly to our operations or those of our collaborators and may impose restrictions on our collection, use and disseminationof individualsâ€™ health information As such, we may be subject to state laws requiring notification of affected individuals and stateregulators in the event of a breach of personal information, including certain health information, which is a broader class of informationthan the health information protected by HIPAA. To the extent we engage in clinical studies and commercial uses of our products outsidethe United States, we may implicate foreign data privacy and security laws and regulations, including the GDPR and legislation of theEuropean Union member states implementing it.Â To the extent we do business in internationalmarkets now, and in the future, any failure by us or our third-party contractors to comply with the strict rules on the transfer of personaldata from outside of the European Union, the United Kingdom, or other foreign country or territory into the United States in accordancewith such laws and regulations may result in the imposition of criminal and administrative sanctions on such contractors, which couldadversely affect our sales, business, financial condition, and results of operations.Â Moreover, patients about whom we or our contractorsor collaborators obtain or share health information, as well as the providers who share this information with us or whom we share thisdata with, may have statutory or contractual rights that limit our ability to use and disclose the information. We may be required toexpend significant capital and other resources to ensure ongoing compliance with applicable privacy and data security laws. Potentialclaims alleging that we have violated individualsâ€™ privacy rights or breached our contractual obligations, even if we are not foundliable, 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 contractorsâ€™ability to develop and commercialize our products and could harm or prevent sales of our technology, or could substantially increase thecosts and expenses of developing, commercializing and marketing our products. Any threatened or actual government enforcement action couldalso generate adverse publicity and require that we devote substantial resources that could otherwise be used in other aspects of ourbusiness.Â Additionally, data collection, privacy and securityhave become the subject of increasing public concern and changing preferences towards data collection, privacy and security could adverselyaffect patient willingness to consent to our collection of their health information. Patients may be reluctant or unwilling to consentto the collecting of their health information, and patients that have opted-in to the collection of their health information may revoketheir consent at any time, including as a result of these concerns or as a result of changes to our data policies that we have implementedor may implement in the future. In particular, the success of our business depends in part on our ability to lawfully obtain health informationfrom our patients. If patients choose not to consent to the collection of their health information as a result of these concerns, or ourcustomers who transfer patient data to us via the use of our products refuse to do so due to concerns for data privacy or potential relatedliabilities, or our consent or data privacy protection and management policies or practices are found to be unlawful, this could negativelyimpact the growth potential for our business.Â Â Â 43Â Â Â We have encountered potential customers in theEU who have been reluctant, and indeed refused, to become customers due to concerns about transferring of any private patient informationfrom their practice in the EU into the United States. Certain such customers have indicated their opinion that such a transfer is, onits face, non-compliant with GDPR requirements due to certain rights of the US Federal Government to seize such data from US domiciledcompanies or storage facilities. We may need to expand our operations to host at least one foreign instance of our cloud-based post-processingsoftware products within a foreign country, such as within the European Union, in order to overcome such concerns and reach and engagemore customers to grow our business in the related territory. If we are unable to sufficiently dissuade these concerns held by certainpotential customers outside of the United States, or do not establish certain changes in our private patient health information data privacypractices, such as moving the hosting of EU-based information to an EU-based instance of our products and storage of related patient healthinformation we receive via use of our products, our sales, business, financial condition, and results of operations could be harmed. Wecould also encounter delays if a clinical study is suspended or terminated by us, by the IRBs or the Ethics Committees of institutionsat 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 studyin accordance with regulatory requirements, including GC.Â Risks related to our intellectual propertyÂ 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 intellectualproperty 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 continueto commercialize our technology, or our other products and services, may be harmed.Â As with other medical device companies, our successdepends, 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 UnitedStates and other countries into which we may expand our business in the future that relate to our technology and any other products, theirmanufacturing processes and their intended methods of use. Furthermore, our success will also depend on our ability to enforce and defendthose patents, as well as our other intellectual property. In some cases, we may not be able to obtain patents relating to our productsand services which are sufficient to prevent third parties, such as our competitors, from copying and competing with other products orservices that are the same, similar, or otherwise competitive with our products and services. Or, our competitors may have rights undercurrent or future out-licenses of our intellectual property which could result in our competitors developing and commercializing productssimilar to or competitive with our products and services. Any failure to obtain, maintain, protect, enforce or defend patent and otherintellectual property protection with respect to our NOCISCAN product suite and related services, or other aspects of our business, couldharm our business, competitive position, financial condition and results of operations.Â Changes in the patent or other intellectual propertylaws, 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 intellectualproperty or narrow the scope of our patents. Additionally, we cannot predict whether the patent applications we are currently pursuingwill issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient protection fromcompetitors or other third parties.Â Â Â Â 44Â Â Â The patent prosecution process is expensive, time-consumingand complex and we may not be able to file,

prosecute, maintain, enforce or license all necessary or desirable patents or patent applicationsat a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and developmentoutput in time to obtain patent protection in one, several, or all geographies. Although we enter into non-disclosure and confidentialityagreements 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 seekpatent protection. Such third parties could also breach obligations with respect to limited uses of our confidential information, whichmay include (i) breaching restrictions against making or inventing improvements or modifications to, or derivations of, our confidentialtechnologies, 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 betweenour inventions and the prior art allow our inventions to be patentable over the prior art. Furthermore, the publication of discoveriesin scientific literature often lags behind the actual discoveries, and patent applications in the United States and other jurisdictionsare typically not published until 18 months after filing, or in some cases not at all. As such, we cannot be certain that we were thefirst to make the inventions claimed in any of our patents or pending patent applications, or that we were the first to file for patentprotection of such inventions. Moreover, in some circumstances, we may not have the right to control the preparation, filing and prosecutionof patent applications, or to maintain the patents, relating to technology that we license from or license to third parties, includingby 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 bestinterests of our business. Furthermore, our license agreements may be terminated by the licensor. Defects of form in the preparation orfiling 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 currentor 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 disagreewith us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised. If there arematerial defects in the form, preparation or prosecution of our patents or patent applications, such patents or applications may be invalidand/or unenforceable. Any of these outcomes could impair our ability to prevent competition from third parties, which may harm our business.Â The strength of patent rights generally, and particularlythe patent position of medical device companies, involves complex legal and scientific questions, can be uncertain, and has been the subjectof much litigation in recent years. This uncertainty includes changes to the patent laws through either legislative action to change statutorypatent law or court action that may reinterpret existing law or rules in ways affecting the scope or validity of issued patents. Our currentor future patent applications may fail to result in issued patents in the United States or foreign countries with claims that cover ourproducts, including our technology. Even if patents do successfully issue from our patent applications, third parties may challenge thevalidity, 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 technologyor any other products we develop, provide exclusivity for these products or prevent others from designing around our claims. If the scopeof any patent protection we obtain is not sufficiently broad, or if we lose any of our patent protection, our ability to prevent our competitorsfrom commercializing similar or identical products could be adversely affected. If the breadth or strength of protection provided by thepatents 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.Â Â Â Â 45Â Â Â Â Patents have a limited lifespan. In the UnitedStates, the natural expiration of a utility patent is generally 20 years after its effective filing date and the natural expiration ofa design patent is generally 14 years after its issue date, unless the filing date occurred on or after May 13, 2015, in which case thenatural expiration of a design patent is generally 15 years after its issue date. However, the actual protection afforded by a patentvaries from country to country, and depends upon many factors, including the type of patent, the scope of its coverage, any terminal disclaimersfiled 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 beavailable; however, the life of a patent, and the protection it affords, is limited. Without patent protection for our technology, wemay be open to competition. Further, if we encounter delays in our development efforts, the period of time during which we could marketour technology under patent protection would be reduced and, given the amount of time required for the development, testing and regulatoryreview of planned or future technology and products, patents protecting such technology and products might expire before or shortly aftersuch products are commercialized. For information regarding the expiration dates of patents in our patent portfolio, see â€œBusinessâ€”IntellectualProperty.â€ Our U.S. issued patents are expected to expire between January 3, 2026 and March 15, 2033, without taking into accountall 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 eliminateany competitive advantage afforded by our patent portfolio. As a result, our patent portfolio may not provide us with sufficient rightsto exclude others from commercializing products similar or identical to ours.Â Moreover, the coverage claimed in a patent applicationcan be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Even if patent applicationslicensed 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 withany meaningful protection, prevent competitors or other third parties from competing with us, or otherwise provide us with any competitiveadvantage. Any patents assigned to us may be challenged, narrowed, circumvented or invalidated by third parties. Consequently, we do notknow 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-infringingmanner, which could harm our business, financial condition and results of operations.Â Some of our patents and patent applications maybe 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 suchthird-party co-ownersâ€™ or licenseeâ€™s interest in such patents or patent applications, such co-owners or cross-licensees maybe able to license or sub-license, respectively, their rights to other third parties, including our competitors, and our competitors couldmarket competing products and technology. In addition, we may need the cooperation of any such co-owners or co-licensees of our patentsin order to enforce such patents against third parties, and such cooperation may not be provided to us. Any of the foregoing could harmour sales, business, financial condition and results of operations.Â We rely on a License from the Regents of the Universityof California, as well as other aspects of our own patented technology and intellectual property, in order to be able to use and sellvarious proprietary technologies that are material to our business, as well as technologies which we intend to use in our future commercialactivities. Our rights to use these licensed technologies and the inventions claimed in the licensed patents, are subject to the continuationof, and our compliance with the terms of the license. The License provides that for so long as we pay patent prosecution costs, the Regentsof the University of California will diligently prosecute and maintain the United States and foreign patents comprising the Patent Rightsusing counsel of its choice, and the UCSF Regents' counsel will take instructions only from The Regents of the University of Californiahas the right to terminate the agreement upon advanced notice in the event of a default by us. The agreement will expire upon the expirationor abandonment of the last of the licensed patents. The patents subject to the agreement expire between 2025 and 2029. The loss of thislicense would materially negatively affect our ability to pursue our business objectives and result in material harm to our business operations.Â Â Â Â 46Â Â Â We may not be successful in obtaining or maintainingnecessary rights to any products or processes we may have or develop through acquisitions and in-licenses.Â 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 orimportant to our business operations. However, we may be unable to acquire, secure, or maintain such licenses to any intellectual propertyor proprietary rights from third parties that we identify as necessary for our technology or any future products we may develop. The acquisitionor licensing of third-party intellectual property or proprietary rights is a competitive area, and our competitors may pursue strategiesto acquire or license third party intellectual property or proprietary rights that we may consider attractive or necessary. Our competitorsmay 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 toacquire or license third party intellectual property or proprietary rights on terms that would allow us to make an appropriate returnon our investment or at all. We have an existing license with the Board of Regents of the University of California, and which covers multiplepatents 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 rightsthat we require for making, using, or selling our products or services, or to maintain the existing licenses to intellectual propertyrights we have, we may have to abandon the development, manufacturing, marketing, or selling of our related products that require thoserights, which could harm our sales, business, financial condition, and results of operations.Â Patents directing to our technology could befound invalid or unenforceable if challenged in court or before administrative bodies in the United States or abroad, which could harmour business, financial condition and results of operations.Â The issuance of a patent is not conclusive asto its inventorship, scope, validity or enforceability, and our patents may be challenged in the courts or patent offices in the UnitedStates and abroad. We may be subject to a third-party pre-issuance submission of prior art to the U.S. Patent and Trademark Office (â€œUSPTOâ€),or become involved in opposition, derivation, revocation, reexamination, post-grant and inter partes review, or IPR, or interference proceedingsor other similar proceedings challenging our patent rights. An adverse determination in any such submission, proceeding or litigationcould reduce the scope of, or invalidate or render unenforceable, such patent rights, allow third parties to commercialize our productsand compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringingthird-party patent rights. Moreover, we may have to participate in interference proceedings declared by the USPTO to determine priorityof invention or in post-grant challenge proceedings, such as oppositions in a foreign patent office, that challenge our priority of inventionor 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 othersfrom using or commercializing similar or identical products or limit the duration of the patent protection of our products. Such proceedingsalso may result in substantial cost and require significant time from our management, even if the eventual outcome is favorable to us.Â In addition, if we initiate legal proceedingsagainst 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 fora validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousnessor non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patentwithheld relevant information from the USPTO, or made a false or misleading statement, or otherwise committed inequitable conduct, duringprosecution. Defenses of these types of claims, regardless of their merit, would involve substantial litigation expense, would resultin reputational harm, and would be a substantial diversion of employee resources from our business. Third parties may also raise claimschallenging the validity or enforceability of our patents before administrative bodies in the United States or abroad, even outside thecontext of litigation, including through re-examination, post-grant review, IPR, interference proceedings, derivation proceedings andequivalent or similar proceedings in foreign jurisdictions (such as opposition proceedings). Such proceedings could result in the revocationof, cancellation of or amendment to our patents in such a way that they no longer relate to our products. The outcome for any particularpatent 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 securingor enforcing a patent could also potentially give rise to other adverse claims, which may include business torts or other causes of actionregarding our enforcement of that patent, and could also potentially carry over and apply downstream to other patents that are relatedto (e.g. claim of priority) the instant patent. If a defendant or other third party were to prevail on a legal assertion of invalidityor 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.Â Â Â 47Â Â Â The medical device industry is

characterizedby patent litigation and in the future we could become subject to actual or threatened patent or other intellectual property litigationalleging our products or services infringe or misappropriate third party rights, which could be costly to address and defend, result inthe diversion of managementâ€™s time and efforts, require us to pay damages, or prevent us from making, using, or selling our existingor future products.Â Patent litigation is prevalent in the medicaldevice 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 proprietaryrights of third parties. We may in the future become party to, or be threatened with, adversarial proceedings or litigation regardingintellectual property rights with respect to our products. Third parties may assert infringement claims against us based on existing orfuture intellectual property rights, regardless of merit. If we are found to infringe a third partyâ€™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 productsand services. We may also elect to enter into such a license in order to settle pending or threatened litigation. However, we may notbe able to obtain any required license on commercially reasonable terms, or at all. Even if we were able to obtain a license, it couldbe non-exclusive, thereby giving our competitors access to the same technologies or methods licensed to us and could require us to paysignificant royalties and other fees. We could be forced, including by court order, to cease commercializing the infringing product orservice. In addition, we could be found liable for monetary damages, which may be significant. If we are found to have willfully infringeda third-party patent, we could be required to pay treble damages and attorneysâ€™ fees. A finding of infringement could prevent usfrom 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 sucha claim might be brought could also potentially carry over to influence other similarly adverse claims being brought, and/or adverse resultsof those additional claims, in other territories where we have or seek a commercial presence. We could also be forced to redesign or otherwisechange those products or services that use or implicate the allegedly infringing intellectual property, which could be costly, disruptiveand infeasible.Â Many of our employees were previously employedat, 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, advisorsand 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 suchemployeeâ€™s former employer. Furthermore, although these agreements may be difficult to enforce, we may in the future be subjectto claims that these individuals are violating non-compete agreements with their former employers. These and other claims that we havemisappropriated the confidential information or trade secrets of third parties can have a similar negative impact on our business, includingwith respect to the infringement claims discussed above.Â Even if we are successful in defending againstintellectual property claims, litigation or other legal proceedings relating to such claims, the claims and related defense may stillcause us to incur significant expenses, cause reputational harm, and could distract our technical and management personnel from theirnormal responsibilities. If we fail in defending any such claims, in addition to paying monetary damages or other settlements, we maylose 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 claimsthat may include cross-licensing of our own patent or other intellectual property rights with the third party bringing the initial adverseclaim against us. This could result in our inability to protect our products and services as exclusively proprietary only to us, and allowthe third party to compete against us, with respect to the inventions or technologies related to those out-licensed rights, and whichcould 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 proceedingsor developments and if securities analysts or investors perceive these results to be negative, it could have a substantial negative impacton the price of our shares of Common Stock. Such litigation or proceedings could substantially increase our operating losses and reduceour resources available for development activities. We may not have sufficient financial or other resources to adequately conduct suchlitigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectivelythan we can because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation oflitigation or other intellectual property related proceedings could harm our business, financial condition and results of operations.Â Â Â 48Â Â Â Obtaining and maintaining our patent protectiondepends 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.Â Obtaining and maintaining our patent protectiondepends on compliance with various procedural measures, document submissions, fee payments and other requirements imposed by governmentpatent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.Â Periodic maintenance fees, renewal fees, annuityfees and various other government fees on patents and patent applications will be due to be paid to the USPTO and various government patentagencies outside of the United States over the lifetime of our patents and applications. The USPTO and various non-U.S. government agenciesrequire 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. Thereare situations, however, in which non-compliance can result in the abandonment or lapse of the patent or patent application, resultingin a partial or complete loss of patent rights in the relevant jurisdiction. In such an event, potential competitors might be able toenter 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. governmentto disclose our confidential information to third parties. To the extent any of our current or future intellectual property is generatedthrough the use of U.S. government funding, the provisions of the Bayh-Dole Act may similarly apply. For example, the National Instituteof Health and the Regents of the University of California have limited rights to use certain of our patents and patent applications forresearch. Any exercise by the government of any of the foregoing rights could harm our business, financial condition, results of operationsand prospects.Â If we fail to comply with our obligations inany current or future agreements under which we license intellectual property rights from third parties or otherwise experience disruptionsto our business relationships with our licensors, we could lose license rights that are important to our business.Â We are, and may become, party to license or

collaborationagreements with third parties to advance our research or allow commercialization of our products. Such agreements may impose numerousobligations, such as development, diligence, payment, commercialization, funding, milestone, royalty, sublicensing, insurance, patentprosecution, enforcement and other obligations on us and may require us to meet development timelines, or to exercise certain effortsto develop and commercialize licensed products, in order to maintain the licenses. In spite of our best efforts, our licensors might concludethat we have materially breached such license agreements and might therefore terminate the license agreements, thereby removing or limitingour ability to develop and commercialize products and technologies covered by these license agreements.Â We have an existing license with the Regents ofthe 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 ourproducts and competitors or other third parties may have the freedom to seek regulatory approval of, and to market, products identicalto ours, at least to the extent of products and services that incorporate the features captured by those previously licensed patent rightsand assuming our licensor permits such competitive activities, either passively or via further out licensing, under their remaining patentrights. If we lose our licensed patent rights, we may also be required to cease our development and commercialization of certain of ourproducts. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, resultsof operations, and prospects.Â Disputes may also arise between us and our licensorsregarding intellectual property subject to a license agreement, including:Â Â Â· the scope of rights granted under the license agreement and other interpretation-related issues; Â Â· 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; Â Â· our right to sublicense patent and other rights to third parties under collaborative development relationships; Â Â· 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; Â Â· the priority of invention of any patented technology; and Â Â· 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. Â Â Â 49Â Â Â In addition, the agreements under which we maylicense intellectual property or technology from third parties are likely to be complex and certain provisions in such agreements maybe susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow whatwe believe to be the scope of our rights to the relevant intellectual property, or increase what we believe to be our financial or otherobligations under the relevant agreement, either of which could have a material adverse effect on our sales, business, financial conditionor results of operations. Moreover, if disputes over intellectual property that we may license prevent or impair our ability to maintainfuture license agreements on acceptable terms, we may be unable to successfully develop and commercialize the affected products, whichcould have a material adverse effect on our sales, business, financial conditions or results of operations.Â Our existing license with the Regents of the Universityof 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 Licensorâ€™s patent rights, under which wehave rights for diagnostic-related patent claims. The balance of remaining rights for therapy-related claims are exclusively licensedto another third-party company. There are risks that the interpretation of which patent rights apply to us under our license, versus whichpatent rights apply to the other third-party company under their license, could be the subject of disagreement or dispute, the existenceof which, and potential adverse result from which, could diminish the scope of rights we actually have. This could also be the subjectof disagreement or dispute with respect to patent prosecution matters along the examination path of applications toward seeking issuedpatents. Any of the above could diminish, or prevent, our ability to commercialize all aspects of our products as intended, and whichcould result in harm to our sales, business, financial condition, or result of operations.Â Our existing license also includes exclusive rightsto certain patents which are co-owned by us and the Board of Regents of the University of California, in relation to inventions that havebeen 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 wouldhave the ability to commercialize, or license the ability to commercialize, products or services covered by those patents competitivelyagainst us. This would result in us losing exclusive proprietary advantage with respect to technologies and methods relating to thosepatents, which could harm our sales, business, financial condition, and results of operations.Â If we are unable to obtain patent term extensionunder the Hatch-Waxman Amendments, our business may be materially harmed.Â Depending upon the timing, duration and specificsof FDA marketing approval of our products, one or more of the U.S. patents assigned or licensed to us may be eligible for limited patentterm 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 compensationfor 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 diligenceduring the testing phase or regulatory review process, to fail to apply within applicable deadlines or prior to expiration of relevantpatents or otherwise to fail to satisfy applicable requirements. Moreover, the time period of the extension or the scope of patent protectionafforded could be less than we request. Only one patent per approved product can be extended, the extension cannot extend the total patentterm beyond 14 years from approval and only those claims covering the approved product, a method for using it or a method for manufacturingit may be extended. If we are unable to obtain patent term extension or restoration or the term of any such extension is less than werequest, the period during which we can enforce our patent rights for the applicable product will be shortened and our competitors mayobtain approval of competing products following our patent expiration. As a result, our ability to generate revenues could be adverselyaffected. Further, if this occurs, our competitors may take advantage of our investment in development and studies by referencing ourclinical and preclinical data and launch their product earlier than might otherwise be the case. If we do not have adequate patent protectionor other exclusivity for our products, our business, financial condition or results of operations could be adversely affected.Â Â Â Â 50Â Â Â We have limited foreign intellectual propertyrights 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.Â We have limited intellectual property rights outsidethe United States. Filing, prosecuting and defending patents on our products in all countries throughout the world would be prohibitivelyexpensive, 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 sellingor importing products made

using our inventions in and into the United States or other jurisdictions. Competitors may use our technologiesin jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringingproducts to territories where we have patent protection but enforcement is not as strong as in the United States. While we do not currentlyoperate or sell our products outside of the United States, these products may compete with our products, and our patents or other intellectualproperty rights may not be effective or sufficient to prevent them from competing. Patent protection must ultimately be sought on a country-by-countrybasis, which is an expensive and time-consuming process with uncertain outcomes. Accordingly, we may choose not to seek patent protectionin certain countries, and we will not have the benefit of patent protection in such countries, which may impede on our ability to growoutside of the United States.Â Many companies have encountered significant problemsin protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularlycertain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, whichcould make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our intellectualproperty and proprietary rights generally. Proceedings to enforce our intellectual property and proprietary rights in foreign jurisdictionscould result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at riskof being invalidated or interpreted narrowly, could put our patent applications at risk of not issuing and could provoke third partiesto assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, maynot be commercially meaningful. Accordingly, our efforts to enforce our intellectual property and proprietary rights around the worldmay be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.Â Many countries have compulsory licensing lawsunder which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability ofpatents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which couldmaterially diminish the value of such patent. If we are forced to grant a license to third parties with respect to any patents relevantto our business, our competitive position may be impaired, and our business, financial condition and results of operations may be harmed.Â Changes in U.S. patent laws, or patent lawsin other countries and jurisdictions, could diminish the value of patents in general, thereby impairing our ability to protect our products.Â Changes in either the patent laws or interpretationof the patent laws in the United States, or elsewhere, could increase the uncertainties and costs surrounding the prosecution of patentapplications and the enforcement or defense of issued patents. Assuming that other requirements for patentability are met, prior to March2013, in the United States, the first to invent the claimed invention was entitled to the patent, while outside the United States, generallythe first to file a patent application was entitled to the patent. After March 2013, under the Leahy-Smith America Invents Act, or theAmerica Invents Act, enacted in September 2011, the United States transitioned to a first inventor to file system in which, assuming thatother requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an inventionregardless 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 itwas made by such third party. This will require us to be cognizant of the time from invention to filing of a patent application. Sincepatent 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 productsor the first to invent any of the inventions claimed in our patents or patent applications.Â Â Â 51Â Â Â The America Invents Act also includes a numberof significant changes that affect the way patent applications are prosecuted and also may affect patent litigation. These include allowingthird-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patentby USPTO administered post-grant proceedings, including post-grant review, inter partes review and derivation proceedings. Because ofa lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in U.S. federal courts necessary to invalidatea patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalideven 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 challengedby the third party as a defendant in a district court action. Additionally, USPTO proceedings provide a venue for challenging the validityof patents at a cost must lower than district court litigation and on much faster timelines. This lower-cost, faster and potentially morepotent tribunal for challenging patents could itself increase the likelihood that our own patents will be challenged. Therefore, the AmericaInvents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications andthe enforcement or defense of our issued patents. In addition, future actions by the U.S. Congress, the federal courts and the USPTO couldcause the laws and regulations governing patents to change in unpredictable ways. Any of the foregoing could harm our business, financialcondition and results of operations.Â In addition, recent U.S. Supreme Court rulingshave 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 createduncertainty with respect to the validity and enforceability of patents, once obtained. For example, after the filing of our earlier filedpatent applications, from which we have received granted patents and also continue to prosecute additional patent applications under priorityfiling claims, certain laws and interpretation of those laws changed. This includes, in particular, new changes that diminish or makeit more difficult to obtain, enforce, or defend as valid, claims related to medical diagnostics, any methods, and in particular any methodsinvolving the human body or medical procedures. Our patent portfolio is principally related to medical diagnostic methods, which in manycases merge these multiple areas of patent laws that have since been changed. Some of our patents were issued prior to certain such changesin the laws occurring, which could potentially result in certain risks that the patents which were initially valid when granted, underthe laws at that time, had become invalid due to the later changes in the laws. Moreover, some of our patents were granted after thesechanges in the laws, but these may still be subject to risk of challenge due to uncertainty in interpreting and applying these newer changesin the laws related to medical diagnostic methods to our issued patent claims. Depending on future actions by the U.S. Congress, the federalcourts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could weaken our ability toobtain new patents or to enforce our existing patents and patents that we might obtain in the future. We cannot predict how this and futuredecisions laws or regulations by the courts, the U.S. Congress or the USPTO may impact the value of our patents. Any similar

adverse changesin the patent laws of other jurisdictions could also harm our business, financial condition, results of operations and prospects.Â We may be subject to claims, including third-partyclaims of intellectual property infringement, misappropriation or other violations against us or our collaborators, challenging the ownershipor inventorship of our intellectual property and, if unsuccessful in any of these proceedings, we may be required to obtain licenses fromthird parties, which may not be available on commercially reasonable terms, or at all, or to cease the development, manufacture and commercializationof one or more of our products.Â The medical device industry is highly competitiveand dynamic. Due to the focused research and development that is taking place by several companies, including us and our competitors inthis field, the intellectual property landscape is in flux and it may remain uncertain in the future. As such, we may be subject to claimsthat current or former employees, collaborators or other third parties have an interest, either as an owner, co-owner, or otherwise, inour patents, trade secrets or other intellectual property as an inventor or co-inventor. Additionally, we could become subject to significantintellectual 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 involvedin developing our products, or could face third-party claims of intellectual property infringement, misappropriation or other violations,including by a licensor from whom weâ€™ve licensed certain intellectual property. These risks apply to our existing license from theRegents of the University of California, both in relation to patent rights we co-own with them as a result of joint invention betweenour and their respective inventors, and in relation to co-existent license rights that we share with another third-party company in someof those patent rights, as further summarized above.Â Â Â 52Â Â Â Litigation may be necessary to defend againstthese and other claims challenging inventorship of our patents, trade secrets or other intellectual property. If we fail in defendingany such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownershipof, or right to use, intellectual property that is important to our products. If we were to lose exclusive ownership of such intellectualproperty, other owners may be able to license their rights to other third parties, including our competitors. We also may be requiredto obtain and maintain licenses from third parties, including parties involved in any such disputes. Such licenses may not be availableon commercially reasonable terms, or at all, or may be non-exclusive. If we are unable to obtain and maintain such licenses, we may needto cease the development, manufacture and commercialization of one or more of our products. The loss of exclusivity or the narrowing ofour patent claims could limit our ability to stop others from using or commercializing similar or identical technology and products. Evenif we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to managementand other employees. Any of the foregoing could harm our business, financial condition and results of operations.Â Additionally, our commercial success depends,in part, on our and any potential future collaboratorsâ€™ ability to develop, manufacture, market and sell any products that we maydevelop and use our proprietary technologies without infringing, misappropriating or otherwise violating the patents and other intellectualproperty or proprietary rights of third parties. It is uncertain whether the issuance of any third-party patent would require us or anypotential collaborators to alter our development or commercial strategies, obtain licenses or cease certain activities. The medical deviceindustry is characterized by extensive litigation regarding patents and other intellectual property rights, as well as administrativeproceedings for challenging patents, including interference, inter partes or post-grant review, derivation and reexamination proceedingsbefore the USPTO or oppositions and other comparable proceedings in foreign jurisdictions.Â Third parties, including our competitors, maycurrently have patents or obtain patents in the future and claim that the manufacture, use or sale of our products infringes upon thesepatents. We have not conducted an extensive search of patents issued or assigned to other parties, including our competitors, and no assurancecan be given that patents containing claims relating to our products, parts of our products, technology or methods do not exist, havenot been filed or could not be filed or issued. In addition, because patent applications can take many years to issue and because publicationschedules for pending patent applications vary by jurisdiction, there may be applications now pending of which we are unaware and whichmay result in issued patents which our current or future products infringe. Also, because the claims of published patent applicationscan change between publication and patent grant, there may be published patent applications that may ultimately issue with claims thatwe infringe. Unintentionally abandoned patents or applications can also be revived, so there may be recently revived patents or applicationsof which we are unaware. As the number of competitors in our market grows and the number of patents issued in this area increases, thepossibility of patent infringement claims against us escalates. Moreover, we may face claims from non-practicing entities, or NPEs, whichhave no relevant product revenue and against whom our own patent portfolio may have no deterrent effect. Third parties may in the futureclaim that our products infringe or violate their patents or other intellectual property rights.Â Â Defense of infringement claims, regardless oftheir merit or outcome, would involve substantial litigation expense and would be a substantial diversion of management and other employeeresources from our business, and may impact our reputation. In the event of a successful claim of infringement against us, we may be enjoinedfrom further developing or commercializing the infringing products and/or have to pay substantial damages for use of the asserted intellectualproperty, including treble damages and attorneysâ€™ fees were we found to willfully infringe such intellectual property. Claims thatwe have misappropriated the confidential information or trade secrets of third parties could harm our business, financial condition andresults of operations. We also might have to redesign any our allegedly infringing products or technologies, which may be impossible orrequire substantial time and monetary expenditure.Â Engaging in litigation, including to defend againstthird-party infringement claims is very expensive, particularly for a company of our size, and time-consuming. In addition, there couldbe public announcements of the results of hearings, motions or other interim proceedings or developments, and if securities analysts orinvestors perceive these results to be negative, it could have a substantial negative impact on our Common Stock price. Such litigationor proceedings could substantially increase our operating losses and reduce the resources available for development activities or anyfuture sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such litigationor proceedings adequately. Some of our competitors may be able to sustain the costs of litigation or administrative proceedings more effectivelythan we can because of greater financial resources and more mature and developed intellectual property portfolios. Uncertainties resultingfrom 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.Â Â Â 53Â Â Â We may become involved in lawsuits to protector enforce our patents and other intellectual property rights, which could be expensive, time-consuming and unsuccessful.Â Competitors may infringe our patents, or the patentsof any current or future licensing partners, or we may be required to defend against claims of infringement. Our ability to enforce ourpatent rights against competitors who infringe our patents depends on our

ability to detect such infringement. It may be difficult todetect infringers who do not advertise the components or processes that are used in their products or services. Moreover, it may be difficultor impossible to obtain evidence of infringement in a competitorâ€™s or potential competitorâ€™s product. For example, many ofour patents relate to methods and related computer processing architectures and structures for post-processing data. The use of thesemethods and structures may not be obvious or certain to assess, and may not be possible or at least may be challenging to reveal or confirmby reverse engineering, based on limited evidence that might be available to us, such as for example from only being able to observe theresults of using those methods or architectures. We may not prevail in any lawsuits that we initiate and the damages or other remediesawarded if we were to prevail may not be commercially meaningful.Â In addition, our patents or the patents of ourlicensing partners also may become involved in inventorship, priority or validity disputes. For example, although we try to ensure thatour employees, consultants and advisors are not in breach of any past contractual obligations and do not use the proprietary informationor 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 theirformer university or employer. Additionally, we may be subject to claims from third parties challenging intellectual property rights weregard as our own, based on claims that our agreements with employees or consultants obligating them to assign intellectual property tous are ineffective or in conflict with prior or competing contractual obligations to assign inventions to a previous employer, or to anotherperson or entity. Furthermore, while it is our policy to require all employees and contractors to execute agreements assigning relevantintellectual property to us, we may also be unsuccessful in executing such an agreement with each party who, in fact, conceives or developsintellectual property that we regard as our own. These assignment agreements may not be self-executing or adequate in scope, and may bebreached or challenged, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, todetermine the ownership of what we regard as our intellectual property. We may not have adequate remedies for any such breaches, and suchclaims could harm our business, financial condition and results of operations.Â To counter or defend against such claims can beexpensive and time-consuming and it may be necessary or we may desire to enter into a license to settle any such claims; however, therecan 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 issueon the grounds that our patents do not cover such technology. An adverse result in any litigation proceeding could put one or more ofour patents at risk of being invalidated or interpreted narrowly. Furthermore, because of the substantial amount of discovery requiredin connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised bydisclosure during litigation.Â Even if resolved in our favor, litigation or otherlegal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our managementand other personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motionsor other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it couldhave a substantial negative impact on our Common Stock price. Such litigation or proceedings could substantially increase our operatinglosses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We maynot have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may beable to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resourcesand more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of patentlitigation or other proceedings could harm our ability to compete in the marketplace, including ability to hire new employees or contractwith independent sales representatives. Additionally, we may lose valuable intellectual property rights or personnel. Any of the foregoingcould harm our business, financial condition and results of operations.Â Â Â Â 54Â Â Â If our trademarks and trade names are not adequatelyprotected, then we may not be able to build name recognition in our markets of interest and our business may be harmed.Â Our registered and unregistered trademarks ortrade names may be challenged, infringed, circumvented, declared generic or determined to be violating or infringing on marks held byothers. We may not be able to protect our rights to these trademarks and trade names, which we need to build or sustain name recognitionamong potential partners, customers and patients in our markets of interest. At times, competitors or other third parties may adopt tradenames 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 firstused by another party in order to extort license fees or damages in those territories in which the original user of the mark had not filedor perfected its rights to the mark. In addition, there could be potential trade name or trademark infringement, or dilution claims broughtby 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 propertymay 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.Â Intellectual property rights do not necessarilyaddress all potential threats, and limitations in intellectual property rights could harm our business, financial condition and resultsof operations.Â The degree of future protection afforded by ourintellectual property rights is uncertain because intellectual property rights have limitations, may evolve, and may not adequately protectour business or permit us to maintain our competitive advantage. For example:Â Â Â· 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; Â Â· 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; Â Â· 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; Â Â· 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; Â Â· 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; Â Â· others may independently develop

similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights; Â Â· it is possible that our current or future pending patent applications will not lead to issued patents; Â Â· it is possible that there are prior public disclosures that could invalidate our patents, or parts of our patents; Â Â· 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; Â Â· 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; Â Â· 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; Â Â· the claims of our patents or patent applications, if and when issued, may not cover our products or technologies; Â Â· 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; Â Â· 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;Â Â Â 55Â Â Â Â Â· 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; Â Â· 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; Â Â· we may not develop additional proprietary technologies that are patentable; Â Â· 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; Â Â· 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; Â Â· the patents of others may harm our business; or Â Â· 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. Â Any of the foregoing could harm our business,financial condition and results of operations.Â If we are unable to protect the confidentialityof our other proprietary information, our business and competitive position may be harmed.Â In addition to patent protection, we also relyon other proprietary rights, including protection of trade secrets, know-how and other confidential or proprietary information that isnot patentable or that we elect not to patent. However, such information can be difficult to protect, and some courts, for instance, areless 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 eachparty that may have or have had access to our trade secrets or proprietary technology and processes. Furthermore, we may not be able toprevent the unauthorized disclosure or use of our technical knowledge or other trade secrets by such third parties, despite the existencegenerally of these confidentiality restrictions. These contracts may not provide meaningful protection or equitable remedies for our tradesecrets, know-how, or other proprietary information in the event of any unauthorized use, misappropriation, or disclosure of such tradesecrets, know-how, or other proprietary information. There can be no assurance that such third parties will not breach their agreementswith us, that we will have adequate remedies for any breach, or that our trade secrets will not otherwise become known or independentlydeveloped by competitors. Despite the protections we do place on our intellectual property or other proprietary rights, monitoring unauthorizeduse and disclosure of our intellectual property is difficult, and we do not know whether the steps we have taken to protect our intellectualproperty or other proprietary rights have or will be adequate. Trade secret violations are often a matter of state law, and the criteriafor protection of trade secrets can vary among different jurisdictions. In addition, the laws of many foreign countries will not protectour intellectual property or other proprietary rights to the same extent as the laws of the United States. Consequently, we may be unableto prevent our proprietary technology from being exploited abroad, which could affect our ability to expand to foreign markets or requirecostly efforts to protect our products.Â We also license rights to use certain proprietaryinformation and technology from third parties. The use of such proprietary information and technology is therefore subject to the obligationsof the applicable license agreement between us and the owner. For example, the software we developed for our technology includes the useof open source software that is subject to the terms and conditions of the applicable open source software licenses that grant us permissionto use such software. The owner of any such proprietary information or technology also might not enforce or otherwise protect its rightsin the proprietary information or technology with the same vigilance that we would, which would allow competitors to use such proprietaryinformation and technology without having to adhere to a license agreement with the owner.Â Â Â 56Â Â Â To the extent our intellectual property or otherproprietary information protection is incomplete, we are exposed to a greater risk of direct competition. A third party could, withoutauthorization, copy or otherwise obtain and use our products or technology, or develop similar products or technology. Our competitorscould purchase our products and attempt to reverse engineer or replicate some or all of the competitive advantages we derive from ourdevelopment efforts or design around our protected products or technology. Our failure to secure, protect and enforce our intellectualproperty rights could substantially harm the value of our products, brand and business. The theft or unauthorized use or publication ofour trade secrets and other confidential business information could reduce the differentiation of our products, substantially and adverselyimpact our sales and commercial operations and harm our business. Additionally, the value of our investment in development or businessacquisitions 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.Â Further, it is possible that others will independentlydevelop the same or similar technology or product or otherwise obtain access to our unpatented technology, and in such cases, we couldnot assert any trade secret rights against such parties. Costly and time-consuming litigation could be necessary to enforce and determinethe scope of our trade secret rights and related confidentiality and nondisclosure provisions. If we fail to obtain or maintain tradesecret protection, or if our competitors otherwise obtain our trade secrets or independently develop technology or products similar toand 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 enforcein many jurisdictions and might not be enforceable in certain cases.Â We also seek to

preserve the integrity and confidentialityof our data and other confidential information by maintaining physical security of our premises and physical and electronic security ofour information technology systems. While we have confidence in these individuals, organizations, systems and tools, agreements or securitymeasures may be breached, whereby detecting the disclosure or misappropriation of confidential information and enforcing a claim thata party illegally disclosed or misappropriated confidential information is difficult, expensive and time-consuming, and the outcome isunpredictable. Further, we may not be able to obtain adequate remedies for any breach.Â Our inability to use software licensed fromthird parties, or our use of open source software under license terms that interfere with our proprietary rights, could disrupt our business.Â Our products, including our technology and methodsused, include the use of open source software that is subject to the terms and conditions of the applicable open source software licensesthat grant us permission to use such software. Although we monitor our use of open source software, the terms of many open source licensesto which we are subject have not been interpreted by U.S. or foreign courts, and there is a risk that such licenses could be construedin 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 theterms of the applicable license or our current policies and procedures. In the future, we could be required to seek licenses from thirdparties 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 usto devote additional research and development resources to change the software underlying our technology, any of which would have a negativeeffect on our business, financial condition and operating results and may not be possible in a timely manner. We and our customers mayalso be subject to suits by parties claiming infringement due to the reliance by our products on certain open source software, and suchlitigation could be costly for us to defend or subject us to injunctions enjoining us from the sale of our products that contain opensource software.Â Alternatively, we may need to re-engineer ourproducts or discontinue using portions of the functionality provided by our products. In addition, the terms of open source software licensesmay require us to provide software that we develop using such software to others on unfavorable terms, such as by precluding us from charginglicense fees, requiring us to disclose our source code, requiring us to license certain of our own source code under the terms of theapplicable open source license or requiring us to provide notice on our products using such code. Any such restriction on the use of ourown 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 ourbusiness.Â Â Â 57Â Â Â Public health crises may have an adverse effecton certain aspects of our business, results of operations, financial condition, and cash flows. The nature and extent of future impactsare highly uncertain and unpredictable.Â Our business is subject to risks associated withpublic health crises, including epidemics and pandemics such as COVID-19. In particular, the preventative and precautionary measures thatwe and other businesses, communities, and governments may take to mitigate the spread of the disease could lead to restrictions on, anddisruptions in, business and personal activities that reduce the demand for deferrable and emergent medical procedures such as surgicalinterventions to treat low back pain. It is not possible to predict the timing of deferrable medical procedures and, to the extent individualsand hospital systems de-prioritize, delay or cancel these procedures, our business, results of operations, financial condition, and cashflows could be negatively affected.Â To date we have not experienced material disruptionsin our business operations. However, while it is not possible at this time to estimate the impact that COVID-19 or other epidemic diseasecould have on our business in the future, particularly as we advance our product development and marketing, the measures taken by thegovernmental authorities, and any future epidemic disease outbreaks could: (i) disrupt our operations and the manufacture or shipmentof MRIs and MRSs used with our products and in our research, preclinical studies and clinical trials (ii) delay, limit or prevent ouremployees 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 trialswill 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 clinicaltrials 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 regulatoryauthorities, which could result in delays in meetings related to planned clinical trials.Â Other risks facing our companyÂ If product liability lawsuits are brought againstus, we may incur substantial liabilities and may be required to limit or halt the marketing and sale of our technology. The expense andpotential unavailability of insurance coverage for liabilities resulting from our technology could harm our business and our ability tosell our technology.Â We face an inherent risk of product liabilityas a result of the marketing and sale of our technology. Although we have established internal procedures designed to minimize risks thatmay arise from quality issues, there can be no assurance that we will eliminate or mitigate occurrences of these issues and associatedliabilities. Our products and services are diagnostic in nature and involve an exam that is non-invasive using other third-party MR scannerproducts and technologies. Those exams are also conducted by other third party MR service providers. The results of using our productsare also intended to provide information to doctors that help them perform a diagnosis for their patient, using all other diagnostic informationthat is available to them. The downstream results from those diagnoses may also lead to certain treatments being performed, which aredecided upon between that treating doctor and the patient (and related payers), and which are conducted by that treating doctor on thepatient. We are not responsible for the performance of those MR scanners, nor for the performance of the MR service providers for conductingthose patient exams using the MR scanners, nor for the final diagnosis performed by a doctor as assisted via the results of our productsin combination with other available information, nor for the decisions and performance on conducting treatments or other on-going patientcare, or the patient outcomes from that care, following the use of our diagnostic assistance product. However, there are risks that certainliability exposures or claims could be threatened or actually filed against us with respect to the performance or results of these otheractivities around and relating to, but not directly caused by, the use of our products, including with respect to the use of our productsin the overall patient care regimen that might result in adverse patient outcomes. Even if we successfully defend any such allegationor claim, this could involve significant risk of liability exposure and significant cost and diversion of resources and focus.Â Â Â Â 58Â Â Â If we cannot successfully defend ourselves againstproduct liability claims, we may incur substantial liabilities or be required to limit or halt commercialization of our products. Regardlessof the merits or eventual outcome, liability claims may result in:Â Â Â· decreased demand for our technology; Â Â· injury to our brand or

reputation; Â Â· initiation of investigations by regulators; Â Â· costs to defend the related litigation; Â Â· increased insurance premiums; Â Â· a diversion of managementâ€™s time and our resources; Â Â· substantial monetary awards to trial participants or patients; Â Â· regulatory investigations, product recalls, withdrawals or labeling, marketing or promotional restrictions; Â Â· loss of revenue; Â Â· exhaustion of any available insurance and our capital resources; and Â Â· the inability to market and sell our products. Â We believe we have adequate product liabilityinsurance, 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 maintainor obtain insurance at a reasonable cost or in an amount adequate to satisfy any liability that may arise. Our insurance policy containsvarious exclusions, and we may be subject to a product liability claim for which we have no coverage. The potential inability to obtainsufficient product liability insurance at an acceptable cost to protect against product liability claims could prevent or inhibit themarketing and sale of products we may develop. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceedour coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to paysuch amounts, which would harm our business, financial condition and results of operations. In addition, any product liability claimsbrought against us, with or without merit, could increase our product liability insurance rates or prevent us from securing continuingcoverage, harm our patient-focused brand, negatively impact our reputation in the industry, significantly increase our expenses and reduceproduct sales.Â Some of our customers may also have difficultyin procuring or maintaining liability insurance to cover their operations, including their use of our products. Medical malpractice carriersare withdrawing coverage in certain states or substantially increasing premiums. If this trend continues or worsens, our customers maydiscontinue using our products and potential additional customers may opt against purchasing our products due to the cost or inabilityto procure insurance coverage.Â The failure of third parties to meet theircontractual, regulatory and other obligations could adversely affect our business.Â 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 managecertain parts of our business. Using these third parties poses a number of risks, such as:Â Â Â Â· they may not perform to our standards or legal requirements; Â Â· they may not produce reliable results; Â Â· they may not perform in a timely manner; Â Â· they may not maintain confidentiality of our proprietary information; Â Â· disputes may arise with respect to ownership of rights to products developed with our partners; and Â Â· disagreements could cause delays in, or termination of, the research, development or commercialization of our products or result in litigation or arbitration. Â If and as any of one or more of these identifiedparties might be replaced in the future by another party with whom we might engage or rely upon for similar technological or businesspurposes, or to the extent we may expand our business to involve and rely on still more additional parties for similar purposes as thoselisted (e.g. additional MR scanner vendors), similar risks would apply to those other parties.Â Â Â 59Â Â Â Moreover, some third parties may be located inmarkets subject to political and social risk, corruption, infrastructure problems and natural disasters, in addition to country-specificprivacy and data security risk given current legal and regulatory environments. Failure of third parties to meet their contractual, regulatoryand other obligations may materially affect our business.Â Litigation and other legal proceedings mayharm our business.Â From time to time in the future we may becomeinvolved 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 proceedingsor investigations, which could have a negative impact on our reputation, business and financial condition and divert the attention ofour management from the operation of our business.Â Litigation is inherently unpredictable and canresult in excessive or unanticipated verdicts, judgements, and/or injunctive relief that affect how we operate our business. We couldincur 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 investigationsin the future, which could harm our business, financial condition and results of operations. Adverse publicity about regulatory or legalaction against us, irrespective of outcome, could damage our reputation and brand image, undermine our customersâ€™ confidence andreduce long-term demand for our products, even if the regulatory or legal action is unfounded or not material to our operations.Â Â Our operating results may fluctuate acrossperiods, which makes our future operating results difficult to predict and could cause our operating results to fall below expectationsor any guidance we may provide.Â Our quarterly and annual operating results mayfluctuate across periods, which makes it difficult for us to predict our future operating results. Accordingly, the results of any onequarter or period should not be relied upon as an indication of future performance. Our quarterly and annual operating results may fluctuatedue to a variety of factors, many of which are outside of our control, including, but not limited to:Â Â Â Â· The level of demand for our technology and any future technology, which may vary significantly from period to period; Â Â· Expenditures that we may incur to acquire, develop or commercialize additional technology; Â Â· The timing and cost of obtaining regulatory approvals or clearances to expand our indications and get future approvals of any future technology or features; Â Â· Pricing pressures; Â Â· Our ability to expand the geographic reach of our commercial efforts; Â Â· 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; Â Â· Coverage and reimbursement policies with respect to our technology, and potential future technology that compete with our products; Â Â· 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; Â Â· Positive or negative coverage in the media or clinical publications of our technology or technology of our competitors or our industry; Â Â· 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; Â Â· The cost of developing our technology, which may vary depending on the terms of our agreements with third-party; and Â Â· Future accounting pronouncements or changes in our accounting policies. Â The cumulative effects of these factors couldresult in fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating resultson a period-to-period basis may not be meaningful. Further, our historical results are not necessarily indicative of results expectedfor any future period, and quarterly results are not necessarily indicative of the results to be expected for the full year or any otherperiod. Investors should not rely on our past results as an indication of our future performance.Â Â Â 60Â Â Â This variability and unpredictability could alsoresult in our failing to meet the expectations of industry or financial analysts or investors for any period. If our revenue or operatingresults 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.Â Â We will incur increased costs as a result ofoperating as a

public company, and our management and board of directors will be required to devote substantial time to compliance withour public company responsibilities and corporate governance practices.Â As a public company, we will incur significantlegal, accounting and other expenses that we did not incur as a private company. We expect such expenses to further increase after weare no longer an emerging growth company. The Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listingrequirements of the Nasdaq Capital Market, and other applicable securities rules and regulations impose various requirements on publiccompanies. Furthermore, most senior members of our management team as well as our board of directors do not have significant experiencewith operating a public company. As a result, our management, board of directors, and other personnel will have to devote a substantialamount of time to compliance with these requirements. Moreover, these rules and regulations will increase our legal and financial compliancecosts and will make some activities more time-consuming and costly. We cannot predict or estimate the amount of additional costs we willincur as a public company or the timing of such costs.Â Risks related to the ownership of our Common Stock and IPO WarrantsÂ Our stock price may be volatile, and the valueof our Common Stock and IPO Warrants may decline.Â The market price of our Common Stock and IPO Warrantsmay be highly volatile and may fluctuate or decline substantially as a result of a variety of factors, some of which are beyond our controlor are related in complex ways, including:Â Â Â· Actual or anticipated fluctuations in our financial condition and results of operations; Â Â· Variance in our financial performance from expectations of securities analysts or investors; Â Â· Changes in the coverage decisions, reimbursement or pricing of our technology; Â Â· Changes in our projected operating and financial results; Â Â· Changes in laws or regulations applicable to our technology; Â Â· Announcements by us or our competitors of significant business developments, acquisitions, or new offerings; Â Â· Publicity associated with issues related to our technology; Â Â· Our involvement in regulatory investigations or litigation; Â Â· Future sales of our Common Stock or other securities, by us or our stockholders, as well as the anticipation of lock-up releases; Â Â· Changes in senior management or key personnel; Â Â· The trading volume of our Common Stock; Â Â· Changes in the anticipated future size and growth rate of our market; Â Â· General economic, regulatory, and market conditions, including economic recessions or slowdowns; Â Â· Changes in the structure of healthcare payment systems; and Â Â· Developments or disputes concerning our intellectual property or other proprietary rights. Â Broad market and industry fluctuations, as wellas 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 ourshares may be subject to increased volatility. In the past, securities class action litigation has often been brought against a companyfollowing a decline in the market price of its securities. This risk is especially relevant for us, because medical device companies haveexperienced significant stock price volatility in recent years. If we face such litigation, it could result in substantial costs and adiversion of managementâ€™s attention and resources, which could harm our reputation and our business.Â Â Â Â 61Â Â Â A significant portionof our total outstanding shares may be sold into the market, which could cause the market price of our Common Stock to drop significantly,even if our business is performing well.Â Sales of a substantial number of shares of ourCommon Stock in the public market could occur at any time. These sales, or the perception in the market that holders of a large numberof shares intend to sell shares, could reduce the market price of our Common Stock.Â You may experience additional dilution if anyof our outstanding common stock warrants are exercised.Â If the holders of any of our outstanding commonstock warrants exercise their warrants, you will experience dilution at the time they exercise their warrants.Â The issuance of CommonStock to White Lion pursuant to the Equity Line Purchase Agreement may cause substantial dilution to our existing shareholders, and thesale of such shares acquired by White Lion could cause the price of our Common Stock to decline.Â Under our Equity LinePurchase Agreement with White Lion, the Company has the right, but not the obligation to require White Lion to purchase, from time totime, up to of $10,000,000 in aggregate gross purchase price of newly issued shares of the Companyâ€™s Common Stock. Through December[***], 2024, the Company has sold 1,800,000 shares to White Lion for total proceeds of $3,216,981. We currently have effective registrationstatements that registers for resale by White Lion up to 22,500,000 shares of Common Stock that we may issue to White Lion under theEquity Line Purchase Agreement, of which there are 21,450,000 remaining to be issued. After White Lion has acquired shares under theEquity Line Purchase Agreement, it may sell all, some or none of those shares. Sales to White Lion by us pursuant to the Equity LinePurchase Agreement under this prospectus may result in substantial dilution to the interests of other holders of our Common Stock.Â The sale of a substantialnumber of shares to White Lion, or anticipation of such sales, could make it more difficult for us to sell equity or equity-related securitiesin the future at a time and at a price that we might otherwise desire. The number of shares of our Common Stock ultimately offered forresale by White Lion is dependent upon the number of shares of Common Stock issued to the White Lion pursuant to the Equity Line PurchaseAgreement. Depending on a variety of factors, including market liquidity of our Common Stock, the issuance of shares to the Selling Securityholdermay cause the trading price of our Common Stock to decline.Â The price of our Common Stock may be volatileand fluctuate substantially, which could result in substantial losses for investors in our Common Stock.Â Our Common Stock price is likely to be volatile.The stock market in general and the market for bio-technology companies in particular, has experienced extreme volatility that has oftenbeen unrelated to the operating performance of particular companies. As a result of this volatility, you may not be able to sell yourCommon Stock at or above your investment price. The market price for our Common Stock may be influenced by many factors, including:Â Â Â· the success of competitive products or technologies; Â Â Â Â Â· regulatory or legal developments in the United States, Â Â Â Â Â· the recruitment or departure of key personnel; Â Â Â Â Â· the level of expenses related to any of our product candidates, and our commercialization efforts; Â Â Â Â Â· actual or anticipated changes in our development timelines; Â Â Â Â Â· our ability to raise additional capital;Â Â Â 62Â Â Â Â Â Â Â· disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our product candidates; Â Â Â Â Â· significant lawsuits, including patent or stockholder litigation; Â Â Â Â Â· variations in our financial results or those of companies that are perceived to be similar to us; Â Â Â Â Â· general economic, industry and market conditions; and Â Â Â Â Â· the other factors described in this â€œRisk Factorsâ€ section. Â Â If our quarterly operatingresults 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 believethat quarterly comparisons of our financial results are not necessarily meaningful and should not be relied upon as an indication of ourfuture performance.Â In the past, followingperiods of volatility in the market price of a companyâ€™s securities, securities class-action litigation often has been institutedagainst that company. Such litigation, if instituted against us, could cause us to incur substantial costs to defend such claims and divertmanagementâ€™s attention and

resources.Â Because we do notexpect to pay dividends for the foreseeable future, investors seeking cash dividends should not purchase shares of our Common Stock. Â We have never declared or paid any cash dividendson our Common Stock. We currently intend to retain future earnings, if any, to finance the expansion of our business. As a result, wedo not anticipate paying any cash dividends in the foreseeable future. Our payment of any future dividends will be at the discretion ofour 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 seekingcash dividends should not purchase our shares.Â If securities analystsdo not publish research or reports about our business or if they publish negative evaluations of our stock, the price of our stock coulddecline.Â The trading market forour 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 commencecoverage of us, the trading price of our stock would likely decrease. Even if we do obtain analyst coverage, if one or more of the analystscovering our business downgrade their evaluations of our stock, the price of our stock could decline. If one or more of these analystscease to cover our stock, we could lose visibility in the market for our stock, which in turn could cause our stock price to decline.Â We are an emerging growth company and a smallerreporting company, and our compliance with the reduced reporting and disclosure requirements applicable to emerging growth companies andsmaller reporting companies could make our Common Stock less attractive to investors.Â We are an emerging growth company, as definedin the JOBS Act, and we expect to take advantage of certain exemptions from various reporting requirements that are applicable to otherpublic companies that are not emerging growth companies, including the auditor attestation requirements of Section 404, reduced disclosureobligations regarding executive compensation in our periodic reports and proxy statements, exemptions from the requirements of holdinga nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approvedand extended adoption period for accounting pronouncements.Â Â Â Â 63Â Â Â Even after we no longer qualify as an emerginggrowth company, we may still qualify as a â€œsmaller reporting company,â€ which would allow us to continue to take advantageof many of the same exemptions from disclosure requirements, including not being required to comply with the auditor attestation requirementsof Section 404 of the Sarbanes-Oxley Act and reduced disclosure obligations regarding executive compensation in this prospectus and ourperiodic reports and proxy statements.Â We cannot predict whether investors will findour Common Stock less attractive as a result of our reliance on these exemptions. If some investors find our Common Stock less attractiveas a result, there may be a less active trading market for our Common Stock and our stock price may be more volatile.Â We will remain an emerging growth company untilthe earliest of (i) the end of the fiscal year following the fifth anniversary of the completion of our IPO, (ii) the first fiscal yearafter our annual gross revenues exceed $1.235 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 ourCommon Stock held by non-affiliates exceeds $700 million as of the end of the second quarter of that fiscal year.Â Provisions in our corporate charter and ourbylaws and under Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may preventattempts by our stockholders to replace or remove our current management.Â The anti-takeover provisions of the Delaware GeneralCorporation Law (the â€œDGCLâ€) may discourage, delay or prevent a change in control by prohibiting us from engaging in a businesscombination with an interested stockholder for a period of three years after the person becomes an interested stockholder, even if a changein control would be beneficial to our existing stockholders.Â Provisions in our corporate charter and our bylawsdiscourage, delay or prevent a merger, acquisition or other change in control of us that stockholders may consider favorable, includingtransactions in which you might otherwise receive a premium for your shares. These provisions also could limit the price that investorsmight 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 preventany attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace membersof our board of directors. Among other things, these provisions:Â Â Â· allow the authorized number of our directors to be changed only by resolution of our board of directors; Â Â Â Â Â· limit the manner in which stockholders can remove directors from the board; Â Â Â Â Â· establish advance notice requirements for stockholder proposals that can be acted on at stockholder meetings and nominations to our board of directors; Â Â Â Â Â· require that stockholder actions must be effected at a duly called stockholder meeting and prohibit actions by our stockholders by written consent; Â Â Â Â Â· limit who may call stockholder meetings; Â Â Â Â Â· authorize our board of directors to issue preferred stock without stockholder approval, which could be used to institute a stockholder rights plan, orÂ so-called â€œpoison pill,â€ 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 Â Moreover, because we are incorporated in Delaware,we are governed by the provisions of SectionÂ 203 of the DGCL, which prohibits a person who owns in excess of 15% of our outstandingvoting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquiredin excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner.Â Â Â 64Â Â Â Our amended and restated certificate of incorporationprovides that the Court of Chancery of the State of Delaware or, under certain circumstances, the federal district courts of the UnitedStates 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 stockholdersâ€™ ability to obtain a favorable judicial forum for disputes with us or our directors, officers,employees or agents.Â Our amended and restated certificate of incorporationprovides that the Court of Chancery of the State of Delaware (or, if the Court of Chancery of the State of Delaware lacks subject matterjurisdiction, any state court located within the State of Delaware or, if all such state courts lack subject matter jurisdiction, thefederal district court for the District of Delaware) is the sole and exclusive forum for the following types of actions or proceedingsunder Delaware statutory or common law for:Â Â Â· any derivative action or proceeding brought on our behalf; Â Â· any action asserting a breach of fiduciary duty; Â Â· any action arising pursuant to the Delaware General Corporation Law, our amended and restated certificate of incorporation, or our amended and restated bylaws; and Â Â· any action asserting a claim against us that is governed by the internal-affairs doctrine. Â These provisions would not apply to suits broughtto enforce a duty or liability created by the Exchange Act or any claim for which the federal district courts of the United States ofAmerica have exclusive jurisdiction. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and statecourts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims.Â Our stockholders cannot waive compliance withthe federal securities laws and the rules and regulations

thereunder. Any person or entity purchasing or otherwise acquiring any interestin shares of our capital stock will be deemed to have notice of, and consented to, the provisions of our amended and restated certificateof incorporation described in the preceding sentences.Â To prevent having to litigate claims in multiplejurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our amended and restatedcertificate of provides that the federal district courts of the United States will be the exclusive forum for resolving any complaintasserting a cause of action arising under the Securities Act. While the Delaware courts have determined that such choice of forum provisionsare facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forumprovisions. In such instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions ofour amended and restated certificate of incorporation in effect upon the effectiveness of our IPO. This may require significant additionalcosts associated with resolving such action in other jurisdictions and there can be no assurance that the provisions will be enforcedby a court in those other jurisdictions.Â These exclusive forum provisions may limit a stockholderâ€™sability 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-forumprovision in our amended and restated certificate of incorporation in effect upon the effectiveness of our IPO to be inapplicable or unenforceablein an action, we may incur further significant additional costs associated with resolving the dispute in other jurisdictions, all of whichcould harm our business and financial condition.Â Â Â Â 65Â Â Â MARKET AND INDUSTRYDATAÂ Unless otherwise indicated,information contained (or incorporated by reference) in this prospectus concerning our industry and the markets in which we operate isbased on information from independent industry and research organizations, other third-party sources and management estimates. Managementestimates are derived from publicly available information released by independent industry analysts and third-party sources, as well asdata from our internal research, and are based on assumptions made by us upon reviewing such data and our knowledge of such industry andmarkets which we believe to be reasonable. Although we believe the data from these third-party sources is reliable, we have not independentlyverified any third-party information. In addition, projections, assumptions and estimates of the future performance of the industry inwhich we operate and our future performance are necessarily subject to uncertainty and risk due to a variety of factors, including thosedescribed in â€œRisk Factorsâ€ and â€œInformationRegarding Forward-Looking Statements.â€ These and other factors could cause results to differ materially from those expressedin the estimates made by the independent parties and by us.Â Â Â Â Â Â Â Â Â Â Â 66Â Â Â USE OF PROCEEDSÂ We estimate that the net proceeds we will receivefrom the sale of our securities in this offering, after deducting commissions and estimated offering expenses payable by us, and assumingno sale of any Pre-Funded Warrants and no exercise of the Common Warrants being issued in this offering, will be approximately $[***],based on an assumed combined public offering price of $[***] per share and accompanying Common Warrants, which was the closing price forour Common Stock on the Nasdaq Capital Market on[***], 2024. If the Common Warrants are exercised in full for cash, the estimated netproceeds will increase to $[***]. We cannot predict when, or if, the Common Warrants will be exercised. It is possible that the CommonWarrants may expire and may never be exercised for cash.Â We intend to use thenet proceeds from this offering, together with our existing cash, to redeem all outstanding shares of our Series B Preferred Stock andSeries C Preferred Stock, each at a redemption price per share equal to $1,000 plus all accrued but unpaid dividends on each such share,with the remaining net proceeds to be used to build out the product platforms, expand our sales and marketing efforts, and for generaland administration expenses and other general corporate purposes.Â Our expected use of netproceeds from this offering represents our current intentions based upon our present plans and business condition. As of the date of thisprospectus, we cannot predict with complete certainty all of the particular uses for the net proceeds to be received upon the completionof this offering or the actual amounts that we will spend on the uses set forth above. We believe opportunities may exist from time totime to expand our current business through the acquisition or in-license of complementary product candidates. While we have no currentagreements for any specific acquisitions or in-licenses at this time, we may use a portion of the net proceeds for these purposes.Â Pending the uses describedabove, we plan to invest the net proceeds from this offering in short- and intermediate-term, interest-bearing obligations, investment-gradeinstruments, certificates of deposit or direct or guaranteed obligations of the U.S. government.Â Â Â Â Â Â Â 67Â Â Â DIVIDEND POLICYÂ We have not declaredor paid any cash dividends on our capital stock since our inception. We intend to retain future earnings, if any, to finance the operationand expansion of our business and do not anticipate paying any cash dividends in the foreseeable future.Â Â CAPITALIZATIONÂ The following table describes our cash and capitalizationas of September 30, 2024:Â Â Â· On an actual basis; and Â Â Â Â Â· on a pro forma as-adjusted basis to give effect to the sale of [***] shares of our common stock in this offering at the assumed offering price of $[***] per share, which was the last reported sale price of our Common Stock on the Nasdaq Capital Market on [***], 2024, after deducting underwriting discounts and commissions and estimated offering expenses payable by us. Â The pro forma as-adjusted information below isillustrative only, and our capitalization following the completion of this offering will be adjusted based on the actual public offeringprice and other terms determined at pricing. You should read this information together with our financial statements and related notesincorporated by reference in this prospectus and the information set forth under the headings â€œUseof Proceedsâ€ in this prospectus and â€œManagementâ€™s Discussion and Analysis of Financial Condition and Results ofOperationsâ€ incorporated by reference in this prospectus.Â Â Â September 30, 2024 Â Â Â Â Â Â Pro Forma Â Â Â Actual Â Â as-adjusted Â (Several financial statement line items excluded for presentation purposes) Â Â Â Â Â Â Â Â Â Cash Â $ 1,322,098 Â Â $ Â Â Common Stock (10,044,728 and 66,297,081 shares) Â Â 100 Â Â Â Â Â Additional Paid-in Capital Â Â 51,782,424 Â Â Â Â Â Accumulated deficit Â Â (49,272,739) Â Â Â Â Total Shareholdersâ€™ Equity Â $ 2,509,785 Â Â $ Â Â Â Each $0.10 increase (decrease) in the assumedpublic offering price of $[***] per share would increase (decrease) the as adjusted amount of additional paid-in capital, total stockholdersâ€™equity and total capitalization by $[***] million, assuming that the number of shares offered by us, as set forth on the cover page ofthis prospectus, remains the same, and after deducting underwriting discounts and commissions and estimated offering expenses payableby us. We may also increase or decrease the number of shares we are offering. Each increase (decrease) of 1,000,000 shares of common stockoffered by us would increase (decrease) the as adjusted amount of each of additional paid-in capital, total stockholdersâ€™ equityand total capitalization by approximately $[***] million, assuming that the assumed price to the public remains the same, and after deductingunderwriting discounts and commissions and estimated expenses payable by us.Â Â Â Â Â Â Â Â Â 68Â Â Â The number of sharesof common stock issued and outstanding, actual and pro forma as adjusted, in the table above is based on our actual shares of our commonstock which were outstanding as of September 30, 2024 (10,044,728) and excludes the following items (which are calculated as of November14, 2024):Â Â Â· 136,123 shares of our common

stock issuable upon the exercise of outstanding stock options granted under our 2015 Stock Plan, Â Â· 33,334 shares of our common stock issuable upon the exercise of outstanding stock options granted under our 2022 Stock Plan, Â Â· 130,093 shares of our common stock reserved for future grant under our 2022 Stock Plan, Â Â· 10,350,000 shares of our common stock issuable upon the exercise of our outstanding February 2024 public offering warrants, Â Â· 5,685,049 shares of our common stock issuable upon the exercise of our outstanding September 2024 warrants, Â Â· 155,610 shares of common stock issuable upon the exercise of our outstanding IPO Warrants, Â Â· 551,815 shares of common stock issuable upon the exercise of outstanding privately placed warrants, Â Â· 10,825 shares of common stock reserved for issuance upon the exercise of an outstanding IPO underwriter representative common stock warrant. Â Â· approximately 3,974,581 shares of common stock which may be issued upon conversion of our outstanding Series B Convertible Preferred Stock at the current conversion price of $0.234, Â Â· approximately 5,685,049 shares of common stock which may be issued upon conversion of our outstanding Series C Convertible Preferred Stock at the current conversion price of $0.1759, and Â Â· up to $6.8 million worth of common stock that may be sold in the future by us to White Lion from time to time pursuant to the Equity Line Purchase Agreement. Â Â Â Â Â Â Â Â Â Â Â 69Â Â Â DILUTIONÂ If you invest in thisoffering, your ownership interest may be diluted immediately depending on the difference between the assumed public offering price pershare of Common Stock (assuming the exercise for cash of all Pre-Funded Warrants issued in this offering) and the as adjusted net tangiblebook value per share of our Common Stock immediately after this offering (assuming the exercise for cash of all Pre-Funded Warrants issuedin this offering).Â Historical net tangible book value (deficit) pershare is determined by dividing our total tangible assets (which excludes deferred offering costs) less our total liabilities by the totalnumber of shares of common stock outstanding. Our historical net tangible book value (deficit) as of September 30, 2024, was $1,219,946,or $0.12 per share, based on 10,044,728 shares of Common Stock outstanding as of that date.Â After giving effect to the sale of [***] sharesof our Common Stock, or up to[***] Pre-Funded Warrants in lieu of shares of Common Stock (and the full exercise of those Pre-Funded Warrants),issued by us and after deducting commissions and estimated offering expenses payable by us, our as-adjusted net tangible book value asof September 30, 2024 would have been approximately $[***]Â million, or $[***] per share. This represents an immediate increase inas adjusted net tangible book value of $[***] per share to our existing stockholders and an immediate dilution of $[***] per share tonew investors participating in this offering, as illustrated by the following table (which assumes no exercise of the Common Warrants).Â The following table illustrates this dilutionper share:Â Assumed combined public offering price per share and accompanying common warrant Â Â Â Â Â $ Â Â Historical net tangible book value per share as of September 30, 2024 Â $ 0.121 Â Â Â Â Â Increase in net tangible book value per share attributable to this offering Â $ Â Â Â Â Â Â As-adjusted net tangible book value per share as of September 30, 2024 after this offering Â Â Â Â Â $ Â Â Dilution per share to new investors participating in this offering Â Â Â Â Â $ Â Â Â Each $0.10 increase (decrease) in the assumedcombined public offering price of $[***] per share and accompanying Common Warrants would increase (decrease) the as-adjusted net tangiblebook value by $[***] per share and the dilution per share to new investors by $[***] per share, assuming the number of shares offeredby us, as set forth on the cover page of this prospectus, remains the same and assuming no Pre-Funded Warrants are sold in this offering,no exercise of the Common Warrants being offered in this offering, that no value is attributed to such Common Warrants and that such CommonWarrants are classified as and accounted for as equity, and after deducting commissions and estimated offering expenses payable by us.Â We may also increase or decrease the number ofshares we are offering. Each increase (decrease) of 1,000,000 shares of common stock we are offering would increase (decrease) our as-adjustednet tangible book value by approximately $[***] million, or $[***] per share, and decrease (increase) the dilution per share to new investorsparticipating in this offering by $[***] per share, assuming that the assumed public offering price remains the same, and after deductingcommissions and estimated offering expenses payable by us. The as-adjusted information discussed above is illustrative only and will changebased on the actual public offering price, number of shares and other terms determined at pricing.Â The foregoing table and calculations are basedon our actual shares of our common stock which were outstanding as of September 30, 2024 (10,044,728) and excludes the following items(which are calculated as of November 14, 2024):Â Â Â· 136,123 shares of our common stock issuable upon the exercise of outstanding stock options granted under our 2015 Stock Plan, Â Â· 33,334 shares of our common stock issuable upon the exercise of outstanding stock options granted under our 2022 Stock Plan, Â Â· 130,093 shares of our common stock reserved for future grant under our 2022 Stock Plan, Â Â· 10,350,000 shares of our common stock issuable upon the exercise of our outstanding February 2024 public offering warrants, Â Â· 5,685,049 shares of our common stock issuable upon the exercise of our outstanding September 2024 warrants, Â Â· 155,610 shares of common stock issuable upon the exercise of our outstanding IPO Warrants, Â Â· 551,815 shares of common stock issuable upon the exercise of outstanding privately placed warrants, Â Â· 10,825 shares of common stock reserved for issuance upon the exercise of an outstanding IPO underwriter representative common stock warrant. Â Â· approximately 3,974,581 shares of common stock which may be issued upon conversion of our outstanding Series B Convertible Preferred Stock at the current conversion price of $0.234, Â Â· approximately 5,685,049 shares of common stock which may be issued upon conversion of our outstanding Series C Convertible Preferred Stock at the current conversion price of $0.1759, and Â Â· up to $6.8 million worth of common stock that may be sold in the future by us to White Lion from time to time pursuant to the Equity Line Purchase Agreement. Â Â Â Â 70Â Â Â MarketPrice of and Dividends on Common Equity and Related Stockholder MattersÂ Our common stock has been traded on the NasdaqStock Market under the symbol â€œACONâ€ since our IPO on April 21, 2022. Our IPO Warrants have been traded on the Nasdaq StockMarket under the symbol â€œACONWâ€ since our IPO on April 21, 2022. As of January 1, 2024, there were approximately 137 holdersof record of our common stock and 1 holder of record of our IPO Warrants. These numbers are based on the actual number of holders registeredat such date and do not include holders whose shares are held in â€œstreet nameâ€ by brokers and other nominees.Â DividendsÂ We have never paid anycash dividends on our common stock. We currently intend to retain all available funds and any future earnings for use in the operationof our business and do not anticipate paying any cash dividends on our common stock in the foreseeable future. Any future determinationto 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.Â Â Â Â Â Â 71Â Â Â Managementâ€™sDiscussion and Analysis of Financial Condition and Results of OperationsÂ You should read thefollowing 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 (â€œU.S. GAAPâ€) and related notesincluded elsewhere in this prospectus. The following discussion contains forward-looking statements that are subject to risks and uncertainties.See â€œSpecial Note Regarding Forward-Looking Statementsâ€ for a discussion of

the uncertainties, risks, and assumptions associatedwith those statements. Actual results could differ materially from those discussed in or implied by forward-looking statements as a resultof various factors, including those discussed below and elsewhere in this prospectus, particularly in the section entitled â€œRiskFactors.â€ Unless we state otherwise or the context otherwise requires, the terms â€œwe,â€ â€œus,â€ â€œourâ€and the â€œCompanyâ€ refer to Aclarion, Inc. Â OverviewÂ Aclarion is a healthcaretechnology company that leverages Magnetic Resonance Spectroscopy (â€œMRSâ€), proprietary signal processing techniques, biomarkers,and augmented intelligence algorithms to optimize clinical treatments. The Company is first addressing the chronic low back pain marketwith Nociscan, the first, evidence-supported, SaaS platform to noninvasively help physicians distinguish between painful and nonpainfuldiscs in the lumbar spine. Through a cloud connection, Nociscan receives magnetic resonance spectroscopy (MRS) data from an MRI machinefor each lumbar disc being evaluated. In the cloud, proprietary signal processing techniques extract and quantify chemical biomarkersdemonstrated to be associated with disc pain. Biomarker data is entered into proprietary algorithms to indicate if a disc may be a sourceof pain. When used with other diagnostic tools, Nociscan provides critical insights into the location of a patientâ€™s low back pain,giving physicians clarity to optimize treatment strategies.Â To date, we have financedour operations primarily through private placements of preferred shares and debt financing, PPP loans that were forgiven, an equity line,an initial public offering on April 21, 2022, and a subsequent public offering on February 27, 2024.Â Since our inception wehave incurred significant operating losses. As of March 31, 2024, we had an accumulated deficit of approximately $46.7 million. Our abilityto generate product revenue sufficient to achieve profitability will depend heavily on the successful commercialization and continueddevelopment of our SaaS platform. We expect that our expenses and capital requirements will increase substantially in connection withour ongoing activities, particularly if and as we:Â Â Â· identify and support Key Opinion Leader (â€œKOLâ€) physicians and radiologists to help secure local payer coverage decisions and spine society support for our technology; Â Â· 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; Â Â· 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; Â Â· 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; Â Â· 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; Â Â· add operational and general administrative personnel which will support our product development programs, commercialization efforts, and our transition to operating as a public company. Â Our primary near-termgrowth strategy is to secure payer contracts (including insurance companies, self-insured employers, Medicare, Medicaid, workmenâ€™scompensation boards et. al.) to cover our Category III CPT codes. We believe that with favorable payer coverage, the Company has the opportunityto more efficiently engage physicians and imaging centers that will adopt our technology.Â As a result, we may needsubstantial additional funding to support our continuing operations and pursue our growth strategy. Until such time as we can generatesignificant revenue from product sales, if ever, we expect to finance our operations through the sale of equity, debt financings or othercapital sources, which may include collaborations with other companies or other strategic transactions.Â Â Â 72Â Â Â As of September 30, 2024,the Company had cash, including $10,000 of restricted cash, of $1,322,098. The Company believes that this cash will be sufficient to fundcurrent operating plans into December 2024. We have based this estimate on assumptions that may prove to be wrong, and we could exhaustour available capital resources sooner than we expect. See â€œLiquidity and capital resources.â€ To finance our operations beyondthat point, we will need to raise additional capital, which cannot be assured. If we are unable to raise additional capital in sufficientamounts or on terms acceptable to us, we may have to significantly delay, scale back, or discontinue the commercialization or furtherdevelopment of our SaaS platform.Â Corporate InformationÂ We were formed under the name Nocimed, LLC, alimited liability company in January 2008, under the laws of the State of Delaware. In February 2015, Nocimed, LLC was converted intoNocimed, Inc. a Delaware corporation. On December 3, 2021, we changed our name to Aclarion, Inc. Our principal executive offices are locatedat 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 thisprospectus.Â Results of operationsÂ Operating activities:Â The following table summarizesour results of operations for the twelve months ended December 31, 2023, and 2022.Â Â Â Year Ended December 31, Â Â Â Â Â Â 2023 Â Â 2022 Â Â 2022 to 2023 Â Â Â Â Â Â (restated) Â Â $ Change Â Revenue Â Â Â Â Â Â Â Â Â Â Â Â Â Revenue Â $ 75,404 Â Â $ 60,444 Â Â $ 14,960 Â Cost of revenue Â Â 75,728 Â Â Â 65,298 Â Â Â 10,430 Â Gross profit (loss) Â Â (324) Â Â (4,854) Â Â 4,530 Â Operating expenses: Â Â Â Â Â Â Â Â Â Â Â Â Sales and marketing Â Â 757,004 Â Â Â 498,003 Â Â Â 259,001 Â Research and development Â Â 873,336 Â Â Â 1,067,992 Â Â Â (194,656) General and administrative Â Â 3,245,317 Â Â Â 3,990,719 Â Â Â (745,402) Total operating expenses Â Â 4,875,657 Â Â Â 5,556,714 Â Â Â (681,057) Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Income (loss) from operations Â Â (4,875,981) Â Â (5,561,568) Â Â 685,587 Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Other income (expense): Â Â Â Â Â Â Â Â Â Â Â Â Interest expense Â Â (608,288) Â Â (1,507,546) Â Â 899,258 Â Changes in fair value of warrant and derivative liabilities Â Â 646,319 Â Â Â â€“ Â Â Â 646,319 Â Loss on issuance of warrants Â Â (72,862) Â Â â€“ Â Â Â (72,862) Other, net Â Â (562) Â Â 521 Â Â Â (1,083) Total other income (expense) Â Â (35,393) Â Â (1,507,025) Â Â 1,471,632 Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Income (loss) before income taxes Â Â (4,911,374) Â Â (7,068,593) Â Â 2,157,219 Â Income tax provision Â Â Â Â Â Â â€“ Â Â Â Â Â Net income (loss) Â $ (4,911,374) Â $ (7,068,593) Â $ 2,157,219 Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Dividends accrued for preferred stockholders Â $ â€“ Â Â $ (415,523) Â $ 415,523 Â Net income (loss) allocable to common stockholders Â $ (4,911,374) Â $ (7,484,116) Â $ 2,572,742 Â Net income (loss) per share allocable to common shareholders Â $ (8.82) Â $ (19.61) Â $ 10.79 Â Weighted average shares of common stock outstanding, basic and diluted Â Â 556,808 Â Â Â 381,598 Â Â Â 175,210 Â Â Â Â Â 73Â Â Â Years ended December 31, 2023, and 2022Â Total revenues. Total revenue for the yearended December 31, 2023, was $75,404, which was an increase of $14,960 from $60,444 for the year ended December 31, 2022. This increasewas primarily due to growing utilization of Nociscan in third-party clinical studies. Volumes and pricing were generally consistent ineach year.Â Cost of Revenue.Â Cost of Revenue iscomprised of hosting and software costs, field support, UCSF royalty cost, NuVasive commission of 6%, partner fees (Radnet), and creditcard fees. Total Cost of Revenue was $75,728 for the year ended December 31, 2023, compared to $65,298 for the year ended December 31,2022, an increase of 16.0%. This increase was primarily due to higher year-over-year scan volumes and related Nociscan report

output.Â Sales and Marketing. Sales and marketingexpenses were $757,004 for the year ended December 31, 2023, compared to $498,003 for the year ended December 31, 2022, an increase of$259,001 or 52.0%. This increase was driven primarily by additional vesting of restricted stock units to our increased number of Key OpinionLeaders.Â Research and Development.Â Researchand development expenses were $873,336 for the year ended December 31, 2023, compared to $1,067,992 for the year ended December 31, 2022,a decrease of $194,656 or 18.2%. This decrease was primarily due to a $123,828 contract milestone payment to UCSF in April 2022, relatedto the initial public offering, and reduced expense in 2023 clinical services.Â Â General and Administrative. General andadministrative expenses were $3,245,317 for the year ended December 31, 2023, a decrease of $745,402 or 18.7%, from $3,990,719 for theyear ended December 31, 2022. This decrease in general and administrative expenses was driven primarily by a higher 2022 compensationexpense related to the vesting of the Executive Chairmanâ€™s and executiveâ€™s outstanding common stock options, offset in partby higher legal and accounting fees in 2023.Â Interest Expense.Â Total Interest expensewas $608,288 for the year ended December 31, 2023, a decrease of $899,258, from the $1,507,546 for the year ended December 31, 2022. Thisdecrease was driven primarily by the $1.3 million beneficial conversion rate charged to interest expense in 2022 for the conversion ofall accrued interest on the Companyâ€™s outstanding secured promissory notes into common shares and common stock warrants in connectionwith the April 2022, initial public offering. The 2023 interest expense was primarily due to the amortization of the note discount associatedwith the unsecured non-convertible promissory notes described in Note 11 to our financial statements â€“ Short Term Notes, ConvertibleDebt, and Derivative Liabilities.Â Changes in Fair Value of Warrant and DerivativeLiabilities. In the year ended December 31, 2023, the Company recorded $646,319 of changes in the fair value of the warrant and derivativeliabilities associated with unsecured non-convertible promissory notes described in Note 4 â€“ Fair Value Measurements and Note 11â€“ Short Term Notes, Convertible Debt, and Derivative Liabilities to our financial statements.Â Other Net Expenses.Â During the yearended December 31, 2023, Other Net expenses were $562, which included bank interest, government fees, and realized exchange rate gain(losses).Â Net income (loss).Â The Company experienceda net loss of $4,911,374 for the year ended December 31, 2023, compared to a net loss of $7,068,593 for the year ended December 31, 2022.In general, the year ended December 31, 2023 excluded two significant expenses that were present during the year 2022, that being thecompensation expense related to the vesting of the Executive Chairmanâ€™s and other executiveâ€™s outstanding common stock options,and the $1.3 million beneficial conversion rate charged to interest expense for the conversion of all accrued interest on the Companyâ€™soutstanding secured promissory notes into common shares and common stock warrants in connection with the April, 2022, initial public offering.Â Â Â 74Â Â Â For the Three Months Ended September 30,2024, and 2023:Â The following table summarizes our results ofoperations for the three months ended September 30, 2024, and 2023.Â Â Â Three Months Ended September 30, Â Â Â Â Â Â 2024 Â Â 2023 Â Â $ Change Â Revenue Â Â Â Â Â Â Â Â Â Â Revenue Â $ 14,407 Â Â $ 19,065 Â Â $ (4,658) Cost of revenue Â Â 21,332 Â Â Â 19,558 Â Â Â 1,774 Â Gross profit (loss) Â Â (6,925) Â Â (493) Â Â (6,432) Â Â Â Â Â Â Â Â Â Â Â Â Â Operating expenses: Â Â Â Â Â Â Â Â Â Â Â Â Sales and marketing Â Â 232,775 Â Â Â 192,896 Â Â Â 39,879 Â Research and development Â Â 195,797 Â Â Â 198,252 Â Â Â (2,455) General and administrative Â Â 860,461 Â Â Â 770,534 Â Â Â 89,927 Â Total operating expenses Â Â 1,289,033 Â Â Â 1,161,682 Â Â Â 127,351 Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â (Loss) from operations Â Â (1,295,958) Â Â (1,162,175) Â Â (133,783) Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Other income (expense): Â Â Â Â Â Â Â Â Â Â Â Â Interest expense Â Â (71,527) Â Â (166,332) Â Â 94,805 Â Loss on exchange of debt Â Â (6,585) Â Â â€“ Â Â Â (6,585) Loss on extinguishment of debt Â Â â€“ Â Â Â â€“ Â Â Â â€“ Â Changes in fair value of warrant and derivative liabilities Â Â 7,591 Â Â Â 330,252 Â Â Â (322,661) Other, net Â Â 303 Â Â Â 245 Â Â Â 58 Â Total other (expense) Â Â (70,218) Â Â 164,165 Â Â Â (234,383) Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â (Loss) before income taxes Â Â (1,366,176) Â Â (998,010) Â Â (368,166) Income tax provision Â Â â€“ Â Â Â â€“ Â Â Â â€“ Â Net income (loss) Â $ (1,366,176) Â $ (998,010) Â $ (368,166) Â Â Â Â Â Â Â Â Â Â Â Â Â Dividends accrued for preferred stockholders Â Â (12,142) Â Â â€“ Â Â Â (12,142) Net (loss) allocable to common stockholders Â $ (1,378,318) Â $ (998,010) Â $ (380,308) Net (loss) per share allocable to common stockholders Â $ (0.15) Â $ (1.87) Â $ 1.72 Â Weighted average shares of common stock outstanding, basic and diluted Â Â 9,437,871 Â Â Â 532,928 Â Â Â 8,904,943 Â Â Total revenues. Total revenues forthe quarter ended September 30, 2024 were $14,407, which was a decrease of $4,658, or 24%, from $19,065 for the quarter ended September30, 2023. The decrease in revenues was driven primarily by the conclusion of certain clinical activity at customer sites utilizing NOCISCANÂ® reports, offset in part by an increase in patient-pay reports.Â Cost of Revenue. Direct cost ofrevenue is comprised of hosting and software costs, field support, UCSF royalty cost, partner fees (Radnet), and credit card fees. Totalcost of revenue was $21,332 for the quarter ended September 30, 2024, compared to $19,558 for the quarter ended September 30, 2023, anincrease of 9%. This increase was primarily due to a change in revenue mix that increased partner fees.Â Â Â 75Â Â Â Sales and Marketing. Marketing expensesinclude post-market clinical and reimbursement consulting, salaries, website support, press releases, conferences, travel, and shared-basedcompensation for Key Opinion Leaders. Sales and marketing expenses were $232,775 for the quarter ended September 30, 2024, compared to$192,896 for the quarter ended September 30, 2023, an increase of $39,879, or 21%. Post-market clinical expenses increased as the Companyfocused on the initiation of the Clarity trial. Marketing expenses also increased with the number of press releases year-over-year. Therewas a partial favorable offset as shared-based compensation decreased in the third quarter of 2024 with the conclusion of Key OpinionLeader grant periods.Â Research and Development. Researchand development expenses were $195,797 for the quarter ended September 30, 2024, compared to $198,252 for the quarter ended September30, 2023, a decrease of $2,455, or 1%.Â General and Administrative. Generaland administrative expenses were $860,461 for the quarter ended September 30, 2024, an increase of $89,927, or 12%, from $770,534 forthe quarter ended September 30, 2023. For the quarter ended September 30, 2024, there was increased investment in investor relations andconsulting, offset in part by reduced bonus expense, D&O insurance premiums, and legal fees compared to the quarter ended September30, 2023.Â Other Income (Expense).Interest expense was $71,527 for the quarter endedSeptember 30, 2024, a decrease of $94,805 from the $166,332 incurred during the quarter ended September 30, 2023. This decrease in interestexpense was due to the ongoing retirement of debt over the nine month period ended September 30, 2024.Â The Companyâ€™s warrant and derivative liabilitiesare recorded at fair value as of each reporting date (see Note 3 to the condensed financial statements). For the quarter ended September30, 2024, the Company recorded a favorable adjustment in fair value of $7,591.Â For the Nine Months Ended September 30,2024, and 2023:Â The following table summarizes our results ofoperations for the nine months ended September 30, 2024, and 2023.Â Â Â Nine Months Ended September 30, Â Â Â Â 2024 Â 2023 Â $ Change Revenue Â Â Â Â Â Â Revenue Â $ 35,492Â Â $ 61,607Â Â $ (26,115)

Cost of revenue Â Â 64,102Â Â Â 56,312Â Â Â 7,790Â Gross profit (loss) Â Â (28,610) Â Â 5,295Â Â Â (33,905) Â Â Â Â Â Â Â Â Â Â Operating expenses: Â Â Â Â Â Â Â Â Â Sales and marketing Â Â 638,869Â Â Â 577,969Â Â Â 60,900Â Research and development Â Â 636,940Â Â Â 652,657Â Â Â (15,717) General and administrative Â Â 2,402,408Â Â Â 2,524,308Â Â Â (121,900) Total operating expenses Â Â 3,678,217Â Â Â 3,754,934Â Â Â (76,717) Â Â Â Â Â Â Â Â Â Â (Loss) from operations Â Â (3,706,827) Â Â (3,749,640) Â Â 42,812Â Â Â Â Â Â Â Â Â Â Other income (expense): Â Â Â Â Â Â Â Â Â Interest expense Â Â (535,199) Â Â (214,850) Â Â (320,349) Loss on exchange of debt Â Â (1,073,317) Â Â â€“Â Â Â (1,073,317) Loss on extinguishment of debt Â Â (111,928) Â Â â€“Â Â Â (111,928) Changes in fair value of warrant and derivative liabilities Â Â 330,632Â Â Â 318,452Â Â Â 12,180Â Other, net Â Â 93,284Â Â Â 11Â Â Â 93,273Â Total other (expense) Â Â (1,296,528) Â Â 103,613Â Â Â (1,400,141) Â Â Â Â Â Â Â Â Â Â (Loss) before income taxes Â Â (5,003,355) Â Â (3,646,027) Â Â (1,357,328Â Income tax provision Â Â â€“Â Â Â â€“Â Â Â â€“Â Net income (loss) Â $ (5,003,355) Â $ (3,646,027) Â $ (1,357,328) Â Â Â Â Â Â Â Â Â Â Dividends accrued for preferred stockholders Â Â (12,142) Â Â â€“ Â Â (12,142) Net (loss) allocable to common stockholders Â $ (5,015,497) Â $ (3,646,027) Â $ (1,369,470) Net (loss) per share allocable to common stockholders Â $ (0.65) Â $ (7.07) Â $ 6.42Â Weighted average shares of common stock outstanding, basic and diluted Â Â 7,699,173Â Â Â 515,975Â Â Â 7,183,198Â Â Â Â 76Â Â Â Total revenues. Total revenues forthe nine months ended September 30, 2024 were $35,492, which was a decrease of $26,115, or 42%, from $61,607 for the nine months endedSeptember 30, 2023. The decrease in revenues was driven primarily by the conclusion of certain clinical activity at customer sites utilizingNOCISCAN Â® reports.Â Cost of Revenue. Direct cost ofrevenue is comprised of hosting and software costs, field support, UCSF royalty cost, partner fees (Radnet), and credit card fees. Totalcost of revenue was $64,102 for the nine months ended September 30, 2024, compared to $56,312 for the nine months ended September 30,2023, an increase of 14%, driven by a price increase related to hosting costs and a change in revenue mix that increased partner fees.Â Sales and Marketing. Marketing expensesinclude post-market clinical and reimbursement consulting, salaries, website support, press releases, conferences, travel, and shared-basedcompensation for Key Opinion Leaders. Sales and marketing expenses were $638,869 for the nine months ended September 30, 2024, comparedto $577,969 for the nine months ended September 30, 2023, an increase of $60,900, or 11%. Increased post-market clinical expense relatedto the Clarity trial, greater marketing expense, and increased benefits costs were offset in part by a reduction in restricted stock vestingexpense related to the Companyâ€™s engagement of Key Opinion Leaders.Â Research and Development. Researchand development expenses were $636,940 for the nine months ended September 30, 2024, compared to $652,657 for the nine months ended September30, 2023, a decrease of $15,717, or 2%.Â General and Administrative. Generaland administrative expenses were $2,402,408 for the nine months ended September 30, 2024, a decrease of $121,900 or 5%, from $2,524,308for the nine months ended September 30, 2023. The decrease was driven by reduced bonus accruals, lower personnel expense, and decreasedD&O insurance premiums, offset in part by higher legal and finance support costs and increased investment in investor relations.Â Other Income (Expense).Interest expense was $535,199 for the nine monthsended September 30, 2024, an increase of $320,349 from the $214,850 incurred during the nine months ended September 30, 2023. This increasein interest expense was due to the increase in debt taken on by the Company in 2023. In May, September and November 2023 the Company issued$2,594,118 aggregate principal amount of unsecured non-convertible notes to certain accredited investors. (see Note 9 to the condensedfinancial statements).Â The Company incurred losses for the nine monthsended September 30, 2024, on three transactions to reduce debt. The first transaction took place between January 22 and January 29, 2024,whereby the Company entered into a series of exchange agreements with investors to issue an aggregate of 644,142 post-split shares ofcommon stock in exchange for $1,519,779 principal and accrued interest on the notes. This transaction accelerated the recognition of therelated note discounts and resulted in a $1,066,732 charge. The second transaction was on March 6, 2024, whereby the Company paid $300,974of principal and accrued interest on the notes. This transaction accelerated the recognition of the related note discounts and resultedin a $111,928 charge. The third transaction was on August 14, 2024, whereby the Company entered into an exchange agreement with investorsto issue an aggregate of 930 shares of B-Series convertible preferred stock in exchange for $930,052 principal and accrued interest onthe notes.Â The Companyâ€™s warrant and derivative liabilitiesare recorded at fair value as of each reporting date (see Note 3 to the condensed financial statements). For the nine months ended September30, 2024, the Company recorded a favorable adjustment in fair value of $330,632.Â Other net income of $93,284 for the nine monthsended September 30, 2024, included a favorable discount to accounts payable of $117,985, offset in part by a $25,000 penalty paid to investorsrelated to a failure to timely register certain commitment shares.Â Critical accounting policies and use of estimatesÂ Our Managementâ€™s Discussion and Analysisof Financial Condition and Results of Operations is based on our financial statements, which have been prepared in accordance with generallyaccepted accounting principles in the United States. The preparation of our financial statements and related disclosures requires us tomake estimates and assumptions that affect the reported amounts of assets and liabilities, costs and expenses and the disclosure of contingentassets and liabilities in our financial statements. We base our estimates on historical experience, known trends and events and variousother factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about thecarrying values of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and assumptionson an ongoing basis. Our actual results may differ from these estimates.Â Â Â 77Â Â Â While our significant accounting policies aredescribed in more detail in the notes to our financial statements, we believe that the following accounting policies are those most criticalto the judgments and estimates used in the preparation of our financial statements.Â Revenue RecognitionÂ 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 controlof the promised services are transferred to our customers. The amount of revenue recognized reflects the consideration the Company expectsto receive in exchange for those services. Our revenues are generated from contracts with customers in the United States and internationally.Â Equity-Based CompensationÂ Certain of our employees and consultants havereceived grants of common stock options and RSUs in our company. These awards are accounted for in accordance with guidance prescribedfor accounting for equity-based compensation. Based on this guidance and the terms of the awards, the awards are equity classified.Â Until our April 2022 initial public offering,we were a private company with no active public market for our common equity. Therefore, we had periodically determined the overall valueof our company and the estimated per share fair value of our common equity at their various dates using contemporaneous valuations performedin accordance with the guidance outlined in the American Institute of CPAâ€™s Practice Aid. Since a public trading market for ourcommon stock has been established in connection with the completion of our initial public

offering, it will no longer be necessary forus to estimate the fair value of our common stock in connection with our accounting for equity awards we may grant, as the fair valueof our common stock will be its public market trading price.Â For financial reporting purposes, we performedcommon stock valuations as a private company with the assistance of a third-party specialist. Subsequent to the initial public offering,the fair value of the Companyâ€™s common stock underlying its equity awards is based on the quoted market price of the Companyâ€™scommon stock on the grant date.Â Going ConcernÂ The Company believes that the net proceeds fromthe common shares offered at-the-market in August 2024 and the issuance of C-Series preferred stock in September 2024 will be sufficientto fund current operating plans into December 2024. The Company has based these estimates, however, on assumptions that may prove to bewrong, and could spend available financial resources much faster than we currently expect. The Company will need to raise additional fundsto continue funding our technology development. Management plans to secure such additional funding.Â As a result of the Companyâ€™s recurring lossesfrom operations and the need for additional financing to fund its operating and capital requirements, there is uncertainty regarding theCompanyâ€™s ability to maintain liquidity sufficient to operate its business effectively, which raises substantial doubt as to theCompanyâ€™s ability to continue as a going concern.Â Liquidity and capital resourcesÂ Sources of liquidityÂ To date, the Company has financed operations primarilythrough public and private offerings of our debt and equity securities and PPP loans that were forgiven.Â During the nine months ended September 30, 2024,the Company completed a public offering of 5,175,000 units (â€œUnitsâ€) at a price of $0.58 per Unit, for gross proceeds of approximately$3.0 million, before deducting offering expenses. Additionally, the Company raised approximately $1.4M of net proceeds from an equityline in January 2024 and $0.3M in April 2024, retired approximately $930K of debt in exchange for 930 shares of B-Series preferred stockin August 2024, issued common stock pursuant to our Reg A+ offering of $529K, and issued 1,000 shares of C-Series preferred stock in September2024 for proceeds of $1.0M.Â Â Â 78Â Â Â As of September 30, 2024, the Company had cash,including $10,000 of restricted cash, of $1,322,098. The Company believes that this cash will be sufficient to fund current operatingplans into December 2024. The Company has based these estimates, however, on assumptions that may prove to be wrong, and could spend availablefinancial resources much faster than we currently expect. The Company will need to raise additional funds to continue funding our technologydevelopment. Management plans to secure such additional funding.Â Cash flows â€“Years ended December 31, 2023, and December 31, 2022Â The following table summarizesour sources and uses of cash for each of the periods presented:Â Â Â Year Ended December 31, Â Â 2023Â 2022 Â Â Â Â (restated) Cash used in operating activitiesÂ $(3,646,947)Â $(4,949,112) Cash used in investing activitiesÂ Â (119,522)Â Â (207,870) Cash provided by financing activitiesÂ Â 3,314,732Â Â Â 6,187,258Â Net increase (decrease) in cash and cash equivalentsÂ $(451,737)Â $1,030,276Â Â Operating activitiesÂ During the year ended December 31, 2023, net cashused in operating activities was $3,646,947. This use of cash consisted primarily of compensation and benefit expense, officersâ€™liability insurance, consulting, tax and audit fees, and maintain our quality system. Cash outlays in the year 2023 were relatively lowerthan the year 2022 due to longer procure-to-pay cycles. During the twelve months ended December 31, 2022, operating activities used $4,949,112,consisting primarily of compensation and benefit expense, consulting, and professional fees.Â Investing activitiesÂ During the year ended December 31, 2023, and 2022,investing activities used $119,522 and $207,870 of cash, respectively. These investing activities consisted almost entirely of patentand license maintenance.Â Financing activitiesÂ During the year ended December 31, 2023, net cashprovided by financing activities was $3,314,732, which included $2,250,000 of proceeds from unsecured non-convertible note financings,1,462,949 of proceeds from an equity line, and $398,217 of cash issuance costs related to both the equity line and debt. During the yearended December 31, 2022, net cash provided by financing activities was $6,187,258, which included $8,552,318 of initial public offeringproceeds (net of underwriter compensation and deductions but excluding $25,000 pre-payment in 2021), $2,000,000 repayment of promissorynotes, and $365,060 of IPO issuance costs.Â Â Â Â 79Â Â Â Cash flows â€“ Nine months ended September30, 2024, and September 30, 2023Â The following table summarizes our sources anduses of cash for each of the periods presented:Â Â Â Nine Months Ended September 30, Â Â 2024Â 2023 Â Â Â Â Â Cash used in operating activitiesÂ $(4,348,748)Â $(2,913,165) Cash used in investing activitiesÂ Â (261,220)Â Â (85,603) Cash provided by financing activitiesÂ Â 4,900,996Â Â Â 1,687,412Â Net increase (decrease) in cashÂ $291,028Â Â $(1,311,356) Â Operating activitiesÂ During the nine months ended September 30, 2024,operating activities used $4,348,748 of cash. The Company significantly reduced accounts payable, primarily legal expenses that had accruedover time, and significantly reduced accrued expenses including payroll, bonuses, board compensation, and audit fees. During the ninemonths ended September 30, 2023, operating activities used $2,913,165 of cash. This use of cash consisted primarily of employee compensationand benefit expense, general liability insurance, contractor compensation, and audit and legal fees.Â Investing activitiesÂ During the nine months ended September 30, 2024,and 2023, investing activities used $261,220 and $85,603 of cash, respectively. These investing activities consisted almost entirely ofpatent and license maintenance.Â Financing activitiesÂ Between January 4 and January 8, 2024, and pursuantto the Equity Line Purchase Agreement, the Company issued to White Lion 452,343 newly issued common shares for proceeds of $1,449,532.On April 26, 2024, the Company issued 1,050,000 common shares for proceeds of $304,500.Â Between January 22 and January 29, 2024, the Companyentered into a series of exchange agreements (the â€œExchange Agreementsâ€) with the accredited investors to exchange principaland accrued interest on the May 2023 Notes for shares of common stock. Pursuant to the Exchange Agreements, the Company issued an aggregateof 644,142 post-split shares of common stock in exchange for $1,519,779 principal and accrued interest on the May 2023 Notes.Â On February 27, 2024, the Company completed apublic offering of 5,175,000 units (â€œUnitsâ€) at a price of $0.58 per Unit, for gross proceeds of approximately $3.0 million,before deducting offering expenses. Each Unit was comprised of (i) one share of common stock or, in lieu of common stock, one prefundedwarrant to purchase a share of common stock, and (ii) two common warrants, each common warrant to purchase a share of common stock. Theprefunded warrants are immediately exercisable at a price of $0.00001 per share of common stock and only expire when such prefunded warrantsare fully exercised. The common warrants are immediately exercisable at a price of $0.58 per share of common stock and will expire fiveyears from the date of issuance.Â On March 6, 2024, the Company paid $300,973 ofprincipal and accrued interest on the November 2023 Notes.Â Between August 12 and August 27, 2024, the Companyissued 1,825,000 shares of common stock pursuant to our Reg A+ offering for proceeds of $529K.Â On August 14, 2024, the Company entered into anexchange agreement (the â€œExchange Agreementâ€) with the accredited investors to exchange $930,052 of principal and accruedinterest on the September 2023 Notes for 930 shares of newly issued Series B convertible preferred stock (â€œSeries B Preferred Stockâ€)at a purchase price of $1,000 per share.Â Â Â 80Â Â Â On September 30, 2024, the Company entered intoa securities purchase agreement with accredited investors for a convertible preferred stock and warrants financing. The Company has

received$1,000,000 of gross proceeds in connection with the closing of this financing. The Company issued 1,000 shares of Series C convertiblepreferred stock (â€œSeries C Preferred Stockâ€) at a purchase price of $1,000 per share of Series C Preferred Stock. The SeriesC Preferred Stock is convertible into Common Stock at an initial conversion price (â€œConversion Priceâ€) of $0.1759 per shareof Common Stock. The Company also issued warrants exercisable for 5,685,049 shares of Common Stock with a 5.5 year term and an initialexercise price of $0.1759 per share.Â During the nine months ended September 30, 2023,the Company sold one (1) share of the Companyâ€™s newly designated Series A preferred stock to Jeffrey Thramann, the Companyâ€™sExecutive Chairman, for a purchase price of $1,000. The share of Series A preferred stock had proportional voting rights that were limitedto the proposal to approve a reverse stock split of the Companyâ€™s common stock. Following the March 24, 2023, special meeting, theCompany redeemed the one outstanding share of Series A preferred stock on March 28, 2023, in accordance with its terms. The redemptionprice was $1,000. No Series A preferred stock remains outstanding.Â During the nine months ended September 30, 2023,the Company issued $1,437,500 May 2023 Notes, with a maturity date of May 16, 2024, for cash proceeds of $1,250,000. The May 2023 Notescontained an original issue discount of 15.0% and accrued interest at an annual rate of 8.0%.Â In September 2023, as agreed to during the issuanceof the May 2023 Notes, the Company exercised their right to an additional financing, issuing $862,500 September 2023 Notes that matureon September 1, 2024, for cash proceeds of $750,000. The September 2023 Notes contained an original issue discount of 15.0% and accruedinterest at an annual rate of 8.0%.Â Funding requirementsÂ Developing medical technology products is a time-consuming,expensive and uncertain process that takes years to complete, and the Company may never generate meaningful revenues. Accordingly, wemay need to obtain substantial additional funds to achieve our business objectives.Â Adequate additional funds may not be availableto us on acceptable terms, or at all. To the extent that the Company raises additional capital through the sale of equity securities,the ownership interest of existing stockholders may be diluted. Any debt or preferred equity financing, if available, may involve agreementsthat include restrictive covenants that may limit our ability to take specific actions, such as incurring additional debt, making capitalexpenditures or declaring dividends, which could adversely impact our ability to conduct our business, and may require the issuance ofwarrants, which could potentially dilute existing stockholdersâ€™ ownership interests.Â If we raise additional funds through licensingagreements and strategic collaborations with third parties, we may have to relinquish valuable rights to our technology, future revenuestreams, research programs, or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raiseadditional funds, we may be required to delay, limit, reduce and/or terminate development of our product candidates or any future commercializationefforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.Â Contractual obligations and commitmentsÂ The Company does not have any contractual obligationsnot otherwise on our balance sheet as of September 30, 2024.Â Off-balance sheet arrangementsÂ The Company 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 SEC.Â Â Â 81Â Â Â Recently issued accounting pronouncementsÂ The Company reviewed all recently issued standardsand has determined that, as disclosed in Note 4 to our condensed financial statements appearing in this quarterly report, there have beenno recent accounting pronouncements not yet effective that have significance, or potential significance, to our Consolidated FinancialStatements.Â Emerging growth company and smaller reportingcompany statusÂ The JOBS Act permits an emerging growth companysuch as us to take advantage of an extended transition period to comply with new or revised accounting standards applicable to publiccompanies until those standards would otherwise apply to private companies. We have elected not to â€œopt outâ€ of this extendedtransition period and, as a result, we will not adopt new or revised accounting standards on the relevant dates on which adoption of suchstandards is required for public entities. Accordingly, our financial statements may not be comparable to other public companies thatdo not elect the extended transition period.Â We are also a â€œsmaller reporting companyâ€meaning that the market value of our stock held by non-affiliates is less than $700 million and our annual revenue was less than $100million during the most recently completed fiscal year. We may continue to be a smaller reporting company if either (i) the market valueof our stock held by non-affiliates is less than $250 million or (ii) our annual revenue was less than $100 million during the most recentlycompleted fiscal year and the market value of our stock held by non-affiliates is less than $700 million. If we are a smaller reportingcompany at the time we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirementsthat are available to smaller reporting companies. Specifically, as a smaller reporting company we may choose to present only the twomost recent fiscal years of audited financial statements in our Annual Report on Form 10-K and, similar to emerging growth companies,smaller reporting companies have reduced disclosure obligations regarding executive compensation.Â Â Â Â Â Â Â Â 82Â Â Â BUSINESSÂ OverviewÂ Aclarion is a healthcare technology company thatleverages Magnetic Resonance Spectroscopy (â€œMRSâ€), and proprietary biomarkers to optimize clinical treatments. Aclarionâ€™stechnology 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 (â€œAIâ€)to assist in quality control processes that flag spectroscopy data indicative of a poor MRS study. The use of AI in this application isearly in its development cycle and is expected to evolve with further research and development. The Company is capturing in databasesboth the raw spectroscopy data and the post-processed spectral data from every Nociscan completed in order to utilize this data as futuretraining data to teach a machine learning algorithms to associate MRS data with clinical outcomes. The use of AI in this application isaspirational and we intend this type of AI research and development to be an ongoing process applied not only to the various treatmentpaths associated with back pain, such as conservative therapies, regenerative and cell therapies and surgical intervention, but also topotentially expand into other clinical explorations involving the diagnosis of brain, breast and prostate tumors.Â 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 chronicdiscogenic low back pain. In this initial application, Aclarion technology is intended to assist surgeons in determining the optimal surgicalprocedure for a patient undergoing surgery for pain isolated to their lumbar spine (the â€œlumbar spineâ€ is comprised of thefive (5) lower vertebrae, L-1 to L-5). Through clinical studies we intend to extend the application of our technology beyond surgicaldecisioning 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 undergoingconservative therapies such as physical therapy or biologic and cell therapies aimed at regenerating the lumbar discs. We plan to expandthe application of our technology beyond the lumbar spine to address neck pain populations in addition to low back pain populations. Toexpand the application of our technology for use in neck pain populations, we will need to overcome

technical changes associated withsecuring adequate MRS data from the cervical disc, which is significantly smaller than the lumbar disc, and there can be no assurancethe Company will be able to overcome these challenges.Â 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 minutesfor each disc undergoing a spectroscopy exam. Whereas a standard MRI produces a signal that is converted into anatomical images, an MRSproduces 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 processingsoftware that transforms spectroscopy data into clear biomarkers. These biomarkers, which are exclusively licensed from the Regents ofUniversity of California, San Francisco (â€œUCSFâ€), 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 pendingU.S. patent applications, and 7 pending Foreign patent applications, including patents and patent applications exclusively licensed fromRegents of the University of California.Â We believe one of the biggest issues driving thecost of treating low back and neck pain patients to the top of the list for healthcare spending is that there is no objective, cost effectiveand noninvasive diagnostics to reliably identify the source of a patientâ€™s pain. We believe the poor surgical outcomes for chronicDLBP are largely due to difficulties in reliably and accurately diagnosing the specific spinal discs that are causing pain. The currentprimary diagnostic standard is the MRI, which is useful for showing abnormal structures and tissue dehydration, but, we believe, cannotreliably identify specific discs that are causing pain. To diagnose specific discs that are causing pain, a needle-based Provocation Discogramtest (â€œPD Testâ€) has been developed. PD Tests have been shown to be highly accurate when performed properly. However, a PDTest is invasive, subjective, and unpleasant for the patient as the patient needs to be awake in order to tell the physician if the painthe 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 toan increased rate of degeneration in these previously normal discs. Based on the limitations and concerns of the PD Test, we believe thereis a significant need for an objective, accurate, personalized, and noninvasive diagnostic test that can reliably determine if an individualdisc is a pain generator. By providing physicians information about whether a disc has the chemical and structural makeup consistent withpain or not, we believe the treatment plan for each patient will lead to more efficient and targeted care that, will in turn, result inlower costs and healthier patient outcomes.Â Â Â 83Â Â Â Aclarion has taken the first steps to demonstratethe potential use of our technology in helping to improve the outcome of surgical intervention for discogenic low back pain patients bypublishing a clinical study in the European Spine Journal in April 2019. The study illustrated that when all discs identified as consistentwith pain by our technology were included in a surgical treatment, 97% of the patients met the criteria for â€œclinical improvementâ€.This compared to only 54% of patients meeting the criteria for clinical improvement if a disc that our technology identified as consistentwith pain, was not included in the surgical treatment.Â In April 2023, Aclarion advanced the evidenceof our technology with a peer-reviewed journal article detailing the Gornet 2-year outcomes published in the European Spine Journal. The2-year outcomes were durable with 1-year outcomes previously published in 2019. At 2-years follow-up, 85% of patients improved when disc(s)identified as consistent with pain by our technology were included in a surgical treatment, compared to only 63% of patients when disc(s)identified as consistent with pain were not treated or disc(s) identified as consistent without pain were treated.Â The results of the 2019 published study led theCPT committee to approve four Category III codes for our technology in January 2021. The NIH also included our technology as one of thehandful 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 subsequentlyselected our technology to be included in their prospective randomized follow-on study that resulted from BACPAC. This new study is calledBiomarkers for the Evaluation of Spinal Treatments (BEST) and is designed to evaluate several technologies that provide data about a patientto see if these technologies can identify subgroups of chronic LBP patients that do better with one of four treatments being evaluatedin the study.Â Evolving science coupled with the understandingof degenerative painful discs has suggested that lumbar discs may become painful due to certain chemical changes, which changes cannotbe identified using standard lumbar MRI imaging. However, an application of MRI scanners called Magnetic Resonance Spectroscopy has beendeveloped by manufacturers of MRI equipment. MRSs are different than MRIs. An MRI generates images of body structures, while an MRS analyzesthe relative amounts of various chemicals in body tissues.Â Aclarion has developed a software applicationcalled NOCISCANÂ® which uses the existing MRS capabilities of many commercially available scanners to non-invasively analyze the chemicalmakeup of intervertebral discs in the spine. The software post-processes the MRS exam data and detects the presence of chemical biomarkersthat we, in conjunction with spine researchers at UCSF, have demonstrated to be associated with degenerative pain and structural integrityof the lumbar discs. After processing the MRS exam data, we send the ordering clinician a report that details how to interpret the resultsof 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 individualpatient.Â Because we believe that spectroscopy is not widelyused for any clinical purposes today, there are practical limitations to the market opportunity that must be addressed. We believe thetwo biggest limitations may be the lack of deployment of spectroscopy software across the installed base of existing MRIs worldwide, andthe fact that only certain MR scanner models are compatible with our technology. For compatible MRI sites that do not currently have spectroscopysoftware installed, the onetime cost of the software ranges from $25,000 to $50,000. Currently, our NOCISCAN platform is only compatiblewith certain MR scanner models provided by SIEMENS, of which there are an estimated 1,500 in the United States, and 4,320 worldwide. Weplan to collaborate with other MRI scanner vendors, as well as SIEMENS, to establish compatibility with their respective scanners andMRS capabilities for use with our products. That may allow us to include discounted pricing on spectroscopy software for MRI sites interestedin providing DLBP patients with the NOCISCAN offering.Â The first application of Aclarionâ€™s technologyis focused on improving surgical decision making when surgical intervention is being contemplated for patients with low back pain. TheCompanyâ€™s first commercial product, which we have named â€œNOCISCANâ€, utilizes our proprietary biomarkers and algorithmsto provide surgeons with information about which intervertebral discs are determined to be consistent with generating pain, and whichare 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 aspainful 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 painfulby NOCISCAN were omitted from the surgical treatment, or discs identified as not painful by NOCISCAN were included in the treatment. Someauthors of this study had a financial relationship with Aclarion, who sponsored the study.Â Â Â 84Â Â Â In April 2023, Aclarion advanced the evidenceof our technology with a peer-reviewed journal article detailing the Gornet 2-year outcomes published in the European Spine Journal. The2-year outcomes were durable with 1-year outcomes previously published in 2019. At 2-years follow-up, 85% of patients improved when disc(s)identified as consistent with pain by our technology were included in a surgical treatment, compared to only 63% of patients when disc(s)identified as consistent with pain were not treated or disc(s) identified as consistent without pain were treated.Â Based on the results of this clinical study, theCompany believes that use of NOCISCAN could become the standard protocol for assisting in the treatment plan of patients with low backpain undergoing surgical intervention. Utilizing the results of our European Spine Journal Study, we applied to the American Medical Associationfor CPT codes to begin the process of securing insurance coverage to pay for NOCISCAN. On January 1, 2021, Category III CPT codes becameeffective. The Company is now executing its plan to commercialize NOCISCAN. See â€œReimbursementâ€ below.Â The core technology underlying NOCISCAN is theuse of MR spectroscopy to identify the chemical makeup of intervertebral discs with a focus on identifying specific proprietary biomarkersknown to be correlated to pain and to the structural degradation of discs. We believe this technology, in combination with advanced machinelearning and AI platforms, has the potential to not only become included in the standard of care for patients undergoing surgical interventionfor low back pain, but to become a core data input for optimally managing entire segments of patients suffering from low back and neckpain.Â Industry OverviewÂ Low Back PainÂ According to the Global Burden of Disease Study2017, low back pain (LBP) is among the top three causes for years lived with disability. A 2020 JAMA (Journal of the American MedicalAssociation) article established the cost of low back and neck pain at $134.5B in the U.S, making it the most costly healthcare conditionin the United States, surpassing cardiac disease, diabetes and cancer.Â Low back pain (LBP) canbe caused by many different problems and abnormalities along and around the spine, other than DLBP, including conditions such as spondylolisthesisor 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 ofthe spine, which reveals clear structural abnormalities, i.e., fractures and tumors. However, in many cases the source of the pain isnot clear. As a result, the success rates of surgical care for LBP ranges from 41 to 57%, with 5-16% early complication and reoperationrates also reported.Â We believe that poorsurgical outcomes for discogenic LBP are largely due to difficulties in reliably and accurately diagnosing the specific spinal discs thatare 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-basedProvocation Discogram test (â€œPD Testâ€) 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 thephysician if the pain the physician is purposefully causing in the disc is the same as the pain the patient feels when they are experiencinga back pain episode. In addition, recent evidence has shown that the action of inserting a needle into a normal disc during PD Test, leadsto an increased rate of degeneration in these previously normal discs.Â Due to the current lackof uniform acceptance of a diagnostic platform to safely and reliably diagnose the specific discs that cause DLBP, patients with DLBPare faced with the options of surgical intervention with a risk of a poor surgical outcomes, or, non-surgical treatment with powerfulpain killing drugs, such as opiates and synthetic opiates. Those patients who choose surgery and have a poor surgical outcome with nosurgical alternatives will be faced with the possibility of enduring disabling, intractable pain, and often extended dangerous pain medicationuse.Â Â Â 85Â Â Â Diagnostic ImagingÂ Diagnostic imaging involvesthe use of non-invasive procedures to generate representations of internal anatomy and function that can be recorded on film or digitizedfor display on a video monitor. Diagnostic imaging procedures facilitate the early diagnosis and treatment of diseases and disorders andmay reduce unnecessary invasive procedures, often minimizing the cost and amount of care for patients. Diagnostic imaging procedures includeMRI, CT, PET, nuclear medicine, ultrasound, mammography, X-ray and fluoroscopy.Â While X-ray remains themost commonly performed diagnostic imaging procedure, one of the fastest growing procedures is the MRI. The number of MRI scans performedannually in the United States continues to grow due to its wider acceptance by physicians and third party payers, an increasing numberof applications for their use and a general increase in demand due to the aging population. MRI has long been a widely accepted diagnosticstandard of care for spine and low back pain, including discogenic low back pain patients, which is the target medical condition for ourdiagnostic products.Â Diagnostic ImagingSettingsÂ Diagnostic imaging servicesare typically provided in one of the following settings:Â Fixed-site,freestanding outpatient diagnostic facilitiesÂ These facilities rangefrom single-modality to multi-modality facilities and are generally not owned by hospitals or clinics. These facilities depend upon physicianreferrals for their patients and generally (although not always) do not maintain dedicated, contractual relationships with hospitals orclinics. 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 workersâ€™compensation providers.Â HospitalsÂ Many hospitals provide both inpatient and outpatientdiagnostic imaging services, typically on site or at a dedicated center located on or nearby the hospital campus. These can be owned andoperated by the hospital and provide imaging services to inpatients as ordered or outpatients through physician referrals. The hospitalnormally bills third-party payors such as managed care organizations, insurance companies, Medicare or Medicaid, and workersâ€™ compensationproviders. We have entered into joint ventures with certain hospitals both provide and manage their diagnostic imaging services, allowingthem to leverage our industry expertise.Â MobileImagingÂ While many hospitalsown or lease their own equipment, certain hospitals provide diagnostic imaging services by contracting with providers of mobile imagingservices. Using specially designed trailers, mobile imaging service providers transport imaging equipment and provide services to hospitalsand clinics on a part-time or full-time basis, thus allowing small to mid-size hospitals and clinics that do not have the patient demandto justify fixed on-site access to advanced diagnostic imaging technology. Diagnostic imaging providers contract directly with the hospitalor clinic and are typically reimbursed directly by them. We do not provide mobile imaging services. The cloud-based software productsand services we do provide, however, are compatible for use for post-processing data that may be acquired by certain MR scanners thatare deployed in a mobile imaging setting and model.Â Â Â Â 86Â Â Â Company HistoryÂ Aclarionâ€™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 (â€œUCSFâ€). Early research, which was published in a major peer-reviewedjournal in 2005, was premised upon a growing suspicion and interest that discs may become painful due to chemical changes, in particularelevated acidity related to hypoxia, that are not tested using a standard MRI. With that theory in mind, Dr. Lotzâ€™s initial studylooked to identify chemical biomarkers for painful discs using MRS, which applies a pulsed magnetic field to tissues in order to vibratethe different chemicals in that tissue and generate a spectrum that allows for measuring those different chemicals based on their differentpeaks along that spectrum. NMR equipment was used to conduct MRS chemical analysis of painful discs that were surgically removed for DLBPfusion surgery versus normal, non-painful discs that were surgically removed from spinal deformity (i.e. scoliosis) patients for lumbarspine reconstruction. Those ex vivo 11T MRS spectral measurement results showed that all (n=9) of the painful discs were distinguishedfrom all of the non-painful discs based on the highly repeatable (100%) differences in their ratios between lactic acid, a painful chemicalresulting from hypoxia, and proteoglycan, a structural chemical of the disc that holds water for hydration. It was observed that withdegenerative painful discs, proteoglycan reduces with the degeneration, and lactic acid elevates with the pain. Hence, the MRS-based testand identifiable structural and degenerative pain biomarkers were able to be identified.Â This work became the subject of the first patentgranted to the Regents of the University of California and exclusively licensed to Aclarion. Thereafter, a strategic collaboration withSIEMENS, a major MRI equipment manufacturer, was initiated and a clinical study, the Gornet Study, involving 73 surgical patients waspublished in the European Spine Journal, a major peer-reviewed publication (See â€œClinical Evidenceâ€ below). Our NOCICALC andNOCOGRAM products were subsequently registered with the FDA, CE marked and launched in the US, EU, and UK markets through a customer paymodel since insurance codes were not yet in existence.Â License Agreement with the Regents of the University of CaliforniaÂ On January 8, 2008, the Company entered into anExclusive License Agreement which was amended and restated on December 9, 2014, (the â€œLicense Agreementâ€) with the Regentsof the University of California, and was further amended on March 31, 2017. The License Agreementencompassed certain intellectual property and patents covering inventions generally characterized as systems, materials, and methods tolocalize 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.Â Pursuant to the License Agreement, the Companyobtained a worldwide, exclusive license to intellectual property including certain patent rights related to the patents and technologywhich 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 technologyand 10% of gross revenues we may receive from possible sub-licensees, affiliates or joint venture partners. Additionally, we agreed topay a minimum annual royalty fee of $50,000, accountable against actual earned royalties, plus other costs and expenses related to theprosecution of existing or future patents related to the technology, and certain additional one-time fees that were contingent upon theoccurrence of certain defined milestones.Â The License Agreement also provides that for solong as we pay patent prosecution costs, the Regents of the University of California will diligently prosecute and maintain the UnitedStates and foreign patents comprising the Patent Rights using counsel of its choice, and the UC Regents' counsel will take instructionsonly from The Regents of the University of California.Â Upon completion of our April 2022 IPO, we wererequired to pay the Regents of the University of California a contingent one-time â€œIndexed Milestone Paymentâ€ of an amountof cash determined by multiplying the amount of shares outstanding at such time the Company raises $1 million in capital, by 3% and thenmultiplying the 3% number by the IPO price. On May 2, 2022, we paid the amount of $123,828 to satisfy the Indexed Milestone Payment obligationincluded within the license agreement.Â The Regents of the University of California hasthe right to terminate the License Agreement upon advanced notice in the event of a default by us. The License Agreement will expire uponthe expiration or abandonment of the last of the licensed patents. The patents subject to the License Agreement expire between 2025 and2029.Â Â Â 87Â Â Â We rely on this license, as well as other aspectsof our own patented technology and intellectual property, in order to be able to use and sell various proprietary technologies that arematerial to our business, as well as technologies which we intend to use in our future commercial activities. Our rights to use theselicensed technologies and the inventions claimed in the licensed patents, are subject to the continuation of, and our compliance withthe terms of the license. The loss of this license would materially negatively affect our ability to pursue our business objectives andresult in material harm to our business operations.Â Transactions with NuVasive, Inc.Â In 2015, NuVasive, Inc. (â€œNuVasiveâ€)purchased approximately $2.0 million of the Companyâ€™s Series B preferred shares. NuVasive and the Company also entered into a marketingagreement pursuant to which NuVasive would be the exclusive, other than the Company, marketing provider for the Companyâ€™s technologyand NuVasive would receive a commission (the â€œCommissionâ€) of all sales of the technology made by NuVasive. In conjunctionwith the marketing agreement, the Company entered into a Right of First Offer (â€œROFOâ€) Agreement pursuant to which the Companyagreed 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 Companyâ€™soutstanding voting securities, a sale of substantially all of the Companyâ€™s assets, or a sale or exclusive license of substantiallyall of the Companyâ€™s intellectual property) NuVasive would have the right to receive notice (â€œROFO Noticeâ€), and NuVasivewould have a 60-day period to determine whether it wanted to acquire the Company on terms set forth in the ROFO Notice. The ROFO obligationswill expire 42 months after the FDA issues its first regulatory clearance of a Company product or service. The ROFO obligations do notapply to any proposed sale event in which the acquisition price is $40 million or more.Â 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 warrantto purchase 171,511 shares of common stock at an exercise price of $.18 per share.Â In February 2020, NuVasive and the Company alsoentered into an amended and restated commission agreement (the â€œCommission Agreementâ€), pursuant to which the Company agreedto pay NuVasive a commission of 6% of certain revenues of the Company related to Aclarionâ€™s Nociscan technology through December31, 2023, and issued to NuVasive the right to receive the Companyâ€™s preferred shares subject to the terms of a $2 million â€œSAFEâ€(Simple Agreement for Future Equity). The SAFE provided that NuVasive would receive $2 million of capital stock if the Company would raisea 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 millionwas 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 Companyissued 1,584,660 Series B-2 preferred shares to NuVasive in December 2021. In connection with the Commission Agreement, NuVasive agreedthat: (i) NuVasive would cease to market the Companyâ€™s technology, (ii) NuVasive would reduce their Commission to 6%, and (iii)Commissions to NuVasive would terminate on December 31, 2023. In December 2021, NuVasiveâ€™s convertible notes were converted intoSeries

B-3 preferred shares.Â Products and SolutionsÂ Aclarion has developed a software applicationcalled NOCISCANÂ®. The product uses the existing MRS capabilities of many commercially available scanners to non-invasively analyzethe chemical makeup of intervertebral discs in the spine. The software post-processes the MRS exam data and detects the presence of chemicalbiomarkers that Aclarion, in conjunction with spine researchers at UCSF, have demonstrated to be associated with degenerative pain andstructural integrity of the lumbar discs. After processing the MRS exam data, Aclarion sends the ordering clinician a report that detailshow to interpret the results of the MRS exam. We believe these results help clinicians make faster and more informed decisions about whichlumbar discs are painful, and which are not. We believe the ordering clinician can then use this information to determine the optimaltreatment plan for an individual patient.Â NOCISCAN is entirely non-invasive and only brieflyextends an otherwise standard MRI exam. The MRI scan is the most frequently used type of pulse sequence for operating Nuclear MagneticResonance (NMR) scanners. It uses a powerful magnet to apply a pulsed magnetic field to a patient, sensors to detect radio waves thatemanate from the resonant vibrations of different chemicals in the body in response to that pulsed magnetic field and a computer to createdetailed images of tissue structures in the patient based on those detected chemical signals. Because water and fat are the most prevalentchemicals 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 resonancesto create an image, MRS creates a spectrum for a tissue with different peaks that represent many different chemicals, in addition to waterand fat, in that tissue. The relative amounts of those chemicals can be calculated by measuring their respective spectral peaks. WhileMRS has been used previously for diagnosing certain cancers (e.g. brain, breast, prostate) by measuring unique chemical biomarkers fortumors, NOCISCAN uses MRS for measuring the relative levels of degenerative pain and structural integrity biomarkers in discs. The relativelevels of degenerative pain and structural integrity biomarkers are derived through the use of proprietary post processing technologies.Â Â Â 88Â Â Â The platform used toconduct a NOCISCAN involves: (i) an MRS exam of an intervertebral disc performed according to a proprietary protocol, (ii) a data transferportal to securely transfer data from the MRS exam to Aclarionâ€™s cloud based post-processer technology, (iii) post-processor technologythat identifies biomarker peaks and leverages calculation tables that evaluate a number of ratios of biomarker peaks, where pain biomarkersare in the numerator and structural biomarkers are in the denominator, and (iv) a final diagnostic report called a Nocigram that identifiesdiscs as painful or not.Â (a)Â Â Â Â NOCISCANMRS Exam Protocol: We have developed a custom software protocol and technique for using commercially available MRS pulse sequencesin 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 reliableMRS data. This protocol is not a product sold by the Company. The software protocol was created by Aclarion for insertion within a pre-existingsoftware file format and is downloaded onto the MRS by the MRS owner, for use within the MRSâ€™s operating system environment. Currently,our software protocol is compatible with only certain MRS models and operating systems available from SIEMENS, as those SIEMENS modelsspecifically provide for user-defined customizations available for running our custom pulse sequences on SIEMENS MRS equipment.Â (b)Â Â Â Â Â DataTransfer: 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 AMBRAÂ® Health, and (2) NOCIWEBÂ®, a custom developed web-interfacedeveloped and offered by Aclarion.Â (c)Â Â Â Â Â TheNOCISCAN Post-Processor Suite: This comprises the products that Aclarion currently markets and sells. The post-processor technologyrequires MRS exam data acquired only according to Aclarionâ€™s proprietary MRS exam protocols described in (a) above. The NOCISCANPost-Processor Suite comprises of two software products that interact with each other:Â Â Â· NOCICALCÂ® 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. Â Â Â Â Â· NOCIGRAMÂ® 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 â€œNOCI+â€ result) versus non-painful (indicated as a â€œNOCI-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 patientâ€™s lumbar spine. The NOCIGRAM report is provided to the physician to aide in the physicianâ€™s diagnosis and treatment planning. NOCIGRAM is commercially available in the United States as â€œClinical Decision Support Softwareâ€ under the 21st Century Cures Act, and as such is not considered a medical device nor regulated by the FDA. Â Advantages over current technology and proceduresÂ NOCISCAN provides new information to help doctorsbetter diagnose which intervertebral discs may contribute to patients back pain and thereby assist in treatment planning and potentiallyimprove patient outcomes.Â More specifically, current standards of care forthe 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 certainnon-discogenic sources of pain, these techniques are unreliable for identifying painful discs in LBP patients. The PD TEST is anothertest that typically follows MRI for the purpose of identifying painful discs. PD Tests have been shown to be highly accurate when performedproperly, however, a PD Test is invasive, subjective and unpleasant for the patient as the patient needs to be awake in order to tellthe physician if the pain the physician is purposefully causing in the disc is the same as the pain the patient feels when they are experiencinga back pain episode. In addition, recent evidence has shown that the action of inserting a needle into a normal disc during a discogramprocedure leads to an increased rate of degeneration in these previously normal discs. We believe NOCISCAN advantages include: (a) enhancingthe ability and value of otherwise standard lumbar MRI exams to, for the first time, reliably identify chemically painful discs causingDLBP; and (b) providing a â€œVirtual Discogramâ„¢â€ as an entirely non-invasive, objectively quantitative, pain-free, non-significantrisk, and more widely adoptable alternative to needle-based PD exams (which share none of those advantages).Â Â Â 89Â Â Â More specifically, NOCISCAN offers many specificadvantages to the marketplace, from a diagnostic point of view, including:Â Â 1) Readily and widely adoptable; Â Â 2) Non-invasive; Â Â 3) Non-painful; Â Â 4) Nonsignificant risk to patients; Â Â 5) Objective, quantitative diagnostic information; Â Â 6) Enhances the diagnostic value of MR exams for painful disc diagnosis in DLBP patients; Â Â 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; Â Â Â Â 8) First and only known ability to non-invasively assess degenerative painful disc chemistry; Â Â 9) More informed ability to reliably diagnose painful vs. non-painful discs; Â Â 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; Â Â 11) More informed ability to reliably diagnose actual ASD in discs following a prior surgery in neighboring discs; Â Â 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 Â Â 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. Â NOCISCAN incorporates many patented technologiesand 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 accuratequantitative chemical measurements. These technical challenges resulted in poor sensitivity and specificity for prior MRS products addressingclinical applications. The novel features and advantages provided in the NOCISCAN platform are designed to address the technical and diagnosticchallenges of MRS in the past. Accordingly, we believe Aclarion improvements do not only propose benefits for disc MRS, but potentiallyfor other MRS applications more broadly. Improvements in processing raw MRS data incorporated in Aclarion IP are summarized below:Â Â 1) Introducing novel signal processing approaches for enhanced reliability of the underlying spectra and related chemical biomarker â€˜peakâ€™ measurements: Â Â a) increased signal noise ratio or â€œSNRâ€ 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 (â€œframe editingâ€), and (ii) a â€œsmartâ€ form of frequency shift correction to align multiple acquisitions for â€œcoherentâ€ averaging; and Â Â Â 90Â Â Â Â 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). Â Â 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. Â Â 3) Evaluating only multi-chemical â€œdegenerative painâ€ 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 ratioâ€™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. Â Â 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. â€œLAALâ€ painful chemical biomarker range combining adjacent Lactic Acid and ALanine peaks, and â€œALPAâ€ combining Alanine, Lactic acid, and Propionic Acid peaks) â€“ thereby removing the need for accurately differentiating each individual peak, and thus reducing the risk for inaccuracy in the spectral measurements and diagnostic interpretations. Â Clinical EvidenceÂ We have pursued a clinical study (the â€œGornetStudyâ€) to demonstrate the benefits of our technology to surgeons, imaging centers, third party payers, and patients. Without strongclinical data in support of our technology to improve clinical outcomes, the opportunity to secure new reimbursement codes and changeexisting treatment pathways would be limited.Â In a clinical study sponsored by us, and authoredby, 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 painfulby NOCISCAN were included in the surgical treatment. This compared to 54% of surgical patients achieving clinically significant improvementwhen discs identified as painful by NOCISCAN were omitted from the surgical treatment, or discs identified as not painful by NOCISCANwere included in the treatment. Some authors of this study had a financial relationship with Aclarion, who sponsored the study.Â This clinical study included 139 chronic low backpain 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 theindustry standard Oswestry Disability Index (ODI), and the Visual Analog Scale (VAS). ODI evaluates patient disability on a scale of 1-100with 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. NOCISCANdata was not used in surgical decision making.Â Post-operatively, patients were separated intovarious groups for analysis. One group consisted of patients where the surgical intervention included every disc that was identified byNOCISCAN as painful. This group consisted of 36 patients with 26 undergoing a one-level surgical procedure and 10 undergoing a two-levelsurgical procedure. 97% (35 of 36) of the patients in this category met the criteria for significant clinical improvement. The one failurein this group did meet the VAS requirement and missed the ODI cutoff of 15 by only one point.Â In another group consisting of 13 patients, adisc identified as painful by NOCISCAN was not included in the surgical intervention. In this group only 54% (7 of 13) of patients metthe criteria for clinically significant improvement.Â Â Â 91Â Â Â In April 2023, Aclarion advanced the evidence of our technology witha peer-reviewed journal article detailing the Gornet 2-year outcomes published in the European Spine Journal. The 2-year outcomes weredurable with 1-year outcomes previously published in 2019. At 2-years follow-up, 85% of patients improved when disc(s) identified as consistentwith pain by our technology were included in a surgical treatment, compared to only 63% of patients when disc(s) identified as consistentwith pain were not treated or disc(s) identified as consistent without pain were treated.Â We believe the results of this study indicatesthat using NOCISCAN data to help determine the appropriate level for surgical intervention will significantly improve the outcomes forpatients undergoing spine surgery for back pain. However, the Gornet Study was a single (relatively small) clinical study at a singleclinical center sponsored by us, and authored by, among others, a spine surgeon who has a financial interest in the Company, and therecan be no assurance that the results of such study accurately support our conclusions related to the market opportunity of our products.Â Market OpportunityÂ The current NOCISCAN product addresses the $10Bthat is spent in the U.S. on spine fusion procedures annually. Our early clinical evidence points to a marked improvement in

surgicaloutcomes when discs identified as painful by our technology are included in the surgical treatment. We believe this market is actionablenow and a significant portion of the proceeds of our IPO will be directed towards commercializing this market opportunity.Â 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 registriesto track NOCISCAN patients regardless of what treatment path they may follow. Through the date of this prospectus, NOCISCAN has only beenevaluated in formal clinical studies for patients primarily undergoing surgical interventions for fusion or disc replacement. The Companyplans 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 allspine 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 marketingour products, regardless of the size of the estimated market.Â Our ultimate objective for NOCISCAN is to addressthe entire low back and neck pain market which at $134.5B annually represents the largest amount of healthcare dollars spent to treatany disease. To address this market, our current algorithms will need to expand to include advanced machine learning techniques that incorporatemultiple data inputs besides the chemical composition of discs. These additional inputs will all need to be correlated to clinical outcomesfor treatments ranging from physical therapy to regenerative therapies, and surgical interventions. To further this process, we have beenselected as a participant in a $150M NIH funded study (the NIH BACPAC Initiativeâ€) focused on evaluating the most promising datainputs for predicting the optimal treatment path for back pain patients and in the NIHâ€™s follow on BEST study to evaluate the clinicalefficacy of using these data inputs for improving clinical results.Â In addition to participation in external studiessuch as the NIH BACPAC and BEST initiatives, we expect to create our own internal data by adding patients undergoing conservative andregenerative treatment plans to our clinical registries correlating NOCISCAN results to outcomes in order to utilize AI to associate spectroscopysignals with the optimal treatment pathway. If we are successful in demonstrating the clinical effectiveness of these associations, weintend 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.Â Although we believe that we are addressing a largeU.S. and European market, there are practical limitations to the market opportunity that must be overcome by us. We believe the two biggestlimitations are the lack of deployment of spectroscopy software across the install base of existing MRIâ€™s worldwide and the factthat only certain MR scanner models are compatible with our technology. For compatible MRI machines, that do not have spectroscopy hardwareand software installed, the onetime cost of the hardware and software ranges from $25,000 to $50,000. Currently, our NOCISCAN platformis only compatible with certain MR scanner models provided by SIEMENS, of which there are an estimated 1,500 in the United States, and4,320 worldwide. We plan to collaborate with other MRI scanner vendors to establish compatibility of their respective scanners and MRScapabilities for use with our products, to include discounted pricing on spectroscopy software for MRI sites interested in providing DLBPpatients with the NOCISCAN offering.Â Â Â 92Â Â Â Plan of Operation and Growth StrategiesÂ Our primary near-term growth strategy is to securepayer contracts to cover our Category III CPT codes. We believe that with favorable payer coverage decisions comes the opportunity tomore efficiently market to spine surgeons and imaging centers to adopt our technology.Â The Company is currently generating the vast majorityof 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.Â Initial Payer CoverageDecisionsÂ In June and July 2024,the Company announced initial payer coverages of Nociscan by AXA and Aviva in London, UK in conjunction with The London Clinic, one ofthe UKâ€™s largest and most renowned independent hospitals. AXA and Aviva is each a leading provider of private medical insurancein the UK.Â Alphatec Strategic Â PartnershipÂ On January 8, 2024, we announced that we had executeda strategic partnership agreement solidifying our previously signed non-binding letter of intent with ATEC Spine, Inc., the wholly ownedoperating subsidiary of Alphatec Holdings, Inc. (â€œATECâ€). ATEC is a medical device company dedicated to revolutionizing theapproach to spine surgery through clinical distinction.Â The agreement contemplates a multi-step strategicpartnership. Under the agreement, ATEC and Aclarion will work together to identify Key Opinion Leader (KOL) surgeons to evaluate our Nociscantechnology. Feedback from these surgeons will inform clinical evaluations designed to assess the utility of Nociscan in conjunction withEOS imaging, the foundation of ATECâ€™s AlphaInformatiX platform. Assuming positive synergies, ATEC and Aclarion will co-market Nociscanin targeted markets. In exchange for select access to ATECâ€™s surgeon network for the evaluation and advancement of Nociscan, Aclarionwill provide ATEC with certain exclusive distribution rights to include Nociscan as part of an integrated procedural solution.Â In order to effectively commercialize our technology,the Company has completed its initial plan to gain the support of up to ten leading spine surgeons as Key Opinion Leaders (KOL) who believeNociscan technology will help them with surgical decisions in their practices. These KOL surgeons are leaders in their field and willbe assisting the Company in generating important clinical data in support of Nociscan, and using that data to help the Company in discussionswith payers to secure positive payment decisions for our Category III CPT codes.Â Based primarily on our KOL surgeons and the strengthof physician engagement in markets, the Company is prioritizing the following markets:Â Â 1. NYC Metropolitan Area Â 2. San Francisco, CA Â 3. Chicago, IL Â 4. Phoenix, AZ Â 5. Miami, FL Â 6. Denver & Colorado Springs, CO Â 7. Detroit, MI Â 8. Indianapolis Â Once a positive local payment decision is securedin a geographical area, we intend to place a market manager and a team of business development professionals into each market to focuson expanding physician support and securing favorable coverage decisions from additional payers in the market. The objective in each marketis to expand the provider network to include additional imaging centers and surgeons so there is increasing geographical coverage. Webelieve increasing our footprint in each market will grow volume and revenue through increased pressure on payers to expand positive coveragedecisions across all of the varied plans associated with each payer.Â Â Â 93Â Â Â We believe the following strategies will contributeto growth in the prescription and use of NOCISCAN.Â Â Â· 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; Â Â Â· Increase third party payer reimbursement coverage via reimbursement code utilization, payer negotiations, growing clinical evidence dossier via published registry studies and Randomized Control Trials (â€œRCTâ€), and converting temporary Category III CPT codes into permanent CPT Category I codes see â€œThird Party Reimbursement â€ below; Â Â Â· Expand MR scanner compatibility to additional scanner models,

including within the Siemens product lines and other manufacturers/vendors; Â Â Â· Expand into international markets; Â Â Â· Evolve the adaptations and positioning of our products to support new emerging technologies, and clinical trials, in particular for injectable biologic and cell therapies; Â Â Â· 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); Â Â Â· Continue to engage and expand Key Opinion Leader (â€œKOLâ€) 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 Â Â Â· 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. Â Strategic RelationshipsÂ SiemensÂ The NOCISCAN product suite is currently compatiblefor use only with certain MR scanner models and configurations provided by SIEMENS. We are not subject to any exclusivity agreement orobligations with SIEMENS, nor do we have any fee sharing, royalty, or other exchange of moneys or payments between us and Siemens. Thenexus for our focused relationship with Siemens resulted from our determination that Siemens scanner models were optimally positionedto support our product. We have had a collaborative relationship with Siemens since 2011.Â Â Â Â Â 94Â Â Â On May 2, 2012, following a prior period of informalcollaboration, we entered a Memorandum of Understanding (â€œMOUâ€) with SIEMENS, under which SIEMENS agreed to support Aclarionâ€™sresearch and development of what later became the NOCISCAN product suite for compatible use with SIEMENS scanners. The MOU included thedevelopment 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-compatibleNOCISCAN Product of Aclarion, Inc. (the â€œSIEMENS Agreementâ€) that we entered into with SIEMENS Healthcare GmbH on December31, 2017. This agreement comprised a collaboration to identify, onboard and provide technical support for the SIEMENS-compatible NOCISCANplatform with early commercial users in the European Union, including a free trial period for those initial commercial users to activateand use the SIEMENS SVS pulse sequence option package that is required to be purchased by our customers in order to perform disc MRS accordingto 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 FrontierApp Store model. While these plans have not yet been realized, the agreement still remains in effect through automatic extensions andwe are in on-going dialogue and negotiations toward some, or possibly all, of these objectives. The Siemens Agreement is terminable.atany 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 effecton our business. Further, there can be no assurance that there will be any joint marketing or that future financial arrangements betweenus and SIEMENs will be established, and even if established, that such agreements will be successful or profitable.Â RadNetÂ Two of the Companyâ€™s imaging centers thatare fully operational to perform NOCISCANâ€™s are owned by RadNet, Inc., (â€œRadNetâ€) a leading provider of outpatient imagingcenters in the United States. RadNet currently own 357 outpatient imaging centers across seven states. Larry Tannenbaum is one of ourformer board members and leads the radiology section of our Medical Advisory Board. The New York/New Jersey area is one of our top targetsfor early commercialization post IPO and we expect to leverage RadNetâ€™s extensive relationship with commercial payers to secureintroductions that we believe will lead to early coverage decisions from payers in support of our growth plans. Although we have ambitionsto grow the RadNet relationship, the current arrangement is limited to the flow of revenue between Aclarion and RadNet for the performanceof an MRS exam by RadNet and the subsequent generation of a Nociscan report by Aclarion.Â Reimbursement Â Current Procedural Terminology or â€œCPTâ€codes are developed by the American Medical Association (â€œAMAâ€) to describe a wide range of health care services providedby 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 referredto interchangeably as â€œLevelsâ€):Â Â Â· 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. Â Â Â· Category II CPT Codes are used for reporting performance measures reducing the necessity for chart review and medical records abstraction. Â Â Â· 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. Â Our NOCISCAN product suite was initially commercializedwithout existing CPT codes or other pathways for seeking reimbursement coverage from third party payers. Accordingly, to date, the commercialuses of our products have been principally paid for directly by patients or their spine surgery care provider. The first third party payerreimbursement occurred in May 2021 via the payment of a Workmanâ€™s Compensation claim in Colorado.Â Â Â 95Â Â Â Effective January 1, 2021, a previously retiredCategory I CPT Code 76390 for MR Spectroscopy was reinstated and reactivated by the Centers for Medicare and Medicaid Services (â€œCMSâ€).This resulted from our own direct efforts with CMS in hopes of achieving this result. In addition, also effective January 1, 2021, theAMA approved four new Category III CPT Codes for performing MRS exams specifically on intervertebral discs. More specifically, these codeswere assigned respectively to: (i) determine and localize discogenic pain via SVS (0609T), (ii) transmit the MRS derived biomarker datafor software analysis (0610T), (iii) post-process the biomarker data for algorithmic analysis to determine relative chemical differencesbetween discs (0611T), and (iv) interpret and report those results. Ambulatory Payment Classification (â€œAPCâ€) pricing assignmentswere 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 theAMA toward these interim objectives. We intend to further explore APC assignments such as a New Technology APC to ensure our NOCISCANproduct suite is assigned an APC that is appropriate in terms of clinical characteristics and resource costs.Â The table below further explains these four newLevel III CPT Codes:Â CPT Code Description 0609T MRS, determination and localization of discogenic pain (cervical, thoracic, or lumbar); acquisition of single voxel data,

per disc, in â‰¥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 Â Due to a lack of operating capital, we have notyet begun to seek reimbursement coverage or promote or suggest our customers use these codes. However, we plan to use the proceeds ofour public offering to hire the personnel and expend our financial resources do so. The Category III Codes become more valuable and usefulupon being converted into Level I, when widespread reimbursement coverage is expected to be achievable. We plan to support conversionof codes from Category III to Category I by advancing multiple clinical studies and related peer-reviewed clinical publications intendedto further support improved patient outcomes (such as success rates following DLBP surgeries), and various economic advantages to be achievedby incorporating the use of our NOCISCAN platform into the DLBP patientâ€™s healthcare journey. However, there can be no assurancethat the Category III codes will be converted and replaced with corresponding Level I Codes, and if there is a delay in the conversionof 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 ourtechnology by patients and health care professionals.Â Intellectual Property - Licenses, Patents andTrademarksÂ 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 protectour technology and any potential future technology related to our NOCISCAN platform through a variety of methods, including seeking andmaintaining patents intended to cover current and future technology, their methods of use and processes, and any other inventions thatare 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 additionalcountries where we believe such foreign filing is likely to be beneficial, including Europe, Australia, Canada, China, Japan, India andSouth Africa.Â Â Â 96Â Â Â On December 9, 2014, the Company entered intoan amended and restated exclusive license agreement (the â€œLicense Agreementâ€) with the Regents of the University of Californiafor certain inventions, generallycharacterized as systems, materials, and methods to localize and evaluate pain and degenerative properties of tissue, molecularmarkers that differentiate painful from non-painful discs; and MR Spectroscopy System and Method for diagnosing painful and non-painfulintervertebral discs (collectivelythe â€œInventionâ€). Â Pursuant to the License Agreement, the Companyobtained a royalty-bearing, worldwide, exclusive license to the Invention, including certain patent rights related to the patents andtechnology 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 escalateseach anniversary and is currently $50,000. UCSF has the right to terminate the agreement upon advanced notice in the event of a defaultby us. The agreement will expire upon the expiration or abandonment of the last of the licensed patents. The U.S. patents subject to theagreement expire between 2026 and 2029, without considering any possible patent term adjustment or extensions and assuming payment ofall appropriate maintenance, renewal, annuity, or other governmental fees.Â As of December 1, 2023, our intellectual propertyportfolio has 22 issued patent and 6 pending patent applications in the U.S., and 17 patent grants and 7 pending patent applications outsidethe 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 toboth the Company and the Regents of the University of California (also exclusively licensed to the Company). Many of these patents relateto, inventions involved in, the Companyâ€™s first product, the NOCISCAN product suite for post-processing disc MRS exam data. Othersrelate to potential enhancements of the NOCISCAN disc MRS exam (as conducted at the MR scanner) and also other alternative diagnosticapproaches (e.g. molecular imaging and gene expression testing). Our portfolio of patents and patent applications, if issued, are expectedto expire between January 30, 2026 and June 16, 2037 in the U.S., in each case without considering any possible patent term adjustmentsor extensions and assuming payment of all appropriate maintenance, renewal, annuity, or other governmental fees.Â Our intellectual property portfolio includes fourpatent families (each reflecting multiple families, if based on different original applications), that relate to our NOCISCAN technologyâ€‰and/orto other potential future pipeline products.Â The first patent family is directed to inventionsfor signal processing techniques to include leveraging artificial intelligence technologies for improving the quality, reliability, andaccuracy of MRS-based chemical biomarker measurements and related diagnostic interpretations. Many of these patented inventions are includedin our NOCICALC product under the NOCISCAN Suite and cover uses specifically for disc MRS, and for MRS in any other tissues. This firstfamily includes 8 issued patents and 1 pending patent application assigned to the Company in the US, and 3 issued patents and 1 pendingpatent application outside the U.S. (Europe and Australia). All of these are assigned to the Company. The U.S. granted patents and pendingpatent applications, if issued, are expected to expire between October 14, 2029 and March 15, 2033, without considering any possible patentterm adjustment or extensions and assuming payment of all appropriate maintenance, renewal, annuity, or other governmental fees.Â The second patent family relates to inventionsfor novel diagnostic systems and methods for providing diagnostically useful information based on MRS-based chemical biomarkers. Manyof these patented inventions are incorporated in our NOCIGRAM product and related diagnostic report under the NOCISCAN Suite and relateto uses specifically for discogenic pain, conditions related to discs more generally, and more broadly any degenerative pain-related diagnosisin any tissue. This family includes patents relating to diagnosing degenerative painful discs (and other tissues) using the primary degenerativepain biomarkers evaluated by our NOCIGRAM product. The second patent family includes 6 issued patents and 3 pending patent applicationsin the US, and 9 patent grants and 6 pending patent applications outside the U.S. (Europe, Australia, Canada, China, Japan, India, SouthAfrica). These are either assigned to the Regents of the University of California or assigned to both the Regents of the University ofCalifornia and the Company, in all cases with the UCâ€™s rights exclusively licensed to the Company. The U.S. granted patents andpending patent applications, if issued, are expected to expire between January 30, 2026 and June 16, 2037, without considering any possiblepatent term adjustment or extensions and assuming payment of all appropriate maintenance, renewal, annuity, or other governmental fees.Â Â Â 97Â Â Â Our third patent family relates to inventionsthat enhance the efficiency and reliability of certain aspects related to conducting MRS exams at the MR scanner. This includes enhancingthe efficiency and quality of NOCISCAN disc MRS exams and other applications of MRS in general. These patented inventions are not currentlyincorporated into our commercial products but are in the research and development phase for potential

pipeline products. This third patentfamily includes 3 issued US patents that are expected to expire on November 23, 2031, without considering any possible patent term adjustmentor extensions and assuming payment of all appropriate maintenance, renewal, annuity, or other governmental fees. These patents are allassigned to the Company. This patent family also includes a pending U.S. patent application that relates to the use of Artificial Intelligencefor enhancing MRS exams, which is in the research and development phase for potential pipeline products.Â Our fourth patent family relates to inventionsfor other novel diagnostic systems and methods that represent potential future pipeline products, or otherwise provide potential exclusionaryrights against related potential competitive threats. This includes patents related to discogenic pain diagnosis using molecular imagingand/or gene expression testing. The fourth patent family includes 4 issued patents and 1 pending patent application in the US, and 5 patentgrants outside the U.S. (Europe, Canada, China). These patents are assigned to the Regents of the University of California and exclusivelylicensed to the Company (and in certain aspects, co-exclusively licensed under which the Company has exclusive rights to diagnostic aspectsand another third-party licensee has limited exclusive rights to only certain treatment aspects). The U.S. granted patents and pendingpatent applications, if issued, are expected to expire between September 21, 2026 and May 29, 2029, without considering any possible patentterm adjustment or extensions and assuming payment of all appropriate maintenance, renewal, annuity, or other governmental fees.Â We cannot be sure that patents will be grantedwith 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 ourtechnology. Please see â€œRisk Factorsâ€‰â€”â€‰Risks Related to Our Intellectual Propertyâ€ for additionalinformation on the risks associated with our intellectual property strategy and portfolio.Â We continually assess and refine our intellectualproperty strategies to fortify our position. We file additional patent applications when our intellectual property strategy warrants suchfilings. 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 patentedinventions, either directly or indirectly, will depend in part on our success in obtaining, defending and enforcing patent claims thatrelate to our technology, inventions, and improvements. With respect to our intellectual property, we cannot provide any assurance thatany of our current or future patent applications will result in the issuance of patents in any particular jurisdiction, or that any ofour current or future issued patents will effectively protect any of our tests or technology from infringement or prevent others fromcommercializing infringing tests or technology. Even if our pending patent applications are granted as issued patents, those patents maybe challenged, circumvented or invalidated by third parties. Consequently, we may not obtain or maintain adequate patent protection forany of our tests or technology.Â In addition to our reliance on patent protectionfor our inventions and technology, we also rely on trade secrets, know-how, confidentiality agreements and continuing technological innovationto develop and maintain our competitive position. For example, some elements of our analytics techniques and processes, computational-biologicalalgorithms and related processes and software are based on unpatented trade secrets and know-how that are not publicly disclosed. Althoughwe take steps to protect our proprietary information and trade secrets, including through contractual means with our employees, advisorsand consultants, these agreements may be breached, and we may not have adequate remedies for any breach. In addition, third parties mayindependently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets ordisclose our technology. As a result, we may not be able to meaningfully protect our trade secrets. For further discussion of the risksrelating to intellectual property, see the section titled â€œRisk Factorsâ€‰â€”â€‰Risks Related to our IntellectualProperty.â€Â Â Â Â 98Â Â Â The Company holds the following trademarks forits previous corporate brand name as well as for its key products and brands (â€œÂ®â€ designates registered trademark, â€œâ„¢â€designates unregistered trademark under common law protection):Â NOCIMEDÂ®Corporate brand nameNOCISCANÂ® - Primary data acquisition exam(procedure) and software-based post-processing suite (product)NOCIGRAMÂ® - Post-processed report, one oftwo products in the NOCISCAN product suiteNOCISCOREÂ® - Feature of NOCIGRAM ReportNOCICALCâ„¢ - MRS spectral processor and biomarkercalculator, one of two products in the NOCISCAN suiteNOCI+â„¢ - Feature of NOCIGRAM ReportNOCI-â„¢ - Feature of NOCIGRAM ReportNOCImildâ„¢ - Feature of NOCIGRAM ReportNOCIWEBâ„¢ - Web-hosted user interfaceSI-SCOREâ„¢ - Feature of NOCIGRAM ReportVIRTUAL DISCOGRAMâ„¢ - Additional name associatedwith NOCIGRAMÂ With respect to involvedmeanings, the recurrent prefix term â€œNOCIâ€ among these marks is derived from Latin origins for â€œpainâ€ (e.g.nerves that report pain are called â€œnociceptorsâ€).Â Research and DevelopmentÂ Research and Development (â€œR&Dâ€)activities at Aclarion primarily explore the use of AI, our post-processing technologies and clinical registry data to expand the useof our technology.Â The Company is researching the application ofAI and machine learning platforms to analyze both the raw spectroscopy data and the post-processed signal to evaluate whether AI platformscan more efficiently and more effectively associate MRS data with clinical outcomes. We expect this type of AI research and developmentto be an ongoing process applied not only to the various treatment paths associated with back pain, i.e., conservative therapies, regenerativeand cell therapies and surgical intervention, but to potentially expand into other clinical explorations involving the diagnosis of brain,breast and prostate tumors.Â Clinical research at Aclarion includes the buildingof clinical registries that provide the data inputs required to train the AI models to improve the efficiency and effectiveness of ourtechnology for surgical decisioning as well as extend the use of our technology for potentially optimizing the treatment of neck and lowback pain through other interventions.Â Clinical registries track the MRS results foreach disc being evaluated and correlates the MRS signature of the disc to patient specific data such as MRI imaging, Oswestry DisabilityIndex (ODI) and Visual Analog Scores (VAS). These methods are proven tools to assess low back pain, clinical treatments performed andto identify conservative therapies such as physical therapy and chiropractic intervention, regenerative and cell therapies or surgicalinterventions. By tracking specific treatments applied to each patient over time and correlating the effectiveness of those treatmentsto the MRS data of each disc, we expect to create a large repository of clinical data that can be used to train advanced machine learningalgorithms that correlate MRS signatures from specific discs to improved outcomes from conservative and regenerative therapies.Â Â Â Â 99Â Â Â Government RegulationÂ United States FDA.Â In the United States, the FDA has broad regulatorypowers with respect to pre-clinical and clinical testing of new medical devices and the designing, manufacturing, labeling, storage, recordkeeping, 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 introducedinto the market be preceded either by a pre-market notification clearance order under sectionÂ 510(k)Â of the Federal Food, Drugand Cosmetic Act (FDCA), or an approved Denovo or pre-market approval (PMA) application. Under the FDCA, medical devices are

classifiedinto one of three classesâ€”ClassÂ I, ClassÂ II or ClassÂ IIIâ€”depending on the degree of risk associated with eachmedical device and the extent of control needed to provide reasonable assurances with respect to safety and effectiveness. ClassÂ Idevices are those for which safety and effectiveness can be reasonably assured by adherence to a set of regulations, referred to as GeneralControls, which require compliance with the applicable portions of the FDAâ€™s Quality System Regulation (QSR) facility registrationand product listing, reporting of adverse events and malfunctions and appropriate, truthful and non-misleading labeling, advertising andpromotional materials. Some ClassÂ I devices, also called ClassÂ I reserved devices, also require premarket clearance by the FDAthrough the 510(k)Â premarket notification process described below. Most ClassÂ I products are exempt from the premarket notificationrequirements, and subject only to registration requirements (which the FDA does not typically review, thus determined and submitted solelyby the applicant product owner).Â ClassÂ II devices are those that are subjectto the General Controls, as well as Special Controls as deemed necessary by the FDA, which can include performance standards, guidelinesand post-market surveillance. Most ClassÂ II devices are subject to premarket review and clearance by the FDA. Premarket review andclearance by the FDA for ClassÂ 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 issubstantially equivalent to a previously cleared 510(k)Â device or a device that was in commercial distribution before MayÂ 28,1976 for which the FDA had not yet called for the submission of pre-market approval applications. To be substantially equivalent, theproposed device must have the same intended use as the predicate device, and either have the same technological characteristics as thepredicate device or have different technological characteristics and not raise different questions of safety or effectiveness than thepredicate device. Clinical data is sometimes required to support substantial equivalence.Â After a 510(k)Â notice is submitted, the FDAdetermines whether to accept it for substantive review. If it lacks necessary information for substantive review, the FDA will refuseto accept the 510(k)Â notification. If it is accepted for filing, the FDA begins a substantive review. By statute, the FDA is requiredto complete its review of, and clear or deny, a 510(k)Â notification within 90Â days of receiving the 510(k)Â notification.As a practical matter, clearance often takes longer, and clearance is never assured. Although many 510(k)Â premarket notificationsare cleared without clinical data, the FDA may require further information, including clinical data, to make a determination regardingsubstantial 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.Â After a device receives 510(k)Â clearance,any modification that could significantly affect its safety or effectiveness, or that would constitute a new or major change in its intendeduse, will require a new 510(k)Â clearance or, depending on the modification, could require a De Novo or PMA application. The FDA requireseach manufacturer to make this determination initially, but the FDA can review any such decision and can disagree with a manufacturerâ€™sdetermination. If the FDA disagrees with a manufacturerâ€™s determination regarding whether a new premarket submission is requiredfor the modification of an existing device, the FDA can require the manufacturer to cease marketing and/or recall the modified deviceuntil 510(k)Â clearance or approval of a De Novo or PMA application is obtained. If the FDA requires us to seek 510(k)Â clearanceor approval of a De Novo or PMA application for any modifications to a previously cleared product, we may be required to cease marketingor recall the modified device until we obtain this clearance or approval. In addition, in these circumstances, we may be subject to significantregulatory fines or penalties for failure to submit the requisite PMA application(s). In addition, the FDA is currently evaluating the510(k) process and may make substantial changes to industry requirements.Â ClassÂ III devices include devices deemedby the FDA to pose the greatest risk such as life-supporting or life-sustaining devices, or implantable devices, in addition to thosedeemed not substantially equivalent following the 510(k)Â process. The safety and effectiveness of ClassÂ III devices cannot bereasonably assured solely by the General Controls and Special Controls described above. Therefore, these devices are subject to the PMAapplication process, which is generally more costly and time consuming than the 510(k)Â process.Â Â Â 100Â Â Â In the event a device might be considered ClassIII due to lack of an equivalent predicate device, but which does not pose a significant risk to patients, it may be â€˜down-classifiedâ€™to a relatively newer De Novo pathway for pre-market notification review and approval, which typically involves burdens and review cycletimes between what are typical for 510(k) and PMA pathways. In addition to the above classifications and related FDA regulatory pathwaysin the United States, certain technologies that were previously considered medical devices have recently been reclassified and not considereda medical device, and thus not regulated by the FDA. On December 13, 2016 the 21st Century Cures Act (â€œCures Actâ€)was signed into law (Public Law 114-255, 130 STAT. 1033), and was designed to help accelerate medical product development and bring newinnovations and advances to patients who need them faster and more efficiently. Section 3060 of the Cures Act was created as an amendmentto section 520 of the Federal Food, Drug, and Cosmetic Act (FD&C Act), which addressed how medical devices are defined. This outlinedsoftware 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.Â In the United States, the NOCISCAN product suiteis only partially regulated as a medical device by the FDA. The NOCICALC product is considered a Class I â€œexemptâ€ medicaldevice and is registered as such with the FDA under product Classification â€œCalculator/Data Processing Module, for Clinical Use,â€Product Code â€œJQP,â€ Regulation Number 862.2100, and Registration Number 3015426626.Â The process to determine whether a product canbe considered a Class I â€œexemptâ€ medical device consists of self-determining whether the product is adequately described byone of the existing categories classified by the FDA. In conjunction with our regulatory consultants, we determined that the product Classificationâ€œCalculator/Data Processing Module, for Clinical Use,â€ adequately described our NOCICALC product.Â In contrast, we believe the NOCIGRAM product isconsidered Clinical Decision Support software (CDS) under the 21st Century Cures Act and not a medical device. As such, webelieve NOCIGRAM is not regulated by the FDA. Our conclusion that NOCISCAN would be considered Clinical Decision Support software (â€œCDSâ€),which under the 21st Century Cures Actâ€™ is not a device and therefore exempted from medical device regulation,â€ is based uponthe following analysis:Â Under the Cures Act provision, a software productis not considered a device if it meets the following four elements:Â Â Â· "[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;" Â Â Â· "[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);" Â Â Â· "[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 Â Â Â· "[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 Â Since December 13, 2016, the FDA has issued draftguidance which provides further insight into the interpretation of the above four elements. The draft guidance, entitled â€œClinicaland Patient Decision Support Softwareâ€ (Dec. 2017) (â€œDraft Guidanceâ€), reviews section 520(o)(l)(E) of the FDC Act andprovides additional clarity on each element.Â 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 recommendationssuch 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 intendeduser (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.Â Â Â 101Â Â Â As described above, FDA will not regulate softwarethat meets the four requirements in the Cures Act as a medical device. Although there are some ambiguities as to the meaning of the relevantstatutory terms, we believe NOCIGRAM meets all four of these requirements.Â 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 chemistryratio values for each disc examined. It is this table that the NOCIGRAM references in performing its analysis.Â Second, NOCIGRAM is intended for the purpose ofdisplaying, analyzing, or printing medical information about a patient or other medical information. The NOCISCORE Table and graphicalplots provide medical information about the patient and analyze the data into classifications.Â Third, NOCIGRAM is intended for the purpose ofsupporting 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 painthat may be discogenic in nature. It does this by providing additional disc chemistry-based information to be considered by the physicianin combination with other available patient information.Â The fourth element of the statute is also metby NOCIGRAM, although the requirements for this element are more involved than the other three elements. This element requires a meansfor 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 independentreview: 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.Â The NOCIGRAM explains the purpose of the intendeduse. It instructs the user that it is intended to provide analyses of chemical ratio information obtained from the NOCICALC product, whichwas separately derived from data via an MRS device, for the purpose of supporting recommendations about diagnosing and/or treating patientswith certain back conditions. This information is explained in the product labeling. The product labeling also explicitly states thatthe intended user is a professional medical healthcare provider trained and skilled in diagnosing and recommending treatment options forlow back pain and related lumbar spine disorders. Thus, both the first and second elements set forth in the Draft Guidance are satisfied.Â As to the third element, the inputs used to generateany calculations for the health care professional consist of the chemical ratio information obtained from the NOCICALC device, and alsothe adjustment and analysis factors (e.g. weighting and thresholding/ranges) for analyzing that disc chemistry data. The labeling forNOCIGRAM 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.Â The fourth element requires that the health careprofessional is able to independently review the rationale for the CDS software recommendation. FDA's Draft Guidance indicates that thesources supporting a recommendation should, among other things, be publicly available. Tracking the statute, FDA suggests that clinicalpractice guidelines and published literature would fit this description. The Company intends to publish the various factors (i.e. weightingand thresholds) applied to adjusting and analyzing the various input chemical ratios, and the correlative analysis to the PD referencetest (as well as certain related treatment outcomes), in medical literature in marketing NOCIGRAM. The user is informed of the medicalliterature in the instructions for use of NOCIGRAM.Â Moreover, the physician-user will have three meansto independently verify the results of the NOCIGRAM. First, the user can manually input the adjustment factors and thresholding of theratios 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 basedon the values obtained from NOCICALC using the methods described in publicly available literature. Third, the user can further verifythe NOCI+/- results of the NOCIGRAM, which are correlated to discogram as a reference test based on clinical trial data, by conductinga discogram on the same discs in the patient. This will either confirm or disprove the correlation of NOCI+/ - to discogram results inthose particular discs in that specific patient. These three verification options sufficiently address the issue of a proprietary databaseor algorithm that is essentially a "black box" to users, creating primary reliance on the CDS software rather than aiding informeddecision making.Â Â Â 102Â Â Â However, although we believe the above analysisis reasonable, whenever a company self classifies, there is a risk that FDA could disagree with the classification. Accordingly, in thatcontext, it is possible that FDA could potentially disagree that the NOCIGRAM falls under the CDS software exemption to the definitionof 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 businesswould be severely negatively impacted.Â FDA clearance or approval, when granted, may entaillimitations on the indicated uses for which a product may be marketed, and such product approvals, once granted, may be withdrawn if problemsoccur after initial marketing. Manufacturers of FDA-regulated products are subject to pervasive and continuing post-approval governmentalregulation, including, but not limited to: (i) the registration and listing regulation, which requires manufacturers to register all manufacturingfacilities and list all medical devices placed into commercial distribution, (ii) the QSR, which requires manufacturers, including thirdparty 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 identificationrequirements, (iv) advertising and promotion requirements, (v) restrictions on sale, distribution or use of a device, (vi) PMA annualreporting requirements, (vii) the FDAâ€™s general prohibition against promoting products for unapproved or â€œoff-labelâ€uses, (viii) the Medical Device Reporting (MDR) regulation, which requires that manufacturers report to the FDA if their device may havecaused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or seriousinjury if it were to reoccur, (ix) medical device correction and removal reporting regulations, which require that manufacturers reportto the FDA field

corrections and product recalls or removals if undertaken to reduce a risk to health posed by the device or to remedya violation of the FDCA that may present a risk to health; recall requirements, including a mandatory recall if there is a reasonableprobability that the device would cause serious adverse health consequences or death; an order of repair, replacement or refund, (x) devicetracking requirements, and (xi) post-approval study and post-market surveillance requirements. The FDA has also established a Unique DeviceIdentification (â€œUDIâ€) system that was phased in over a period of years. The UDI system requires manufacturers to mark certainmedical devices distributed in the United States with unique device identifiers.Â The FDA recently finalized its guidance for managingpost-market cybersecurity for connected medical devices. This guidance places additional expectations on our technology to build in cybersecuritycontrols when we design and develop our devices to assure safe performance in the face of cyber threats. It is also incumbent on us tomonitor third party software for new vulnerabilities and verify and validate any software updates or patches meant to address vulnerabilities.Â Our facilities, records and manufacturing processesare subject to periodic unscheduled inspections by the FDA. Failure to comply with the applicable United States medical device regulatoryrequirements 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 partialsuspension of production, the FDAâ€™s refusal to issue certificates to foreign governments needed to export products for sale in othercountries, the FDAâ€™s refusal to grant future premarket clearances or approvals, withdrawals or suspensions of current product clearancesor approvals and criminal prosecution.Â Coverage and Reimbursement.Â Government and private sector initiatives to limitthe growth of healthcare costs, including price regulation and competitive pricing, coverage and payment policies, comparative effectivenesstherapies, technology assessments and managed care arrangements, are continuing in many countries where we do business, including theUnited States, Europe and Asia. As a result of these changes, the marketplace has placed increased emphasis on the delivery of more cost-effectivemedical therapies. In addition, because there is generally no separate reimbursement from third-party payers to our customers for manyof 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 productsand technologies.Â Healthcare cost containment efforts have alsoprompted domestic hospitals and other customers of medical devices to consolidate into larger purchasing groups to enhance purchasingpower, and this trend is expected to continue. The medical device industry has also experienced some consolidation, partly in order tooffer a broader range of products to large purchasers. As a result, transactions with customers are larger, more complex and tend to involvemore long-term contracts than in the past. These larger customers, due to their enhanced purchasing power, may attempt to increase thepressure on product pricing.Â Â Â 103Â Â Â Significant healthcare reforms have had an impacton medical device manufacturer and hospital revenues. The Patient Protection and Affordable Care Act as amended by the Health Care andEducation and Reconciliation Act of 2010, collectively referred to as the Affordable Care Act, is a sweeping measure designed to expandaccess to affordable health insurance, control healthcare spending and improve healthcare quality. Many states have also adopted or areconsidering changes in healthcare policies, in part due to state budgetary pressures. Ongoing uncertainty regarding implementation ofcertain aspects of the Affordable Care Act makes it difficult to predict the impact the Affordable Care Act or state law proposals mayhave on our business.Â Other Healthcare Laws.Â Â In addition to FDA restrictions on marketing andpromotion 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 valueprovided to healthcare providers.Â As a participant in the healthcare industry, weare subject to extensive regulations protecting the privacy and security of patient health information that we receive, including theHealth Insurance Portability and Accountability Act of 1996 (HIPAA), as amended by the Health Information Technology for Economic andClinical 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 â€œprotected health information.â€ The HIPAA privacy regulations do not preempt state laws and regulations relatingto personal information that may also apply to us. Our failure to comply with these regulations could expose us to civil and criminalsanctions.Â The HIPAA provisions also created federal criminalstatutes that prohibit among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcarebenefit 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 coveringup a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment forhealthcare benefits, items or services. A person or entity does not need to have actual knowledge of the statutes or specific intent toviolate them in order to have committed a violation. Also, many states have similar fraud and abuse statutes or regulations that may bebroader in scope and may apply regardless of payer, in addition to items and services reimbursed under Medicaid and other state programs.Â The federal Anti-Kickback Statute prohibits, amongother 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 recommendingthe purchase, lease or order of items or services for which payment may be made, in whole or in part, under Medicare, Medicaid or otherfederal healthcare programs. The term â€œremunerationâ€ has been broadly interpreted to include anything of value. Although thereare a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, the exceptions andsafe harbors are drawn narrowly. Further, a claim including items or services resulting from a violation of the federal Anti-KickbackStatute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act.Â The federal False Claims Act prohibits, amongother things, any person or entity from knowingly presenting, or causing to be presented, a false or fraudulent claim for payment or approvalto the federal government, or knowingly making, using or causing to be made or used a false record or statement material to a false orfraudulent claim to the federal government. A claim includes â€œany request or demandâ€ for money or property presented to theU.S. Government. Medical device manufacturers have been held liable under these laws if they are deemed to cause the submission of falseor fraudulent claims by, for example, providing customers with inaccurate billing or coding information.Â These laws impact the kinds of financial arrangementswe 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 operationsare 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 subjectto 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 restructuringof our operations, any of which could adversely affect our ability to operate our business and our results of operations.Â Â Â 104Â Â Â Additionally, there has been a trend towards increasedfederal and state regulation of payments and other transfers of value provided to healthcare professionals or entities. The federal PhysicianPayment Sunshine Act requires that certain device manufacturers track and report to the government information regarding payments andother transfers of value to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and theirfamily members. A manufacturerâ€™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 perÂ year,and up to an aggregate of $1Â million perÂ year for â€œknowing failures.â€ Certain states also mandate implementationof 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.Â We are subject to similar laws in foreign countrieswhere we conduct business. For example, within the EU, the control of unlawful marketing activities is a matter of national law in eachof 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. Industryassociations also closely monitor the activities of member companies. If these organizations or authorities name us as having breachedour obligations under their regulations, rulesÂ or standards, our reputation would suffer and our business and financial conditioncould be adversely affected.Â Other Foreign Healthcare Regulations Â We are also subject to regulation in the foreigncountries in which we manufacture and market our products. For example, the commercialization of certain products, including certain medicaldevices, in the EU is regulated under a system that presently requires all such products sold in the EU to bear the CE markâ€”an internationalsymbol of adherence to quality assurance standards.Â The International Medical Device Regulators Forumhas implemented a global approach to auditing manufacturers of medical devices. This audit system, called the Medical Device Single AuditProgram (â€œMDSAPâ€), provides for an annual audit of a medical device manufacturer by a certified body on behalf of variousregulatory authorities. Current authorities participating in MDSAP include the Therapeutic Goods Administration of Australia, Brazilâ€™sAgencia Nacional de Vigilancia Sanitaria, Health Canada, Japanâ€™s Ministry of Health, Labour and Welfare, and the Japanese Pharmaceuticalsand Medical Devices Agency and the FDA. It is expected that more regulatory authorities will participate in MDSAP in the future.Â We, and other medical device manufacturers, arecurrently adjusting to major changes in the EUâ€™s decades-old regulatory framework which governs market access to the EU. The MedicalDevices Regulation (â€œMDRâ€) went into effect on May 26, 2021 and replaces the EUâ€™s prior Medical Device Directive (93/42/EEC).Â Our NOCISCAN product suite is subject to theseEU regulations, and is CE Marked via self-certification as a Class I medical device. However, this was secured prior to enactment of theMDR. Under the MDR, we expect to be considered a Class II medical device and subject to stricter requirements for pre-market review andcertification for CE Marking by a Notified Body, including with respect to clinical data that must be submitted in support of our claimedindications and labeling. However, manufacturers of certain classes of currently approved medical devices will have a transition timeto meet certain aspects of the new requirements under the MDR.Â A grace period until May 2024 is provided for Class I medical devicesthat were self-certified for CE Marking prior to the MDR conversion to become CE Mark certified as a Class II medical device by a NotifiedBody. We are still, however, required to continue monitoring and ensuring our on-going compliance with certain other provisions underthe new MDR requirements with respect to post-market surveillance of our products, as of May 2021.Â The EU Parliament has voted to extend the MedicalDevice Regulation (MDR 2017/745) transition period. The extension will see the May 2024 deadline postponed until 2027 for higher-riskClass III and implantable IIb devices, and May 2028 for lower-risk Class I, IIa, and other IIb devices.Â The MDR differs in several important ways fromthe EUâ€™s prior MDD directives for medical devices and active implantable medical devices. The most significant changes in the regulationinclude:Â Â Â· 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 â€œprediction and prognosisâ€ of a disease or other health condition; Â Â Â· 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; Â Â Â 105Â Â Â Â Â· The MDR requires rigorous post-market oversight of medical devices; Â Â Â· The MDR will allow the EU Commission or expert panels to publish â€œCommon Specificationsâ€, such as requirements for technical documentation, risk management, or clinical evaluation, which devices shall be required to meet; Â Â Â· Devices will be reclassified according to risk, contact, duration, and invasiveness; Â Â Â· Systematic clinical evaluation will be required for ClassÂ IIa and ClassÂ IIb medical devices; and Â Â Â· All currently approved devices must be recertified in accordance with the new MDR requirements. Â 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 regulationsthat previously also covered commercial practices in the U.K. While our CE Mark still applies for the U.K., other U.K. requirements forregulatory monitoring and compliance must also be met. Our quality and regulatory compliance systems and practices are currently in theprocess of being updated for ensuring compliance with the applicable U.K. regulations.Â General Data Protection RegulationÂ The implementation on MayÂ 25, 2018 of theGeneral Data Protection Regulation (â€œGDPRâ€), a regulation in the EU on data protection and privacy for all individuals inthe EU and the European Economic Area (â€œEEAâ€), applies to all enterprises, regardless of location, that are doing businessin the EU or that collect and analyze data tied to EU and EEA residents. GDPR creates a range of new compliance obligations, includingstringent technical and security controls surrounding the storage, use, and disclosure of personal information, and significantly increasesfinancial penalties for noncompliance (including possible fines of up to 4% of global annual turnover for the preceding financial yearor â‚¬20 million (whichever is higher) for the most serious infringements).Â In JulyÂ 2020, the European Commission invalidatedthe EU.-U.S. Privacy Shield framework, of which we were registrants. This has resulted in some uncertainty related to continuing obligationsand future data transfer compliance obligations.Â California Consumer Privacy ActÂ The California Consumer Privacy Act, â€œCCPAâ€,became effective on JanuaryÂ 1, 2020 along with a number of complex privacy regulations affecting the processing of personal informationof California residents. If we fail to comply with the CCPA, we may be subject to significant financial penalties or adverse regulatoryactions. In addition to the CCPA, the California legislature is exploring additional regulations to expand the

scope and depth of thestateâ€™s data protection controls.Â CompetitionÂ 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 serviceorganization. We believe that currently, there is a scarcity of new diagnostic platforms on the market, or otherwise proposed and approachingthe market, that are competitive with our products for our primary intended discogenic low back pain indication. Accordingly, our primarycompetition resides with the current diagnostic standards over which our products are intended to improve â€“ in particular, X-ray,lumbar MRI, and provocative discography (PD). While we believe our products are positioned for synergistic use with lumbar MRI, and toenhance the diagnostic value of lumbar MR exams, the existing reliance on MRI as a standard of care for our indication, and other potentialenhancements to those platforms and techniques, nonetheless also represent competition. To the extent these other platforms representour primary competitors, they are mainly provided by large, well-capitalized companies with significant market share and resources. Ourcompetitors have more established sales and marketing programs than we do and have greater name recognition. These competitors also havelong operating histories and may have more established relationships with our potential customers. In addition to competing for marketshare, competitors may develop or acquire patents or other rights that may limit our ability to compete.Â Â Â 106Â Â Â Competition could resultin price reductions, reduced margins and loss of our potential market share. We believe that our NOCISCAN product suite is superior tocurrently known competition in this market as follows:Â Â Â· We believe we are superior to standard lumbar MRI because: Â Â o 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; Â Â Â Â o 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 Â Â Â Â o 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. Â Â Â· We believe we are superior to standard Provocation Discogram (PD) because: Â Â o PD is highly invasive, whereas our test is entirely non-invasive; Â Â Â Â o PD is painful by deliberate design, whereas our test is entirely pain-free; Â Â Â Â o 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; Â Â Â Â o PD is subjective, based both on patient reporting of subjective pain and physician subjectivity in interpreting results, whereas our test is entirely objective; and Â Â Â Â o 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. Â EmployeesÂ As of November 14, 2024, we had 7 total employees,3 of whom were engaged in research and development activities, 1 engaged in strategy and business development, and 3 of whom were engagedin general administration. We believe that we maintain good relations with our employees.Â Legal ProceedingsÂ From time to time, we may be involved in litigationrelating to claims arising out of our operations in the normal course of business. We are not currently a party to any material legalproceedings, the adverse outcome of which, in our managementâ€™s opinion, individually or in the aggregate, could have a materialadverse 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 materialinterest adverse to our interest.Â Â Â 107Â Â Â Segment InformationÂ We operate in a single operating segment and asingle reporting segment. Operating segments are defined as components of an enterprise about which separate financial information isregularly evaluated by the chief operating decision maker function (which is fulfilled by our chief executive officer) in deciding howto allocate resources and in assessing performance. Our chief executive officer allocates resources and assesses performance based uponfinancial information at the level. Since we operate in one operating segment, all required financial segment information is presentedin the financial statements.Â Our corporate informationÂ We were formed under the name Nocimed, LLC, alimited liability company in January 2008, under the laws of the State of Delaware. In February 2015, Nocimed, LLC was converted intoNocimed, Inc. a Delaware corporation. On December 3, 2021, we changed our name to Aclarion, Inc. Our principal executive offices are locatedat 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 itpart of this Annual Report. We have included our website address in this Annual Report solely as an inactive textual reference.Â Implications of being an emerging growth company and a smaller reportingcompanyÂ We qualify as an â€œemerging growth companyâ€as defined in the Jumpstart our Business Startups Act of 2012 (the â€œJOBS Actâ€). An emerging growth company may take advantageof specified reduced reporting and other burdens that are otherwise applicable generally to public companies. These provisions include:Â Â Â· 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 Managementâ€™s Discussion and Analysis of Financial Condition and Results of Operations disclosure; Â Â Â Â Â· 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 â€œSarbanes-Oxley Actâ€); Â Â Â Â Â· an exemption from compliance with any new requirements adopted by the Public Company Accounting Oversight Board (the â€œPCAOBâ€) requiring mandatory audit firm rotation; Â Â Â Â Â· reduced disclosure about executive compensation arrangements; and Â Â Â Â Â· an exemption from the requirement to seek non-binding advisory votes on executive compensation or golden parachute arrangements. Â We may take advantage of these provisions untilwe are no longer an emerging growth company. We will remain an emerging growth company until the earliest of (1) the last day of the fiscalyear (a) following the fifth anniversary of the completion of our IPO, (b)Â in which we have total annual gross revenue of at least$1.235 billion or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that isheld 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 billionin non-convertible debt during the prior three-year period.Â We have taken advantage of the reduced reportingrequirements in this Annual Report. Accordingly, the information contained herein may be different from the information you receive fromother public companies that are not emerging growth companies.Â The JOBS Act permits an emerging growth companysuch as us to take advantage

of an extended transition period to comply with new or revised accounting standards applicable to publiccompanies until those standards would otherwise apply to private companies.Â Â Â 108Â Â Â We are also a â€œsmaller reporting companyâ€meaning that the market value of our stock held by non-affiliates is less than $700 million and our annual revenue was less than $100million during the most recently completed fiscal year. We may continue to be a smaller reporting company if either (i) the market valueof our stock held by non-affiliates is less than $250 million or (ii) our annual revenue was less than $100 million during the most recentlycompleted fiscal year and the market value of our stock held by non-affiliates is less than $700 million. If we are a smaller reportingcompany at the time we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirementsthat are available to smaller reporting companies. Specifically, as a smaller reporting company we may choose to present only the twomost recent fiscal years of audited financial statements in our Annual Report on Form 10-K and, similar to emerging growth companies,smaller reporting companies have reduced disclosure obligations regarding executive compensation.Â Â Available InformationÂ Our internet address is www.aclarion.com. OurAnnual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to those reports can be foundon 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 prospectus. The SEC maintainsa public website, www.sec.gov, which includes information about and the filings of issuers that file electronically with the SEC.Â Â Â 109Â Â Â Management,Governance, Director Compensation, Executive CompensationÂ Executive officers and directorsÂ Set forth below are the names, ages and positions of our executive officers and directors as of November 14, 2024.Â Â Name Â Age Â Position(s) held Â Served as a Director and/or Officer Since Â Executive OfficersÂ Â Â Â Â Â Â Â Jeff Thramann, M.D. Â 60 Â Executive Chairman and Director Â 2020(1) Brent Ness Â 58 Â Chief Executive Officer, President and Director Â 2021(2) John Lorbiecki Â 61 Â Chief Financial Officer Â 2021(3) Ryan Bond Â 53 Â Chief Strategy Officer Â 2021(4) Â Â Â Â Â Â Â Non-Employee Directors Â Â Â Â Â Â Â Â Â Â Â Â Â Â Scott Breidbart, M.D. Â 68 Â Director Â (5) Steve Deitsch Â 53 Â Director Â (5) David Neal Â 53 Â Director Â (6) William Wesemann Â 69 Â Director Â (6) Amanda Williams Â 47 Â Director Â (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. Â Executive OfficersÂ Â Jeff Thramann, M.D., Executive Chairmanand Director: Jeff Thramann has been a director since September, 2020. He was also an executive Director since March 2021, whichis an executive officer of the Company. He transitioned to Executive Chairman at the time of our April 2022 IPO. He oversees strategicinitiatives, capitalization and governance at the company. This includes day-to-day involvement in working with senior management to establishthe strategic vision of the Company, assist in KOL development, work with the Chief Executive Officer and Chief Financial Officer on financialplans, clinical reimbursement and product strategies, and assisting the Chief Executive Officer in recruitment and hiring of senior executivesand the pursuit of business development activities. His responsibilities also include leading investor relations efforts, building theboard 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 experiencesacross radio and podcast listening. Dr. Thramann founded Auddia Inc. in January 2012. In 2002, Dr. Thramann was the founder (and becamethe chairman) of Lanx, LLC (â€œLanxâ€). Lanx was an innovative medical device company focused on the spinal implant market thatcreated the interspinous process fusion space with the introduction of its patented Aspen product. Lanx was sold to Biomet, Inc., an internationalorthopedic conglomerate, in November, 2013. Concurrent with Lanx, in July, 2006 Dr. Thramann was the founder and chairman of ProNerve,LLC (â€œProNerveâ€). ProNerve was a healthcare services company that provided monitoring of nerve function during high-risk surgicalprocedures affecting the brain and spinal cord. ProNerve was sold to Waud Capital Partners, a private equity firm, in 2012. Prior to ProNerveand concurrent with Lanx, Dr. Thramann was the founder and chairman of U.S. Radiosurgery (â€œUSRâ€). USR is a healthcare servicescompany that provides advanced radiosurgical treatments for tumors throughout the body. USR became the largest provider of robotic guidedCyberKnife 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 practiceserving Boulder County, Colorado. Dr. Thramann is the named inventor on over 100 U.S. and international issued and pending patents. Hecompleted 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 electricalengineering management at the U. S. Military Academy in West Point, NY.Â Â Â Â 110Â Â Â 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 becamePresident and Chief Commercial Officer of Cleerly, Inc. (â€œCleerlyâ€). Cleerly is a developer of an AI enabled non-invasivedigital care pathway aimed at improving clinicians understanding of their patientsâ€™ 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 2016to December 2019, Mr. Ness was the Chief Operating Officer of Mighty Oak Medical (â€œMighty Oakâ€) whose principal products progressedfrom pre-FDA clearance through an international full market launch of their platform called FIREFLY.Â FIREFLY is a 3D Printed patientspecific solution that is intended to provide spine surgeons with a highly accurate alternative to navigation and robotic applicationsin the spinal navigation space. FIREFLY involves the use of CT scans as the core data upon which sophisticated pre-surgical plans arecreated along with guides and bone models. From 2014 through 2016, Mr. Ness was the Chief Commercial Officer of HeartFlow, Inc. (â€œHeartflowâ€).HeartFlow is a medical technology company that created and developed a non-invasive cardiac test enabling physicians to make more informeddecisions for their patients with suspected coronary heart disease. Mr. Ness led the business from pre-FDA clearance through a globalexpansion of early adopter sites. Along with the senior leadership team at HeartFlow, he deployed a strong clinical evidence-based approachin the early launch of the SaaS platform to engage Key Opinion Leader Physicians and the third-party payer community. This resulted inthe issuance of Category III CPT Codes and multiple private payer coverage decisions. From 2008 through 2013, he was President of ProNerve,LLC, (â€œProNerve"). ProNerve is a provider of intraoperative neuromonitoring services which involves the use of a variety ofelectro-physiological monitoring procedures during spine and brain surgery, to allow early warning and avoidance of injury to nervoussystem structures. As President of

ProNerve, Mr. Ness presided over a roll up of the highly fragmented Interoperative Nerve MonitoringIndustry. 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 Presidentof Sales Operations, which companies are suppliers of diagnostic imaging equipment.Â Mr. Ness currently serves as an advisor to MightyOak Medical, K2 Capital and Cleerly. Mr. Ness has a Bachelorâ€™s Degree in Marketing from the University of North Dakota and an MBAfrom the University of Colorado.Â 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 experiencewhich 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, healso advised Fusion Robotics LLC through their merger with Integrity Implants Inc., now doing business as Accelus Inc. From January 2020through April 2021, Mr. Lorbiecki held the lead finance role at Honeybee Robotics, an aerospace company that designs and builds advancedrobotic systems. He led the financial dimensions of the strategic planning process, managed monthly project reviews to measure progressand ensure economic targets were met, and oversaw monthly accounting activities. From March 2017 through July 2018, he served as ChiefOperating Officer at Colorado Therapeutics LLC, a medical startup focused on innovative biologic soft tissue repair products where hewas instrumental in completing the relocation of the company headquarters and increasing manufacturing capacity. From 1991 through 2017he 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 aBachelorâ€™s Degree in Economics from the University of St. Thomas where he graduated magna cum laude and an MBA from the Universityof Chicago Booth School of Business.Â Â Ryan Bond, Chief Strategy Officer: Mr.Bond became our Chief Strategy Officer in September 2021. From December 2018 to August 2021, he has been our Vice President, BusinessDevelopment, where he led business development, sales and marketing including a limited commercial launch of Aclarionâ€™s cloud-basedSaaS with early adopters in the US, EU, and UK, Mr. Bond coordinated multiple research trials sponsored by our customers, where Aclarionâ€™sproprietary, adjunctive diagnostic technology is employed. Mr. Bond was instrumental in working with reimbursement consultants to gainCategory III CPT Codes for Aclarion with assigned APC rates and advocating to CMS for the removal of a long-standing non-coverage policyfor magnetic resonance spectroscopy (MRS, CPT Code 76390). From November 2014 to September 2018 Mr. Bond was Director, Healthcare Solutionsat 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 (â€œAcceleroâ€),a consulting firm focused on musculoskeletal service line development using a combination of strategic organizational development programsand a proprietary cloud-based business intelligence tool that discretely measured a cadre of clinical, functional, operational, and volume-basedmetrics, 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 Bachelorâ€™s of Science Degree inEngineering from the Russ College of Engineering and Technology.Â Â Â 111Â Â Â Non-employee directorsÂ Â 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 AffinityHealth Plans from January 2018 until its purchase in November 2021. From October 2016 to January 2018, he was Chief Medical Officer ofSolera Health and from October 2015 to September 2016, he was the Chief Clinical Officer of Emblem Health. From November 2008 to October2015, Mr. Breidbart served as the Chief Medical Officer of Empire BlueCross BlueShield, and from May 1998 to August 2008 he had variousroles in medical management for HealthNet. Dr. Breidbart practiced pediatric endocrinology for ten years on the faculty of New York MedicalCollege. He is Board Certified in Pediatrics and Pediatric Endocrinology and is licensed to practice medicine in NY. He holds a BA inMathematics from Yale, an MD from Columbia, and an MBA from Pace University. We believe Dr. Breidbartâ€™s experience with medicalmanagement and medical reimbursement matters provides him with the appropriate set of skills to serve as a member of our board of directors.Â Steve Deitsch, Director: SteveÂ Deitschis currently the CFO of OrganOx, a medical device company which is changing the paradigm in liver transplantation. Steve has extensivestrategic, operational, and financial leadership experience at both publicly traded and privately held companies. From September 2020to April 2024, Steve served as Chief Financial Officer at Paragon 28, a medical device company focused on surgical implants for the footand ankle. 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 AugustÂ 2015 to April 2017, Mr. Deitsch served as Executive VicePresident, 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 July2015 and as Vice President Finance, Biomet Corporate Controller from February 2014 to JulyÂ 2014. Mr. Deitsch was the Chief FinancialOfficer of Lanx from September 2009 until it was acquired by Biomet in October 2013. From 2002 to 2009, Mr. Deitsch also served in varioussenior financial leadership roles at Zimmer Holdings, Inc. (now part of Zimmer Biomet, Inc.), including Vice President Finance, Reconstructiveand Operations, and Vice President Finance, Europe. Steve is a director and audit committee chair of Auddia Inc. (NASDAQ: AUUD), sinceFebruary of 2021. Mr. Deitsch holds a B.S. in Accounting from Ball State University and has an in-active CPA license. We believe Mr. Deitschâ€™sfinancial, management and healthcare experience provides him with the appropriate set of skills to serve as a member of our board of directors.Â David Neal, Director: Mr. Neal hasbeen a director since September 2016. He is the founder and a current member of SC Capital 1 LLC which was formed in 2016. SC Capital1 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-networth families. From 2000 to 2015, he held various positions with UBS, including Portfolio Manager and manager of a Regional Office inWichita Kansas. He was on the Hutchinson Regional Medical Center board of directors for 9 years and currently is a member of the boardof the Hutchinson Community Foundation. He holds a Bachelor of Sport Science degree from the University of Kansas and a Master of ManagementScience degree from the John Cook School of Business at Saint Louis University. We believe Mr. Nealâ€™s experience in medical technologyinvestment provides him with the appropriate set of skills to serve as a member of our board of directors.Â 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 2002his experience included serving in chief executive, sales leadership, and advisory roles at technology companies. Since 2004, he has beena director of

LivePerson (Nasdaq: LPSN), a global technology company that develops conversational commerce and AI software. He is alsoa 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). We believe Mr. Wesemannâ€™sexperience in technology investing provides him with the appropriate set of skills to serve as a member of our board of directors.Â Amanda Williams, Director: Ms. Williamshas been Senior Vice President for Clinical and Regulatory at MedAlliance, a Cordis company, which is a healthcare company focused ontreating peripheral and coronary artery disease with the Selution drug coated balloon, since August 2023. From September 2018 to May 2023,she was the Senior Vice President of Clinical, Quality and Regulatory at ViewRay, Inc. (Nasdaq: VRAY), a healthcare company that integratesreal time MRI imaging of tumors with the delivery of high dose radiation for improved treatment accuracy. 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 SpectraneticsCorp., (now part of Philips), and from 2003 to 2010 she was Manager, and then Director of Regulatory of AGA Medical Corp (now part ofAbbott). Prior to these roles, she worked as a Regulatory Specialist with Vascular Solutions and as a Chemist with GE â€“ Osmonics.In these positions, she worked on a diverse range of products, including cardiovascular treatment, implantable heart defect device, combinationdrug/device and large capital equipment (both imaging and treatment) devices.Â At Spectranetics, she led teams that completed multipleglobal randomized clinical studies. She holds a Master of Science in Regulatory from Northeastern University and a Bachelor of Sciencein Chemistry from the University of Minnesota. We believe Ms. Williamsâ€™ medical clinical and regulatory matters provides her withthe appropriate set of skills to serve as a member of our board of directors.Â Â Â 112Â Â Â Section 16(a) Beneficial Ownership Reporting ComplianceÂ Following our IPO, Section 16(a) of the ExchangeAct requires our directors, executive officers, and persons holding more than 10% of our common stock to report their initial ownershipof the common stock and other equity securities and any changes in that ownership in reports that must be filed with the SEC. The SEChas designated specific deadlines for these reports, and we must identify in our Annual Report on Form 10-K those persons who did notfile these reports when due.Â Based solely on a review of reports furnishedto us, or written representations from reporting persons, we believe all directors, executive officers, and 10% owners timely filed allreports regarding transactions in our securities required to be filed in 2023 by Section 16(a) under the Exchange Act.Â Election of OfficersÂ Our executive officers are appointed by, and serveat the discretion of, our board of directors. There are no family relationships among any of our directors or executive officers.Â Composition of the Board of DirectorsÂ Our board of directors currently consists of sevenmembers. Four of our directors are independent within the meaning of the independent director guidelines of the Nasdaq Stock Market.Â Each directorâ€™s term continues until theelection and qualification of his successor, or his earlier death, resignation or removal. Our restated certificate of incorporation andrestated bylaws authorize only our board of directors to fill vacancies on our board of directors.Â Board Leadership Structure and Role in RiskOversightÂ Our corporate governance guidelines provide thatunless the board chair is an independent director, the board shall appoint a Lead Independent Director. The Lead Independent Directorchairs the executive sessions of the independent directors, coordinates the activities of the other independent directors and performssuch 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.Â Risk is inherent with every business, and howwell 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 riskswe face, while the board, as a whole and through its committees, has responsibility for the oversight of risk management. In its riskoversight role, the board has the responsibility to satisfy itself that the risk management processes designed and implemented by managementare 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. Seniormanagement attends the board meetings and is available to address any questions or concerns raised by the board on risk management andany other matters. The Lead Independent Director and the independent board members work together to provide strong, independent oversightof our management and affairs through the boardâ€™s standing committees and, when necessary, executive sessions of the independentdirectors.Â Director IndependenceÂ Under the rules of Nasdaq, independent directorsmust comprise a majority of a listed companyâ€™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 companyâ€™s audit, compensationand nominating and governance committees be independent. Under the rules of Nasdaq, a director will only qualify as an â€œindependentdirectorâ€ if, in the opinion of that companyâ€™s board of directors, that person does not have a relationship that would interferewith the exercise of independent judgment in carrying out the responsibilities of a director.Â Â Â Â 113Â Â Â Audit committee members must also satisfy theindependence 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 ofdirectors or any other board committee: (i) accept, directly or indirectly, any consulting, advisory or other compensatory fee from thelisted company or any of its subsidiaries; or (ii) be an affiliated person of the listed company or any of its subsidiaries. We currentlysatisfy the audit committee independence requirements of Rule 10A-3. Additionally, compensation committee members must not have a relationshipwith us that is material to the directorâ€™s ability to be independent from management in connection with the duties of a compensationcommittee member.Â Our board of directors has undertaken a reviewof the independence of each director and considered whether each director has a material relationship with us that could compromise hisability to exercise independent judgment in carrying out his responsibilities. As a result of this review, our board of directors determinedthat all of our directors, except for Jeffrey Thramann, Brent Ness and David Neal are â€œindependent directorsâ€ as defined underthe 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 regardto each directorâ€™s business and personal activities and relationships as they may relate to us and our management.Â Committees of our board of directorsÂ Audit CommitteeÂ 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 requirementsfor independence under the current Nasdaq and SEC rules and regulations. Each member of our audit committee is financially literate. Inaddition, our board of directors has determined that Stephen Deitsch is an â€œaudit committee

financial expertâ€ as defined inItem 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. Ouraudit committee is directly responsible for, among other things:Â Â Â· selecting and hiring our independent registered public accounting firm; Â Â· the qualifications, independence and performance of our registered public accounting firm; Â Â· the preparation of the audit committee report to be included in our annual proxy statement; Â Â· our compliance with legal and regulatory requirements; Â Â· our accounting and financial reporting processes, including our financial statement audits and the integrity of our financial statements; and Â Â· reviewing and approving related-person transactions. Â Compensation CommitteeÂ Our compensation committee is comprised of AmandaWilliams, Scott Breidbart, and Bill Wesemann, with Mr. Wesemann serving as chairman. Each member of our compensation committee is a non-employeedirector, as defined by Rule 16b-3 promulgated under the Exchange Act and meets the requirements for independence under the current Nasdaqlisting standards and SEC rules and regulations. Our compensation committee is responsible for, among other things:Â Â Â· evaluating, recommending, approving and reviewing executive officer compensation arrangements, plans, policies and programs; Â Â· evaluating and recommending non-employee director compensation arrangements for determination by our board of directors; Â Â· administering our cash-based and equity-based compensation plans; and Â Â· overseeing our compliance with regulatory requirements associated with the compensation of directors, officers and employees. Â Â Â Â Â 114Â Â Â Nominating and Governance CommitteeÂ Our nominating and governance committee is comprisedof Bill Wesemann, Scott Breidbart, and Amanda Williams, with Amanda Williams serving as its chairman. Each member of our nominating andgovernance committee meets the requirements for independence under the current Nasdaq listing standards. Our nominating and governancecommittee is responsible for, among other things:Â Â Â· identifying, considering and recommending candidates for membership on our board of directors; Â Â· overseeing the process of evaluating the performance of our board of directors; and Â Â· advising our board of directors on other corporate governance matters. Â Consideration of Director NomineesÂ Director QualificationsÂ There are no specific minimum qualifications thatthe Board requires to be met by a director nominee recommended for a position on our board, nor are there any specific qualities or skillsthat are necessary for one or more members of our board to possess, other than as are necessary to meet the requirements of the rulesand regulations applicable to us. The Nominating and Governance Committee considers a potential director candidateâ€™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 appropriatefor the Company. In assessing potential directors, the Nominating and Governance Committee may consider the current needs of the boardand the Company to maintain a balance of knowledge, experience and capability in various areas.Â Stockholder NominationsÂ In accordance with our bylaws, a stockholder wishingto nominate a director for election at an annual meeting of stockholders must timely submit a written proposal of nomination to us atour executive offices. To be timely, a written proposal of nomination for an annual meeting of stockholders must be received at least90 calendar days but no more than 120 calendar days before the first anniversary of the date on which we held our annual meeting of stockholdersin the immediately preceding year;Â provided,Â however, that in the event that the date of the annual meeting isadvanced or delayed more than 30 calendar days from the anniversary of the annual meeting of stockholders in the immediately precedingyear, the written proposal must be received: (i) at least 90 calendar days but no more than 120 calendar days prior to the date of theannual meeting; or (ii) no more than 10 days after the date we first publicly announce the date of the annual meeting.Â 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 thenext meeting at which such person would face election or re-election, an irrevocable resignation effective upon acceptance of such resignationby the board, and (6) such other information concerning such nominee as would be required to be disclosed in a proxy statement solicitingproxies for the election of such nominee as a director in an election contest (even if an election contest is not involved), or that isotherwise required to be disclosed pursuant to Section 14 of the 1934 Act and the rules and regulations promulgated thereunder (includingsuch personâ€™s written consent to being named as a nominee and to serving as a director if elected).Â A stockholder interested in submitting a nomineefor election to the board should refer to our bylaws for additional requirements. Upon receipt of a written proposal of nomination meetingthese requirements, the Nominating and Governance Committee of the Board will evaluate the nominee in accordance with its charter andthe characteristics listed above.Â Â Â 115Â Â Â Evaluating Nominees for DirectorÂ Our Nominating and Corporate Governance Committeeconsiders director candidates that are suggested by members of the committee, other members of our Board, members of management, advisorsand our stockholders who submit recommendations in accordance with the requirements set forth in our Bylaws, as described above. Our Boardhas in the past engaged a third-party search firm to identify potential candidates for consideration by the Nominating and GovernanceCommittee and election to our Board. The Nominating and Corporate Governance Committee may, in the future, retain third-party search firmsto identify Board candidates on terms and conditions acceptable to the Nominating and Corporate Governance Committee to assist in theprocess of identifying or evaluating director candidates. The Nominating and Corporate Governance Committee evaluates all nominees fordirector using the same approach whether they are recommended by stockholders or other sources. The Nominating and Corporate GovernanceCommittee reviews candidates for director nominees in the context of the current composition of our Board and committees, the operatingrequirements of the Company and the long-term interests of our stockholders. In conducting this assessment, the Nominating and CorporateGovernance Committee considers the director nomineeâ€™s qualifications, diversity, skills and such other factors as it deems appropriategiven 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 reviewssuch directorsâ€™ overall service to the Board, the committees and the Company during their term, including the number of meetingsattended, level of participation, quality of performance and any other relationships and transactions that might impair such directorsâ€™independence. In the case of new director candidates, the Nominating and Corporate Governance Committee will also determine whether thenominee must be independent for Nasdaq purposes, which determination will be based upon applicable Nasdaq listing standards and applicableSEC 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, experiencesand expertise to the Board.Â The Nominating and Corporate Governance Committeewill evaluate the proposed directorâ€™s candidacy, including proposed candidates recommended by stockholders, and recommend whetherthe Board should nominate the proposed director candidate for election by our stockholders.Â Stockholder Communications with the BoardÂ Any stockholder or interested party who desiresto 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 processedby the office of our CFO. Communications concerning accounting, audit, internal accounting controls and other financial matters will bereferred to the Chair of the Audit Committee. Other matters will be referred to the board, the non-employee directors or individual directors,as appropriate.Â The board has instructed the CFO to review allcommunications so received and to exercise his discretion not to forward to the board correspondence that is inappropriate such as businesssolicitations, frivolous communications and advertising, routine business matters and personal grievances. However, any director may atany time request the CFO to forward any and all communications received by the CFO but not forwarded to the directors.Â Compensation committee interlocks and insiderparticipation Â None of the current members of our compensationcommittee has ever been an executive officer or employee of ours. None of our executive officers currently serves, or has served duringthe last completed fiscal year, on the compensation committee or board of directors of any other entity that has one or more executiveofficers serving as a member of our board of directors or compensation committee.Â Â Â 116Â Â Â Code of Business Conduct and EthicsÂ Our board of directors has adopted a code of businessconduct and ethics that applies to all of our employees, officers and directors, including our Chief Executive Officer and other executiveand 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 prospectus does not include or incorporate by reference the information on our website intothis prospectus. We intend to disclose future amendments to certain provisions of our code of business conduct and ethics, or waiversof these provisions, on our website or in public filings to the extent required by the applicable rules.Â Number of MeetingsÂ During 2023, the board held a total of nine meetings.Our Audit Committee held seven meetings in 2023, our Compensation Committee held five meetings in 2023, and our Nominating and GovernanceCommittee held one meeting. Each director attended at least 75% of the aggregate of the total number of meetings of the board and theboard committees on which he or she served during 2023.Â Board Member Attendance at Annual Stockholder MeetingsÂ Although we do not have a formal policy regardingdirector attendance at annual stockholder meetings, directors are encouraged to attend these annual meetings absent extenuating circumstances.Â Non-Employee Director CompensationÂ Our non-employee directors began serving on ourboard following our April 2022 IPO.Â Our Executive Chairman, Dr. Thramann, and ourPresident and Chief Executive Officer, Mr. Ness, do not receive compensation for their services as a director.Â Our board of directors approved the followingcompensation for our non-employee directors in 2023. Our non-employee directors receive annual cash compensation of (i) $25,000 for serviceon the board (ii) $15,000 for service as the Audit Committee chair, and (iii) $5,000 for service on each board committee. All cash paymentswill be made quarterly in arrears, and pro-rated for any partial quarters of service.Â The following Director Compensation Table summarizesthe compensation of each of our non-employee directors for services rendered to us during the year ended December 31, 2023:Â Name Â Fees Earned or Paid in Cash ($) Â Â Stock Awards ($) Â Â Option Awards ($) Â All Other Compensation($) Â Total ($) Scott Breidbart Â 40,000 Â -0- Â -0- Â -0- Â 40,000 Steve Deitsch Â 45,000 Â -0- Â -0- Â -0- Â 45,000 David Neal Â 25,000 Â -0- Â -0- Â -0- Â 25,000 William Wesemann Â 40,000 Â -0- Â -0- Â -0- Â 40,000 Amanda Williams Â 35,000 Â -0- Â -0- Â -0- Â 35,000 Â Executive Compensation OverviewÂ As an â€œemerging growth company,â€ wehave opted to comply with the executive compensation disclosure rules applicable to â€œsmaller reporting companies,â€ as suchterm is defined in the rules promulgated under the Securities Act.Â Â Â 117Â Â Â This section provides an overview of the compensationawarded to, earned by, or paid to each individual who served as our principal executive officer during our fiscal year 2023, and our nextthree most highly compensated executive officers in respect of their service to our company for fiscal year 2023. Our named executiveofficers, or the Named Executive Officers, for the year ended DecemberÂ 31, 2023, are:Â Â Â· Jeffrey Thramann, Executive Chairman; Â Â· Brent Ness, Chief Executive Officer; Â Â· John Lorbiecki, Chief Financial Officer; and Â Â· Ryan Bond, Chief Strategy Officer. Â Summary Compensation Table Year Ended December31, 2023Â The following table contains information aboutthe compensation paid to or earned by each of our Named Executive Officers during the two most recently completed fiscal years.Â Name and Principal Position Year Salary($) Â Â Bonus ($)(1)(2) Â Stock Awards ($) Â Option Awards ($)(3) Â All Other Compensation ($) Â Total($) Â Jeff Thramann, Executive Director 2023 Â 300,000 Â Â Â Â â€“ Â Â â€“ Â Â 300,000 Â Â 2022 Â 300,000 Â 18,750 Â Â â€“ Â Â 252,369 Â â€“ Â Â 571,119 Â Brent Ness, Chief Executive Officer 2023 Â 300,000 Â Â Â Â â€“ Â Â Â Â Â Â Â 300,000 Â Â 2022 Â 300,000 Â 118,750(4) Â Â â€“ Â Â 90,704 Â â€“ Â Â 509,454 Â Ryan Bond, Chief Strategy Officer 2023 Â 200,000 Â Â Â Â Â Â Â Â Â Â Â Â Â 200,000 Â Â 2022 Â 200,000 Â 19,532(5) Â Â â€“ Â Â â€“ Â â€“ Â Â 219,532 Â John Lorbiecki, Chief Financial Officer 2023 Â 225,000 Â Â Â Â Â Â Â Â Â Â Â Â Â 225,000 Â Â 2022 Â 225,000 Â 89,871(6) Â Â â€“ Â Â 19,747 Â â€“ Â Â 334,618 Â _____ (1) The Company has a discretionary annual cash bonus program. The Company has not yet determined and approved annual cash bonuses for the year 2023. (2) Except for the amounts described below in notes 4, 5, and 6, the 2022 bonus amounts reflect cash bonus amounts earned in the 2022 year (as determined and approved by our compensation committee in March 2023) but which amounts have not been paid to date. Such bonus amounts will not be paid until the Company has additional funding and cash liquidity. (3) 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 15 to our financial statements included in this prospectus. (4) Under the terms of his employment agreement, Mr. Ness received a bonus payment of $100,000 upon the IPO completed in April 2022. (5) The Company implemented a cash bonus plan related to the temporary deferral of all employeesâ€™ base salaries by 50% effective as of October 16, 2020. Under this program, $8,594 was paid to Mr. Bond in 2022. (6) Under the terms of his employment agreement, Mr. Lorbiecki received a bonus payment of $28,125 upon the IPO completed in April 2022. Â Â Â Â 118Â Â Â Employment AgreementsÂ Dr. Jeff ThramannÂ 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:Â Â Â· Receive a salary of $25,000 per month.; Â

Â Â Â Â· Be appointed as Executive Director (an executive officer position with the Company), as an â€œat willâ€ employee, until the date of the IPO, at which time he transitioned from Executive Director to Executive Chairman, an executive officer of the Company. Â Â Â Â Â· Be issued options (the â€œThramann Optionsâ€) to purchase 75,302 shares (1,204,820 shares before our January 3, 2024 Â reverse stock split) of common stock (the â€œThramann Option Sharesâ€) of the Company subject to the terms and conditions set forth in the Companyâ€™s equity incentive plan, at an exercise price of $31.04 ($1.94 before our January 3, 2024 reverse stock split) 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. Â Brent NessÂ On September 15, 2021, we entered into an EmploymentAgreement with Brent Ness. The employment agreement provides that Mr. Ness would:Â Â Â· Be appointed Chief Executive Officer of the Company. Â Â Â Â Â· 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. Â Â Â Â Â· Commencing in 2022, Mr. Ness will be eligible to receive, upon certain conditions, an annual incentive bonus up to 50% of Mr. Nessâ€™ base salary Â Â Â Â Â· Mr. Nessâ€™ employment agreement is terminable â€˜at willâ€™ by the Company. If the Company terminates Mr. Nessâ€™ 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. Â Â Â Â Â· Be issued options to purchase 21,337 shares (341,365 shares before our January 3, 2024 reverse stock split) of common stock of the Company, subject to the terms and conditions set forth in the Companyâ€™s equity incentive plan, at an exercise price of $31.04 ($1.94 before our January 3, 2024 Â reverse stock split) 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. Â John Lorbiecki Â On September 22, 2021, we entered into an EmploymentAgreement with John Lorbiecki. The employment agreement provides that Mr. Lorbiecki would:Â Â Â· Be appointed Chief Financial Officer of the Company as an â€œat willâ€ employee. Â Â Â Â Â· Receive an annual base salary of $225,000. Â Â Â Â Â· Commencing in 2022, Mr. Lorbiecki will be eligible to receive, upon certain conditions, an annual incentive bonus up to 50% of Mr. Lorbieckiâ€™s base salary. Â Â Â 119Â Â Â Â Â Â Â Â· Mr. Lorbieckiâ€™s employment agreement is terminable â€˜at willâ€™ by the Company. If the Company terminates Mr. Lorbieckiâ€™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. Â Â Â Â Â· Be issued options to purchase 4,185 shares (66,934 shares before our January 3, 2024 reverse stock split) of common stock of the Company subject to the terms and conditions set forth in the Companyâ€™s equity incentive plan, at an exercise price of $31.04 ($1.94 before our January 3, 2024 reverse stock split) per share. The stock options have a 10-year term. The stock options will vest in 48 equal installments on each monthly anniversary of the date of grant, such that the grant will become fully vested and exercisable on the four-year anniversary of the date of grant. Â Outstanding Equity Awards at December 31, 2023Â The following table sets forth information regardingequity awards held by our Named Executive Officers as of December 31, 2023. Information in this table has been adjusted for our January3, 2024 reverse stock split.Â Â Â Â Â Â Â Â Option Awards Â Â Â Stock Awards Â Number of Â Â Â Number of Â Â Â Â Â Â Â Â Â Â Â Number of Â Â Â Market Â Â Â Â Â Â Â Â Securities Â Â Â Securities Â Â Â Â Â Â Â Â Â Â Â Shares or Â Â Â Value of Â Â Â Â Â Â Â Â Underlying Â Â Â Underlying Â Â Â Â Â Â Â Â Â Â Â Â Units of Â Â Â Shares or Â Â Â Â Â Â Â Â Unexercised Â Â Â Unexercised Â Â Â Option Â Â Â Â Â Â Â Stock That Â Â Â Units That Â Â Â Â Â Â Â Â Options Â Â Â Options Â Â Â Exercise Â Â Â Option Â Â Â Have Not Â Â Â Have Not Â Â Â Â Grant Â Â Â (#) Â Â Â (#) Â Â Â Price Â Â Â Expiration Â Â Â Vested Â Â Â Vested Â Name Â Â Date Â Â Â Exercisable Â Â Â Unexercisable Â Â Â ($) Â Â Â Date Â Â Â (#) Â Â Â ($) Â Dr. Jeffrey Thramann Â Â 9/27/2021 Â Â Â 75,302 Â Â Â â€“ Â Â Â $31.04 Â Â Â 9/27/2031 Â Â Â â€“ Â Â Â â€“ Â Â Â Â 9/14/2022 Â Â Â 11,581 Â Â Â â€“ Â Â Â $31.04 Â Â Â 9/14/2032 Â Â Â â€“ Â Â Â â€“ Â Brent Ness Â Â 9/27/2021 Â Â Â 12,002 Â Â Â 9,335 Â Â Â $31.04 Â Â Â 9/27/2031 Â Â Â â€“ Â Â Â â€“ Â Â Â Â 9/14/2022 Â Â Â 2,658 Â Â Â 2,067 Â Â Â $31.04 Â Â Â 9/14/2032 Â Â Â â€“ Â Â Â â€“ Â Ryan Bond Â Â 2/19/2019 Â Â Â 1,339 Â Â Â â€“ Â Â Â $21.44 Â Â Â 2/19/2029 Â Â Â â€“ Â Â Â â€“ Â Â Â Â 9/4/2021 Â Â Â 382 Â Â Â â€“ Â Â Â $31.04 Â Â Â 9/4/2031 Â Â Â â€“ Â Â Â â€“ Â John Lorbiecki Â Â 9/27/2021 Â Â Â 2,267 Â Â Â 1,918 Â Â Â $31.04 Â Â Â 9/27/2031 Â Â Â â€“ Â Â Â â€“ Â Â Â Â 9/14/2022 Â Â Â 558 Â Â Â 472 Â Â Â $31.04 Â Â Â 9/14/2032 Â Â Â â€“ Â Â Â â€“ Â Â Â Â Â Â 120Â Â Â CertainRelationships and Related Party TransactionsÂ In addition to the executive officer and directorcompensation 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 officersor beneficial holders of more than 5% of any class of our capital stock, or 5% security holders, or any immediate family member of, orperson sharing the household with, any of these individuals, had or will have a direct or indirect material interest.Â In 2021, we paid a total of $125,324 to the Regentsof the University of California pursuant to our License Agreement with them Professor Jeffrey Lotz, PhD. who was a director of the Companyprior 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 memberof our Scientific Advisory Board. We will continue to make payments toÂ the Regents of the University of CaliforniaÂ for the durationof our License Agreement with UCSF (See â€œBusiness- License Agreement with the Regents of the University of Californiaâ€ above).Â We have entered into a number of investment andcommercial transactions with Nuvasive. See â€œBusiness â€“ Transactions with Nuvasive.â€Â Since January 2019, SC Capital 1 LLC and ClarkGunderson, M.D. have invested in (i) our Series B-1 preferred stock financing and (ii) our 6% convertible preferred note financing. Suchinvestments were made on the same terms offered to other investors. David Neal, one of our directors, is the founder and a current memberof SC Capital 1, LLC. Until December 2022, SC Capital 1 LLC owned more than 10% of our outstanding common shares.Â On February 16, 2023, we entered into a securitiespurchase agreement with Jeffrey Thramann, our Executive Chairman pursuant to which we issued and sold one (1) share of the Companyâ€™snewly designated Series A Preferred Stock for an aggregate purchase price of $1,000.Â The share of Series A Preferred Stock will have15,000,000 votes and will vote together with the outstanding shares of the Companyâ€™s common stock as a single class exclusivelywith respect to any proposal to amend the Companyâ€™s Certificate of Incorporation to effect a reverse stock split of the Companyâ€™scommon stock. The share of Series A Preferred Stock will be voted, without action by the holder, on any such reverse stock split proposalin the

same proportion as shares of common stock are voted on such proposal (excluding any common shares that are not voted).Â The Series A Preferred Stock otherwise has novoting rights, except as may otherwise be required by the General Corporation Law of the State of Delaware. The share of Series A PreferredStock is not convertible into, or exchangeable for, shares of any other class or series of stock or other securities of the Company. Theshare 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 PreferredStock 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. Uponsuch redemption, the holder of the Series A Preferred Stock will receive consideration of $1,000.00 in cash. We redeemed the one outstandingshare of Series A preferred stock on March 28, 2023.Â Policy for approval of related-person transactionsÂ We have adopted a related-person transaction policythat requires audit committee review and approval of any transaction, arrangement or relationship in which we are a participant and oneof our executive officers, directors, director nominees or each person whom we know to beneficially own more than 5% of our outstandingcommon stock (a â€œ5% stockholderâ€) (or their immediate family members), each of whom we refer to as a â€œrelated person,â€has a direct or indirect material interest.Â Â Â Â 121Â Â Â PrincipalStockholdersÂ The following table sets forth information regardingthe beneficial ownership of our common stock as of November 14, 2024 by (i) each person who beneficially owned more than 5% of our outstandingshares of common stock, (ii) each director, (iii) each Named Executive Officer and (iv) all of our directors and executive officers asa group. Unless otherwise indicated, the address of each executive officer and director is c/o listed below is c/o Aclarion, Inc., 8181Arista Place, Suite 100, Broomfield, Colorado 80021.Â The number of shares of common stock â€œbeneficiallyownedâ€ by each stockholder is determined under rules issued by the SEC regarding the beneficial ownership of securities. This informationis not necessarily indicative of beneficial ownership for any other purpose. Under these rules, beneficial ownership of shares of ourcommon stock includes (1) any shares as to which the person or entity has sole or shared voting power or investment power, and (2) anyshares as to which the person or entity has the right to acquire beneficial ownership within 60 days after November 14, 2024.Â The calculations set forth below are based upon10,431,159 shares of common stock outstanding at November 14, 2024. Unless otherwise indicated below, and subject to community propertylaws where applicable, to our knowledge, all persons named in the table have sole voting and investment power with respect to their sharesof common stock. The After Offering column below has been calculated assuming that we will offer [***] shares of Common Stock at an assumedoffering price of $[***] per share, which is equal to the closing price of our common stock on the Nasdaq Capital Market on[***], 2024.Â Â Â Prior to Offering Â Â After Offering Â Name of Beneficial Owner Â Amount and Nature of Beneficial Ownership Â Â Approximate Percentage of Outstanding Shares of Common Stock Â Â Amount and Nature of Beneficial Ownership Â Â Approximate Percentage of Outstanding Shares of Common Stock Â 5% Stockholders: Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â None Â Â â€“ Â Â Â â€“ Â Â Â â€“ Â Â Â â€“ Â Executive Officers and Directors: Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Jeff Thramann (1) Â Â 86,882 Â Â Â * Â Â Â 86,882 Â Â Â * Â Brent Ness (2) Â Â 23,060 Â Â Â * Â Â Â 23,060 Â Â Â * Â John Lorbiecki (3) Â Â 5,635 Â Â Â * Â Â Â 5,635 Â Â Â * Â Ryan Bond (4) Â Â 4,284 Â Â Â * Â Â Â 4,284 Â Â Â * Â David Neal (5) Â Â 18,201 Â Â Â * Â Â Â 18,201 Â Â Â * Â William Wesemann (6) Â Â 8,112 Â Â Â * Â Â Â 8,112 Â Â Â * Â Amanda Williams (7) Â Â 3,500 Â Â Â * Â Â Â 3,500 Â Â Â * Â Stephen Deitsch (7) Â Â 3,500 Â Â Â * Â Â Â 3,500 Â Â Â * Â Scott Breidbart (7) Â Â 3,500 Â Â Â * Â Â Â 3,500 Â Â Â * Â All directors and executive officers as a group (9 persons) Â Â 156,674 Â Â Â 1.5% Â Â Â 156,674 Â Â Â * Â _____ * Represent beneficial ownership of less than 1% (1) Represents outstanding stock options held by Dr. Thramann. (2) Mr. Nessâ€™ beneficial ownership includes 1,281 common shares, 21,716 vested options, and 63 IPO Warrants, and excludes 4,343 unvested options. (3) Mr. Lorbieckiâ€™s beneficial ownership includes 1,400 common shares and 4,235 vested options, and excludes 977 unvested options. (4) Mr. Bondâ€™s beneficial ownership includes 1,250 common shares, 1,721 vested options, and 1,313 IPO Warrants. (5) Mr, Nealâ€™s beneficial ownership includes 11,658 common shares, 2,150 IPO Warrants, and 4,393 vested options. (6) Mr. Wesemannâ€™s beneficial ownership includes 3,296 common shares, 4,128 vested stock options, and 688 IPO Warrants, and excludes 437 unvested stock options. (7) Includes 3,500 vested stock options and excludes 438 unvested stock options. Â Â Â 122Â Â Â DESCRIPTION OF CAPITAL STOCKÂ The following description is intended as asummary of our certificate of incorporation (which we refer to as our â€œcharterâ€) and our bylaws, each of which is filed asan exhibit to the registration statement of which this prospectus forms a part, and to the applicable provisions of the Delaware GeneralCorporation Law. Because the following is only a summary, it does not contain all of the information that may be important to you. Fora complete description, you should refer to our charter and bylaws.Â We have two classes of securities registered underSection 12 of the Exchange Act. Our shares of common stock are listed on The Nasdaq Stock Market under the trading symbol â€œACON.â€Our IPO Warrants are listed on the Nasdaq Stock Market under the trading symbol â€œACONW.â€Â Authorized Capital StockÂ Our authorized capital stock consists of 200,000,000shares of common stock, par value $0.00001 per share, and 20,000,000 shares of preferred stock, par value $0.00001 per share.Â Â Common StockÂ The holders of our common stock are entitled toone vote for each share held on all matters submitted to a vote of the stockholders. The holders of our common stock do not have any cumulativevoting rights. Holders of our common stock are entitled to receive ratably any dividends declared by our board of directors out of fundslegally available for that purpose, subject to any preferential dividend rights of any outstanding preferred stock. Our common stock hasno preemptive rights, conversion rights or other subscription rights or redemption or sinking fund provisions.Â In the event of our liquidation, dissolution orwinding up, holders of our common stock will be entitled to share ratably in all assets remaining after payment of all debts and otherliabilities and any liquidation preference of any outstanding preferred stock. Each outstanding share of common stock is duly and validlyissued, fully paid and non-assessable.Â Preferred StockÂ Our board will have the authority, without furtheraction by our stockholders, to issue up to 20,000,000 shares of preferred stock in one or more series and to fix the rights, preferences,privileges and restrictions thereof. These rights, preferences and privileges could include dividend rights, conversion rights, votingrights, terms of redemption, liquidation preferences, sinking fund terms and the number of shares constituting, or the designation of,such series, any or all of which may be greater than the rights of common stock. The issuance of our preferred stock could adversely affectthe voting power of holders of common stock and the likelihood that such holders will receive dividend payments and payments upon ourliquidation. In addition, the issuance of preferred stock could have the effect of delaying, deferring or preventing a change in controlof our company or other

corporate action.Â We issued 930 shares of newly issued Series B convertiblepreferred stock on August 14, 2024. The Series B Preferred Stock is convertible into common stock at an initial conversion price of $0.234per share of common stock.Â We issued 1,000 shares of newly issued Series C convertiblepreferred stock on September 30, 2024. The Series C Preferred Stock is convertible into common stock at an initial conversion price of$0.1759 per share of common stock.Â Anti-Takeover Effects of Delaware Law and Provisionsof our Charter and our BylawsÂ Certain provisions of the DGCL and of our charterand our bylaws could have the effect of delaying, deferring or preventing another party from acquiring control of us and encouraging personsconsidering unsolicited tender offers or other unilateral takeover proposals to negotiate with our board of directors rather than pursuenon-negotiated takeover attempts. These provisions include the items described below.Â Â Â 123Â Â Â Delaware Anti-TakeoverStatuteÂ We are subject to theprovisions of Section 203 of the DGCL. In general, Section 203 prohibits a publicly held Delaware corporation from engaging in a â€œbusinesscombinationâ€ with an â€œinterested stockholderâ€ for a three-year period following the time that this stockholder becomesan interested stockholder, unless the business combination is approved in a prescribed manner. Under Section 203, a business combinationbetween a corporation and an interested stockholder is prohibited unless it satisfies one of the following conditions:Â Â Â· before the stockholder became interested, our Board approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder; Â Â Â Â Â· upon consummation of the transaction which resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the voting stock outstanding, shares owned by persons who are directors and also officers, and employee stock plans, in some instances, but not the outstanding voting stock owned by the interested stockholder; or Â Â Â Â Â· at or after the time the stockholder became interested, the business combination was approved by our Board and authorized at an annual or special meeting of the stockholders by the affirmative vote of at least two-thirds of the outstanding voting stock which is not owned by the interested stockholder. Â Â Section 203 defines abusiness combination to include:Â Â Â· any merger or consolidation involving the corporation and the interested stockholder; Â Â Â Â Â· any sale, transfer, lease, pledge, exchange, mortgage or other disposition involving the interested stockholder of 10% or more of the assets of the corporation; Â Â Â Â Â· subject to exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder; or Â Â Â Â Â· the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation. Â In general, Section 203defines an interested stockholder as any entity or person beneficially owning 15% or more of the outstanding voting stock of the corporationand any entity or person affiliated with or controlling or controlled by the entity or person.Â Board Compositionand Filling VacanciesÂ Our charter providesthat stockholders may remove directors only for cause and only by the affirmative vote of the holders of at least two-thirds of our outstandingcommon stock. Our charter and bylaws authorize only our board of directors to fill vacant directorships, including newly created seats.In addition, the number of directors constituting our board of directors may only be set by a resolution adopted by a majority vote ofour entire board of directors. These provisions would prevent a stockholder from increasing the size of our board of directors and thengaining control of our board of directors by filling the resulting vacancies with its own nominees. This makes it more difficult to changethe composition of our board of directors but promotes continuity of management.Â No Written Consentof StockholdersÂ Our charter and bylawsprovide that all stockholder actions are required to be taken by a vote of the stockholders at an annual or special meeting, and thatstockholders may not take any action by written consent in lieu of a meeting. This limit may lengthen the amount of time required to takestockholder actions and would prevent the amendment of our bylaws or removal of directors by our stockholders without holding a meetingof stockholders.Â Â Â 124Â Â Â Meetings of StockholdersÂ Our charter and bylawsprovide that only a majority of the members of our Board then in office, our Executive Chairman or our Chief Executive Officer may callspecial meetings of stockholders and only those matters set forth in the notice of the special meeting may be considered or acted uponat a special meeting of stockholders.Â Â Advance Notice RequirementsÂ Our bylaws provide advancenotice procedures for stockholders seeking to bring matters before our annual meeting of stockholders or to nominate candidates for electionas directors at our annual meeting of stockholders. Our bylaws also specify certain requirements regarding the form and content of a stockholderâ€™snotice. These provisions might preclude our stockholders from bringing matters before our annual meeting of stockholders or from makingnominations for directors at our annual meeting of stockholders if the proper procedures are not followed. We expect that these provisionsmight also discourage or deter a potential acquirer from conducting a solicitation of proxies to elect the acquirerâ€™s own slateof directors or otherwise attempting to obtain control of our company.Â Amendment to our Charterand BylawsÂ The DGCL, provides, generally,that the affirmative vote of a majority of the shares entitled to vote on any matter is required to amend a corporationâ€™s certificateof incorporation or bylaws, unless a corporationâ€™s certificate of incorporation or bylaws, as the case may be, requires a greaterpercentage. Our bylaws may be amended or repealed by a majority vote of our board of directors or the affirmative vote of the holdersof at least two-thirds of the votes that all our stockholders would be entitled to cast in an annual election of directors. In addition,the affirmative vote of the holders of at least two-thirds of the votes that all our stockholders would be entitled to cast in an electionof directors is required to amend or repeal or to adopt certain provisions of our charter.Â Undesignated preferredstockÂ Our charter providesfor 20,000,000 authorized shares of preferred stock. The existence of authorized but unissued shares of preferred stock may enable ourboard to discourage an attempt to obtain control of us by means of a merger, tender offer, proxy contest or otherwise. For example, ifin the due exercise of its fiduciary obligations, our board of directors were to determine that a takeover proposal is not in the bestinterests of our stockholders, our board could cause shares of convertible preferred stock to be issued without stockholder approval inone or more private offerings or other transactions that might dilute the voting or other rights of the proposed acquirer or insurgentstockholder or stockholder group. In this regard, our charter grants our board broad power to establish the rights and preferences ofauthorized and unissued shares of preferred stock. The issuance of shares of preferred stock could decrease the amount of earnings andassets available for distribution to holders of shares of common stock. The issuance may also adversely affect the rights and powers,including voting rights, of these holders and may have the effect of delaying, deterring or preventing a change in control of us.Â Choice of ForumÂ Our charter providesthat the Court of Chancery of the State of Delaware is the exclusive forum for the following types of actions or proceedings: any derivativeaction or proceeding brought on behalf of the Company, any action asserting a claim of breach of a fiduciary duty owed by any director,officer or other employee of the Company to the Company or the Companyâ€™s stockholders, any action asserting a claim against theCompany arising pursuant to any provision of the DGCL or the Companyâ€™s certificate of incorporation or bylaws, or any action assertinga claim against the

Company governed by the internal affairs doctrine. Our charter also provides that unless the Company consents in writingto the selection of an alternative forum, the federal district courts of the United States of America shall be the exclusive forum forthe resolution of any complaint asserting a cause of action arising under the Securities Act. Despite the fact that the certificate ofincorporation provides for this exclusive forum provision to be applicable to the fullest extent permitted by applicable law, Section27 of the Exchange Act, creates exclusive federal jurisdiction over all suits brought to enforce any duty or liability created by theExchange Act or the rules and regulations thereunder and Section 22 of the Securities Act, creates concurrent jurisdiction for federaland state courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder.As a result, this provision of the Companyâ€™s certificate of incorporation would not apply to claims brought to enforce a duty orliability created by the Exchange Act, or any other claim for which the federal courts have exclusive jurisdiction. However, there isuncertainty as to whether a Delaware court would enforce the exclusive federal forum provisions for Securities Act claims and that investorscannot waive compliance with the federal securities laws and rules and regulations thereunder.Â Â Â 125Â Â Â Unless the Company consentsin writing to the selection of an alternative forum, the federal district courts of the United States of America shall be the exclusiveforum for the resolution of any complaint asserting a cause of action arising under the Securities Act.Â Nasdaq-Listed IPOWarrantsÂ Each IPO Warrant representsthe right to purchase one share of common stock at an exercise price of $4.35 (pre-split), or $69.60 (after giving effect to our January3, 2024 reverse stock split). The IPO Warrants are exercisable beginning April 21, 2022, will terminate on the 5th anniversary date theIPO Warrants are first exercisable. The exercise price and number of shares for which each IPO Warrant may be exercised is subject toadjustment in the event of stock dividends, stock splits, reorganizations or similar events affecting our common stock.Â Holders of the IPO Warrantsmay exercise their IPO Warrants to purchase shares of our common stock on or before the termination date by delivering an exercise notice,appropriately completed and duly signed. Payment of the exercise price for the number of shares for which the IPO Warrants is being exercisedmust be made within two trading days following such exercise. In the event that the registration statement relating to the IPO Warrantshares (the â€œIPO Warrant Sharesâ€) is not effective, a holder of IPO Warrants may only exercise its IPO Warrants for a netnumber of IPO Warrant Shares pursuant to the cashless exercise procedures specified in the IPO Warrants. IPO Warrants may be exercisedin whole or in part, and any portion of an IPO Warrant not exercised prior to the termination date shall be and become void and of novalue. The absence of an effective registration statement or applicable exemption from registration does not alleviate our obligationto deliver common stock issuable upon exercise of an IPO Warrant.Â Upon the holderâ€™sexercise of an IPO Warrant, we will issue the shares of common stock issuable upon exercise of the IPO Warrant within three trading daysof our receipt of notice of exercise, subject to timely payment of the aggregate exercise price therefor.Â The shares of commonstock issuable on exercise of the IPO Warrants will be, when issued in accordance with the IPO Warrants, duly and validly authorized,issued and fully paid and non-assessable. We will authorize and reserve at least that number of shares of common stock equal to the numberof shares of common stock issuable upon exercise of all outstanding warrants.Â If, at any time an IPOWarrant is outstanding, we consummate any fundamental transaction, as described in the IPO Warrants and generally including any consolidationor merger into another corporation, the consummation of a transaction whereby another entity acquires more than 50% of our outstandingcommon stock, or the sale of all or substantially all of our assets, or other transaction in which our common stock is converted intoor exchanged for other securities or other consideration, the holder of any IPO Warrants will thereafter receive upon exercise of theIPO Warrants, the securities or other consideration to which a holder of the number of shares of common stock then deliverable upon theexercise or conversion of such IPO Warrants would have been entitled upon such consolidation or merger or other transaction.Â The IPO Warrants arenot exercisable by their holder to the extent (but only to the extent) that such holder or any of its affiliates would beneficially ownin excess of 4.99% of our common stock.Â Amendments and waiversof the terms of the IPO Warrants require the written consent of the holder of such IPO Warrants and us. The IPO Warrants were issued inbook-entry form under a warrant agent agreement between V-Stock Transfer Company, Inc. as warrant agent, and us, and shall initially berepresented by one or more book-entry certificates deposited with The Depository Trust Company, or DTC, and registered in the name ofCede & Co., a nominee of DTC, or as otherwise directed by DTC.Â You should review a copy of the warrant agentagreement and the form of the IPO Warrants, each of which are included as exhibits to the registration statement of which this prospectusis a part.Â Â Â 126Â Â Â Transfer Agent, Registrar, Warrant AgentÂ The transfer agent andregistrar for our common stock and the warrant agent for our IPO Warrants is VStock Transfer LLC, 18 Lafayette Place, Woodmere, NY 11598.Â At November 14, 2024, after giving effect to our January3, 2024 reverse stock split, there were 10,431,159 shares of our common stock outstanding, and approximately 137 stockholders of record.No shares of our preferred stock are outstanding.Â Other Outstanding WarrantsÂ As of October 2, 2024, after giving effect to ourJanuary 3, 2024 reverse stock split, we had 16,597,689 other outstanding common stock warrants (in addition to our IPO Warrants describedabove). The terms of these warrants are (i) 123,566 warrants with a per share exercise price of $0.29 and expiring 2028, (ii) 26,673 warrantswith a per share exercise price of $69.60 and expiring 2027, (iii) 1,576 warrants with a per share exercise price of $0.0002 and expiring2028, (iv) 400,000 warrants with a per share exercise price of $0.1759 and expiring 2029, (v) 10,350,000 warrants issued as part of aFebruary 2024 public offering, with a per share exercise price of $0.58 and expiring 2029, and (vi) 5,685,049 warrants issued as partof a September 2024 private placement, with a per share exercise price of $0.1759 and expiring 2030.Â The per share exercise price of the warrants describedin clause (i) and (ii) above is subject to a â€œfull ratchetâ€ adjustment if the Company issues securities at an effective pershare price lower than the then effective warrant exercise price.Â These warrants have a net exercise provision underwhich its holder may, in lieu of payment of the exercise price in cash, surrender the warrant and receive a net amount of shares basedon the fair market value of the underlying shares at the time of exercise of the warrant after deduction of a number of shares equal invalue to the aggregate exercise price. The warrants contain provisions for the adjustment of the exercise price and the number of sharesissuable upon the exercise of the warrant in the event of certain stock dividends, stock splits, reorganizations, reclassifications andconsolidations.Â In connection with our April 2022 IPO, we issued awarrant (the â€œIPO Representativeâ€™s Warrantâ€), which enables our IPO underwriter to purchase up to an aggregate of 10,825post-split shares of Common Stock, at an exercise price equal to $87.04 per share. The IPO Representativeâ€™s Warrant may be exercisedbeginning on October 26, 2022 until April 26, 2027.Â Â Â Â 127Â Â Â DESCRIPTION OF SECURITIESWE ARE OFFERINGÂ Â Common StockÂ Voting. The holders of our Common Stockare entitled to one vote for each share held on all matters submitted to a vote of the stockholders. The holders of our Common Stock donot have any cumulative voting rights.Â Dividends. Holders of our Common Stockare entitled to receive ratably any dividends declared by our board of directors out of funds legally available for that purpose, subjectto any preferential dividend

rights of any outstanding preferred stock.Â Liquidation and Dissolution. In the eventof our liquidation, dissolution or winding up, holders of our Common Stock will be entitled to share ratably in all assets remaining afterpayment of all debts and other liabilities and any liquidation preference of any outstanding preferred stock.Â Other Rights and Restrictions. Our commonstock has no preemptive rights, conversion rights or other subscription rights or redemption or sinking fund provisions.Â Listing. Our Common Stock is listed onthe Nasdaq Capital Market under the symbol â€œACON.â€Â Transfer Agent and Registrar. The transferagent and registrar for our Common Stock is VStock Transfer, LLC.Â Delaware Law Affecting Business Combinations.We are subject to the provisions of Section 203 of the General Corporation Law of the State of Delaware (the â€œDGCLâ€). Subjectto certain exceptions, Section 203 prohibits a publicly held Delaware corporation from engaging in a â€œbusiness combinationâ€with an â€œinterested stockholderâ€ for a period of three years after the person became an interested stockholder, unless thebusiness combination is approved in a prescribed manner. A â€œbusiness combinationâ€ includes mergers, asset sales and othertransactions resulting in a financial benefit to the interested stockholder. Subject to exceptions, an â€œinterested stockholderâ€is a person who, together with affiliates and associates, owns, or within the prior three years did own, 15% or more of the corporationâ€™svoting stock.Â Series A Common WarrantsÂ The following summary of certain terms and provisionsof the Series A Common Warrants that are being offered hereby is not complete and is subject to, and qualified in its entirety by, theprovisions of the Series A Common Warrant, the form of which will be filed as an exhibit to the registration statement of which this prospectusforms a part. Prospective investors should carefully review the terms and provisions of the form of Series A Common Warrant for a completedescription of the terms and conditions of the Series A Common Warrants.Â The issuance of Common Warrant Shares upon exerciseof the Series A Common Warrants is subject to Stockholder Approval under applicable rules and regulations of Nasdaq.Â The following is a brief summary of the SeriesA Common Warrants and is still subject in all respect to the provisions contained in the form of Series A Common Warrants.Â Â Â Â 128Â Â Â Â Duration and Exercise PriceÂ Each Series A Common Warrant will have an exerciseprice equal to $[***] per share, will become exercisable on the Stockholder Approval Date (the â€œInitial Exercise Dateâ€) andwill expire on the fifth anniversary of the Initial Exercise Date. The exercise price and number of shares of Common Stock issuable uponexercise is subject to appropriate adjustment in the event of stock dividends, stock splits, reorganizations or similar events affectingour Common Stock and the exercise price. The Series A Common Warrants will be issued separately from the Common Stock and may be transferredseparately immediately thereafter.Â ExercisabilityÂ The Series A Common Warrants will be exercisable,at the option of each holder, in whole or in part, by delivering to us a duly executed exercise notice accompanied by payment in fullfor the number of shares of our Common Stock purchased upon such exercise (except in the case of a cashless exercise as discussed below).Generally, a holder (together with its affiliates) may not exercise any portion of such holderâ€™s Common Warrants to the extent thatthe holder would own more than 4.99% of the outstanding Common Stock (or at the election of a holder prior to the date of issuance, 9.99%)immediately after exercise, except that upon at least 61 daysâ€™ prior notice from the holder to us, the holder may increase the amountof ownership of outstanding stock after exercising the holderâ€™s warrants up to 9.99% of the number of shares of our Common Stockoutstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms ofthe common warrants.Â Cashless ExerciseÂ If, at the time a holder exercises its SeriesA Common Warrants, a registration statement registering the issuance of the shares of Common Stock underlying the Series A Common Warrantsunder the Securities Act is not then effective or available for the issuance of such shares, then in lieu of making the cash payment otherwisecontemplated to be made to us upon such exercise in payment of the aggregate exercise price, the holder may elect instead to receive uponsuch exercise (either in whole or in part) the net number of shares of Common Stock determined according to a formula set forth in theSeries A Common Warrant.Â Fundamental TransactionsÂ In the event we consummate a merger or consolidationwith or into another person or other reorganization event in which our Common Stock is converted or exchanged for securities, cash orother property, or we sell, lease, license, assign, transfer, convey or otherwise dispose of all or substantially all of our assets orwe or another person acquire 50% or more of our outstanding shares of Common Stock, then following such event, the holders of the Warrantswill be entitled to receive upon exercise of the Warrants the same kind and amount of securities, cash or property which the holders wouldhave received had they exercised the Warrants immediately prior to such fundamental transaction. Any successor to us or surviving entityshall assume the obligations under the Warrants. Additionally, as more fully described in the Series A Common Warrants, in the event ofcertain fundamental transactions, the holders of the warrants will be entitled to receive consideration in an amount equal to the BlackScholes value of such warrants on the date of consummation of such transaction.Â Exercise Price AdjustmentsÂ In addition, and subject to certain exemptions,if we sell, enter into an agreement to sell, or grant any option to purchase, or sell, enter into an agreement to sell, or grant any rightto reprice (excluding Exempt Issuances, as defined in the Underwriting Agreement), or otherwise dispose of or issue (or announce any offer,sale, grant or any option to purchase or other disposition) any shares of Common Stock, at an effective price per share less than theexercise price of the Series A Common Warrants then in effect, the exercise price of the Series A Common Warrants will be reduced to thelower of such price or the lowest VWAP during the five consecutive trading days immediately following such dilutive issuance or announcementthereof (subject to a floor price of $[***] prior to the Shareholder Approval Date and a floor price of $[***] beginning on the ShareholderApproval Date, each the â€œFloor Priceâ€), and the number of shares issuable upon exercise will be proportionately adjusted suchthat the aggregate exercise price will remain unchanged.Â Â Â Â 129Â Â Â If at any time on or after the date of issuancethere occurs any share split, share dividend, share combination recapitalization or other similar transaction involving our Common Stockand the lowest daily volume weighted average price during the period commencing five consecutive trading days immediately preceding andthe five consecutive trading days commencing on the date of such event is less than the exercise price of the Series A Common Warrantsthen in effect, then the exercise price of the Series A Common Warrants will be reduced to the lowest daily volume weighted average priceduring such period and the number of shares issuable upon exercise will be proportionately adjusted such that the aggregate price willremain unchanged, subject to the applicable floor price.Â On the 11th trading day after Stockholder Approval(the â€œReset Dateâ€), the Series A Common Warrantsâ€™ exercise price will be adjusted to equal the lowest of (i) the exerciseprice then in effect, (ii) the greater of (a) the lowest daily volume weighted average price of the shares of Common Stock during theperiod commencing on the first trading day after the Stockholder Approval Date and ending following the close of trading on the tenthtrading day thereafter (the â€œReset Periodâ€), and (b) the Floor Price in effect as of the Reset Date, and (iii) the lowestvolume weighted average price during the period commencing five (5) consecutive trading days immediately preceding the Reset Date, andthe number of shares issuable upon exercise will be will be increased such that the aggregate exercise price of the warrants on the issuancedate for the shares of Common Stock

underlying the warrants then outstanding shall remain unchanged.Â The exercise price and the number of shares issuableupon exercise of the Series A Common Warrants is subject to appropriate adjustment in the event of stock splits, stock dividends, recapitalizations,reorganizations, schemes, arrangements or similar events affecting our Common Stock.Â Any reduction to the exercise prices of the SeriesA Warrants and resulting increase in the number of shares of Common Stock underlying the Warrants will be subject to the Floor Price.Â TransferabilityÂ Subject to applicable laws, a Series A CommonWarrant may be transferred at the option of the holder upon surrender of the Common Warrant to us together with the appropriate instrumentsof transfer.Â Â Fractional SharesÂ No fractional shares of Common Stock will be issuedupon the exercise of the Common Warrants. Rather, the number of shares of Common Stock to be issued will, at our election, either be roundedup to the next whole share or we will pay a cash adjustment in respect of such final fraction in an amount equal to such fraction multipliedby the exercise price.Â Trading MarketÂ There is no established trading market for theSeries A Common Warrants, and we do not expect an active trading market to develop. We do not intend to apply to list the Common Warrantson any securities exchange or other trading market. Without a trading market, the liquidity of the Series A Common Warrants will be extremelylimited.Â Right as a StockholderÂ Except as otherwise provided in the Series A CommonWarrants or by virtue of such holderâ€™s ownership of our shares of Common Stock, the holder of a Series A Common Warrant does nothave the rights or privileges of a holder of our Common Stock, including any voting rights, until the holder exercises the Common Warrant.Â Waivers and AmendmentsÂ The Series A Common Warrants may be modified oramended, or the provisions thereof waived with the written consent of the Company and the respective holder.Â Â Â Â 130Â Â Â Series B Common WarrantsÂ The following summary of certain terms and provisionsof the Series B Common Warrants that are being offered hereby is not complete and is subject to, and qualified in its entirety by, theprovisions of the Series B Common Warrant, the form of which will be filed as an exhibit to the registration statement of which this prospectusforms a part. Prospective investors should carefully review the terms and provisions of the form of Series B Common Warrant for a completedescription of the terms and conditions of the Series B Common Warrants.Â The issuance of Common Warrant Shares upon exerciseof the Series B Common Warrants is subject to Stockholder Approval under applicable rules and regulations of Nasdaq.Â Duration and Exercise PriceÂ Each Series B Common Warrant will have an exerciseprice equal to $[***] per share, will become exercisable on the Initial Exercise Date and will expire on the two and one-half (2.5) yearanniversary of the Initial Exercise Date. The exercise price and number of shares of Common Stock issuable upon exercise is subject toappropriate adjustment in the event of stock dividends, stock splits, reorganizations or similar events affecting our Common Stock andthe exercise price. The Series B Common Warrants will be issued separately from the Common Stock and may be transferred separately immediatelythereafter.Â ExercisabilityÂ The Series B Common Warrants will be exercisable,at the option of each holder, in whole or in part, by delivering to us a duly executed exercise notice accompanied by payment in fullfor the number of shares of our Common Stock purchased upon such exercise (except in the case of a cashless exercise as discussed below).Generally, a holder (together with its affiliates) may not exercise any portion of such holderâ€™s Series B Common Warrants to theextent that the holder would own more than 4.99% of the outstanding Common Stock (or at the election of a holder prior to the date ofissuance, 9.99%) immediately after exercise, except that upon at least 61 daysâ€™ prior notice from the holder to us, the holder mayincrease the amount of ownership of outstanding stock after exercising the holderâ€™s warrants up to 9.99% of the number of sharesof our Common Stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordancewith the terms of the common warrants.Â Cashless Exercise & and Alternative Cashless ExerciseÂ If, at the time a holder exercises its SeriesB Common Warrants, a registration statement registering the issuance of the shares of Common Stock underlying the Series B Common Warrantsunder the Securities Act is not then effective or available for the issuance of such shares, then in lieu of making the cash payment otherwisecontemplated to be made to us upon such exercise in payment of the aggregate exercise price, the holder may elect instead to receive uponsuch exercise (either in whole or in part) the net number of shares of Common Stock determined according to a formula set forth in theSeries B Common Warrant.Â Holders may also effect an â€œalternativecashless exerciseâ€ at any time while the Series B Common Warrants are outstanding following the Initial Exercise Date. Under thealternate cashless exercise option, the holder of the Series B Common Warrant, has the right to receive an aggregate number of sharesequal to the product of (i) the aggregate number of shares of Common Stock that would be issuable upon a cashless exercise of the SeriesB Common Warrant and (ii) 3.0.Â Â Â Â Â 131Â Â Â Fundamental TransactionsÂ In the event we consummate a merger or consolidationwith or into another person or other reorganization event in which our Common Stock is converted or exchanged for securities, cash orother property, or we sell, lease, license, assign, transfer, convey or otherwise dispose of all or substantially all of our assets orwe or another person acquire 50% or more of our outstanding shares of Common Stock, then following such event, the holders of the SeriesB Common Warrants will be entitled to receive upon exercise of the Series B Common Warrants the same kind and amount of securities, cashor property which the holders would have received had they exercised the Series B Common Warrants immediately prior to such fundamentaltransaction. Any successor to us or surviving entity shall assume the obligations under the Series B Common Warrants. Additionally, asmore fully described in the Series B Common Warrants, in the event of certain fundamental transactions, the holders of the warrants willbe entitled to receive consideration in an amount equal to the Black Scholes value of Series B Common Warrants on the date of consummationof such transaction.Â Â Exercise Price AdjustmentsÂ If at any time on or after the date of issuancethere occurs any share split, share dividend, share combination recapitalization or other similar transaction involving our Common Stockand the lowest daily volume weighted average price during the period commencing five consecutive trading days immediately preceding andthe five consecutive trading days commencing on the date of such event is less than the exercise price of the Series B Common Warrantsthen in effect, then the exercise price of the Series B Common Warrants will be reduced to the lowest daily volume weighted average priceduring such period and the number of shares issuable upon exercise will be proportionately adjusted such that the aggregate price willremain unchanged, subject to the applicable floor price.Â On the 11th trading day after Stockholder Approval(the â€œReset Dateâ€), the Series B Common Warrantsâ€™ exercise price will be adjusted to equal the lowest of (i) the exerciseprice then in effect, (ii) the greater of (a) the lowest daily volume weighted average price of the shares of Common Stock during theperiod commencing on the first trading day after the Stockholder Approval Date and ending following the close of trading on the tenthtrading day thereafter (the â€œReset Periodâ€), and (b) the Floor Price in effect as of the Reset Date, and (iii) the lowestvolume weighted average price during the period commencing five (5) consecutive Trading Days immediately preceding the Reset Date, andthe number of shares issuable upon exercise will be will be increased such that the aggregate exercise price of the warrants on the issuancedate for the shares of Common Stock underlying the warrants then outstanding shall remain

unchanged.Â The exercise price and the number of shares issuableupon exercise of the Series B Common Warrants is subject to appropriate adjustment in the event of stock splits, stock dividends, recapitalizations,reorganizations, schemes, arrangements or similar events affecting our Common Stock.Â Any reduction to the exercise prices of the SeriesB Warrants and resulting increase in the number of shares of Common Stock underlying the Series B Common Warrants will be subject to theFloor Price.Â TransferabilityÂ Subject to applicable laws, a Series B CommonWarrant may be transferred at the option of the holder upon surrender of the Common Warrant to us together with the appropriate instrumentsof transfer.Â Â Â Â Â 132Â Â Â Fractional SharesÂ No fractional shares of Common Stock will be issuedupon the exercise of the Series B Common Warrants. Rather, the number of shares of Common Stock to be issued will, at our election, eitherbe rounded up to the next whole share or we will pay a cash adjustment in respect of such final fraction in an amount equal to such fractionmultiplied by the exercise price.Â Trading MarketÂ There is no established trading market for theSeries B Common Warrants, and we do not expect an active trading market to develop. We do not intend to apply to list the Series B CommonWarrants on any securities exchange or other trading market. Without a trading market, the liquidity of the Series B Common Warrants willbe extremely limited.Â Right as a StockholderÂ Except as otherwise provided in the Series B CommonWarrants or by virtue of such holderâ€™s ownership of our shares of Common Stock, the holder of a Series B Common Warrant does nothave the rights or privileges of a holder of our Common Stock, including any voting rights, until the holder exercises the Series B CommonWarrant.Â Waivers and AmendmentsÂ The Series B Common Warrants may be modified or amended, or the provisionsthereof waived with the written consent of the Company and the respective holder.Â Pre-Funded WarrantsÂ The following summary of certain terms and provisionsof the Pre-Funded Warrants that are being offered hereby is not complete and is subject to, and qualified in its entirety by, the provisionsof the Pre-Funded Warrant, the form of which will be filed as an exhibit to the registration statement of which this prospectus formsa part. Prospective investors should carefully review the terms and provisions of the form of Pre-Funded Warrant for a complete descriptionof the terms and conditions of the Pre-Funded Warrants.Â Duration and Exercise PriceÂ Each Pre-Funded Warrant offered hereby will havean initial exercise price per share of Common Stock equal to $0.001. The Pre-Funded Warrants will be immediately exercisable and willexpire when exercised in full. The exercise price and number of shares of Common Stock issuable upon exercise is subject to appropriateadjustment in the event of share dividends, share splits, reorganizations or similar events affecting our shares of Common Stock and theexercise price. Subject to the rules and regulations of the applicable trading market, we may at any time during the term of the Pre-FundedWarrant, subject to the prior written consent of the holders, reduce the then current exercise price to any amount and for any periodof time deemed appropriate by our board of directors. The Pre-Funded Warrants will be issued in certificated form only.Â Â Â Â 133Â Â Â ExercisabilityÂ The Pre-Funded Warrants will be exercisable, atthe option of each holder, in whole or in part, by delivering to us a duly executed exercise notice accompanied by payment in full forthe number of shares of Common Stock purchased upon such exercise (except in the case of a cashless exercise as discussed below). A holder(together with its affiliates) may not exercise any portion of the Pre-Funded Warrant to the extent that the holder would own more than4.99% of the outstanding shares of Common Stock immediately after exercise, except that upon at least 61 daysâ€™ prior notice fromthe holder to us, the holder may increase the amount of beneficial ownership of outstanding shares after exercising the holderâ€™sPre-Funded Warrants up to 9.99% of the number of our shares of Common Stock outstanding immediately after giving effect to the exercise,as such percentage ownership is determined in accordance with the terms of the Pre-Funded Warrants. Purchasers of Pre-Funded Warrantsin this offering may also elect prior to the issuance of the Pre-Funded Warrants to have the initial exercise limitation set at 9.99%of our outstanding shares of Common Stock.Â Cashless ExerciseÂ The Pre-Funded Warrants may also be exercised,in whole or in part, by means of a cashless exercise, in which case the holder would receive upon such exercise the net number of sharesof Common Stock determined according to the formula set forth in the Pre-Funded Warrant.Â Fundamental TransactionsÂ In the event of a fundamental transaction, asdescribed in the Pre-Funded Warrants and generally including any reorganization, recapitalization or reclassification of our Common Stock,the sale, transfer or other disposition of all or substantially all of our properties or assets, our consolidation or merger with or intoanother person, the acquisition of more than 50% of our outstanding Common Stock, or any person or group becoming the beneficial ownerof 50% of the voting power represented by our outstanding Common Stock, the holders of the Pre-Funded Warrants will be entitled to receiveupon exercise of the Pre-Funded Warrants the kind and amount of securities, cash or other property that the holders would have receivedhad they exercised the Pre-Funded Warrants immediately prior to such fundamental transaction.Â TransferabilityÂ Subject to applicable laws, a Pre-Funded Warrantmay be transferred at the option of the holder upon surrender of the Pre-Funded Warrants to us together with the appropriate instrumentsof transfer.Â Fractional SharesÂ No fractional shares of Common Stock will be issuedupon the exercise of the Pre-Funded Warrants. Rather, the number of shares of Common Stock to be issued will, at our election, eitherbe rounded down to the nearest whole number or we will pay a cash adjustment in respect of such final fraction in an amount equal to suchfraction multiplied by the exercise price.Â Â Â Â Â 134Â Â Â Trading MarketÂ There is no established trading market for thePre-Funded Warrants, and we do not expect a market to develop. We do not intend to apply for a listing of the Pre-Funded Warrants on anysecurities exchange or other nationally recognized trading system. Without an active trading market, the liquidity of the Pre-Funded Warrantswill be limited. The Common Stock issuable upon exercise of the Pre-Funded Warrants is currently listed on the Nasdaq Capital Market.Â Right as a StockholderÂ Except as otherwise provided in the Pre-FundedWarrants or by virtue of such holderâ€™s ownership of our shares of Common Stock, the holder of a Pre-Funded Warrant does not havethe rights or privileges of a holder of our Common Stock, including any voting rights, dividends or other rights as a stockholder of us,until the holder exercises the Pre-Funded Warrant.Â Warrant CertificateÂ The Pre-Funded Warrants will be issued in certificated form.Â Waivers and AmendmentsÂ The Pre-Funded Warrants may be modified or amended,or the provisions thereof waived with the written consent of us and the respective holder.Â Lock-up agreementsÂ In connection with thisoffering, we, our officers and our directors agreed that, for a period of [***] days from December [***], 2024 (the date of this prospectus),we and they will not, without the prior written consent of Dawson James Securities, Inc. dispose of or hedge any shares or any securitiesconvertible into or exchangeable for our common stock, subject to certain exceptions.Â Dawson James Securities,Inc. in their sole discretion may release any of the securities subject to these lock-up agreements at any time. If the restrictions underthe lock-up agreements are waived, shares of our common stock may become available for resale into the market, subject to applicable law,which could reduce the market price for our common stock. See â€œUnderwriting.â€Â Rule 144Â In general, under Rule144, as currently in effect, once we have been subject to the public company reporting requirements of the Exchange Act, for at least90 days, a person (or persons whose shares are required to be aggregated) who is not deemed to have been

one of our â€œaffiliatesâ€for purposes of Rule 144 at any time during the three months preceding a sale, and who has beneficially owned restricted securities withinthe meaning of Rule 144 for at least six months, including the holding period of any prior owner other than one of our â€œaffiliates,â€is entitled to sell those shares in the public market (subject to the lock-up agreements referred to above, if applicable) without complyingwith the manner of sale, volume limitations or notice provisions of Rule 144, but subject to compliance with the public information requirementsof Rule 144.Â Rule 144(a)(1) definesan â€œaffiliateâ€ of an issuing company as a person that directly, or indirectly through one or more intermediaries, controls,or is controlled by, or is under common control with, such issuer. Directors, officers and holders of ten percent or more of the Companyâ€™svoting securities (including securities which are issuable within the next sixty days) are deemed to be affiliates of the issuing company.If such a person has beneficially owned the shares proposed to be sold for at least one year, including the holding period of any priorowner other than â€œaffiliates,â€ then such person is entitled to sell such shares in the public market without complying withany of the requirements of Rule 144 (subject to the lock-up agreements referred to above, if applicable).Â Â Â 135Â Â Â In general, under Rule144, as currently in effect, once we have been subject to the public company reporting requirements of the Exchange Act for at least 90days, our â€œaffiliates,â€ as defined in Rule 144, who have beneficially owned the shares proposed to be sold for at least sixmonths, including the holding period of any prior owner other than one of our â€œaffiliates,â€ are entitled to sell in the publicmarket, upon expiration of any applicable lock-up agreements and within any three-month period, a number of those shares of our commonstock that does not exceed the greater of:Â Â Â· 1% of the number of common shares then outstanding; or Â Â Â Â Â· the average weekly trading volume of our common stock on the Nasdaq during the four calendar weeks preceding the filing of a notice on Form 144 with respect to such sale. Â Such sales under Rule144 by our â€œaffiliatesâ€ or persons selling shares on behalf of our â€œaffiliatesâ€ are also subject to certain mannerof sale provisions, notice requirements and to the availability of current public information about us.Â Rule 701Â The Rule 701 exemptionis not available to Exchange Act reporting companies. In general, under Rule 701 as currently in effect, any of our employees, directors,officers, consultants or advisors who acquired common stock from us in connection with a written compensatory stock or option plan orother written agreement in compliance with Rule 701 under the Securities Act before the effective date of our IPO registration statement(to the extent such common stock is not subject to a lock-up agreement) is entitled to rely on Rule 701 to resell such shares beginning90 days after we become subject to the public company reporting requirements of the Exchange Act. Our affiliates can resell shares inreliance on Rule 144 without having to comply with the holding period requirement, and non-affiliates of the Company can resell sharesin reliance on Rule 144 without having to comply with Rule 144â€™s current public information and holding period requirements in Rule144. Accordingly, subject to any applicable lock-up agreements, beginning 90 days after our IPO, under Rule 701 persons who are non-affiliatesmay resell those shares without complying with the minimum holding period or public information requirements of Rule 144, and affiliatesof the Company may resell those shares without compliance with Rule 144â€™s minimum holding period requirements.Â Â Â 136Â Â Â UNDERWRITINGÂ Dawson James Securities, Inc. (â€œDawson Jamesâ€)is acting as the underwriter of the offering. We have entered into an underwriting agreement dated [_____], 2024, with Dawson James.Subject to the terms and conditions of the underwriting agreement, we have agreed to sell to the underwriter named below, and the underwriteragreed to purchase, at the public offering price less the underwriting discounts set forth on the cover page of this prospectus, the numberof common stock listed next to its name in the following table.Â UnderwriterÂ Number of Shares and Accompanying Common WarrantsÂ Â Number of Pre-Funded Warrants and Accompanying Common WarrantsÂ Dawson James Securities, Inc.Â Â Â Â Â Â Â Â TotalÂ Â Â Â Â Â Â Â Â Â The underwriter is committed to purchase all theshares of common stock or pre-funded warrants in lieu of offered by us, other than those covered by the over-allotment option to purchaseadditional shares of common stock described below, if they purchase any shares of common stock. The obligations of the underwriter maybe terminated upon the occurrence of certain events specified in the underwriting agreement. Furthermore, pursuant to the underwritingagreement, the underwriterâ€™s obligations are subject to customary conditions, representations and warranties contained in the underwritingagreement, such as receipt by the underwriter of officersâ€™ certificates and legal opinions.Â The underwriter is offering the shares of commonstock and pre-funded warrants subject to prior sale, when, as and if issued to and accepted by them, subject to approval of legal mattersby their counsel and other conditions specified in the underwriting agreement. The underwriter reserves the right to withdraw, cancelor modify offers to the public and to reject orders in whole or in part.Â Over-Allotment Option to Purchase AdditionalShares of Common Stock, Pre-Funded Warrants, Series A Common Warrants and Series B Common WarrantsÂ We have granted an option to theunderwriter, exercisable for 45 days after the date of this prospectus, to purchase up to [**][***] additional shares of commonstock and/or Pre-Funded Warrants, representing 15.0% of the aggregate number of shares of common stock and Pre-Funded Warrants soldin the offering) at the public offering price, less the underwriting discount. The underwriter may exercise this option in whole orin part at any time within 45 days after the date of the offering to cover over-allotments. The purchase price to be paid peradditional share will be equal to the public offering price of one share of common stock less the underwriting discount. If thisoption is exercised in full to purchase shares of common stock, the total price to the public will be $[***] and the total netproceeds, before expenses, to us will be $[***]. We have also granted an option to the underwriter, exercisable for 45 days afterthe date of this prospectus, to purchase up to [**][***] additional Class A and up to [**][***] additional Class B Warrants, in eachcase representing 15.0% of the aggregate number of Class A and Class B Warrants, respectively, sold in the offering at a nominalprice per warrant to cover over-allotments. The underwriter may exercise this option in whole or in part at any time within 45 daysafter the date of the offering. The underwriter may exercise the option with respect to the Class A and Class B Warrants withoutexercising it with respect to the common stock and/or Pre-Funded WarrantsÂ Discounts, Commissions and ReimbursementÂ The following table shows the per share and perPre-Funded Warrant and underwriting discounts and commissions we will pay in connection with the sale of the securities in this offering.The information assumes either no exercise or full exercise by the underwriter of its over-allotment option.Â Â Â Per Share and Accompanying Common WarrantsÂ Â Per Pre-Funded Warrant and Accompanying Common WarrantsÂ Â Total with No Over-AllotmentÂ Â Total with Over-AllotmentÂ Public offering priceÂ $Â Â Â $Â Â Â $Â Â Â $Â Â Underwriting discounts and commissions to be paid by us ([***]%):Â $Â Â Â $Â Â Â $Â Â Â $Â Â Proceeds to us, before expenses(2)Â $Â Â Â $Â Â Â $Â Â Â $Â Â Â The underwriter proposes to offer the shares of common stock and pre-fundedwarrants to the public at the public offering price set forth on the cover of this prospectus. In addition, the underwriter may offersome of the shares of common stock or pre-funded warrants to other securities dealers at such price less a concession not in excess of$[***] per share of common stock. If all of the shares of common stock or pre-funded warrants in lieu of are not sold at the public offeringprice, the underwriter may change the offering price and other selling terms by means of a

supplement to this prospectus.Â Â Â Â 137Â Â Â We estimate that our portion of the total expenses of this offeringpayable by us will be $[____], excluding underwriting discounts and commissions. We have agreed to reimburse the underwriters for certainof its out-of-pocket and accountable costs for this offering, including, but not limited to, fees of the underwritersâ€™ legal counselin an amount not to exceed $160,000 in the aggregate.Â Indemnification Â We have agreed to indemnify the underwriter againstcertain liabilities, including liabilities under the Securities Act, or to contribute to payments that the underwriter or such other indemnifiedparties may be required to make in respect of those liabilities.Â Determination of Offering PriceÂ The combined public offering price per shareand Common Warrants and the combined public offering price per Pre-Funded Warrant and Common Warrants we are offering and the exerciseprices and other terms of the warrants were negotiated between us and the investors, in consultation with the underwriter based on thetrading of our Common Stock prior to this offering, among other things. Other factors considered in determining the public offering pricesof the securities we are offering and the exercise prices and other terms of the warrants include the history and prospects of our company,the stage of development of our business, our business plans for the future and the extent to which they have been implemented, an assessmentof our management, general conditions of the securities markets at the time of the offering and such other factors as were deemed relevant.Â The final public offering price will be determinedbetween us, the underwriter and the investors in the offering, and may be at a discount to the current market price of our Common Stock.Therefore, the assumed public offering price used throughout this prospectus may not be indicative of the final public offering price.There is no established public trading market for the Common Warrants or Pre-Funded Warrants, and we do not expect such markets to develop.In addition, we do not intend to apply for a listing of the Common Warrants or Pre-Funded Warrants on any national securities exchangeor other nationally recognized trading system.Â Lock-Up AgreementsÂ We have agreed not to (i) offer, pledge, sell,contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrantto purchase, lend, or otherwise transfer or dispose of, directly or indirectly, any shares of capital stock of the Company or any securitiesconvertible into or exercisable or exchangeable for shares of capital stock of the Company; (ii) file or cause to be filed any registrationstatement with the Commission relating to the offering of any shares of capital stock of the Company or any securities convertible intoor exercisable or exchangeable for shares of capital stock of the Company, other than pursuant to a registration statement on Form S-8for employee benefit plans;, whether any such transaction described in clause (i), (ii) or (iii) above is to be settled by delivery ofshares of capital stock of the Company or such other securities, in cash or otherwise; or (iv) publicly announce an intention to effectany transaction specified in clause (i), (ii) or (iii), for a period of 90 days following entry into the underwriting agreement (theâ€œLock-up Periodâ€). These restrictions on future issuances are subject to exceptions for (i) the issuance of shares of ourCommon Stock sold in this offering and the issuance of the Warrants and shares of Common Stock issuable upon exercise of those Warrants,(ii) the issuance by the Company of Common Stock upon the exercise of stock options, warrants or the conversion of a security, in eachcase, that is outstanding on the date hereof, (iii) the grant by the Company of stock options or other stock-based awards, or the issuanceof shares of capital stock of the Company under any stock compensation plan of the Company in effect on the date hereof. The foregoingrestrictions shall not apply to an at-the-market offering of Common Stock conducted by the Company.Â In addition, each of our directors and executiveofficers has entered into a lock-up agreement with the underwriter. Under the lock-up agreements, the directors and executive officersmay not, during the period commencing on the date of the final prospectus relating to the offering and ending 180 days thereafter, (1)offer, pledge, sell, contract to sell, grant, lend, or otherwise transfer or dispose of, directly or indirectly, any shares of capitalstock or any securities convertible into or exercisable or exchangeable for shares of capital stock, whether currently owned or thereafteracquired or with respect to which the director or executive officer has or thereafter acquires the power of disposition (collectively,the â€œLock-Up Securitiesâ€); (2) enter into any swap or other arrangement that transfers to another, in whole or in part, anyof the economic consequences of ownership of the Lock-Up Securities; (3) establish or increase a put equivalent position or liquidateor decrease a call equivalent position within the meaning of Section 16 of theÂ Exchange ActÂ and the rules and regulations ofthe SEC promulgated thereunder with respect to any Common Stock owned directly by the director or executive officer (including holdingas a custodian) or with respect to which the director or executive officer has beneficial ownership within the rules and regulationsof the SEC, whether any such transaction described in clause (1) or (2) above is to be settled by delivery of Lock-Up Securities, incash or otherwise; (4) make any demand for or exercise any right with respect to the registration of any Lock-Up Securities; or (5) publiclydisclose the intention to make any offer, sale, pledge or disposition, or to enter into any transaction, swap, hedge or other arrangementrelating to any Lock-Up Securities.Â Â Â 138Â Â Â Electronic Distribution Â This prospectus in electronic format may be madeavailable on websites or through other online services maintained by the Company, the underwriter, or by its affiliates. Other than thisprospectus in electronic format, the information on the Companyâ€™s and/or underwriterâ€™s website and any information containedin any other website maintained by the Company or underwriter is not part of this prospectus or the registration statement of which thisprospectus forms a part, has not been approved and/or endorsed by us or the underwriter, and should not be relied upon by investors.Â Stabilization and Other TransactionsÂ The underwriter pursuant to Regulation M underthe Securities Exchange Act of 1934 may engage in short sale transactions, stabilizing transactions, syndicate covering transactionsor the imposition of penalty bids in connection with this offering. These activities may have the effect of stabilizing or maintainingthe market price of the units at a level above that which might otherwise prevail in the open market. Establishing short sales positionsmay involve either â€œcoveredâ€ short sales or â€œnakedâ€ short sales. â€œCoveredâ€ short sales are salesmade in an amount not greater than the underwritersâ€™ option to purchase additional units in this offering. The underwriter mayclose out any covered short position by either exercising the overallotment option or purchasing our units in the open market or frommarket participants. In determining the source of securities to close out the covered short position, the underwriter will consider,among other things, the price of securities available for purchase in the market as compared to the price at which they may purchaseunits through the overallotment option. â€œNakedâ€ short sales are sales in excess of the option to purchase additional units.The underwriters must close out any naked short position by purchasing units in the open market. A naked short position is more likelyto be created if the underwriters are concerned that there may be downward pressure on the price of the units in the open market afterpricing that could adversely affect investors who purchase in this offering. A stabilizing bid is a bid for the purchase of common stockon behalf of the underwriter for the purpose of fixing or maintaining the price of the common stock. A syndicate covering transactionis the bid for or the purchase of common stock on behalf of the underwriters to reduce a short position incurred by the underwritersin connection with the offering. Similar to other purchase transactions, the underwritersâ€™ purchases to cover the syndicate shortsales may have the effect of raising or maintaining the market

price of our common stock or preventing or retarding a decline in themarket price of our common stock. As a result, the price of our common stock may be higher than the price that might otherwise existin the open market. A penalty bid is an arrangement permitting the underwriters to reclaim the selling concession otherwise accruingto a syndicate member in connection with the offering if the securities originally sold by such syndicate member are purchased in a syndicatecovering transaction and therefore have not been effectively placed by such syndicate member. Neither we, nor the underwriter make anyrepresentation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the priceof our securities. The underwriter is not obligated to engage in these activities and, if commenced, may end any of these activitiesat any time. These transactions may be effected on Nasdaq, in the over-the-counter market or otherwise.Â Listing & Transfer AgentÂ Our Common Stock is listed on the Nasdaq CapitalMarket under the symbol â€œACON.â€ On December [***], 2024, the reported closing price per share of our Common Stock was $[***].The final public offering price will be determined between us and the underwriter, and may be at a discount to the current market priceof our Common Stock. Therefore, the assumed public offering price used throughout this prospectus may not be indicative of the final publicoffering price. There is no established public trading market for the Common Warrants, or the Pre-Funded Warrants, and we do not expectsuch markets to develop. In addition, we do not intend to apply for a listing of the Common Warrants, or the Pre-Funded Warrants on anynational securities exchange or other nationally recognized trading system.Â The transfer agent and registrar for our CommonStock is VStock Transfer, LLC, 18 Lafayette Pl, Woodmere, NY 11598, telephone: (212)828-8436.Â Â Â Â 139Â Â Â Other Activities and RelationshipsÂ The underwriter and certain of its affiliatesare full service financial institutions engaged in various activities, which may include securities trading, commercial and investmentbanking, financial advisory, investment management, investment research, principal investment, hedging, financing and brokerage activities.The underwriter and certain of its affiliates have, from time to time, performed, and may in the future perform, various commercial andinvestment banking and financial advisory services for us and our affiliates, for which they received or will receive customary fees andexpenses.Â In the ordinary course of their various businessactivities, the underwriter and certain of its affiliates may make or hold a broad array of investments and actively trade debt and equitysecurities (or related derivative securities) and financial instruments (including bank loans) for their own account and for the accountsof their customers, and such investment and securities activities may involve securities and/or instruments issued by us and our affiliates.If the underwriter or its affiliates have a lending relationship with us, they routinely hedge their credit exposure to us consistentwith their customary risk management policies. The underwriter and its affiliates may hedge such exposure by entering into transactionsthat consist of either the purchase of credit default swaps or the creation of short positions in our securities or the securities ofour affiliates, including potentially the Common Stock offered hereby. Any such short positions could adversely affect future tradingprices of the Common Stock offered hereby. The underwriter and certain of its affiliates may also communicate independent investment recommendations,market color or trading ideas and/or publish or express independent research views in respect of such securities or instruments and mayat any time hold, or recommend to clients that they acquire, long and/or short positions in such securities and instruments.Â Offer and Sale Restrictions Outside the UnitedStatesÂ Other than in the United States, no action hasbeen taken by us or the underwriter that would permit a public offering of the securities offered by this prospectus in any jurisdictionwhere action for that purpose is required. The securities offered by this prospectus may not be offered or sold, directly or indirectly,nor may this prospectus or any other offering material or advertisements in connection with the offer and sale of any such securitiesbe distributed or published in any jurisdiction, except under circumstances that will result in compliance with the applicable rules andregulations of that jurisdiction. Persons into whose possession this prospectus comes are advised to inform themselves about and to observeany restrictions relating to the offering and the distribution of this prospectus. This prospectus does not constitute an offer to sellor a solicitation of an offer to buy any securities offered by this prospectus in any jurisdiction in which such an offer or a solicitationis unlawful.Â Â Â Â 140Â Â Â LEGAL MATTERSÂ Carroll Legal LLC, Denver,CO will pass upon the validity of the shares of common stock offered hereby for us. The underwriter is represented by ArentFox SchiffLLP, Washington, DC.Â EXPERTSÂ Haynie & Company,independent registered public accounting firm, has audited the financial statements of the Company as of December 31, 2023 and for theyear ended December 31, 2023, as set forth in their report included herein. The report of Haynie & Company contains an explanatoryparagraph about the ability of the Company to continue as a going concern. The 2023 financial statements of the Company are included inthis prospectus and elsewhere in this registration statement in reliance of Haynie & Companyâ€™s report, given on their authorityas experts in accounting and auditing.Â CohnReznick LLP, independentregistered public accounting firm, has audited the restated financial statements of Aclarion, Inc. (â€œthe Companyâ€) as of December31, 2022 and for the year ended December 31, 2022, as set forth in their report included herein. The report of CohnReznick LLP containsan explanatory paragraph about the ability of the Company to continue as a going concern. The restated 2022 financial statements of theCompany are included in this prospectus and elsewhere in this registration statement in reliance of CohnReznick LLPâ€™s report, givenon their authority as experts in accounting and auditing.Â CHANGE IN ACCOUNTANTSÂ In 2023, CohnReznick LLP resigned as our independentregistered public accounting firm and we retained Haynie & Company, as our independent registered public accounting firm. We had nodisagreements with CohnReznick on any matter of accounting principles or practices, financial statements disclosure, or auditing scopeof procedures during our most recent fiscal year prior to our change in independent registered public accounting firm, which, if not resolvedto the satisfaction of CohnReznick, would have caused it to make reference to the matter in its report.Â WHERE YOU CAN FINDMORE INFORMATIONÂ We have filed with theSEC a registration statement on Form S-1 under the Securities Act with respect to the shares of our common stock being offered by thisprospectus. This prospectus, which constitutes part of that registration statement, does not contain all of the information set forthin the registration statement or the exhibits and schedules that are part of the registration statement. Some items included in the registrationstatement are omitted from the prospectus in accordance with the rules and regulations of the SEC. For further information with respectto us and the common stock offered in this prospectus, we refer you to the registration statement and the accompanying exhibits and schedulesfiled therewith. Statements contained in this prospectus regarding the contents of any contract or any other document that is filed asan exhibit to the registration statement are not necessarily complete, and each such statement is qualified in all respects by referenceto the full text of such contract or other document filed as an exhibit to the registration statement.Â We are subject to theinformation and periodic reporting requirements of the Exchange Act, and we file periodic reports, proxy statements and other informationwith the SEC. These periodic reports, proxy statements and other information are available for inspection and copying at the public referenceroom of the SEC. The SEC also maintains a website that contains reports, proxy and information statements and other information

regardingregistrants that file electronically with the SEC. The address of the SEC website is www.sec.gov.Â You may access our annualreports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports filed or furnished pursuantto Section 13(a) or 15(d) of the Exchange Act with the SEC free of charge at our website as soon as reasonably practicable after suchmaterial is electronically filed with, or furnished to, the SEC.Â Â Â Â 141Â Â Â Our website address iswww.aclarion.com. The reference to our website address does not constitute incorporation by reference of the information contained onour website, and you should not consider information on our website to be part of this prospectus.Â You may also requesta copy of these filings, at no cost to you, by writing or telephoning us at the following address:Â Aclarion, Inc.Attn: Investor Relations8181 Arista Place, Suite100Broomfield, Colorado 80021Telephone: (833) 275-2266Â Â Â Â Â Â Â Â Â Â Â Â 142Â Â Â INDEX TO FINANCIAL STATEMENTSÂ Â Aclarion, Inc. Page Financial Statements Â Â Â Report of Independent Registered Public Accounting Firm - Haynie & Company LLP (ID# 457) F-2 Â Â Report of Independent Registered Public Accounting Firm CohnReznick LLP (ID# 596) F-3 Â Â Balance Sheets at December 31, 2023, and 2022 F-4 Â Â Statements of Operations, for the Years Ended December 31, 2023, and 2022 F-5 Â Â Statements of Changes in Stockholdersâ€™ Equity (deficit), for the Years Ended December 31, 2023 and 2022 F-6 Â Â Statements of Cash Flows, for the Years Ended December 31, 2023, and 2022 F-8 Â Â Notes to Financial Statements F-9 Â Â Â Â Â Â Â Â Balance Sheets at September 30, 2024 and December 31, 2023 F-32 Â Â Statements of Operations, for the Nine Months Ended September 30, 2024 and 2023 F-33 Â Â Statements of Changes in Stockholdersâ€™ Equity (deficit), for the Nine Months Ended September 30, 2024 and 2023 F-34 Â Â Statements of Cash Flows, for the Nine Months Ended September 30, 2024 and 2023 F-36 Â Â Notes to Financial Statements F-37 Â Â Â Â Â F-1Â Â Â Â Report of IndependentRegistered Public Accounting FirmÂ To the Board of Directors andStockholdersof Aclarion, Inc.Â Opinion on theFinancial StatementsÂ We have audited the accompanyingbalance sheet of Aclarion, Inc. (the Company) as of December 31, 2023, and the related statements of operations, changes in stockholdersâ€™equity (deficit), and cash flows for the year then ended, and the related notes (collectively referred to as the financial statements).In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December31, 2023, and the results of its operations and its cash flows for the year then ended, in conformity with accounting principles generallyaccepted in the United States of America.Â Substantial Doubtabout the Companyâ€™s Ability to Continue as a Going ConcernÂ The accompanying financialstatements 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 shareholdersâ€™equity that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters arealso described in Note 2. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.Â Basis for OpinionÂ These financial statementsare the responsibility of the Companyâ€™s management. Our responsibility is to express an opinion on the Companyâ€™s financialstatements based on our audit. 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 applicablerules and regulations of the Securities and Exchange Commission and the PCAOB.Â We conducted our auditin accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assuranceabout whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required tohave, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audit, we are requiredto obtain an understanding of internal control over financial reporting, but not for the purpose of expressing an opinion on the effectivenessof the Companyâ€™s internal control over financial reporting. Accordingly, we express no such opinion.Â Our audit included performingprocedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing proceduresthat respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in thefinancial statements. Our audit also included evaluating the accounting principles used and significant estimates made by management,as well as evaluating the overall presentation of the financial statements. We believe that our audit provides a reasonable basis for ouropinion.Â Â /s/ Haynie & CompanyÂ Haynie & CompanySaltLake City, UtahFebruary 20, 2024, exceptfor Notes 2 and 17, as to which the date is March 28, 2024Â We have served as theCompanyâ€™s auditor since 2023Â PCAOB ID 0457Â Â Â Â F-2Â Â Â Reportof Independent Registered Public Accounting FirmÂ To the Board of Directors andStockholdersAclarion, Inc.Broomfield, ColoradoÂ Opinion on the Financial StatementsÂ We have audited the accompanyingbalance sheet of Aclarion, Inc. (the â€œCompanyâ€) as of December 31, 2022, and the related statements of operations, changesin stockholdersâ€™ equity (deficit) and cash flows for the year then ended, and the related notes (collectively referred to as thefinancial statements). In our opinion, the financial statements present fairly, in all material respects, the financial position of theCompany at December 31, 2022, and the results of its operations and its cash flows for the year then ended, in conformity with accountingprinciples generally accepted in the United States of America.Â Restatement to correct the 2022 financial statementsÂ As discussed in Note 3 to the financial statements,the 2022 financial statements have beenÂ restatedÂ to correct misstatements.Â The financial statements of the Company as ofDecember 31, 2022, before the effects of the adjustments for the correction of the errors described in Note 3, were audited by DaszkalBolton LLP who issued an unqualified opinion on those statements in their report, containing explanatory language that substantial doubtexists about the entityâ€™s ability to continue as a going concern, dated February 27, 2023. Effective March 1, 2023, CohnReznickLLP acquired certain people and assets of Daszkal Bolton LLP.Â Going Concern UncertaintyÂ The accompanying financial statements have beenprepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the financial statements, the Company hassuffered recurring losses from operations and an accumulated deficit that raise substantial doubt about its ability to continue as a goingconcern. Management's plans in regard to these matters are also described in Note 2. The financial statements do not include any adjustmentsthat might result from the outcome of this uncertainty.Â Basis for OpinionÂ These financial statementsare the responsibility of the Companyâ€™s management. Our responsibility is to express an opinion on the Companyâ€™s financialstatements based on our audit. 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 applicablerules and regulations of the Securities and Exchange Commission and the PCAOB.Â We conducted our audit in accordance with thestandards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financialstatements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engagedto perform, an audit of its internal control over financial reporting. As part of our audit, we

are required to obtain an understandingof internal control over financial reporting, but not for the purpose of expressing an opinion on the effectiveness of the Companyâ€™sinternal control over financial reporting. Accordingly, we express no such opinion.Â Our audit included performing procedures to assessthe risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respondto those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements.Our audit also included evaluating the accounting principles used and significant estimates made by management, as well as evaluatingthe overall presentation of the financial statements. We believe that our audit provides a reasonable basis for our opinion.Â Â /s/ CohnReznick LLPÂ CohnReznickLLPSunrise, FloridaÂ June 12, 2023, except for Note 1, 2024 Reverse Stock Split, Note 7,SUPPLEMENTAL FINANCIAL INFORMATION, Prepaids and other current assets and Accrued and other liabilities, and Note 14, Net Loss Per Shareof Common Stock, as to which the date is February 21, 2024.Â We have servedas the Companyâ€™s auditor from 2021 (such date takes into account the acquisition of certain people and assets of Daszkal BoltonLLP by CohnReznick LLP effective March 1, 2023) to 2023Â Â Â F-3Â Â Â Aclarion, Inc.Balance SheetsDecember 31, 2023 and 2022 Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â December 31,Â Â Â 2023Â Â 2022Â Â Â Â Â Â (restated)Â ASSETSÂ Â Â Â Â Â Â Â Current assets:Â Â Â Â Â Â Â Â Cash and cash equivalentsÂ $1,021,069Â Â $1,472,806Â Restricted cashÂ Â 10,000Â Â Â 10,000Â Accounts receivable, netÂ Â 13,270Â Â Â 18,569Â Prepaids & other current assetsÂ Â 245,030Â Â Â 199,701Â Total current assetsÂ Â 1,289,369Â Â Â 1,701,076Â Â Â Â Â Â Â Â Â Â Non-current assets:Â Â Â Â Â Â Â Â Property and equipment, netÂ Â 1,782Â Â Â 3,346Â Intangible assets, netÂ Â 1,168,623Â Â Â 1,210,207Â Total non-current assetsÂ Â 1,170,405Â Â Â 1,213,553Â Â Â Â Â Â Â Â Â Â Total assetsÂ $2,459,774Â Â $2,914,629Â Â Â Â Â Â Â Â Â Â LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Current liabilities:Â Â Â Â Â Â Â Â Accounts payableÂ $760,535Â Â $462,202Â Accrued and other liabilitiesÂ Â 857,722Â Â Â 226,469Â Note payable, net of discountÂ Â 1,125,724Â Â Â â€"Â Warrant liabilityÂ Â 289,165Â Â Â â€"Â Derivative liabilityÂ Â 121,326Â Â Â â€"Â Liability to issue equityÂ Â 33,297Â Â Â â€"Â Total current liabilitiesÂ Â 3,187,769Â Â Â 688,671Â Â Â Â Â Â Â Â Â Â Commitments and contingencies (See Note 12)Â Â â€"Â Â Â â€"Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Stockholders' equity (deficit)Â Â Â Â Â Â Â Â Common stock - $0.00001 par value, 200,000,000 authorized and 825,459 and 491,345 shares issued and outstanding (see Note 13)Â Â 8Â Â Â 5Â Additional paid-in capitalÂ Â 43,553,523Â Â Â 41,596,106Â Accumulated deficitÂ Â (44,281,526)Â Â (39,370,153) Total stockholdersâ€™ equity (deficit)Â Â (727,995)Â Â 2,225,958Â Â Â Â Â Â Â Â Â Â Total liabilities and stockholdersâ€™ equity (deficit)Â $2,459,774Â Â $2,914,629Â Â See Accompanying Notes to Financial StatementsÂ Â Â Â Â F-4Â Â Â Aclarion, Inc.Statements of OperationsFor the Years Ended December 31, 2023, and 2022Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Year Ended December 31,Â Â Â 2023Â Â 2022Â Â Â Â Â Â (restated)Â RevenueÂ Â Â Â Â Â Â Â RevenueÂ $75,404Â Â $60,444Â Cost of revenueÂ Â 75,728Â Â Â 65,298Â Gross profit (loss)Â Â (324)Â Â (4,854) Â Â Â Â Â Â Â Â Â Operating expenses:Â Â Â Â Â Â Â Â Sales and marketingÂ Â 757,004Â Â Â 498,003Â Research and developmentÂ Â 873,336Â Â Â 1,067,992Â General and administrativeÂ Â 3,245,317Â Â Â 3,990,719Â Total operating expensesÂ Â 4,875,657Â Â Â 5,556,714Â Â Â Â Â Â Â Â Â Â Income (loss) from operationsÂ Â (4,875,981)Â Â (5,561,568) Â Â Â Â Â Â Â Â Â Other income (expense):Â Â Â Â Â Â Â Â Interest expenseÂ Â (608,288)Â Â (1,507,546) Changes in fair value of warrant and derivative liabilitiesÂ Â 646,319Â Â Â â€"Â Loss on issuance of warrantsÂ Â (72,862)Â Â â€"Â Other, netÂ Â (562)Â Â 521Â Total other income (expense)Â Â (35,393)Â Â (1,507,025) Â Â Â Â Â Â Â Â Â Income (loss) before income taxesÂ Â (4,911,374)Â Â (7,068,593) Income tax provisionÂ Â â€"Â Â Â Â â€"Â Net income (loss)Â $(4,911,374)Â $(7,068,593) Â Â Â Â Â Â Â Â Â Dividends accrued for preferred stockholdersÂ $â€"Â Â $(415,523) Net income (loss) allocable to common stockholdersÂ $(4,911,374)Â $(7,484,116) Net income (loss) per share allocable to common stockholdersÂ $(8.82)Â $(19.61) Weighted average shares of common stock outstanding, basic and dilutedÂ Â 556,808Â Â Â 381,598Â Â See Accompanying Notes to Financial StatementsÂ Â Â Â F-5Â Â Aclarion,Inc.Statements of Changes in Stockholders' Equity(Deficit)For the Years Ended December 31, 2023and 2022 (restated)Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Series AÂ Â Series A-1, A-2, A-3, A-4Â Â Series B, B-1Â Â Â Preferred StockÂ Â Preferred StockÂ Â Preferred StockÂ Â Â SharesÂ Â ValueÂ Â SharesÂ Â ValueÂ Â SharesÂ Â ValueÂ Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Balance, December 31, 2021Â Â â€"Â Â $â€"Â Â Â 6,247,695Â Â $62Â Â Â 12,434,500Â Â $124Â Share-based compensationÂ Â â€"Â Â Â â€"Â Â Â â€"Â Â Â â€"Â Â Â â€"Â Â Â â€"Â Preferred stock dividend payableÂ Â â€"Â Â Â â€"Â Â Â â€"Â Â Â â€"Â Â Â â€"Â Â Â â€"Â Conversion of preferred stock to common stockÂ Â â€"Â Â Â â€"Â Â Â (6,247,695)Â Â (62)Â Â (12,434,500)Â Â (124) Conversion of preferred dividends payable to common stockÂ Â â€"Â Â Â â€"Â Â Â â€"Â Â Â â€"Â Â Â â€"Â Â Â â€"Â Conversion of accrued interest on promissory notesÂ Â â€"Â Â Â â€"Â Â Â â€"Â Â Â â€"Â Â Â â€"Â Â Â â€"Â Issuance of common stock and warrants related to IPO, net issuance costsÂ Â â€"Â Â Â â€"Â Â Â â€"Â Â Â â€"Â Â Â â€"Â Â Â â€"Â Issuance of common sharesÂ Â â€"Â Â Â â€"Â Â Â â€"Â Â Â â€"Â Â Â â€"Â Â Â â€"Â Issuance of warrantsÂ Â â€"Â Â Â â€"Â Â Â â€"Â Â Â â€"Â Â Â â€"Â Â Â â€"Â IPO issuance costsÂ Â â€"Â Â Â â€"Â Â Â â€"Â Â Â â€"Â Â Â â€"Â Â Â â€"Â Exercise of convertible note warrantsÂ Â â€"Â Â Â â€"Â Â Â â€"Â Â Â â€"Â Â Â â€"Â Â Â â€"Â Net income (loss)Â Â â€"Â Â Â â€"Â Â Â â€"Â Â Â â€"Â Â Â â€"Â Â Â â€"Â Balance, December 31, 2022Â Â â€"Â Â $â€"Â Â Â â€"Â Â $â€"Â Â Â â€"Â Â $â€"Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Balance, December 31, 2022Â Â â€"Â Â $â€"Â Â Â â€"Â Â $â€"Â Â Â â€"Â Â $â€"Â Share-based compensationÂ Â â€"Â Â Â â€"Â Â Â â€"Â Â Â â€"Â Â Â â€"Â Â Â â€"Â Issuance of common sharesÂ Â â€"Â Â Â â€"Â Â Â â€"Â Â Â â€"Â Â Â â€"Â Â Â â€"Â Proceeds from sale of Series A preferred stockÂ Â 1Â Â Â 1,000Â Â Â â€"Â Â Â â€"Â Â Â â€"Â Â Â â€"Â Redemption of Series A preferred stockÂ Â (1)Â Â (1,000)Â Â â€"Â Â Â â€"Â Â Â â€"Â Â Â â€"Â Commitment shares - note financingÂ Â â€"Â Â Â â€"Â Â Â â€"Â Â Â â€"Â Â Â â€"Â Â Â â€"Â Issuance of warrants - note financingÂ Â â€"Â Â Â â€"Â Â Â â€"Â Â Â â€"Â Â Â â€"Â Â Â â€"Â Issuance of common shares - equity lineÂ Â â€"Â Â Â â€"Â Â Â â€"Â Â Â â€"Â Â Â â€"Â Â Â â€"Â Commitment common shares - equity lineÂ Â â€"Â Â Â â€"Â Â Â â€"Â Â Â â€"Â Â Â â€"Â Â Â â€"Â Common share issuance costs - equity lineÂ Â â€"Â Â Â â€"Â Â Â â€"Â Â Â â€"Â Â Â â€"Â Â Â â€"Â Cashless exercise of pre-funded warrantsÂ Â â€"Â Â Â â€"Â Â Â â€"Â Â Â â€"Â Â Â â€"Â Â Â â€"Â Conversion of vested restricted stock units to common sharesÂ Â â€"Â Â Â â€"Â Â Â â€"Â Â Â â€"Â Â Â â€"Â Â Â â€"Â Common share - stock split round upÂ Â â€"Â Â Â â€"Â Â Â â€"Â Â Â â€"Â Â Â â€"Â Â Â â€"Â Net income (loss)Â Â â€"Â Â Â â€"Â Â Â â€"Â Â Â â€"Â Â Â â€"Â Â Â â€"Â Balance, December 31, 2023Â Â â€"Â Â $â€"Â Â Â â€"Â Â $â€"Â Â Â â€"Â Â $â€"Â Â Â Â Â Â F-6Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Series B-2, B-3Â Â Â Â Â Â Â Â AdditionalÂ Â Â Â Â Â Â Â Â Preferred StockÂ Â Common StockÂ Â Paid-InÂ Â AccumulatedÂ Â Â Â Â Â SharesÂ Â ValueÂ Â SharesÂ Â

ValueÂ Â CapitalÂ Â DeficitÂ Â TotalÂ Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Balance, December 31, 2021Â Â 5,812,809Â Â $â€"Â Â Â 56,605Â Â $1Â Â $19,054,243Â Â Â (31,886,036)Â $(12,831,606) Share-based compensationÂ Â â€"Â Â Â â€"Â Â Â â€"Â Â Â â€"Â Â Â 1,186,658Â Â Â â€"Â Â Â 1,186,658Â Preferred stock dividend payableÂ Â â€"Â Â Â â€"Â Â Â â€"Â Â Â â€"Â Â Â â€"Â Â Â (415,523)Â Â (415,523) Conversion of preferred stock to common stockÂ Â (5,812,809)Â Â â€"Â Â Â 204,945Â Â Â 2Â Â Â 7,102,472Â Â Â â€"Â Â Â 7,102,287Â Conversion of preferred dividends payable to common stockÂ Â â€"Â Â Â â€"Â Â Â 61,534Â Â Â 1Â Â Â 4,272,420Â Â Â â€"Â Â Â 4,272,421Â Conversion of accrued interest on promissory notesÂ Â â€"Â Â Â â€"Â Â Â 26,673Â Â Â â€"Â Â Â 1,855,158Â Â Â â€"Â Â Â 1,855,158Â Issuance of common stock and warrants related to IPO, net issuance costsÂ Â â€"Â Â Â â€"Â Â Â 135,313Â Â Â 1Â Â Â 8,552,338Â Â Â â€"Â Â Â 8,552,340Â Issuance of common sharesÂ Â â€"Â Â Â â€"Â Â Â 2,500Â Â Â â€"Â Â Â 102,000Â Â Â â€"Â Â Â 102,000Â Issuance of warrantsÂ Â â€"Â Â Â â€"Â Â Â â€"Â Â Â â€"Â Â Â 1,280Â Â Â â€"Â Â Â 1,280Â IPO issuance costsÂ Â â€"Â Â Â â€"Â Â Â â€"Â Â Â â€"Â Â Â (530,463)Â Â â€"Â Â Â (530,463) Exercise of convertible note warrantsÂ Â â€"Â Â Â â€"Â Â Â 3,776Â Â Â â€"Â Â Â â€"Â Â Â â€"Â Â Â â€"Â Net income (loss)Â Â â€"Â Â Â â€"Â Â Â â€"Â Â Â â€"Â Â Â â€"Â Â Â (7,068,593)Â Â (7,068,593) Balance, December 31, 2022Â Â â€"Â Â $â€"Â Â Â 491,345Â Â $5Â Â $41,596,106Â Â $(39,370,153)Â Â 2,225,958Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Balance, December 31, 2022Â Â â€"Â Â $â€"Â Â Â 491,345Â Â $5Â Â $41,596,106Â Â $(39,370,153)Â $2,225,958Â Share-based compensationÂ Â â€"Â Â Â â€"Â Â Â â€"Â Â Â â€"Â Â Â 456,000Â Â Â â€"Â Â Â 456,000Â Issuance of common sharesÂ Â â€"Â Â Â â€"Â Â Â 1,852Â Â Â â€"Â Â Â â€"Â Â Â â€"Â Â Â â€"Â Proceeds from sale of Series A preferred stockÂ Â â€"Â Â Â â€"Â Â Â â€"Â Â Â â€"Â Â Â â€"Â Â Â â€"Â Â Â 1,000Â Redemption of Series A Preferred stockÂ Â â€"Â Â Â â€"Â Â Â â€"Â Â Â â€"Â Â Â â€"Â Â Â â€"Â Â Â (1,000) Commitment shares - note financingÂ Â â€"Â Â Â â€"Â Â Â 21,210Â Â Â â€"Â Â Â 175,619Â Â Â â€"Â Â Â 175,619Â Issuance of warrants - note financingÂ Â â€"Â Â Â â€"Â Â Â â€"Â Â Â â€"Â Â Â 67,500Â Â Â â€"Â Â Â 67,500Â Commitment common shares - equity lineÂ Â â€"Â Â Â â€"Â Â Â 11,719Â Â Â â€"Â Â Â â€"Â Â Â â€"Â Â Â â€"Â Common share issuance costs - equity lineÂ Â â€"Â Â Â â€"Â Â Â â€"Â Â Â â€"Â Â Â (204,647)Â Â â€"Â Â Â (204,647) Issuance of common shares - equity lineÂ Â â€"Â Â Â â€"Â Â Â 285,938Â Â Â 3Â Â Â 1,462,946Â Â Â â€"Â Â Â 1,462,949Â Cashless exercise of pre-funded warrantsÂ Â â€"Â Â Â â€"Â Â Â 3,396Â Â Â â€"Â Â Â â€"Â Â Â â€"Â Â Â â€"Â Conversion of vested restricted stock units to common sharesÂ Â â€"Â Â Â â€"Â Â Â 9,930Â Â Â â€"Â Â Â â€"Â Â Â â€"Â Â Â â€"Â Common share - stock split round upÂ Â â€"Â Â Â â€"Â Â Â 70Â Â Â â€"Â Â Â â€"Â Â Â â€"Â Â Â â€"Â Net income (loss)Â Â â€"Â Â Â â€"Â Â Â â€"Â Â Â â€"Â Â Â â€"Â Â Â (4,911,374)Â Â (4,911,374) Balance, December 31, 2023Â Â â€"Â Â $â€"Â Â Â 825,459Â Â $8Â Â $43,553,523Â Â $(44,281,526)Â Â (727,995) Â Â Â See Accompanying Notes to Financial StatementsÂ Â Â Â F-7Â Â Aclarion, Inc.Statements of Cash FlowsFor the Years Ended December 31, 2023 and 2022 Â Â Â Â Â Â Â Â Â Year Ended December 31,Â Â Â 2023Â Â 2022Â Â Â Â Â Â (restated)Â Cash flows from operating activitiesÂ Â Â Â Â Â Â Â Net income (loss)Â $(4,911,374)Â $(7,068,593) Adjustments to reconcile net income (loss) to net cash used in operation activities:Â Â Â Â Â Â Â Â Depreciation and amortizationÂ Â 162,670Â Â Â 143,622Â Share-based compensationÂ Â 456,001Â Â Â 1,186,658Â Amortization of deferred issuance costsÂ Â 497,656Â Â Â â€"Â Changes in fair value of warrants and derivativeÂ Â (646,319)Â Â â€"Â Non-cash interest related to bridge fundingÂ Â 98,685Â Â Â â€"Â Warrants issued as non- cash finance chargeÂ Â 72,862Â Â Â â€"Â Share-based vendor paymentsÂ Â â€"Â Â Â 102,000Â Loss on disposal of furniture and equipmentÂ Â â€"Â Â Â 3,789Â Interest conversion discount settled in equityÂ Â â€"Â Â Â 1,299,507Â Â Â Â Â Â Â Â â€"Â Change in assets and liabilitiesÂ Â Â Â Â Â Â Â Accounts receivableÂ Â (1,491)Â Â (12,290) Prepaids and other current assetsÂ Â (38,539)Â Â (87,522) Accounts payableÂ Â 220,633Â Â Â (603,102) Accrued and other liabilitiesÂ Â 448,459Â Â Â (113,893) Accrued interest on promissory and convertible notesÂ Â (6,190)Â Â 200,712Â Net cash (used in) operationsÂ Â (3,646,947)Â Â (4,949,112) Â Â Â Â Â Â Â Â Â Investing ActivitiesÂ Â Â Â Â Â Â Â Proceeds from sale of furnitureÂ Â â€"Â Â Â 1,000Â Intangible assets - PatentsÂ Â (119,522)Â Â (208,870) Net cash (used in) investing activitiesÂ Â (119,522)Â Â (207,870) Â Â Â Â Â Â Â Â Â Financing ActivitiesÂ Â Â Â Â Â Â Â Bridge funding issuance costsÂ Â (323,301)Â Â â€"Â Equity line issuance costsÂ Â (74,916)Â Â â€"Â Proceeds from equity lineÂ Â 1,462,949Â Â Â â€"Â Proceeds from issuance of promissory notesÂ Â 2,250,000Â Â Â â€"Â Proceeds from sale of Series A preferred stockÂ Â 1,000Â Â Â â€"Â Redemption of Series A Preferred stockÂ Â (1,000)Â Â â€"Â IPO cash issuance costsÂ Â â€"Â Â Â (365,060) Repayment of promissory notesÂ Â â€"Â Â Â (2,000,000) Issuance of common stock and warrants related to IPO, net deductionsÂ Â â€"Â Â Â 8,552,318Â Net cash provided by financing activitiesÂ Â 3,314,732Â Â Â 6,187,258Â Â Â Â Â Â Â Â Â Â Net increase (decrease) in cash and cash equivalentsÂ Â (451,737)Â Â 1,030,276Â Â Â Â Â Â Â Â Â Â Cash, cash equivalents, and restricted cash, beginning of periodÂ Â 1,482,806Â Â Â 452,530Â Cash, cash equivalents, and restricted cash, end of periodÂ $1,031,069Â Â $1,482,806Â Â Â Â Â Â Â Â Â Â Non- cash activitiesÂ Â Â Â Â Â Â Â Accrued debt issuance costs related to bridge fundingÂ Â 22,150Â Â Â â€"Â Accrued debt issuance costs related to equity lineÂ Â 129,731Â Â Â â€"Â Issuance of warrants related to bridge fundingÂ Â 67,500Â Â Â â€"Â Original issuance discount (15%) related to bridge fundingÂ Â 344,118Â Â Â â€"Â Liability to issue common sharesÂ Â 33,297Â Â Â â€"Â Issuance of commitment shares related to bridge fundingÂ Â 175,619Â Â Â â€"Â Fair value of warrants and derivative related to first tranche bridge fundingÂ Â 742,988Â Â Â â€"Â Fair value of warrants and derivative related to second tranche bridge fundingÂ Â 153,810Â Â Â â€"Â Fair value of warrants and derivative related to third tranche bridge fundingÂ Â 160,012Â Â Â â€"Â Dividends accrued on preferred sharesÂ Â â€"Â Â Â 415,523Â Conversion of preferred stock to common stockÂ Â â€"Â Â Â 25,754,379Â Conversion of preferred stock dividends to common stockÂ Â â€"Â Â Â 4,272,421Â Conversion of accrued interest on promissory notes to common stock and warrantsÂ Â â€"Â Â Â 1,856,438Â Issuance of underwriter's warrants related to IPOÂ Â â€"Â Â Â 199,246Â Designation of prepaid expenses to IPO issuance costsÂ Â â€"Â Â Â 165,403Â Â See Accompanying Notes to Financial StatementsÂ Â F-8Â Â Â Aclarion, Inc.Notes to Financial Statements For the Years Ended December 31, 2023 and 2022Â Â NOTE 1. THE COMPANY AND BASIS OF PRESENTATIONÂ The CompanyÂ Aclarion, Inc., formerly Nocimed, Inc., (the â€œCompanyâ€or â€œAclarionâ€) is a healthcare technology company that leverages magnetic resonance spectroscopy (â€œMRSâ€), anda proprietary biomarker to optimize clinical treatments. The Company was formed in February 2015, is incorporated in Delaware, and hasits principal place of business in Broomfield, Colorado.Â Â Risks and UncertaintiesÂ The Company is subject to various risks and uncertaintiesfrequently 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, andmanagement of potential rapid growth. To address these

risks, the Company must, among other things, develop its customer baseÍ¾ implementand successfully execute its business and marketing strategyÍ¾ develop follow-on productsÍ¾ provide superior customer serviceÍ¾and attract, retain, and motivate qualified personnel. There can be no guarantee that the Company will be successful in addressing theseor other such risks.Â Initial Public OfferingÂ On April 21, 2022, the registration statementfor our initial public offering (â€œIPOâ€) was declared effective. In connection with the effectiveness of the IPO registrationstatement:Â Â Â· we effected a 1-for-7.47 reverse stock split of our outstanding common stock (2022 Stock Split)Í¾ Â Â Â Â Â· 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 presentedÍ¾ Â Â Â Â Â· we filed a restated Certificate of Incorporation with the State of Delaware and we adopted new restated BylawsÍ¾ Â Â Â Â Â· certain outstanding common stock warrants were exercised on a net share basisfor 60,408 common shares (3,776 shares after giving effect to the 2024 Stock Split)Í¾ Â Â Â Â Â· 24,495,004 outstanding shares of our preferred stock were converted into 3,279,117 common shares (204,945 common shares after giving effect to the 2024 Stock Split)Í¾ Â Â Â Â Â· all accrued dividends on our outstanding Series B, B-1, B-2 and B-3 preferred stock were converted to 984,429 common shares (61,527 common shares after giving effect to the 2024 Stock Split)Í¾ and Â Â Â Â Â· all accrued interest on the Company's outstanding secured promissory notes was converted into (i) 426,768 common shares (26,673 common shares after giving effect to the 2024 Stock Split) and (ii) warrants to purchase 426,768 shares of common stock (26,673 common shares after giving effect to the 2024 Stock Split), with beneficial conversion rates charged to interest expense upon conversion. Â On April 26, 2022, the Company completed itsIPO 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 (equivalentto 0.0625 of a common share following the 2024 Split) and (ii) one warrant to purchase one share of common stock (adjusted to 0.0625of a common share following the 2024 Split) with a per share exercise price of $4.35 (adjusted to $69.60 following the 2024 Split). Followingthe commencement of the IPO, the underwriters partially exercised their over-allotment option and purchased additional common stock warrantsto purchase 324,750 common shares (adjusted to 20,297common shares following the 2024 Split). After deducting underwriter's commissions and expenses, we received net proceeds of approximately$8.6million and our common stock and warrants started trading on Nasdaq under the ticker symbols â€œACONâ€ and â€œACONWâ€,respectively.Â Â Â Â F-9Â Â Â In connection with the IPO, we issued to therepresentative of the underwriters a common stock warrant to purchase 173,200 shares of common stock (10,825shares after giving effect to the 2024 Stock Split) with an exercise price of $5.44 ($87.04 on a post-2024 Split basis) per share.The representative's warrants are exercisable commencing October 26, 2022 and will expire on April 26, 2027.Â On April 21, 2022, options to purchase1,204,819 shares of common stock (75,301common shares after giving effect to the 2024 Stock Split) previously awarded to the Company's Executive Chairman, Dr. JeffreyThramann, vested in connection with the completion of the IPO pursuant to the terms of such options. The per share exercise price ofthese options is $1.94 ($31.04 on a post-2024 Split basis) per share. The options have a 10-year term.Â On April 21, 2022, in connection with the IPO,the Companyâ€™s 2022 Aclarion Equity Incentive Plan, or â€œ2022 Planâ€, became effective. Our board of directors has appointedthe compensation committee of our board of directors as the committee under the 2022 Plan with the authority to administer the 2022 Plan.At the 2022 Plan effective date, the aggregate number of our shares of common stock that could be issued or used for reference purposesunder the 2022 Plan could not exceed 2,000,000 shares (125,000 shares after giving effect to the 2024 Stock Split), subject to adjustmentsas described in the 2022 Plan.Â 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 paidto James Peacock.Â On May 2, 2022, in connection with the IPO, theCompany paid the University of California - San Francisco the amount of $123,828 to satisfy the Indexed Milestone Payment obligation includedwithin the exclusive license agreement.Â 2022 Reverse Stock SplitÂ On April 21, 2022, the Company effected a 1-for-7.47reverse stock split (the â€œ2022 Stock Splitâ€) of its issued and outstanding common stock.Â 2024 Reverse Stock SplitÂ In March 2023 the Companyâ€™sstockholders approved a reverse stock split proposal at a ratio in the range of one-for-five to one-for-fifty, with the final ratioto be determined by the Company's board in its discretion without further approval from the Company's stockholders. In January 2024,the Company's board subsequently approved the final reverse stock split ratio of one-for-sixteen(the â€œ2024 Stock Splitâ€), which resulted in a reduction in the number of outstanding shares of common stock,warrants, stock options and restricted share units and a proportionate increase in the value of each share or strike price of thewarrants and stock options. The common stock began trading on a reverse split-adjusted basis on the NASDAQ on January 4, 2024.Â As a result of the 2022 Stock Split and the 2024Stock Split, unless described otherwise, all references to common stock, share data, per share data and related information containedin these financial statements have been retrospectively adjusted to reflect the effect of the stock splits for all periods presented.In addition, any fractional shares that would otherwise be issued as a result of the stock splits were rounded up to the nearest wholeshare. Further, the number of shares issuable and exercise prices of stock options and warrants have been retrospectively adjusted inthese financial statements for all periods presented to reflect the 2022 Stock Split and the 2024 Stock Split.Â The following tables present selected share informationreflecting on a retroactive basis the reverse stock splits as of and for the years ended December 31, 2023 and 2022:Â Equity statement informationÂ Â Â Â Â Â Â Â December 31Â Â Â 2023Â Â 2022Â Common shares issued and outstanding - pre-2024 split, 13,206,229 and 7,861,515 sharesÂ $132Â Â $79Â Common shares issued and outstanding - post-2024 split, 825,459 and 491,345 sharesÂ $8Â Â $5Â Additional paid-in capital - pre-2024 splitÂ $43,553,399Â Â $41,596,032Â Additional paid-in capital - post-2024 splitÂ $43,553,523Â Â $41,596,106Â Â Â Schedule of share informationreflecting on a retroactive basis the reverse stock splitsÂ Â Â Â Â Â Â Â Â Â Â Â Year ended December 31Â Â Â 2023Â Â 2022Â Weighted average shares outstanding, basic and diluted - pre-2024 splitÂ Â 8,908,934Â Â Â 6,105,569Â Weighted average shares outstanding, basic and diluted - post-2024 splitÂ Â 556,808Â Â Â 381,598Â Basic and diluted net loss per shares attributable to common stockholders - pre-2024 splitÂ $(0.55)Â $(1.23) Basic and diluted net loss per shares attributable to common stockholders - post-2024 splitÂ $(8.82)Â $(19.61) Â Basis of PresentationÂ The accompanying financial statements have beenprepared in accordance with generally accepted accounting principles in the United States of America (â€œGAAPâ€).Â Â Â Â F-10Â Â Â NOTE 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIESÂ Use of EstimatesÂ The preparation of financial statements in conformitywith accounting principles generally accepted in the United States of America requires management to make estimates and assumptions thataffect the reported amounts of assets and liabilities and disclosures of contingent assets and liabilities at the date of the financialstatements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.Â The financial statements include some amountsthat are based on management's best estimates and judgments. The most significant estimates relate to depreciation, amortization,

valuationof capital stock, and valuation of warrants and options to purchase shares of the Company's preferred and common stock. These estimatesmay be adjusted as more current information becomes available, and any adjustment could be significant.Â Valuationof Derivative InstrumentsÂ Financial Accounting Standards Board (â€œFASBâ€)Accounting Standards Codification (â€œASCâ€) 815-40, Derivatives and Hedging: Contracts on an Entityâ€™s Own Equity,addresses whether an equity-linked contract qualifies as equity in the entityâ€™s financial statements. Agreements where an entityhas insufficient authorized and unissued shares to settle the contract generally are accounted for as a liability and marked to fair valuethrough earnings each reporting period. The Company evaluates its financial instruments to determine if such instruments are liabilitiesor contain features that qualify as embedded derivatives. For financial instruments that are accounted for as liabilities, the derivativeinstrument is initially recorded at its fair value and is then revalued at each reporting date, with changes in the fair value reportedas charges or credits to income.Â Fair Value of Financial InstrumentsÂ ASC 820, Fair Value Measurements, provides guidanceon the development and disclosure of fair value measurements. Under this accounting guidance, fair value is defined as an exit price,representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between marketparticipants at the measurement date. As such, fair value is a market-based measurement that should be determined based on assumptionsthat market participants would use in pricing an asset or a liability.Â The accounting guidance classifies fair valuemeasurements in one of the following three categories for disclosure purposes:Â Level 1 - Unadjusted quoted pricesin active markets for identical instruments that are accessible by the Company on the measurement date.Â Level 2 - Quoted prices in marketsthat are not active or inputs which are either directly or indirectly observable.Â Level 3 - Unobservable inputsfor the instrument requiring the development of assumptions by the Company.Â The Company analyzes all financial instrumentswith features of both liabilities and equity under the Financial Accounting Standard Boardâ€™s (â€œFASBâ€) accounting standardfor such instruments. Under this standard, financial assets and liabilities are classified in their entirety based on the lowest levelof input that is significant to the fair value measurement.Â The carrying values of the Companyâ€™s financialinstruments including cash equivalents, restricted cash, accounts receivable, and accounts payable are approximately equal to their respectivefair values due to the relatively short-term nature of these instruments. The Companyâ€™s warrant liabilities and derivative liabilitiesare estimated using level 3 inputs (see Note 4).Â Â Â Â F-11Â Â Â Derivative Financial InstrumentsÂ The Company has derivative financial instrumentsthat are not hedges and do not qualify for hedge accounting. Changes in the fair value of these instruments are recorded in other income(expenses), on a net basis in the Consolidated Statements of Operations and Comprehensive Loss.Â Cash and Cash EquivalentsÂ The Company considers all highly liquid instrumentspurchased with an original maturity of three months or less to be cash equivalents. The Company had nocash equivalents for all periodspresented. The Company maintains cash deposits at several financial institutions, which are insured by the Federal Deposit Insurance Corporationup to $250,000. The Companyâ€™s cash balance may at times exceed these limits. On December 31, 2023, and 2022, the Company had approximately$761,800 and $1,229,000, respectively, in excess of federally insured limits. The Company continually monitors its positions with, andthe credit quality of, the financial institutions with which it invests. The Company maintains no international bank accounts. As of December31, 2023, $10,000 of the Companyâ€™s cash was restricted as collateral related to the credit card program offered by our bank.Â Accounts Receivable, Less Allowance for DoubtfulAccountsÂ The Company estimates an allowance for doubtfulaccounts based upon an evaluation of the current status of receivables, historical experience, and other factors as necessary. It is reasonablypossible that the Companyâ€™s estimate of the allowance for doubtful accounts will change. The allowance for doubtful accounts was$0on December 31, 2023, and 2022.Â RevenueRecognitionÂ Revenues are recognized when a contract with acustomer exists, and at that point in time when we have delivered a Nociscan report to our customer. Revenue is recognized in the amountthat 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 thebilling schedules in its sales arrangements. Payment terms range generally from 30 to 90 days, from the date of invoice.Â Geographic Locations & SegmentsÂ Approximately 13% and 9% of the Companyâ€™srevenues were generated from contracts with customers outside the United States in the years ended December 31, 2023, and 2022, respectively.All invoices are billed in the currency of the customers and are recorded in US Dollars at the then spot rate, which automatically isconverted to dollars upon receipt and deposited in the Companyâ€™s bank. Differences between the amounts received and the amountsinitially recorded are reflected in Other Income (Expense).Â Segment DisclosureÂ The CompanyhasÂ a singleÂ operating and reporting segment, which is the delivery of Nociscan reports to our customers. The Companyâ€™sChief Executive Officer reviews financial information for purposes of making operating decisions and assessing financial performance.Â Property and EquipmentÂ Property and equipment are stated at cost andare depreciated using the straight-line method over the estimated useful lives of the related assets. Furniture and fixtures are depreciatedoverÂ 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.Â Â Â Â F-12Â Â Â Impairment of Long-Lived AssetsÂ The Companyreviews long-lived assets, including intangible assets, property and equipment, for impairment whenever events or changes in businesscircumstances 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.Â Sales and Marketing ExpensesÂ The Company expenses the costs of sales and marketingits products and services as incurred. The primary drivers of cost have been employee payroll, website and branding development, pressreleases, attendance at various industry conferences, Key Opinion Leader consulting fees in the form of restricted stock grants, and travelexpenses.Â Research and Development CostsÂ Costs relatedto research, design and development of products are charged to research and development expense as incurred. These costs include directcompensation, benefits, and other headcount related costs for research and development personnel; costs for materials used in researchand development activities; costs for outside services and allocated portions of facilities and other corporate costs. The Company hasentered into research and clinical study arrangements with selected hospitals, cancer treatment centers, academic institutions and researchinstitutions worldwide. These agreements support the Companyâ€™s internal research and development capabilities.Â General& AdministrativeÂ Generaland administrative expenses primarily consist of personnel and related costs, including stock-based compensation, legal fees relatingto both intellectual property and corporate matters, accounting and audit related costs, insurance, corporate communications and publiccompany expenses, information technology, depreciation,

amortization and maintenance, and fees for consulting, business development andother professional services.Â Liquidity, Capital Resources and Going ConcernÂ As of December 31, 2023, we had cash ofapproximately $1.0 million. Subsequent to December 31, 2023, the Company raised capital using anequity line and a secondary public offering (refer to Note 17 â€“ Subsequent Events to our financial statements). We believe our currentcash will fund our operating expenses and capital expenditure requirements into the third quarter of 2024, approaching our final maturityrepayment of our unsecured non-convertible note, which is due in September 2024. The Company has based these estimates, however, on assumptions that may prove to be wrong, and could spend available financialresources much faster than we currently expect. The Company will need to raise additional funds to continue funding our technologydevelopment and commercialization efforts over the following twelve months. Management has plans to secure such additionalfunding.Â As a result of the Companyâ€™s recurring lossesfrom operations, and the need for additional financing to fund its operating and capital requirements, there is uncertainty regardingthe Companyâ€™s ability to maintain liquidity sufficient to operate its business effectively, which raises substantial doubt as tothe Companyâ€™s ability to continue as a going concern.Â Â Â Â Â F-13Â Â Â Share-Based CompensationÂ The Company accounts for stock-based awards inaccordance with provisions of ASC Topic 718, Compensationâ€”Stock Compensation, under which the Company recognizes the grant-datefair value of stock-based awards issued to employees and nonemployee board members as compensation expense on a straight-line basis overthe vesting period of the award, while awards containing a performance condition are recognized as expense when the achievement of theperformance criteria is achieved. The Company uses the Black-Scholes option pricing model to determine the grant-date fair value of stockoptions. The Company records expense for forfeitures in the periods they occur.Â The exercise or strike price of each option isnot less than 100% of the fair market value of the Common Stock subject to the option on the date the option is granted.Â The Company issues restricted stock unit awardsto non-employee consultants who are providing various services. The awards are valued at the market price on the date of the grant. Theawards vest over the contract life and based on achievement of targeted performance milestones.Â On occasion, the Company grants common stock tocompensate vendors for services rendered.Â Deferred Financing CostsÂ 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 financingsare completed. Upon the completion of an equity financing, these costs are recorded as a reduction of additional paid-in capital of therelated offering. Upon the completion of the IPO in April 2022, approximately $1.5 million of offering costs related to the IPO were reclassifiedto additional paid-in capital. Upon the completion of the issuance of shares pursuant to the equity line in the fourth quarterof 2023, $204,647 of offering costs were reclassified to additional paid-in capital.Â Emerging Growth Company StatusÂ The Company is an emerging growth company, asdefined in the Jumpstart Our Business Startups Act of 2012 (the â€œJOBS Actâ€). Under the JOBS Act, emerging growth companiescan delay the adoption of new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as thosestandards apply to private companies. The Company has elected to use this extended transition period for complying with certain new orrevised accounting standards that have different effective dates for public and private companies.Â Income TaxesÂ The Company follows the asset and liability methodof accounting for income taxes under ASC 740, â€œIncome Taxes.â€ Deferred tax assets and liabilities are recognized for the estimatedfuture tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilitiesand their respective tax bases. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxableincome in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets andliabilities of a change in tax rates is recognized in income in the period that included the enactment date. Valuation allowances areestablished, when necessary, to reduce deferred tax assets to the amount expected to be realized. As of December 31, 2023, the Companyhad deferred tax assets related to certain net operating losses. A valuation allowance was established against these deferred tax assetsat their full amount, resulting in a zero balance of deferred tax assets on the consolidated balance sheets as of December 31, 2023 and2022.Â Â Â Â Â F-14Â Â Â Â NOTE 3. 2022 RESTATEMENT OF PREVIOUSLY ISSUEDFINANCIAL STATEMENTSÂ The full details of the restatement to the financialstatements for the year ended December 31, 2022, are reported in Note 4 to the financial statements as of December 31, 2022 that wereincluded by the Company in its amended annual report on Form 10-K/A filed with the Securities and Exchange Commission on June 12, 2023.Â Â NOTE 4. FAIR VALUE MEASUREMENTSÂ In accordance with ASC 820 (Fair Value Measurementsand Disclosures), the Company uses various inputs to measure the outstanding warrants, certain embedded redemption features associatedwith the senior note to Aclarion, Inc. on a recurring basis to determine the fair value of the liability. Schedule of recurring basis to determine the fair value of the liabilityÂ Â Â Â Â Â Â Â Â Â Â Â Â Â Â Fair value measured as of December 31, 2023Â Â Â Fair value on December 31, 2023Â Â Quoted prices in active markets (Level 1)Â Â Significant other observable inputs (Level 2)Â Â Significant unobservable inputs (Level 3)Â Warrant liabilityÂ $289,165Â Â $â€“Â Â $â€“Â Â $289,165Â Derivative LiabilityÂ Â 121,326Â Â Â â€“Â Â Â â€“Â Â Â 121,326Â Total Fair valueÂ $410,491Â Â $â€“Â Â $â€“Â Â $410,491Â Â There were no transfers between Level 1, 2, and3 during the year ended December 31, 2023.Â The following table presents changes in Level3 liabilities measures at fair value for the year ended December 31, 2023. Both observable and unobservable inputs were used to determinethe fair value positions that the Company has classified within the Level 3 category. Schedule of liabilities measures at fair valueÂ Â Â Â Â Â Â Â Â Â Â Warrant LiabilityÂ Â Derivative LiabilityÂ Â TotalÂ Balance - January 1, 2023Â $â€“Â Â $â€“Â Â $â€“Â Additional warrant and derivative liabilityÂ Â 736,249Â Â Â 320,561Â Â Â 1,056,810Â Change in fair valueÂ Â (447,084)Â Â (199,235)Â Â (646,319) Balance â€“ December 31, 2023Â $289,165Â Â $121,326Â Â $410,491Â Â Â The fair value of the embedded derivative liabilitiesassociated with the Senior Notes Payable was estimated using a probability weighted discounted cash flow model to measure the fair value.This involves significant Level 3 inputs and assumptions including an (i) estimated probability and timing of certain financing eventsand event of default, and (ii) the Companyâ€™s risk-adjusted discount rate.Â The fair value of the warrants to purchase sharesof common stock was estimated using a Monte Carlo simulation using the following assumptions. Â Schedule of assumptionsÂ Â Â Â Â Â Â Â Â As of IssuanceÂ Â As of Dec 31, 2023Â Â Â Warrant LiabilityÂ Â Warrant LiabilityÂ Strike PriceÂ $0.63Â Â $0.27Â Contractual term (years)Â Â 5.0Â Â Â 5.0Â Volatility (annual)Â Â 80.0%Â Â Â 80.0%Â Risk-free rateÂ Â 3.52%Â Â Â 3.89%Â Floor Financing priceÂ $0.50Â Â $0.14Â Â Â Â Â Â Â F-15Â Â Â NOTE 5. RECENT ACCOUNTING PRONOUNCEMENTSÂ 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 Entityâ€™s Own Equity (Subtopic815-40) (â€œASU 2020-06â€), which simplifies the accounting for convertible instruments. The guidance removes certain accountingmodels that separate the embedded conversion features from the host contract for convertible instruments. The guidance also modifies howcertain convertible instruments, that may be

settled in cash or shares, impact the calculation of diluted earnings per share. ASU 2020-06allows for a modified or full retrospective method of transition. This update is effective for emerging growth companies following privatecompany adoption dates in fiscal years beginning after December 15, 2023, including interim periods within those fiscal years, and earlyadoption is permitted. The Company adopted this standard as of April 1, 2022, using the modified retrospective approach. The adoptionof this standard did not have a material impact on the Company's consolidated financial statements and related disclosures.Â On January 1, 2023, the Company adopted ASU 2016-13,Financial Instruments â€“ Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments, as amended, whichreplaces the incurred loss methodology with an expected loss methodology, that is referred to as a current expected loss methodology (CECL).CECL was required to be implemented for small business reporting companies after December 31, 2022. The measurement of expected lossesunder the CECL methodology is applicable to financial assets measured at amortized cost, including trade receivables, loan receivablesand held-to-maturity debt securities. It also applies to off balance sheet credit exposures not accounted for as insurance, loan commitments,standby letters of credit, financial guarantees, and similar instruments and net investment in leases, as accounted for by the lessorunder ASC 842. In addition, ASC 326 made changes to the available for-sale debt securities. One such change is to require credit lossesbe accounted for as an allowance instead of a write-down on available for-sale securities that management does not intend to sell, orbelieves it is more likely than not that they will be required to sell.Â The Company has adopted ASC 326 using the retrospectiveapproach for all financial assets measured at amortized cost, which consists of trade receivables. The Company estimates the likelihoodof collection considering trade receivables-based factors such as the creditworthiness of its customers. There are no off-balance sheetassets or guarantees. The Company recorded no change to retained earnings due to the adoption of ASC 326.Â As of this date, the Company has not purchased,nor does it intend to purchase, debt securities, eroded or financial assets, or leases within the scope of the pronouncement. If it does,it will use the prospective transition approach.Â Â NOTE 6. REVENUEÂ Contract BalancesÂ The timing of revenue recognition, billings, andcash collections may result in trade, unbilled receivables, and deferred revenues on the balance sheets. At times, revenue recognitionmay occur before the billing, resulting in an unbilled receivable, which would represent a contract asset. The contract asset would bea component of accounts receivable and other assets for the current and non-current portions, respectively. In the event the Company receivesadvances or deposits from customers before revenue is recognized, this would result in a contract liability. In years ending December31, 2023, and 2022, the Company invoiced as services were performed and did not invoice in advance; the company has no contract balances.Â Â Â Â F-16Â Â Â NOTE 7. SUPPLEMENTAL FINANCIAL INFORMATIONÂ Balance SheetsÂ Accounts receivable, netÂ Accounts receivable, net consistedof the following: Schedule of accounts receivableÂ Â Â Â Â Â Â December 31,Â Â Â 2023Â Â 2022Â Â Â Â Â Â Â Accounts receivable (1)Â $13,270Â Â $18,569Â Less: Allowance for doubtful accountsÂ Â â€“Â Â Â â€“Â Accounts receivable, netÂ $13,270Â Â $18,569Â Â (1) Accounts receivable denominated in foreign currencies represent less than 15% of accounts receivable in all periods. Â Prepaids and other current assets Schedule of prepaids and other current assetsÂ Â Â Â Â Â Â December 31,Â Â Â 2023Â Â 2022Â Â Â Â Â Â Â Short term depositsÂ $50,000Â Â $50,100Â Deferred offering costsÂ Â 100,588Â Â Â â€“Â Prepaid insurance D & OÂ Â 34,769Â Â Â 83,478Â Prepaid insurance otherÂ Â 17,884Â Â Â 16,475Â Prepaid, otherÂ Â 41,635Â Â Â 49,564Â Other receivablesÂ Â 154Â Â Â 84Â Â Â $245,030Â Â $199,701Â Â Accounts payable Schedule of accounts payableÂ Â Â Â Â Â Â December 31,Â Â Â 2023Â Â 2022Â Â Â Â Â Â Â Accounts payableÂ $758,821Â Â $457,558Â Credit cards payableÂ Â 1,714Â Â Â 4,644Â Â Â $760,535Â Â $462,202Â Â Accrued and other liabilities Schedule of accrued and other liabilitiesÂ Â Â Â Â December 31,Â Â Â 2023Â Â 2022Â Â Â Â Â Â Â Accrued payrollÂ $162,887Â Â $â€“Â Accrued bonusÂ Â 262,580Â Â Â 134,704Â Accrued board compensationÂ Â 62,500Â Â Â 31,250Â Accrued committee compensationÂ Â 30,000Â Â Â 15,000Â Accrued audit and legal expensesÂ Â 89,082Â Â Â 33,919Â Investment banking and related feesÂ Â 139,906Â Â Â â€“Â Accrued interestÂ Â 98,685Â Â Â â€“Â Other accrued expensesÂ Â 12,082Â Â Â 11,596Â Â Â $857,722Â Â $226,469Â Â Â Â Â Â Â F-17Â Â Â Statements of OperationsÂ Other expense, net consistedof the following: Schedule of other expenseÂ Â Â Â Â Â Â Year Ended December 31,Â Income/(Expense)Â 2023Â Â 2022Â Â Â Â Â Â Â Bank InterestÂ $172Â Â $2,511Â TaxesÂ Â (1,144)Â Â (800) Foreign Currency Gain (Loss)Â Â 145Â Â Â (1,190) OtherÂ Â 265Â Â Â â€“Â Â Â $(562)Â $521Â Â Â NOTE8. LEASESÂ Rent expense for the year ended December 31,2023, and 2022 was $0 and $36,070,respectively. The Company entered into a subleasing agreement in 2021 and realized $0and $26,340of sublease income for the year ended December 31, 2023, and 2022. Both the lease and sublease are netted within the general& administrative line item in the Statements of Operations. Our prior office lease and sublease expired on June 30, 2022.Â NOTE 9. PROPERTY, PLANT, AND EQUIPMENTÂ Property and equipment are stated at cost andare depreciated using the straight-line method over the estimated useful lives of the related assets. Furniture and fixtures are depreciatedover 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.Â The Companyâ€™s property and equipment areas follows: Schedule ofÂ property and equipmentÂ Â Â Â Â Â Â December 31,Â Â Â 2023Â Â 2022Â Â Â Â Â Â Â Furniture and fixturesÂ $â€“Â Â $â€“Â Computer and office equipmentÂ Â 13,032Â Â Â 13,032Â SoftwareÂ Â 42,150Â Â Â 42,150Â Other EquipmentÂ Â â€“Â Â Â 18,190Â Â Â Â 55,182Â Â Â 73,372Â Less: Accumulated depreciationÂ Â (53,400)Â Â (70,026) Property and equipment, netÂ $1,782Â Â $3,346Â Â Â Depreciation expense related to property and equipmentwere $1,564 and $4,500 for the years ended December 31, 2023, and 2022, respectively.Â During 2022 the company received proceeds of $1,000 from the sale ofproperty and equipment.Â Future depreciation and amortization of property,equipment, and software is as follows: Schedule of future depreciation of propertyand equipmentÂ Â Â 2024Â $1,186Â 2025Â Â 596Â TotalÂ $1,782Â Â Â Â Â Â F-18Â Â Â NOTE 10. INTANGIBLE ASSETSÂ The Companyâ€™s intangible assets are as follows: Schedule of intangible assetsÂ Â Â Â Â Â Â December 31, 2023Â Â December 31, 2022Â Â Â Â Â Â Â Patents and licensesÂ $2,267,251Â Â $2,147,728Â OtherÂ Â 5,017Â Â Â 5,017Â Total intangible assets grossÂ Â Â 2,272,268Â Â Â 2,152,745Â Less: accumulated amortizationÂ Â (1,103,645)Â Â (942,538) Intangible assets, netÂ $1,168,623Â Â $1,210,207Â Â Amortization expense related to purchased intangibleassets was $161,107 and $139,121 for the years ended December 31, 2023, and 2022, respectively.Â UC royalties are paid annually, amortized overtwelve months, and charged to cost of revenue.Â Patents and trademarks are reviewed at least annuallyfor impairment. No impairment was recorded through December 31, 2023, and 2022, respectively.Â Future amortization of intangible assets is asfollows: Schedule of future amortization of intangible assetsÂ Â Â 2024Â $169,002Â 2025Â Â 168,951Â 2026Â Â 168,951Â 2027Â Â 168,951Â 2028 and beyondÂ Â 492,768Â TotalÂ $1,168,623Â Â Â NOTE 11. SHORT TERM NOTES,

CONVERTIBLE DEBT,AND DERIVATIVE LIABILITIESÂ Convertible NotesÂ As of December 31, 2022, there were no ConvertibleNotes payable and outstanding. There was no convertible note activity in the year ended December 31, 2023.Â Senior Notes PayableÂ In May 2023, the Company issued $1,437,500 unsecured senior notes thatmature on May 16, 2024 (â€œthe Senior Notes Payableâ€), for cash proceeds of $1,250,000. The Senior Notes Payable contain anoriginal issue discount of 15.0% and accrue interest at an annual rate of 8.0%.Â In September 2023, as agreed to during the issuance of the Senior NotesPayable, the Company exercised their right to an additional financing, issuing $862,500 unsecured senior notes that mature on September1, 2024 ("the Series B Notes Payable) for cash proceeds of $750,000. The Series B Notes Payable contain an original issue discountof 15.0% and accrue interest at an annual rate of 8.0%.Â Â Â Â Â F-19Â Â Â In November 2023, the Company issued $294,118 unsecured senior notesthat mature on April 19, 2024 (â€œthe Series C Notes Payableâ€), for cash proceeds of $250,000. The Senior Notes Payable containan original issue discount of 15.0% and accrue interest at an annual rate of 8.0%.Â The Company incurred issuance costs, recorded as deferred financingcosts, of $296,313 relating to due diligence and legal costs associated with the issuance of the notes.Â The Company evaluated the embedded redemption and contingent interestfeatures in the notes to determine if such features were required to be bifurcated as an embedded derivative liability. In accordancewith ASC 815-40, Derivatives and Hedging Activities, the embedded redemption features and contingent interest feature were accounted foras derivative liabilities at the date of issuance and shall be adjusted to fair value at each reporting date. The Company fair valuedsuch derivative liabilities and recorded a debt discount at issuance of the notes of $320,561.Â The Company issued warrants to purchase 1,232,156and 744,890 shares of common stock (77,010 and 46,556 shares, respectively, after giving effect to the 2024 Stock Split) to the holdersof the Senior Notes Payable and Series C Notes Payable (collectively the â€œSenior Notes Warrantsâ€) with an exercise price of$0.6262 and $0.2856 per share ($10.02 and $4.58 post-2024 split), respectively. The Company accounted for the warrants in accordance withthe guidance contained in ASC 815 â€œDerivatives and Hedgingâ€ whereby under that provision these warrants did not meet the criteriafor equity treatment and were recorded as a liability. As such, these warrants are recorded at fair value as of each reporting date withthe change in fair value reported within other income in the accompanying consolidated statements of operations as â€œChange in fairvalue of warrant liabilityâ€ until the warrants are exercised, expired or other facts and circumstances lead the warrant liabilityto be reclassified to stockholdersâ€™ equity. The fair value of the Senior Notes Warrants at issuance was $736,249 and was recordedas a debt discount. The Company incurred issuance costs of $72,862 relating to the Senior Notes Warrants which was recorded as a day 1expense due to the liability classification of such warrants.Â In connection with the issuance of the SeniorNotes Payable and Series C Notes Payable, the Company paid a commitment fee in the form of 339,360 and 148,978 shares (21,210 and 9,311shares after giving effect to the 2024 Stock Split) of unregistered common stock to the holders, respectively. The aggregate commitmentfees had a fair value at issuance of $208,916 and are recorded as a deferred financing cost.Â The resulting debt discounts from the derivative liabilities, warrantliabilities and deferred financing costs were presented as a direct deduction from the carrying amount of that debt liability and amortizedto interest expense using the effective interest rate method. For the year ended December 31, 2023, the Company recognized $497,763 inamortization of debt discounts and deferred financing costs which is recorded in interest expense.Â The following table reconciles the aggregateamount for the Senior Notes Payable, Series B Notes Payable, and Series C Notes Payable as well as the unamortized deferred financingcosts and debt discounts relating to the derivative liabilities and warrant liabilities. Schedule of derivative liabilities and warrantliabilitiesÂ Â Â Â Â Â Â Â Â Â December 31, 2023Â Â December 31, 2022Â Note PayableÂ $2,594,118Â Â $â€“Â Less: Unamortized Discounts and Deferred Financing CostsÂ Â Â Â Â Â Â Â Â WarrantsÂ Â (557,782)Â Â â€“Â DerivativeÂ Â (235,628)Â Â â€“Â Deferred financing costsÂ Â (675,184)Â Â â€“Â Â Â (1,468,394)Â Â â€“Â Â Â $1,125,724Â Â $â€“Â Â Â Â Â Â F-20Â Â Â Secured Promissory Notes PayableÂ In June 2021, the Company issued $2.0 millionof promissory notes that matured at the earlier of the consummation of a Qualified Financing or May 31, 2022. The promissory notes incorporatedthe following major attributes: secured by a lien and security interest on substantially all of the Companyâ€™s assetsÍ¾ interestaccrues at 33%Í¾ holder option to convert the accrued interest into the Company securities being offered in a Qualified Financingat 30% (i.e. 70% discount) of the price being paid by other investors in the Qualified FinancingÍ¾ and automatic conversion in thecase 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 promissory notes remained outstanding after May 31, 2022, theCompany had the option to extend the promissory notes upon the payment of an extension fee, which consisted of warrants to purchase 150,000shares (1,255 shares after giving effect to the 2022 and 2024 Stock Splits) with a five-year term, to purchase shares of the Companyâ€™scommon stock at a price of $ 0.01 per share ($1.20 post-2022 and 2024 splits).Â On April 21, 2022, the registration statementfor our IPO was declared effective. In connection with the effectiveness of the IPO registration statement, all accrued interest on theCompany's outstanding secured promissory notes were converted into (i) 426,768 (26,673 after giving effect to the 2024 Stock Split) commonshares and (ii) warrants to purchase 426,768 shares of common stock (26,673 common shares after giving effect to the 2024 Stock Split)with a $1,299,507 beneficial conversion rate charged to interest expense.Â On April 27, 2022, the Company used $2 millionof the IPO proceeds to retire all outstanding secured promissory notes.Â NOTE 12. COMMITMENTS AND CONTINGENCIESÂ Royalty AgreementÂ The Company has an exclusive license agreementwith the Regents of the University of California to make, use, sell and otherwise distribute products under certain of the Regents ofthe University of Californiaâ€™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 yearin which the minimum payment was made. The license agreements expire upon expiration of the patents and may be terminated earlier if theCompany so elects. The U.S. licensed patents that are currently issued expire between 2026 and 2029, without considering any possiblepatent 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, 2023, and 2022.Â Additionally, the Company was obligated to makea 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 (1,783 shares after giving effect to the 2024 Stock Split) of Company common stocktimes the IPO price of $4.34 ($69.44 post-2024 Stock Split). On May 2, 2022, in connection with the IPO, the Company paid the Universityof California - San Francisco the amount of $123,828 to satisfy the Indexed Milestone Payment obligation included within the exclusivelicense agreement.Â LitigationÂ To date, the Company has not been involved inlegal proceedings arising in the ordinary course of its business. If any legal proceeding occurs, the Company would record a provisionfor a loss when it believes that it is both probable that a loss has been incurred and the amount can be reasonably estimated,

althoughlitigation is inherently unpredictable and is subject to significant uncertainties, some of which are beyond the Companyâ€™s control.Should any of these estimates and assumptions change or prove to have been incorrect, the Company could incur significant charges relatedto legal matters that could have a material impact on its results of operations, financial position and cash flows.Â Â Â Â Â F-21Â Â Â Stock Option Grant to our Executive ChairmanÂ In September 2021, the Board of Directors approveda stock option grant of 1,204,819 shares (75,301 after giving effect to the 2024 Stock Split) 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 roundfinancing, the merger of the Company with a SPAC, or the sale of the Company. The amount of stock options that would vest upon such specifiedevents depended upon the terms and timing of the applicable event.Â On April 21, 2022, options to purchase 1,204,819shares of common stock (75,301 shares post-2024 Stock Split) previously awarded to Dr. Jeffrey Thramann vested in connection with thecompletion of the IPO pursuant to the terms of such options. The exercise price of these options is $1.94 ($31.04 post-2024 Stock Split)per share. The options have a 10-year term.Â On September 15, 2022, the Board of Directors approved a stock optiongrant to purchase an additional 185,285 (11,580 post-2024 Stock Split) shares of common stock to Dr. Thramann. The exercise price of theoptions is $1.94 ($31.04 post-2024 Stock Split) per share, they are fully vested, and they have a 10-year term.Â Â NOTE13. STOCKHOLDERSâ€™ EQUITYÂ The Company filed an Amended and Restated Certificateof Incorporation on April 21, 2022, as part of the IPO. The Company is authorized to issue two classes of stock to be designated, respectively,â€œCommon Stockâ€ and â€œPreferred Stock.â€ The total number of shares which the Company is authorized to issue is twohundred twenty million (220,000,000) shares. Two hundred million (200,000,000) shares are authorized to be Common Stock, having a parvalue 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.Â Prior to the IPO, the Company had authorized twoclasses of shares. These classes included shares of common stock and preferred stock. There was one authorized series of shares of commonstock 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.Â The preferred shares converted to common shareson a 1:1 pre-split basis immediately prior to the Stock Split on April 21, 2022. Those common shares were adjusted to reflect the 2022Stock Split and 2024 Stock Split as described in Note 1 Reverse Stock Split.Â Preference Amounts Â Issue Date Â Total Face Value of Investment Â Â Issue Purchase Price/Share Â Â Â Â Â Â Â Â Â Â Â Â Series A-1 Preferred Stock Â 12/31/2014 Â $ 1,247,541 Â Â $ 0.70 Â 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. Â Â Â Â Â Â Â Â Â Â Â Â Â Series A-2 Preferred Stock Â 12/31/2014 Â $ 1,114,797 Â Â $ 0.77 Â 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. Â Â Â Â Â Â Â Â Â Â Â Â Â Series A-3 Preferred Stock Â 12/31/2014 Â $ 795,002 Â Â $ 0.85 Â 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. Â Â Â Â Â F-22Â Â Â Preference Amounts Â Issue Date Â Total Face Value of Investments Â Â Issue Purchase Price/Share Â Â Â Â Â Â Â Â Â Â Â Â Series A-4 Preferred Stock Â 12/31/2014 Â $ 1,965,288 Â Â $ 0.94 Â 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. Â Â Â Â Â Â Â Â Â Â Â Â Â Series B Preferred Stock Â 12/5/2015 Â $ 5,013,579 Â Â $ 1.00 Â 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. Â Â Â Â Â Â Â Â Â Â Â Â Â 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. Â Â Â Â Â Â Â Â Â Â Â Series B-1 Preferred Stock Â 7/27/2017 Â $ 1,500,000 Â Â $ 1.26 Â Â Â 8/2/2018 Â $ 5,217,698 Â Â $ 1.26 Â Â Â 3/1/2019 Â $ 2,463,328 Â Â $ 1.26 Â Â Â Â Â Â Â Â Â Â Â Â Â 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. Â Â Â Â Â Â Â Â Â Â Â Â Â 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. Â Â Â Â Â Â Â Â Â Â Â Â Series B-2 Preferred Stock Â 12/3/2021 Â $ 1,774,819 Â Â $ 1.12 Â Â Â Â Â Â Â Â Â Â Â Â Â 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. Â Â Â Â Â Â Â Â Â Â Â Â Â 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. Â Â Â Â Â Â Â Â Â Â Â Â Â Series B-3 Preferred Stock Â 12/3/2021 Â $ 5,327,468 Â Â $ 1.26 Â Â Â Â Â Â Â Â Â Â Â Â Â 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. Â Â Â Â Â Â Â Â Â Â Â Â Â 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. Â Â WarrantsÂ As of December 31, 2023, IPO Warrants to purchase155,610 shares of common stock (post-split), and other warrants to purchase 165,555 shares of common stock (post-split) were outstanding.Â Â Â Â Â F-23Â Â Â Warrants issued in connection with the IPOÂ In connection with the Companyâ€™s IPO, allaccrued interest on the Company's outstanding secured promissory notes were converted into (i) 26,673 (post-2024 Stock Split) common sharesand (ii) warrants to purchase 26,673 shares of common stock (post-2024 Stock Split), with beneficial conversion rates charged to interestexpense upon conversion. These warrants have an exercise price of $69.60 (post-2024 Stock Split) per share and expiring 2027.Â In the IPO, the Company sold 2,165,000 units ata public

offering price of $4.35 per unit. Each unit consisted of (i) one share of common stock (equivalent to 0.0625 of a common sharefollowing the 2024 Split) and (ii) one warrant to purchase one share of common stock (adjusted to 0.0625 of a common share following the2024 Split) warrant with a per share exercise price of $4.35 (adjusted to $69.60 following the 2024 Split). On April 22, 2022, the underwriterspartially exercised their over-allotment option and purchased additional common stock warrants to purchase 324,750 common shares (adjustedto 20,297 common shares following the 2024 Split). The common stock and the IPO Warrants were immediately separable and issued separatelyin 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.Â In connection with the IPO, we issued to the representativeof the underwritersâ€™ common stock warrants to purchase 10,825 shares of common stock (post-2024 Stock Split) with an exercise priceof $87.04 (post-2024 Stock Split) per share. The representative's warrants are exercisable commencing October 26, 2022, and will expireon April 26, 2027.Â The Company evaluated the terms of all warrantsissued 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 wereequity classified, the Company recorded the proceeds from the IPO, net of issuance costs, within common stock at par value and the balanceof proceeds to additional paid in capital.Â Other Outstanding WarrantsÂ As of December 31, 2023, we had otheroutstanding warrants to purchase 128,057shares of common stock (post-split) (in addition to our IPO Warrants described above). The terms of these warrants are (i) warrantsto purchase 123,566shares of common stock (post-split) with a per share exercise price of $2.315(post split) and expiring 2028, and warrants to purchase 4,491common shares (post split) with a per share exercise price of $0.0002(post-split) and expiring 2028.Â The per share exercise price of the warrantsdescribed in clause (i) above is subject to a â€œratchetâ€ adjustment if the Company issues securities at an effective per shareprice lower than the then effective warrant exercise price.Â White Lion EquityLine AgreementÂ On October 9, 2023, the Company entered into anequity line common stock purchase agreement (the â€œEquity Line Purchase Agreementâ€) and a related registration rights agreementwith White Lion Capital, LLC (â€œWhite Lionâ€). Pursuant to the Equity Line Agreement, the Company has the right, but not theobligation to require White Lion to purchase, from time to time, up to $10,000,000 in aggregate gross purchase price of newly issued sharesof the Companyâ€™s common stock, subject to certain limitations and conditions set forth in the Equity Line Purchase Agreement.Â Â Â Â Â F-24Â Â Â It is anticipated that the Company may sell sharesof common stock to White Lion from time-to-time over a sales period that expires December 31, 2024. The number of shares ultimately offeredfor sale to White Lion under the Equity Line Purchase Agreement is dependent upon the number of shares we elect to sell to White Lionunder the Equity Line Purchase Agreement. The actual number of shares of common stock that are sold to White Lion may depend based ona number of factors, including the market price of our common stock during the time that the Equity Line Purchase Agreement in is effect.The actual gross proceeds the Company may derive from the Equity Line Purchase Agreement may be less than $10.0Â million, which mayimpact our future liquidity. Because the price per share of each share sold to White Lion will fluctuate during the sales period, it isnot currently possible to predict the number of shares that will be sold or the actual gross proceeds to be raised in connection withthose sales, if any.Â The Company currently has an effective registrationstatement to register for resale by White Lion 2,500,000shares of common stock. White Lion may ultimately purchase all or some of these shares. After White Lion has acquired shares underthe Equity Line Purchase Agreement, it may sell all, some or none of those shares. Sales to the Selling Securityholder by us pursuantto the Equity Line Purchase Agreement may result in substantial dilution to the interests of other holders of our common stock.Â The sale of a substantial number of shares toWhite Lion, or anticipation of such sales, could make it more difficult for us to sell equity or equity-related securities in the futureat a time and at a price that we might otherwise desire. The number of shares of our common stock ultimately offered for resale by WhiteLion is dependent upon the number of shares of common stock issued to White Lion pursuant to the Equity Line Purchase Agreement. Dependingon a variety of factors, including market liquidity of our common stock, the issuance of shares to White Lion may cause the trading priceof our common stock to decline.Â In consideration for the commitments of WhiteLion, as described above, the Company issued to White Lion 187,500 pre-split shares (11,719 post-2024 Stock Split) of Common Stock (theâ€œCommitment Sharesâ€), having a value of $75,000 based upon the closing sale price of Common Stock on October 6, 2023.Â As of December 31, 2023, the Company sold to WhiteLion 4,575,000 newly issued pre-split common shares (285,938 post-2024 Stock Split) for proceeds of $1,462,949.Â NOTE14. NET LOSS PER SHARE OF COMMON STOCKÂ In January 2024, the Companyâ€™s board approvedthe final reverse stock split ratio of one-for-sixteen, which resulted in a reduction in the number of outstanding shares of common stockand a proportionate increase in the value of each share. The common stock began trading on a reverse split-adjusted basis on the NASDAQon January 4, 2024. The retrospective effect of the reverse stock split has been incorporated on a retrospective basis in the tabulardisclosures of loss per share and weighted average outstanding shares for the fiscal years 2023 and 2022 herein.Â Basic and diluted net loss per share is computedby dividing net loss attributable to stockholders by the weighted average number shares of common stock outstanding, vested restrictedstock units, and pre-funded warrants during the year. Potentially dilutive outstanding shares of common stock equivalents were excludedfrom the computation of diluted net loss per share for loss periods presented because including them would have been antidilutive.Â A post-split reconciliation of the numerator anddenominator used in the calculation of basic and diluted net loss per share attributable to stockholders follows:Â Schedule of reconciliation of basic and diluted net loss per shareÂ Â Â Â Â Â Â December 31,Â Â Â Â Â Â 2022Â Â Â 2023Â Â (restated)Â Numerator:Â Â Â Â Â Â Net loss allocable to common shareholders used to compute basic and diluted loss per common shareÂ $(4,911,374)Â $(7,484,116) Denominator:Â Â Â Â Â Â Â Â Â Weighted average shares used to compute basic and dilutive loss per share (post-split)Â Â 556,808Â Â Â 381,598Â Â Â Â Â F-25Â Â Â The following outstanding potentially dilutivesecurities were excluded from the calculation of dilutive loss per share attributable to common stockholders because their impact wouldhave been antidilutive for the period presented: Schedule of anti-dilutive securities excluded from computation of earnings per shareÂ Â Â Â Â Â Â Â December 31, 2023Â Â December 31, 2022Â Â Â Â Â Â Â Shares issuable on Series A and B convertible preferred stockÂ Â â€“Â Â Â 51,236Â Shares issuable on warrantsÂ Â 255,270Â Â Â 145,624Â Shares issuable on restricted stock unitsÂ Â 49,185Â Â Â 3,127Â Shares issuable on optionsÂ Â 171,033Â Â Â 155,114Â Â Â Â 475,488Â Â Â 355,101Â Â NOTE 15. STOCK-BASED COMPENSATIONÂ 2022 Aclarion Equity Incentive PlanÂ On April 21, 2022, in connection with theIPO, the Companyâ€™s 2022 Aclarion Equity Incentive Plan, or â€œ2022 Planâ€, went into effect. Our board of directorshas appointed the compensation committee of our board of directors as the committee under the 2022 Plan with the authority toadminister the 2022 Plan. The aggregate number of our shares of common stock that may be issued or used for reference purposes underthe 2022 Plan is 2,000,000shares (125,000 post

2024 Stock Split), with an automatic increase on January 1st of each year, for a period of not more than tenyears, commencing on January 1st of the year following the year in which the IPO Date occurs and ending on (and including) January1, 2032, in an amount equal to 5% of the total number of shares of Capital Stock outstanding on December 31st of the precedingcalendar year. Notwithstanding the foregoing, the Board may act prior to January 1st of a given year to provide that there will beno January 1st increase in shares for such year or that the increase in shares for such year will be a lesser number of shares ofCommon Stock than would otherwise occur pursuant to the preceding sentence.Â As of the year ended December 31, 2023, the aggregatenumber of our shares of common stock that may be issued or used for reference purposes under the 2022 Plan was 2,470,814 (154,426 post-split).On January 1, 2024, the 2022 Plan had an automatic increase of 660,311 (41,270 post-split) shares which was 5% of the total number of sharesof Capital Stock outstanding on December 31, 2023.Â Options granted under the 2022 Plan may be incentivestock options or non-statutory stock options, as determined by the administrator at the time of grant of an option. Restricted stockmay also be granted under the 2022 Plan. The options vest in accordance with the grant terms and are exercisable for a period of up to10 years from grant date.Â The Company did not grant any stock options forthe twelve months ended December 31, 2023. The fair value of the options granted for theÂ twelve months ended December 31, 2022 wereestimated at the date of grant using the Black-Scholes-Merton option pricing model with the following assumptions: Schedule of assumptions used for valuationÂ Â Â Risk-free interest rate (4/2022 â€“ 8/2022)Â Â 1.99%Â Risk-free interest rate (9/2022 â€“ 12/2022)Â Â 3.67%Â Dividend yieldÂ Â â€“Â Expected termÂ Â 6-8 yearsÂ Expected volatilityÂ Â 66.35%Â Â Â Â Â F-26Â Â Â Nocimed, Inc. 2015 Stock PlanÂ The Company maintains the Nocimed, Inc. 2015 StockPlan, or the â€œExisting Planâ€, under which the Company could grant 152,558 shares (after giving effect to the 2024 Stock Split)or options of the Company to our employees, consultants, and other service providers. The Company suspended the Existing Plan in connectionwith the April 2022, initial public offering. The Company did not grant any stock options under the Existing Plan for the twelve monthsended December 31, 2022. No further awards will be granted under the Existing Plan, but awards granted prior to the suspension date willcontinue in accordance with their terms and the terms of the Existing Plan.Â Determining Fair Value of Stock OptionsÂ The fair value of each grant of stock optionswas determined by the Company using the methods and assumptions discussed below. Each of these inputs is subjective and generally requiressignificant judgment to determine.Â Valuation and Amortization Method â€”TheCompany estimates the fair value of its stock options using the Black-Scholes-Merton option-pricing model. This fair value is then amortizedover the requisite service periods of the awards.Â Expected Termâ€”The Company estimatesthe expected term of stock option by taking the average of the vesting term and the contractual term of the option, as illustrated bythe simplified method.Â Expected Volatilityâ€”The expectedvolatility is derived from the Companyâ€™s expectations of future market volatility over the expected term of the options.Â Risk-Free Interest Rateâ€”The risk-freeinterest rate is based on the U.S. Treasury yield curve on the date of grant.Â Dividend Yieldâ€”The dividend yieldassumption is based on the Companyâ€™s history and expectation of no dividend payouts.Â Stock Award Activity Â A post-split summary of option activity underthe Companyâ€™s equity incentive plans is as follows: Schedule of option activityÂ Â Â Â Â Â Â Â Â Â Â Â Â Options Outstanding Â Â Weighted- Average Exercise PriceÂ Â Weighted- Average Remaining Contractual Life (In Years)Â Balance at December 31, 2021Â Â 140,980 Â Â $29.47Â Â Â 9.2Â Options grantedÂ Â 33,334 Â Â $36.80Â Â Â 9.6Â Options exercisedÂ Â â€“ Â Â Â Â Â Â Â Â Â Options forfeited/expiredÂ Â (3,138) Â $20.32Â Â Â 5.6Â Balance at December 31, 2022Â Â 171,176 Â Â Â 31.07Â Â Â 8.4Â Options grantedÂ Â â€“ Â Â Â Â Â Â Â Â Â Options exercisedÂ Â â€“ Â Â Â Â Â Â Â Â Â Options forfeited/expiredÂ Â (1,720) Â $23.64Â Â Â 6.0Â Balance at December 31, 2023Â Â 169,456 Â Â $31.15Â Â Â 7.5Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Exercisable at December 31, 2023Â Â 147,977 Â Â $30.57Â Â Â 7.4Â Â Â Â Â Â F-27Â Â Â The aggregate intrinsic value in the table aboveof the unexercised options reflects the total pre-tax intrinsic value (the difference between the Nasdaq closing price on December 30,2023, and the exercise price of the options that would have been received by option holders if all options exercisable had been exercised.Â Â The aggregate intrinsic value of options outstandingat December 31, 2023 is $0. The aggregate intrinsic value of vested and exercisable options at December 31, 2022 is $0.Â As of December 31, 2023, there was approximately$327,853 of total unrecognized compensation cost related to non-vested stock options, which is expected to be recognized over the next21 months.Â The Company adjusts expense for actual forfeituresin the periods they occur.Â Restricted Stock Units Â During the twelve month period endingDecember 31, 2023, 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 RSUs for 26,506common shares (after giving effect to the 2024 Stock Split).Â Post-split RSU activity under the 2022 Plan wasas follows for the year ended December 31, 2023: Schedule of RSU activity Â Â Â Â Â Â Â Â Â Â RSUâ€™s Outstanding Â Â Weighted-Average Grant-Date Fair value per Unit Â Nonvested as of December 31, 2021 Â Â â€“ Â Â $ â€“ Â Granted Â Â 30,120 Â Â Â 13.12 Â Vested Â Â (3,864) Â Â 13.92 Â Forfeited Â Â â€“ Â Â Â â€“ Â Nonvested as of December 31, 2022 Â Â 26,256 Â Â Â 13.12 Â Granted Â Â 26,506 Â Â Â 8.52 Â Vested Â Â (22,936) Â Â 10.40 Â Forfeited Â Â (14,077) Â Â 10.11 Â Nonvested as of December 31, 2023 Â Â 15,749 Â Â $ 10.72 Â Â The grant date fair value for a RSU is the marketprice of the common stock on the date of grant. The total fair value of RSUs vested during 2023 was $226,918.Â As of December 31, 2023, there was approximately$43,468 total unrecognized compensation cost related to non-vested RSUs, which is expected to be recognized over the next nine months.Â Common Stock Subject to VestingÂ The Company entered into a contract for consultingservices shortly after the completion of the IPO in April 2022. The contract included a fee payable in the form of 40,000 (2,500 aftergiving effect to the 2024 Stock Split) restricted common shares that vested over six months. The shares were issued in November 2022after the shares vested. Stock-based vendor payments of $102,000 were recognized on the date of grant and recorded as general and administrativeexpense.Â Â Â Â Â F-28Â Â Â Stock-based Compensation ExpenseÂ The following table summarizes the total stock-basedcompensation expense included in the Companyâ€™s statements of operations for the periods presented: Schedule of stock-based compensation expenseÂ Â Â Â Â Â Â December 31,Â Â Â Â Â Â 2022Â Â Â 2023Â Â (restated)Â Sales and marketingÂ $228,437Â Â $57,298Â Research and developmentÂ Â 9,725Â Â Â (259) General and administrativeÂ Â 217,839Â Â Â 1,129,619Â Total stock-based compensationÂ $456,001Â Â $1,186,658Â Â Â NOTE 16. INCOME TAXESÂ The Company accounts for income taxes under ASC740-10, which provides for an asset and liability approach of accounting for income taxes. Under this approach, deferred tax assets andliabilities are recognized based on anticipated future tax consequences, using currently enacted tax laws, attributed to temporary differencesbetween the carrying amounts of assets and liabilities for financial reporting purposes and the amounts calculated for income tax purposes.Â A reconciliationof the federal income tax rates to the Companyâ€™s effective tax rates for the year ended December 31, 2023 consist ofthe following:

Schedule of reconciliationof the federal income tax ratesÂ Â Â Â Â Â Â 2023Â Â U.S. federal statutory rateÂ Â 21.0Â % Â Effects of:Â Â Â Â Â State taxes, net of federal benefitÂ Â 7.0Â % Â Stock based compensationÂ Â (0.6)% Â Permanent differencesÂ Â (0.3)% Â OtherÂ Â (0.3)% Â Change in valuation allowanceÂ Â (26.8)% Â Effective rateÂ Â â€“Â % Â Â Significantcomponents of the Companyâ€™s deferred tax assets as of December 31, 2023 are summarized below. Schedule of deferred tax assetsÂ Â Â Â Â Â Â 2023Â Â Deferred tax asset:Â Â Â Â Â Net operating lossesÂ $9,235,000Â Â Stock based compensationÂ Â 479,000Â Â Total deferred tax assetÂ Â 9,714,000Â Â Less valuation allowanceÂ Â (9,714,000)Â Net deferred income tax liabilityÂ $â€“Â Â Â Â Â Â Â F-29Â Â Â The Company recognizesdeferred tax assets to the extent that it believes that these assets are more likely than not to be realized. In making such a determination,the Company considers all available positive and negative evidence, including future reversals of existing taxable temporary differences,projected future taxable income, tax-planning strategies, and results of recent operations. The Company assessed the need for a valuationallowance of $9,714,000 required as of December31, 2023, as the Company determined it is more likely than not the deferred tax assets will not be realized. Our net deferred tax assetand valuation allowance increased by $1,315,000for the year ended December 31, 2023. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income duringthe periods in which those temporary differences become deductible.Â The Company has evaluatedits income tax positions and has determined that it does not have any uncertain tax positions. The Company will recognize interest andpenalties related to any uncertain tax positions through its income tax expense.Â The Company files incometax returns in the U.S., Colorado, and California jurisdictions and is subject to examination by the various taxing authorities.Â NOTE 17. SUBSEQUENT EVENTSÂ ReverseStock SplitÂ In March 2023 the Companyâ€™s stockholdersapproved a reverse stock split proposal at a ratio in the range of one-for-five to one-for-fifty, with the final ratio to be determinedby the Company's board in its discretion without further approval from the Company's stockholders. In January 2024, the Company's boardapproved the final reverse stock split ratio of one-for-sixteen, which resulted in a reduction in the number of outstanding shares ofcommon stock and a proportionate increase in the value of each share. The common stock began trading on a reverse split-adjusted basison the NASDAQ on January 4, 2024.Â The following table presents selected shareinformation reflecting on a retroactive basis the reverse stock splits for the years ended December 31, 2023 and 2022:Â Â Â Year ended December 31, Â Â Â 2023 Â Â 2022 Â Weighted average shares outstanding, basic and diluted - pre-2024 split Â Â 8,908,934 Â Â Â 6,105,569 Â Weighted average shares outstanding, basic and diluted - post-2024 split Â Â 556,808 Â Â Â 381,598 Â Basic and diluted net loss per shares attributable to common stockholders - pre-2024 split Â $ (0.55) Â $ (1.23) Basic and diluted net loss per shares attributable to common stockholders - post-2024 split Â $ (8.82) Â $ (19.61) Â White Lion EquityLine AgreementÂ On October 9, 2023, theCompany entered into an equity line common stock purchase agreement (the â€œEquity Line Purchase Agreementâ€) and a related registrationrights agreement with White Lion Capital, LLC (â€œWhite Lionâ€). Pursuant to the Equity Line Agreement, the Company has the right,but not the obligation to require White Lion to purchase, from time to time, up to $10,000,000 in aggregate gross purchase price of newlyissued shares of the Companyâ€™s common stock, subject to certain limitations and conditions set forth in the Equity Line PurchaseAgreement.Â Pursuant to the EquityLine Purchase Agreement (see Note 13: Stockholders Equity), the Company issued to White Lion 452,343 newly issued post-split common sharesfor proceeds of $1,449,532, between January 4, 2024 and January 8, 2024. Through March 15, 2024, the Company has issued 750,000 shares(after giving effect to the 2024 Stock Split) to White Lion for total proceeds of $2,912,481.Â Â Â Â Â F-30Â Â Â ExchangeAgreements and Repayment of Unsecured Non-Convertible Notes Â In May, September and November 2023 the Company issued $2,594,118 aggregateprincipal amount of unsecured non-convertible notes to certain accredited investors.Â Between January 22 andJanuary 29, 2024, the Company entered into a series of exchange agreements (the â€œExchange Agreementsâ€) with the accreditedinvestors to exchange principal and accrued interest on these notes for shares of common stock. Pursuant to the Exchange Agreements, theCompany issued an aggregate of 644,142 post-split shares of common stock in exchange for $1,519,779 principal and accrued interest onthe notes. Following these exchanges, the remaining outstanding balance of principal and interest on the notes was $1,145,037.Â On March 6, 2024, theCompany paid $300,973 of principal and accrued interest on certain unsecured non-convertible notes. Following this payment, the remainingoutstanding balance of principal and interest on the notes was $898,380.Â The Company and the accreditedinvestors may elect in the future to effect additional exchanges of the notes for common stock. Any such future exchanges would be negotiatedand agreed to among the parties.Â Public Offering;Placement Agent Agreement; Warrants; Prefunded WarrantsÂ On February 26, 2024, the Company entered into a placement agency agreement(the â€œPlacement Agent Agreementâ€) with Maxim Group LLC (â€œMaximâ€ or the â€œPlacement Agentâ€) pursuantto which the Company engaged Maxim as the placement agent for a registered public offering by the Company (the â€œOfferingâ€),of an aggregate of 5,175,000 units (â€œUnitsâ€) at a price of $0.58 per Unit, for gross proceeds of approximately $3.0 million,and net proceeds of $2.7M after deducting expenses.Â Each Unit is comprised of (i) one share of common stock or, in lieuof common stock or one prefunded warrant to purchase a share of common stock, and (ii) two common warrants, each common warrant to purchasea share of common stock. The prefunded warrants are immediately exercisable at a price of $0.00001 per share of common stock and onlyexpire when such prefunded warrants are fully exercised. The common warrants are immediately exercisable at a price of $0.58 per shareof common stock and will expire five years from the date of issuance.Â The Company intends to use the proceeds from the Offering, togetherwith our existing cash, to fund clinical studies, repay outstanding debt, build out product platforms, expand our sales and marketingefforts, and for general and administration expenses and other general corporate purposes.Â The Offering closed on February 27, 2024.Â Nasdaq Delisting NoticesÂ As previously disclosed, the Company received written notice from Nasdaqon March 3, 2023, that the Company was not in compliance with Nasdaq Listing Rule 5550(b)(1) (the â€œEquity Ruleâ€), which requiresthe Company to maintain a minimum of $2.5 million in stockholdersâ€™ equity for continued listing on The Nasdaq Capital Market. Subsequentto a hearing before a Nasdaq Hearings Panel, the Company was granted an extension, ultimately, through February 27, 2024, to evidencecompliance with the Rule.Â As a result of the Offering described above, the Company received confirmationfrom Nasdaq on February 29, 2024, stating that the Company has regained compliance with the Equity Rule, as required by the Hearing Panelâ€™sdecision dated November 7, 2023. The Company will be subject to a Mandatory Panel Monitor for a period of one year. If, within that one-yearmonitoring period, Nasdaq finds the Company again out of compliance with the Equity Rule, the Company will not be permitted to providethe Staff with a plan of compliance with respect to that deficiency, and Staff will not be permitted to grant additional time for theCompany to regain compliance with respect to that deficiency, nor will the company be afforded an applicable cure or compliance period.Instead, Staff will issue a Delist Determination Letter, and the Company will have an opportunity to request a

new hearing with the initialHearings Panel, or a newly convened Hearings Panel if the initial Hearings Panel is unavailable. The Company will have the opportunityto respond and present to the Hearings Panel. The Companyâ€™s securities may be at that time delisted from Nasdaq.Â Â Â Â F-31Â Â Â Â Aclarion, Inc.Condensed Balance Sheets Â Â Â Â Â Â Â Â Â September 30, 2024Â Â December 31, 2023Â Â Â (Unaudited)Â Â Â Â ASSETSÂ Â Â Â Â Â Â Â Current assets:Â Â Â Â Â Â Â Â Cash and cash equivalentsÂ $1,312,098Â Â $1,021,069Â Restricted cashÂ Â 10,000Â Â Â 10,000Â Accounts receivable, netÂ Â 16,951Â Â Â 13,270Â Prepaids and other current assetsÂ Â 558,272Â Â Â 245,030Â Total current assetsÂ Â 1,897,321Â Â Â 1,289,369Â Â Â Â Â Â Â Â Â Â Non-current assets:Â Â Â Â Â Â Â Â Property and equipment, netÂ Â 892Â Â Â 1,782Â Intangible assets, netÂ Â 1,289,839Â Â Â 1,168,623Â Total non-current assetsÂ Â 1,290,731Â Â Â 1,170,405Â Â Â Â Â Â Â Â Â Â Total assetsÂ $3,188,052Â Â $2,459,774Â Â Â Â Â Â Â Â Â Â LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Current liabilities:Â Â Â Â Â Â Â Â Accounts payableÂ $331,765Â Â $760,535Â Accrued and other liabilitiesÂ Â 330,232Â Â Â 857,722Â Note payable, net of discountÂ Â â€“Â Â Â 1,125,724Â Warrant liabilityÂ Â 16,270Â Â Â 289,165Â Derivative liabilityÂ Â â€“Â Â Â 121,326Â Liability to issue equityÂ Â â€“Â Â Â 33,297Â Total current liabilitiesÂ Â 678,267Â Â Â 3,187,769Â Â Â Â Â Â Â Â Â Â Total liabilitiesÂ Â 678,267Â Â Â 3,187,769Â Â Â Â Â Â Â Â Â Â Stockholders' equity (deficit)Â Â Â Â Â Â Â Â Common stock - $0.00001 par value, 200,000,000 authorized and 10,044,728 and 825,459 shares issued and outstanding (see Note 11)Â Â 100Â Â Â 8Â Series B preferred stock - $0.00001 par value, 20,000,000 authorized and 930 and 0 shares issued and outstanding (see Note 11)Â Â â€“Â Â Â â€“Â Series C preferred stock - $0.00001 par value, 20,000,000 authorized and 1,000 and 0 shares issued and outstanding (see Note 11)Â Â â€“Â Â Â â€“Â Additional paid-in capitalÂ Â 51,782,424Â Â Â 43,553,523Â Accumulated deficitÂ Â (49,272,739)Â Â (44,281,526) Total stockholdersâ€™ equity (deficit)Â Â 2,509,785Â Â Â (727,995) Â Â Â Â Â Â Â Â Â Total liabilities and stockholdersâ€™ equity (deficit)Â $3,188,052Â Â $2,459,774Â Â See accompanying notes to condensed financial statements.Â Â Â Â F-32Â Â Â Aclarion, Inc.Condensed Statements of Operations (unaudited) Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Three Months Ended September 30,Â Â Nine Months Ended September 30,Â Â Â 2024Â Â 2023Â Â 2024Â Â 2023Â Â Â Â Â Â Â Â Â Â Â Â Â Â RevenueÂ Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â RevenueÂ $14,407Â Â $19,065Â Â $35,492Â Â $61,607Â Cost of revenueÂ Â 21,332Â Â Â 19,558Â Â Â 64,102Â Â Â 56,312Â Gross profit (loss)Â Â (6,925)Â Â (493)Â Â (28,610)Â Â 5,295Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Operating expenses:Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Sales and marketingÂ Â 232,775Â Â Â 192,896Â Â Â 638,869Â Â Â 577,969Â Research and developmentÂ Â 195,797Â Â Â 198,252Â Â Â 636,940Â Â Â 652,657Â General and administrativeÂ Â 860,461Â Â Â 770,534Â Â Â 2,402,408Â Â Â 2,524,308Â Total operating expensesÂ Â 1,289,033Â Â Â 1,161,682Â Â Â 3,678,217Â Â Â 3,754,934Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â (Loss) from operationsÂ Â (1,295,958)Â Â (1,162,175)Â Â (3,706,827)Â Â (3,749,640) Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Other income (expense):Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Interest expenseÂ Â (71,527)Â Â (166,332)Â Â (535,199)Â Â (214,850) Loss on exchange of debtÂ Â (6,585)Â Â â€“Â Â Â (1,073,317)Â Â â€“Â Loss on extinguishment of debtÂ Â â€“Â Â Â â€“Â Â Â (111,928)Â Â â€“Â Changes in fair value of warrant and derivative liabilitiesÂ Â 7,591Â Â Â 330,252Â Â Â 330,632Â Â Â 318,452Â Other, netÂ Â 303Â Â Â 245Â Â Â 93,284Â Â Â 11Â Total other income (expense)Â Â (70,218)Â Â 164,165Â Â Â (1,296,528)Â Â 103,613Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Income (loss) before income taxesÂ Â (1,366,176)Â Â (998,010)Â Â (5,003,355)Â Â (3,646,027) Income tax provisionÂ Â â€“Â Â Â â€“Â Â Â â€“Â Â Â â€“Â Net income (loss)Â $(1,366,176)Â $(998,010)Â $(5,003,355)Â $(3,646,027) Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Dividends accrued for preferred stockholdersÂ Â (12,142)Â Â â€“Â Â Â (12,142)Â Â â€“Â Net income (loss) allocable to common stockholdersÂ $(1,378,318)Â $(998,010)Â $(5,015,497)Â $(3,646,027) Net income (loss) per share allocable to common shareholdersÂ $(0.15)Â $(1.87)Â $(0.65)Â $(7.07) Weighted average shares of common stock outstanding, basic and dilutedÂ Â 9,437,871Â Â Â 532,928Â Â Â 7,699,173Â Â Â 515,975Â Â See accompanying notes to condensed financial statements.Â Â Â Â F-33Â Â Â Aclarion, Inc.Condensed Statements of Changes in Stockholders'Equity (Deficit)(Unaudited)Â Series A Â Â Series B Â Â Series C Â Â Â Preferred Stock Â Â Preferred Stock Â Â Preferred Stock Â Â Â Shares Â Â Value Â Â Shares Â Â Value Â Â Shares Â Â Value* Â Balance, December 31, 2022 Â Â â€“ Â Â $ â€“ Â Â Â â€“ Â Â $ â€“ Â Â Â â€“ Â Â $ â€“ Â Share-based compensation Â Â â€“ Â Â Â â€“ Â Â Â â€“ Â Â Â â€“ Â Â Â â€“ Â Â Â â€“ Â Proceeds from sale of Series A preferred stock Â Â 1 Â Â Â 1,000 Â Â Â â€“ Â Â Â â€“ Â Â Â â€“ Â Â Â â€“ Â Redemption of Series A Preferred stock Â Â (1) Â Â (1,000) Â Â â€“ Â Â Â â€“ Â Â Â â€“ Â Â Â â€“ Â Net income (loss) Â Â â€“ Â Â Â â€“ Â Â Â â€“ Â Â Â â€“ Â Â Â â€“ Â Â Â â€“ Â Balance, March 31, 2023 Â Â â€“ Â Â $ â€“ Â Â Â â€“ Â Â $ â€“ Â Â Â â€“ Â Â $ â€“ Â Share-based compensation Â Â â€“ Â Â Â â€“ Â Â Â â€“ Â Â Â â€“ Â Â Â â€“ Â Â Â â€“ Â Commitment shares - 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note financing Â Â 21,210 Â Â Â â€“ Â Â Â 175,619 Â Â Â â€“ Â Â Â 175,619 Â Issuance of warrants - note financing Â Â â€“ Â Â Â â€“ Â Â Â 37,500 Â Â Â â€“ Â Â Â 37,500 Â Net income (loss) Â Â â€“ Â Â Â â€“ Â Â Â â€“ Â Â Â (1,464,557) Â Â (1,464,557) Balance, June 30, 2023 Â Â 512,555 Â Â $ 5 Â Â $ 42,028,387 Â Â $ (42,018,169) Â Â 10,223 Â Share-based compensation Â Â â€“ Â Â Â â€“ Â Â Â 137,307 Â Â Â â€“ Â Â Â 137,307 Â Issuance of common shares Â Â 1,852 Â Â Â â€“ Â Â Â â€“ Â Â Â Â â€“ Â Â Â â€“ Â Issuance of warrants - note financing Â Â â€“ Â Â Â â€“ Â Â Â 22,500 Â Â Â â€“ Â Â Â 22,500 Â Net income (loss) Â Â â€“ Â Â Â â€“ Â Â Â â€“ Â Â Â (998,010)Â Â Â (998,010) Balance, Sept 30, 2023 Â Â 514,407 Â Â $ 5 Â Â $ 42,188,194 Â Â $ (44,281,526) Â $ (827,980)Â Balance, December 31, 2023 Â Â 825,459 Â Â $ 8 Â Â $ 43,553,524 Â Â $ (44,281,526) Â $ (727,995) Share-based compensation Â Â â€“ Â Â Â â€“ Â Â Â 85,827 Â Â Â â€“ Â Â Â 85,827 Â Issuance of common shares related to restricted stock units Â Â 4,261 Â Â Â â€“ Â Â Â â€“ Â Â Â â€“ Â Â Â â€“ Â Issuance of common shares - equity line of credit Â Â 452,343 Â Â Â 5 Â Â Â 1,449,527 Â Â Â â€“ Â Â Â 1,449,532 Â Issuance of commitment shares - note financing Â Â 9,312 Â Â Â â€“ Â Â Â 33,297 Â Â Â â€“ Â Â Â 33,297 Â Cashless exercise of pre-funded warrants Â Â 2,915 Â Â Â â€“ Â Â Â â€“ Â Â Â â€“ Â Â Â â€“ Â Issuance of common stock and warrants related to public offering, net issuance costs Â Â 5,175,000 Â Â Â 52 Â Â Â 2,691,339 Â Â Â â€“ Â Â Â 2,691,391 Â Public offering and line of credit issuance costs Â Â â€“ Â Â Â â€“ Â Â Â (399,106) Â Â â€“ Â Â Â (399,106) Issuance of common shares - debt for equity exchange Â Â 644,142 Â Â Â 6 Â Â Â 1,771,600 Â Â Â â€“ Â Â Â 1,771,606 Â Round up conversion related to reverse stock split Â Â 40,068 Â Â Â â€“ Â Â Â â€“ Â Â Â â€“ Â Â Â â€“ Â Net income (loss) Â Â â€“ Â Â Â â€“ Â Â Â â€“ Â Â Â (2,399,102) Â Â (2,399,102) Balance, March 31, 2024 Â Â 7,153,500 Â Â $ 72 Â Â $ 49,186,006 Â Â $ (46,680,628) Â Â 2,505,449 Â Share-based compensation Â Â â€“ Â Â Â â€“ Â Â Â 70,305 Â Â Â â€“ Â Â Â 70,305 Â Issuance of common shares related to restricted stock units Â Â 7,171 Â Â Â â€“ Â Â Â â€“ Â Â Â â€“ Â Â Â â€“ Â Issuance of common shares - equity line of credit Â Â 1,050,000 Â Â Â 10 Â Â Â 304,490 Â Â Â â€“ Â Â Â 304,500 Â Net income (loss) Â Â â€“ Â Â Â â€“ Â Â Â â€“ Â Â Â (1,238,077) Â Â (1,238,077) Balance, June 30, 2024 Â Â 8,210,671 Â Â $ 82 Â Â $ 49,560,800 Â Â $ (47,918,705) Â Â 1,642,177 Â Share-based compensation Â Â â€“ Â Â Â â€“ Â Â Â 74,706 Â Â Â â€“ Â Â Â 74,706 Â Issuance of common shares related to restricted stock units Â Â 9,057 Â Â Â â€“ Â Â Â â€“ Â Â Â â€“ Â Â Â â€“ Â Issuance of common shares related to RegA+ Â Â 1,825,000 Â Â Â 18 Â Â Â 451,953 Â Â Â â€“ Â Â Â 451,971 Â Issuance of B-Series Preferred Stock - debt for equity exchange Â Â â€“ Â Â Â â€“ Â Â Â 930,052 Â Â Â â€“ Â Â Â 930,052 Â B-Series Preferred Stock issuance costs Â Â â€“ Â Â Â â€“ Â Â Â (35,000) Â Â â€“ Â Â Â (35,000) C-Series Preferred Stock issuance costs Â Â â€“ Â Â Â â€“ Â Â Â (55,000) Â Â â€“ Â Â Â (55,000) Issuance of C-Series preferred stock Â Â â€“ Â Â Â â€“ Â Â Â 602,900 Â Â Â â€“ Â Â Â 602,900 Â Common stock issuance costs Â Â â€“ Â Â Â â€“ Â Â Â (210,228) Â Â â€“ Â Â Â (210,228) Issuance of C-Series warrants Â Â â€“ Â Â Â â€“ Â Â Â 397,100 Â Â Â â€“ Â Â Â 397,100 Â Issuance of RegA+ warrants Â Â â€“ Â Â Â â€“ Â Â Â 77,283 Â Â Â â€“ Â Â Â 77,283 Â Capitalization of B-Series preferred stock dividends Â Â â€“ Â Â Â â€“ Â Â Â (12,142) Â Â 12,142 Â Â Â â€“ Â Net income (loss) Â Â â€“ Â Â Â â€“ Â Â Â â€“ Â Â Â (1,366,176) Â Â (1,366,176) Balance, September 30, 2024 Â Â 10,044,728 Â Â $ 100 Â Â $ 51,782,424 Â Â $ (49,272,739) Â Â 2,509,785 Â Â Â See accompanying notes to condensed financial statements.Â Â Â Â F-35Â Â Â Aclarion, Inc.Condensed Statements of Cash Flows (unaudited) Â Â Â Â Â Â Â Â Â Nine Months Ended September 30,Â Â Â 2024Â Â 2023Â Cash flows from operating activitiesÂ Â Â Â Â Â Â Â Net income (loss)Â $(5,003,355)Â $(3,646,027) Â Â Â Â Â Â Â Â Â Adjustments to reconcile net income (loss) to net cash used in operating activities:Â Â Â Â Â Â Â Â Depreciation and amortizationÂ Â 140,893Â Â Â 120,886Â Share-based compensationÂ Â 230,837Â Â Â 356,469Â Loss on exchange of debtÂ Â 1,073,317Â Â Â â€“Â Loss on extinguishment of debtÂ Â 111,928Â Â Â â€“Â Amortization of deferred issuance costsÂ Â 502,516Â Â Â 156,159Â Change in fair value related to warrants and derivativeÂ Â (330,632)Â Â (318,452) Non-cash interest related to bridge fundingÂ Â 58,002Â Â Â 48,954Â Change in assets and liabilitiesÂ Â Â Â Â Â Â Â Accounts receivableÂ Â (2,351)Â Â (9,409) Prepaids and other current assetsÂ Â (329,306)Â Â 34,182Â Accounts payableÂ Â (443,068)Â Â 207,771Â Accrued and other liabilitiesÂ Â (326,399)Â Â 103,695Â

Note payable, net of discountÂ Â (31,129)Â Â 32,607Â Net cash (used in) operationsÂ Â (4,348,748)Â Â (2,913,165) Â Â Â Â Â Â Â Â Â Investing activitiesÂ Â Â Â Â Â Â Â Intangible assets - PatentsÂ Â (261,220)Â Â (85,603) Net cash (used in) investing activitiesÂ Â (261,220)Â Â (85,603) Â Â Â Â Â Â Â Â Â Financing activitiesÂ Â Â Â Â Â Â Â Issuance of common stock and warrants related to public offering, net deductionsÂ Â 2,691,391Â Â Â â€"Â Proceeds from equity lineÂ Â 1,754,032Â Â Â â€"Â Proceeds from common stock and warrant RegA+ offeringÂ Â 529,254Â Â Â â€"Â Proceeds from sales of C-Series preferred stock and warrantsÂ Â 1,000,000Â Â Â â€"Â Repayment of promissory notesÂ Â (300,973)Â Â â€"Â Common stock cash issuance costsÂ Â (714,332)Â Â â€"Â Preferred stock cash issuance costsÂ Â (35,000)Â Â â€"Â Bridge fund cash issuance costsÂ Â (23,375)Â Â (312,588) Proceeds from bridge fundingÂ Â â€"Â Â Â 2,000,000Â Proceeds from sale of Series A preferred stockÂ Â â€"Â Â Â 1,000Â Redemption of Series A Preferred stockÂ Â â€"Â Â Â (1,000) Net cash provided by financing activitiesÂ Â 4,900,996Â Â Â 1,687,412Â Â Â Â Â Â Â Â Â Â Net increase (decrease) in cash and cash equivalentsÂ Â 291,028Â Â Â (1,311,356) Cash, cash equivalents and restricted cash, beginning of periodÂ Â 1,031,069Â Â Â 1,482,806Â Cash, cash equivalents and restricted cash, end of periodÂ $1,322,098Â Â $171,450Â Â Â Â Â Â Â Â Â Â Non-cash activitiesÂ Â Â Â Â Â Â Â Dividends accrued on preferred sharesÂ Â 12,142Â Â Â â€"Â Exchange of indebtedness for preferred sharesÂ Â 930,052Â Â Â â€"Â Issuance of common shares in exchange for debtÂ Â 1,771,606Â Â Â â€"Â Issuance of bridge fund commitment sharesÂ Â 33,297Â Â Â â€"Â Accrued issuance costs related to preferred stockÂ Â 55,000Â Â Â â€"Â Accrued issuance costs related to common stockÂ Â 94,733Â Â Â â€"Â Designation of prepaid expenses to common stock issuance costsÂ Â 919,439Â Â Â â€"Â Issuance of common shares related to restricted stock unitsÂ Â 216,397Â Â Â â€"Â Fair value of warrants and derivative related to bridge fundingÂ Â â€"Â Â Â 896,798Â Accrued debt issuance costs related to bridge fundingÂ Â â€"Â Â Â 16,225Â Issuance of warrants related to bridge fundingÂ Â â€"Â Â Â 60,000Â Issuance of commitment shares related to bridge fundingÂ Â â€"Â Â Â 175,619Â Original issue discount (15%) related to bridge fundingÂ Â â€"Â Â Â 300,000Â Â See accompanying notes to condensed financial statements.Â Â Â Â F-36Â Â Â Aclarion, Inc.Notes to Condensed Financial Statements (unaudited)Â Â NOTE 1. THE COMPANY AND BASIS OFPRESENTATIONÂ The CompanyÂ Aclarion, Inc., formerly Nocimed, Inc., (the â€œCompanyâ€or â€œAclarionâ€) is a healthcare technology company that leverages magnetic resonance spectroscopy (â€œMRSâ€), anda proprietary biomarker to optimize clinical treatments. The Company was formed in February 2015, is incorporated in Delaware, and hasits principal place of business in Broomfield, Colorado.Â Basis of PresentationÂ The accompanying condensed financial statements havebeen prepared in accordance with generally accepted accounting principles in the United States of America (â€œGAAPâ€) and pursuantto the rules and regulations of the Securities and Exchange Commission (â€œSECâ€) for interim financial information. Accordingly,they do not include all of the information required by U.S. GAAP for complete financial statements. The interim condensed financial statementsreflect all adjustments that are of a normal recurring nature and that are considered necessary for a fair representation of the resultsfor the periods presented and should be read in conjunction with the audited financial statements and notes thereto for the year endedDecember 31, 2023, which include a complete set of footnote disclosures, including our significant accounting policies. The December 31,2023, condensed balance sheet was derived from the December 31, 2023, audited financial statements. They should be read in conjunctionwith the financial statements and notes thereto included in our Annual report on Form 10-K, filed with the SEC on March 28, 2024. Theresults for interim periods are not necessarily indicative of the results that may be expected for a full fiscal year or for any otherfuture period.Â ReclassificationsÂ Certain financing activities stated in the CondensedStatements of Cash Flows in the Quarterly Report on Form 10-Q reporting the six-month period ending June 30, 2024, have been reclassifiedto conform to the current periodâ€™s presentation.Â In the Quarterly Report on Form 10-Q for the six-monthperiod ending June 30, 2024, the Condensed Statements of Cash Flows included separate line items to report cash issuance costs relatedto our common stock fund raising activities, the equity line ($262,744) and public offering ($256,094). In this Quarterly Report on Form 10-Qfor the nine-month period ending September 30, 2024, the Condensed Statements of Cash Flows include one line item to report cumulativecash issuance costs for all common stock financing activities in the period.Â This reclassification had no effect on the netincome or net assets as previously reported.Â Risks and UncertaintiesÂ The Company is subject to various risks and uncertaintiesfrequently 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, andmanagement of potential rapid growth. To address these risks, the Company must, among other things, develop its customer baseÍ¾ implementand successfully execute its business and marketing strategyÍ¾ develop follow-on productsÍ¾ provide superior customer serviceÍ¾and attract, retain, and motivate qualified personnel. There can be no guarantee that the Company will be successful in addressing theseor other such risks.Â 2024 Reverse Stock SplitÂ In March 2023 the Companyâ€™s stockholders approveda reverse stock split proposal at a ratio in the range of one-for-five to one-for-fifty, with the final ratio to be determined by theCompany's board in its discretion without further approval from the Company's stockholders. In January 2024, the Company's board subsequentlyapproved the final reverse stock split ratio of one-for-sixteen (the â€œ2024 Stock Splitâ€), which resulted in a reduction inthe number of outstanding shares of common stock, warrants, stock options and restricted share units and a proportionate increase in thevalue of each share or strike price of the warrants and stock options. The common stock began trading on a reverse split-adjusted basison the NASDAQ on January 4, 2024.Â As a result of the 2024 Stock Split, unless describedotherwise, all references to common stock, share data, per share data and related information contained in these financial statementshave been retrospectively adjusted to reflect the effect of the stock splits for all periods presented. In addition, any fractional sharesthat would otherwise be issued as a result of the stock splits were rounded up to the nearest whole share. Further, the number of sharesissuable and exercise prices of stock options and warrants have been retrospectively adjusted in these financial statements for all periodspresented to reflect the 2024 Stock Split.Â Â Â Â F-37Â Â Â The following tables present selected share informationreflecting on a retroactive basis the reverse stock splits as of and for the year ended December 31, 2023: Schedule of equity statement informationÂ Â Â Â Â December 31,Â Â Â 2023Â Common shares issued and outstanding - pre-2024 split, 13,206,229 sharesÂ $132Â Common shares issued and outstanding - post-2024 split, 825,459 sharesÂ $8Â Additional paid-in capital - pre-2024 splitÂ $43,553,399Â Additional paid-in capital - post-2024 splitÂ $43,553,523Â Schedule of share information reflecting on a retroactive basis the reverse stock splitsÂ Â Â Â Â Year ended December 31,Â Â Â 2023Â Weighted average shares outstanding, basic and diluted - pre-2024 splitÂ Â 8,908,934Â Weighted average shares outstanding, basic and diluted - post-2024 splitÂ Â 556,808Â Basic and diluted net loss per shares attributable to common stockholders - pre-2024 splitÂ $(0.55) Basic and diluted net loss per shares attributable to common stockholders - post-2024 splitÂ $(8.82) Â Nasdaq $1.00Minimum Bid Price NoticeÂ On April 8, 2024, we received a written notice (the

â€œBid PriceNoticeâ€) from the Listing Qualifications Department of The Nasdaq Stock Market (â€œNasdaqâ€) indicating that the Companywas not in compliance with the $1.00 minimum bid price requirement set forth in Nasdaq Listing Rule 5550(a)(2) for continued listing onThe Nasdaq Capital Market (the â€œBid Price Requirementâ€).Â The Bid Price Notice did not result in the immediate delisting of the Companyâ€™scommon stock from The Nasdaq Capital Market.Â The Nasdaq Listing Rules require listed securities to maintain a minimumbid price of $1.00 per share and, based upon the closing bid price of the Companyâ€™s common stock for the 30 consecutive businessdays for the period ending April 5, 2024, the Company no longer met this requirement.Â The Notice indicated that the Company will beprovided 180 calendar days (or until October 7, 2024) in which to regain compliance. We did not regain compliance with Rule 5550(a)(2)prior to the expiration of the initial 180 calendar day period on October 7, 2024. On October 8, 2024, we received from the Nasdaq staff(the â€œStaffâ€) written notification that our securities are subject to delisting from the Nasdaq Capital Market. We had anappeal hearing on October 10, 2024 before a Nasdaq hearings panel (the â€œPanelâ€) appeal the delisting notice from the Staff.While the appeal process is pending, the suspension of trading of our common stock will be stayed. Our common stock will continue to tradeon Nasdaq until the hearing process concludes and the Panel issues a written decision. The Panel has granted the Company an extensionuntil January 31, 2025 to demonstrate compliance with the Bid Price Requirement.Â At the Companyâ€™s special stockholdersâ€™ meeting on September23, 2024, the Companyâ€™s stockholders approved a proposal to grant discretionary authority to our board of directors to (i) amendour certificate of incorporation to combine outstanding shares of our common stock into a lesser number of outstanding shares, or a â€œreversestock split,â€ at a specific ratio within a range of one-for-five (1-for-5) to a maximum of a one-for-fifty (1-for-50) split, withthe exact ratio to be determined by our board of directors in its sole discretion; and (ii) effect the reverse stock split, if at all,within one year of the date the proposal was approved by stockholders. The Company intends to implement a reverse stock split in the nearfuture in order to assist with the Companyâ€™s compliance with Nasdaqâ€™s Bid Price Requirement.Â Â Â Â Â F-38Â Â Â Nasdaq Stockholder Equity NoticeÂ On August 22, 2024, the Company received a letterfrom Nasdaq indicating that that the Company was not in compliance with the requirement to have at least $2,500,000 in stockholdersâ€™equity (the â€œStockholdersâ€™ Equity Requirementâ€). In its quarterly report on Form 10-Q for the period ended June 30,2024, the Company reported stockholdersâ€™ equity of $1,642,177, and, as a result, did not satisfy Listing Rule 5550(b)(1).Â Accordingly, the Staff determined to delist ourcommon stock from Nasdaq. Nasdaqâ€™s letter provided the Company until August 29, 2024 to request an appeal of this determination.The Company requested a hearing before the Panel to appeal the delisting notice from the Staff. The hearing request stays any suspensionor delisting action pending the conclusion of the hearing process and the expiration of any additional extension period granted by thePanel following the hearing.Â We had an appeal hearing on October 10, 2024 beforethe Panel to appeal the delisting notice from the Staff. The Panel granted the Company an extension until January 31, 2025 to demonstratecompliance with the Stockholders' Equity Requirement. While the appeal process is pending, the suspension of trading of the Companyâ€™scommon stock will be stayed. Our common stock will continue to trade on Nasdaq until the hearing process concludes and the Panel issuesits final written determination.Â The Company intends to take all reasonable measuresavailable to regain compliance under the Nasdaq Listing Rules and remain listed on Nasdaq. The Company is currently evaluating its availableoptions to resolve the deficiency and regain compliance with the Nasdaq minimum stockholdersâ€™ equity requirement.Â NOTE 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIESÂ Use of EstimatesÂ The preparation of financial statements in conformitywith accounting principles generally accepted in the United States of America requires management to make estimates and assumptions thataffect the reported amounts of assets and liabilities and disclosures of contingent assets and liabilities at the date of the financialstatements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.Â The financial statements include some amounts thatare based on management's best estimates and judgments. The most significant estimates relate to depreciation, amortization, and valuationof warrants, warrant and derivative liabilities, and options to purchase shares of the Company's common stock. These estimates may beadjusted as more current information becomes available, and any adjustment could be significant.Â Valuation of Derivative InstrumentsÂ Financial Accounting Standards Board (â€œFASBâ€)Accounting Standards Codification (â€œASCâ€) 815-40, Derivatives and Hedging: Contracts on an Entityâ€™s Own Equity,addresses whether an equity-linked contract qualifies as equity in the entityâ€™s financial statements. Agreements where an entityhas insufficient authorized and unissued shares to settle the contract generally are accounted for as a liability and marked to fair valuethrough earnings each reporting period. The Company evaluates its financial instruments to determine if such instruments are liabilitiesor contain features that qualify as embedded derivatives. For financial instruments that are accounted for as liabilities, the derivativeinstrument is initially recorded at its fair value and is then revalued at each reporting date, with changes in the fair value reportedas charges or credits to income.Â Â Â Â F-39Â Â Â Fair Value of Financial InstrumentsÂ ASC 820, Fair Value Measurements, provides guidanceon the development and disclosure of fair value measurements. Under this accounting guidance, fair value is defined as an exit price,representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between marketparticipants at the measurement date. As such, fair value is a market-based measurement that should be determined based on assumptionsthat market participants would use in pricing an asset or a liability.Â The accounting guidance classifies fair value measurementsin one of the following three categories for disclosure purposes:Â Level 1 - Unadjusted quoted pricesin active markets for identical instruments that are accessible by the Company on the measurement date.Â Level 2 - Quoted prices in marketsthat are not active or inputs which are either directly or indirectly observable.Â Level 3 - Unobservable inputs forthe instrument requiring the development of assumptions by the Company.Â The Company analyzes all financial instruments withfeatures of both liabilities and equity under the Financial Accounting Standard Boardâ€™s (â€œFASBâ€) accounting standardfor such instruments. Under this standard, financial assets and liabilities are classified in their entirety based on the lowest levelof input that is significant to the fair value measurement.Â The carrying values of the Companyâ€™s financialinstruments including cash equivalents, restricted cash, accounts receivable, and accounts payable are approximately equal to their respectivefair values due to the relatively short-term nature of these instruments. The Companyâ€™s warrant liabilities and derivative liabilitiesare estimated using level 3 inputs (see Note 3).Â Derivative Financial InstrumentsÂ The Company has derivative financial instruments thatare not hedges and do not qualify for hedge accounting. Changes in the fair value of these instruments are recorded in other income (expenses),on a net basis in the Consolidated Statements of Operations.Â Cash and Cash EquivalentsÂ The Company considers all highly liquid instrumentspurchased with an original maturity of three months or less to be cash equivalents. The Company had no cash equivalents at September 30,2024 and December 31, 2023. The Company maintains cash deposits at several financial institutions, which are insured by the FDIC up to$250,000. The

Companyâ€™s cash balance may at times exceed these limits. On September 30, 2024, and December 31, 2023, the Companyhad $973,093 and $761,800, respectively, in excess of federally insured limits. The Company continually monitors its positions with, andthe credit quality of, the financial institutions with which it invests. The Company maintains no international bank accounts. As of September30, 2024, $10,000 of the Companyâ€™s cash was restricted as collateral related to the credit card program offered by our bank.Â Accounts Receivable, Less Allowance for DoubtfulAccountsÂ The Company estimates an allowance for doubtful accountsbased upon an evaluation of the current status of receivables, historical experience, and other factors as necessary. It is reasonablypossible that the Companyâ€™s estimate of the allowance for doubtful accounts will change. The allowance for doubtful accounts was$0 on September 30, 2024, and December 31, 2023.Â Â Â Â F-40Â Â Â Revenue RecognitionÂ Revenues are recognized when a contract with a customerexists, and at that point in time when we have delivered a Nociscan report to our customer. Revenue is recognized in the amount that reflectsthe negotiated consideration expected to be received in exchange for those reports. Following the delivery of the report, the companyhas 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 schedulesin its sales arrangements. Payment terms range generally from 30 to 90 days from the date of invoice.Â Liquidity, Capital Resources and Going ConcernÂ The Company believes that the net proceeds from thecommon shares offered at-the-market in August 2024 and the issuance of C-Series preferred stock in September 2024 will be sufficient tofund current operating plans into December 2024. 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 tocontinue funding our technology development. Management plans to secure such additional funding.Â As a result of the Companyâ€™s recurring lossesfrom operations and the need for additional financing to fund its operating and capital requirements, there is uncertainty regardingthe Companyâ€™s ability to maintain liquidity sufficient to operate its business effectively, which raises substantial doubt as tothe Companyâ€™s ability to continue as a going concern.Â Share-Based CompensationÂ The Company accounts for stock-based awards in accordancewith provisions of ASC Topic 718, Compensationâ€”Stock Compensation, under which the Company recognizes the grant-date fair valueof stock-based awards issued to employees and nonemployee board members as compensation expense on a straight-line basis over the vestingperiod of the award, while awards containing a performance condition are recognized as expense when the achievement of the performancecriteria is achieved. The Company uses the Black-Scholes-Merton option pricing model to determine the grant-date fair value of stock options.The Company records expense for forfeitures in the periods they occur.Â The exercise or strike price of each option is notless than 100% of the fair market value of the Common Stock subject to the option on the date the option is granted.Â The Company issues restricted stock unit awards tonon-employee consultants who are providing various services. The awards are valued at the market price on the date of the grant. The awardsvest over the contract life and based on achievement of targeted performance milestones.Â On occasion, the Company grants common stock to compensatevendors for services rendered.Â DeferredFinancing CostsÂ 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 financingsare completed. Upon the completion of an equity financing, these costs are recorded as a reduction of additional paid-in capital of therelated offering. Approximately $543,500 of issuance costs related to the public offering in February 2024 were reclassified to additionalpaid-in capital ($310,100 deducted from proceeds, and $239,400 paid in cash). During the nine months ended September 30, 2024, approximately$375,939 of costs related to all other common stock issuances, and $90,000 of costs related to preferred stock issuances were reclassifiedto additional paid-in capital.Â Â Â Â F-41Â Â Â Emerging Growth Company StatusÂ The Company is an emerging growth company, as definedin the Jumpstart Our Business Startups Act of 2012 (the â€œJOBS Actâ€). Under the JOBS Act, emerging growth companies can delaythe adoption of new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standardsapply to private companies. The Company has elected to use this extended transition period to comply with certain new or revised accountingstandards that have different effective dates for public and private companies.Â NOTE 3. FAIR VALUE MEASUREMENTSÂ In accordance with ASC 820 (Fair Value Measurementsand Disclosures), the Company uses various inputs to measure the outstanding warrants, certain embedded redemption features associatedwith the senior note to Aclarion, Inc. on a recurring basis to determine the fair value of the liability. Schedule of recurring basis to determine the fair value of the liabilityÂ Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Fair value measured as of September 30, 2024Â Â Â Fair value on September 30, 2024Â Â Quoted prices in active markets (Level 1)Â Â Significant other observable inputs (Level 2)Â Â Significant unobservable inputs (Level 3)Â Warrant liabilityÂ $16,270Â Â $â€“Â Â $â€“Â Â $16,270Â Derivative LiabilityÂ Â â€“Â Â Â â€“Â Â Â â€“Â Â Â â€“Â Total Fair valueÂ $16,270Â Â $â€“Â Â $â€“Â Â $16,270Â Â There were no transfers between Level 1, 2, and 3during the nine months ended September 30, 2024.Â Â The following table presents changes in Level 3 liabilitiesmeasures at fair value for the nine months ended September 30, 2024. Both observable and unobservable inputs were used to determine thefair value positions that the Company has classified within the Level 3 category. Schedule of liabilities measures at fair valueÂ Â Â Â Â Â Â Â Â Â Â Â Â Â Â Warrant LiabilityÂ Â Derivative LiabilityÂ Â TotalÂ Balance â€“ December 31, 2023Â $289,165Â Â $121,326Â Â $410,491Â Exchange and Payoff of Notes PayableÂ Â â€“Â Â Â (63,589)Â Â (63,589) Change in fair valueÂ Â (272,895)Â Â (57,737)Â Â (330,632) Balance â€“ September 30, 2024Â $16,270Â Â $â€“Â Â $16,270Â Â The fair value of the embedded derivative liabilitiesassociated with the Senior Notes Payable was estimated using a probability weighted discounted cash flow model to measure the fair value.This involves significant Level 3 inputs and assumptions including an (i) estimated probability and timing of certain financing eventsand event of default, and (ii) the Companyâ€™s risk-adjusted discount rate.Â The fair value of the warrants to purchase sharesof common stock was estimated using a Monte Carlo simulation using the following assumptions. Schedule of assumptions Â Â Â Â Â Â Â Â Â Â Â As of Dec 31, 2023 Â Â As of Sept 30, 2024 Â Â Â Warrant Liability Â Â Warrant Liability Â Strike Price Â $ 4.32 Â Â $ 0.29 Â Contractual term (years) Â Â 5.0 Â Â Â 5.0 Â Volatility (annual) Â Â 80.0% Â Â Â 120.0% Â Risk-free rate Â Â 3.89% Â Â Â 3.58-4.44% Â Floor Financing price Â $ 2.24 Â Â $ 0.14 Â Â Â Â Â Â Â F-42Â Â Â NOTE 4. RECENT ACCOUNTINGPRONOUNCEMENTSÂ To date, there have been no recent accounting pronouncementsnot yet effective that have significance, or potential significance, to our Consolidated Financial Statements.Â NOTE 5. REVENUEÂ Contract BalancesÂ The timing of revenue recognition, billings, andcash collections may result in trade, unbilled receivables, and deferred revenues on the balance sheets. At times, revenue recognitionmay occur before the billing, resulting in an unbilled receivable, which would represent a contract asset. The contract asset would bea component of accounts receivable and other assets for the current and non-current

portions, respectively. In the event the Companyreceives advances or deposits from customers before revenue is recognized, this would result in a contract liability.Â NOTE 6. SUPPLEMENTAL FINANCIAL INFORMATIONÂ Balance SheetsÂ Prepaids and other current assets: Schedule of prepaid and other current assets Â Â Â Â Â Â Â Â September 30, 2024 Â Â December 31, 2023 Â Short term deposits Â $ 50,000 Â Â $ 50,000 Â Deferred offering costs Â Â 94,682 Â Â Â 100,588 Â Prepaid insurance D&O Â Â 169,011 Â Â Â 34,769 Â Prepaid insurance, other Â Â â€“ Â Â Â 17,884 Â Prepaid clinical costs Â Â 165,417 Â Â Â â€“ Â Prepaid exchange fees Â Â 30,883 Â Â Â â€“ Â Prepaid other Â Â 48,279 Â Â Â 41,635 Â Other receivables Â Â â€“ Â Â Â 154 Â Â Â $ 558,272 Â Â $ 245,030 Â Â Accounts payable Schedule of accounts payable Â Â Â Â Â Â Â Â September 30, 2024 Â Â December 31, 2023 Â Accounts payable Â $ 331,793 Â Â $ 758,821 Â Credit cards payable Â Â (28)Â Â Â 1,714 Â Â Â $ 331,765 Â Â $ 760,535 Â Â Accrued and other liabilities: Schedule of accrued and other liabilities Â Â Â Â Â Â Â Â September 30, 2024 Â Â December 31, 2023 Â Accrued payroll Â $ â€“ Â Â $ 162,887 Â Accrued bonus Â Â 126,425 Â Â Â 262,580 Â D&O financing Â Â 32,052 Â Â Â â€“ Â Accrued audit and legal expenses Â Â 81,490 Â Â Â 89,082 Â Accrued interest Â Â â€“ Â Â Â 98,685 Â Accrued board compensation Â Â 46,250 Â Â Â 92,500 Â Other accrued liabilities Â Â 44,015 Â Â Â 151,988 Â Â Â $ 330,232 Â Â $ 857,722 Â Â Â Â Â F-43Â Â Â NOTE 7. LEASESÂ The Company had no office lease for the quarter endedSeptember 30, 2024, and the year ended December 31, 2023.Â NOTE 8. INTANGIBLE ASSETSÂ The Companyâ€™s intangible assets are as follows: Schedule of intangible assets Â Â Â Â Â Â Â Â September 30, 2024 Â Â December 31, 2023 Â Patents and licenses Â $ 2,528,470 Â Â $ 2,267,251 Â Other Â Â 5,017 Â Â Â 5,017 Â Â Â Â Â 2,533,487 Â Â Â 2,272,268 Â Less: accumulated amortization Â Â (1,243,648)Â Â Â (1,103,645) Intangible assets, net Â $ 1,289,839 Â Â $ 1,168,623 Â Â Patents and licenses costs are accounted for asintangible assets and amortized over the life of the patent or license agreement and charged to research and development.Â Amortization expense related to purchased intangibleassets was $49,732 and $40,797 for the three months ended September 30, 2024, and 2023, respectively. Amortization expense related topurchased intangible assets was $140,003 and $119,602 for the nine months ended September 30, 2024, and 2023, respectively.Â Patents and trademarks are reviewed at least annuallyfor impairment. No impairment was recorded through September 30, 2024, and December 31, 2023, respectively.Â Future amortization of intangible assets is as follows: Schedule of future amortization of intangible assets Â Â Â Â 2024 Â $ 52,214 Â 2025 Â Â 208,857 Â 2026 Â Â 208,857 Â 2027 Â Â 208,857 Â 2028 and beyond Â Â 611,054 Â Total Â $ 1,289,839 Â Â NOTE 9. SHORT TERM NOTES ANDCONVERTIBLE DEBTÂ Â Convertible Notes:Â As of December 31, 2023, there were no ConvertibleNotes payable and outstanding. There was no convertible note activity in the three months ended September 30, 2024.Â Â Â Â F-44Â Â Â Senior Notes PayableÂ In May 2023, the Company issued $1,437,500unsecured senior notes with a maturity date of May16, 2024 (the â€œMay 2023 Notesâ€), for cash proceeds of $1,250,000.The May 2023 Notes contained an original issue discount of 15.0%and accrued interest at an annual rate of 8.0%.Â In September 2023, as agreed to during theissuance of the May 2023 Notes, the Company exercised their right to an additional financing, issuing $862,500unsecured senior notes that mature on September1, 2024 (the â€œSeptember 2023 Notesâ€) for cash proceeds of $750,000.The September 2023 Notes contained an original issue discount of 15.0%and accrued interest at an annual rate of 8.0%.Â In November 2023, the Company issued $294,118unsecured senior notes with a maturity date of April19, 2024 (the â€œNovember 2023 Notesâ€), for cash proceeds of $250,000.The November 2023 Notes contained an original issue discount of 15.0%and accrue interest at an annual rate of 8.0%.Â The Company incurred issuance costs, recorded as deferredfinancing costs, of $361,675 relating to due diligence and legal costs associated with the issuance of the May 2023 Notes, the September 2023 Notes, and the November2023 Notes (the â€œSenior Notesâ€).Â The Company evaluated the embedded redemptionand contingent interest features in Senior Notes to determine if such features were required to be bifurcated as an embeddedderivative liability. In accordance with ASC 815-40, Derivatives and Hedging Activities, the embedded redemption features andcontingent interest feature were accounted for as derivative liabilities at the date of issuance and shall be adjusted to fair valueat each reporting date. The Company fair valued such derivative liabilities and recorded a debt discount at issuance of the SeniorNotes of $320,561.Â The Company issued warrants to purchase 77,010and 46,556 shares of common stock (1,232,156 and 744,890 shares before giving effect to the 2024 Stock Split) to the holders of theMay 2023 Notes and November 2023 Notes (collectively the â€œSenior NotesWarrantsâ€) with an exercise price of $10.02 and $4.58 per share ($0.6262 and $0.2856 pre-2024 split), respectively. TheCompany accounted for the warrants in accordance with the guidance contained in ASC 815 â€œDerivatives and Hedgingâ€whereby under that provision these warrants did not meet the criteria for equity treatment and were recorded as a liability. Assuch, these warrants are recorded at fair value as of each reporting date with the change in fair value reported within other incomein the accompanying consolidated statements of operations as â€œChange in fair value of warrant liabilityâ€ until thewarrants are exercised, expired or other facts and circumstances lead the warrant liability to be reclassified tostockholdersâ€™ equity. The fair value of the Senior Notes Warrants at issuance was $736,249 and was recorded as a debtdiscount. The Company incurred issuance costs of $72,862 relating to the Senior Notes Warrants which was recorded as a day 1 expensedue to the liability classification of such warrants.Â In connection with the issuance of the May 2023Notes and November 2023 Notes, the Company paid a commitment fee in the form of 21,210 and 9,311 shares (339,360 and 148,978 shares beforegiving effect to the 2024 Stock Split) of unregistered common stock to the holders, respectively. The aggregate commitment fees had afair value at issuance of $208,916 and were recorded as a deferred financing cost.Â The resulting debt discounts from the derivative liabilities,warrant liabilities and deferred financing costs were presented as a direct deduction from the carrying amount of that debt liabilityand amortized to interest expense using the effective interest rate method. For the three months ended September 30, 2024, the Companyrecognized $60,226 in amortization of debt discounts and deferred financing costs which is recorded in interest expense.Â Between January 22 and January 29, 2024, theCompany entered into a series of exchange agreements (the â€œExchange Agreementsâ€) with the accredited investors toexchange principal and accrued interest on the May 2023 Notes for shares of common stock. Pursuant to the Exchange Agreements, theCompany issued an aggregate of 644,142post-split shares of common stock in exchange for $1,519,779principal and accrued interest on the May 2023 Notes. Following these exchanges, the remaining outstanding balance of principal andinterest on the Senior Notes was $1,145,037.This transaction accelerated the recognition of the related note discounts and resulted in a $1,066,732charge.Â Â Â Â F-45Â Â Â On March 6, 2024, the Company paid $300,973of principal and accrued interest on the November 2023 Notes. Following this payment, the remaining outstanding balance of principaland interest on Senior Notes was $898,380.This transaction accelerated the recognition of the related note discounts and resulted in a $111,928charge.Â On August 14, 2024, the Company entered into anexchange agreement (the â€œExchange Agreementâ€) with the accredited investors to exchange $930,052of principal and accrued interest on the September

2023 Notes for 930shares of newly issued Series B convertible preferred stock (â€œSeries B Preferred Stockâ€) at a purchase price of $1,000per share. The Series B Preferred Stock is convertible into Common Stock at an initial conversion price (â€œConversionPriceâ€) of $0.234per share. Following these exchanges, the remaining outstanding balance of principal and interest on the Senior Notes was $0.This transaction accelerated the recognition of the related note discounts and resulted in a $6,585charge.Â The following table reconciles the aggregate amountfor the Senior Notes as well as the unamortized deferred financing costs anddebt discounts relating to the derivative liabilities and warrant liabilities. Schedule of derivative liabilities and warrant liabilitiesÂ Â Â Â Â Â Â September 30, 2024Â Â December 31, 2023Â Note PayableÂ $â€“Â Â $2,594,118Â Less: Unamortized Discounts and Deferred Financing CostsÂ Â Â Â Â Â Â Â WarrantsÂ Â â€“Â Â Â (557,582) DerivativeÂ Â â€“Â Â Â (235,628) Deferred financing costsÂ Â â€“Â Â Â (675,184) Â Â Â â€“Â Â Â (1,468,394) Â Â $â€“Â Â $1,125,724Â Â NOTE 10.COMMITMENTS AND CONTINGENCIESÂ Royalty AgreementÂ The Company has an exclusive license agreementwith the Regents of the University of California to make, use, sell and otherwise distribute products under certain of the Regents ofthe University of Californiaâ€™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 yearin which the minimum payment was made. The license agreements expire upon expiration of the patents and may be terminated earlier if theCompany so elects. The U.S. licensed patents that are currently issued expire between 2026 and 2029, without considering any possiblepatent term adjustment or extensions and assuming payment of all appropriate maintenance, renewal, annuity, or other governmental fees.The Company recorded royalty costs of $12,500 for the three months ended September 30, 2024, and 2023, respectively, and $37,500 for thenine months ended September 30, 2024, and 2023, respectively, as Cost of Revenue.Â LitigationÂ To date, the Company has not been involved in legalproceedings arising in the ordinary course of its business. If any legal proceeding occurs, the Company will record a provision for aloss when it believes that it is both probable that a loss has been incurred and the amount can be reasonably estimated, although litigationis inherently unpredictable and is subject to significant uncertainties, some of which are beyond the Companyâ€™s control. Shouldany of these estimates and assumptions change or prove to have been incorrect, the Company could incur significant charges related tolegal matters that could have a material impact on its results of operations, financial position and cash flows.Â Â Â Â F-46Â Â Â NOTE 11. STOCKHOLDERSâ€™ EQUITYÂ The Company filed an Amended and Restated Certificateof Incorporation on April 21, 2022, as part of the Companyâ€™s initial public offering. The Company was authorized to issue two classesof stock to be designated, respectively, â€œcommon stockâ€ and â€œpreferred stock.â€ The total number of shares whichthe Company was authorized to issue was two hundred twenty million (220,000,000) shares. Two hundred million (200,000,000) shares wereauthorized to be common stock, having a par value per share of $0.00001. Twenty million (20,000,000) shares were authorized to be preferredstock, having a par value per share of $0.00001. As of September 30, 2024, the Company had 10,044,728 common shares outstanding.Â Reverse Stock SplitÂ The Company held a special meeting of stockholderson March 24, 2023. At the special meeting, our stockholders approved one proposal, which was to grant discretionary authority to our boardof directors to (i) amend our certificate of incorporation to combine outstanding shares of our common stock into a lesser number of outstandingshares, or a â€œreverse stock split,â€ at a specific ratio within a range of one-for-five (1-for-5) to a maximum of a one-for-fifty(1-for-50) split, with the exact ratio to be determined by our board of directors in its sole discretion; and (ii) effect the reversestock split, if at all, within one year of the date the proposal was approved by stockholders.Â In January 2024, the Company's board subsequentlyapproved the final reverse stock split ratio of one-for-sixteen (the â€œ2024 Stock Splitâ€), which resulted in a reduction inthe number of outstanding shares of common stock, warrants, stock options and restricted share units and a proportionate increase in thevalue of each share or strike price of the warrants and stock options. The common stock began trading on a reverse split-adjusted basison the NASDAQ on January 4, 2024.Â Public OfferingÂ On February 27, 2024, the Company completed a publicoffering of 5,175,000 units (â€œUnitsâ€) at a price of $0.58 per Unit, for gross proceeds of approximately $3.0 million, beforededucting offering expenses. Each Unit was comprised of (i) one share of common stock or, in lieu of common stock, one prefunded warrantto purchase a share of common stock, and (ii) two common warrants, each common warrant to purchase a share of common stock. The prefundedwarrants were immediately exercisable at a price of $0.00001 per share of common stock and only expire when such prefunded warrants arefully exercised. The common warrants were immediately exercisable at a price of $0.58 per share of common stock and will expire five yearsfrom the date of issuance.Â White Lion Equity Line AgreementÂ On October 9, 2023, the Company entered into anequity line common stock purchase agreement (the â€œEquity Line Purchase Agreementâ€) and a related registration rightsagreement with White Lion Capital, LLC (â€œWhite Lionâ€). Pursuant to the Equity Line Purchase Agreement, the Company hasthe right, but not the obligation to require White Lion to purchase, from time to time, up to $10,000,000in aggregate gross purchase price of newly issued shares of the Companyâ€™s common stock, subject to certain limitations andconditions set forth in the Equity Line Purchase Agreement.Â Pursuant to the Equity Line Purchase Agreement,the Company issued to White Lion 1,050,000 newly issued common shares for proceeds of $304,500 on April 26, 2024. Through September 30,2024, the Company has issued 1,800,000 shares to White Lion for total proceeds of $3,216,981.Â Series A Preferred StockÂ In February 2023 the Company sold one (1) share ofthe Companyâ€™s newly designated Series A preferred stock to Jeffrey Thramann, the Companyâ€™s Executive Chairman, for a purchaseprice of $1,000. The share of Series A preferred stock had proportional voting rights that were limited to the proposal to approve a reversestock split of the Companyâ€™s common stock. Following the March 24, 2023, special meeting, the Company redeemed the one outstandingshare of Series A preferred stock on March 28, 2023, in accordance with its terms. The redemption price was $1,000. No Series A preferredstock remains outstanding.Â Â Â Â F-47Â Â Â Series B Preferred StockÂ On August 14, 2024, the Company entered into anexchange agreement (the â€œExchange Agreementâ€) with accredited investors to exchange $930,052of principal and accrued interest on the September 2023 Notes for 930shares of newly issued Series B convertible preferred stock (â€œSeries B Preferred Stockâ€) at a purchase price of $1,000per share. The Series B Preferred Stock is convertible into Common Stock at an initial conversion price (â€œConversionPriceâ€) of $0.234per share.Â Cumulative preferred dividends capitalized as of September 30, 2024are $12,142.Â Series C Preferred Stock FinancingÂ On September 30, 2024, the Company entered into asecurities purchase agreement with accredited investors for a convertible preferred stock and warrants financing. The Company has received$1,000,000 of gross proceeds in connection with the closing of this financing. The Company issued 1,000 shares of Series C convertiblepreferred stock (â€œSeries C Preferred Stockâ€) at a purchase price of $1,000 per share of Series C Preferred Stock. The SeriesC Preferred Stock is convertible into Common Stock at an initial conversion price (â€œConversion Priceâ€) of $0.1759 per shareof Common Stock. The Company also issued warrants exercisable for

5,685,049 shares of Common Stock with a 5.5 year term and an initialexercise price of $0.1759 per share.Â The Preferred Stock key terms are summarizedas follows:Â Preference Amounts Â Issue Date Â Total Face Value of Investment Â Â Issue Purchase Price/Share Â Â Â Â Â Â Â Â Â Â Series B Preferred Stock Â 8/14/2024 Â $ 930,052 Â Â $ 1,000 Â Â·ranks senior to the Common Stock with respect to dividends and rights upon liquidationÂ·Stated value of $1,000 per preferred shareÂ·10% per annum dividend rate payable in cash or stock; Company has the option to cumulate or â€œcapitalizeâ€ or dividends,in which case the accrued dividend amount shall be added to the stated valueÂ·has a liquidation preference equal to the greater of (a) 125% of the applicable liquidation value and (b) the amount per share suchholder would receive if such holder converted the preferred shares into common stock immediately prior to the date of such paymentÂ·convertible into common stock at the option of the holder at an initial fixed conversion price of $0.234 per share of common stock,subject to exchange cap and beneficial ownership limitationsÂ·conversion price is subject to certain price-based anti-dilution adjustments in the event that the Company issues or sells any sharesof common stock for a consideration per share less than the conversion price then in effectÂ·at any time, the Company has the right to redeem all, but not less than all, of the preferred shares then outstanding in cash at aprice equal to at a 25% premium to the greater of (i) the applicable redemption amount and (ii) the equity value of the shares of ourcommon stock underlying the preferred shares included in the applicable redemption amountÂ·no voting rights except as otherwise required by law (or with respect to approval of certain actions)Â Â Â Â Â Â Â Â Â Â Â Â Â Series C Preferred Stock Â 9/30/2024 Â $ 1,000,000 Â Â $ 1,000 Â Â·ranks senior to the common stock with respect to dividends and rights upon liquidationÂ·Stated value of $1,000 per preferred shareÂ·10% per annum dividend rate payable in cash or stock; Company has the option to cumulate or â€œcapitalizeâ€ or dividends,in which case the accrued dividend amount shall be added to the stated valueÂ·has a liquidation preference equal to the sum of (i) the Black Scholes value of the warrants issued in connection with the SeriesC Preferred Stock and (ii) the greater of (a) 125% of the applicable liquidation value and (b) the amount per share such holder wouldreceive if such holder converted the preferred shares into common stock immediately prior to the date of such paymentÂ·convertible into common stock at the option of the holder at an initial fixed conversion price of $0.1759 per share of common stock,subject to exchange cap and beneficial ownership limitationsÂ·conversion price is subject to certain price-based anti-dilution adjustments in the event that the Company issues or sells any sharesof common stock for a consideration per share less than the conversion price then in effectÂ·at any time, the Company has the right to redeem all, but not less than all, of the preferred shares then outstanding in cash at aprice equal to at a 25% premium to the greater of (i) the applicable redemption amount and (ii) the equity value of the shares of ourcommon stock underlying the preferred shares included in the applicable redemption amountÂ·no voting rights except as otherwise required by law (or with respect to approval of certain actions)Â·In connection with the Series C Preferred Stock, the Company also issued warrants exercisable for 5,685,049 shares of common stockwith a 5.5 year term and an initial exercise price of $0.1759 per shareÂ Â Â Â Â Â Â F-48Â Â Â WarrantsÂ The following table summarizes the Companyâ€™soutstanding warrants as of September 30, 2024. The warrants and related strike prices have been adjusted to reflect the 2024 Stock Split. Schedule of warrants and related strike prices Â Â Â Â Â Â Â Â Â Issue Date Â Strike Price Â Â Number Outstanding Â Â Expiration April 21, 2022 (1) Â $ 69.60 Â Â Â 155,610 Â Â April 21, 2027 April 21, 2022 Â $ 87.04 Â Â Â 10,825 Â Â April 21, 2027 April 21, 2022 Â $ 69.60 Â Â Â 26,673 Â Â April 21, 2027 May 16, 2023 Â $ 0.29 Â Â Â 77,010 Â Â May 16, 2028 November 21, 2023 Â $ 0.29 Â Â Â 46,556 Â Â November 21, 2028 November 21, 2023 Â $ 0.00001 Â Â Â 1,576 Â Â November 21, 2028 February 27, 2024 Â $ 0.58 Â Â Â 10,350,000 Â Â February 27, 2029 August 27, 2024 (2) Â $ 0.1759 Â Â Â 400,000 Â Â August 27, 2029 September 30, 2024 (2) Â $ 0.1759 Â Â Â 5,685,049 Â Â April 1, 2030 Â (1) These warrants were issued as part of the Companyâ€™s initial public offering completed April 2022, and trade on Nasdaq under the ticker symbol â€œACONW.â€ (2) The per share exercise price of these warrants is subject to a â€œratchetâ€ adjustment if the Company issues securities at an effective per share price lower than the then effective warrant exercise price. The strike price of $0.1759 is current through the Series C preferred stock issuance closed September 30, 2024. Â NOTE 12. NET LOSS PER SHARE OF COMMON STOCKÂ Basic and diluted net loss per share is computedby dividing net loss attributable to stockholders by the weighted average number shares of common stock outstanding during the periodand shares issuable for vested restricted stock units. Potentially dilutive outstanding shares of common stock equivalents were excludedfrom the computation of diluted net loss per share for loss periods presented because including them would have been antidilutive.Â A reconciliation of the numerator and denominatorused in the calculation of basic and diluted net loss per share attributable to stockholders follows: Schedule of reconciliation of basic and diluted net loss per share Â Â Â Â Â Â Â Â Â Three Months Ended September 30, Â Â Â 2024 Â Â 2023 Â Numerator: Â Â Â Â Â Â Â Â Â Net (loss) allocable to common stockholders used to compute basic and diluted loss per common share Â $ (1,378,318)Â Â $ (998,010)Â Denominator: Â Â Â Â Â Â Â Â Â Weighted average shares outstanding used to compute basic and dilutive loss per share Â Â 9,430,357 Â Â Â 513,172 Â Weighted average shares issuable for vested restricted stock units and pre-funded warrants Â Â 7,514 Â Â Â 19,756 Â Â Â $ 9,437,871 Â Â $ 532,928 Â Â Â Â Â Nine Months Ended September 30, Â Â Â 2024 Â Â 2023 Â Numerator: Â Â Â Â Â Â Net (loss) allocable to common stockholders used to compute basic and diluted loss per common share Â $ (5,015,497)Â Â $ (3,646,027)Â Denominator: Â Â Â Â Â Â Â Â Weighted average shares outstanding used to compute basic and dilutive loss per share Â Â 7,688,398 Â Â Â 503,334 Â Weighted average shares issuable for vested restricted stock units and pre-funded warrants Â Â 10,775 Â Â Â 12,642 Â Â Â $ 7,699,173 Â Â $ 515,975 Â Â Â Â F-49Â Â Â The following outstanding potentially dilutive securitieswere excluded from the weighted average calculation of dilutive loss per share attributable to common stockholders because their impactwould have been antidilutive for the period presented: Schedule of anti-dilutive securities excluded from computation of earnings per share Â Â Â Â Â Â Â Â Â September 30, 2024 Â Â September 30, 2023 Â Â Â Â Â Â Â Â Â Preferred stock (as-converted) Â 1,514,912 Â Â â€“ Â Warrants Â Â 10,239,459 Â Â Â 3,809,619 Â Restricted stock units Â Â 15,734 Â Â Â 780,297 Â Stock options Â Â 169,458 Â Â Â 2,738,820 Â Â Â Â 11,939,563 Â Â Â 7,328,736 Â Â NOTE 13. STOCK BASED COMPENSATIONÂ 2022 Aclarion Equity Incentive PlanÂ On April 21, 2022, in connection with the IPO, theCompanyâ€™s 2022 Aclarion Equity Incentive Plan, or â€œ2022 Planâ€, went into effect. Our board of directors has appointedthe 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 125,000 shares(2,000,000 prior to the 2024 Stock Split), 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 initial public offering date (April 2022) occurs and ending on (andincluding) January 1, 2032, in an amount equal to 5% of the total number of shares of Capital Stock outstanding on December 31st

of thepreceding calendar year. Notwithstanding the foregoing, the Board may act prior to January 1st of a given year to provide that there willbe 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 CommonStock than would otherwise occur pursuant to the preceding sentence.Â As of the year ended December 31, 2023, the aggregatenumber of our shares of common stock that may be issued or used for reference purposes under the 2022 Plan was 154,426 (2,470,814 pre-split).On January 1, 2024, the 2022 Plan had an automatic increase of 41,270 (660,311 pre-split) shares which was 5% of the total number of sharesof Capital Stock outstanding on December 31, 2023.Â Options granted under the 2022 Plan may be incentivestock options or non-statutory stock options, as determined by the administrator at the time of grant of an option. Restricted stock mayalso be granted under the 2022 Plan. The options vest in accordance with the grant terms and are exercisable for a period of up to 10years from grant date.Â No options were granted in the nine months ended September30, 2024.Â Nocimed, Inc. 2015 Stock PlanÂ The Company maintains the Nocimed, Inc. 2015 StockPlan, or the â€œExisting Planâ€, under which the Company could grant 152,558 shares (after giving effect to the 2024 Stock Split)or options of the Company to our employees, consultants, and other service providers. The Company suspended the Existing Plan in connectionwith the April 2022, initial public offering. The Company did not grant any stock options under the Existing Plan for the twelve monthsended December 31, 2022, and thereafter. No further awards will be granted under the Existing Plan, but awards granted prior to the suspensiondate will continue in accordance with their terms and the terms of the Existing Plan.Â Â Â Â F-50Â Â Â Determining Fair Value of Stock OptionsÂ The fair value of each grant of stock options wasdetermined by the Company using the methods and assumptions discussed below. Each of these inputs is subjective and generally requiressignificant judgment to determine.Â Valuation and Amortization Method â€”TheCompany estimates the fair value of its stock options using the Black-Scholes-Merton option-pricing model. This fair value is then amortizedover the requisite service periods of the awards.Â Expected Termâ€”The Company estimates theexpected term of stock option by taking the average of the vesting term and the contractual term of the option, as illustrated by thesimplified method.Â Expected Volatilityâ€”The expected volatilityis derived from the Companyâ€™s expectations of future market volatility over the expected term of the options.Â Risk-Free Interest Rateâ€”The risk-freeinterest rate is based on the 10-year U.S. Treasury yield curve on the date of grant.Â Dividend Yieldâ€”The dividend yield assumptionis based on the Companyâ€™s history and expectation of no dividend payouts.Â Stock Award Activity Â A summary of option activity under the Companyâ€™sincentive plans is as follows: Schedule of option activity Â Â Â Â Â Â Â Â Â Â Â Â Options Outstanding Â Â Weighted Average Exercise Price Â Â Weighted Average Remaining Contractual Life (In Years) Â Balance at December 31, 2023 Â Â 169,456 Â Â $ 31.15 Â Â Â 7.5 Â Options granted Â Â â€“ Â Â Â â€“ Â Â Â â€“ Â Options exercised Â Â â€“ Â Â Â â€“ Â Â Â â€“ Â Options forfeited/expired Â Â â€“ Â Â Â â€“ Â Â Â â€“ Â Balance at September 30, 2024 Â Â 169,456 Â Â $ 31.15 Â Â Â 6.7 Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Exercisable at December 31, 2023 Â Â 147,977 Â Â $ 30.57 Â Â Â 7.4 Â Exercisable at September 30, 2024 Â Â 158,468 Â Â $ 30.91 Â Â Â 6.7 Â Â The aggregate intrinsic value of options outstandingat September 30, 2024 is $0. The aggregate intrinsic value of vested and exercisable options at September 30, 2024 is $0.Â As of September 30, 2024, there was approximately$154,839 of total unrecognized compensation cost related to non-vested stock options, which is expected to be recognized over the next12 months.Â Â Â Â Â F-51Â Â Â Restricted Stock UnitsÂ In the nine months ended September 30, 2024, theCompany had no new grants of RSUs under the 2022 Plan.Â Post-split RSU activity under the 2022 Plan wasas follows for the nine months ended September 30, 2024: Schedule of RSU activity Â Â Â Â Â Â Â Â RSUâ€™s Outstanding Â Â Weighted-Average Grant-Date Fair value per Unit Â Nonvested as of December 31, 2023 Â Â 15,749 Â Â $ 10.72 Â Granted Â Â â€“ Â Â Â â€“ Â Vested Â Â (5,469) Â Â 10.57 Â Forfeited Â Â (10,280) Â Â 10.80 Â Nonvested as of September 30, 2024 Â Â â€“ Â Â $ â€“ Â Â The grant date fair value for a RSU is the marketprice of the common stock on the date of grant. The total share-based compensation expense related to RSUs recognized during the ninemonths ended September 30, 2024, was $57,824.Â As of September 30, 2024, there was approximately$0 total unrecognized compensation cost related to non-vested RSUs.Â As of September 30, 2024, the Company has no obligationto issue shares of common stock associated with vested Restricted Stock Units.Â Stock-based Compensation ExpenseÂ The following table summarizes the total stock-basedcompensation expense included in the Companyâ€™s statements of operations for the periods presented: Schedule of stock-based compensation expense Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Three months ended September 30, Â Â Nine months ended September 30, Â Â Â 2024 Â Â 2023 Â Â 2024 Â Â 2023 Â Sales and marketing Â $ 17,091 Â Â $ 79,608 Â Â $ 57,824 Â Â $ 186,604 Â Research and development Â Â 1,971 Â Â Â 2,055 Â Â Â 6,081 Â Â Â 7,670 Â General and administrative Â Â 55,644 Â Â Â 55,644 Â Â Â 166,932 Â Â Â 162,195 Â Total share based compensation Â $ 74,706 Â Â $ 137,307 Â Â $ 230,837 Â Â $ 356,469 Â Â NOTE 14. SUBSEQUENT EVENTSÂ None.Â Â Â Â F-52Â Â Â Â Up to [***] Shares of Common StockUp to [***] Pre-Funded Warrants to Purchase[***] Shares of Common StockUp to [***] Series A Common Warrants to Purchaseup to [***] Shares of Common StockUp to [***] Series B Common Warrants to Purchaseup to [***] Shares of Common StockUp to [***] Sharesof Common Stock Underlying the Pre-Funded Warrants, Series A Common Warrants, and Series B Common WarrantsÂ Â Â ACLARION, INC.Â Â Â Â Â Â Â Â PROSPECTUSÂ Â Â [***],202[***]Â Â Dawson James Securities,Inc.Â Â Â Â Â Â Â Â Â Â PART IIÂ INFORMATION NOT REQUIREDIN PROSPECTUSÂ ItemÂ 13. Other Expenses of Issuance and Distribution. Â The following table setsforth the costs and expenses, other than the underwriting discounts and commissions, payable in connection with the sale of common stockbeing registered. All amounts shown are estimates, except the Securities and Exchange Commission registration fee.Â Securities and Exchange Commission registration feeÂ Â [***]Â Financial Industry Regulatory Authority filing feeÂ Â [***]Â Legal fees and expensesÂ Â [***]Â Accountantsâ€™ fees and expensesÂ Â [***]Â Printing expensesÂ Â [***]Â Transfer agent and registrar fees and expensesÂ Â [***]Â MiscellaneousÂ Â [***]Â TotalÂ $250,000Â Â ItemÂ 14. Indemnification of Directors and Officers. Â We are incorporated underthe laws of the state of Delaware. Section 145 of the Delaware General Corporation Law provides that a Delaware corporation may indemnifyany persons who are, or are threatened to be made, parties to any threatened, pending or completed action, suit or proceeding, whethercivil, criminal, administrative or investigative (other than an action by or in the right of such corporation), by reason of the factthat such person was an officer, director, employee or agent of such corporation, or is or was serving at the request of such person asan officer, director, employee or agent of another corporation or enterprise. The indemnity may include expenses (including attorneysâ€™fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by such person in connection with such action,suit or proceeding, provided that such person acted in good faith and in a manner he or she reasonably believed to be in or not opposedto the corporationâ€™s best interests and, with respect to any criminal action or proceeding, had no reasonable cause to believe thathis or her conduct was illegal. A Delaware corporation may indemnify any persons who are, or are threatened to be made, a party

to anythreatened, pending or completed action or suit by or in the right of the corporation by reason of the fact that such person was a director,officer, employee or agent of such corporation, or is or was serving at the request of such corporation as a director, officer, employeeor agent of another corporation or enterprise. The indemnity may include expenses (including attorneysâ€™ fees) actually and reasonablyincurred by such person in connection with the defense or settlement of such action or suit provided such person acted in good faith andin a manner he or she reasonably believed to be in or not opposed to the corporationâ€™s best interests except that no indemnificationis permitted without judicial approval if the officer or director is adjudged to be liable to the corporation. Where an officer or directoris successful on the merits or otherwise in the defense of any action referred to above, the corporation must indemnify him or her againstthe expenses that such officer or director has actually and reasonably incurred. Our charter and bylaws provide for the indemnificationof our directors and officers to the fullest extent permitted under the Delaware General Corporation Law.Â Section 102(b)(7) ofthe Delaware General Corporation Law permits a corporation to provide in its certificate of incorporation that a director of the corporationshall not be personally liable to the corporation or its stockholders for monetary damages for breach of fiduciary duties as a director,except for liability for:Â Â Â· any breach of the directorâ€™s duty of loyalty to the corporation or its stockholders; Â Â Â Â Â· any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law; Â Â Â Â Â· any act related to unlawful stock repurchases, redemptions or other distributions or payment of dividends; or Â Â Â Â Â· any transaction from which the director derived an improper personal benefit. Â Â Â II-1Â Â Â These limitations ofliability do not affect the availability of equitable remedies such as injunctive relief or rescission. Our charter also authorizes usto indemnify our officers, directors and other agents to the fullest extent permitted under Delaware law.Â As permitted by Section145 of the Delaware General Corporation Law, our bylaws provide that:Â Â Â· we may indemnify our directors, officers and employees to the fullest extent permitted by the Delaware General Corporation Law, subject to limited exceptions; Â Â Â Â Â· we may advance expenses to our directors, officers and employees in connection with a legal proceeding to the fullest extent permitted by the Delaware General Corporation Law, subject to limited exceptions; and Â Â Â Â Â· the rights provided in our bylaws are not exclusive. Â Section 174 of the DelawareGeneral Corporation Law provides, among other things, that a director who willfully or negligently approves of an unlawful payment ofdividends or an unlawful stock purchase or redemption may be held liable for such actions. A director who was either absent when the unlawfulactions were approved, or dissented at the time, may avoid liability by causing his or her dissent to such actions to be entered in thebooks containing minutes of the meetings of the board of directors at the time such action occurred or immediately after such absent directorreceives notice of the unlawful acts.Â As permitted by the DelawareGeneral Corporation Law, we have entered and expect to continue to enter into agreements to indemnify our directors, executive officersand other employees as determined by our board of directors. Under the terms of our indemnification agreements, we are required to indemnifyeach of our directors and officers, to the fullest extent permitted by the laws of the state of Delaware, if the basis of the indemniteeâ€™sinvolvement was by reason of the fact that the indemnitee is or was a director, or officer, of the company or any of its subsidiariesor was serving at the companyâ€™s request in an official capacity for another entity. We must indemnify our officers and directorsagainst (1) attorneysâ€™ fees and (2) all other costs of any type or nature whatsoever, including any and all expenses and obligationspaid or incurred in connection with investigating, defending, being a witness in, participating in (including on appeal) or preparingto defend, be a witness or participate in any completed, actual, pending or threatened action, suit, claim or proceeding, whether civil,criminal, administrative or investigative, or establishing or enforcing a right to indemnification under the indemnification agreement.The indemnification agreements also set forth certain procedures that will apply in the event of a claim for indemnification thereunder.These indemnification provisions and the indemnification agreements may be sufficiently broad to permit indemnification of our officersand directors for liabilities, including reimbursement of expenses incurred, arising under the Securities Act.Â Â In addition, we havepurchased a policy of directorsâ€™ and officersâ€™ liability insurance that insures our directors and officers against the costof defense, settlement or payment of a judgment in some circumstances.Â The form of UnderwritingAgreement, filed as Exhibit 1.1 hereto, provides for indemnification by the underwriter of us and our officers who sign this RegistrationStatement and directors for specified liabilities, including matters arising under the Securities Act.Â Item 15. Recent Sales of Unregistered Securities. Â Note: Data in this Item15 has not been adjusted for our recent reverse stock split in January 2024.Â During the three-yearperiod preceding the date of filing of this registration statement, we have issued securities in the transactions described below withoutregistration under the Securities Act.Â In February 2020, theCompany issued to NuVasive a $2 million â€œSAFEâ€ (Simple Agreement for Future Equity). In December 2021, the SAFE was convertedinto shares of Series B-2 Preferred Stock.Â In February 2020 andcontinuing through June 2021, the Company initiated a financing in the form of 6% Convertible Promissory Notes due June 30, 2021. Thisfinancing raised $2,130,010 during 2020 and $814,000 during the first six months of 2021. In December 2021, all notes were converted intoshares of Series B-3 Preferred Stock.Â In connection with theabove-referenced note financing, the Company also issued certain common stock warrants. Such warrants were exercised immediately priorto the Companyâ€™s April 2022 IPO, resulting in the issuance of 76,156 shares (post-reverse stock split) of common stock.Â Â Â II-2Â Â Â In June 2021, the Companyissued $2.0 million of Promissory Notes that mature at the earlier of the consummation of a Qualified Financing or May 31, 2022. The notesincorporated the following major attributes; interest on the Notes accrues at 33%, and the accrued interest would automatically convertinto the securities offered in a Qualified Financing, at a per security price equal to the offering price of the Qualified Financing multipliedby 0.30 (70% discount).Â From January 1, 2019through the date of the Companyâ€™s April 2022 IPO, we granted to our consultants, employees, officers and directors options to purchasean aggregate of 16,073,154 shares (pre-reverse stock split) of Common Stock at per share exercise prices ranging from $0.18 to $0.26 (pre-reversestock split) under our 2015 Stock Plan. Included in those totals were grants made during 2021 of options to purchase an aggregate of 14,234,688shares (pre-reverse stock split) of Common Stock at a per share exercise price of $0.26 (pre-reverse stock split).Â From January 1, 2019through the date of the Companyâ€™s April 2022 IPO, we granted to our consultants, employees, officers and directors options to purchasean aggregate of 16,073,154 shares (pre-reverse stock split) of Common Stock at per share exercise prices ranging from $0.18 to $0.26 (pre-reversestock split) under our 2015 Stock Plan. Included in those totals were grants made during 2021 of options to purchase an aggregate of 14,234,688shares (pre-reverse stock split) of Common Stock at a per share exercise price of $0.26 (pre-reverse stock split).Â From January 1, 2019through the date of the Companyâ€™s April 2022 IPO, we issued an aggregate of 10,000 shares of Common Stock pursuant to the exerciseof options by our consultants, employees, officers and directors.Â In connection with ourApril 2022 IPO:Â Â Â· certain outstanding common stock warrants were exercised on a net share basis for 60,408 common sharesÍ¾ Â Â· 24,495,004 (pre-split) outstanding shares of our

preferred stock were converted into 3,279,117 post-split shares of common stockÍ¾ Â Â· 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 sharesÍ¾ Â Â· 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; and Â Â· 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. Â In November 2022, weissued 40,000 unregistered and restricted shares to a vendor as partial payment for services rendered by such vendor.Â In May and September2023, we issued $2.3 million of unsecured non-convertible promissory notes. In connection with this note issuance, the Company issued(x) 339,360 shares of common stock as a commitment fee, (y) 1,232,156 common stock warrants with a five-year term and an initial exerciseprice of $0.6262 per share, and (z) 100,973 prefunded common stock warrants to a broker dealer firm as a commission.Â In October 2023, we entered into an equity linecommon stock purchase agreement (the â€œPurchase Agreementâ€) with White Lion Capital LLC. Pursuant to the Purchase Agreement,the Company has the right, but not the obligation, to require White Lion to purchase, from time to time, up to $10,000,000 in aggregategross purchase price of newly issued shares of the Companyâ€™s common stock, subject to certain limitations and conditions set forthin the Purchase Agreement. This includes 187,500 shares of common stock we issued to White Lion as commitment shares. In October 2023,we sold 375,000 shares of common stock to White Lion pursuant to the Purchase Agreement. Through September 30, 2024, the Company hasissued 1,800,000 shares to White Lion.Â Â Â Â II-3Â Â Â In November 2023, weissued $294,117.65 of unsecured non-convertible promissory notes. In connection with this note issuance, the Company issued (x) 148,978shares of common stock as a commitment fee, (y) 744,890 common stock warrants with a five-year term and an initial exercise price of $0.2865per share, and (z) 25,210 prefunded common stock warrants to a broker dealer firm as a commission.Â From January 22 throughJanuary 29, 2024, we issued 644,142 shares of common stock in connection with a series of exchange agreements with the accredited investorsto exchange principal and accrued interest on the certain outstanding non-convertible note for shares of common stock.Â We issued 930 shares of newly issued Series Bconvertible preferred stock on August 14, 2024. The Series B Preferred Stock is convertible into common stock at an initial conversionprice of $0.234 per share of common stock.Â We issued 1,000 shares of newly issued SeriesC convertible preferred stock on September 30, 2024. The Series C Preferred Stock is convertible into common stock at an initial conversionprice of $0.1759 per share of common stock.Â On November 27, 2024, the Company and White Lionentered into an amendment to the Equity Line Purchase Agreement that (subject to stockholder approval), among other things, extended theexpiration date of the Equity Line Purchase Agreement from December 31, 2024 to December 31, 2025. In consideration for the commitmentsof White Lion under this amendment, the Company issued to White Lion 560,915 shares of Common Stock as commitment shares, having a valueof $100,000 based upon the Nasdaq minimum price closing sale price of the Common Stock determined as of November 27, 2024.Â These sales and issuanceswere made in reliance upon Section 3(a)(9) or Section 4(a)(2) of the Securities Act of 1933, as amended, and Regulation D, Rule 506 (d),and did not involve any placement agents, commissions, or any public offering. The persons and entities who received such securities haverepresented their intention to acquire these securities for investment only and not with a view to or for sale in connection with anydistribution thereof, and appropriate legends are be affixed to all share certificates issued. All recipients have adequate access throughtheir relationship with us to information about us.Â Â Â Â Â Â Â II-4Â Â Â ItemÂ 16. Exhibits and Financial Statement Schedules. Â (a)Exhibits. The following exhibits are filed as part of this Registration Statement:Â Â Exhibit Number Â Description of Document Â Â Incorporated by reference from Form Â Filing Date Â Exhibit Number Â Filed Herewith Â Â Â Â Â Â Â Â Â Â Â Â 1.1* Â Form of Underwriting Agreement Â Â Â Â Â Â Â Â 1.2 Â IPO Underwriting Agreement dated April 21, 2022 Â 8-K Â 04-27-2022 Â 1.1 Â Â 1.3 Â Form of February 2024 Placement Agent Agreement Â S-1/A Â 02-23-2024 Â 1.1 Â Â 3.1 Â Amended and Restated Certificate of Incorporation of the Company Â 8-K Â 04-27-2022 Â 3.1 Â Â 3.2 Â Certificate of Amendment dated January 3, 2024 to the Amended and Restated Certificate of Incorporation Â 8-K Â 01-04-2024 Â 3.1 Â Â 3.3 Â Bylaws of the Company Â 8-K Â 04-27-2022 Â 3.2 Â Â 3.4 Â Certificate of Designation of Series A Preferred Stock Â 8-K Â 02-17-2023 Â 3.1 Â Â 3.5 Â Amendment to Bylaws dated June 12, 2024 Â 8-K Â 6-18-2024 Â 3.1 Â Â 3.6 Â Series B Convertible Preferred Stock Certificate of Designations dated August 14, 2024 Â 8-K Â 08-16-2024 Â 3.1 Â Â 3.7 Â Series C Convertible Preferred Stock Certificate of Designations dated September 30, 2024 Â 8-K Â 10-01-2024 Â 3.1 Â Â 4.1 Â Form of Common Stock Certificate Â 10-Q Â 06-06-2022 Â 4.1 Â Â 4.2 Â Form of IPO Warrant Â 8-K Â 04-27-2022 Â 4.1 Â Â 4.3 Â Form of IPO Representativeâ€™s Common Stock Purchase Warrant Â 8-K Â 04-27-2022 Â 4.2 Â Â 4.4 Â Description of Securities Â 10-Q Â 06-06-2022 Â 4.4 Â Â 4.5 Â February 2024 Form of Common Warrant Â S-1/A Â 02-06-2024 Â 4.5 Â Â 4.6 Â February 2024 Form of Pre-Funded Warrant Â S-1/A Â 02-06-2024 Â 4.6 Â Â 4.7 Â February 2024 Form of Warrant Agency Agreement Â S-1/A Â 02-23-2024 Â 4.7 Â Â 4.8* Â Form of Series A Common Warrant Â Â Â Â Â Â Â Â 4.9* Â Form of Series B Common Warrant Â Â Â Â Â Â Â Â 4.10* Â Form of Pre-Funded Warrant Â Â Â Â Â Â Â Â 4.11* Â Form of Securities Purchase Agreement Â Â Â Â Â Â Â Â 4.12* Â Form of Warrant Agency Agreement Â Â Â Â Â Â Â Â 5.1* Â Opinion of Carroll Legal LLC Â Â Â Â Â Â Â Â 10.1 # Employment Agreement of Jeff Thramann Â S-1/A Â 03-23-2022 Â 10.1 Â Â 10.2 # Employment Agreement of Brent Ness Â S-1/A Â 03-23-2022 Â 10.2 Â Â 10.3 # Employment Agreement of John Lorbiecki Â S-1/A Â 03-23-2022 Â 10.3 Â Â 10.4 # Form of Aclarion, Inc. 2022 Equity Incentive Plan Â S-1 Â 01-06-2022 Â 10.4 Â Â 10.5 Â Senior Secured Bridge Note Â S-1/A Â 03-04-2022 Â 10.5 Â Â 10.6 Â License Agreement with UCSF the Regents of the University of California Â S-1 Â 01-06-2022 Â 10.6 Â Â 10.7 Â Amendment to UC License Agreement Â S-1/A Â 03-04-2022 Â 10.7 Â Â 10.8 ** NuVasive Amended and Restated Commission Agreement dated February 28, 2020 Â S-1/A Â 03-23-2022 Â 10.8 Â Â 10.9 Â Amended and Restated Investor Rights Agreement dated July 27, 2017 Â S-1/A Â 03-23-2022 Â 10.9 Â Â 10.10 Â First Amendment to Amended and Restated Investor Rights Agreement dated February 20, 2020 Â S-1/A Â 03-23-2022 Â 10.10 Â Â 10.11 Â NuVasive SAFE (Simple Agreement for Future Equity) dated February 28, 2020 Â S-1/A Â 03-23-2022 Â 10.11 Â Â 10.12 ** Right of First Offer Agreement Â S-1/A Â 03-23-2022 Â 10.12 Â Â 10.13 Â First Amendment to Right of First Offer Agreement Â S-1/A Â 03-23-2022 Â 10.13 Â Â 10.14 Â Second Amendment to Right of First Offer Agreement Â S-1/A Â 03-23-2022 Â 10.14 Â Â 10.15 Â Convertible Note and Warrant Purchase Agreement Â S-1/A Â 03-23-2022 Â 10.16 Â Â 10.16 Â Warrant Agent Agreement dated April 21, 2022 Â 8-K Â 04-27-2022 Â 10.1 Â Â Â Â Â Â II-5Â Â Â Exhibit Number Â Description of Document Â Incorporated by reference from Form Â Filing Date Â Exhibit Number Â Filed Herewith Â Â Â Â Â Â Â Â Â Â Â 10.17 Â Siemens Strategic Collaboration Agreement Â S-1 Â 01-06-2022 Â 10.17 Â Â 10.18 # Aclarion, Inc. 2022 Equity Incentive Plan â€“ Form of Option Grant Notice and Stock Option Agreement Â S-1 Â 01-06-2022 Â 10.20 Â Â 10.19 # Aclarion, Inc. 2022 Equity Incentive Plan â€“ Form of RSU Grant Notice and RSU

Agreement Â S-1 Â 01-06-2022 Â 10.21 Â Â 10.20 # Nocimed, Inc. 2015 Stock Plan Â S-8 Â 05-26-2022 Â 99.4 Â Â 10.21 # Nocimed, Inc. 2015 Stock Plan â€“ Form of Option Grant Notice and Stock Option Agreement Â S-8 Â 05-26-2022 Â 99.5 Â Â 10.22 Â Securities Purchase Agreement dated February 16, 2023 between Aclarion, Inc. and Jeffrey Thramann Â 8-K Â 02-17-2023 Â 10.1 Â Â 10.23 Â Form of Securities Purchase Agreement Â 8-K Â 05-17-2023 Â 10.1 Â Â 10.24 Â Form of Unsecured Non-Convertible Note Â 8-K Â 05-17-2023 Â 10.2 Â Â 10.25 Â Form of Common Stock Warrant Â 8-K Â 05-17-2023 Â 10.3 Â Â 10.26 Â Form of Registration Rights Agreement Â 8-K Â 05-17-2023 Â 10.4 Â Â 10.27 Â Waiver related to Unsecured Non-Convertible Notes Â 8-K Â 08-14-2023 Â 10.1 Â Â 10.28 Â White Lion Purchase Agreement Â 8-K Â 10-10-2023 Â 10.1 Â Â 10.29 Â White Lion Registration Rights Agreement Â 8-K Â 10-10-2023 Â 10.2 Â Â 10.30 Â February 2024 Form of Lock-Up Agreement Â S-1/A Â 02-06-2024 Â 10.31 Â Â 10.31 Â February 2024 Form of Securities Purchase Agreement Â S-1/A Â 02-06-2024 Â 10.32 Â Â 10.32 Â Form of Securities Purchase Agreement dated November 21, 2023 Â 8-K Â 11-22-2023 Â 10.1 Â Â 10.33 Â Form of Unsecured Non-Convertible Note dated November 21, 2023 Â 8-K Â 11-22-2023 Â 10.2 Â Â 10.34 Â Form of Common Stock Warrant dated November 21, 2023 Â 8-K Â 11-22-2023 Â 10.3 Â Â 10.35 Â Form of Registration Rights Agreement dated November 21, 2023 Â 8-K Â 11-22-2023 Â 10.4 Â Â 10.36 Â Form of January 2024 Exchange Agreement Â 8-K Â 01-23-2024 Â 10.1 Â Â 10.37 Â Form of Subscription Agreement Â 1-A/A Â 06-20-2024 Â 4.1 Â Â 10.38 Â Form of Exchange Agreement dated August 14, 2024 Â 8-K Â 08-16-2024 Â 10.1 Â Â 10.39 Â Form of Warrant Purchase Agreement dated August 14, 2024 Â 8-K Â 08-29-2024 Â 10.2 Â Â 10.40 Â Form of Securities Purchase Agreement dated September 30, 2024 Â 8-K Â 10-01-2024 Â 10.1 Â Â 10.41 Â Form of Common Stock Warrant dated September 30, 2024 Â 8-K Â 10-01-2024 Â 10.2 Â Â 10.42 Â Form of Registration Rights Agreement dated September 30, 2024 Â 8-K Â 10-01-2024 Â 10.3 Â Â 10.43 Â Amendment dated as of November 27, 2024 to Common Stock Purchase Agreement, dated as of October 9, 2023, by and between White Lion Capital, LLC and Aclarion, Inc. Â 8-K Â 11-27-2024 Â 10.1 Â Â 23.1 Â Consent of Haynie & Company Â Â Â Â Â Â Â X 23.2 Â Consent of CohnReznick LLP, Independent Registered Public Accounting Firm Â Â Â Â Â Â Â X 23.3* Â Consent of Carroll Legal LLC (included in Exhibit 5.1) Â Â Â Â Â Â Â Â 24.1 Â Power of Attorney (Included on Signature Page) Â Â Â Â Â Â Â Â X 107 Â Filing Fees Â Â Â Â Â Â Â X _____ * To be filed by amendment to this Registration Statement. ** Certain information contained in this Exhibit has been redacted and appears as â€œXXXXXâ€ as the disclosure of same would be a disadvantage to the Registrant in the marketplace *** Previously filed. # Indicates management contract or compensatory plan. Â (b) Financial statement schedules.Â Schedulesnot listed above have been omitted because the information required to be set forth therein is not applicable or is shown in the FinancialStatements or notes thereto.Â Â Â II-6Â Â Â Item 17. Undertakings. Â (a) The undersigned registrant hereby undertakes: Â Â (1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement: Â Â i. To include any prospectus required by SectionÂ 10(a)(3)Â of the Securities Act of 1933; Â ii. To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to RuleÂ 424(b)Â if, in the aggregate, the changes in volume and price represent no more than 20 percent change in the maximum aggregate offering price set forth in the â€œCalculation of Registration Feeâ€ table in the effective registration statement; Â iii.Â To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement. Â Â Â (2) That, for the purpose of determining any liability under the Securities Act of 1933, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof. Â Â Â Â (3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering. Â Â (4) That for the purpose of determining any liability under the Securities Act of 1933 in a primary offering of securities of the undersigned registrant pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser: Â Â i. Any preliminary prospectus or prospectus of the undersigned registrant relating to the offering required to be filed pursuant to RuleÂ 424; Â ii. Any free writing prospectus relating to the offering prepared by or on behalf of the undersigned registrant or used or referred to by the undersigned registrant; Â iii. The portion of any other free writing prospectus relating to the offering containing material information about the undersigned registrant or its securities provided by or on behalf of the undersigned registrant; and Â iv. Any other communication that is an offer in the offering made by the undersigned registrant to the purchaser. Â (5) That for the purpose of determining liability under the Securities Act of 1933 to any purchaser, if the registrant is subject to RuleÂ 430C, each prospectus filed pursuant to RuleÂ 424(b)Â as part of a registration statement relating to an offering, other than registration statements relying on RuleÂ 430B or other than prospectuses filed in reliance on RuleÂ 430A, shall be deemed to be part of and included in the registration statement as of the date it is first used after effectiveness. Provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such first use, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such date of first use. Â Â (b) Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue. Â Â Â II-7Â Â Â (c) The undersigned registrant hereby undertakes that: Â Â (1) For

purposes of determining any liability under the Securities Act of 1933, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon RuleÂ 430A and contained in a form of prospectus filed by the registrant pursuant to RuleÂ 424(b)(1)Â or (4)Â or 497(h)Â under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective. Â (2) For the purpose of determining any liability under the Securities Act of 1933, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof. Â Â Â Â Â Â II-8Â Â Â SIGNATURESÂ Pursuant to the requirementsof the Securities Act of 1933, as amended, the registrant has duly caused this Registration Statement on Form S-1 to be signed on itsbehalf by the undersigned, thereunto duly authorized, in the city of Broomfield, in the State of Colorado, on this 10th day of December,2024.Â Â ACLARION, INC. Â Â Â Â By: Â /s/ John Lorbiecki Â Â Â John Lorbiecki Â Â Â Chief Financial Officer Â KNOW ALL MEN BY THESEPRESENTS, that each person whose signature appears below constitutes and appoints John Lorbiecki and Brent Ness his or her true and lawfulattorneys-in-fact and agents, with full power to act separately and full power of substitution and re-substitution, for him or her andin his or her name, place and stead, in any and all capacities, to sign any and all amendments (including post-effective amendments) tothis registration statement and all additional registration statements pursuant to Rule 462(b) of the Securities Act of 1933, as amended,and to file the same, with all exhibits thereto, and all other documents in connection therewith, with the Securities and Exchange Commission,granting unto said attorneys-in-fact and agents full power and authority to do and perform each and every act in person, hereby ratifyingand confirming all that said attorneys-in-fact and agents or his or her substitute or substitutes may lawfully do or cause to be doneby virtue hereof.Â Pursuant to the requirementsof the Securities Act of 1933, as amended, this Registration Statement on Form S-1 has been signed by the following persons in the capacitiesand on the dates indicated.Â Signature Â Title Â Date Â Â Â Â Â /s/ Brent Ness Â Chief Executive Officer and Director Â December 10, 2024 Brent Ness Â (Principal Executive Officer) Â Â Â Â President and Director Â Â Â Â Â Â Â Â Â Â Â Â /s/ John Lorbiecki Â Chief Financial Officer Â December 10, 2024 John Lorbiecki Â (Principal Financial and Accounting Officer) Â Â Â Â Â Â Â Â Â Â Â Â /s/ Jeffrey Thramann Â Executive Chairman and Director Â December 10, 2024 Jeffrey Thramann Â Â Â Â Â Â Â Â Â Â Â Â Â Â /s/ David Neal Â Director Â December 10, 2024 David Neal Â Â Â Â Â Â Â Â Â Â Â Â Â Â /s/ William Wesemann Â Director Â December 10, 2024 William Wesemann Â Â Â Â Â Â Â Â Â Â Â Â Â Â /s/ Amanda Williams Â Director Â December 10, 2024 Amanda Williams Â Â Â Â Â Â Â Â Â Â Â Â Â Â /s/ Stephen Deitsch Â Director Â December 10, 2024 Stephen Deitsch Â Â Â Â Â Â Â Â Â Â Â Â Â Â /s/ Scott Breidbart Â Director Â December 10, 2024 Scott Breidbart Â Â Â Â Â Â Â Â S-1Â Exhibit 23.1Â CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTINGFIRMÂ We consent to the use in this Registration Statement on Form S-1 of Aclarion, Inc. of our report dated February 20, 2024 and March 28,2024, with respect to the financial statements of Aclarion, Inc. as of December 31, 2023, and for the year then ended. Our audit reportincludes an explanatory paragraph relating to Aclarion, Inc.â€™s ability to continue as a going concern.Â We also consent to the reference to our firm under the caption "Experts" in such Prospectus.Â Â Â /s/Haynie & CompanyÂ Salt Lake City, UtahÂ December 10, 2024 Exhibit 23.2Â Â CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTINGFIRMÂ We consent to the inclusion in this Registration Statement on FormS-1 and related Prospectus, of our report dated June 12, 2023, except for Note 1, 2024 Reverse Stock Split, Note 7, SUPPLEMENTAL FINANCIALINFORMATION, Prepaids and other current assets and Accrued and other liabilities, and Note 14, Net Loss Per Share of Common Stock, asto which the date is February 21, 2024, with respect to the restated financial statements of Aclarion, Inc. as of December 31, 2022 andfor the year then ended. Our audit report includes an explanatory paragraph relating to Aclarion, Inc.â€™s ability to continue asa going concern.Â We also consent to the reference to our firm under the caption â€œExperts.â€Â Â /s/ CohnReznick LLPÂ Sunrise, FloridaÂ December 10, 2024Â Â Â Â Â Exhibit 107Â Calculation of Filing Fee TablesÂ S-1(Form Type)Â Aclarion, Inc.(Exact Name of Registrant as Specified in its Charter)Â Table 1: Newly Registered and Carry ForwardSecuritiesÂ Â Â Security Type Â Security Class Title Â Fee Calculation or Carry Forward Rule Â Amount Registered Â Proposed Maximum Offering Price Per Share Â Maximum Aggregate Offering Price(1)(2) Â Fee Rate Â Amount of Registration Fee Fees to be Paid Â Â Equity Â Â Common Stock, $0.001 par value per share Â Â 457 (o) Â Â â€” Â Â Â â€” Â Â Â $ 10,500,000 (3) Â Â 0.00015310 Â Â $ 1,607.55 Â Fees to be Paid Â Â Equity Â Â Series A Common Warrants accompanying the Common Stock or Pre-Funded Warrants Â Â Other (4) Â Â â€” Â Â Â â€” Â Â Â Â Â (4) Â Â â€” Â Â Â â€” Â Fees to be Paid Â Â Equity Â Â Series B Common Warrants accompanying the Common Stock or Pre-Funded Warrants Â Â Other (4) Â Â â€” Â Â Â â€” Â Â Â Â Â (4) Â Â â€” Â Â Â â€” Â Fees to be Paid Â Â Equity Â Â Pre-Funded Warrants Â Â Other (4) Â Â â€” Â Â Â â€” Â Â Â Â Â (3)(4) Â Â â€” Â Â Â â€” Â Fees to be Paid Â Â Equity Â Â Common Stock underlying the Pre-Funded Warrants (3) Â Â 457 (o) Â Â â€” Â Â Â â€” Â Â Â Â Â (3) Â Â â€” Â Â Â â€” Â Fees to be Paid Â Â Equity Â Â Common Stock underlying the Series A Common Warrants Â Â 457 (o) Â Â â€” Â Â Â â€” Â Â Â $ 10,500,000 Â Â $ 0.00015310 Â Â $ 1,607.55 Â Fees to be Paid Â Â Equity Â Â Common Stock underlying the Series B Common Warrants Â Â 457 (o) Â Â â€” Â Â Â â€” Â Â Â $ 10,500,000 Â Â $ 0.00015310 Â Â $ 1,607.55 Â Fees Previously Paid Â Â Equity Â Â Common Stock, par value $0.001 per share Â Â 457 (o) Â Â â€” Â Â Â â€” Â Â Â Â â€” Â Â Â â€” Â Carry Forward Securities Â Â â€” Â Â â€” Â Â â€” Â Â Â â€” Â Â Â â€” Â Â Â â€” Â Â Â â€” Â Â Â â€” Â Total Offering Amounts Â Â Â Â Â Â Â Â Â Â Â Â $ 31,500,000 Â Â Â Â Â Â $ 4,822.65 Â Total Fees Previously Paid Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â â€” Â Total Fee Offset Â â€” Â Net Fee Due Â $ 4,822.65 Â Â (1) Estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(o) under the Securities Act of 1933, as amended (the â€œSecurities Actâ€). (2) Pursuant to Rule 416(a) under the Securities Act, there are also being registered an indeterminable number of additional securities as may be issued to prevent dilution resulting from share splits, share dividends or similar transactions. (3) The proposed maximum aggregate offering price of the Common Stock proposed to be sold in the offering will be reduced on a dollar-for-dollar basis based on the offering price of any Pre-Funded Warrants sold in the offering and the proposed maximum aggregate offering price of the Pre-Funded Warrants proposed to be sold in the offering will be reduced on a dollar-for-dollar basis based on the offering price of any Common Stock sold in the offering, and, as such, the proposed maximum aggregate offering price of the Common Shares and Pre-Funded Warrants (including the Common Stock issuable upon exercise of the Pre-Funded Warrants), if any, is $10,500,000. (4) Pursuant to Rule 457(g) of the Securities Act, no separate registration fee

is required for the warrants because the warrants are being registered in the same registration statement as the Common Stock issuable upon exercise of the warrants. Â Â