FORM 1-K

Filing Date: **2023-11-06** | Period of Report: **2023-06-30**
SEC Accession No. 0001683168-23-007641

FILER

IdentifySensors Biologics Corp.
CIK:**1817371**| IRS No.: **851615176** | State of Incorp.:**DE** | Fiscal Year End: **1231**
Type: **1-K** | Act: **33** | File No.: **24R-00537** | Film No.: **231379231**
SIC: **8000** Health services

Mailing Address
20600 CHAGRIN BLVD.,
SUITE 450
SHAKER HEIGHTS OH 44122

Business Address
20600 CHAGRIN BLVD.,
SUITE 450
SHAKER HEIGHTS OH 44122
216-543-3031

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

FORM 1-K

ANNUAL REPORT PURSUANT TO REGULATION A
OF THE SECURITIES ACT OF 1933

For the fiscal year ended June 30, 2023

IdentifySensors Biologics Corp.

(Exact Name of Registrant as specified in its charter)

Delaware	**85-1615176**
(State or other jurisdiction of incorporation)	(IRS Employer Identification Number)
20600 Chagrin Boulevard, Suite 450 Shaker Heights, Ohio (Address of principal executive offices)	**44122** (zip code)

(216) 543-3031
(Registrant's telephone number, including area code)

Title of each class of securities issued pursuant to Regulation A:
Common Stock, $0.0001 par value

Part II.

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 1-K includes forward-looking statements, which reflect our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. These forward-looking statements speak only as of the date of this Form 1-K and are subject to a number of risks, uncertainties and assumptions described under the sections in this Form 1-K entitled "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" and elsewhere in this Form 1-K. Forward-looking statements are identified by terms such as "may," "will," "should," "expect," "plan," "anticipate," "could," "intend," "target," "project," "contemplates," "believes," "estimates," "predicts," "potential" or "continue" or the negative of these terms or other similar expressions. Readers are cautioned not to place undue reliance on these forward-looking statements, which are based on the information available to management at this time and which speak only as of this date.

Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified and some of which are beyond our control, you should not rely on these forward-looking statements as predictions of future events.

The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. Moreover, we operate in an evolving environment.

New risk factors and uncertainties may emerge from time to time, and it is not possible for management to predict all risk factors and uncertainties. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise.

This Form 1-K also incorporates by reference estimates and other statistical data made by independent parties and by us relating to market size and growth and other data about our industry. This data involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates. In addition, projections, assumptions and estimates of our future performance and the future performance of the markets in which we operate are necessarily subject to a high degree of uncertainty and risk.

Item 1. Business

As used in this Annual Report, all references to the "Company," "ISB," "we," "us," and "our" refer to IdentifySensors Biologics Corp.

Overview

Check4® is a rapid electrochemical molecular gene detection platform intended to detect different types of pathogens. Check4® uses a disposable one-time use cartridge and a reusable reader to easily perform the test for a given pathogen. The platform can also be used with a multiplexed cartridge to detect several pathogens all at once. The user takes a saliva sample, the cartridge is inserted into the reader, the user inserts their saliva sample into the cartridge and within minutes the reader sends its data to the Cloud for recording and interpretation. Results are displayed in approximately 5 minutes on the user's smartphone. The graphene ink consistency and performance is the challenge to making an accurate sensor. We continue to explore with different formulations of the ink to achieve the required results. Thus far in the lab we have obtained results that are inconsistent but good.

Check4® was initially designed as an alternative to the laboratory-based reverse transcription polymerase chain reaction (RT-PCR) tests for COVID-19. Since the World Health Organization declared the end of COVID-19 as a world health emergency in May of 2023, we intend to develop similar test cartridges for other bacteria and viruses, using the same nano-sensor platform. Examples of additional tests include Influenzas A & B, RSV, Ebola, Hepatitis C, HIV, Legionella, MRSA, Lyme, and Zika.

In July 2022, We entered into an agreement for the initial technical and assessment of the Check4 reader and cartridge design with Jabil Inc., a contract manufacturer based in St. Petersburg, Florida. The goal of the agreement was: (i) to vet the current design, evaluate functionality and propose modifications for production application, and (ii) through a heuristic analysis, to understand the features of the device that are considered imperative to a successful user experience. We expected the agreement with Jabil to help us review our first-generation product enclosures to better fit for large scale manufacturing of the cartridge and reader. Product development is now fixed for manufacture, and we are now working with another contract manufacturer called East West Manufacturing, LLC in Wisconsin; and we filed our first FDA pre-submission for Ebola and Marburg viruses during 2023. The US FDA has allowed us to file under Emergency Use Authorization (EUA) for Ebola because of the seriousness of this viral illness and the perceived advantages of our technology. See *Testing and Evaluating Platform Devices Seeking FDA Approval* below. We also have a total of 5 Pre-submission to the FDA.

As of the date of this Annual Report, we have successfully and repeatedly identified the specific gene for target RNA in heat-inactivated virus saliva test samples and in heat-inactivated clinical saliva samples at n comparable to lab-based RT-PCR tests, for COVID-19: and have now done the same for Flu A & B, RSV and Ebola. The time of detection is within five minutes. Development has shown repeatable results under various conditions using clinical samples required by regulators, manufacturers, and consumers. Internal testing has also shown Check4® to be able to multiplex detection of up to 4 different pathogens in one cartridge. The product is now in scaled manufacturing with East West Manufacturing, LLC in Wisconsin. We entered into an agreement finalizing the terms of the manufacturing agreement on August 8, 2023.

On January 18, 2023, we entered into a license agreement with the University of Florida Board of Trustees, as owner of UF Innovate/ Accelerate, to license the use of the space or spaces in the building located at 12085 Research Drive, Alachua, Florida, 32615/747 SW 2nd Ave., Gainesville, Florida (the "Licensed Space"). The Licensed Space shall be used solely as an office, light manufacturing, or laboratory research space. We will have full access to and use of the Licensed Space and the right to use and access all common areas within the Licensed Space on an "as available" basis. The term of the license agreement is for 12 months but has a 30 day out clause and we will pay $7,000 per month for the license to use the Licensed Space.

In February 2023, we entered into a license agreement with the University of Florida. The purpose of the agreement is to license the non-exclusive use of the University of Florida Nanoscale Research Facility and the University of Florida Major Analytical Instrumentation Center (the "Facilities"). The term of the agreement is one year from its effective date. The agreement can be terminated by the University of Florida upon seven days written notice to us, for any or no reason. All rights title and interest in and to any intellectual property developed or conceived solely by us in the Facilities or through the use of the Facilities will belong to us. All rights title and interest in and to any intellectual property developed or conceived jointly by us and any employees of the University of Florida in the Facilities or through the use of the Facilities will belong jointly to us and to and the University of Florida. As of this date there is no shared IP between University of Florida and us.

In March of 2023 we acquired five key Quality Management Systems ("QMS") and Regulatory personnel. This team is led by Ghazi Kashmolah, our Executive Vice President of Regulatory Affairs, who has 30 years of experience in quality and regulatory work. Until recently, he was the executive vice president of regulatory affairs and chief quality officer at Lucira Health, where he was responsible for FDA approval and achieved the first multiplex COVID/FLU diagnostic test for direct-to-consumer. Under the direction of Mr. Kashmolah, our QMS and Regulatory team is currently diligently working on preparing five submissions to the US FDA, which we expect to file in 2023.

In April of 2023 we engaged the services of MedTech Review LLC to provide business development, public sector relations, investor relations and other consulting services to us. All services will be provided by John Beasley and Joe Ostendorf. The agreement renews on a month-to-month basis, and the consultants will be compensated on an hourly basis. Under the terms of the consulting agreement, the consultants will assist our Executive Vice President of Regulatory Affairs with: (i) advice in regulatory requirements in different countries and regions; (ii) the development of regulatory strategies, identification of risks and risk mitigation; (iii) the preparation of regulatory submissions; and (iv) services in connection with respiratory viruses, Hep C and HIV, Ebola, Diarrheal and equatorial viruses, such as Dengue, Zika, west Nile, etc.

The development of our products has not been completed and has not been subjected to any third-party testing. We cannot yet market or sell any of our products in certain markets that require FDA like approval. Even if we obtain such approval, we cannot guaranty that our products will obtain any market acceptance.

Market Opportunity

As of December 31, 2022, over 3.7 billion RT-PCR tests were conducted and reported world-wide for Flu, Covid and other pathogens like RSV. Testing was widely viewed as a critical component to combating COVID-19, and we believe it will continue to remain a critical component to combating other communicable diseases, such as the Flu and RSV. Our goal is to provide a test that is: (i) as accurate as RT-PCR tests; (ii) faster and more accurate than PCR and antigen tests; (iii) can be used at home or at the "point-of-care;" and (iv) less expensive than other molecular tests currently on the market.

Despite being the world's largest test provider, during the COVID-19 pandemic, the U.S. struggled to satisfy demand for a cost-effective, rapid, and highly accurate molecular test that could be conducted at home or at the "point-of-care". The inadequacies of testing in the U.S. seemed to be due in-part by an over-reliance on resource-intensive, yet highly accurate laboratory-based RT-PCR tests and cost-effective, yet inaccurate antigen tests. While RT-PCR is considered the most accurate diagnostic method for most viruses, including COVID-19, available today, the lab-based test is far too resource intensive to be deployed at scale either for Covid or for other communicable diseases.

A stopgap that addressed some of the testing inadequacies was the rapid antigen testing. Antigen tests are known to be rapid and inexpensive, however they are also known to be less accurate than molecular tests. Antigen tests also demonstrated difficulty in identifying infected individuals with low viral loads, limiting its ability to serve as an effective testing tool. While antigen tests are cheap,

they are not reliable. Check4 tests are intended to be competitive in price and much more accurate with a low level of detection (LOD) and could be capable of detecting infection in asymptotic patients.

We intend to fill the gap in testing capability for other communicable diseases by developing an affordable molecular test that can be conducted frequently and returns results within minutes, not only for Covid19, but for other pathogens such as the Flu A and the Flu B, influenza, etc. We intend for our test to detect the specific genes of these pathogens at concentrations comparable to lab-based RT-PCR tests, while overcoming many of the limitations of existing molecular tests.

Our proposed approach avoids the limiting element of other molecular tests such as enzymatic reactions (reverse transcriptase), amplification, sample preservation or sample transportation, exposure to extremes of temperature, which can introduce error and raises the risk of inaccurate results achieving elevated levels of testing for communicable diseases. During the COVID-19 pandemic and usual Flu outbreak, RT-PCR tests demonstrated to be far too resource intensive, due to the high cost per test and the lengthy amount of time it takes for the test to return results. Laboratory-based testing seems to have too many moving parts to be an effective tool for managing the spread of infections in large populations. On the other hand, rapid antigen tests are inaccurate and will continue to be so as viruses mutate.

Table 1 presents critical elements of RT-PCR molecular tests and how our electrochemical molecular test compares to them. We intend our test to be faster, more scalable, more cost-effective, digital and to present fewer production and operational challenges by not relying on enzymes or reagents that have supply availability and quality issues. We also have a simple sample collection and testing method that does not require sample preservation, or amplification and returns results in minutes.

Table 1: Comparison of Critical Test Elements Between Laboratory-Based RT-PCR Tests and IdentifySensors Biologics' Rapid Electrochemical Point-of-Care Test

Critical Test Element	**Laboratory-Based RT-PCR Molecular Tests**	**IdentifySensors Biologics Electrochemical Test**
Sample Collection	Nasal or Throat Swab	Saliva
Sample Preservation/Transportation	Yes	No
Selectivity/Sensitivity	EUA [1] and some Pre-EUA	Pre-EUA
Use of Enzymes & Reagents	Yes	No
Use of Amplification	Yes	No
Speed	Days (Often)	Minutes (Always)
Scalability	Low (Laboratory-Based)	High (Point-of-Care)
Cost-Effectiveness	Low (actual $150/test)	High (estimated $25-50/test with one-time purchase of reusable reader for $50-112 wholesale)
Test Output	Manual/Written (Often)	Automatic/Digital (Always)
Test Reporting	Manual/Transcribed (Often)	Automatic/Cloud (Always)
Extremes of Temperature Sensitive	Yes	No

Intended Target Markets

We intend to target primarily three markets: 1) essential businesses, testing clinics and other healthcare facilities (referred throughout as Businesses), 2) individuals and families (referred throughout as Individuals & Families), and 3) public sector agencies responsible for providing highly available and affordable Flu, RSV and COVID-19 testing (referred throughout as Public).

1. **Businesses** operating in critical and essential industries such as education, healthcare, retail, transportation and trade, travel and hospitality and agriculture among other industries need a fast, accurate and inexpensive high-volume option for implementing robust testing programs. The simplicity of our platform could allow the test to be administered at a nurse's station using a saliva test sample, with the results being transmitted to a secure private cloud where the results are stored and managed. The system could also automatically perform the standard reporting to state health laboratories and the CDC, enabling real-time tracking, tracing, and more efficient management of health resources. The system could also integrate with Electronic Health Record

(EHR) systems, Customer Relationship Management (CRM) systems and various other security and enterprise data systems. Point of Care (POC) is our primary target for initial marketing.

2. **Individuals & Families** need a fast, accurate and inexpensive personal diagnostic platform for regular testing to mitigate the risk of contracting communicable diseases from daily activities. The platform device intends to be able to be operated by untrained individuals at home or in non-clinical settings using saliva samples, with results being transmitted wirelessly within minutes to a software app on a personal smart device. Standard routine reporting for infectious disease can be performed automatically via the cloud.

3. **Public** needs access to rapid, accurate and inexpensive testing technology that definitively diagnoses infectious diseases like Flu and COVID-19 infections. The diagnostic platform intends to serve public sector entities responsible for administering high volumes of public infectious disease testing. The platform intends to be operated by trained professionals in non-clinical settings such as airports, ports of entry, train stations, parking lots or other public testing locations, with results transmitted by Wide Area Network (WAN) to the private cloud for rapid processing, tracking, tracing and pandemic resource management. Standard routine reporting for infectious disease can be performed automatically via the cloud.

Overview of the Diagnostics & Medical Laboratories Industry

The total addressable market for laboratory-based molecular tests depends on how many tests are conducted each day. We believe that testing demand is in-part a function of price per test, accuracy of the test and timeliness of delivering test results.

The two largest providers of molecular tests, Quest Diagnostic and Laboratory Corporation of America Holdings dominate the Diagnostics and Medical Laboratory Industry controlling about 32 percent of the market.

Prior to the pandemic, the Diagnostics & Medical Laboratories industry generated $52.3 billion in annual revenue and $3.7 billion in annual profit. More than 60 percent of the revenue comes from pathology services, which is the branch of medicine that deals with examination of biological samples for forensic or diagnostic purposes.

Centralized lab-based pathology services, however, faced significant challenges during the COVID-19 pandemic. For example, when testing for COVID-19 along with other pathogens, rapid delivery of results became the primary factor in determining whether a test was valuable. The growing need for test results that are not only accurate but timely, can place the entire business model of centralized lab-based pathology services at risk for disruption by point-of-care devices. This disruptive trend was well underway prior to the pandemic, and the health crisis rapidly accelerated the market transition.

Sample Collection

Sample collection is required for all diagnostic testing, and how the sample is collected impacts not only the accuracy of the test, but also overall cost-effectiveness and even the risk of virus transmission.

For example, most molecular-assay tests could require about 20 different reagents, consumables, and other pieces of equipment. The tests could also require a trained medical professional to invasively swab patient's throat or nasal cavity. However, sample collection supplies including swabs, sample transport mediums and personal protective equipment (PPE) proved to be in short supply during the COVID-19 pandemic and could be in short supply in future health crisis.

This centralized method of sample collection presents risks not only for preserving the test sample, which is critical for test accuracy, but also the sample collection method exposes medical professionals to virus transmission risk, particularly when adequate PPE is not available.

As a result, health authorities have moved aggressively to approve alternative transport mediums (such as saline) and different types of sample collection methods such as saliva and lower-respiratory-tract samples. Studies indicate that the test results from such alternative sample collection methods could be as accurate as those taken from swabs.

Approval of new sample-collection methods have not only opened the door to “at-home” sample collection, but also “at-home” testing.

Transitioning to Point-of-Care Diagnostic Devices

While the World Health Organization has declared the end of the COVID-19 pandemic as a global health emergency, other health crisis could be looming, and new testing techniques and technologies are desperately needed to help facilitate rapid, at-home diagnostic devices that could effectively perform early diagnoses of various pathogens and diseases before they cause a problem for the afflicted individual, their daily contacts and their surrounding community.

We believe that the market transition to point-of-care from lab-based testing is being driven in-part by innovative technologies that provide better and earlier disease diagnosis, accompanied by new treatments and therapeutics. Earlier diagnosis and targeted treatments could help to drastically improve health outcomes.

Other factors are also impacting the market shift, including population aging, preventive medicine, insurance coverage of testing services and increasing healthcare expenditure.

Preventive Medicine

Medical professionals are increasingly practicing preventative medicine, where testing bodily fluids is a primary tool. Many medical problems are reflected in patient’s bodily fluid before any noticeable symptoms. The rising cost of healthcare in the U.S. has encouraged the use of preventive care, including laboratory testing, to decrease patient’s need for costly procedures further down the road.

Cost of Services, Reimbursements and Health Expenditure

For laboratory-based testing, the patient is estimated to pay about 10 percent of costs. While the cost sharing is designed to reduce overuse of laboratory-based testing health services by making patients more aware of service costs, the reimbursement levels by private and public insurers also signals the high value of such services. A new CPT billing code[1] has been established for a multiplexed molecular gene test that could allow point of care providers to easily perform the Check4 tests in their offices with a substantial margin, we believe this new CPT code might help position the Check4 test platform as a market favorite.

Under the centralized laboratory-based testing model, the patient does not initiate the use of laboratory testing, rather, physicians refer patients to laboratories. Since physicians or other healthcare providers request laboratory tests to aid with the diagnoses or monitoring of a patient’s medical condition, demand is more sensitive to the number of physician visits than to the cost of industry services. This sensitivity to demand would not be a constrain under a decentralized testing model that uses point-of-care diagnostics.

Product Development & Implementation

The molecular self-test that we intend to offer is a simple saliva test that will seek out the very specific genes of different pathogens in the saliva test sample. Unlike other molecular tests including the RT-PCR test, our test intends to not require liquid reagents, enzymes and most importantly the duplication and amplification of the target genes of the pathogens.

Testing for pathogens typically involves three types of settings: at a clinic or doctor’s office, at a public testing station and more recently at a home using a self-test. The setting is determined primarily by the type of test and the ability of untrained individuals to conduct the test.

During the COVID-19 pandemic, RT-PCR tests were conducted in CLIA-certified laboratories, with test samples being collected at clinics, public testing stations and at home using collection kits that were mailed to labs for testing. Other types of tests such as antigen and antibody tests are different than RT-PCR in that they could be conducted at the point-of-care, which can include clinics, testing stations and the home.

We believe that a highly accurate rapid molecular test conducted at private businesses, clinics and homes could have provided a better management of pandemic and routine illness resources and an overall better response to a health crisis.

Our objective is to deliver a highly accurate molecular-based test capable of rapid results and automatic reporting of results in various settings including at businesses and clinics, at homes and at public testing stations.

---

[1] Current Procedural Terminology (CPT) codes are numbers assigned to each task and service that an individual can obtain from a healthcare provider.

Target Segments & Customers

The segments we intend to initially target are determined in-part by regulatory standards, the opportunity cost of virus outbreaks and by negative health outcomes associated with widespread infectious diseases like COVID-19. These segments could include clinics, medical facilities, businesses operating in essential industries, and individuals and families interested in frequent testing as a means of managing the risk of all communicable diseases, including COVID-19 exposure. Ultimately, we believe our testing platform is applicable to everyone everywhere, in the U.S. and world-wide.

Health Outcomes Among Leading Factors in Identifying Target Segments & Customers

Older people, particularly those with underlying health conditions are most susceptible to negative health outcomes from Flu, RSV and COVID-19, and should be tested often. As of November 30, 2021, more than 90 percent of deaths involving COVID-19 in the U.S. were attributed to people aged 50 or older. The oldest cohort, age 85 and older accounted for the largest share of 27 percent, followed by age group 75-84 accounting for 26 percent of COVID-19 deaths, age group 65-74 accounting for 23 percent, and age 50-64 accounting for 18 percent of deaths through November 10, 2021. The Flu also claims roughly 60,000 lives each year, and Covid continues to cause death around the world and in the US.

In the U.S., 34 percent of the population is age 50 or older and an estimated 60 percent of American adults have at least one chronic medical condition. While not all chronic conditions have proven to be associated with negative health outcomes from COVID-19, obesity is one of the most common underlying health conditions associated with severe COVID-19, and 40 percent of U.S. adults have obesity. The other underlying health conditions shown to be most associated with negative health outcomes from COVID-19 in the U.S., include chronic kidney disease, chronic obstructive pulmonary disease, weakened immune system, heart condition, sickle cell disease, type 2 diabetes and anxiety or fear-related disorders.

We estimate that over 90 million of the 246 million adults living in the U.S. or 37 percent of Americans are at a higher risk of serious illness if infected with Flu, RSV and COVID-19. We also believe that 1.7 billion people, comprising of 22 percent of the global population is considered “at-risk” of severe Flu A, RSV and COVID-19 by having at least one underlying health condition.

While there are many factors that seem to make the U.S. population more susceptible to severe infectious diseases one factor could be that the U.S. population is simply less healthy than the populations of comparable developed nations. The U.S. has the highest chronic disease burden and obesity rate of any country, which is two times higher than the OECD average. The U.S., compared to peer nations, has among the highest number of hospitalizations from preventable causes and the highest rate of avoidable deaths.

Progressive & Assisted Living Facilities Most At-Risk

Given that older people with underlying or chronic health conditions seem to be most susceptible to severe Flu, RSV and COVID-19, we intend to target states where high-risk individuals live, particularly those that hold as significant number of progressive and assisted living facilities.

Our management team estimates that more than half of people living in 60 percent of U.S. states could be considered to have higher risk of serious illness from Flu, RSV and COVID-19.

Progressive and assisted living facilities are seen to be among the highest priority target markets. In 2019-2022, there were approximately 1.4 million residents receiving care across 15,483 nursing facilities in the U.S., with about 86 percent of those facilities having deficiencies related to controlling and preventing infection. Deficiencies related to the spread of infectious disease are common in nursing facilities and often go unaddressed.

The U.S. states with the highest share of nursing homes with deficiencies related to the spread of infection include California, Michigan, Idaho, Delaware, Illinois, Mississippi, Missouri, and Alabama. The share of facilities in these states with infection prevention and control deficiencies exceeds 50 percent. Given the importance of following infection control procedures in mitigating the spread of viruses, facilities that have historically reported infection control deficiencies could be at elevated risk of a serious infectious disease outbreak.

Essential Industries Have a High Opportunity Cost of Disruption from Infectious Disease

We intend to prioritize the following segments and customers: education and healthcare services, wholesale and retail trade, leisure and hospitality, transportation and utilities, and agriculture and related food processing, among other essential industries. All together, these industries operating in the U.S. employed 81.7 million people in 2019-2022 or more than half of total employment. Prioritization of these segments is subject to change.

Education and healthcare are the largest industry in the U.S. by number of employed persons with 35.9 million or 23 percent of total employment in 2019-2022, followed by wholesale and retail trade with 19.7 million employed or 13 percent of the 2019 total. The leisure and hospitality industry employed 14.6 million or 9 percent of total employment in 2019 and transportation and utilities employed 9.0 million or 6 percent and agriculture and related food processing employed 2.4 million or 2 percent of the total. Prioritization of these intended segments is subject to change.

Intellectual Property

We have licensed intellectual property that intends to help create a competitive advantage in detecting pathogens in humans, animals, and agriculture. The intellectual property portfolio that we license consists of at least eight issued utility patents and ten pending patents. We have the right to world-wide use for the healthcare sector of these eight granted patents and ten pending patents as well as future patents through perpetual licenses with our parent companies, IdentifySensors, LLC and IdentifySensors Fresh Food Enterprises, LLC (“ISFFE”). IdentifySensors LLC owns a majority interest in ISFFE. ISFFE owns a majority interest in the us.

Table 2: Active and Patent Pending Portfolio

Business Vertical	Product Line	Granted Patent Numbers
Clinical Diagnostics	Check4® (includes all clinical pathogens)	20230011293, 11614439, 11340210, 11172339, 11179061, 10395503, 9922525, 11527141 (10 additional patents pending being prosecuted globally)
Food Safety & Sustainability	Check4Fresh™ (includes foodborne pathogens)	7667593, 7176793, 7911336, 8629770, 8674827, 9922525, 10395503, 10555505, 11140880 (5 additional patents pending)
Infrastructure & Environmental Monitoring	Check4Leaks™ (includes wastewater & emission monitoring)	9922525, 10395503, 10490053, 11024146, 20180321214 (5 additional patents pending being prosecuted globally)
National Security	Check4Threats™ (includes CBRN threats)	7667593, 7176793, 7911336, 8629770, 8674827, 9922525, 10395503, 11179061, 11172339, 10395503, 9922525

Description of License Agreement

ISFFE has granted us an exclusive license to use the carbon nanotube intellectual property, including patents, patents pending, technology, enhancements, tradenames, trademarks, trade secrets and processes. We can make, use, and sell any products derived from the intellectual

property in the clinical diagnostic industry only. ISFFE does not own all such intellectual property but has rights to grant the license pursuant to a separate license agreement from Identify Sensors, LLC, which in turn licenses the intellectual property from Dr. Gregory Hummer (see "**Risk Factors—Conflicts of Interest**").

Licensed IP. The intellectual property licensed to us includes seven (7) patents and seven (7) patents pending, as described below. We also have the right to use the tradename "IdentifySensors." We believe that such intellectual property is sufficient to develop and commercialize the products and services we intend to offer.

No Fees or Royalties. We do not pay ISFFE any royalties or other fees for the use of the licensed intellectual property. ISFFE could receive dividends, if any, from us with respect to our in proportion to its ownership percentage.

Term. The License Agreement is perpetual but is subject to early termination by ISFFE only if we attempt to assign the rights to the License Agreement to a third party without ISFFE's consent.

Scope of License. The license is worldwide and permits us to make, use and sell our products anywhere in the world. We can only use the licensed intellectual property in the clinical diagnostic industry. IdentifySensors, LLC and ISFFE has or may in the future grant the right to use the intellectual property in other industries or for other applications and we will have no rights or interest in such other industries or applications.

Ownership of Enhancements, Improvements and Modifications. The License Agreement provides that all enhancements, improvements, modifications, or other changes to the intellectual property will be the exclusive property of ISFFE, even if developed by us, but ISFFE will license such enhancements or developments back to us pursuant to the License Agreement.

Indemnification. We have agreed to indemnify and defend ISFFE against any suits, claims or damages arising from its actions, from any product liability related to our products and from our breach of the License Agreement. ISFFE has agreed to indemnify and defend us against claims of infringement by third parties.

Patent Description

The patents licensed to us from IdentifySensors, LLC have broad claims to devices, systems, and methods for detecting chemicals and pathogens. These patents are licensed to IdentifySensors, LLC or owned by IdentifySensors, LLC and IdentifySensors, LLC has granted to us the exclusive right to make, use and practice within the clinical diagnostics business vertical as described in this Annual Report. Ownership and right to enforce of all patents shown and future patents derived within the business vertical reside with IdentifySensors, LLC.

Production & Marketing

Testing and Evaluating Platform Devices Seeking FDA Approval

The FDA has specified templates for commercial manufacturers seeking Emergency Use Authorization (EUA) and DeNovo pathways[2]. We intend to closely follow provided templates, particularly those templates that relate to molecular diagnostic tests in crafting a test and development plan. We now have 5 pre-submissions into the FDA covering Ebola, Marburg, Covid19, Flu A&B and RSV A&B

The test and development plan could consist of steps aimed at generating the appropriate data and information required by the FDA for pre-EUA and EUA submission for Ebola and Marburg viruses. FDA recommends that the following validation studies be conducted for all infectious diseases molecular diagnostic assay: (i) Limit of Detection, (ii) Inclusivity, (iii) Cross-reactivity, and (iv) Clinical Evaluation. ISB's first multiplexed respiratory cartridge will be presented to the FDA in 2023 via the FDA Break-Through pathway. ISB intends to file at least 7 FDA application in 2023 for various infectious agents.

[2] The De Novo request provides a marketing pathway to classify novel medical devices for which general controls alone, or general and special controls, provide reasonable assurance of safety and effectiveness for the intended use, but for which there is no legally marketed predicate device.

Product Manufacturing Standards

We intend to pursue current good manufacturing practice (CGMP), a system for ensuring that products are consistently produced and controlled according to quality standards. The process could be designed to minimize the risks involved in any pharmaceutical production that cannot be eliminated through testing the final product. We intend to be ISO 13485 certified by end of November 2023.

CGMP requirements for medical devices in part 820 (21 CFR part 820) were first authorized by section 520(f) of the Federal Food, Drug, and Cosmetic Act (the Code). The Code was amended in 1990, when FDA undertook the revision of the CGMP regulation to add the design controls authorized by the Safe Medical Devices Act. The amended Code provides consistency, to the extent possible, with the requirements for quality systems contained in applicable international standards, primarily, the International Organization for Standards (ISO) 9001:1994 "Quality Systems--Model for Quality Assurance in Design, Development, Production, Installation, and Servicing," and the ISO committee draft revision of ISO/CD 13485 "Quality Systems--Medical Devices--Supplementary Requirements to ISO 9001."

We also intend to follow guidance on product manufacturing for molecular diagnostic devices provided by FDA. Under FDA guidance, we intend to meet product manufacturing requirements, including providing information on the following: manufacturing capabilities, production capacity, production timeframe, components included with test, software validation, testing capabilities and sample stability.

In addition to our intention of complying with CGMP practices and FDA standards, we intend to work with manufacturing partners that are ISO-certified (ISO 9001, ISO 13485 and EN ISO 13485) and compliant to FDA 21 CFR820.

Scaling Diagnostic Platform Production

The diagnostic platform is intended to be based on semiconductors currently in volume production by Tier-1 semiconductor manufacturers or chip printers. This could provide many options for sourcing components and negotiating assembly contracts. We selected East West Manufacturing, LLC, a Georgia limited liability company, and global manufacturer and supplier, to scale production of our products.

Existing ISO-9001 qualified component distribution channels intend to support initial product ramp-up to minimize the risk of counterfeit components.

The durable components of the platforms intend to be designed using mainstream electronics manufacturing processes allowing us to have a variety of vendors concurrently manufacturing to minimize the risk of single-point failure.

All products intend to be designed for automated test and assembly to decrease costs and increase uniformity.

Distribution & Marketing Channels

Distributors are essential partners in getting medical device products to market. They often add efficiency to a supply chain that connects two highly fragmented markets – the more than 6,500 medical device companies and the more than 180,000 healthcare facilities that serve as points of dispensation.

Product Pricing & Positioning

One of the primary intended goals in the development of our proposed platforms is to significantly lower the testing costs and drastically reduce test result turnaround time from days to minutes. The estimated price per test for our diagnostic platform is expected to be $25-50 plus a one-time purchase of durable components, which price range are set forth below. The durable component is a reusable reader that integrates with a smartphone for $50-112.

Table 3: Estimated Pricing for Each Diagnostic Platform

Estimated Price	BUSINESS	HOME	PUBLIC
Durable Components	$112.00	$50-112.00	$50-$112.00
Disposable Components	$50.00	$25-50.00	$50.00

Note: 1) Durable components consist of a reader. The reader intends to transmit test measurement data to the Cloud where it can be interpreted further to generate a test result. Disposable components consist of a saliva sample collection swab and a test cartridge. The test cartridge contains the biosensor that can connect with the reader. **2)** Estimated pricing is subject to change.

Go to Market Strategy & Addressable Market

The purpose of developing a "Go-to-Market" (GTM) strategy is to connect the dots in a coherent plan, orchestrate activities and align strategic resources towards a common goal of growing sales. Equally important, a GTM strategy provides a framework for measuring progress in achieving near-term goals or long-term strategic business growth objectives. It also helps early identification and diagnosis any issues that hamper success.

While a GTM is helpful for planning, such plans always change throughout the course of a business, and we expect our business is no different – the following GTM strategy is subject to change.

The intended audience is segmented among three groups: 1) Businesses operating in essential industries that need to establish robust testing programs; 2) Individuals and families that need to be tested frequently, and 3) Public sector agencies responsible for providing available and affordable testing to the general population. The intended goal of our product is to eliminate the threats that pathogens present to humanity.

Intended Target Audience

Our initial intended target markets include businesses in various industries, individuals and public agencies.

Businesses operating in essential industries, particularly education and healthcare, trade and transportation, leisure and hospitality, retail and agriculture production and processing among other industries need a fast, accurate and inexpensive high-volume diagnostic platform for implementing robust testing programs. While the definition of essential workforce can vary by state, the Department of Homeland Security (DHS) defines essential and critical infrastructure industries to include: law enforcement, public safety and other first responders; education; food and agriculture; energy; water and wastewater; transportation and logistics; public works and infrastructure support services; communications and information technology; other government-based operations and essential functions; critical manufacturing; hazardous materials; financial services; chemical; defense industrial base; commercial facilities; real estate and shelter facilities and hygiene products and services. We intend to prioritize education and healthcare, trade and transportation, leisure and hospitality and agriculture production and processing, and expand to other essential industries as opportunities allow. Prioritization of intended target markets is subject to change.

The four intended target business markets that we intend to prioritize account for more than half of U.S. employment or 70.8 million workers across 53 U.S. states and territories. The top ten U.S. states with the most workers in our four intended markets include: California, Texas, Florida, New York, Pennsylvania, Illinois, Ohio, Georgia, North Carolina, and Michigan.

Table 4: Top Ten States by Number of Employees in Four Essential Industry Intended Target Markets

State	Education/ Healthcare	Trade/ Transportation	Leisure/ Hospitality	Agriculture Production/ Processing	Total
California	2,781,960	3,125,777	2,037,941	465,789	8,411,467
Texas	1,707,227	2,560,847	1,395,933	9,738	5,673,745
Florida	1,345,619	1,846,258	1,256,803	345,216	4,793,896
New York	2,021,931	1,576,216	950,151	38,435	4,586,733
Pennsylvania	1,245,269	1,145,166	568,394	76,342	3,035,171
Illinois	931,789	1,209,998	618,648	1,224	2,761,659
Ohio	915,342	1,051,076	561,707	56,435	2,584,560
Georgia	589,162	957,514	496,456	20,334	2,063,466
North Carolina	613,320	863,655	511,397	23,487	2,011,859
New Jersey	676,785	898,563	382,017	29,160	1,986,525
Michigan	666,704	805,029	425,697	11,184	1,908,614
Total	**13,495,108**	**16,040,099**	**9,205,144**	**1,077,344**	**39,817,695**

Not surprisingly, the three states with the largest essential industry workforce, also happen to have the highest number of infectious disease cases. As of June 30, 2021, California led total case count with 5,033,935, followed by Texas with 4,296,053 and Florida with 3,684,332.

Examining addressable markets by each of the four intended target industries provides a similar picture with one exception being agriculture production. The most populous states are not always the ones most involved in agriculture production. Iowa, New Mexico, and Kentucky rank among the top five states that employ the most agriculture workers.

Other industries, however, reflect states that simply employ the most people. Trade and transportation are the largest intended target markets by number of employees nationally with a total of 28.3 million workers across 53 U.S. states and territories. Education and healthcare are the second largest with a total of 23.5 million workers, followed by leisure and hospitality with 16.4 million and agriculture production with 2.6 million workers.

Individuals and families need a fast, accurate and inexpensive personal diagnostic platform for regular testing to mitigate the risk of contracting COVID-19 and other infectious diseases from routine daily activities. There were 128.6 million resident households in the U.S. in 2019, with an average of 2.5 people per household, totaling about 321.5 million people. The resident household population of 321.5 million accounts for 98 percent of the 328.2 million people accounted for in the U.S. during 2019.

The largest U.S. states by resident households such as California, Texas, Florida, New York, and Pennsylvania also happen to be the largest employers and where Flu, RSV and COVID-19 case counts are highest.

Public agencies need access to rapid, accurate and inexpensive testing technology that can be deployed efficiently through the general population in case of a health emergency. These tests also need to definitively diagnose the targeted infectious disease, such as the Flu and/or COVID-19. Our diagnostic platform intends to serve the public sector entities that are responsible for administering high volumes of public infectious disease testing.

Intended Addressable Market

Table 5 presents estimates of the intended addressable market based on a range of diagnostic tests performed in a year broken-down by target market. The range consists of lower bound estimates of the number of tests per year for each target market and upper bound estimates of the number of tests per year for each target market. The lower bound estimates total 730 million tests a year, which equates to 60.8 million a month and 2 million a day. The upper bound estimates total 1.5 billion tests a year, which equates to 121.7 million a month and 4 million a day. While these estimates are subject to change and can end up being significantly different than actual values.

We believe that these are reasonable estimates given that during the period between October 31, 2021 and June 11, 2022, 10.7 million self-tests were reported by users, and 361.9 laboratory based and point of care tests were reported[3].

Table 5: Estimated Addressable Market Based on a Range of Annual Testing Capacity in the U.S.

Target Market	Lower Bound Number of Tests/Yr. (Millions)	Upper Bound Number of Tests/Yr. (Millions)
(A)Business: Private, High-Volume Testing for Essential Workers Administered by Trained Personnel	442.4M	592.7M
(B)Individuals: Private, Regular Self-Testing for Individuals & Families Administered by Individual	180.0M	602.9M
(C)Public: High-Volume Testing for Anyone Administered by Trained Personnel	107.7M	264.4M
TOTAL	**730.1M**	**1.5B**

Notes: The lower bound estimate of the number of tests for (A) *Businesses* assumes testing of approximately 25% of Tier 1 essential workers in each state. Tier 1 essential workers include the following industries: education, healthcare, trade and transportation, leisure and hospitality and agriculture production. Tier 1 essential workers are tested about two times per month or approximately 24 times per year. The upper bound estimate of the number of tests for Businesses assumes that less than 50% of Tier 1 essential workers in each state are tested less than two times per month or less than 24 times per year. The lower bound estimate of the number of tests for (B) *Individuals* assumes that about 1% of a state's population could be tested every week. The upper bound estimate of the number of tests uses the assumption that approximately 8.5% of a state's population is tested every week. The lower bound estimate of the number of tests for (C) *Public* is based on proposed levels of testing (daily tests/100k people) by each state for mitigating the spread of COVID-19. The upper bound estimate of the number of tests for Public is based on proposed levels of testing (daily tests/100k people) by each state for suppressing the spread of Flu, RSV and COVID-19. For both the lower bound and upper bound estimate we assume to deliver a quarter of the testing capacity.

Our Rapid Molecular Diagnostic Value Proposition

We intend to help deliver widespread testing of different pathogens that is not only affordable, but effective by providing immediate test results. Our molecular self-test could be performed at home and is intended to be so simple that anyone can do it. The test intends to have the following advantages over other molecular tests:

- Detects the nucleic acid that is inside the virus without using sample preservation, sample transportation, reverse transcription, amplification or enzymes and reagents that are in short supply.
- Uses unprepared saliva as the test sample instead of nasopharyngeal swab.
- Cost per test is intended to be about four times less expensive than the cost of laboratory-based molecular tests.
- Test results intended to be provided in minutes not days.
- Platform intends to allow for frequent testing including daily.
- Test results intend to be provided in a digital output that can be transmitted to smartphone using Bluetooth.
- Test results intend to be automatically reported to state lab and CDC via AIMES platform.
- Easily manufactured in the U.S. and could be scaled to meet demand.
- Platform could be used for many other viruses like Influenza A and B and bacterial pathogens.

---

[3] Center for Disease Control. 2022. *COVID-19 Self-Test Data: Challenges and Opportunities — United States, October 31, 2021–June 11, 2022*. May 1, 2023. https://www.cdc.gov/mmwr/volumes/71/wr/mm7132a1.htm

Government Regulation

The Food and Drug Administration (FDA) is responsible for protecting the public health by ensuring safety, efficacy and security of human and veterinary drugs, biological products and medical devices. The agency also ensures the safety of the U.S. food supply, cosmetics and products that emit radiation.

COVID-19 was declared as a Public Health Emergency (PHE) under Section 319 of the Public Health Services Act. As of the date of this Annual Report, such declaration has expired. However, the end of the PHE does not impact the FDA'S ability to authorize devices, including tests, for emergency use. Existing emergency use authorizations (EUAs) for devices remain in effect, and the FDA may continue to issue new EUAs going forward while the EUA declarations under section 564 of the Federal Food, Drug, and Cosmetic Act are in effect and when the criteria for issuance of an EUA are met.

Description of Property. We entered into a 24-month lease in Shaker Heights, Ohio, effective April 1, 2022 with monthly rental payments of $1,600.00. We entered into a twelve-month lease effective June 1, 2022 for office space in Austin, Texas with monthly rental payments of $2,050. The Austin lease was terminated as the staff now work from home. Our lab was moved to Gainesville, Florida to the University of Florida Innovation Center where the space is about 2400 sq feet of professional lab space. Rent for this space is $7,000 a month, paid on a month to month basis. We believe that such office space is likely to be sufficient for the foreseeable future.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion relates to the historical operations and financial statements of IdentifySensors Biologics Corp for the fiscal year ended June 30, 2023, and the fiscal year ended June 30, 2022.

Forward-Looking Statements

The following Management's Discussion and Analysis should be read in conjunction with our financial statements and the related notes thereto included elsewhere in this annual report. The Management's Discussion and Analysis contains forward-looking statements that involve risks and uncertainties, such as statements of our plans, objectives, expectations, and intentions. Any statements that are not statements of historical fact are forward-looking statements. When used, the words "believe," "plan," "intend," "anticipate," "target," "estimate," "expect," and the like, and/or future-tense or conditional constructions ("will," "may," "could," "should," etc.), or similar expressions, identify certain of these forward-looking statements. These forward-looking statements are subject to risks and uncertainties that could cause actual results or events to differ materially from those expressed or implied by the forward-looking statements in this annual report. Our actual results and the timing of events could differ materially from those anticipated in these forward-looking statements. Factors that could cause or contribute to such differences in results and outcomes include, without limitation, those specifically addressed under the heading "Risks Factors" in our various filings with the Securities and Exchange Commission. We do not undertake any obligation to update forward-looking statements to reflect events or circumstances occurring after the date of this annual report.

Company Overview

IdentifySensors Biologics Corp., is a Delaware corporation, founded on June 11, 2020. Since inception, we have been in the business of developing tests for viral and bacterial pathogens like COVID-19 but applicable to other diseases as well. We are now manufacturing our products and expect to complete initial prototypes during the fiscal year 2023. However, before any commercial sales occur in the

U.S., we must complete extensive testing and obtain approval from the U.S. Food and Drug Administration. Such efforts will require significant additional capital.

Because our products and services were initially specifically designed to address the testing needs for COVID-19, recent developments in the pandemic have caused us to broaden the testing capabilities of our products targeting other pathogens such as Ebola and Marburg viruses. We have made 5 pre-submissions to the FDA and intend to have FDA clearance for testing Ebola/Marburg virus by the end of 2023. We intend to commence generating revenues in the first quarter of 2024.

As of June 30, 2023, we had not yet commenced commercial sales or generated any revenue. Our activities since inception have consisted of formation activities, establishing agreements, and raising capital, principally through the sales of common stock and loans from affiliates. Our expenses have been primarily research and development costs, administrative expenses, and professional fees. We will incur significant additional research & development, and significant manufacturing expenses. We are dependent upon additional capital resources for the commencement of our planned principal operations and is subject to significant risks and uncertainties; including failing to secure additional funding to operationalize our planned operations or failing to profitably operate the business.

Financial Condition and Results of Operations

We have incurred recurring losses to date. Our financial statements have been prepared assuming that we will continue as a going concern and, accordingly, do not include adjustments relating to the recoverability and realization of assets and classification of liabilities that might be necessary should we be unable to continue in operation.

We expect we will require additional capital to meet our long-term operating requirements. We expect to raise additional capital through, among other things, the sale of equity or debt securities. We have invested in manufacturing machinery that will facilitate our CMs in producing our product.

Results of Operations

Fiscal Year Ended June 30, 2023

We incurred a net loss for the fiscal year ended June 30, 2023, of $4,384,431.

No revenue was earned or recognized during the fiscal year ended June 30, 2023. During our fiscal year ended June 30, 2023, we raised $4,379,637 from the sale of common stock.

Total operating expenses in the year ended June 30, 2023, were $4,374,677 as compared to $3,063,289 for year ended June 30, 2022. The increase is because as of June 30, 2022, we had not started prototype manufacturing. Operating expenses include $2,225,512 in research and development expenses, $218,930 in manufacturing expenses, $578,959 in marketing expenses, $1,082,121 in office and administrative expenses, and $269,155 in professional fees.

Research and Development. Research and development costs were $2,225,512 for the year ended June 30, 2023, as compared to $1,374,083 for the year ended June 30, 2022. The research and development expenses consist of $170,889 to Purdue University, subcontractor expenses of $452,718, payroll costs of $872,446, computer costs of $28,065, rental costs of $25,539, consulting costs of $2,230,133, miscellaneous costs of $57,555 and lab supply costs of $388,166 for the year end June 30, 2023, as compared to $1,374,083 in research and development expenses for the year ended June 30, 2022. The research and development expenses consist of $123,105 to Purdue University, subcontractor expenses of $406,333, payroll costs of $140,539, manufacturing costs of $29,469, computer costs of $100,668, rental costs of $15,300, miscellaneous costs of $24,491 and lab supply costs of $534,178 for the year end June 30, 2022. The increase in research and development expenses is due to increased testing and lab costs related to testing and analysis to meet the validation requirements which are necessary in order to obtain approvals needed to sell products to customers.

Office and Administrative Expenses. Office and administrative expenses for the year ended June 30, 2023, were $1,082,121 and consist of consulting, management services, sales consulting, stock awards, and our company operations. Office and administrative expenses for the year ended June 30, 2022, were $1,047,234 and consist of management services, stock awards and company operations. The increase is

attributable to us issuing additional stock compensation as well as increased general expenses as FDA processes and regulatory processes are ongoing.

Professional Expenses. Legal and professional expenses for the year ended June 30, 2023, were $269,155 and consist of accounting and audit fees, legal expenses associated with business activities as well as patents and Security and Exchange Commission requirements, consulting expenses of members of management, and expenses related public offerings and operations of the Company. Legal and professional expenses for the year ended June 30, 2022, were $253,937 and consist of accounting and audit fees, legal expenses associated with contracts, expenses related public offerings and operations of the Company. The increase in professional fees is due to the cost of the services rendering increasing.

Manufacturing Expenses. We incurred manufacturing expenses during the year ended June 30, 2023, of $218,930. These expenses consisted of the costs incurred in order to manufacture prototypes. No manufacturing expenses were incurred for the year ended June 30, 2022. We expect expenses to be substantial for upcoming manufacturing.

Marketing Expenses. Marketing expenses for the year ended June 30, 2023 were $578,959. These costs consisted of advertising, marketing, and consulting related to marketing. There were a small amount of marketing expenses incurred during the year ended June 30, 2022, however, during the year ended June 30, 2022, they were classified as a component of office and administrative expenses.

Other Income (Expense). Other income (expense) was $(9,754) for the year ended June 30, 2023, which consisted of $44 of interest income, and $9,798 for interest expense on a related party loan. Other income (expense) was $2,230 for the year ended June 30, 2022, which consisted of $11,662 rental income from a sub-lease in Cedar Park, Texas, and $9,432 for interest expense on a related party loan.

Fiscal year Ended June 30, 2022

We incurred a net loss for the fiscal year ended June 30, 2022, of $3,061,059.

No revenue was earned or recognized during the fiscal year ended June 30, 2022. During our fiscal year ended June 30, 2022, we raised $4,088,105 from the sale of common stock.

Liquidity and Capital Resources

Our cash balance at June 30, 2023 was $1,470,562 compared to $1,995,851 at June 30, 2022. We do not believe these cash reserves are sufficient to cover our expenses for our operations for fiscal year ending June 30, 2024. We will require additional funding for our ongoing operations.

At our current level of operations, we expend approximately $400,000 per month, meaning that we would require $4,800,000 in available cash to fund operations through June 30, 2024. However, our business plans anticipated that we would commence prototype testing and apply for approval of the FDA during this fiscal year. Such activities would require substantial additional capital, estimated to be approximately $5,000,000. We do not have any commitments for such amount of capital either through debt or equity financing. If we do not raise the capital required to implement our business plan, we may need to curtail necessary research and development activities, delay completion and testing of prototypes and defer the application for FDA approval. Such delays would have a materially adverse effect on our operations and our prospects for success.

We may be required to offer rescission to certain investors in our Regulation A Offering. We were obligated to file our annual report for the year ended June 30, 2021, within 120 days after the end of the year. We did not file such reports on a timely basis. As a result, the exemption from registration under Regulation A may not have been available for the sale of certain shares of common stock. We offered rescission to investors who purchased shares during the period such filings were late and to return the amount invested per SEC guidelines. We estimate that an aggregate of approximately $234,000 was invested during the period from June 30, 2021 to March 3, 2022 during which such reports were late. None of the investors elected rescission and no amount has been accrued on the June 30, 2023 financial statements.

We plan to continue to fund our operations and capital funding needs through equity financing and the exercise of warrants issued in private placements. There is no assurance that we will be able to raise money through this offering or through the exercises of warrants. There are no assurances that we will be able to obtain further funds required for our continued operations. Even if additional financing is available, it may not be available on terms we find favorable. Failure to secure the needed additional financing will have an adverse effect on our ability to remain in business.

Plan of Operation and Funding

We expect to continue research and development at our facility in Gainesville, Florida. We will also continue to establish relationships with prospective manufacturers, distributors, and large prospective customers. Existing working capital, further advances, together with anticipated capital raises and anticipated cash flow are not expected to be adequate to fund our operations over the next twelve months. Our CEO and other consultants and employees have agreed to defer payment of certain salaries or fees until we have adequate capital resources to implement our business plan. We have no lines of credit or other bank financing arrangements. We have financed operations to date through proceeds from the sale of our common stock, warrant exercises and convertible loans. The onset of manufacturing and required FDA clinical testing, will see a need for increased capital raise.

Management anticipates additional increases in operating expenses relating to: (i) developmental expenses; and (ii) manufacturing expenses. Manufacturing cost will be a larger percentage of spending as we build about 37,000 finished cartridges. We intend to finance these expenses through the sale of additional shares of securities and through the exercise of outstanding warrants.

Additional issuances of equity or convertible debt securities will result in dilution to our current shareholders. Further, such securities might have rights, preferences, or privileges senior to our common stock. Additional financing may not be available upon acceptable terms, or at all. If adequate funds are not available or are not available on acceptable terms, we may not be able to take advantage of prospective new business endeavors or opportunities, which could significantly and materially restrict our business operations.

Material Commitments

As of the date of this annual report, we do not have any material commitments except the leases described in Note 5 to the Financial Statements.

Transactions with Related Parties

During the fiscal year ended June 30, 2023, we entered several transactions with related parties. For a description of such transactions, see Note 6 to the Financial Statements. Such transactions were undertaken to secure capital for our operations or to retain the employment or professional services of the related party. The transaction prices were not determined based on arm's-length negotiations, although we believe that the prices were on terms no less favorable to the Company than those available from unrelated third parties. No fairness or other valuation opinions were obtained from third party valuation firms.

Purchase of Significant Equipment

We do not have any commitments to purchase equipment but have purchased significant equipment since June 30, 2023.

Off-Balance Sheet Arrangements

As of the date of this annual report, we do not have any off-balance sheet arrangements that have or are reasonably likely to have a current or future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources that are material to investors.

Going Concern

As reflected in the accompanying financial statements, we had an accumulated deficit of $9,414,533 at June 30, 2023 and net loss from operations of $4,374,677.

We do not yet have a history of financial stability. Historically, the principal source of liquidity has been the issuance of equity securities and related party advances. In addition, we are in the development stage and has not generated any revenues since inception. These factors raise substantial doubt about our ability to continue as a going concern.

The ability of the Company to continue operations is dependent on the success of management's plans and raising of capital through the issuance of equity securities, until such time that funds provided by operations are sufficient to fund working capital requirements.

We will require additional funding to finance the growth of its current and expected future operations as well as to achieve its strategic objectives. The Company believes its current available cash is insufficient to meet its cash needs for the near future. There can be no assurance that financing will be available in amounts or terms acceptable to the Company, if at all.

The accompanying financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. These financial statements do not include any adjustments relating to the recovery of the recorded assets or the classification of the liabilities that might be necessary should the Company be unable to continue as a going concern.

Critical Accounting Policies and Estimates

For a discussion of our accounting policies and related items, please see the Notes to the Financial Statements.

Quantitative and Qualitative Disclosure About Market Risk.

Not applicable.

Item 3. Directors and Officers

Our current directors and officers are as follows:

Name	Position	Age
Executive Officers		
Dr. Gregory Hummer	Chief Executive Officer	70
Bruce Raben	President and Secretary	69
Ann M. Hawkins	Chief Financial Officer and Treasurer	69
Jeff Spagnola	Chief Marketing Officer and Sales Director	62
Ghazi Kashmolah	Executive Vice President Regulatory Affairs, Chief Quality Officer and Chief Operating Officer	60
Directors		
Dr. Gregory Hummer	Director	70
Bruce Raben	Director	69

Devotion of Time by Executive Officers

Some of our executive officers are part time contractors. The following table sets forth their monthly commitment based upon the number of hours currently worked.

Name	Commencement Date	Estimated Hourly Commitment (per week)
Dr. Gregory Hummer	October 1, 2020	40 hours
Bruce Raben	October 1, 2020	Up to 20 hours
Ann M. Hawkins	October 23, 2020	Up to 20 hours
Jeff Spagnola	October 13, 2020	Up to 20 hours
Ghazi Kashmolah	February 9, 2023	40 hours

Business Experience of Executive Officers

Dr. Gregory Hummer, Chief Executive Officer and Director. Dr. Hummer was the Co-Founder of IdentifySensors, LLC in 2015. Dr. Hummer has developed patented nanotechnology, including cost-effective printed circuit sensors that communicate wirelessly with remote data terminals and nearby smartphones. This technology has broad application including security and environmental monitoring of explosives, harmful gases and chemicals that have the potential to disrupt business operations. Dr. Hummer was the Founder and CEO, Simplicity Health Plans (www.simplicityhealthplans.com) in 2008. Dr. Hummer also founded the self-funded group health StayFit (www.thestayfitplan.com) which is a Software-as-a-Service (SaaS) provider of Consumer Driven Health Plans (CDHP), Health Savings Accounts (HSA), Corporate Wellness Programs and Medical Bill Claims Processing. The StayFit technology is backed by patented Point-of-Service Adjudication and Payment System. Dr. Hummer is the co-owner of Blue Pearl Yachts (www.bluepearlyachts.com). Dr. Hummer designed and developed "*Blue Pearl*" a 114-foot Clipper Ketch Sailing Yacht. Dr. Hummer worked at St. Luke's Hospital, as Treasurer of Medical Staff and Trauma Surgeon for 16 years.

Dr. Hummer attended The Ohio State University, Columbus, OH — Medical Doctor, 1978 (3 years) Residency: General Surgery, Cleveland Clinic Hospital University of Notre Dame, South Bend, IN — Pre-professional Biochemistry and Computer Engineering, 1975. He is the author of over 20 published articles on High Deductible Health Plans and Health Savings Accounts, Point-of-Service Payment Technology, Self-Funded Health Plans and Corporate Wellness.

Bruce Raben, President and Director. Mr. Raben has been an investment, merchant banker and private investor for over 30 years and was a founding partner of Hudson Capital Advisors, LLC. Starting in 1979 at Drexel Burnham Lambert, he worked on many leveraged buyouts and recapitalizations including Mattel Toys, SFN Co.'s, Magma Copper, Warnaco, Mellon Bank and Grant Street Bank, and John Fairfax. Mr. Raben then went on to co-found the Corporate Finance Department at Jefferies & Co. in 1990. At Jefferies, he led the creation of the Energy group and the Gaming group and helped engineer the recapitalization of TransTexas Gas.

Mr. Raben opened the west coast office for CIBC's high yield finance and merchant banking activities in 1996. Shortly thereafter, he was the principal architect of CIBC's financing and co-founding of what became Global Crossing where he sat on the board. At its peak, CIBC's $30 million investment was worth in excess of $5.0 billion. Mr. Raben has sat on numerous public and private boards of investee and client companies. These include, Foodmaker, Rival Manufacturing, Magnetek, Warnaco, Terex, Global Crossing, Equity Marketing and Fresh Direct. Mr. Raben received his B.A. from Vassar College in 1975 and his MBA from Columbia University in 1979.

Ann M. Hawkins, Chief Financial Officer and Treasurer. Ms. Hawkins is a member of Edward C. Hawkins & Co., Ltd., a CPA firm and a member of Hawkins & Company, LLC., a law firm, both of which are based in Cleveland, Ohio. She received her law degree from Marquette University and received her B.B.A with Honors from the University of Notre Dame. Ms. Hawkins is a member of the American Bar Association, Ohio Bar Association, Florida Bar Association, Wisconsin Bar Association and Ohio Society of Certified Public Accountants. She is also admitted to United States Supreme Court, Supreme Court of the States of Ohio, Wisconsin, and Florida, Tax Court, and various federal courts.

Jeff Spagnola, Chief Marketing Officer. Mr. Spagnola spent 34 years in the communications industry working in a variety of sales and technical marketing roles. Early sales roles at NCR, Case Communications and Develcon Electronics prepared him for leadership roles at Cisco Systems, a global communications equipment provider. During 26 years at Cisco Systems, Mr. Spagnola's leadership assisted

Cisco in growing from a domestic business with revenue of $79.0 million (1991) to a global business with nearly $50.0 billion of revenue and over 75,000 employees. At Cisco Systems, Mr. Spagnola had many leadership roles including global sales management, global marketing, Service Provider business development, acquisition targeting and integration, government relations and partner management. Mr. Spagnola was a frequent speaker at both industry conferences and standards forums and was a spokesperson for Cisco's service provider business to Investors, Industry Analysts and Press. He has also held board positions at the Center for Telecommunication Management (https://www.marshall.usc.edu/ctm-team) at the University of Southern California's Marshall School of Business and also represented Cisco on the board of SuperComm, the largest United States tradeshow for the Service Providers. Mr. Spagnola is a graduate of the University of Dayton with a Bachelor of Science degree in Data Processing (1983). Born and raised in Cleveland Ohio, he and his wife Whitney now live in Kenwood, CA and have two grown children.

Ghazi Kashmolah, Executive Vice President, Regulatory Affairs and Chief Quality Officer. Since August 2021, he served as Chief Quality Officer and Executive Vice President Regulatory Affairs of Lucira Health. Prior to that, he was Chief Quality Assurance, Regulatory Affairs, and EH&S Officer at Orchid Orthopedic Solutions LLC, a medical device company, from September 2019 to August 2021. Prior to that, he led quality and regulatory affairs as Senior Vice President of QA/RA for DJO Global, Inc., a medical device company, from May 2013 to April 2019, Vice President of QA/RA at OSI Systems, Inc., a designer and manufacturer of specialized electronic systems and components, from March 2010 to May 2013, and Vice President of Global QA/RA at Life Technologies, a biotech company acquired by life sciences company Thermo Fisher Scientific Inc. in 2014, from November 2007 to November 2009. At Cardinal Health, Inc., a health care services company, Mr. Kashmolah was Vice President, Global Operations including manufacturing, supply chain, and quality, from January 2001 to July 2005. Mr. Kashmolah received a B.S. in electrical engineering from Wayne State University, an M.S. in electrical engineering from West Coast University, and an Executive M.B.A. from University of Iowa Tippie School of Management.

Compensation of Directors and Executive Officers

The table below summarizes all compensation paid to our directors and officers for all services rendered in all capacities for the fiscal year ended on June 30, 2023.

Name	Position	Cash Compensation	Other Compensation	Total Compensation
Dr. Gregory Hummer[(1)]	Chief Executive Officer	$156,667		$156,667
Bruce Raben	President	$60,000		$60,000
Thomas G. Sors	Chief Science Officer	$21,000		$21,000
Ann M. Hawkins[(2)]	Chief Financial Officer	-		-
Jeff Spagnola	Chief Marketing Officer and Sales Director	-		-
Ghazi Kashmolah	Executive Vice President, Regulatory Affairs and Chief Quality Officer	$158,451		$158,451

(1) Compensation increases as the annualized revenue of the company increases. If annualized revenue is averaging $20,000,000, then the quarterly payment to Dr. Hummer increases to $200,000, if revenue is averaging $40,000,000, then the quarterly payment increases to $300,000 and if the revenue is averaging $50,000,000, then the quarterly payment increases to $400,000. Further increases are determined by the Board of Directors.

(2) Thomas G. Sors stepped down of his position as the Company's Chief Science Officer on March 1, 2023.

(3) No compensation was paid directly to Ms. Hawkins. The Company paid $58,149 for accounting fees to Edward C. Hawkins & Co., Ltd., which is managed by Ms. Hawkins.

(4) Mr. Kashmolah's start date was February 9, 2023.

Employment and Consulting Agreements

We have entered into Contractor Agreements with each of Dr. Greg Hummer, Bruce Raben, Ann Hawkins and Jeff Spagnola have agreed to pay each a quarterly fee. The contract for Dr. Hummer's services is with IdentifySensors, LLC. The total amounts which have been accrued have not all been paid.

We entered into an employment agreement with Ghazi Kashmolah on February 9, 2023, to provide services as our Executive Vice President of Regulatory Affairs and Chief Quality Officer. Mr. Kashmolah shall provide services to us and to our affiliates, IdentifySensors Fresh Food Enterprises LLC and IdentifySensors LLC. The employment agreement stipulates at will employment and the provision of full time, exclusive services to us and our affiliates. It includes standard confidentiality, non-solicitation, and non-piracy provisions, as well as the assignment of all intellectual property developed by Mr. Kashmolah in connection with the services provided for our benefit. Mr. Kashmolah shall be entitled to receive a salary of $16,667 to be paid on the first and 15th day of each month for the first 12 months of his employment term. He will be entitled to receive a $150,000 bonus upon obtaining FDA approval for our first test, and a bonus equivalent to 30% of his base salary upon the achievement of certain revenue goals set by our board of directors. The employment agreement also includes payment of health benefits and contributions to Mr. Kashmolah's 401(K) plan. As part of his compensation package, Mr. Kashmolah received 400,000 stock options at a price of $4.50 per Share. The options vest in installments of 25,000 shares each at the end of each calendar quarter during Mr. Kashmolah's employment term, provided that he remains employed by the Company on the vesting dates.

Indemnification Agreements

Except for the general indemnification of the directors and officers of the Company provided by the Bylaws and the Certificate of Incorporation in accordance with Delaware General Corporation Law, we currently are not a party to any indemnification agreement with any director or officer of the Company. We may enter into agreements to indemnify any or all of our Board of Directors or officers at some time in the future. We believe that these agreements could be necessary to attract and retain qualified persons as executive personnel. The Company is aware that one of its consultants, Christopher Bongiorno, has been named in an SEC proceeding in connection with events occurring from 2015 to 2018 unrelated to the Company's operations and unrelated to this Offering. Effective July 15, 2023 the Company has terminated the consulting relationship with Christopher Bongiorno and his affiliates.

Equity Incentive or Stock Option Plan

Our Board of Directors and a majority of our stockholders have adopted and approved the 2020 Stock Incentive Plan (the "Plan"), pursuant to which we may grant or award stock or options to purchase stock up to a maximum of 9,222,227 shares. The awards may be given to employees, consultants, directors or other persons who render services to us. Awards are granted at the current fair market value of the Common Stock at the date of award. Awards may be subject to vesting provisions and repurchase rights in favor of the Company. The Plan is administered by the Board of Directors, unless a Compensation Committee is formed at which time the committee will administer the Plan.

As of the date hereof, the Board of Directors have made the following awards to executive officers and key consultants:

NAME	NO. OF SHARES[1]	DATE OF GRANT	COMPANY REPURCHASE SCHEDULE
Thomas G. Sors[(2)]	555,556	July 9, 2020	138,890 shares immediately and the remainder in 16 equal quarterly installments commencing on December 31, 2020.
Anne T. Hummer	416,667	July 9, 2020	145,833 shares immediately and the remainder in 16 equal quarterly installments commencing on December 31, 2020.
Lia A. Stanciu-Gregory	1,388,889	July 9, 2020	1,388,889 shares vested pursuant to her agreement and the remainder were forfeited upon the termination of her service for the Company.
Edmond DeFrank	111,112	July 9, 2020	All vest upon grant of patent, as long as within 4 years. Per a written action by the board of directors, 75% of the shares vested during the year ended June 30, 2022.
Rodney Corder	277,778	July 9, 2020	138,889 shares immediately and on January 8, 2022.

Bruce Raben	416,667	July 9, 2020	145,834 shares immediately, 145,834 shares on the first anniversary, and 125,000 shares on the second anniversary.
Patrick Roche	416,667	July 9, 2020	145,833 shares immediately and the remainder in 16 equal quarterly installments commencing on December 31, 2020.
Ghazi Kashmolah	400,000	May 5, 2023	Stock options with a strike price of $4.50 per share. Shares vest in installments of 25,000 each per quarter at the end of each quarter
Herma Hoda	10,000	May 5, 2023	Stock options with a strike price of $4.50 per share. The shares will vest upon the achievement of 2 separate employment related milestones: (i) making a submission for regulatory approval; and (ii) getting the submission approved
Kevin Amacker	10,000	May 5, 2023	Stock options with a strike price of $4.50 per share. The shares will vest upon the achievement of 2 separate employment related milestones: (i) making a submission for regulatory approval; and (ii) getting the submission approved.
Andrea Wallin	10,000	May 5, 2023	Stock options with a strike price of $4.50 per share. The shares will vest upon the achievement of 2 separate employment related milestones: (i) making a submission for regulatory approval; and (ii) getting the submission approved.
Felicia Hosey	10,000	May 5, 2023	Stock options with a strike price of $4.50 per share. The shares will vest upon the achievement of 2 separate employment related milestones: (i) making a submission for regulatory approval; and (ii) getting the submission approved.

[1]The number of shares above reflects the effect of a 1-for-3.6 reverse stock split effective as of September 30, 2020.

[(2)]Thomas G. Sors was engaged as an independent contractor on August 1, 2020 to provided services as our Chief Science Officer. Dr. Sors stepped down of his position as our Chief Science Officer on March 1, 2023.

Item 4. Security Ownership of Management and Certain Securityholders

The following tables set forth the ownership of our voting securities based on an aggregate of Common Shares issued and outstanding as of June 30, 2023. The information includes beneficial ownership by (i) each director and officer, (ii) all of our directors and executive officers as a group, and (iii) each person or entity who, to our knowledge, owns more than 10% of our Shares. Unless otherwise indicated, the address of each beneficial owner is 20600 Chagrin Boulevard, Suite 450, Shaker Heights, Ohio 44122.

The information presented below regarding beneficial ownership of our voting securities has been presented in accordance with the rules of the Securities and Exchange Commission and is not necessarily indicative of ownership for any other purpose. Under these rules, a person is deemed to be a "beneficial owner" of a security if that person has or shares the power to vote or direct the voting of the security or the power to dispose or direct the disposition of the security. A person is deemed to own beneficially any security as to which such person has the right to acquire sole or shared voting or investment power within 60 days through the conversion or exercise of any convertible security, warrant, option or other right. More than one person may be deemed to be a beneficial owner of the same securities.

Number and address of beneficial owner	Number of Shares	Nature of Beneficial Ownership	Percentage of class
Dr. Gregory Hummer[(1)]	42,277,778	Indirect	93.93%

Bruce Raben	145,834	Direct	*
Thomas G. Sors[(2)]	164,931	Direct	*
Ghazi Kashmolah	400,000	Direct	*
All directors and Officers as a group	42,988,543		94.95%

*Less than one percent.

(1) Includes 42,277,778 shares of Common Stock owned by IdentifySensors Fresh Food Enterprises, LLC, of which Dr. Hummer is the sole Manager. Dr. Hummer therefore has the power to vote these shares but otherwise disclaims beneficial ownership.

(2) Dr. Thomas G. Sors stepped down as our Chief Science Officer on March 1, 2021.

Item 5. Interest of Management and Others in Certain Transactions

Except as set forth in connection with Mr. Kashmolah's employment agreement, we have not entered into any transaction for the period ended June 30, 2022; and currently there are no proposed transactions, in which either us or any of our subsidiaries was or is to be a party, and where the amount involved exceeds $120,000, in which: (i) any of our directors or executive officers; (ii) any person who beneficially owns, directly or indirectly, shares carrying more than 10% of the voting rights attached to our outstanding Shares; or (iii) any member of the immediate family (including spouse, parents, children, siblings and in-laws) of any of the above persons, had or has a direct or indirect material interest.

Voting Control by CEO

IdentifySensors Fresh Food Enterprises, LLC owns more than 84% of the issued and outstanding voting shares of the Company. Dr. Hummer is the sole Manager of ISFFE and has the right to vote such shares. As a result, Dr. Hummer has sole voting control over our business and affairs.

No Ownership of the Intellectual Property

We have acquired rights to use the intellectual property invented by Dr. Hummer pursuant to a License Agreement with IdentifySensors Fresh Food Enterprises, LLC, which Dr. Hummer controls. See "Description of Business—License Agreement" In the event of any conflict with Dr. Hummer, the Company could lose access to and rights to use the intellectual property upon which our products will be developed.

No Arms'-Length Agreements.

The agreements between us and Dr. Hummer or his affiliated entities have not been negotiated at arms'-length. While we believe that the terms and conditions of such agreements are fair, there can be no assurances that we could not obtain more favorable terms from a third party.

Management Not Required to Devote Full Time and Energy

None of Dr. Hummer, Ann Hawkins and Jeff Spagnola is obligated to devote their respective full time and energy to our business and each has other business activities that may require a substantial amount of time and attention. We will not, therefore, be entitled to the full time and energy of such personnel.

Item 6. Other Information

Not applicable.

Item 7. Financial Statements

INDEX TO FINANCIALS STATEMENTS

MEADEN & MOORE

Report of Independent Registered Public Accounting Firm

Board of Directors and Shareholders

IdentifySensors Biologics Corp.

Opinion on the Financial Statements
We have audited the accompanying balance sheets of IdentifySensors Biologics Corp. (the "Company") as of June 30, 2023 and 2022, and the related statements of operations, changes in stockholders' equity (deficit), and cash flows for the years 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 June 30, 2023 and 2022, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Going Concern
The accompanying financial statements have been prepared assuming that the entity 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 net capital deficiency that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

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

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

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

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

Meaden & Moore, Ltd.
Cleveland, Ohio

We have served as the Company's auditor since 2022.

November 3, 2023

IdentifySensors Biologics Corp.
Balance Sheets

	June 30, 2023	June 30, 2022
ASSETS		
Current assets:		
Cash	$ 1,470,562	$ 1,995,851
Prepaid expenses	17,608	43,791
Total current assets	1,488,170	2,039,642
Property, plant and equipment	683,985	75,582
Operating lease right-of-use asset	146,285	32,572
Deposits	873,861	9,838
Total assets	$ 3,192,301	$ 2,157,634
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	$ 545,768	$ 173,258
Accrued contractor expense	0	45,496
Accrued contractor expense – related party	1,158,021	640,525
Accrued legal and accounting – related party	43,198	86,937
Accrued payroll	36,843	8,109
Subscription refunds payable	9,173	9,173
Operating lease liability	93,212	15,677
Total current liabilities	1,886,215	979,175
Long term liabilities:		
Operating lease liability	53,991	17,016
Note payable – related party	176,274	167,274
Total long term liabilities	230,265	184,290
Total liabilities	2,116,480	1,163,465
Stockholders' equity (deficit)		
Preferred stock, $0.0001 par value; 50,000,000 shares authorized, no shares issued and outstanding as June 30, 2023 and June 30, 2022	–	–
Common stock, $0.0001 par value: 350,000,000 shares authorized; 47,982,801 shares issued and outstanding at June 30, 2023 and 46,603,550 at June 30, 2022	4,878	4,724
Additional paid-in capital	10,485,476	6,019,547
Accumulated deficit	(9,414,533)	(5,030,102)
Total stockholders' equity (deficit)	1,075,821	994,169
Total liabilities and stockholders' equity (deficit)	$ 3,192,301	$ 2,157,634

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

IdentifySensors Biologics Corp.
Statements of Operations

	For the Year Ended June 30, 2023	For the Year Ended June 30, 2022
Revenue	$ –	$ –
Operating expenses:		
Research and development expenses	2,225,512	1,374,083
Manufacturing	218,930	–
Marketing	578,959	388,035
Office and administrative expenses	1,082,121	1,047,234
Professional fees	269,155	253,937
Total operating expenses	4,374,677	3,063,289
Loss from operations	(4,374,677)	(3,063,289)
Other Income (Expense)		
Interest expense	(9,798)	(9,432)
Interest income	44	–
Rental income	–	11,662
Total Other Income (Expense)	(9,754)	2,230
Loss before provision for federal income taxes	(4,384,431)	(3,061,059)
Provision for federal income taxes	–	–
Net loss	$ (4,384,431)	$ (3,061,059)
Net loss per common share - basic and diluted	$ (0.09)	$ (0.08)
Weighted average common shares outstanding - basic and diluted	47,265,897	45,242,201

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

IdentifySensors Biologics Corp.
Statement of Changes in Stockholders' Equity (Deficit)
For Year Ended June 30, 2023 and 2022

	Preferred Stock		Common Stock		Additional		Total
	Number of Shares	Amount	Number of Shares	Amount	Paid-In Capital	Accumulated (Deficit)	Stockholders' (Deficit)
Balance – July 1, 2021	–	$ –	44,849,439	$ 4,485	$ 1,831,494	$ (1,969,043)	$ (133,064)
Common stock issued for cash	–	–	980,223	99	3,460,245	–	3,460,344
Stock options vested	–	–	–	–	99,413	–	99,413
Warrants issued	–	–	–	63	627,698	–	627,761
Restricted stock awards vested	–	–	773,888	77	697	–	774
Net loss for the period	–	–	–	–	–	(3,061,059)	(3,061,059)
Balance - June 30, 2022	–	$ –	46,603,550	$ 4,724	$ 6,019,547	$ (5,030,102)	$ 994,169
Common stock issued for cash	–	–	867,803	87	4,217,212	–	4,217,299

Stock options vested	–	–	–	–	85,939	–	85,939
Warrants issued	–	–	–	16	162,322	–	162,338
Restricted stock awards vested	–	–	506,948	51	456	–	507
Net loss for the period	–	–	–	–	–	(4,384,431)	(4,384,431)
Balance - June 30, 2023	–	$ –	47,978,301	$ 4,878	$ 10,485,476	$ (9,414,533)	$ 1,075,821

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

IdentifySensors Biologics Corp.
Statements of Cash Flow

	For the Year Ended June 30, 2023	For the Year Ended June 30, 2022
Cash from operating activities:		
Net loss	$ (4,384,431)	$ (3,061,059)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock based compensation	86,446	100,187
Depreciation	49,852	1,315
Amortization	114,510	14,221
Changes in operating assets and liabilities:		
Prepaid expenses	26,183	60,287
Operating lease right-of-use asset	(113,712)	(15,542)
Security deposit	(864,023)	(3,888)
Accounts payable and accrued liabilities	829,506	572,801
Accrued interest	9,000	8,886
Net cash used in operating activities	(4,246,669)	(2,322,792)
Cash from investing activities:		
Purchase of equipment	(658,257)	(76,897)
Net cash used in investing activities	(658,257)	(76,897)
Cash flows from financing activities:		
Issuance of common stock and warrants for cash	4,379,637	4,088,105
Net cash provided by financing activities	4,379,637	4,088,105
Net change in cash	(525,289)	1,688,416
Cash - beginning of period	1,995,851	307,435
Cash - end of period	$ 1,470,562	$ 1,995,851
Supplemental Cash Flow Disclosures		
Cash paid for interest	$ –	$ –
Cash paid for income taxes	$ –	$ –
Issuance of warrants for stock	$ 3,052,500	$ 4,055,000

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

IDENTIFYSENSORS BIOLOGICS CORP
Notes to the Financial Statements
For the Year Ended June 30, 2023 and 2022

Note 1 Organization and Summary of Significant Accounting Policies

Nature of Operations

The Company, IdentifySensors Biologics Corp., is a Delaware corporation ("Company") founded on June 11, 2020. Since inception, the Company has been in the business of developing tests for viral and bacterial pathogens, initially specifically for Covid19, and lately for Ebola and Marburg viruses and to develop a Staph bacteria test in hospitals.

As of June 30, 2023, the Company has not yet commenced planned principal operations nor generated revenue. The Company's activities since inception have consisted of formation activities, establishing agreements, and preparations to raise capital, and the development of prototypes. Once the Company commences its planned principal operations, it will incur significant additional expenses. The Company is dependent upon additional capital resources for the commencement of its planned principal operations and is subject to significant risks and uncertainties; including failing to secure additional funding to operationalize the Company's planned operations or failing to profitably operate the business.

Basis of Presentation

The accompanying financial statements were prepared in conformity with accounting principles generally accepted in the United States of America ("U.S. GAAP").

Reverse Stock Split

On September 29, 2020, the Company amended its Certificate of incorporation to implement a 1-for -3.6 reverse stock split of its common stock. The reverse stock split did not cause an adjustment to the par value or the authorized shares of the common stock. As a result of the reverse stock split, the Company adjusted the share amounts under its stock incentive plan, outstanding options and common stock.

Revenue Recognition

No revenue has been earned or recognized as of June 30, 2023 or June 30, 2022. See Note 5 regarding rental revenue recognized as of June 30, 2023 and June 30, 2022.

Cash and Cash Equivalents

All liquid debt instruments, purchased with a maturity of 3 months or less, are considered to represent cash and cash equivalents. There were no cash equivalents as of June 30, 2023, and 2022.

Use of Estimates

The preparation of financial statements in conformity with generally accepted accounting principles requires Company management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosures of contingent assets and liabilities at the date financial statements and the reported amounts of revenues and expenses during the reporting period. Accordingly, actual results could differ from those estimates.

Property, Plant and Equipment

Property, plant and equipment are carried at cost. Expenditures for maintenance and repairs are charged to operations as incurred. Depreciation expense was $49,852 as of June 30, 2023 and $1,315 as of June 30, 2022.

The Company primarily follows the straight line method of depreciation utilizing the following range of lives:

Class	Years
Software	3
Equipment	5

Property, plant, and equipment consists of the following as of June 30, 2023 and 2022:

Class	June 30, 2023	June 30, 2022
Software	$ 236,721	$ 73,847
Equipment	498,431	3,050
Accumulated Depreciation	(51,167)	(1,315)
Net – Property, plant, and equipment	$ 683,985	$ 75,582

Income Taxes

FASB ASC 740-10 requires the affirmative evaluation that it is more likely-than-not, based on the technical merits of a tax position, that an enterprise is entitled to economic benefits resulting from positions taken in income tax returns. If a tax position does not meet the more-likely-than-not recognition threshold, the benefit of that position is not recognized in the financial statements. FASB ASC 740-10 also requires companies to disclose additional quantitative and qualitative information in their financial statements about uncertain tax positions. There are no unrealized tax benefits as of June 30, 2023.

The Company intends to file a U.S. federal tax return and other tax returns as required. All tax periods since inception remain open to examination.

The Company classifies penalties and interest expense associated with its tax positions as a component of general and administrative expenses. For the years ended June 30, 2023 and June 30, 2022 no interest and penalties associated with the Company's tax positions have been recognized in the Company's statements of operations or the balance sheet.

Research and Development Expenses

Research and development expenses are charged to expense as incurred. Research and development expenses include, but are not limited to, product development, clinical and regulatory expenses, materials, supplies, and related subcontract expenses. The expenses assigned to molecular gene detection sensors are for product commercialization to Purdue University and outside contractors and manufacturers. The Company is now in the phase of early manufacturing and seeking out manufacturing partners as well as government grants.

The research expenses are assigned to the research sensor project to demonstrate proof of principle in the detection of pathogens by rapid molecular gene identification in patients. Expenses support supplies and manpower to produce a working prototype. These expenses include compensation support of key personnel and consultants to develop a commercialization plan.

Marketing Expenses

Marketing expenses are charged to expense as incurred. Marketing expenses include, but are not limited to, generating investment leads, advertising for investment leads, advertising, consulting related to advertising, marketing of products, ad placements, and advertising consultants. Marketing expense for the years ended June 30 2023 and 2022 were $578,959 and $388,035, respectively.

Fair Value measurements

When required to measure assets or liabilities at fair value, the Company uses a fair value hierarchy based on the level of independent, objective evidence surrounding the inputs used. The Company determines the level within the fair value hierarchy in which the fair value measurements in their entirety fall. The categorization within the fair value of hierarchy is based upon the lowest level of input that is significant to the fair value measurement. Level I uses quoted prices in active markets for identical assets or liabilities. Level 2 uses significant other observable inputs, and Level 3 uses significant unobservable inputs. The amount of the total gains or losses for the period are included in earnings that are attributable to the change in unrealized gains or losses relating to those assets and liabilities still held at the reporting date.

Related Parties

The Company follows ASC 850, "Related Party Disclosures," for the identification of related parties and disclosure of related party transactions.

Basic and diluted earnings per share

Basic earnings per share is calculated by dividing net income (loss) by the weighted average number of common shares outstanding during the period. Diluted earnings per share is calculated based on the weighted average number of common shares outstanding during the period plus the effect of potentially dilutive common stock equivalents, including stock options, warrants to purchase the Company's common stock, restricted stock, and convertible note payable. For the year ended June 30, 2023, and 2022, potentially dilutive common stock equivalents not included in the calculation of diluted earnings per share because they were anti-dilutive are as follows:

	June 30, 2023	June 30, 2022
Warrants	440,185	303,475
Options	1,074,212	284,500
Total possible dilutive shares	1,514,397	587,975

Stock-based compensation

Stock-based compensation to employees and non-employees consist of stock options, warrants to purchase common stock and restricted shares that are recognized in the statement of operations based on their fair values at the date of grant. The fair value of shares of common stock is set by the Company's Board of Directors.

The Company's Board of Directors calculates the fair values of option and warrant grants utilizing the Black-Scholes pricing model, wherever possible, or by obtaining expert opinions, wherever possible. Assumptions used in using the Black-Scholes pricing include: (1) volatility based on the average volatility rate of similar companies, (2) risk free interest rate based on the U.S. Treasury yield for a term consistent with expected life of the awards in effect at the time of the grant, (3) the expected life of the option or warrants, and (4) expected cash dividend rate on shares of common stock. During the year ending June 30, 2023, and 2022 volatility was based on average rates for similar publicity traded companies.

The amount of stock-based compensation recognized during a period is based on the value of the portion of the awards that are ultimately expected to vest. The resulting stock-based compensation expense for employee awards is generally recognized on a straight-line basis over the vesting period of the award.

Common stock purchase warrants

Common stock purchase warrants and other derivative financial instruments are classified as equity if the contracts (1) require physical settlement or net-share settlement, or (2) give the Company a choice of net-cash settlement or settlement in its own shares (physical settlement or net-share settlement). Contracts which (1) require net-cash settlement (including a requirement to net cash settle the contract if an event occurs and if that event is outside the control of the Company), (2) give the counterparty a choice of net-cash settlement or settlement in shares (physical settlement or net-share settlement), or (3) that contain reset provisions that do not qualify for the scope exception are classified as liabilities. The Company assesses classification of its common stock purchase warrants and other derivatives at each reporting date to determine whether a change in classification between equity and liabilities is required.

Leases

Effective July 1, 2020, the Company has adopted FASB ASC 842. Pursuant to FASB ASC 842 operating lease liabilities and their corresponding right-of-use assets are initially recorded based on the present value of lease payments over the expected remaining lease term. Certain adjustments to the right-of-use asset may be required for items such as incentives received. The interest rate implicit in lease contracts is typically not readily determinable. As a result, the Company utilizes its incremental borrowing rate to discount lease payments, which reflects the fixed rate at which the Company could borrow on a collateralized basis the amount of the lease payments in the same currency, for a similar term, in a similar economic environment. Prospectively, the Company will adjust the right-of-use assets for straight-line rent expense, or any incentives received and remeasure the lease liability at the net present value using the same incremental borrowing rate that was in effect as of the lease commencement or transition date.

Pursuant to FASB ASC 842, the Company has elected not to recognize leases with an original term of one year or less on the balance sheet. Options to renew a lease are not included in the Company's assessment unless there is reasonable certainty that the Company will renew. Assumptions made by the Company at the commencement date are re-evaluated upon occurrence of certain events, including a lease modification. A lease modification results in a separate contract when the modification grants the lessee an additional right of use not included in the original lease and when lease payments increase commensurate with the standalone price for the additional right of use. When a lease modification results in a separate contract, it is accounted for in the same manner as a new lease.

Note 2 Going Concern

The Company's financial statements are prepared using U.S. GAAP, applicable to a going concern which contemplates the realization of assets and liquidation of liabilities in the normal course of business. During the years ended June 30, 2023 and June 30, 2022, the Company had a net loss of $4,384,431 and $3,061,059 respectively. As of June 30, 2023 and June 30, 2022, the Company had an accumulated deficit of $9,414,533 and $5,030,102, respectively. The Company has not established sufficient revenue to cover its operating costs and will require additional capital to continue. The Company's ability to continue as a going concern is dependent on obtaining adequate capital to fund operating losses until it becomes profitable. If the Company is unable to obtain adequate capital, it could be forced to cease operations. These factors raise substantial doubt about the Company's ability as a going concern.

To continue as a going concern, the Company will need, among other things, additional capital resources. Management's plan to obtain such resources includes: the sales of equity instruments; traditional financing such as loans, and to obtain capital from management and significant stockholders sufficient to meet its minimum operating expenses. However, management cannot provide any assurance that the Company will be successful in accomplishing this plan.

There is no assurance that the Company will be able to obtain sufficient additional funds needed or that such funds, if available, will be obtainable on terms satisfactory to the Company. In addition, profitability will ultimately depend upon the level of revenues received from business operations. However, there is no assurance that the Company will attain profitability. The accompanying financial statements do not include any adjustments that might be necessary if the Company is unable to continue as a going concern.

Note 3 Recent Accounting Pronouncements

In August 2020, the FASB issued ASU 2020-06, ASU Subtopic 470-20 "Debt-Debt with Conversion and Other Options" and ASC subtopic 815-40 "Hedging-Contracts in Entity's Own Equity". The standard reduced the number of accounting models for convertible debt instruments and convertible preferred stock. Convertible instruments that continue to be subject to separation models are (1) those with embedded conversion features that are not clearly and closely related to the host contract, that meet the definition of a derivative,

and that do not qualify for a scope exception from derivative accounting; and (2) convertible debt instruments issued with substantial premiums for which the premiums are recorded as paid-in capital. The amendments in this update are effective for fiscal years ended June 30, 2023. The Company has determined there was not an impact of the adoption of this standard on its financial statements.

Note 4 Income Taxes

All income taxes referred to herein are taxes in the United States. Deferred tax is recognized on differences between the carrying amounts of assets and liabilities in the financial statements and their corresponding tax basis (known as temporary differences). Deferred tax liabilities are recognized for all temporary differences that are expected to increase taxable profit and taxes payable in the future.

Deferred tax assets are recognized for all temporary differences that are expected to reduce taxable profit in the future. Deferred tax assets are measured at the highest amount that, based on current or estimated future taxable profit, is more likely than not to be recovered.

The net carrying amount of deferred tax assets is reviewed at each reporting date and is adjusted to reflect the current assessment of future taxable profits and future tax rates. Any adjustments are recognized in profit or loss.

Deferred tax is calculated at the tax rates that are expected to apply to the taxable profit (tax loss) of the periods in which it expects the deferred tax asset to be realized or the deferred tax liability to be settled, on the basis of tax rates that have been enacted or substantively enacted by the end of the reporting period for said future periods.

The net operating loss can only be used to offset up to 80% of net income. The remainder of the net operating loss can be carried forward indefinitely. As management of the Company cannot determine that it is more likely than not that the Company will realize the benefit of the deferred tax assets, a valuation allowance equal to 100% of net deferred tax asset exists at June 30, 2023 and 2022. As of June 30, 2022, the net operating loss carried forward is $3,667,205. The Company's tax returns for the period ended June 30, 2023 have not been filed as of the date of these financial statements.

The provision (benefit) for income taxes consists of the following:

	June 30, 2023	June 30, 2022
Federal Income Tax		
Current	$ –	$ –
Deferred	–	–
Total Federal Income Tax (provision)	$ –	$ –

The Company's current provision (benefit) for Federal income taxes of $0 is reconciled to the tax calculated at the statutory rate of 21% as follows:

	June 30, 2023	June 30, 2022
Federal taxes based on net loss		
Before Federal tax expense	$ (920,731)	$ (642,822)
Add tax on the following:		
Permanent differences	2,452	3,522
Temporary differences		
Book-to-tax depreciation	(114,864)	(16,299)
Capitalized R&D expenses	336,957	–
Stock compensation expense	18,047	21,050
Unpaid related party expenses	99,489	117,037
Unpaid related party interest	2,058	1,981
Change in deferred taxes from net operating loss	576,592	515,531

Provision for Federal Income Taxes	$ –	$ –

Significant components of deferred income tax assets and liabilities follows:

	June 30, 2023	June 30, 2022
Deferred tax liability	$ –	$ –
Net operating loss carryover	1,563,553	642,822
Permanent differences	2,452	3,522
Temporary differences	341,687	123,769
Valuation allowance	(1,907,692)	(770,113)
Net deferred tax asset (liability)	$ –	$ –

Note 5 Leases and Commitments

The Company entered into a lease agreement effective April 1, 2022, for a facility located in Shaker Heights, Ohio. The lease is a twenty-four-month lease with twenty-four monthly payments beginning on April 1, 2022. Base payments of $1,600 are due on the first day of each month. The lease is classified as an operating lease under FASB ASC 842 and a right of use asset is recorded on the balance sheet of $13,960 as of June 30, 2023 and $32,572 as of June 30, 2022, and a liability of $14,222 as of June 30, 2023 and $32,693 is recorded on the balance sheet as of June 30, 2022. Operating lease costs for the year ended June 30, 2023, and 2022 were $20,437 and $4,800 respectively.

The Company entered into a twelve-month lease agreement effective June 1, 2022 for office space in Austin, Texas. The lease agreement provides for monthly payments of $2,050 per month. The lease is classified as a short-term lease under FASB ASC 842, and is not reflected on the balance sheet. The lease was not renewed after June 30, 2023. Lease payments for the year ended June 30, 2023 were $38,882 and June 30, 2022 were $2,050.

The Company also entered into a lease agreement effective March 1, 2023, for a facility located in Gainesville, Florida. The lease is a twenty-four-month lease with twenty-four monthly payments beginning on March 1, 2023. Base payments of $6,825 are due on the first day of each month along with sales tax each month of $478. The lease is classified as an operating lease under FASB ASC 842 and a right of use asset is recorded on the balance sheet of $132,325 and $0 as of June 30, 2023 and 2022 and a liability of $132,982 as of June 30, 2023 and 0 is recorded on the balance sheet as of June 30, 2022. Lease costs for the year ended June 30, 2023, and the 2022 were $21,632 and $0, respectively. The lease has a renewal option, which extends the terms for an additional year. The lease can be cancelled at any time by the lessor.

The Right-of-use assets are summarized below:

	June 30, 2023	**June 30, 2022**
Office Lease	$ 191,363	$ 37,226
Less accumulated amortization	(45,078)	(4,654)
Right-of-use, net	$ 146,285	$ 32,572

Amortization on the right-of -use asset is included in office and administrative expenses on the statements of operations.

Operating lease liabilities are summarized below:

	June 30, 2023	**June 30, 2022**
Office Lease	$ 147,203	$ 32,693
Less: current portion	(93,212)	(15,677)

Long term portion	$ 53,991	$ 17,016

Following is a maturity of annual undiscounted cash flows for operating lease liabilities as of June 30, 2023:

	2024 and After
Maturing in fiscal year-ended	$ 96,300
Maturing after fiscal year-ended	54,600
Total	150,900
Less: Imputed interest	(3,697)
Liability recognized in the balance sheet	$ 147,203

The Company had subleased space in the facility located in Cedar Park, Texas. The agreement is a month-to-month rental that provides for monthly rental payments of $1,000. Rental income for the year ended June 30, 2023 and 2022 was $0 and $11,662, respectively.

Note 6 Related Party Transactions

Compensation owed to the Chief Executive Officer, Chief Financial Officer and Treasurer, Chief Science Officer, President and Secretary, Chief Marketing Officer and Sales Director for services for the year ended June 30, 2023 and 2022, was as follows:

	June 30, 2023	June 30, 2022
Chief Executive Officer	$ 400,000	$ 400,000
Chief Financial Officer and Treasurer	$ 40,000	$ 40,000
Chief Science Officer	$ 28,000	$ 26,667
President and Secretary	$ 80,000	$ 80,000
Chief Marketing Officer and Sales Director	$ 80,000	$ 80,000

Amounts owed to the Chief Executive Officer, Chief Financial Officer and Treasurer, Chief Science Officer, President and Secretary, Chief Marketing Officer and Sales Director for services are classified as accrued contractor expense – related party on the balance sheets.

On July 29, 2020, the Company borrowed $150,000 from IdentifySensors Fresh Food Enterprises LLC, a shareholder in the Company. The note bears interest at a rate 6% per annum. The note and accrued interest is due on July 28, 2024. Interest accrued on the note as of June 30, 2023, and June 30, 2022, was $26,274 and $17,274, respectively. The amount is classified as note payable – related party on the balance sheet.

During the years ended June 30, 2023 and June 30, 2022, the Company incurred expenses for accounting services in the amount of $72,282 and $125,915, respectively to Edward C. Hawkins & Co., Ltd., an entity owned 50% by the Chief Financial Officer and 50% by another related party. As of June 30, 2023, and June 30, 2022, the Company owed Edward C. Hawkins & Co., Ltd. $25,344 and $85,068, respectively. The amount is classified as accrued legal and accounting – related party on the balance sheet.

During the years ended June 30, 2023 and June 30, 2022, the Company incurred expenses for legal services in the amount of $12,033 and $1,231 respectively to Hawkins and Company LLC, an entity owned 50% by the Chief Financial Officer and 50% by another related party. As of June 30, 2023, and June 30, 2022, the Company owed Hawkins and Company LLC $11,810 and $1,869, respectively. The amount is classified as accrued legal and accounting – related party on the balance sheet.

During the years ended June 30, 2023 and 2022, the Company incurred expenses for consulting services in the amount of $222,541 and $331,330 respectively to Integra Ventures LLC, an entity fully owned by a partial owner of IdentifySensors Fresh Food Enterprises LLC. As of June 30, 2023, and June 30, 2022, the Company owed Integra Ventures LLC $33,959 and $13,850, respectively. The amount is

classified as accrued contractor expense – related party on the balance sheet. The consulting agreement with Integra Ventures LLC was terminated on July 15, 2023.

During the years ended June 30, 2023 and 2022, the Company incurred expenses for software development in the amount of $22,032 and $82,438, respectively to MCO Advantage, Ltd., an entity owned 50% by the Chief Executive Officer and 50% by another related party. The balance owed to MCO Advantage, Ltd. as of June 30, 2023, and June 30, 2022, was $975 and $0, respectively. The amount is classified as accrued contractor expense – related party on the balance sheet.

During the years ended June 30, 2023 and 2022, the Company incurred expenses for consulting and bookkeeping services in the amount of $41,667 and $40,000, respectively to Healthcare Office Systems Inc., an entity fully owned by a related party. The balance owed to Healthcare Office Systems Inc. as of June 30, 2023, and June 30, 2022, was $3,333 and $0, respectively. The amount is classified as accrued contractor expense – related party on the balance sheet.

Note 7 Stockholders' Equity

Authorized Capital Stock

On June 11, 2020, the Company filed a Certificate of Incorporation with the State of Delaware to authorize the Company to issue 400,000,000 shares, consisting of 350,000,000 shares of Common Stock, and 50,000,000 shares of Preferred Stock. The Company has two offerings where it is selling shares of the Company's common stock: Regulation A and Regulation D. Both offerings give the same common stock with the same voting rights and the same per share price of $4.50 as of June 30, 2023 and June 30, 2022. Regulation D investors can qualify to receive warrants whereas Regulation A investors do not.

	Shares issued pursuant to Reg A	Shares issued pursuant to Reg D
Outstanding as of June 30, 2021	42,490,345	2,395,114
Issued to consultants	–	773,868
Issued to investors	7,123	937,100
Outstanding as of June 30, 2022	42,497,468	4,106,082
Issued to consultants	–	506,948
Issued to investors	231,309	640,994
Outstanding as of June 30, 2023	42,728,777	5,254,024

Common Stock

During the year ended June 30, 2023, the Company had the following common stock transactions:

- Issued 640,994 shares of common stock pursuant to the Regulation D offering and 231,309 shares of common stock under the Regulation A offering for total cash proceeds of $4,379,637.
- Issued warrants to purchase 506,948 shares common. The par value is $0.001 per share.

During the year ended June 30, 2022, the Company had the following common stock transactions:

- Issued 973,100 shares of common stock pursuant to the Regulation D offering and 7,123 shares of common stock pursuant to the Regulation A offering for total cash proceeds of $4,088,105.
- Issued 773,888 warrants to purchase shares of common stock pursuant to the Regulation D offering.

Stock Options

On July 1, 2020, the Company's shareholders adopted a Stock Incentive Plan that was approved by the Board of Directors on July 9, 2020. Pursuant to the Plan, the Company's consultants were awarded Restricted Stock Awards in 2020. Compensation expense is recognized

over the vesting period of the awards based on the par value of the stock at the issue date, which for stock awards during the year ended June 30, 2022, was $0.001 per share. The stock was not traded in an open market on the date of grant and par value has been determined by the Board of Directors. Shares under the Plan vest according to each individual award agreement, which may include both performance based and time-based vesting.

Total shares issuable under the plan were 9,722,222 at June 30, 2023, and 7,770,000 shares were granted during the year ended June 30, 2021, none were granted in 2022, none were granted in 2023.

A summary of the changes in the Company's awarded shares for the year ended June 30, 2023 follows:

	Shares	Par Value
As of June 30, 2021	5,577,709	$ 5,578
Forfeited	–	–
Outstanding as of June 30, 2022	4,803,822	4,804
Exercisable as of June 30, 2022	773,887	$ 774

	Shares	Par Value
Outstanding as of June 30, 2022	4,803,822	$ 4,804
Granted	–	–
Forfeited	–	–
Outstanding as of June 30, 2023	1,330,697	1,331
Exercisable as of June 30, 2023	3,473,125	$ 3,473

As of June 30, 2023, there was $4,297 of total unrecognized compensation cost related to nonvested shares granted under the Plan. The cost is expected to be recognized over a weighted average period of 0.20 years.

As of June 30, 2022 there was $4,804 of total unrecognized compensation cost related to non-vested shares granted under the Plan. The cost is expected to be recognized over a weighted average period of 0.6 years.

The following summarizes the number of options granted and outstanding during the years ended June 30, 2023, and June 30, 2022:

	Number of Shares
Outstanding, June 30, 2021:	12,500
Granted:	272,000
Expired or Forfeited:	–
Exercised:	–
Outstanding, June 30, 2022:	284,500
Granted:	862,222
Expired or Forfeited:	(72,500)
Exercised:	(10)
Outstanding, June 30, 2023:	1,074,212
Exercisable, June 30, 2023:	108,490

No options expired during the year ended June 30, 2023, or the year ended June 30, 2022.

The following summarizes the vesting schedules for the options:

Date of Grant	Number of Shares	Exercise Price	Percent Vested at Date of Grant	Percent Vested Monthly Thereafter	Expiration Date
March 10, 2021	12,500	$4.00	10.00%	6.00%	March 9, 2031
September 1, 2021	2,000	$5.25	100.00%	0.00%	September 1, 2026
October 8, 2021	100,000	$4.25	0.00%	n/a	October 8, 2026
January 1, 2022	30,000	$5.25	0.00%	2.78%	September 30, 2023
January 5, 2022	20,000	$4.25	0.00%	2.78%	September 30, 2023
February 1, 2022	30,000	$4.25	0.00%	4.17%	February 27, 2026
February 19, 2022	30,000	$4.00	0.00%	4.17%	February 27, 2026
April 1, 2022	30,000	$4.25	0.00%	2.78%	June 30, 2023
April 1, 2022	30,000	$4.25	0.00%	2.78%	September 30, 2023
May 5, 2023	400,000	$4.50	0.00%	2.08%	May 4, 2028
May 5, 2023	240,000	$4.50	0.00%	n/a	May 4, 2028
May 26, 2023	222,222	$4.50	0.00%	n/a	May 26,2026

All options vest as described above, provided the Optionee continues to provide continuous service.

The average remaining contractual life of the options outstanding was 3.36 years and 9.43 years as of June 30, 2023, and June 30, 2022, respectively.

The options are reported at fair value as determined at a valuation between $0.47 and $3.58 per share using the Black-Scholes method. An expected price volatility of 79.79%, a risk-free interest rate of 5.13%, and a dividend yield of 0% was used in the calculation of the fair value as of June 30, 2023. An expected price volatility of 122%, a risk-free rate of return of 3.08%, and a dividend yield of 0% was used in the calculation of the fair value as of June 30, 2022.

At June 30, 2023, the intrinsic value of the outstanding options was $232,427.

At June 30, 2022 the intrinsic value of the outstanding options was $15,412.

Warrants

Warrants the Company issues for services provided are recorded as compensation expense and included in office and administrative expense on the statements of operations. Compensation expense for warrants issued for the year ended June 30, 2023, and June 30, 2022, was $0 and $0, respectively.

The Company also issues warrants to common stockholders as part of a Regulation D offering based on specified levels of investment, which are detailed as follows:

Amount Invested	**Number of Warrants**	**Exercise Price (per share)**	**Aggregate Exercise Price**

$100,000 to 199,999	4,750	$5.25	$24,937.50
$200,000 to 299,999	11,425	$5.25	$59,981.25
$300,000 to 399,999	20,000	$5.25	$105,000.00
$400,000 or more	30,475	$5.25	$159,993.75

During the year ended June 30, 2023, the Company issued 136,710 warrants to stockholders who had purchased shares through the Regulation D offering for achieving specified levels of investment, to purchase common stock with a weighted average price of $5.25 per share. All warrants outstanding are exercisable as of June 30, 2023.

During the year ended June 30, 2022, the Company issued 252,550 warrants consisting of 0 shares for compensation and 252,550 shares to stockholders who had purchased shares through the Regulation D offering for achieving specified levels of investment, to purchase common stock with a weighted average price of $4.70 per share. All warrants outstanding were exercisable at June 30, 2023.

The following summarizes the number of shares of warrants during the years ended June 30, 2023, and the year ended June 30, 2022, respectively:

	Number of Warrants
Balance at June 30, 2021:	50,925
Granted:	252,500
Exercised:	–
Expired:	–
Balance at June 30, 2022:	303,425
Granted:	220,423
Exercised:	–
Expired:	–
Balance at June 30, 2023:	523,848

The fair value of the warrants outstanding at June 30, 2023, using the Black-Scholes method, is estimated at $974,688. An expected average price volatility of 79.79%, an average risk-free interest rate of 5.13%, and a dividend yield of 0% was used in the calculation of the fair value. The intrinsic value of the warrants as of June 30, 2022, is $(1,747,951).

The fair value of the warrants outstanding at June 30, 2022, using the Black-Scholes method is estimated at $812,351. An expected average price volatility of 107%, an average risk-free interest rate of 3.07%, and a dividend yield of 0% was used in the calculation of the fair value. The intrinsic value of the warrants as of June 30, 2022, was $(752,768).

Note 8 Compliance/Contingency

The Company was obligated to file its annual report for the year ended June 30, 2021, with the Securities and Exchange Commission within 120 days after the end of the year, and did not file the reports on a timely basis. As a result, the exemption from registration may not have been available for the sale of certain shares of common stock. The Company offered rescission to investors who purchased shares during the period such filings were late and to return the amount invested per the SEC guidelines. The Company estimates that an aggregate of $234,000.00 was invested during the period June 30, 2021 through March 3, 2022 during which reports were late. None of the investors requested refunds and no amount has been accrued on June 30, 2023 balance sheet.

Note 9 Subsequent Events

Management has evaluated subsequent events through November 3, 2023, the date the financial statements were available to be issued.

On July 15, 2023, the Company terminated the consulting agreement with Integra Ventures, LLC.

On August 8, 2023, the Company executed a Master Supply Agreement with East West Manufacturing, LLC, for the manufacture and supply of the different components of the Company's tests. East West is a global manufacturer and supplier focused on the development of products, from design through to distribution. The Company believes East West has the capabilities required to scale the manufacturing of the Company's products.

Item 8 Exhibits

Exhibits

Exhibit Number	Description
2.1	Certificate of Incorporation, incorporated by reference to the Company's Regulation A Offering Statement on Form 1-A as filed with the SEC on October 27, 2020.
2.2	Certificate of Amendment of Certificate of Incorporation, incorporated by reference to the Company's Regulation A Offering Statement on Form 1-A as filed with the SEC on October 27, 2020.
2.3	Bylaws, incorporated by reference to the Company's Regulation A Offering Statement on Form 1-A as filed with the SEC on October 27, 2020.
3.1	2020 Stock Incentive Plan, incorporated by reference to the Company's Regulation A Offering Statement on Form 1-A as filed with the SEC on October 27, 2020.
3.2	Form of Stock Award Agreement, incorporated by reference to the Company's Regulation A Offering Statement on Form 1-A as filed with the SEC on October 27, 2020.
4.1	Form of Subscription Agreement, incorporated by reference to the Company's Regulation A Offering Statement on Form 1-A as filed with the SEC on October 27, 2020.
6.1	Saas Services Agreement with Novation Solutions, Inc., incorporated by reference to the Company's Regulation A Offering Statement as filed with the SEC on July 26, 2023.
6.2	License Agreement with IdentifySensors Fresh Food Enterprises, LLC, incorporated by reference to the Company's Regulation A Offering Statement on Form 1-A as filed with the SEC on October 27, 2020.
6.3	Sublease Agreement with Dr. Gregory Hummer/MCO Advantage, incorporated by reference to the Company's Regulation A Offering Statement on Form 1-A as filed with the SEC on October 27, 2020.
6.4	Contractor Agreement with Thomas G. Sors, incorporated by reference to the Company's Regulation A Offering Statement on Form 1-A as filed with the SEC on October 27, 2020 .
6.5	Contractor Agreement with Ann Hawkins, incorporated by reference to the Company's Regulation A Offering Statement on Form 1-A as filed with the SEC on October 27, 2020
6.6	Contractor Agreement with Jeff Spagnola, incorporated by reference to the Company's Regulation A Offering Statement on Form 1-A as filed with the SEC on October 27, 2020
6.7	Contractor Agreement with Dr. Greg Hummer, incorporated by reference to the Company's Regulation A Offering Statement on Form 1-A as filed with the SEC on October 27, 2020
6.8	Contractor Agreement with Bruce Raben, incorporated by reference to the Company's Regulation A Offering Statement on Form 1-A as filed with the SEC on October 27, 2020
6.9	Employment Agreement with Ghazi Kashmolah, incorporated by reference to the Company's Regulation A Offering Statement on Form 1-A POS as filed with the SEC on June 15, 2023.
6.10	Employment Agreement with Ricardo de Medeiros, incorporated by reference to the Company's Regulation A Offering Statement on Form 1-A POS as filed with the SEC on June 16, 2023.
6.11	Employment Agreement with Felicia Hosey, incorporated by reference to the Company's Regulation A Offering Statement on Form 1-A POS as filed with the SEC on June 15, 2023.

6.12		Employment Agreement with Kevin Amacker, incorporated by reference to the Company's Regulation A Offering Statement on Form 1-A POS as filed with the SEC on June 15, 2023.
6.13		Employment Agreement with Andrea Wallin, incorporated by reference to the Company's Regulation A Offering Statement on Form 1-A POS as filed with the SEC on June 15, 2023.
6.14		Employment Agreement with Herma Hoda, incorporated by reference to the Company's Regulation A Offering Statement on Form 1-A POS as filed with the SEC on June 15, 2023.
6.15		Consulting Agreement with MedTech Review LLC, incorporated by reference to the Company's Regulation A Offering Statement on Form 1-A POS as filed with the SEC on June 15, 2023.
6.16		Incubator Space License Agreement with UF Innovate/Accelerate, incorporated by reference to the Company's Regulation A Offering Statement on Form 1-A POS as filed with the SEC on June 15, 2023.
6.17		License Agreement with the University of Florida, incorporated by reference to the Company's Regulation A Offering Statement on Form 1-A POS as filed with the SEC on June 15, 2023.
6.18		Statement of Work with Jabil Inc. IdentifySensors Biologics Check4, incorporated by reference to the Company's Regulation A Offering Statement on Form 1-A POS as filed with the SEC on June 15, 2023.
6.19		Transfer Agent Agreement with Colonial Stock Transfer, incorporated by reference to the Company's Regulation A Offering Statement on Form 1-A/A as filed with the SEC on December 4, 2020.
6.20		Dealmaker Agreement, incorporated by reference to the Company's Regulation A Offering Statement on Form 1-A POS as filed with the SEC on February 25, 2021.
6.21	*	Master Supply Agreement by and between IdentifySensors Biologics Corp. and East West Manufacturing, LLC dated August 8, 2023.
8.1		Escrow Agreement, incorporated by reference to the Company's Regulation A Offering Statement on Form 1-A/A as filed with the SEC on December 4, 2020.
11.1	*	Consent of Meaden & Moore, Ltd.

*Filed herewith

SIGNATURES

Pursuant to the requirements of Regulation A, the issuer has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

IDENTIFYSENSORS BIOLOGICS CORP.

By: */s/ Gregory Hummer*
Dr. Gregory Hummer,
Chief Executive Officer and Director

Date: November 6, 2023

Pursuant to the requirements of Regulation A, this report has been signed by the following persons on behalf of the issuer in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Gregory Hummer Dr. Gregory Hummer	Chief Executive Officer and Director	November 6, 2023
/s/ Ann M. Hawkins Ann M. Hawkins	Chief Financial Officer	November 6, 2023

Exhibit 6.21

"Next-Generation Digital Diagnostics"

MASTER SUPPLY AGREEMENT

THIS SUPPLY AGREEMENT (this "Agreement") is effective as of August 8, 2023 (the "**Effective Date**"), by and between **IdentifySensors Biologics Corp**. a Delaware corporation with an address at 20600 Chagrin Blvd. STE 450 Shaker Heights, OH 44122 ("**ISB**") and **East West Manufacturing, LLC,** a Georgia limited liability company, with an address at 4170 Ashford Dunwoody Road Suite 560 Atlanta, GA, USA 30319 ("**Supplier**"). ISB and Supplier may each be referred to in this agreement individually as a "Party" and collectively as the "Parties."

WHEREAS, ISB is, among other things, in the business of designing, marketing and distributing a custom *in vitro* diagnostic medical device intended to detect and differentiate infections disease pathogens for point-of-care and over-the-counter use. Supplier is, in the business of providing manufacturing services which includes delivering products and goods built to specification and turn-key finished diagnostic medical devices in a high-volume manufacturing environment,

WHEREAS, subject to the terms and conditions of this Agreement, the Parties desire for Supplier to manufacture for, and sell to, ISB the Product (as defined below), and

NOW, THEREFORE, in consideration of the mutual covenants contained in this Agreement, the foregoing recitals and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties agree as follows:

1. DEFINITIONS

The following capitalized terms have the following meanings:

1.1 "**Affiliate**" means, with respect to a Person, any other Person that, as of the Effective Date or at any time thereafter, Controls, is Controlled by, or is under common Control with such first Person. Such other Person is an Affiliate only as long as such Control exists. For the purposes of this definition, "**Control**" means the possession, directly or indirectly, of: (a) more than 50% of the voting interests of a Person; or (b) the power to direct or cause the direction of the management or policies of a Person, whether through the ownership of voting interests, by agreement with respect to the voting of voting interests, by other agreement conferring control over management or policy decisions, by virtue of the power to control the composition of the board of directors or managers or otherwise. The terms "**Controlling**" and "**Controlled**" have correlative meanings.

1.2 "**Authorized Representative**" means the representatives of ISB as designated by ISB in writing from time-to-time. As of the Effective Date, the sole Authorized Representative of ISB is: Ghazi Kashmolah, EVP and Chief Quality Officer. As of the Effective Date, there are no Affiliates of ISB. ISB will inform Supplier if new Authorized Representatives or Affiliates are added during the Term of this Agreement.

1.3 "**Authorized Subcontractors**" has the meaning set forth in Section 4.6(a).

1.4 "**Confidential Information**" and related definitions have the respective meanings set forth in Section 13.

1.5 "**Customer**" means any customer or prospective customer or other recipient of any product or service of ISB or any of its Affiliates.

1.6 "**Delivery Date**" means, with respect to a Product, the delivery date for such Product set forth on a Purchase Order issued under this Agreement which are consistent with the terms of this Agreement.

1.7 "**End of Life Notice**" and "**End of Life Order**" have the respective meanings set forth in Section 3.8.

1.8 "**Epidemic Quality Failure Event**" means failure of more than 10% of the Products that occur within any 3-month period from the date of shipment which is a result of a breach of Supplier's obligations pursuant to the Agreement.

1.9 "**Excess Product Volume**" has the meaning set forth in Section 3.5.

1.10 "**Force Majeure Event**" has the meaning set forth in Section 18.

1.11 "**Forecast**" has the meaning set forth on Section 3.1(b).

1.12 "**ISB Intellectual Property Developments**" means any Intellectual Property that (a) arises under, or is invented, created, conceived, reduced to practice or otherwise developed by ISB and (b) that is invented, created, conceived, reduced to practice or otherwise developed by Supplier or any Authorized Subcontractor specifically for the purposes of the Product or at the direction of ISB, in each case, in connection with this Agreement.

1.13 "**ISB Materials**" means all materials owned or licensed by ISB or its Affiliates related to ISB's products or technologies (including the Products) provided by or on behalf of ISB to Supplier.

1.14 "**Inspection Period**" has the meaning set forth in Section 5.4.

1.15 "**Intellectual Property**" means, collectively, all of the following in any country or other jurisdiction: (a) all issued patents and pending patent applications (including without limitation utility models, design patents, certificates of invention and applications for certificates of invention and priority rights), including all provisional applications, substitutions, continuations, continuations-in-part, divisions, renewals, reissues, re-examinations and extensions thereof; (b) all trade secret rights and other know-how rights (whether at law, in equity or otherwise); (c) all copyrights (whether registered or not), applications therefor, moral rights and other rights associated with original works of authorship (whether by law, in equity or otherwise); (d) all other intellectual property or proprietary rights of any type or nature whatsoever; and (e) all rights of any type or nature whatsoever (whether at law, in equity or otherwise) to use or otherwise exploit any of the foregoing.

1.16 "**Manufacturing Information**" means all information and instructions pertaining to the development, manufacture, testing, operation, packaging, shipping and supply of Products, including manufacturing instructions, formulations, recipes, processes, methods, conditions, techniques, SOPs, drawings, CAD files, lists of materials, parts lists, BOMs, vendor lists, specifications, designs, data, work instructions, and all modifications or updates to any of the foregoing.

1.17 "**Material Lead-Time**" means, with respect to any raw material used in the manufacture of a Product, the minimum period of time between placement of an order by or on behalf of Supplier for such material and receipt of such material by or on behalf of Supplier.

1.18 "**Manufacturing Lead-Time**" means, the minimum period of time between receipt of all necessary materials to the time that supplier complete finished products and ready to deliver to ISB or ISB's designated customer(s)

1.19 "**Person**" means any person or entity, whether an individual, corporation, partnership, limited partnership, limited liability company, trust, foundation, unincorporated organization, business association, firm, joint venture, or other legal entity recognized in any jurisdiction in the world.

1.20 "**Procurement Representative**" means an employee within ISB's or any of its Affiliate's Supply Chain Department that is expressly authorized to purchase on behalf of ISB or its Affiliates.

1.21 "**Product**" means each product described in an applicable Purchase Order hereunder and any new versions, derivatives or iterations of such Product.

1.22 "**Purchase Order**" means a written purchase order issued by ISB or its Affiliate for Products as set forth in Section 3 below.

1.23 "**Purchase Price**" has the meaning set forth in Section 9.1.

1.24 "**Quality Agreement**" means the quality agreement set forth in **Exhibit C**.

1.25 "**Blanket Purchase Order**" has the meaning set forth in Section 3.1.

1.26 "**Shortage of Supply**" has the meaning set forth in Section 5.5.

1.27 "**Specifications**" means, with respect to a Product, manufacturing specifications (including materials, recipes and formulations), physical properties, performance requirements, testing and other specifications for such Product set forth in an applicable Purchase Order; provided, the Specifications as of the Effective Date are attached hereto as **Exhibit B**.

1.28 "**Supplier Facility**" means each supplier facility expressly approved in advance in writing by ISB which includes Supplier's Wisconsin and Costa Rica facilities.

1.29 "**Subcontractor**" or "**Sub-tier supplier**" (as used in the Quality Agreement) means an Affiliate of Supplier, or other Third Party, to whom Supplier wishes to delegate any of Supplier's manufacturing or supply obligations under this Agreement.

1.30 "**Term**", "**Initial Term**" and "**Renewal Term**" have the respective meanings set forth in Section 10.1.

1.31 "**Third Party**" means any Person other than the Parties and their respective Affiliates.

1.32 "**Manufacturing Scrap Rate**" refers to the percentage of waste or unusable materials generated during the manufacturing process. It is a key performance indicator that measures the production quality and output of a manufacturing operation.

2. SCOPE OF AGREEMENT

2.1 Purpose. Subject to the terms and conditions of this Agreement, Supplier will manufacture and deliver Products to ISB and its Affiliates.

2.2 Terms of Agreement. The Parties agree that the express terms and conditions of this Agreement (including any Exhibits and Schedules hereto), the applicable Purchase Order issued in accordance with this Agreement and the applicable Blanket Purchase Order exclusively govern and control each Party's rights and obligations regarding the manufacture, supply, purchase and delivery of the Products. Any terms or conditions of any quotations, invoices or other documents or communications (including package inserts or labels), whether included with a Product, on a website or otherwise, that are additional or contrary to or otherwise different from the terms and conditions of this Agreement, such Purchase Order or Blanket Purchase Order, and any other attempts by Supplier to modify, supersede, supplement or otherwise alter this Agreement, are hereby expressly rejected, are null and void and have no force and effect. In the event of conflict, this Agreement supersedes all terms and conditions included in any Purchase Order.

3. PURCHASE OF MATERIALS; ORDER PROCEDURE

3.1 Blanket Purchase Order; Forecasts.

(a) Certain Products may be identified on and ordered and purchased according to the mutually agreed terms and conditions set forth in a Blanket Purchase Order ("**Blanket Purchase Order**"). The Blanket Purchase Order will address rolling weekly

forecast requirements, associated sourcing of raw materials or other materials or components and associated supply and purchase obligations.

(b) For Products that are not subject to a Blanket Purchase Order, ISB will provide to Supplier a non-binding forecast on a calendar monthly basis representing ISB's estimated requirements for each Product for the following 3 (three) calendar quarters (each, a "**Forecast**"). Supplier may accept the maximum capacity set forth in the Forecast (the "**Accepted Forecast**") or reject the Forecast in whole or in part ("**Rejected Forecast**") within 10 business days of receipt of the Forecast; provided, Supplier identifies the basis for the justification. Supplier and ISB will work together in good faith with respect to any options for production with respect to any Rejected Forecast. Supplier will use each Accepted Forecast for the purpose of planning material and capacity requirements and ordering raw materials or other materials or components for Products. A Forecast does not constitute a binding commitment by ISB to purchase any forecasted volume or any other particular volume of a Product.

3.2 Procurement; Material Liability Exposure.

(a) Supplier shall procure materials and components ("**Materials**") for the manufacture and delivery of the Products subject to the terms of and in accordance with this Agreement. ISB will be liable to Supplier for Supplier's actual costs for any Materials purchased by or on behalf of Supplier based on (a) an accepted Purchase Order or (b) a Forecast; provided, ISB has executed an accompanying written authorization to procure materials in connection with such Forecast ("**LOA**"). Supplier shall not procure Materials without a corresponding Purchase Order or LOA.

(b) Supplier shall inform ISB of the number of days that Supplier's vendors ("**Sub-Suppliers**") report are required to procure Materials, including transit time (collectively, "**Material Lead Time**"). Material Lead Time is based upon dates communicated by Sub-Suppliers and may subsequently change beyond Supplier's control. Supplier shall inform ISB of the number of days required for kitting, manufacturing, assembly, inspection, packaging, transit, and similar fulfillment-related activities (collectively, "**Transformation Lead Time**"). The sum of Material Lead Time and Transformation Lead Time shall constitute "**Product Lead Time**".

(c) Supplier shall schedule delivery of Materials to occur on or about the reported delivery date of the Material having the longest Material Lead Time (such Material, "**Longest-Lead Material**"). If the Longest-Lead Material's reported delivery date is subsequently delayed, Supplier shall attempt to delay delivery of other Materials as needed to minimize inventory aging. ISB may request in writing that Supplier attempt to expedite delivery of Materials ahead of the Longest-Lead Material (which may be provided by email), and in requesting such expedited delivery ISB acknowledges the resulting increased risk of Excess Inventory requiring disposition at ISB's expense.

(d) Minimum order quantities, economic order quantities, factory packaging quantities, and similar quantity requirements ("**Quantity Requirements**") imposed by Sub-Suppliers may exceed the volume of Materials required for the production of Products pursuant to a Purchase Order or LOA. Supplier shall communicate such Quantity Requirements to ISB and use reasonable efforts to minimize excess Materials resulting from Quantity Requirements, and ISB accepts all costs and expenses for such excess Materials.

(e) Should any Materials pursuant to a Purchase Order or LOA require prepayment by Supplier to a Sub-Supplier of at least ten thousand dollars ($10,000) in the aggregate, Supplier shall notify ISB and ISB shall issue an Inventory Deposit equal to the prepayment amount prior to procuring such Materials.

3.3 Inventory Classification and Inventory Allowance.

(a) Excess Inventory. As used herein, "**Excess Inventory**" means any Materials procured by Supplier in accordance with this Agreement which (a) have aged in Supplier's inventory for more than sixty (60) days since receipt, or (b) are due to be delivered to Supplier in accordance with Supplier's contractual obligations to its Sub-Suppliers and for which Customer has agreed to accept liability prior to Supplier's agreement to accept such contractual obligations to its Sub-Suppliers. Excess Inventory which has aged in Supplier's inventory for more than three hundred sixty-five (365) days shall be considered "**Long-Term Excess Inventory**".

(b) Obsolete Inventory. As used herein, "**Obsolete Inventory**" means any Materials procured by Supplier in accordance with this Agreement which are not associated with an active or future Product's bill of materials as provided by Customer to Supplier.

(c) Current Inventory. As used herein, "**Current Inventory**" means any Materials procured by Supplier in accordance with this Agreement which are not classified as Excess Inventory (including Long-Term Excess Inventory) or Obsolete Inventory.

(d) Inventory Allowance. Supplier, at no cost to Customer, shall extend an inventory allowance to Customer for the purpose of financing Current Inventory and Excess Inventory (excluding Long-Term Excess Inventory). Such allowance ("**Inventory Allowance**") shall be calculated as follows:

Inventory Allowance = {[T6M Revenue + (F3M Backlog x 2)] x Blended CBOM Weight} x (60 / 365)

If Customer does not have six months of revenue history with Supplier to populate the above calculation, the below alternate calculation shall control until Supplier has established six months of revenue history, after which the above calculation shall control.

Inventory Allowance = [(F3M Backlog x 2) x Blended CBOM Weight] x [60 / (365 / 2)]

In the above calculations, "**T6M Revenue"** means the six-month revenue generated by Customer's Product purchases from Supplier, "**F3M Backlog**" means the forward three-month forecasted revenue based on Customer's backlog of Product purchases from Supplier, and "**Blended CBOM Weight**" means the aggregate dollar value of Materials as a percentage of Customer's Product purchase price. Materials are permitted to age for sixty (60) of three hundred sixty-five (365) days in the measurement period before being considered Excess Inventory.

For purposes of example only, if T6M Revenue equals four hundred thousand dollars ($400,000), F3M Backlog equals three hundred thousand dollars ($300,000), and Blended CBOM Weight equals 70%, the resultant Inventory Allowance shall be calculated as {[$400,000 + ($300,000 x 2)] x .70} x (60 / 365) = $115,068. If Customer's Current Inventory + Excess Inventory – Long-Term Excess Inventory is greater than the Inventory Allowance, such variance shall be considered the "**Overage**".

(e) Inventory Allowance Calculation and Reporting. On a monthly basis, Supplier shall recalculate and report for the current calendar month (a) the Inventory Allowance by refreshing T6M Revenue and F3M Backlog, as applicable, and (b) Customer's usage of the Inventory Allowance. Such report ("**Inventory Allowance Report**") shall include the forecasted Inventory Allowance usage for the following two (2) calendar months. The Blended CBOM Weight shall be recalculated in January of each calendar year, and Supplier shall recalculate Blended CBOM Weight upon Customer's reasonable request. Supplier reserves the right to recalculate the Inventory Allowance and any of its components at its reasonable discretion.

(f) Inventory Allowance Overages. Should the Overage exceed five thousand dollars ($5,000) for the current month, Customer shall within ten (10) days issue a Purchase Order containing an "**Inventory Deposit**" to Supplier for the Overage amount. Supplier shall invoice Customer for such Inventory Deposit which shall be paid by Customer upon invoice receipt.

(g) Inventory Deposit Credits. If the Inventory Allowance calculation for a particular month reveals that some portion of Inventory Deposits previously issued by Customer to Supplier are no longer required to ensure compliance with this Agreement, and if the excess Inventory Deposit amount exceeds five thousand dollars ($5,000) for the current month, Supplier shall within ten (10) days issue a credit memo to Customer's account equal to the excess Inventory Deposit amount.

(h) Inventory Allowance Noncompliance. Should Customer not comply with Section 3.6, Supplier shall levy an interest charge on the Inventory Allowance Overage amount with such interest charge being equal to the Secured Overnight Financing Rate (as of the date that such interest charge is levied), invoiced monthly, with such invoices due for payment by Customer as per standard Payment Term defined in the MSA, Should the Inventory Allowance remain overextended for at least 180 (60) days, Supplier shall invoice Customer at the current Product purchase price + 5% until the Inventory Allowance is no longer overextended.

(i) Disposition. Following notification from Supplier of Long-Term Excess Inventory or Obsolete Inventory, Customer shall issue Purchase Orders to Supplier for such inventory at Supplier's actual Material cost + 3% procurement overhead and direct

Supplier to (a) ship such Materials to Customer EXW (Incoterms 2020) Supplier's facility with shipping costs billable to Customer, or (b) scrap such Materials with scrapping costs billable to Customer (collectively, the "**Disposition Options**"). Purchase Orders for Long-Term Excess Inventory shall be issued by Customer to Supplier within ten (10) days of notification, and Purchase Orders for Obsolete Inventory shall be issued by Customer to Supplier within ninety (90) days of obsolescence, with such date of obsolescence determined by Supplier in its reasonable, good-faith discretion in accordance with Section 3.2. Should Customer not dispose of Long-Term Excess Inventory or Obsolete Inventory as described herein, the value of such inventory shall be considered an Overage, and such Overage amount shall be subject to the terms described in Section 3.8. All invoices for Long-Term Excess Inventory or Obsolete Inventory and related fees shall be paid by Customer within ten (10) days.

(j) Inventory Mitigation Efforts. At Customer's request, Supplier shall make reasonable efforts to minimize Customer's liability for Excess Inventory by attempting to cancel, return, restock, or divert Materials to other recipients if the value of such Materials is greater than or equal to one thousand dollars ($1,000.00) in the aggregate (such efforts, "**Inventory Mitigation Efforts**"). Customer acknowledges that such actions may incur cancellation, restocking, and/or similar fees beyond Supplier's control, in which case Supplier shall communicate in writing such fees to Customer, and Customer's written consent to proceed with disposition (which may be provided by email) shall constitute Customer's agreement to be liable for any and all such fees.

3.4 Order Placement.

(a) By ISB. ISB and its Affiliates will make all purchases of Products by submitting firm Purchase Orders to Supplier through an Authorized Representative of ISB or an Affiliate. Only Authorized Representatives of ISB or an Affiliate are permitted to submit Purchase Orders. Each Purchase Order shall include (without limitation) the following information:

(i) Part Number for each Product Ordered;
(ii) Product Specifications for each Product ordered (or a reference to such Specifications in a prior Purchase Order);
(iii) Specific test(s) or testing methodology(ies) for the Product;
(iv) Packaging and labeling information;
(v) Quantity of each Product ordered;
(vi) Shipping Terms;
(vii) Shipping Method;
(viii) Delivery / Due Date;
(ix) Unit Price; and
(x) Total Price,

together with such other information and may be required for Supplier to deliver under the Purchase Order. ISB will provide Supplier with the names and shipping addresses of each recipient of Products pursuant to each Purchase Order; provided, that such shipping instructions are in accordance with Supplier's minimum release quantity requirements (which Supplier shall provide to ISB in writing). In the event that the delivery date and the due date are not the same, then: (1) if Supplier holds Products made available for shipment more than 30 days, then ISB shall pay to Supplier an administrative fee of one percent (1%) of the Unit Price per month (prorated) and (2) Supplier shall not be obligated to hold any Products made available for shipping longer than ninety (90) days.

(b) Acceptance. Supplier shall accept or reject all Purchase Orders within 2 business days of receipt. Notwithstanding the foregoing, Supplier shall accept all Purchase Orders which do not exceed the volume set forth in any Accepted Forecast (provided that such Purchase Order includes all other terms consistent with this Agreement). Notwithstanding the foregoing, if any Purchase Order for a Product exceeds 100% of the most recent Accepted Forecast for such Product provided by ISB to Supplier (such excess, the "**Excess Product Volume**"), (i) Supplier will use commercially reasonably efforts to deliver such Excess Product Volume by the Delivery Date for such Product specified in such Purchase Order subject to the applicable Material Lead-Times.

3.5 Demand Changes. Supplier will take commercially reasonable steps to accommodate any increase or decrease in ISB's demand for Product. Without limiting the generality of the foregoing, at a minimum, Supplier will establish and maintain a supply chain that can accommodate at least a 100% of the quantity of Products included in any Accepted Forecast.

3.6 Change Order.

(a) No later than ten (10) days prior to the Delivery Date specified in a particular Purchase Order, ISB may request Supplier to expedite, reschedule within the calendar month, or cancel (in whole or in part) any Purchase Order by providing Supplier written notice of such change request. Within two (2) business days (or such sooner time as reasonably practicable) after the request of change provided by ISB to Supplier, Supplier will provide ISB with confirmation or rejection of whether it can fulfill the requested change and, if applicable, a written quotation detailing the new purchase price (if different from the then current Purchase Price for such Product) for such Product incorporating such change and any other impacts on the delivery of the Product.. Upon the mutual written agreement by ISB and Supplier of such new purchase price (if any) for such Product and a plan for implementing such change, Supplier will implement such change in accordance with such agreement. In the event of a cancellation (in whole or in part) of such Purchase Order, Supplier will cease the manufacture and packaging of, and all other work with respect to, the Product to which such cancellation pertains as soon as reasonably practicable.

(b) ISB's liability for any cancelled Purchase Order will be determined as follows:

(i) With respect to any Materials that were purchased by Supplier to manufacture the Products that are the subject of such cancelled Purchase Order, Supplier shall use commercially reasonable efforts to: (A) use or repurpose such Materials for other products or customers or (B) return such Materials to the applicable vendor or restock, or divert Materials to other recipients. If Supplier is able to mitigate liability under a cancelled Purchase Order pursuant to this Section 3.7(b)(i), ISB's maximum liability with respect to such cancelled Purchase Order will be limited to any reasonable cancellation/restock fees that ISB has authorized in writing Supplier to incur in connection with such mitigation. If Supplier is unable to mitigate liability (whether in whole or in part) under a cancelled Purchase Order, ISB shall reimburse Supplier for the costs of the Materials plus a 5% administrative fee.

(ii) With respect to any finished or partially finished Product that is the subject of such cancelled Purchase Order, . ISB will be liable for such finished or partially finished Product, provided that in no event will such liability of ISB exceed the Purchase Price for such Product.

(iii) Upon ISB's request, Supplier will provide ISB with documentation detailing and certifying any liability of ISB remaining after Supplier's good faith mitigation efforts as set forth in this Section 3.7(b).

3.7 End of Life Products and Components. If ISB determines that a Product is end of its life, no longer needs to be made, ISB will provide 6 months (180 days) prior written notice of such determination ("**End of Life Notice**") to the Supplier, and ISB may place end-of-life Purchase Orders for such Product (each, an "**End of Life Order**") subject to Section 3.1(b). If Supplier determines a Product or component of a Product is no longer available to ISB, Supplier will use commercially reasonably efforts to provide as much notice as reasonably possible, with a goal of providing six (6) months notice to ISB of such unavailability. The Parties will work together in good faith to mitigate the impact of such unavailability.

4. MANUFACTURE

4.1 In General. Supplier will manufacture each Product (a) only at a Supplier Facility, (b) in conformance with the Specifications for such Product, (c) in accordance with all applicable laws, rules, and regulations applicable to the manufacturing of the Product, and (d) otherwise in accordance with this Agreement, including without limitation, the Quality Agreement.

4.2 Product Specification Changes.

(a) Changes by Supplier. Supplier may from time to time recommend to ISB ways to improve performance or other aspects of a Product or decrease production or related costs of a Product. Supplier may request such changes in accordance with the Quality Agreement. In no event will Supplier make any changes to a Product or any manufacturing process or techniques with respect to a Product without first obtaining prior written approval from ISB in accordance with the Quality Agreement.

(b) Changes by ISB. ISB has the right to request any change, as defined in the Quality Agreement, to Products and incorporate such change therein in accordance with the Quality Agreement. Within 10 business days after the date of notice provided by ISB to Supplier with respect to such change, Supplier will provide ISB with a written quotation detailing the new purchase price (if

different from the then current Purchase Price for such Product) for such Product incorporating such change. Upon the mutual written agreement by ISB and Supplier of such new purchase price (if any) for such Product and a plan for implementing such change, Supplier will implement such change in accordance with such agreement. If the parties do not execute a mutual written agreement, then the change will not be implemented.

(c) Revising Exhibits. To the extent that implementation of a Product change pursuant to the Quality Agreement requires any revision to any document, Specification or any other information included or referenced in this Agreement, the Parties will amend this Agreement as necessary in accordance with Section 19.4.

4.3 Manufacture Failure Recovery Plan. In recognition of the possibility that Supplier could lose the capability to manufacture Products for or supply Products to ISB due to a Force Majeure Event, Supplier will, within 60 days after the Effective Date, develop and submit to ISB a recovery plan designed to allow Supplier, within 30 days after the date of such Force Majeure Event, to resume the manufacture and supply to ISB of Products in fulfillment of all Purchase Orders. Such plan at a minimum will include alternate sourcing strategies for materials and Products. ISB reserves the right to request changes, modifications or updates to such plan at any time during the Term.

4.4 Manufacture Lead Time and Location.

(a) Manufacturing Lead Time is used to define the minimum period of time between Suppliers' receipt of all necessary materials to the time that Supplier complete finished products and ready to deliver to ISB or ISB's designated customer(s). Supplier shall use commercially reasonable efforts to meet or exceed its manufacturing lead time for the number of units included in any Accepted Forecast.

(b) Manufacturing location ties into cost of product and quality, compliance and regulatory requirements therefore any of manufacturing location by Supplier needs to receive ISB's written approval 90 days prior to change of location.

4.5 Manufacture Scrap Rate: Scrap in manufacturing can result from defects, errors, or inefficiencies during production. It includes both materials that are completely unusable and items that require rework but are rendered unsuitable for their original purpose. By measuring and tracking scrap rates, Parties can evaluate the effectiveness of Supplier manufacturing processes and make informed decisions to improve efficiency and reduce waste. ISB and Supplier agree in principle:

(a) Essentially for scraps caused by Supplier during manufacturing process, Supplier should be 100% responsible for material and labor costs.

(b) Supplier agrees Manufacture Scrap Rate of 15% or less has already been included in the agreement in term of manufacturing lead time and costs of Product.

(c) In regard to scrap increases caused by engineering change orders, if the change order was initiated by the Supplier and approved by ISB, both parties should equally share the costs exceeding 15%; if the change order was initiated by ISB, ISB should be solely responsible for the scraps and obsolesce of materials.

4.6 Subcontractors.

(a) Authorized Use of Subcontractors.

(i) Supplier may not use any Subcontractor or otherwise outsource or delegate any of its obligations or performance under this Agreement without ISB's prior express written authorization. For the avoidance of doubt, no wholly owned subsidiary of Supplier shall be deemed a Subcontractor.

(ii) If Supplier desires to engage a Subcontractor, Supplier will provide ISB with a written request for authorization to use such Subcontractor, which ISB may grant or deny in its sole discretion. Supplier will promptly provide to ISB any information requested by ISB to assist ISB in its evaluation of any potential Subcontractor, including information regarding whether the Subcontractor

qualifies as a small business, small disadvantaged business, or women-owned small business as defined in 48 CFR 52.219-8, and Supplier will ensure that a confidentiality agreement is executed with such potential Subcontractor in a form satisfactory to ISB prior to any discussions regarding, or relating to any of Supplier's obligations under, this Agreement. The Subcontractors for which ISB provides its prior written authorization pursuant to this Section 4.6(a)(ii) shall be referred to in this Agreement as "**Authorized Subcontractors**".

(iii) Supplier will enter into a legally enforceable written agreement with each Authorized Subcontractor that (A) incorporates and fully complies with all applicable terms and conditions set forth in this Agreement, (B) without limiting the foregoing, imposes confidentiality obligations at least as restrictive as those contained in this Agreement, and (C) expressly designates ISB and its Affiliates as intended third party beneficiaries of such agreement.

(iv) Supplier will notify ISB promptly in writing upon the occurrence of any changed circumstance affecting the ownership, control or management of any Authorized Subcontractor (including any change of control of any Authorized Subcontractor). Supplier agrees that ISB may cause Supplier to terminate any Subcontractor at any time in ISB's reasonable discretion.

(b) Supplier Obligations. Supplier will be solely responsible for, and will pay when due, all fees, costs or other payments owed to any Subcontractor. Supplier will not increase the Purchase Price due to any fees, costs or other payments owed to any Subcontractors. Supplier will be responsible and liable for all actions or omissions by its Subcontractors under this Agreement.

(c) Subcontractor Acknowledgement and Compliance. Upon ISB's request with respect to a Subcontractor, Supplier will deliver to ISB a subcontractor acknowledgment in a form approved by ISB in writing and consistent with this Agreement executed by such Subcontractor ("**Subcontractor Acknowledgement**"). Any breach of any Subcontractor Acknowledgment by such Subcontractor will also be deemed a breach of this Agreement by Supplier, for which Supplier will be jointly and severally liable with such Subcontractor.

4.7 Dedicated Equipment.

(a) Purchase and Ownership. Prior to the Effective Date, ISB has purchased the manufacturing equipment specified in the "**Dedicated Equipment List**" attached hereto as **Exhibit D** ("**Dedicated Equipment**"). The-Dedicated Equipment will be delivered Supplier at the manufacturing address. Unless-otherwise-agreed-by-the-Parties-in-a-separate written agreement, title to all Dedicated Equipment will remain with ISB.

(b) Use and Maintenance. Supplier agrees to use such-equipment: (i) only for the manufacture of Products for ISB; and (i) in a manner consistent with the design and intended function of the equipment. Supplier shall be responsible for the maintenance and repair of the Dedicated Equipment during the Term of this Agreement.

(c) Transfer of Title. In the event that Supplier desires to purchase the Dedicated Equipment from ISB, the Parties shall enter into a separate signed written agreement based on fair market terms and conditions to effectuate such a transfer in title.

5. PACKAGING; DELIVERY; FULFILLMENT OF PURCHASE ORDERS

5.1 Labeling and Packaging. Supplier will label and package Products: (a) in accordance with (i) the instructions set forth in an applicable Purchase Order (which may include such applicable laws, rules, requirements and regulations as identified by ISB); and (ii) the Quality Agreement. Supplier will minimize the use of extraneous packaging materials (in order to minimize environmental impact) in such a way that does not compromise the safety or protection of the Products during storage or shipment. Supplier and ISB will reasonably cooperate with each other in the optimization of labeling and packaging in order to comply with the foregoing requirements in Section 5.1.

5.2 Marking. Supplier will include the applicable Purchase Order number and Product part number on all invoices, packages, crates, boxes or other shipping containers, bills of lading, express receipts, correspondence and other documents relating to any Purchaser Order. The Supplier will also include all necessary information, as provided in writing by ISB, on all exterior shipping materials, including the applicable destination address, Purchase Order number and Product part number. For multiple containers in a given shipment, Supplier will label each exterior container with a sequential number and the total number of containers in such shipment (for example, 1 of 5, 2 of 5, etc.)

5.3 Delivery.

(a) Delivery; Title and Risk of Loss. Supplier will deliver the Products FCA supplier's facility designated in the applicable Purchase Order (Incoterms, current edition). Title and risk of loss to Products will transfer to ISB when Products are made available at the Supplier location. With respect to accepted Purchase Orders that require deliveries in scheduled installments or increments, Supplier shall use commercially reasonable efforts to not deviate from such schedule (provided all Delivery Dates are in accordance with the terms of this Agreement). Supplier shall ensure Products will be delivered no earlier than three business days prior to the Delivery Date specified in an accepted Purchaser Order. ISB reserves the right to reject incomplete or early Product shipments and to return all or part of such shipments at Supplier's risk and expense. Partial deliveries of Products ordered pursuant to a Purchase Order will be deemed late shipments, and such Purchase Order will only be considered completely fulfilled when all Products have been delivered in accordance with such Purchase Order. If Supplier is required to use expedited delivery methods in order to meet the scheduled Delivery Date due to failure of Supplier to: (i) meet manufacturing or shipping deadlines; (ii) comply with ordinary shipping methodologies and requirements; and/or (iii) adhere to other industry standards with regard to the manufacture, delivery and shipment of the Units in a timely manner, then Supplier will be responsible for the payment of any additional shipping charges.

(b) Shipping and Insurance. ISB shall be responsible for all shipping and freight costs, including all associated duties, taxes and fees and shall designate a shipper and insurer. . If ISB fails to specify a shipper or insurer or requests that Supplier make arrangements for shipping and insurance, Supplier will identify potential shippers and provide quotes from such shippers; provided, ISB will have the right to specify the shipper that will be used to ship Products and Supplier shall be entitled to mark up the total amount charged by such Supplier-identified shipper/insurer. If ISB is arranging and making payment directly to a shipper/insurer, Supplier shall make Products available for collection at Supplier's facility. Supplier may not combine in the same shipping container Products to be sent to different receiving locations or Products with other types of products. As ISB carries its own cargo insurance, Supplier shall not request additional insurance coverage from ISB's preferred service providers; provided, ISB shall accept all risk of loss associated with transit in accordance with Section 5.3(a).

(c) Customs. For international shipments, Supplier is responsible for export clearance and providing export documentation. Supplier will ensure all customs and export/import compliance documents for Products are detailed and accurate.

5.4 Product Inspection; Acceptance/Rejection of Products. Within a commercially reasonable amount of time (not to exceed 30 days) after ISB's receipt of a Product ("**Inspection Period**"), ISB will perform any tests and analyses ISB deems appropriate or necessary to determine if such Product meets the Specifications for such Product and the other requirements set forth in this Agreement. If the Product is damaged, defective or fails to meet any of the Specifications for such Product or any other requirements set forth in this Agreement, ISB may reject such Product shipment (in whole or in part). If ISB intends to reject a Product shipment, ISB will, within 30 days after the Inspection Period, inform Supplier in writing of its rejection of all or any part of such Product shipment and its reasons for such rejection. If ISB rejects a Product and such Product is defective, Supplier will, at Supplier's discretion, promptly provide replacement Product that meets the Specifications for such Product and the other requirements set forth in this Agreement at Supplier's sole expense (in which case the inspection, acceptance and rejection procedure set forth in this Section 5.4 will apply to such replacement Product) or credit the aggregate Purchase Price for such rejected Products against the applicable invoice. A Product not timely rejected as provided in this Section 5.4 will be deemed accepted, and ISB's sole remedy for defective or non-conforming Products after acceptance is set forth in Section 6. Any Products that are rejected by ISB due to failure to meet the Specifications or any other requirements set forth in this Agreement will be disposed of by ISB unless Supplier requests such rejected Products be returned at Supplier's sole expense.

5.5 Fulfillment of Purchase Orders.

(a) Shortage of Supply. If Supplier is unable, or anticipates that it will be unable, to supply the quantities of Products included in any Accepted Forecast (a "**Shortage of Supply**"), Supplier will promptly notify ISB in writing of such Shortage of Supply and provide ISB with its best estimate of the duration of such Shortage of Supply. During such Shortage of Supply, upon ISB's request, Supplier will reasonably cooperate with ISB to secure adequate supplies of materials and components from alternative sources, including, if applicable.

(b) Failure to Deliver or Meet Requirements; Delay. If Supplier fails to deliver to ISB at least 90% (ninety five percent) of the quantities of Products ordered by ISB for delivery in a particular calendar quarter or 80% (in the aggregate) of the quantities of Products ordered by ISB for delivery in any two consecutive calendar quarters, in each case, in accordance with Purchase Orders pursuant to an Accepted Forecast and that meet the Specifications for such Products and the other requirements set forth in this Agreement, such event will be deemed a "**Persistent Supply Failure**". Notwithstanding anything to the contrary in Section 16 or otherwise, a Persistent Supply Failure will be deemed to have occurred even if due to a Force Majeure event. Upon the occurrence of any Persistent Supply Failure, Supplier will: (A) use commercially reasonable efforts to assist ISB in securing supply terms for raw materials and other materials and components included in the Products that are similar to the terms in Supplier's agreements with its suppliers of such raw materials and other materials and components; and (B) otherwise diligently and reasonably cooperate with ISB without charge as necessary to transition the manufacture of the Products to ISB or an alternative supplier.

(c) Significant Delay. If Supplier fails to meet the delivery requirements for a Product pursuant to the Purchase Order for such Product or as otherwise mutually agreed upon by the Parties, once ten percent (10%) of the deliveries are late, then ISB will be entitled to initiate and place Supplier into a probational status whereby they may terminate the Agreement.

(d) Safety Stock. Within sixty (60) days following the Effective Date, ISB may place a Purchase Order to Supplier to maintain two (2) months safety stock for the Product and, upon completion of the Products, Supplier will invoice ISB for the Products and hold such safety stock pending the written direction of ISB.

6. WARRANTY; RECALL; EPIDEMIC QUALITY FAILURE.

6.1 Product Warranties. All Products will be manufactured in strict compliance with the Specifications and be free from defects in Supplier's workmanship under normal use and operation. Such warranties under this Agreement will survive for a period of twenty-four 24 months following delivery of the Product in accordance with this Agreement (the "Warranty Period"), and Supplier's obligations under such warranties will not be affected by, any delivery, inspection, testing or acceptance of, or any payment for, a Product provided under this Agreement.

6.2 Remedy for Breach of Warranty. ISB will notify Supplier in writing of a Product that does not, during the Warranty Period for such Product, conform with any of the warranties set forth in this Agreement within 15 days after ISB makes such determination and return such product to Supplier. Supplier will, at Supplier's discretion, repair or replace such nonconforming Product (at Supplier's sole cost and expense, including costs for the return of nonconforming Products as requested by Supplier) or credit ISB's account for the Purchase Price for such nonconforming Product within 15 business days after its receipt of such Product. If Supplier elects to repair the nonconforming Product, the Supplier will provide to ISB a detailed account of what actions Supplier undertook to repair the nonconforming Product. A Product repaired or replaced in accordance with this Section 6.2 will be covered by the warranty set forth in this Agreement for the remainder of the Warranty Period. In the event that ISB returns any Product as defective and such product is defective, Supplier will reimburse ISB for the out-of-pocket shipping costs of such return.

6.3 Recall. If ISB determines in its sole and reasonable discretion, or any governmental authority determines, that any Products sold to ISB are defective due to a breach of this Agreement and a recall campaign is necessary, ISB will have the right to implement such recall campaign in consultation with Supplier. If a recall campaign is deemed necessary then in ISB's sole discretion, Supplier shall agree to either return defective Products to Supplier or destroy such Products at Supplier's sole cost and risk (unless such recall is caused by a design defect in ISB's design, in which case ISB shall bear the cost and risk to the extent such recall is caused by a design defect in ISB's design). If a recall campaign is implemented, at ISB's option and Supplier's sole cost (unless such recall is caused by a design defect in ISB's design, in which case ISB shall bear the cost and risk to the extent such recall is caused by a design defect in ISB's design), Supplier will promptly repair or replace any defective Products and provide such repaired or replaced Products to ISB or

ISB's designee. Supplier will be liable for all of ISB's direct costs associated with any recall campaign and Supplier will pay all reasonable expenses associated with determining whether a recall campaign is necessary (unless such recall is caused by a design defect in ISB's design, in which case ISB shall bear the cost and risk to the extent such recall is caused by a design defect in ISB's design).

6.4 Epidemic Quality Failure.

(a) If an Epidemic Quality Failure Event occurs:

(i) ISB may invoke a production line shutdown until root cause is determined.

(ii) Supplier shall promptly notify ISB and shall provide, if known, a description of the failure, and the suspected lot numbers, serial numbers or other identifiers, and Delivery dates, of the failed Products.

(iii) ISB shall make available to Supplier, samples of the failed Products for testing and analysis. Upon receipt of such failed Product from ISB, Supplier shall promptly provide its preliminary findings regarding the cause of the failure. The Parties shall cooperate and work together to determine the root cause. Thereafter, Supplier shall promptly provide the results of its root cause corrective analysis, its proposed plan for the identification of and the repair and/or replacement of the affected Products, and such other appropriate information. Supplier shall recommend a corrective action program which identifies the affected Products for repair or replacement, and which minimizes disruption to the end customer. ISB and Supplier shall consider, evaluate, and determine the corrective action program.

(b) If an Epidemic Quality Failure persists and it not resolved to the reasonable satisfaction of ISB for a period of six (6) months after such Epidemic Quality Failure is identified by either party, then Supplier shall have the right to make a claim for indemnification pursuant to Section 15. The remedies in Section 6.4(a) for Epidemic Quality Failure shall be in addition to any other remedies ISB may have under this Agreement.

7. COOPERATION

7.1 Manufacturing Information. Supplier will assemble and provide to ISB all Manufacturing Information pertaining to the Products in a format specified by ISB. In addition, at the written request of ISB, Supplier will provide (on a not more frequent than biannual basis): Product version; quantity of material in process; current processing steps; expected completion date of current process; and expected shipping date. . Supplier will use commercially reasonable efforts to promptly respond to additional reasonable information requests from ISB.

7.2 Business Review Meetings. At mutually agreed upon times and not less frequently than twice per calendar year, the Parties will conduct business review meetings (either in person or via teleconference) to review the status of the Parties' respective performance under this Agreement, the Parties' business relationship, business direction or developments and any other concerns and matters of interest related to the Products or this Agreement (including pricing, quality control, development of technology and logistics). Both Parties will: (a) pro-actively participate in such meetings by (i) presenting detailed analyses of the Parties' respective performance under this Agreement and outlining any issues or concerns with respect thereto, and (ii) proposing solutions for any ongoing issues or disputes in connection with this Agreement; (b) ensure that representatives having the appropriate level of authority and experience attend such business review meetings; and (c) use commercially reasonable efforts to ensure that any appropriate personnel specifically and reasonably requested by the other Party attend such business review meetings, subject to the availability of such personnel.

8. INTELLECTUAL PROPERTY

8.1 Use of ISB Name and Logo. Supplier may not, without ISB's prior written consent, use any names, logos, trade names, trade dress, trademarks or other source identifiers of ISB or any of its Affiliates. No rights or licenses to any names, logos, trademarks, trade dress, trademarks or other source identifiers of ISB or any of its Affiliates are granted hereunder.

8.2 ISB Materials. ISB may from time to time provide Supplier with ISB Materials to assist Supplier in performing its obligations under this Agreement. All ISB Materials are and will remain the sole property of ISB. Subject to the terms and conditions of this Agreement, ISB hereby grants Supplier and its Affiliates a limited non-exclusive, non-transferable, non-sublicensable right to internally use the ISB Materials solely during the Term solely for internal purposes to enable Supplier to perform its obligations under this Agreement. Supplier may not directly or indirectly (on behalf of itself or any Third Party): (a) disassemble, reverse-engineer, decompile, or reverse-assemble any of the ISB Materials; (b) sell, transfer, sublicense, or otherwise permit any Third Party to access, use or possess any of the ISB Materials, except as otherwise expressly agreed in advance in writing by ISB; or (c) modify, correct, adapt, translate, enhance or otherwise prepare any derivative works of or improvements to any of the ISB Materials.

8.3 Intellectual Property Developments. All ISB Intellectual Property Developments will be solely and exclusively owned by ISB from the time of their invention, creation, conception or development. Supplier, for itself and on behalf of its Affiliates and Authorized Subcontractors, and their respective employees and agents, agrees to assign and hereby irrevocably assigns (and hereby represents and warrants that it has the right to so assign) to ISB all right, title and interest in and to all ISB Intellectual Property Developments. At ISB's sole cost and expense, Supplier will use commercially reasonable efforts, and will ensure that its Affiliates and Authorized Subcontractors will use commercially reasonable efforts, to assist ISB in securing and recording ISB's rights in and to all ISB Intellectual Property Developments anywhere in the world, including requiring employees and independent contractors to execute any applications, specifications, oaths, assignments or other instruments that ISB may reasonably request. Supplier acknowledges Supplier's services and products hereunder are work for hire for which Supplier acknowledges Supplier has been fully renumerated.

8.4 Display of Products; Sales of Products to Third Parties. Supplier may not (a) display, disclose or demonstrate to or for any Third Party a Product that is customized for ISB or (b) sell, transfer, convey, supply, distribute or otherwise provide any Third Party with any products or services, or components thereof, based on or derived from any Confidential Information of ISB or any of its Affiliates or ISB Intellectual Property Developments.

8.5 No Implied Licenses. Only licenses and rights expressly granted herein will be of legal force and effect. No license or other right will be created hereunder by implication, estoppel or otherwise.

9. FINANCIAL TERMS; PAYMENT

9.1 Pricing. The Purchase Price as of the Effective Date is set forth on **Exhibit A**. Purchase Prices will be subject to quarterly review by the Parties (and at such other times as may be requested by ISB or Supplier). Changes to Purchase Prices, and in the manner and timing of their implementation, will be agreed upon by the Parties on a fair and reasonable basis. If the Parties cannot come to an agreement on pricing within ninety (90) days of a request for review, then the Party seeking an adjustment to pricing (or either of them if both parties are seeking an adjustment), may give notice of termination of this Agreement to the other Party under Section 10.5. It is agreed that any failure to agree on changes to Purchase Prices, and any consequential termination of this Agreement under Section 10.5 is not a dispute that shall be subject to the dispute resolution provisions in Section 18.1 of this Agreement. For the purposes of this Agreement, "Purchase Price" shall mean the then current purchase price as agreed by the Parties pursuant to this Section. All Purchase Prices are in United States Dollars.

9.2 Invoicing. Unless otherwise specified in a particular Purchase Order, upon the Products being made available for shipment at Supplier's location (subject to Section 5.3), Supplier will issue a separate invoice under this Agreement to ISB's or its Affiliate's (as applicable) Accounts Payable Department on the day such shipment is made pursuant to the applicable Purchase Order and this Agreement. Each invoice must set forth in reasonable detail the amounts payable by ISB with respect to such shipment and the following information: (a) Purchase Order number; (b) Product part number; (c) the quantity of Products shipped; (d) the date shipped; (e) the address of the facility of Supplier at which the Products were made available for shipping; and (f) any other information reasonably requested by ISB to be on the invoice or necessary for identification of the Products in such shipment. ISB will not honor draft invoices or bills.

9.3 Payment Terms. Payments for undisputed amounts due under this Agreement by ISB are due within thirty (30) calendar days after ISB's receipt of Supplier's invoice. The Parties acknowledge and agree that any payment by ISB or its Affiliate for a Product will not be deemed to constitute acceptance of such Product or waive ISB's or its Affiliate's rights to inspect or reject a Product as set forth in this Agreement.

9.4 Disputed Amounts. In the event of a good faith dispute regarding any payments due or alleged to be due under this Agreement, ISB may withhold the disputed amount pending resolution of the dispute. The Parties agree that ISB's withholding of the disputed amount will not constitute a breach of this Agreement, nor will it be grounds for Supplier to suspend its performance hereunder.

9.5 Taxes and Duties. The Purchase Price is exclusive of any taxes, including present and future state, county, city and district sales and use, transfer, goods and services, excise, gross receipts, business and occupation, withholding or similar taxes (collectively, "Transaction Taxes"), which are the sole responsibility and liability of ISB. ISB shall deliver to Supplier a tax exemption certificate with respect to applicable sales and use tax.

9.6 Cost Reductions; Annual Price Reductions**.** ISB and Supplier intend to work together in good faith throughout the term of this Agreement to reduce cost to achieve a mutually agreed upon annual price reduction goal of five percent (5%) (the "**Manufacturing Efficiency Cost Reduction**"). In addition, ISB and Supplier intend to work together in good faith throughout the Term of this Agreement to reduce cost based on the increased volume that will result in cost reductions per item (the "**Volume Cost Reduction**") as per the annual "**Volume Table Price Break**" as mutually agreed upon by the Parties in writing on an annual basis. Supplier agrees to submit ideas for cost reduction to ISB based on current specifications of the Product, components, and manufacturing process. Furthermore, either Party may from time to time give written notice to the other Party proposing that the specifications for the Product, Product components or manufacturing process be changed, together with the estimated decrease, if any, in the cost as a result of implementing such change. The other Party shall, within thirty (30) days of receipt of such notice, advise the proposing Party in writing as to whether it agrees to proceed with such change in the specifications (such agreement not to be unreasonably withheld, conditioned or delayed). If the Product, Product components, manufacturing process or specifications are changed based on agreement between the Parties according to this Section, the Parties shall share the total Savings (as defined below) as follows, depending upon how the Savings are achieved:

a. For any Manufacturing Efficiency Cost Reduction that results in Savings, such Savings shall be shared equally by reducing the then-current Purchase Price in effect between Supplier and ISB by an amount equal to fifty percent (50%) of the achieved Savings for the initial 12 months; and beyond this initial 12 month period, ISB shall receive 75% of the realized Savings for the second twelve (12) months, and then 100% of such realized Savings thereafter.

b. For any Savings that are achieved as a result of a capital expenditure (including external standards approval costs and increased temporary headcount to execute on the project and non-production headcount) by either Party (including interest paid thereon) or tooling change, then if the Party that is incurring the capital expenditure agrees to fund the capital expenditure, such Party shall receive 100% of the realized Savings until such Party recovers the full amount of the incremental capital investment, and such Party shall provide monthly reporting evidencing the payments, including any interest paid thereon, for any such capital expenditures.

c. "Savings" for purposes of this Section shall mean any reduction of the then-current Purchase Price that is the result of a cost-savings project initiated by one of the parties and shall not include any reduction in price for Materials that is simply due to market fluctuations. Savings shall be "achieved" and the initial 12 months of Savings shall begin to elapse upon the later of (a) the date that the first units are produced using the updated materials, design, manufacturing process, or other enhancement, and (b) the date that the Party agreeing to fund the capital expenditure has recovered the full amount of the incremental capital investment. Supplier shall update the pricing on the next quarterly CBOM update. Supplier and ISB will meet and agree upon any credit due to ISB for prior quarters when the savings was implemented during the middle of the quarter.

10. TERM AND TERMINATION

10.1 Term. The initial term of this Agreement will commence as of the Effective Date and, unless earlier terminated as provided in this Agreement, will continue for three years (the "Initial Term"). After the expiration of the Initial Term, this Agreement will automatically renew for successive renewal terms of one year (each a "Renewal Term"), unless either Party provides written notice to the other Party of its intention not to renew the Agreement at least six months (180 days) prior to the expiration of the then-current Term. The Initial Term and any Renewal Terms are collectively referred to as the "Term".

10.2 Termination of Convenience. ISB is able to elect to terminate this Agreement for convenience but subject to providing the Supplier a minimum of 180 days prior written notice.

10.3 Material Breach. In the event either Party commits a material breach of this Agreement (including if any of the representations or warranties of either Party proves to be untrue in any material respect) the other Party may terminate this Agreement upon 30 days prior written notice unless, prior to the expiration of such 30-day period, the breaching Party completely cures such breach. Such written notice will identify and reasonably describe the basis for such termination. Supplier's inability to manufacture or deliver an entire class or category of any Product in accordance with the terms of this Agreement will be deemed a material breach of Supplier's obligations for the purposes of this Section 10.3.

10.4 Failure to Pay. Either Party may terminate this Agreement if the other Party (i) is generally unable to pay, or fails to pay its debts for a period of fifteen Business Days after the payments are due, (ii) files or has filed against it, a petition for voluntary or involuntary bankruptcy or otherwise becomes subject, voluntarily or involuntarily, to any proceeding under any domestic or foreign bankruptcy or insolvency Law, (iii) makes or seeks to make a general assignment for the benefit of its creditors, or (iv) applies for or has appointed a receiver, trustee, custodian or similar agent appointed by order of any court of competent jurisdiction to take charge of or sell any material portion of its property or business.

10.5 Unresolved Pricing Dispute. Either Party may terminate this Agreement in accordance with Section 9.1 in the event of an unresolved pricing dispute described in Section 9.1 upon thirty (30) days' advance written notice.

10.6 Effect of Termination. Upon the expiration or termination of this Agreement, all rights, obligations and duties provided hereunder will terminate unless otherwise expressly provided in this Section 10.4 or in Section 10.5. Upon the expiration or termination of this Agreement, each Party will promptly pay all undisputed amounts owed and accrued hereunder. Supplier will honor all unfulfilled accepted Purchase Orders submitted prior to the expiration or termination of this Agreement unless the basis for the termination is non-payment by ISB.

10.7 Survival. Sections 1, 3.7, 5.3, 6, 8, 9, 10.3, 12, 13, 15, 16, 17, 18 and 19 will survive the expiration or termination of this Agreement.

11. Reserved.

12. CONFIDENTIALITY

12.1 Confidential Information. The Parties acknowledge that, by virtue of the activities to be performed and the relationships created under this Agreement, each Party (the "**Receiving Party**") may have access to information that the other Party (the "**Disclosing Party**") considers to be confidential ("**Confidential Information**"). Confidential Information may include designs, formulas, algorithms, trade secrets, know-how, customer lists, cost and pricing information, business and marketing plans, and other technical, business and financial information. Confidential Information that constitutes trade secret information of the Disclosing Party will be identified or marked as "Trade Secret" at the time of disclosure and, with respect to an intangible disclosure, will be summarized and confirmed as "Trade Secret" in writing within 30 days after such disclosure. Without limiting the generality of the foregoing, the Parties agree that all Specifications, ISB Materials and ISB Intellectual Property Developments constitute Confidential Information of ISB. Notwithstanding any provision in this Agreement to the contrary, Confidential Information does not include information that: (a) at the time of disclosure to the Receiving Party is generally publicly known through no breach of this Agreement or any other obligation of confidentiality owed to the Disclosing Party or any of its Affiliates; (b) after disclosure hereunder, becomes generally publicly known by publication or otherwise through no breach of this Agreement or any other obligation of confidentiality owed to the Disclosing Party or any of its Affiliates; (c) was known by or in the possession of the Receiving Party or any Affiliate of the Receiving Party at the time of disclosure under this Agreement by the Disclosing Party through no breach of this Agreement or any other obligation of confidentiality owed to the Disclosing Party or any of its Affiliates; (d) is independently developed by or for the Receiving Party without reference to or use of, in whole or in part, any of the Disclosing Party's Confidential information; or (e) the Receiving Party receives from a Third Party that is under no obligation of confidentiality to the Disclosing Party or any of its Affiliates with respect to such information.

12.2 Disclosure and Use of Confidential Information. During the Term and for a period of five (5) years after the expiration or termination of this Agreement (provided however, that all restrictions with respect to information identified or marked as "Trade Secret" will continue so long as such information retains its status as trade secret under applicable law), the Receiving Party will (on its behalf and on behalf of its Affiliates):

(a) Without limiting anything set forth in this Section 13, hold the Disclosing Party's Confidential Information in confidence using at least the same standard of care that is used by the Receiving Party with respect to its own confidential information (but in no event less than reasonable care);

(b) Not disclose or make available any of the Confidential Information of the Disclosing Party to any Third Party, except as provided in Section 11.3; and

(c) Not use the Disclosing Party's Confidential Information for any purpose other than to perform its obligations and exercise its rights under this Agreement.

12.3 Authorized Disclosure. The Receiving Party may disclose the Disclosing Party's Confidential Information to the extent that such disclosure is:

(a) Made to Affiliates, employees and approved contractors (but in the case Supplier is the Receiving Party, only Authorized Subcontractors) of the Receiving Party that have a specific need to know in order for the Receiving Party to be able to perform its obligations and exercise its rights under this Agreement, solely to the extent necessary for such purpose and pursuant to written confidentiality and non-use restrictions at least as restrictive as those set forth in this Agreement;

(b) In the case where ISB is the Receiving Party, made to ISB's Affiliate(s) in order for ISB and such Affiliate(s) to be able to perform their respective obligations and exercise their respective rights under this Agreement.

(c) Made in response to a valid order of a court of competent jurisdiction or other governmental authority; provided, however, that such Receiving Party will, to the extent permitted by applicable law, give written notice to the Disclosing Party within ten days after receipt of such order and, at the Disclosing Party's expense, give the Disclosing Party a reasonable opportunity to quash such order and to obtain a protective order requiring that the Confidential Information and documents that are the subject of such order be held in confidence by such court or governmental or regulatory body or, if disclosed, be used only for the purposes for which the order was issued; and provided, further, that if such disclosure order is not quashed or a protective order is not obtained, the Confidential Information disclosed in response to such court or governmental order will be limited to that information which is legally required to be disclosed in response to such court or governmental order;

(d) Otherwise required by applicable law; provided, that the Disclosing Party will give the Receiving Party written notice of such disclosure at least 30 days in advance of such disclosure to the extent possible and practicable and permitted by applicable law and will reasonably consider any comments received from the Receiving Party; or

(e) Made by the Receiving Party with the prior express written consent of the Disclosing Party.

12.4 Terms of this Agreement. The terms of this Agreement constitute Confidential Information of both Parties.

12.5 Return of Confidential Information. After expiration or termination of this, upon the written request of the Disclosing Party, the Receiving Party promptly will (a) return to the Disclosing Party all materials containing or embodying any of the Disclosing Party's Confidential Information or (b) destroy all materials containing or embodying any of the Disclosing Party's Confidential Information and certify such destruction in writing to the Disclosing Party. Notwithstanding the foregoing, (i) the Receiving Party will be authorized to retain one copy of the Disclosing Party's Confidential Information in its Legal Department solely for archival purposes to determine any continuing obligations of the Receiving Party with respect to the Disclosing Party's Confidential Information and (ii) the Receiving Party will not be required to destroy or delete electronic copies (including emails) that have become embedded in its electronic storage systems through routine backup processes. Any of the Disclosing Party's Confidential Information retained by the Receiving Party will continue to be subject to all of the confidentiality, non-use and other terms and conditions of this Agreement.

13. GENERAL REPRESENTATIONS AND WARRANTIES; WARRANTY DISCLAIMER

13.1 General Warranties. Each Party represents and warrants that:

(a) Such Party is duly organized, validly existing and in good standing under the laws of the jurisdiction of its domicile, and has all requisite power and authority to carry on its business as such business is now being conducted;

(b) This Agreement has been duly authorized, executed, and delivered by such Party and constitutes the legal, valid and binding obligation of such Party, enforceable against such Party in accordance with its terms, except as enforceability may be limited by applicable law relating to bankruptcy, receivership or similar laws affecting creditors' rights generally or by equitable principles relating to enforceability;

(c) Such Party has all necessary rights, powers, and authority to enter into this Agreement and to carry out its obligations hereunder; and

(d) Such Party has not entered into any other agreements, nor will it enter into any other agreements, that render or would render it incapable of timely and satisfactorily performing any of its obligations under this Agreement, or place it in a position of conflict of interest, or be inconsistent or in conflict with any of its obligations hereunder.

13.2 Additional Warranties by Supplier. Supplier represents, warrants, and covenants to ISB that: (a) there are no actions, suits, proceedings, or investigations commenced or, to the best of its knowledge and belief, contemplated or threatened against Supplier that could in any way affect Supplier ability to supply the Products, or ISB's and its Affiliates', and its and their respective Customers' right to use the Products; (b) when provided by Supplier, the Products will be provided free and clear of all liens, claims, encumbrances, and other restrictions (except any United States export controls, United States trade embargoes and other similar restrictions on the export or re-export of technical data and products) arising through Supplier other than those contemplated by this Agreement. . Notwithstanding anything to the contrary, Supplier makes no representation, warranty, or covenant with respect to infringement, violation, misappropriation or unauthorized use of Third Party Intellectual Property as a result of, based upon or attributable to (x) the design of the Product, (y) the use of a Product; or (z) compliance with the Specifications or other requirements of ISB (including use of Third Party components or parts specified or required by ISB).

13.3 WARRANTY DISCLAIMER. THE EXPRESS WARRANTIES SET FORTH IN THIS AGREEMENT (INCLUDING IN SECTION 8.3 AND SECTION 14.1) ARE THE PARTIES' RESPECTIVE EXCLUSIVE WARRANTIES WITH RESPECT TO THIS AGREEMENT, AND ALL OTHER EXPRESS OR IMPLIED WARRANTIES (INCLUDING THE IMPLIED WARRANTIES OF MERCHANTABILITY, NON-INFRINGEMENT OF THIRD PARTY RIGHTS AND FITNESS FOR A PARTICULAR PURPOSE) ARE HEREBY EXPRESSLY DISCLAIMED.

14. COMPLIANCE WITH LAWS; REGULATORY AND SAFETY REQUIREMENTS

14.1 Compliance with Laws. Without limiting anything set forth in this Agreement, each Party will comply with all applicable laws and regulations (including all export laws and regulations) of governmental bodies or agencies in its performance under this Agreement.

15. INDEMNIFICATION

15.1 Infringement Indemnification.

(a) Subject to Section 16.4, Supplier will defend, indemnify, and hold harmless ISB and its Affiliates and their respective officers, directors, employees, representatives, successors and assigns (collectively, the "**ISB Indemnitees**") from and against any and all (a) claims, actions, proceedings or other demands brought by any Third Party (collectively, "**Claims**") alleging that the manufacture of the Products infringes any Intellectual Property right of such Third Party, except to the extent that such infringement is caused solely

by Supplier's compliance with Specifications provided by ISB to Supplier, and (b) associated losses, liabilities, expenses, damages, settlements and costs (including reasonable attorneys' fees and court costs) (collectively, "**Liabilities**").

(b) Subject to Section 16.4, ISB will defend, indemnify, and hold harmless Supplier and its Affiliates, and their respective officers, directors, employees, representatives, successors and assigns (collectively, the "**Supplier Indemnitees**") from and against any and all (a) Claims alleging that any of the Products or the use, sale, offer for sale, importation, exportation or other exploitation of the Products infringes any Intellectual Property right of such Third Party, except to the extent that such infringement is caused solely by Supplier's manufacture of the Products, and (b) associated Liabilities.

15.2 General Indemnification by Supplier. Subject to Section 15.4, Supplier will defend, indemnify, and hold harmless the ISB Indemnitees from and against any and all Claims and associated Liabilities to the extent resulting from (a) Supplier's breach of this Agreement or (b) Supplier's gross negligence or willful misconduct.

15.3 General Indemnification by ISB. Subject to Section 15.4, ISB will defend, indemnify, and hold harmless Supplier, its Affiliates, and their respective officers, directors, employees, representatives, successors, and assigns (collectively, the "**Supplier Indemnitees**") from and against any and all Claims to the extent resulting from (a) ISB's breach of this Agreement, (b) ISB's gross negligence or willful misconduct or (c) the Products (excluding any Claim associated with Supplier's breach of this Agreement).

15.4 Indemnification Conditions. Each Party's obligations set forth in this Section 14 are conditioned upon the Party seeking indemnification (a) giving the indemnifying Party reasonably prompt written notice of the applicable Claim; provided, however, that failure to provide such notice will not relieve the indemnifying Party from its liability or obligations under this Section 16, except to the extent the indemnifying Party's defense of such Claim is directly and materially prejudiced by such failure; (b) permitting the indemnifying Party to control the defense and settlement of such Claim; provided, however, that the indemnifying Party may not settle such Claim, enter into or otherwise consent to an adverse judgment or order, or make any admission as to liability or fault that may adversely affect the indemnified Party, without the indemnified Party's prior written consent, which will not be unreasonably withheld or delayed; and (c) reasonably cooperating with the indemnifying Party, at the indemnifying Party's expense, in connection with the defense and settlement of such Claim, including providing accurate and complete information requested by the indemnifying Party. Further, the indemnified Party will have the right to participate (but not control) and be represented in any Claim by counsel of its selection at its own cost.

15.5 Insurance. Supplier will obtain and maintain (a) product liability, (b) product liability, and (c) property damage liability insurance coverage during the Term and for a period of three years thereafter. Such insurance will have policy limits of: (a) no less than $2,000,000 per occurrence of product liability; (b) no less than $1,000,000 per occurrence for death or personal injury, $1,000,000 per occurrence for real and personal property damage; and (c) $10,000,000 umbrella aggregate liability per year; (d) include ISB and its Affiliates as additional insureds and ensure notification per insurable event, should one occur. Upon ISB's request, Supplier will provide ISB a certificate of insurance evidencing such insurance coverage. Supplier's insurance coverage will be primary over any other potentially applicable insurance. Supplier hereby waives, and Supplier will cause its insurers to waive, any right of subrogation or other recovery against ISB, its Affiliates or their insurers.

16. LIMITATION OF LIABILITY

EXCEPT WITH RESPECT TO LIABILITY ARISING FROM A PARTY'S OBLIGATIONS UNDER BREACH OF SECTION 8 (INTELLECTUAL PROPERTY) OR SECTION 13 (CONFIDENTIALITY) OR GROSS NEGLIGENCE OR WILLFUL MISCONDUCT UNDER THIS AGREEMENT, NEITHER PARTY WILL BE LIABLE TO THE OTHER PARTY FOR ANY INCIDENTAL, INDIRECT, EXEMPLARY, PUNITIVE, SPECIAL, OR CONSEQUENTIAL DAMAGES UNDER ANY CIRCUMSTANCES, REGARDLESS OF WHETHER EITHER PARTY HAD BEEN ADVISED OF, KNEW OR SHOULD HAVE KNOWN OF THE POSSIBILITY OF SUCH DAMAGES. EXCEPT WITH RESPECT TO LIABILITY ARISING FROM A PARTY'S OBLIGATIONS UNDER, BREACH OF SECTION 8 (INTELLECTUAL PROPERTY) OR SECTION 13 (CONFIDENTIALITY) OR GROSS NEGLIGENCE OR WILLFUL MISCONDUCT UNDER THIS AGREEMENT, BUT OTHERWISE TO THE EXTENT PERMITTED BY LAW, A PARTY'S TOTAL AND CUMULATIVE LIABILITY TO THE OTHER PARTY ARISING UNDER OR IN CONNECTION WITH THIS AGREEMENT, WHETHER IN CONTRACT, TORT (INCLUDING NEGLIGENCE), STRICT LIABILITY, MISREPRESENTATION, BREACH OF STATUTORY DUTY OR OTHERWISE, WILL IN NO EVENT EXCEED THE

AGGREGATE AMOUNT RECEIVED BY SUPPLIER FOR THE PURCHASE OF PRODUCTS UNDER THIS AGREEMENT DURING THE TWELVE (12) MONTH PERIOD IMMEDIATELY PRIOR TO THE EVENT GIVING RISE TO THE CLAIM. SUPPLIER'S LIABILITY FOR ISB'S DIRECT COSTS AND EXPENSES ASSOCIATED WITH ANY RECALL CAMPAIGN UNDER SECTION 6.3 SHALL BE LIMITED TO THE GREATER OF (A) ONE MILLION DOLLARS ($1,000,000) OR THE AGGREGATE AMOUNT RECEIVED BY SUPPLIER FOR THE PURCHASE OF PRODUCTS UNDER THIS AGREEMENT DURING THE TWELVE (12) MONTH PERIOD IMMEDIATELY PRIOR TO THE EVENT GIVING RISE TO THE CLAIM. AS USED IN THE IMMEDIATELY PRECEDING SENTENCE, "CONTRACT YEAR" SHALL MEAN EACH SUCCESSIVE 12-MONTH PERIOD DURING THE TERM, WITH THE FIRST SUCH PERIOD BEGINNING ON THE EFFECTIVE DATE.

17. FORCE MAJEURE

Neither Party will be in breach of this Agreement or liable for any failure or delay of such Party in performing its obligations under this Agreement to the extent that such failure or delay was caused directly by any event beyond such Party's reasonable control, without such Party's fault or negligence and that by its nature could not have been foreseen by such Party or, if it could have been foreseen, was unavoidable (including acts of God or of the public enemy, fires, floods, civil commotions, epidemics, quarantine restrictions, strikes or labor disputes (other than strikes or labor disputes by Supplier's employees or contractors), freight embargoes, threatened terrorism, terrorism or unusually severe weather) (a "**Force Majeure Event**"). Supplier's financial inability to perform, changes in cost or availability of materials, components or services, market conditions or supplier actions or contract disputes will not excuse performance by Supplier under this Section 16.

18. DISPUTE RESOLUTION

18.1 Dispute Resolution Objective. The Parties recognize that disputes may arise that might not be readily resolved, and it is the Parties' objective to establish procedures to facilitate the resolution of disputes in an expedient manner by mutual cooperation and without resorting to litigation. Unless otherwise expressly provided in this Agreement and except for claims for injunctive relief, specific performance, or any other equitable relief, and claims by a Party asserting infringement of such Party's Intellectual Property, each of which may either: (a) be submitted for arbitration as set forth herein; or (b) pursued in a court as set forth herein, all disputes will be subject to this Section 18.1. Either Party may initiate the dispute resolution procedure of this Section 18.1 by giving the other Party written notice of any dispute ("**Notice of Dispute**").

18.2 Negotiation**.**

(a) The Parties shall attempt in good faith to initially resolve any and all disputes, controversies, or claims arising out of, in connection with, or relating to this Agreement ("Disputes") promptly by negotiation. Within ten (10) Business Days of a Notice of Dispute provided to a Party, the Parties shall meet in person, or by teleconference, at a mutually agreeable time and place and thereafter as often as they reasonably deem necessary, to attempt in good faith to resolve the Dispute.

18.3 Arbitration.

(a) In the event the Parties are unable to resolve any dispute by negotiations or mediation as set forth in Section 18.2 above within four (4) months after the Notice of Dispute, the Parties shall submit the dispute to binding arbitration before a single arbitrator agreeable to both Parties. If the Parties cannot agree on an arbitrator within thirty (30) Business Days after the commencement of the arbitration, each Party shall select an arbitrator, who is not employed by or a consultant to either Party, and the two selected arbitrators will select a third arbitrator, who is not employed by or a consultant to either Party. Any arbitrator chosen hereunder must have reasonable educational training and reasonable scientific, patent, and/or industry experience relevant to the particular dispute.

(b) The arbitrator's decision will be binding on the Parties and will be final and non-appealable. Any decision by the arbitrator will not be interpreted as an admission against interest of any Party and will not be admissible as evidence in any subsequent court action with a third party.

(c) The non-prevailing Party shall pay the costs of any arbitration pursuant to this Section 18.3.

18.4 Court Proceedings. Unless otherwise provided in this Agreement, neither Party may institute any court proceedings concerning any dispute relating to this Agreement. The dispute resolution procedure of this Section 18 is the sole remedy, unless otherwise provided elsewhere in this Agreement, for resolving disputes. Notwithstanding the foregoing, the Parties may initiate court proceedings in a court of competent jurisdiction to enforce any arbitration award between the Parties.

18.5 Governing Law; Jurisdiction. This Agreement and any dispute, controversy or claim arising out of, in connection with or related to this Agreement or its subject matter or formation will be governed and construed in accordance with the laws of the State of Delaware, without regard to provisions on the conflicts of laws. Any legal action or other proceeding (including arbitration) to resolve such dispute, controversy or claim will take place in a court of competent jurisdiction. Each Party expressly consents to the personal jurisdiction and venue of such courts for the purpose of any such legal action or other proceeding. Supplier hereby waives any right it may otherwise have to assert any rights or defenses under the laws of any other jurisdiction, or to require that litigation brought by or against it in connection with this Agreement be conducted in the courts or other forums of any other jurisdiction. Supplier further expressly waives any defenses of lack of personal jurisdiction, venue, or forum non conveniens. The United Nations Convention on Contracts for the International Sale of Products does not apply to this Agreement.

18.6 Injunctive Relief. Supplier acknowledges that any use or disclosure of ISB's Confidential Information, ISB Intellectual Property Developments or ISB Materials other than strictly in accordance with this Agreement will cause irreparable damage to ISB. Therefore, in the event of any such actual or threatened use or disclosure, ISB will be entitled, in addition to all other rights and remedies available at law or in equity, to obtain injunctive relief against the breach or threatened breach of any obligations hereunder without posting a bond or other security as a condition for obtaining any such relief.

18.7 Cumulative Remedies. Except as otherwise provided herein, the exercise of any right or remedy provided in this Agreement will be without prejudice to the right to exercise any other right or remedy herein or provided by law or equity.

19. GENERAL

19.1 Severability; No Waiver. If any term or provision of this Agreement is invalid, illegal or unenforceable in any jurisdiction, such invalidity, illegality or unenforceability will not affect any other term or provision of this Agreement or invalidate or render unenforceable such term or provision in any other jurisdiction. Upon a determination that any term or provision is invalid, illegal or unenforceable, the Parties will negotiate in good faith to modify this Agreement to effect the original intent of the Parties as closely as possible in order that the transactions contemplated by this Agreement be consummated as originally contemplated by the Parties to the greatest extent possible. The failure or delay of either Party to exercise any right or remedy provided in this Agreement or to require any performance of any term of this Agreement may not be construed as a waiver, and no single or partial exercise of any right or remedy provided in this Agreement, or the waiver by either Party of any breach of this Agreement, will prevent a subsequent exercise or enforcement of, or be deemed a waiver of any subsequent breach of, the same or any other term of this Agreement.

19.2 Assignment. Neither Party may assign or otherwise transfer, or delegate any of its obligations under, this Agreement or any rights or obligations under this Agreement without the prior written consent of the other Party, except that either Party ("**Assigning Party**") may, without the other Party's prior written consent, assign this Agreement in its entirety (i) in connection with a consolidation or reorganization of such Assigning Party or (ii) to an acquirer or successor of all or substantially all of (A) the business or assets of such Assigning Party to which this Agreement relates or (B) the equity of such Assigning Party, in each case (A) and (B) whether by merger, sale, assignment, operation of law or otherwise, provided, however, in each case, if Supplier is the Assigning Party, Supplier may not assign or otherwise transfer or delegate any of its obligations under this Agreement (or any rights or obligations under this Agreement) to a competitor of ISB; and (b) ISB may, with Supplier's prior written consent (which shall not be unreasonably withheld, conditioned or delayed), assign or transfer this Agreement, and may delegate or subcontract any or all of its rights and obligations under this Agreement, to one or more of its Affiliates. If either Party assigns this Agreement in accordance with the foregoing (a) or (b), such assigning Party will give the other Party written notice of such assignment. Any purported assignment or other transfer of this Agreement (in whole or in part) in violation of this Section 19.2 will be null and void.

19.3 Successors and Assigns. Subject to Section 2, this Agreement will be binding upon and inure to the benefit of each of the Parties and their permitted successors and assigns.

19.4 Entire Agreement; Amendment. This Agreement, including all Exhibits attached hereto and Purchase Orders and Blanket Purchase Orders referenced herein, represents the entire agreement between the Parties regarding the subject matter hereof and supersedes all prior discussions, communications, agreements, and understandings of any kind and nature between the Parties. The Parties acknowledge and agree that by entering into this Agreement, they do not rely on any statement, representation, assurance or warranty other than as expressly set forth in this Agreement. Each Party agrees that it will have no right or remedy (other than for breach of contract) in respect of any statement, representation, assurance or warranty (whether made negligently or innocently) other than as expressly set forth in this Agreement. Nothing in this Section 19.4 will exclude or limit any liability for fraud. No amendment to this Agreement will be effective unless in writing and signed by both Parties.

19.5 Relationship of the Parties. The Parties are independent contractors under this Agreement and nothing in this Agreement may be construed as creating a partnership, joint venture or agency relationship between the Parties or as granting either Party the authority to bind or contract any obligation in the name of the other Party or to make any statements, representations, warranties or commitments on behalf of the other Party.

19.6 Headings; Interpretation; Miscellaneous. Sections, titles and headings in this Agreement are for convenience only and are not intended to affect the meaning or interpretation of this Agreement. Whenever required by the context, the singular term includes the plural, the plural term includes the singular, and the gender of any pronoun includes all genders. As used in this Agreement, except as the context may otherwise require, the words “include,” “includes,” “including,” and “such as” are deemed to be followed by “without limitation” or “but not limited to,” whether or not they are in fact followed by such words or words of like import, “will” and “shall” are used synonymously, and “discretion” means sole and absolute discretion. Except as expressly stated, any reference to “days” will be to calendar days, and “business day” means all days other than Saturdays, Sundays, or a national or local holiday recognized in the United States, any reference to “calendar month” will be to the month and not a thirty (30) day period, and any reference to “calendar quarter” will mean the first three calendar months of the year, the fourth through sixth calendar months of the year, the seventh through ninth calendar months of the year, and the last three calendar months of the year. Whenever the last day for the exercise of any right or the discharge of any obligation hereunder falls on, or any notice is deemed to be given on, a Saturday, Sunday or national or local holiday recognized in the United States, the Party having such right or obligation will have until 5:00 pm PT on the next succeeding business day to exercise such right or to discharge such obligation or the Party giving notice will be deemed to have given notice on the next succeeding business day. No usage of trade, course of performance, or other regular practice between the Parties may be used to interpret or alter the terms or conditions of this Agreement. Unless otherwise expressly provided in this Agreement, any agreement, instrument or statute defined or referred to means such agreement, instrument or statute as from time to time amended, modified, or supplemented, including (in the case of agreements or instruments) by waiver or consent and (in the case of statutes) by succession of comparable successor statutes and references to all attachments thereto and instruments incorporated therein. The Parties have participated jointly in the negotiation and drafting of this Agreement. If an ambiguity or question of intent or interpretation arises, this Agreement will be construed as if drafted jointly by the Parties, and no presumption or burden of proof will arise favoring or disfavoring any Party because of the authorship of any provision of this Agreement.

19.7 Counterparts. This Agreement may be executed in one or more counterparts, each of which will be deemed to be an original, and all of which will constitute one and the same instrument.

19.8 Costs. Except as expressly provided in this Agreement, each Party will pay its own costs incurred in connection with the negotiation, preparation and execution of this Agreement and any documents referred to in this Agreement.

19.9 Time is of the Essence. Time is of the essence with respect to the performance of Supplier’s obligations under this Agreement.

[SIGNATURE PAGE FOLLOWS]

The parties have executed this Master Supply Agreement as of the Effective Date.

ISB:

ISB HEALTH, INC.

By: /s/ Greg Hummer

Name: Greg Hummer

Title: CEO

Email: XXXX

Address: 20600 Chagrin Blvd Suite 450
Shaker Heights, Ohio 44122

SUPPLIER:

EAST WEST MANUFACTURING, LLC

By: /s/ Scott Ellyson

Name: Scott Ellyson

Title: CEO

Email: XXXX

Address: 4170 Ashford Dunwoody Rd
Suite 5600
Atlanta, GA 30319
Attn: General Counsel

EXHIBIT A

Material Costs and Purchase Price

The Parties acknowledge and agree that the pricing methodology is being negotiated in good faith as of the Effective Date. The Parties shall continue to work together in good faith to finalize the pricing methodology no later than ten (10) business days after the Effective Date and mutually execute an amendment setting forth Exhibit A upon reaching such agreement.

EXHIBIT B

Specifications

Below are the starting specifications as of the Effective Date. The Parties will coordinate in good faith with regard to future revision changes. Each Purchase Order will specify SKU and revision for each item ordered.

ITEM NUMBER	ITEM NAME
860-00001 rev 1	Check4 Reader Rx and Ebola Test Kit
860-00002 rev 1	Check4 Reader and Respiratory Rx Test Kit
860-00003 rev 1	Ebola/Marburg Cartridge Kit
860-00004 rev 1	Respiratory Rx Cartridge Kit
860•00005	Respiratory OTC Cartridge Kit
860-00006	Check4 Reader and Respiratory OTC Test Kit
860-00007 rev 1	Check4 Reader Rx Kit
860-00008	Check4 Reader OTC Kit

EXHIBIT C

Quality Agreement

Table of Contents

1 INTRODUCTION AND PURPOSE.

1.1 Introduction.

1.1.1 IdentifySensors Quality Policy.

IdentifySensors Biologics is committed to delivering products with the highest standards of quality, safety, and performance to revolutionize the at home and point of care testing market for infectious diseases. To uphold this commitment, IdentifySensors Biologics shall:

(a) Develop and manufacture quality products that meet and exceed customer expectations;

(b) Drive a customer focused culture of continuous improvement;

(c) Ensure continued effectiveness of the Quality Management System; and

(d) Comply with all applicable regulatory and statutory requirements.

1.1.2 **Engagement.** Supplier has been retained by IdentifySensors to supply or provide certain products or services which are incorporated into IdentifySensors' products. This Quality Agreement is effective upon execution by the Parties and shall, at all times, apply to the Product(s) or Service(s) provided by Supplier to IdentifySensors. Hereinafter, the Product(s) and/or Service(s) provided by Supplier to IdentifySensors shall individually and collectively be referred to as the "**Product**". Where indicated by the context used herein, the term "Product" also includes any portion of the Product, including, without limitation, a production lot.

1.1.3 **Definitions.** Capitalized terms used herein and not otherwise defined shall have the same meanings as given them in the corresponding Supply or Services Agreement (as appropriate).

1.2 Purpose.

1.2.1 **Purpose.** This Quality Agreement addresses the quality management system requirements for the Product(s).

1.2.2 **Regulatory Requirements.** This Quality Agreement is intended to ensure that the manufacturing of the Product will be safe and effective, will fulfill Product Requirements and that all Product meet all applicable Regulatory Requirements. As used herein, "**Regulatory Requirements**" means in relation to the engagement referenced in Section 1.1.2 above, all applicable domestic and foreign federal, state, and local laws, statutes, acts, ordinances, rules, codes, standards, guidelines and regulations, applicable to the Supplier provided under either a Supply or Services Agreement (as appropriate).Without limiting the generality of the foregoing, "**Regulatory Requirements**" means all the rules and regulations applicable to the labeling, re-labeling, packaging, processing, assembly, record creation, record retention, record modification, record transmission (including by electronic means), storage, handling, transport (including exportation and importation of Product within the United States, or to or from the United States and any other country), and reporting of Regulated Product, including without limitation: (a) the Federal Food, Drug, and Cosmetic Act, as amended, 21 U.S.C. 301 et seq., (the "**FD&C Act**"); (b) current good manufacturing practice requirements ("**cGMP**") as set forth in the Food and Drug Administration ("**FDA**") quality system regulations; (c) quality management system ("**Quality Management System**") requirements of ISO 13485 (and any amendments thereto); (d) IdentifySensors' requirements and/or specifications with which a Product, process, service or other activity must conform, including without limitation, blueprints, bill of material, assembly drawings, device master records ("**DMR**"), specifications for materials, approved suppliers, validated processes, and product testing methods in each case which have been provided to Supplier in writing (hereinafter collectively referred to as the ("**Product Requirements**"); and (e) FDA regulations regarding electronic records and electronic signatures at 21 CFR Part 11 as applicable to the product.

1.2.3 **Continuous Improvements.** In the event that quality issues, not otherwise addressed in this Quality Agreement, arise during Product manufacture and quality evaluations, then Supplier agrees to implement continual improvement activities (including, without limitation, performance enhancements and corrective actions) that the Supplier and IdentifySensors deem necessary or appropriate to improve, assure, or otherwise maintain the quality of the Product.

2 SCOPE AND EFFECT.

2.1 **Effect.** The terms of this Quality Agreement are intended to be consistent with and supplement the terms of any Supply or Services Agreement. Notwithstanding the foregoing, with respect to any specific Product or Service, in the event of any conflict between terms in this Quality Agreement and any Supply or Services Agreement, or any amendment or statement of work related thereto, then the documents shall govern in this order: (a) the Supply or Services Agreement (as appropriate); (b) any related amendment or statement of work; and (c) this Quality Agreement.

2.2 **Product Registration.** Each Party shall be responsible for registering its facilities with the appropriate Regulatory Agency, as such term is defined in Section 15.1 (Regulatory Agency) below or agencies and for maintaining any such registrations and/or licenses in accordance with FDA's Device Establishment regulations. Supplier shall maintain, and keep readily available, all documentation and forms relating to such registrations and/or licenses.

2.3 **Compliance with Laws.** The manufacturing of all Products complies with applicable federal, state and local laws, statutes, rules, regulations, ordinances, and orders promulgated by the country wherein the product is manufactured and the United States, including those laws, rules and regulations and industry standards related to health, safety, labeling, product claims, product safety, product composition, adulteration and intended use.

2.4 **Duration of Agreement.** This Quality Agreement shall commence upon the Effective Date and shall remain in effect as long as Supplier manufactures and/or supplies Products to IdentifySensors. Notwithstanding the foregoing, any section of this Quality Agreement which has a document retention or survival requirement shall survive the termination of this Quality Agreement for the period of time designated in the corresponding section of this Quality Agreement. IdentifySensors and Supplier shall endeavor to review this Quality Agreement on a regular basis, but no less than every three (3) years.

3 COMMUNICATION AND DESIGNATION OF QUALITY REPRESENTATIVE.

Quality Representative. Each Party shall designate the appropriate person(s) from its respective quality unit (the "**Quality Representative**") to be responsible for maintaining communication about quality assurance for the Product and this Quality
3.1 Agreement, including sending and receiving any notice(s) described or required herein. Appendix I attached hereto and incorporated herein by reference, sets forth the complete contact information for each Party's respective Quality Representative(s) and an initial and/or brief description of the Product(s).

4 SUPPLIER QUALITY MANAGEMENT SYSTEM REQUIREMENTS.

Quality Management System. Supplier shall implement and maintain a Quality Management System in accordance with FDA's cGMP/QS requirements and ISO 13485 for Regulated Product- Quality management systems-requirements for regulatory
4.1 purposes. Supplier shall provide IdentifySensors with updated certificates of Quality Management System certification as they are obtained and renewed. Supplier shall also provide a copy of any governmental license for medical device manufacturing including, but not limited to, applicable ISO and FDA records and certificates.

4.2 **Notification.** Supplier shall notify IdentifySensors of a change of leadership, location, registration, certification, capability, partnership, ownership, force majure etc., within a reasonable timeframe for IdentifySensors to react accordingly.

5 INTERNAL QUALITY MANAGEMENT SYSTEM (QMS) AUDITS AND CORRECTIVE ACTION.

QMS Audits. Each Party will establish procedures for QMS audits and conduct such audits to ensure that its QMS meets the established QMS requirements and to determine the effectiveness for the QMS as set forth in ISO 13485, (Measurement, Analysis and Improvement). Quality audits shall be conducted by individuals who do not have direct responsibility for the
5.1 matters being audited. Corrective action(s), including a re-audit of deficient matters, shall be taken when necessary. A report of the results of each quality audit, and re-audit(s) where taken, shall be made and such reports shall be reviewed by management having responsibility for the matters audited. The dates and results of quality audits and re-audits shall be documented.

5.2 **Corrective and Preventive Actions.** Each party shall establish and maintain procedures for implementing corrective and preventive action system(s) in accordance with ISO 13485. The procedures shall include requirements for and documentation of:

5.2.1 **Analysis.** Analyzing processes, work operations, concessions, quality audit reports, quality records, service records, complaints, returned product, and other sources of quality data to identify existing and potential causes of nonconforming product, or other quality problems. Appropriate statistical methodology shall be employed where necessary to detect recurring quality problems;

5.2.2 **Investigation.** Investigating the cause of nonconformities relating to product, processes, and the quality system;

5.2.3 **Corrective and Preventative Actions.** Identifying the action(s) needed to correct and prevent recurrence of nonconforming product and other quality problems;

5.2.4 **Verification and Validation.** Verifying or validating the corrective and preventive action to ensure that such action is effective and does not adversely affect the finished device;

5.2.5 **Implementation and Recording.** Implementing and recording changes in methods and procedures needed to correct and prevent identified quality problems;

5.2.6 **Dissemination of Information.** Ensuring that information related to quality problems or nonconforming product is disseminated to those directly responsible for assuring the quality of such product or the prevention of such problems; and

5.2.7 **Management Review.** Submitting relevant information on identified quality problems, as well as corrective and preventive actions, for management review.

6 TRAINING AND EDUCATION.

6.1 **Training and Record Retention.** Supplier shall establish procedures for determining the necessary education and identifying training requirements for all employees, including temporary employees, entrusted with any work affecting quality to ensure that all personnel are trained to adequately perform their assigned responsibilities and training records are retained per the requirements of ISO 13485.

6.2 **Defects and Errors.** As part of their training, personnel shall be made aware of device nonconformities which may occur from the improper performance of their specific jobs. Further, personnel who perform verification and validation activities shall be made aware of nonconformities and errors that may be encountered as part of their job functions.

7 ENVIRONMENT AND BUILDINGS.

7.1 **Environment.** The buildings and environment (including, without limitation, computers, equipment, documents, records, and qualified utilities such as HVAC) in which the Product is received, distributed, processed, developed, manufactured, or stored by Supplier, and the personnel that perform these operations for Supplier, shall be adequately controlled by established procedures: (a) in accordance with QS Regulations, including, quality management system requirements of ISO 13485,;and (b) to ensure that the Product will consistently meet Product Requirements. The environmental control system(s) shall be periodically inspected to verify that the system, including necessary equipment, is adequate and functioning properly. These activities shall be documented and reviewed.

7.2 **Security.** Supplier has and will maintain controlled and secured access to all facilities it uses to manufacture, package, test, label, or store Product. All third-party visitors will be required by Supplier to sign-in and be escorted during any site visit.

7.3 **Supplier Personnel.** In accordance with QS Regulations/cGMPs, Supplier shall be responsible to establish and maintain requirements for the health, cleanliness, personal practices, and clothing of personnel if contact between such personnel and Product (or the environment in which the Product is processed, manufactured or distributed) could reasonably be expected to have an adverse effect on Product quality.

7.4 **Buildings.** Supplier's facilities in which the Product (including any components, in-process devices, manufacturing material, accessories, finished devices, or other element relating to the Product) is handled, stored, packaged, unpackaged, labeled, or otherwise processed, shall be orderly and suitably designed (including, without limitation, with adequate space for performance of functions and distinct operations or processes should be separated to prevent product mixing/mix-ups or other contamination) to meet the requirements of the QS Regulations.

7.5 **Approved Facility.** Supplier will manufacture, package, test, label, and store the Product only at the facility or facilities ISO 13485 registered at Supplier's Wisconsin and Costa Rica facilities and will not transfer any of such operations for the Product to third parties or other sites or facilities, other than the suppliers listed in their Quality Management System registration without the prior written agreement of IdentifySensors. Supplier must submit any proposed changes to IdentifySensors using IdentifySensors' Supplier Change Request Form ("**SCR**") at least ninety (90) days prior to the proposed change effective date. IdentifySensors reserves the right to audit the new facility/additional facility/third party to ensure it meets IdentifySensors' compliance requirements.

7.6 **Contamination Control.** Supplier's facility (or facilities) shall be designed and managed to prevent, reduce, or control potential contamination of the Product by any chemical and/or microbial substances that could reasonably be expected to have an adverse effect on the quality/ effectiveness of the Product. Such contamination controls include, but are not limited to: sanitation practices for Supplier personnel such as designated areas for eating, drinking, and smoking; written procedures respecting use and removal of hazardous substances to prevent any adverse effect on the quality of the Product; and written pest control procedures respecting use and removal of insecticides, rodenticides, or other such substances to prevent any adverse effect on the quality of the Product.

8 PROCESS AND DESIGN CONTROL.

8.1 **Production and Process Controls.** Supplier shall establish procedures to develop, conduct, monitor, control, validate processes (where process results cannot be fully verified by subsequent inspection and testing) and qualify equipment. Validation activities, process changes and deviations shall be documented. Supplier shall establish and maintain procedures for monitoring and control of production processes to ensure that the Product conforms to Product Requirements, i.e. ISO 13485 7.1 (Planning of Product Realization). The monitoring and control methods, data, date performed, individual(s) performing the process and the major equipment used shall be documented.

8.2 **General Controls.** Supplier shall, more specifically, assure that production equipment and quality measurement equipment, including mechanical, electronic, automated, chemical, or other equipment, are: (a) operated by trained personnel; and (b) properly calibrated to the appropriate and suitable standard (i.e. ISO 13485 7.5.1) (Control of Production and Service Provision) and 7.6 (Control of Monitoring and Measuring Devices).

8.3 **Process Documentation.** Supplier shall develop, and IdentifySensors shall approve, the following:

8.3.1 **Maps and Flow Charts.** Production Process Map or Process Flow Chart identifying the planned manufacturing, assembly and testing steps, and their respective sequence. Planned critical control points shall also be identified.

8.3.2 **Dynamic Control Plans.** Documented risk assessment, such as a PFMEA or Dynamic Control Plans ("**DCPs**") for the planned manufacturing, assembly, and testing steps. Process steps shall correlate with the production process map. Risk reduction measures, such as additional test or inspection points, shall require updating the process map with the additional identified control points or measures.

8.3.3 **Master Process Validation Plan.** Master Process Validation Plan documenting all the necessary Installation Qualifications ("**IQ**"), Operational Qualifications ("**OQ**"), and Performance Qualifications ("**PQ**") activities. The Master Validation Plan ("**MVP**") shall identify all systems, processes, and methods that are considered "special" and therefore require validation. In addition, the MVP shall identify those processes, operations, and inspections that require verification and/or qualification only, (e.g., gage repeatability and reproducibility studies, operator qualification, etc.). The MVP shall also identify the relative sequence for conducting such validation and verification efforts. Hard copies of all Process Validation documentation are to be furnished to IdentifySensors as necessary upon request.

8.3.4 **Equipment Qualifications.** Equipment Qualifications, e.g., IQ and an Operational Qualification-Equipment ("**OQ-E**") with approved protocols and test reports.

8.3.5 **Process Validations.** Process Validations, e.g., Operational Qualification-Process ("**OQ-P**") and PQ shall have approved protocols and test reports which include test data, results, date and signature of the individual(s) approving the validation and where appropriate the major equipment validated.

8.3.6 **Cleaning.** Supplier is responsible for ensuring that adequate cleaning is carried out between Product lots to prevent Product contamination. The cleaning procedure will be reviewed by Supplier before the first Product production lots are manufactured.

8.3.7 **Delays.** IdentifySensors acknowledges and agrees that any delay in approval may impact the Delivery Dates associated with the Products.

8.4 **Equipment Controls.** All equipment used to manufacture, or in the manufacture of, the Product shall meet specific requirements, be appropriately designed, constructed placed, and installed to facilitate maintenance, adjustment, cleaning, and use in accordance with QS Regulations, including, without limitation, ISO 13485 7.5.1 (Control of Production and Service Provision) and 7.6 (Control of Monitoring and Measuring Devices).

8.4.1 **Written Procedures and Schedules.** Supplier shall establish and maintain written maintenance procedures and schedules and shall specifically document the performance of all maintenance activities ISO 13485 7.5 (Production and Service Provision).

8.4.2 **Periodic Inspection.** Supplier shall conduct and document completion of periodic inspections to ensure Supplier's adherence to equipment maintenance procedures and schedules. ISO 13485, 7.5 (Production and Service Provision) and 4.2 (Control of Documents).

8.4.3 **Information Availability.** In accordance with QS Regulations, Supplier shall ensure that any inherent limitations or allowable tolerances are either: (a) visibly posted on or near any equipment requiring periodic adjustments; or, (b) are readily available to personnel performing these adjustments.

8.5 **Manufacturing Materials.** In the event that any material or substance used in, or used to facilitate, the manufacturing process (including without limitation, abrasives, cleaning agents, lubricating oils, mold release compounds, maskants, adhesives, blasting media, and dye penetrant) could reasonably be expected to be present on or in the Product as a residue or impurity, and not by design or intent, then Supplier shall establish and maintain written procedures for the use and removal of such manufacturing material to ensure that it is removed or limited to an amount that does not adversely affect the quality of the Product and Supplier shall document all such removal or reduction activities.

8.6 **Automated Processes.** In the event that computers or automated data processing systems (i.e., hardware and software) are used as part of the production of the Product and/or Supplier's Quality Management System, then Supplier shall be responsible to validate computer software and associated equipment for its intended use according to a written protocol and in accordance with QS Regulations/cGMPs and FDA/Regulatory Agency guidance/information documentation concerning software validation. Supplier shall be responsible to ensure that all software changes shall be validated before approval and implementation; and, all such validation activities and results shall be documented, in accordance with ISO 13485 7.5.2. (Validation of Processes for Production and Service Provision).

8.7 **Serialization.** Supplier shall be responsible for implementation and maintenance of an adequate system to provide serialization of products in accordance with IdentifySensors provided specifications.

8.8 **Calibration.**

8.8.1 **Calibration Program.** To assure adequate and continuous performance of measurement equipment with respect to accuracy and precision, Supplier shall establish and implement a calibration program that is at least as stringent as that required by QS Regulations/cGMPs, including, without limitation, ISO 13485 7.6 (Control of Monitoring and Measuring Devices).

8.8.2 **Documentation.** Calibration of equipment shall be conducted under appropriate environmental controls and documented to include: equipment identification, calibration date, calibrator, and date next calibration is due. Calibration shall be traceable to and conducted in accordance with the applicable national standard of the country in which the calibration occurs.

8.8.3 **Product Records.** Inspection devices and methods used in the manufacturing process are to be referenced by the inspection device number in the relevant inspection protocol or product record, as defined in Section 9.1.2 (Product Records).

8.8.4 **Laboratory Services.** In the event that Supplier uses a contract calibration laboratory to perform required calibration activities, then Supplier shall ensure that such laboratory is qualified, and Supplier shall have and maintain evidence that Supplier's equipment was calibrated according to QS Regulations/cGMPs.

9 DOCUMENT CONTROLS AND RETENTION.

9.1 **Product Records.** Supplier shall possess and retain detailed written records of all Supplier activities relating to the Product (collectively referred to as the "**Product Records**"), including, but not limited to the following:

9.1.1 **Scope of Records.** By way of example, and not as an exhaustive list, Product Records include, but are not limited to, all documents concerning the manufacture, testing, quality, validation, traceability, remanufacture, packaging, labeling, inspection, and shipping activities relating to the Product.

9.1.2 **Required Documents.** Product Records also include all documents required by this Quality Agreement, the Supply Agreement and applicable QS Regulations/cGMPs, including, but not limited to, the compilation of documents comprising a device or product history record ("**DHR**"), device or product master record ("**DMR**"), and device or product history file ("**DHF**") as defined in QS Regulations/cGMPs and ISO 13485, 4.2 Documentation Requirements and any applicable medical device requirements in the markets the Products are intended for (EU MDD/MDR, IVDD/IVDR, ANVISA, JPAL).

9.1.3 **Supplier Responsibility.** Unless otherwise agreed to in a written document signed by the Parties and incorporated herein by reference, Supplier shall be responsible to maintain the DHR, DMR, and DHF for the Product in accordance with QS Regulations/cGMPs.

9.1.4 Education and Training. Supplier shall establish procedures for and maintain all records related to necessary education and training requirements for all employees, including temporary employees, entrusted with any work affecting quality to ensure that all personnel are trained to adequately perform their assigned responsibilities per ISO 13485, 6.2 Human Resources.

9.2 **Document Controls.** Supplier shall establish and maintain an up-to-date written document control system for controlling the Product Records in accordance with the requirements set forth in this Quality Agreement, the Supply Agreement, and the document control provisions in the QS Regulations, including, without limitation, ISO 13485, 4.2 Documentation Requirements.

9.3 **Document Approval and Distribution.** Supplier shall designate individual(s) to review for adequacy and approve prior to issuance all documents established to meet Quality Management System and Product requirements. Approval dates and signatures of the approvers shall be documented. Documents established to meet the requirements of this part shall be available at all locations for which they are designated, used, or otherwise necessary, and all obsolete documents shall be promptly removed from all points of use.

9.4 **Document Changes.** Changes to documents shall be reviewed and approved by an individual(s) in the same function or organization that performed the original review and approval, unless specifically designated otherwise. Approved changes shall be communicated in a timely manner. Supplier shall maintain records of changes to documents. Change records shall include a description of the change, identification of the affected documents, the signature of the approving individual(s), the approval date, and when the change becomes effective.

9.5 **Maintenance and Safekeeping of Product Records.** Supplier shall maintain the Product Records in accordance with this Quality Agreement and applicable QS Regulations/cGMPs as set forth in ISO 13485, 4.2 Documentation Requirements (including, without limitation, maintaining Product Records at Supplier's facilities or other reasonably accessible location, storage to minimize deterioration and prevent loss, and backing-up automated data).

9.6 **Electronic Records and Signatures.**

9.6.1 **Format and Location.** Electronic Records are records that are maintained in electronic format in place of paper format. In addition to the other provisions of this section, with respect to all Product Records that are created, modified, maintained, archived, retrieved, transmitted, or provided to FDA as Electronic Records, Supplier shall comply with all applicable FDA provisions to ensure the authenticity, integrity, and confidentiality of electronic records, and to ensure that the signer cannot readily repudiate a signed record as not genuine. Specifically, Supplier shall adopt procedures and controls including, without limitation, procedures and controls regarding validation of systems to ensure accuracy, reliability, consistent intended performance, and the ability to discern invalid or altered records; protection of records to enable their accurate and ready retrieval throughout the required retention period; limiting system access to authorized individuals and use of authority checks to ensure that only authorized individuals use the system or access Electronic Records; use of

secure, computer-generated, time-stamped audit trails to independently record the date and time of operator entries and actions that create, modify, or delete Electronic Records; and use of appropriate operational system checks and device checks to determine the validity of data input sources or operational instructions, as appropriate. Any system used by Supplier to create, modify, maintain, archive, retrieve, or transmit Product Records as Electronic Records shall be a closed system, meaning an environment in which system access is controlled by persons who are responsible for the content of electronic records that are on the system.

9.6.2 **Definition of Electronic Signature.** Electronic Signatures are a computer data compilation of any symbol or series of symbols executed, adopted, or authorized by an individual to be the legally binding equivalent of the individual's handwritten signature. With regard to any Electronic Signatures used on or with respect to Product Records, Supplier shall comply with all applicable FDA provisions including, without limitation, ensuring the uniqueness of Electronic Signatures; basing Electronic Signatures upon biometrics or use of at least two distinct identification components, such as an identification code and password, that are periodically checked or revised; following loss management procedures to electronically de-authorize lost, missing, stolen, or otherwise potentially compromised devices that bear or generate identification code or password information; initial and periodic testing of such devices; and using transaction safeguards to detect, report, and prevent unauthorized use of passwords or identification codes.

9.7 **Record Retention.** Supplier shall retain all Product Records for a period of time equivalent to the design and expected life of the Product or the Regulated Products in which the Product is intended to be included, provided, however, such period shall not be less than 5 years from date of Regulated Product release for commercial distribution. Notwithstanding the foregoing, Supplier shall not alter, destroy, or otherwise dispose of any Product Records without IdentifySensors' prior written authorization.

9.8 **Access to Product Records.** Supplier shall provide copies of any or all Product Records to IdentifySensors within two business days from the date of IdentifySensors' written request for any Product Records.

10 CHANGE CONTROL.

10.1 **Significance of Change Control.** Supplier acknowledges and agrees that changes to any process, system, or activity (including, without limitation, designs, specifications, procurement, suppliers, raw materials, manufacturing, shipping, labeling, packaging, tests, testing methods, calibration standards, standard operating procedures, equipment, software, maintenance, contamination controls, quality systems, and documents containing the procedures and specifications for the Product) relating to the Product can impact the Product Requirements. Supplier further acknowledges and agrees that certain manufacturing changes may require regulatory filings and/or regulatory approval prior to implementing any such change. Supplier shall not make any changes to process, materials, locations etc., without the written approval of IdentifySensors.

10.2 **Supplier's Change Control System.** Supplier shall establish and maintain an up-to-date change control system with written policies and procedures for identifying, addressing, documenting, and implementing changes to any specification, method, process, or procedure (from manufacturing to delivery) relating to the Product(s). Such changes shall be verified, or where appropriate validated according to ISO 13485 7.5, before implementation and these activities shall be documented. Any such changes shall be approved by appropriate personnel (including IdentifySensors' Quality Representative if regulatory filings and/or regulatory approval is required) and in accordance with the document change procedures set forth in ISO 13485, 4.2 Documentation Requirements.

10.3 **Verification and Validation.** Such changes shall be verified, or where appropriate validated according to ISO 13485 7.5 (Validation of Processes for Production and Service Provision), before implementation and these activities shall be documented. Such changes shall be approved by appropriate personnel and in accordance with the document change procedures set forth in ISO 13485 7.3 (Control of Design and Development Changes).

10.4 **Notice of Proposed Changes.**

10.4.1 **Content of Notice**. In the event that Supplier identifies or is made aware of a potential change to any process, system, or activity relating to the Product, Supplier shall promptly, and in no event later than three (3) business days after becoming aware of the potential change, notify IdentifySensors of the potential change. Changes include, but are not limited to:

(a) Product form, fit or function change;

(b) Manufacturing Process change, including Sterilization;

(c) Manufacturing Location change;

(d) Tier II or Tier III Supplier change;

(e) Labelling or Packaging Change;

(f) Raw Material Change

(g) Supplier Name Change, Change in Registration, Relocation; and/or

(h) Mold Change.

10.4.2 **Supplier Change Request Form.** If IdentifySensors verifies that the change will be evaluated or made, Supplier will initiate the change by using the IdentifySensors Supplier Change Request Form. Each SCR shall, at a minimum, set forth a narrative description of the proposed change, identification of any documents affected by the proposed change, Supplier's plan for addressing and implementing the proposed change, and when the proposed change would become effective.

10.5 **Change Approval.** Supplier may only implement SCR changes to product, process, system, or activity relating to the Product after written approval from an authorized IdentifySensors Quality Representative via the Supplier Change Notification form. Supplier is required to provide written notification of change and to complete the IdentifySensors Supplier Change Notification form prior to implementation.

10.6 **10.6 Change Management; Manufacturers or Service Providers.** In the event that Supplier is a manufacturer or service provider with respect to the Product, Supplier agrees and certifies that the Product Requirements will be approved by both Parties' Quality Representatives. No changes to the Product Requirements will be implemented without the signed authorization from IdentifySensors Quality Representative, in accordance with IdentifySensors' internal procedure for supplier change requests. IdentifySensors shall obtain any and all required product approvals or clearances by governmental authorities, including FDA, prior to change implementation. While either IdentifySensors or Supplier may submit to each other a SCR to change or revise an established production procedure neither may release affected product without written approval by the Quality Representative of the respective quality assurance departments.

11 DEVIATIONS.

11.1 **No Deviations.** Supplier will not deviate from Product Requirements (including, without limitation, approved procedures, drawings, methods, or specifications concerning the Product) except as permitted in accordance with the provisions in Section 10 (Change Control) above with IdentifySensors Quality approval.

11.2 **Investigation.** Deviations, if any, from Product Requirements shall be timely investigated, documented, and closed by Supplier in accordance with QS Regulations/cGMPs and Supplier's established change control or non-conformance procedures.

11.3 **Notice.** Supplier will promptly, within one (1) business day, notify IdentifySensors' Quality Representative in writing of any deviations that could reasonably be expected to have any impact on Product Requirements.

11.4 **IdentifySensors Access.** Supplier will provide IdentifySensors with access, including investigations and documents, to review all deviations relating to the Product. IdentifySensors will be responsible to assess product safety and effectiveness of every deviation submitted for approval.

12 SUPPLIER'S PURCHASING AND ACCEPTANCE ACTIVITIES.

12.1 **Supplier's Purchasing Controls.** Supplier shall establish and maintain written requirements and procedures to ensure that all services or product(s) purchased or otherwise received by Supplier conform to all Product Requirements.

12.2 Sub-Supplier Selection and Verification.

12.2.1 **Definition.** The term "Sub-Suppliers" means any component supplier, material supplier, service provider, consultant, contract laboratory, contractor, or other third-party vendor who provides to Supplier any product(s) or services concerning, or that could otherwise reasonably be expected to have any effect on, the Product.

12.2.2 **Sub-Supplier Qualification.** IdentifySensors shall establish and maintain written requirements, including quality requirements, for evaluating, selecting, and assessing (including, without limitation, audits and performance analyses) any Sub-Suppliers to ensure that each Sub-Supplier is qualified, including accreditation where applicable, and able to provide the product(s) or service(s) in accordance with any specified requirements, including quality requirements. IdentifySensors shall ensure that all laboratories used for conducting tests related to manufacture, packaging, testing, labeling, or storing the Product are compliant with relevant laboratory practices and are qualified in all the methodology associated with the Product. IdentifySensors may elect to perform an audit on vendors to be used for analytical testing.

12.2.3 **Sub-Suppliers Identified by IdentifySensors.** If IdentifySensors identifies a specific Sub- Supplier or otherwise requests that Supplier use a specific Sub-Supplier, then Supplier agrees to use the specific Sub-Supplier(s) identified by IdentifySensors. Supplier may identify a new Sub-Supplier and implement such change in accordance with the change control procedures in Section 10 (Change Control) above as changes may require regulatory filings or approvals. Nonconforming product identified by Supplier attributed to Sub-Suppliers is to be handled in accordance with Supplier's Quality Management System requirements via the creation of an MRB and notification to IdentifySensors.

12.3 Purchasing, Receiving and Testing of Sub-Supplier Products and Services.

12.3.1 **Materials Selection.** IdentifySensors must establish and use documented selection and verification criteria (including, without limitation, quality level/grade, dimensions, materials, performance, or other such features) to ensure that all services or product(s) that Supplier purchases or otherwise receives from a Sub-Supplier are selected to fully satisfy Product Requirements.

12.3.2 **Acceptance Procedures.** To assure that products or services received from a Sub-Supplier are properly identified, processed, and stored when received, Supplier shall establish and maintain standard operating procedures and written criteria for accepting services or products from Sub-Suppliers (including, without limitation, acceptance activities performed, dates, results, names of individuals performing acceptance activities, name of Sub-Supplier, description of component, quantity, catalog number, quarantine, batch identification and acceptance status) in accordance with QS Regulations, including without limitation.

12.3.3 **Verification Testing, Inspection. and Validation.** Supplier shall conduct appropriate testing and/or inspection to ensure that any component, product or material that Supplier receives from any Sub-Supplier will comply with the applicable Product Requirements. If testing and inspection cannot fully verify such results, then Supplier shall implement appropriate validation processes to assure that any component, product or material that Supplier receives from any Sub-Supplier will function reliably for the intended purpose and in accordance with all Product Requirements. Written records of all such testing, inspection, or validation (e.g., identity of component tested, testing methodology, test data and results) must be maintained by Supplier and made available to IdentifySensors for review upon written request. Supplier shall, at a

minimum, conduct at least a visual inspection for contamination, damage, and identification that the component, product or service supplied is as specified in the applicable purchase order.

12.3.4 **Acceptance and Rejection Records.** Supplier shall maintain written records detailing Supplier's basis for deciding that products or services it received from a Sub-Supplier were either inspected and accepted or rejected.

12.3.5 **Certificate of Conformance.** Supplier may receive product on a Certificate of Conformance from the Sub Supplier upon adequate qualification of the Sub Supplier by IdentifySensors.

13 MATERIAL USE, STORAGE, IDENTIFICATION AND TRACEABILITY.

13.1 **Storage of Materials.** Supplier shall establish and maintain procedures for control of storage areas and stock rooms for product to prevent mix-ups, damage, deterioration, contamination, or other adverse effects pending distribution. Where Supplier provides raw material, Supplier needs to manage the inventory and maintain its traceability. Supplier shall handle and store IdentifySensors products in accordance with the product specifications as labelled on the products as well as in product specification documentation (i.e. device drawings).

13.2 **Identification.** Supplier shall establish and maintain procedures for identifying product during all stages of receipt, production, and shipment to prevent mix-ups per ISO 13485, 7.5 Production and Service Provision.

13.3 **Traceability Controls.** Supplier shall establish and maintain procedures to trace any material or component that relates to or is otherwise part of the Product via a unit, lot or batch control number in accordance with cGMPs/QS Regulations, including ISO 13485, 7.5 Traceability. Supplier shall document such traceability controls in order to facilitate corrective action.

13.4 **Obsolete. Deteriorated, Expired. and Rejected Materials.** Supplier shall establish and maintain procedures to control product that does not conform to specified requirements, see section 15.4. Obsolete, deteriorated, expired, and rejected material(s) shall be specifically identified as such by Supplier and separated into a designated quarantine area to prevent any mix-ups and to prevent any inadvertent use of obsolete, deteriorated, or rejected materials in the Product in accordance with ISO 13485, 8.3 Control of non-conforming product.

13.5 **Acceptance Status.** Supplier shall identify by suitable means the acceptance status of Product, to indicate the conformance or nonconformance of Product with acceptance criteria. The identification shall be maintained throughout manufacturing, packaging, labeling, installation, and servicing of the product to ensure that only product which has passed the required acceptance activities is distributed, used, or installed.

13.6 **Materials Compliance.** Supplier shall be responsible for ensuring its operations comply with all applicable laws and regulations in which Product is subject to; provided, Supplier shall not be responsible for compliance with respect to any Sub-Supplier designated by IdentifySensors. Applicable laws and regulations may include, but not limited to:

13.6.1 **EU Restrictions of Hazardous Substances Directive.** The EU Restrictions of Hazardous Substances Directive 2011/65/EU (RoHS 2); EU Regulation No 1907/2006 concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH); the Waste Electrical and Electronic Equipment Directive 2012/19/EU (WEEE); and the Batteries Directive 2006/66/EC and its amendments; and any other environmental product stewardship directives. The Supplier shall provide evidence of compliance to the abovementioned regulations and directives to IdentifySensors.

13.6.2 **Dodd-Frank Act.** Conflict Minerals as described in Dodd-Frank Act Section 1502, July 21, 2010 where such materials are used "in the manufacture or contract to manufacture Products" where "conflict minerals are necessary to the functionality or production of the product."

13.6.3 **California Proposition 65.** California Proposition 65 (Safe Drinking Water and Toxic Enforcement Act of 1986). The Supplier shall collaborate with IdentifySensors to determine what documents/records are required to ensure this requirement is met for Products intended to be sold in the USA. This may include but is not limited to:

(a) A material declaration or test report containing the following information: If Prop 65 chemicals are present in the product, a list of the Prop 65 chemicals present in the product and an analysis which determines if exposure to the Prop 65 chemical(s) exceed(s) the applicable Safe Harbor Level;

(b) If Prop 65 chemicals are not present in the product, a statement declaring the absence of Prop 65 chemicals;

(c) Material Safety Data Sheets and or Technical Data sheets as applicable; and

(d) Any other documentation as required by IdentifySensors to make a Prop 65 determination as applicable.

14 LABELING AND PACKAGING.

14.1 Labeling.

14.1.1 Definitions. The terms "**Label**" and "**Labeling**" shall have the meanings set forth in ISO 13485.

14.1.2 **Approved Labeling.** Labelling is provided by IdentifySensors. To the extent that the Product includes Labeling, Supplier shall only use Labeling that is pre-approved and specified by IdentifySensors for the applicable use. Supplier shall be responsible to obtain such written approval. Approval of labeling shall consist of master label approval and shall not require each individual label to be approved. Master label approval shall be retained by IdentifySensors.

(a) If Product is safety marked by Supplier (i.e., Intertek, TUV, UL, CSA, etc.) Supplier shall have regular follow-up service inspections and manufacture the product in accordance with the applicable US and Canadian Product Safety Listing/Classification Report. Supplier shall have documentation to demonstrate conformance to the Product Safety listing/Classification Report.

(b) Supplier is responsible for ensuring that the Product is labeled with a unique device identifier (UDI), as applicable, and as required by IdentifySensors. Supplier/ IdentifySensors is responsible for acquiring a Global Trade Item Number (GTIN) and Data Universal Numbering System UDUNS) and publishing the same to the Global Unique Device Identification Database (GUDID).

14.1.3 **Labeling Controls.** To the extent that the Product includes Labeling, Supplier shall establish and maintain procedures to control Labeling activities including, without limitation, label integrity, label verification/validation, procurement, area inspection, storage, issuance, and labeling-related operations in accordance with cGMP and IQS Regulations, and ISO 13485 4.2 Documentation Requirements.

14.2 **Suitable Packaging.** Supplier shall examine the Product to assure that such containers and packaging: (a) are in accordance with Product Requirements; and (b) are not damaged or misbranded. Furthermore, Product shall be packed in such a way as to prevent the inadvertent mixing of multiple lots of parts.

15 TESTING, EVALUATION, AND NONCONFORMANCE ACTIVITY.

15.1 **Testing; Inspection.** Supplier shall be responsible to conduct appropriate testing and/or conformance inspection to ensure that the Product will be produced in accordance with Product Requirements.

15.2 Testing Methodology.

15.2.1 **IdentifySensors Directed Testing.** In the event that IdentifySensors designates a specific test(s) or testing methodology(ies) for the Product, then Supplier shall perform such testing at such times and in such manner as designated by IdentifySensors.

15.2.2 **Supplier Testing.** In the event that IdentifySensors does not designate a specific test or testing methodology for the Product, then Supplier shall conduct appropriate testing in accordance with accepted industry standards. If no such industry accepted test or testing methodology is available, then Supplier will provide IdentifySensors with the testing methodology or evaluation specifications that Supplier uses to ensure that the Product will function reliably for the intended purpose and in accordance with Product specifications. In either of the foregoing events, Supplier shall ensure that IdentifySensors is adequately informed of the tests and/or testing methodology(ies) to be used by Supplier and Supplier shall be responsible to obtain IdentifySensors' approval of all such tests and/or testing methods.

15.3 **Testing Records.** Written records documenting all testing and/or conformance inspection activities, including all test data and results, relating to the Product must be maintained by Supplier and made available for review by IdentifySensors promptly upon written request.

15.4 **Nonconforming Product.** In accordance with the QS Regulations, Supplier shall establish and maintain procedures to control Product that does not conform to or fulfill Product Requirements (a "**Nonconformity"** or "**Nonconformance**"). Such procedures shall address the identification, documentation, evaluation, segregation, and disposition of nonconforming Product.

15.4.1 **Evaluation of Nonconformity.** Supplier shall evaluate every Nonconformance and make a written determination, including the justification for the determination, whether an investigation is needed. Such documentation shall be made available for review by IdentifySensors promptly upon written request. Supplier shall notify IdentifySensors in writing of any Nonconformity that will be investigated, including any Nonconformity that may be identified after the Product's distribution.

15.4.2 **Investigation of Nonconformity.** Supplier shall investigate any Nonconformity that could reasonably be expected to have an adverse effect on the ability to meet IdentifySensors' specified requirements of the Product. Supplier shall quarantine any such nonconforming Product. Each investigation shall be documented, including the outcome of any data or tests respecting Product requirements. Investigation documentation shall be made available for review by IdentifySensors promptly upon written request.

15.4.3 **Nonconformity Review and Disposition.** Supplier shall establish and maintain procedures that define the responsibility for review and the authority for the disposition of nonconforming Product. The procedures shall set forth the review and disposition process. Disposition of nonconforming Product shall be documented. Documentation shall include the justification for use, if any, of nonconforming Product and the signature of the individual(s) authorizing such use; provided, however, that Supplier must obtain IdentifySensors' prior written approval before use of any "Use As Is" disposition. Any such approval will be on a lot by lot basis.

15.4.4 **Rework.** Supplier shall establish and maintain procedures for rework, to include retesting and reevaluation of the nonconforming Product after rework, to ensure that the Product meets its then-current approved specifications. Rework and reevaluation activities, including a determination of any adverse effect from the rework upon the Product, shall be documented. Supplier shall ensure product DHR's are updated upon rework with all relevant documentation as well as undergo review and release in accordance with Supplier document control procedures. Unless prior written approval is received from IdentifySensors, Supplier shall not perform or arrange for the performance of any rework activities, including repackaging or relabeling activities, related to any nonconforming Product.

16 PRODUCT RELEASE AND DISTRIBUTION.

16.1 **Product Release by Supplier.** Supplier shall establish and maintain procedures for control and distribution of finished devices to ensure that only those devices approved for release are distributed

16.1.1 Supplier Review. Before releasing or shipping the Product, Supplier shall:

(a) Review all Product Records concerning the production history of the Product, including, without limitation, confirming acceptance status records and that the Product has passed all applicable tests and inspections;

(b) Ensure that correct control numbers are identified and documented prior to Product release; and

(c) Conduct appropriate inspections to ensure that the Product is accurately identified and manufactured and/or distributed in accordance with Product Requirements. Supplier shall document all such pre-release review activities.

16.1.2 Delivery Documentation. Supplier shall provide the following information with each delivery:

(a) Consignee (Ship To:) Name and Address;

(b) Device Name and Part Number;

(c) IdentifySensors PO Number;

(d) Lot Number;

(e) Quantity Shipped;

(f) Date Shipped; and

(g) Certificate of Analysis and/or Certificate of Conformance.

16.1.3 **Certificate of Conformance.** In accordance therewith, Supplier shall include with each shipment a Certificate of Conformance ("**Certificate of Conformance**"). All attributes that require certification will be indicated on the Specifications and/or communicated upon issuance of each purchase order. All certified attributes must include the tolerance/range as indicated on the print, if applicable, and the actual value as tested, inspected or observed. All Certificates of Conformance must also include the following:

(a) Supplier Name;

(b) IdentifySensors Part Name;

(c) IdentifySensors Part# and Revision Level;

(d) IdentifySensors Purchase Order Number;

(e) Supplier Lot Number;

(f) Quantity Shipped; and

(g) Date Manufactured.

16.1.4 **Distribution.** Supplier shall ensure that shipping carton(s) and/or containers used for distribution of the Product are constructed to protect the Product from alteration or damage during all processing, storage, handling and distribution activities. Prior to shipping any Product to IdentifySensors, or to such destination as may be designated by IdentifySensors, Supplier shall examine such carton(s) and/or container(s) to assure that they:

(a) Are not damaged or misbranded;

(b) Are in accordance with Product Requirements; and

(c) Include a packing list, attached securely to the outside of the shipping carton(s) or container(s), that includes date, purchase order number, catalog number, drawing revision level, quantity shipped, lot number, material heat and/or lot number if applicable, part description, NCR number (if applicable), expiration dates for catalog number and associated lot number (if applicable), and expiration date for catalog number without a lot number (if applicable).

17 PRODUCT EVALUATION AND MARKET RELEASE.

17.1 **Final Market Release.** Unless otherwise agreed to by the Parties in writing, IdentifySensors will release the Product, or the finished device in which the Product is otherwise incorporated, to market. Supplier acknowledges and agrees that any data, documents, or information it provides concerning the Product may be used by IdentifySensors in any final market release by IdentifySensors.

18 COMPLAINT HANDLING.

18.1 **Response.** IdentifySensors is responsible for responding to the end-user complaints. Supplier will support IdentifySensors in the resolution of complaint investigation. Supplier will notify IdentifySensors if a complaint is received through the supplier so that IdentifySensors may process the complaint through its own Complaint Handling System.

18.2 **Complaints.** The term "**Complaint**" shall have such meaning as set forth in quality management system requirements of ISO 13485.

18.3 **Complaint Handling System.** Supplier shall have a established a system to receive, record, and investigate Product related complaints.

18.4 **Complaint Files.** Supplier shall have established a system to record and keep a register of product related complaints. Complaint registers and/or files shall contain all pertinent information related to the complaint including, but not limited to, documented reviews, investigations, and evaluations.

18.5 **Notice.** IdentifySensors will receive all complaints from end users. Supplier shall within two (2) business days submit to IdentifySensors a copy of any records or other documentation, which Supplier has received or created relating thereto. This section shall survive termination of this Quality Agreement.

18.6 **Complaint Investigation.** IdentifySensors is responsible for the initial assessment and, if appropriate, initial investigation of Complaints alleging an event that could be reportable to the FDA under FDA Regulated Product reporting regulations, and/or another Regulatory Agency as required. Notwithstanding the foregoing provision, Supplier will investigate Complaints if requested to do so by IdentifySensors. Supplier will provide an investigation report to IdentifySensors within the thirty (30) days-standard unless complaint investigation report is requested to be completed in ten (10) business days after IdentifySensors' request for a Supplier investigation. Supplier's investigation shall be completed and documented in accordance with cGMPs/QS Regulations.

18.7 **Device Reporting.** IdentifySensors shall be responsible for reporting to each relevant Regulatory Agency all Complaints and adverse events relating to a Product that are required to be reported under the FDA Regulated Product quality management system requirements of ISO 13485, or other applicable agency reporting regulations.

19 FIELD REMEDIATION - CORRECTIONS AND REMOVALS.

19.1 **Notice of Correction or Removal.** IdentifySensors shall notify the Supplier within one (1) business day if the Product, including any production lot, is subject to any correction and/or removal, including, but not limited to, a recall, market withdrawal or stock recovery, regardless of whether such correction and/or removal is initiated, IdentifySensors and/or any third party, including a Regulatory Agency. This section shall survive termination of this Quality Agreement.

19.2 **Cooperation.** The Parties shall cooperate to affect the timely handling and disposition of any correction and/or removal involving the Product. Such cooperation may include, but is not limited to, Supplier investigating and coordinating any such correction involving the Product and/or Supplier providing IdentifySensors with an initial response or preliminary report. Notwithstanding the foregoing, the Parties agree that IdentifySensors shall have final decision-making authority with respect to corrections and/or removals that involve the Product, including, but not limited to, filing any reports with a Regulatory Agency.

19.3 **Remediation Records.** Each Party will maintain detailed written records of all sales and shipments of the Product to ensure both effective administration of any correction and/or removal involving the Product.

19.4 **Remediation Reporting.** Each Party shall be responsible for reporting remediation actions to all applicable governmental regulatory authorities and/or agencies.

20 QUALITY AND MANUFACTURING AUDIT.

20.1 **Audit.** The term "**Audit**" means a systematic, independent, and documented examination of Supplier's: (a) Quality Management System to determine whether Supplier is in compliance with quality system procedures, that the procedures are implemented effectively, that adequate controls are in-place, that the procedures are suitable to achieving quality system objectives and Product Requirements, and that the Quality Management System is in accordance with applicable cGMPs/QS Regulations and ISO 13485 (and any amendments thereto); and (b) operations and facility(ies) for purposes of reviewing Supplier's processes and/or practices, including Product Records, relating to the manufacture of the Product(s). Upon reasonable advance written notice to Supplier, IdentifySensors shall have the right, but not the obligation, to conduct one Audit in each calendar year or more frequently (for cause)in the event of systemic performance or quality- related issues, including without limitation, upon the occurrence of any of the following triggering events: (w) Supplier's receipt of a warning letter, untitled letter, or any observations, (e.g., Form FDA-483) from any Regulatory Agency relating to the manufacture, packaging, testing or labeling of the Product; (x) IdentifySensors' rejection of the Product, including any production lot, where IdentifySensors determined that such Product failed to meet Product Requirements or the QSR/cGMPs; (y) the development of any adverse trends about the Product; and/or (z) for verification of implementation and effectiveness of any corrective action plan.

20.2 **Audit Procedure.** Supplier shall provide IdentifySensors with access to Supplier's facilities, Product Records, and/or operations to conduct the Audit during normal business hours and in a manner, as reasonably practicable under the circumstances, not to interfere with Supplier's normal and ordinary operations. IdentifySensors' representative(s) or agent(s) conducting an Audit will be qualified to conduct such audits, shall comply with Supplier's safety and security rules, and will execute a commercially reasonable confidentiality agreement respecting the information obtained during the Audit. Each Party's respective Quality Representative shall work together to coordinate and effectuate the Audit; provided, however, that Supplier shall not in any manner unreasonably delay, condition, or otherwise interfere with IdentifySensors' right to conduct the Audit.

20.3 **Access to Supplier Records.** IdentifySensors shall have the right to obtain copies of all Product Records during an Audit and Supplier also shall make the following available for IdentifySensors' review and inspection: (a) all equipment and facilities used in, or in relation to, the manufacture of the Product; (b) records and supporting documents (e.g., manufacturing, analytical, and testing documentation, nonconformance reports) with respect to each production lot of the Product; (c) any written communications between Supplier and any Regulatory Agency concerning the Product; and/or (d) any field alert, recall, market withdrawal, correction, or stock recovery of any production lot of the Product.

20.4 **Corrective and Preventive Action Plan.**

Findings. In the event that an Audit finds or identifies any condition(s) that are not in compliance with this Quality Agreement, Product Requirements, or cGMPs/QS Regulations (hereinafter a "**Finding**"), then: (a) Supplier may be placed on a no future business or restricted procurement status with IdentifySensors; and (b) Supplier shall be responsible to

20.4.1 provide IdentifySensors with a written corrective action plan within 30 days-standard after the receipt of the Audit report. The corrective action plan shall, at a minimum, set forth a narrative description detailing Supplier's steps for addressing each Finding and implementing proposed containment, corrective and as applicable-preventive actions, and when such corrective and preventive actions would be implemented.

Failure to Comply. In the event that Supplier fails to provide an acceptable corrective and preventive action plan to

20.4.2 IdentifySensors within the requisite thirty (30) days-standard after the receipt of the Audit report, then Supplier shall remain on no future business or restricted procurement with IdentifySensors.

21 REGULATORY CONTROLS.

21.1 **Regulatory Agency.** The term "**Regulatory Agency**" means any local, state, regional, U.S. federal, or non-U.S., governmental or regulatory agency, Registrar, Notified Body or relevant competent authority including, without limitation, the FDA.

21.2 **Supplier Registration.** Supplier shall maintain, and keep readily available, all documentation and forms relating to any registrations and/or licenses with Regulatory Agencies.

21.3 **Notice of Inspection Related to Product.** Supplier will, within two (2) business days, notify IdentifySensors of Supplier's receipt of notice of, or the occurrence of, any inspection of Supplier by a Regulatory Agency that involves or otherwise impacts the Product. Supplier will permit a representative from IdentifySensors to be present at any such inspection by a Regulatory Agency to the extent that such inspection relates to the Product or IdentifySensors.

21.4 Regulatory Communications.

Notice. Supplier will notify IdentifySensors within two (2) business days of Supplier's receipt of any warning letter,

21.4.1 untitled letter, or any observations from a Regulatory Agency (e.g., Form FDA-483) that identify or impact the Product and/or IdentifySensors.

Access to Records. Supplier will provide copies to IdentifySensors of all written communications between Supplier and any Regulatory Agency that specifically relate to the Product or the packaging, testing, processing, storage, or distribution

21.4.2 of the Product. Such communications will be provided to IdentifySensors within two (2) business days of receipt or issuance by Supplier. If necessary to protect confidentiality, Supplier may redact or black-out information (e.g., names or other identifiers) that does not bear on the substantive content of the communication that relates to the Product or IdentifySensors.

21.5 **Cooperation.** To the extent that any inspection or action by a Regulatory Agency directly affects the Product and/or IdentifySensors and to the extent permitted by applicable law, Supplier agrees to cooperate and confer with IdentifySensors prior to Supplier submitting any response to a Regulatory Agency. To the extent permitted by applicable law Supplier further agrees to obtain IdentifySensors' consent, which will not be unreasonably withheld or delayed, before Supplier makes any commitment to a Regulatory Agency that would affect the Product and/or IdentifySensors.

EXHIBIT D

Dedicated Equipment

- Nordson Vantage Dispenser System
- Check4 Cartridge Post Assembly Test Fixture
- Reader Functional Test Fixture (FTF)
- Check4 PCBA ICT Test Fixture

- Vacuum Sealer with Nitrogen Purge
- Hot Bar Tool
- Heat Staking Tool
- Label Printers

The Parties may add additional items to this list of Dedicated Equipment by mutual agreement from time to time.

Exhibit 11.1

Consent of Independent Registered Public Accounting Firm

To the Board of Directors of IdentifySensors Biologics Corp.

We hereby consent to the inclusion in the forgoing annual report of IdentifySensors Biologics Corp. (the "Company") on the Form 1-K of our report dated November 3, 2023 relating to our audit of the balance sheet as of June 30, 2023, and statements of operations, changes in stockholders' equity (deficit) and cash flows for the year then ended. Our report dated November 3, 2023, related to these financial statements, included an emphasis paragraph regarding an uncertainty as to the Company's ability to continue as a going concern.

/s/ Meaden & Moore, Ltd.

Certified Public Accountants

November 3, 2023