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

FORM 10-K

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the Fiscal Year ended December 31, 2022

OR

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

Commission file number: 000-56257

ACCUSTEM SCIENCES, INC.
(Exact Name of Registrant as Specified in Its Charter)

Delaware	**87-3774438**
(State of other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
5 Penn Plaza, 19th Floor, #1954 New York, NY	**10001**
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: 00 44 2074952379

Securities registered pursuant to Section 12(b) of the Act: None

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

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock	ACUT	OTCQB Venture Marketplace ("OTCQB")

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

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

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

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

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

Large accelerated filer ☐
Non-accelerated filer ☒

Accelerated filer ☐
Smaller reporting company ☒
Emerging growth company ☒

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

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

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

The aggregate market value of the Company's common stock held by non-affiliates of the registrant was $3,098,285, computed by reference to the closing sale price of the common stock on the OTCQB Venture Marketplace on June 30, 2022, the last business day of the registrant's most recently completed second fiscal quarter.

As of February 15, 2023, there were 11,346,535 shares of Common Stock, $0.001 par value outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Proxy Statement for the registrant's 2023 Annual Meeting of Stockholders, or the Proxy Statement, which the Registrant intends to file pursuant to Regulation 14A with the Securities and Exchange Commission not later than 120 days after the Registrant's fiscal year end of December 31, 2022, are incorporated by reference into Part III of this Annual Report on Form 10-K.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS AND OTHER INFORMATION CONTAINED IN THIS REPORT

This Annual Report on Form 10-K (this "Annual Report") contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, that are intended to be covered by the "safe harbor" created by those sections. Forward-looking statements, which are based on certain assumptions and describe our future plans, strategies and expectations, can generally be identified by the use of forward-looking terms such as "believe," "expect," "may," "will," "should," "would," "could," "seek," "intend," "plan," "goal," "project," "estimate," "anticipate," "strategy," "future," "likely" or the negative thereof or other variations thereon or other comparable terminology. All statements other than statements of historical facts included in this Annual Report regarding our strategies, prospects, financial condition, operations, costs, plans and objectives are forward-looking statements. Examples of forward-looking statements include, but are not limited to, statements we make regarding: expectations for revenues, cash flows and financial performance and the anticipated results of our ongoing development and business strategies.

Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based only on our current beliefs, expectations and assumptions regarding the future of our business, future plans and strategies, projections, anticipated events and trends, the economy and other future conditions. Because forward-looking statements relate to the future, they are subject to inherent uncertainties, risks and changes in circumstances that are difficult to predict and many of which are outside of our control. Our actual results and financial condition may differ materially from those indicated in the forward-looking statements. Therefore, you should not rely on any of these forward-looking statements. Important factors that could cause our actual results and financial condition to differ materially from those indicated in the forward-looking statements include, but are not limited to, the following:

- the success, cost and timing of our clinical development of our products, including the progress of, and results from, our preclinical and
- clinical trials of StemPrintER products, our discovery programs and other potential product candidates;
- our ability to obtain and maintain regulatory approval of our product candidates, and any related restrictions, limitations or warnings in the label of any of our product candidates, if approved;
- our ability to compete with companies currently marketing or engaged in the development of treatments for indications that our product candidates are designed to target;
- our plans to pursue research and development of other future product candidates;
- the potential advantages of our product candidates and those being developed;
- the rate and degree of market acceptance and clinical utility of our product candidates;
- the success of our collaborations and partnerships with third parties;
- our estimates regarding the potential market opportunity for our product candidates;
- our sales, marketing and distribution capabilities and strategy;
- our ability to establish and maintain arrangements for manufacture of our product candidates;
- our intellectual property position;
- our expectations related to the use of capital;
- the effect of the COVID-19 pandemic, including mitigation efforts and economic effects, on any of the foregoing or other aspects of our business operations, including but not limited to our preclinical studies and future clinical trials;
- our estimates regarding expenses, future revenues, capital requirements and needs for additional financing;
- the impact of government laws and regulations; and
- our competitive position.

The forward-looking statements are based upon management's beliefs and assumptions and are made as of the date of this report. We undertake no obligation to publicly update or revise any forward-looking statements included in this report. You should not place undue reliance on these forward-looking statements.

This report also contains or may contain estimates, projections and other information concerning our industry and our business, including data regarding the estimated size of our markets and their projected growth rates. Information that is based on estimates, forecasts, projections or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances reflected in this information. Unless otherwise expressly stated, we obtained these industry, business, market and other data from reports, studies and similar data prepared by third parties, industry and general publications, government data and similar sources. In some cases, we do not expressly refer to the sources from which these data are derived.

Unless otherwise stated or the context otherwise requires, the terms "AccuStem" "we," "us," "our" and the "Company" refer collectively to AccuStem and, where appropriate, its subsidiaries.

Summary of Risk Factors

Our business is subject to numerous risks and uncertainties, including those highlighted in this section below, that represent challenges that we face in connection with the successful implementation of our strategy. The occurrence of one or more of the events or circumstances described in more detail in the risk factors below, alone or in combination with other events or circumstances, may have an adverse effect on our business, cash flows, financial condition and results of operations. Such risks include, but are not limited to:

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

- We need substantial additional funding to complete the development of our product candidates, which may not be available on acceptable terms, if at all. Failure to obtain this necessary capital when needed may force us to delay, limit or terminate certain of our product development, research operations or future commercialization efforts, if any.
- Our recurring losses from operations raise substantial doubt about our ability to continue as a going concern. There is no assurance that we will be successful in executing upon our operating plan and be able to maintain an adequate level of liquidity, which would result in not being able to continue as a going concern.
- Our rights to develop and commercialize our product candidates are subject to the terms and conditions of licenses granted to us by others. If we fail to comply with our obligations under our existing and any future intellectual property licenses with third parties, we could lose license rights that are important to our business.
- If we are unable to obtain and maintain patent protection for our product candidates and technology, or if the scope of our patent protection is not sufficiently broad, our competitors could develop and commercialize similar products and technology.
- We do not have collaborations in place with institutions for utility studies and there is no guarantee that we will be able to demonstrate prospective clinical utility of the StemPrintER.
- We are dependent on third parties who provide certain resources and services to us, as we have limited resources.
- We operate in a competitive market and will face competition from competitors involved in multi-gene prognostic assay for the prediction of risk of recurrence in luminal (ER+/HER2-) breast cancer patients.
- We are reliant upon the expertise and continued service of a small number of key individuals of our management, Board of Directors and scientific advisors.
- Even if we are successful in completing all pre-clinical studies and clinical trials, we may not be successful in commercializing one or more of our product candidates.
- We will need to expand our organization and may experience difficulties in managing this growth, which could disrupt our operations.
- Our employees, independent contractors, consultants, commercial partners, collaborators and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

Item 1. Business

Company Overview

We are a clinical stage diagnostics company dedicated to improving quality of life and outcomes for the more than 18 million people worldwide who are diagnosed with cancer each year. Our plan is to develop and commercialize a suite of novel genomic tests that support decision making along the entire continuum of oncology care. Our focus will be the commercialization of our proprietary genomic test, StemPrintER, for patients with early stage breast cancer, and we estimate this market opportunity represents more than $1.3 billion in annual revenue.

Our primary product candidate is StemPrintER, a 20-gene prognostic assay intended to predict the risk of distant recurrence (“DR”) in luminal (ER+/HER2-negative) breast cancer patients. The assay was developed to measure the “stemness” of tumors, or how much a tumor behaves like stem cells which could indicate how likely a cancer is to recur or be resistant to standard treatments, ultimately impacting how patients are managed by their multi-disciplinary care team. StemPrintER has been validated in several clinical cohorts and studies, the largest of which are a consecutive series of approximately 2,400 patients from the European Institute of Oncology (“IEO”) and approximately 800 patients from the TransATAC study. In the IEO cohort, StemPrintER High Risk patients (“SPRS High”) were 1.85 times more likely to have a distant recurrence compared to Low Risk (“SPRS Low”) patients (Figure 1) and in the TransATAC cohort, SPRS High patients were 4.27 times more likely to experience a distant recurrence compared to SPRS Low Risk patients (Figure 2). Together, these data confirm that StemPrintER is highly prognostic for outcomes in patients with breast cancer and indicate the potential utility of the test in the oncology clinic.

Beyond our initial plans for StemPrintER, we believe there is significant opportunity to expand our product portfolio. First, given the broad applicability of tumor “stemness”, which has been evaluated in a multitude of different cancers, we believe the StemPrint platform will have meaningful clinical utility beyond breast cancer. As such, we will seek to validate and commercialize StemPrint for a variety of different tumor types. In addition, we plan to offer ancillary commodity testing (e.g., hereditary genetic testing, somatic mutation testing) that augments our proprietary assays and provides additional information and value to patients and physicians throughout the patient care continuum.

We hold licensing rights for the MSC test, which is designed to help determine whether lung nodules identified by LDCT screening are benign or malignant.

Company History and Acquisition

AccuStem Sciences Limited was created in connection with its demerger (spin-off) from Tiziana Life Sciences plc ("Tiziana") and AccuStem Sciences Limited ("Old AccuStem") was incorporated in England and Wales on June 5, 2020 as a private company. The demerger was conditional upon, among other things, court approval of a Tiziana capital reduction, which was approved by special resolution of Tiziana's stockholders on October 2, 2020. The court sanctioned the related Tiziana capital reduction on October 27, 2020, and the demerger became effective on October 30, 2020.

The demerger agreement provided for the transfer by Tiziana to us of the entire issued share capital of StemPrintER Sciences, the Tiziana entity to which Tiziana contributed all of the assets and intellectual property relating to the StemPrint project and $1,353,373 (£1,000,000) in cash.

For the purposes of the demerger, Tiziana first transferred the assets relating to the StemPrint project (primarily the benefit of the License from IEO/University of Milan and an outsourced research program) to a separate company, StemPrintER Sciences, together with $1,353,373 (£1,000,000) in cash. As a result of this step, StemPrintER Sciences became an operating entity. In the next step, Tiziana transferred StemPrintER Sciences' shares to us in return for shares to Tiziana's stockholders, on a one for one basis, and Tiziana declared a dividend in specie to its stockholders of those shares.

Tiziana has and will continue to provide certain limited management and administrative services to us following the completion of the demerger pursuant to the terms of the shared services agreement entered into with us on January 1, 2021. Pursuant to the terms of the shared services agreement, Tiziana agreed to provide various administrative, financial, legal, tax, insurance, facility, information technology and other services to us at a price based on a mutually agreed to cost allocation. The shared services agreement had an initial term through December 2021 and has been renewed automatically thereafter for successive three month terms. The parties may mutually terminate the shared services agreement at any time. In addition, we can terminate the shared services agreement upon 30 days prior written notice. Both parties may terminate the agreement upon the failure of the other party to perform its respective material obligations.

On December 1, 2021 AccuStem Sciences Inc., a Delaware corporation ("New AccuStem"), became the successor issuer to Old AccuStem, pursuant to Rule 12g-3(a) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Such succession occurred following the effectiveness, on December 1, 2021 (the "Effective Time"), of a United Kingdom court-approved scheme of arrangement (the "Scheme of Arrangement") in which (i) every 20 ordinary shares, £0.01 par value per share, of Old AccuStem (the "Old AccuStem Ordinary Shares") were exchanged for one share of common stock, $0.001 par value per share, of New AccuStem (the "New AccuStem Common Stock") and (ii) every 10 ADS representing two Old AccuStem Ordinary Shares were exchanged for one New AccuStem Common Stock, which resulted in New AccuStem becoming the holding company of Old AccuStem. On December 30, 2021, we completed the dissolution of Old AccuStem.

Emerging Growth Company Status

We qualify as an "emerging growth company" as defined in the U.S. Jumpstart Our Business Startups Act of 2012. An emerging growth company may take advantage of specified reduced reporting and other requirements that are otherwise applicable generally to public companies. This includes an exemption from the auditor attestation requirement in the assessment of our internal control over financial reporting pursuant to the Sarbanes-Oxley Act. We may take advantage of this exemption for up to five years or such earlier time that we are no longer an emerging growth company. We will cease to be an emerging growth company if we have more than $1.07 billion in total annual gross revenue, have more than $700.0 million in market value of our common stock held by non-affiliates or issue more than $1.0 billion of non-convertible debt over a three-year period. We may choose to take advantage of some but not all of these provisions that allow for reduced reporting and other requirements.

StemPrintER and Market Opportunity in Breast Cancer

Each year, more than two million women are diagnosed with breast cancer worldwide. Endocrine receptor positive (ER+) breast cancers constitute the majority of breast cancer cases (~75%) and display remarkable variability in clinical behavior. This heterogeneity makes prognosis and therapy response often challenging to predict using the standard clinicopathological features of the tumor. Although the overall prognosis for this group of patients is good, a significant proportion (~20%) of these patients will experience distant recurrence in the first ten years post-surgery. For ER+ patients who also have a negative HER2 status (HER2-), the standard of care is endocrine therapy with the addition of adjuvant chemotherapy in those patients considered to be at risk of recurrence according to clinicopathological parameters. However, it has become apparent that these parameters are often insufficient to predict risk of recurrence in ER+/HER2- breast cancer patients, and, as a consequence, a significant proportion of these patients are either over- or under-treated. We anticipate StemPrintER will be used in conjunction with clinical evaluation to identify a patient's risk of recurrence to help physicians optimize treatment planning throughout the care continuum.

We believe StemPrintER has a novel biological basis in the stem cell biology and interrogates the intrinsic content and aggressiveness of cancer stem cells of the primary tumor. The assay uses a reliable real-time quantitative reverse transcription polymerase chain reaction (qRT-PCR), formalin-fixed, paraffin-embedded (FFPE) platform for testing. StemPrintER was developed and clinically validated in a retrospective analysis using a consecutive series of approximately 2,400 patients with breast cancer from the IEO. Subsequently, StemPrintER was independently validated using a cohort of approximately 800 ER+/HER2- postmenopausal patients from the prospective, randomized TransATAC trial.

Our plan is to commercialize StemPrintER across all clinical subtypes of early stage breast cancer representing an estimated population of 798,000 patients, and translating to a serviceable market opportunity of more than $1.3 billion.

StemPrintER Scientific Background

The development and validation of multi-gene assays that interrogate the underlying biology of tumors for accurate prognostication of individual cancer patients has represented an expanding area of research for more than a decade. The theory that all tumors arise from cancer stem cells, and the increasing recognition of their relevance to tumor heterogeneity and disease course suggests that the knowledge of the "degree of stemness" of a breast cancer, or how much a tumor behaves like stem cells, might substantially advance individualized patient management. Research has shown that a "high stemness" signature in cancer is a primary rationale for disease recurrence given cancer stem cells are highly adaptable and able to grow indefinitely. StemPrintER was developed to be a novel genomic predictor of patient outcomes based on a cluster of 20 stem cell genes whose expression levels would be capable of stratifying patients into two distinct groups: those at very low risk of cancer recurrence and those at an increased risk of their cancer returning. This information is intended to inform treatment planning at various timepoints throughout the patient care continuum.

Our initial research focused on genes that could discriminate mammary stem cells from progeny cells in normal breast tissue. Only those genes that were expressed at higher levels in mammary stem cells versus progeny were selected. Selection criteria were based on the premise that cancer stem cells might display traits reminiscent of those present in normal mammary stem cells and, since cancer stem cells are rare, the selection of overexpressed genes (mammary stem cells versus progeny) afforded a higher likelihood of scoring differences, with respect to under-expressed genes.

Based on existing published research, several of the 20 stem cell genes display evident connection to metastatic dissemination through their role in matrix degradation, migration, invasion and engraftment (e.g., MMP1, SNF, MIEN1, PHLDA2, EPB41L5). For other genes in the signature (RACGAP1, H2AFZ, H2AFJ, APOBEC3B, CENPW, TOP2A CDK1) it was considered possible, or even probable, that they were significant in the establishment of cancer stem cell phenotypes and might be linked to involvement in genomic instability. A final set of genes, whose putative role in metastasis is less obvious, includes those involved in: (a) metabolism reprogramming and mitochondrial physiology (MRPS23, NDUFB10, Phb); (b) mRNA ribonucleoparticle biogenesis, mRNA transcription, splicing and export, and RNA processing and degradation events (ALYREF, EXOSC4); and (c) survival/escape from apoptosis, which is connected to resistance to hormonal and/or chemotherapy through hijacking of signaling pathways, such as TGF-beta and pi3k-AKT-mTOR (NOL3, LY6E, EIF4EBP1). Evidence for a mechanistic link between the 20 genes and the cancer stem cell phenotype comes from the observation that these genes are frequently overexpressed in breast cancer, sometimes as a consequence of gene amplification.

StemPrintER Clinical Research History

Through a validation study analyzing a large prospective, randomized cohort of breast cancer patients with high-quality follow-up, and a series of retrospective studies based on the use of fresh tumor samples and gene expression profiles from additional breast cancer patients, it has been established that StemPrintER predicts the individual likelihood of developing distant metastases in luminal (ER+/HER2-) and triple negative breast cancers. Of note, our genomic predictor comprises a set of genes that do not belong (with one exception) to any other genomic tool or molecular classifier described for triple negative or luminal breast cancers. We accordingly believe that the result of our research is the development of a unique tool capable of probing into the “degree of stemness”, and hence into the clinical outcome, of breast cancers.

The largest validation study for StemPrintER involved the retrospective analysis of nearly 2,400 breast tumor samples collected through the IEO clinical network. In this published study, StemPrint and StemPrintER were highly prognostic for early and late recurrences in luminal (ER+/HER2-) and triple negative (ER-/PR-/HER2-) breast cancer patients, independent of standard clinical characteristics.

In the TransATAC cohort of ER+/HER2- post-menopausal breast cancer patients, a team of scientists from the IEO conducted an independent validation of StemPrintER using banked study samples in collaboration with the Royal Marsden Hospital and Queen Mary University in London. The likelihood ratio x2 (LRx2) and Kaplan-Meier survival analyses were used to assess prognostic information provided by StemPrintER and OncotypeDX. Comparative analyses were made for DR risk over the entire 10-year follow-up period, as well as in the early (0-5 years) or late (5-10 years) interval. Our study results showed that StemPrintER was highly prognostic for recurrence risk (Hazard Ration (High Risk vs. Low Risk)= 4.27 (95% CI: 2.67-6.84), $p<0.0001$). Additionally, StemPrintER outperformed Oncotype DX RS in 10-year DR risk prediction in all patients, as well as in N0 and N1-3 patients.

Commercialization of the StemPrint Platform and StemPrintER

From a clinical standpoint, although future studies are warranted to increase the level of clinical evidence of the reliability and applicability of the 20-gene test, the recent independent validation using the TransATAC cohort demonstrates the immediate relevance of StemPrintER for the clinical management of breast cancer patients, in particular for those with ER+/HER2- disease. These luminal patients represent the majority (~75%) of newly-diagnosed cases and display high molecular heterogeneity and variability in their clinical behavior. Accordingly, ER+/HER2- breast cancer patients can greatly benefit from accurate stratification of their risk of recurrence for the development of an optimal treatment plan.

Historically in breast cancer, multi-gene assays have been used to inform the role of systemic therapy following surgery. While we believe that StemPrintER may have the same ability, especially in identifying patients with excellent long-term prognosis who would not derive significant benefit from adjuvant chemotherapy, we plan to focus on answering alternative clinical questions not addressed by current commercially-available products. We will devote our resources to obtaining established cohorts of patients and running prospective clinical trials that may demonstrate a broader utility for StemPrintER.

In order to commercialize a proprietary genomic classifier, it must meet two important benchmarks- the test must have sufficient data to be used in the clinical management of patients and have enough peer reviewed publications to obtain reimbursement from CMS and other payers. As of February 2022, with our second validation publication in the European Journal of Cancer, we believe StemPrintER has met the minimum threshold to enable commercialization. Thus, we plan to launch StemPrintER once we have achieved several key milestones. First we will identify or build a laboratory ("commercial laboratory") that will be responsible for processing, testing and reporting StemPrintER results for all commercial samples. Further, we plan to transfer StemPrintER from the laboratories in which they were developed to the commercial laboratory. Finally, once testing is established in the commercial laboratory, we will seek to obtain U.S. Clinical Laboratory Improvement Amendments of 1988 ("CLIA") certification so that we are able to report results for clinical use and to seek reimbursement from the Centers for Medicare and Medicaid Services. We anticipate that it will take at least 18 months to complete these milestones. Once those tasks are complete, we plan to initially launch StemPrintER in the US and then expand to other markets as we evaluate clinical need and revenue opportunity. See " - IEO/University of Milan License Agreement" for information regarding the License which could impact our ability to implement our plans.

To augment the value proposition of StemPrintER, we also plan to offer additional "commodity" testing (e.g., IHC receptor testing, hereditary genetic testing). These additional tests should create significant value for our customers while leveraging existing laboratory equipment and processes for economy of scale and providing additional revenue opportunities to the Company.

Given the broad applicability of tumor "stemness", which has been evaluated in a multitude of different cancers, we believe the StemPrint platform will have meaningful clinical utility beyond breast cancer. As such, we will seek to validate and commercialize StemPrint in a variety of different tumor types. Each tumor type, where applicable, would also include ancillary testing to boost our value proposition to customers.

Reimbursement Strategy

Our revenue is expected to be derived from different sources including standard private third-party and government medical insurance coverage and reimbursement models. Prior to full commercial scaling, we expect to focus our sales efforts on a small number of early adopting sites to establish ordering history with payers, effective logistics and additional clinical utility, subject to successful validation trials and approvals under the CLIA certification or upon the obtaining of a CE mark for the test, which serves as proof of conformity with European health, safety and environmental production standards.

Competition

Genetic and genomic testing play an important and continually evolving role in the oncology space. In breast cancer, there are several companies that offer genomic testing that might be competitive with StemPrintER.

Breast Cancer

Breast Cancer Index (Hologic) is an assay that is designed to predict the likelihood of late breast cancer recurrence and determine the need for extended endocrine therapy (an additional five years of endocrine therapy beyond the standard five years). The test is for pre- and post-menopausal patients with ER+/HER2- disease and up to three positive lymph nodes.

EndoPredict (Myriad) is a CE-marked assay that is designed to predict the likelihood of metastases developing within ten years of an initial breast cancer diagnosis. The test is for pre- and post-menopausal patients with early stage ER+/HER2- breast cancer and up to three positive lymph nodes.

MammaPrint (Agendia) is an FDA-cleared, CE-marked assay that is designed to assess the risk of distant recurrence within 5 years and whether a person would benefit from chemotherapy. The test is for pre- and post-menopausal patients with stage 1 or 2 breast cancer, with a tumor size of 5 centimeters or less, and LN-negative or LN-positive disease (up to three positive nodes). The test can be used irrespective of ER and HER2 status.

OncotypeDX is a CE-marked assay that is designed to assess the risk of distant metastasis and to predict the need for chemotherapy in patients with ER+/HER2- breast cancer. The test can be used in pre- and post-menopausal patients with up to three positive lymph nodes.

Prosigna (Veracyte) is a CE-marked assay designed to provide information on breast cancer subtype and to predict distant recurrence-free survival at ten years. The test is for postmenopausal patients with early-stage ER+/HER2- breast cancer that is LN-negative or LN-positive (up to 3 positive nodes).

Pan Cancer

The "commodity" testing that we plan to offer (e.g., IHC receptor testing, somatic mutation testing, hereditary genetic testing) has numerous competitors in industry (e.g., Ambry, Color Health, Foundation Medicine, Guardant, Invitae, Laboratory Corporation of America, Natera, Neogenomics, Quest Diagnostics, Tempus) and academic and hospital settings.

Government Regulation

U.S. health regulatory overview

The following provides an overview of key aspects of laboratory service and medical device regulation within the U.S. It should be noted this overview does not address every facet of regulation at the federal and state level, but only those that would generally be most relevant to the activities described in this registration statement.

Federal and state clinical laboratory licensing requirements

The CLIA governs the operations of all clinical laboratories operating in or returning results to individuals in the U.S. CLIA is administered by The Centers for Medicare & Medicaid Services ('CMS'), in partnership with state health departments. A clinical laboratory is defined as a laboratory that performs testing on specimens derived from humans for the purpose of providing information for the diagnosis, prevention or treatment of disease, or the assessment of health. Clinical laboratories must hold a certificate applicable to the type of laboratory examinations they perform and must demonstrate compliance with regulations addressing, among other things, personnel qualification and training, record keeping, quality control, and proficiency testing, all of which are intended to ensure the timeliness, reliability, and accuracy of clinical laboratory testing services. CLIA requires that laboratories demonstrate or verify the analytical validity of all tests they perform. Where a clinical laboratory analyses specimens based on a proprietary test method (i.e., a laboratory developed test, 'LDT'), the laboratory must, among other things, document the accuracy, precision, specificity, sensitivity of, and establish a reference range for, such test.

CMS provides for exemption from CLIA for states that develop clinical laboratory standards that are at least as stringent as federal requirements. Both New York and Washington State are exempt from CLIA. The NYS Clinical Laboratory Evaluation Program requires all independent clinical laboratories operating in, or testing specimens from, NYS to obtain a laboratory permit prior to commencing operations, and all clinical laboratories performing LDTs to submit test validation documentation demonstrating the tests' analytical and clinical validity.

Failure to comply with CLIA certification and state clinical laboratory licensure requirements may result in a range of enforcement actions, including certificate or license suspension, limitation, or revocation, directed plan of action, onsite monitoring, civil monetary penalties, criminal sanctions, and revocation of the laboratory's approval to receive Medicare and Medicaid payment for its services, as well as significant adverse publicity.

Food and Drug Administration

The FDA regulates, among other medical products, "medical devices" which include certain articles intended for use in the diagnosis, prevention, cure, mitigation, or treatment of disease or intended to effect the structure or function of the body. Whether a product is intended for use as a medical device is generally determined, in the first instance, based on the manufacturer's product labelling, which includes the label affixed to the product, materials distributed with the product, and promotional communications concerning the product.

Devices classified as Class I (low risk), generally may be marketed without FDA pre-market review, but are subject to "general controls", including establishment registration, device listing, record keeping, medical device reporting, and quality system regulations, including design controls. Devices classified as Class II (moderate risk), may, in addition to general controls, also be subject to "special controls" (e.g., performance standards / manufacturing standards, post-market surveillance, patient registries, special labelling requirements, pre-market data requirements and guidelines), and also generally must obtain 510(k) premarket clearance or DeNovo authorization from FDA. Class III (high risk) devices must, in addition to general controls, obtain FDA pre-market approval through the submission of a pre- market approval application that contains evidence, including data from adequate and well- controlled clinical studies, demonstrating that the device is safe and effective for its intended use. In general, devices that require FDA pre-market clearance or DeNovo authorization may not be commercially distributed or promoted prior to obtaining such authorization, although they may be distributed and used for the purpose of developing the clinical data necessary to support FDA marketing applications, subject to certain limitations. Post-market changes to a cleared / authorized or approved device also may be subject to prior review by FDA, depending on the scope of the change and its potential impact on device safety and effectiveness.

It should also be emphasized that this pre-market review process is only one facet of FDA's regulation. For example, FDA regulates product labelling, including promotional claims; the manufacturing of medical devices, including their design, under FDA quality system requirements; clinical trials with new or modified products; and post-market monitoring for, reporting of, and action related to, safety concerns. Failure to comply with applicable pre and post-market device requirements can result in a determination by FDA that a device is "adulterated" (Section 501) or "misbranded" (Section 502) in violation of the U.S. Federal Food, Drug, and Cosmetics Act. The statute provides for a number of penalties, including seizure, injunction, criminal, and civil monetary penalties, for the sale or distribution of adulterated or misbranded devices. In general, prior to undertaking enforcement action, FDA will notify a regulated entity of a violation or suspected 36 violation through a communication, such as a "Warning Letter" or "Untitled Letter". If FDA identifies violations during inspection of a manufacturer's facility, the agency will issue a Form 483 listing the identified violation and directing the manufacturer to make the necessary corrections.

FDA regulation of software

Commercially distributed software applications that meet the definition of a medical device may be subject to FDA pre-market authorization, depending on their classification and software function. These include both applications that are components of a hardware medical device and certain "standalone" software. In 2017, FDA issued final guidance adopting international principles established by the International Medical Device Regulators Forum for the clinical evaluation of software as a medical device ("SaMD"), which refers to software that is intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device. In 2019, FDA issued a guidance that provides guidance on FDA's oversight of device software functions including mobile medical apps that meet the definition of a device. While the guidance is not binding on either FDA or regulated industry, FDA intends to consider the principles in developing regulatory approaches for SaMD as well as for digital health technologies.

FDA regulation of LDTs

FDA regulates a category of medical devices, called in vitro diagnostic medical devices, or IVDs, that are used in the collection, preparation, and examination of specimens from the human body. IVDs include reagents, instruments, and systems that are intended for use in diagnosis of disease or other conditions, including the state of health, in order to cure, mitigate, treat, or prevention disease or its sequelae. FDA historically has taken the position that tests developed in-house by a clinical laboratory and used to analyze patient specimens meet the definition of an IVD and fall within the agency's regulatory jurisdiction. At the same time, FDA historically has for the most part exercised "enforcement discretion," i.e., has not required clinical laboratories performing LDTs to comply with IVD device requirements. In the past, FDA has signaled intent to modify its enforcement discretion policy with regard to LDT regulation, and in 2014 proposed a regulatory framework for LDTs, which it abandoned before implementation in 2016. The U.S. Department of Health and Human Services (HHS) has determined that LDTs do not require a premarket review with FDA, but rather an applicant may voluntarily submit a premarket notification or premarket approval (or an Emergency Use Authorization in the case of COVID-19 tests) for their LDT. It is possible that Congress will enact legislation directing FDA to regulate LDTs.

On June 24, 2021, the U.S. Congress continued its effort to establish a new, risk-based framework for the review and approval of LDTs that would accelerate innovation and improve the quality of testing, reintroduced a revised version of the Verifying Accurate Leading-edge IVCT Development (VALID) Act. In its initial construction, the VALID Act may have a significant impact on clinical laboratories as they will need to comply with several new requirements, including:

- Registration and listing with FDA;
- Quality requirements;
- Investigational studies;
- Premarket review and approval or clearance;
- Adverse event reporting; and
- Corrections and removals.

While the VALID Act outlines a framework for these elements (among others), the law, if enacted, would direct FDA over the following years to promulgate regulations and issue guidance documents, giving clinical laboratories and others the opportunity to participate in shaping the new IVCT regulatory program.

The U.S. Federal Trade Commission and Consumer Protection Laws

Within the U.S., the U.S. Federal Trade Commission ("FTC"), has authority to regulate advertising for most medical devices and for laboratory services. In addition, various state consumer protection laws exist which can similarly regulate claims that are being made by entities with respect to what benefits their products or services can provide to consumers. In some instances, FTC or U.S. states have taken action with respect to medical products based on claims being made with respect to, e.g., their benefits to patients, seeking various penalties, such as injunctions and substantial fines. Activities have focused more, to date, on products that are sold directly to consumers, such as dietary supplements, as opposed to prescription products ordered by physicians, although the possibility exists that FTC or other consumer protection bodies could take steps to regulate claims with respect to IVDs or LDTs.

Fraud and Abuse

The significant U.S. fraud and abuse laws include the:

- Anti-Kickback Statute: the federal U.S. Anti-Kickback Statute (42 U.S. Code § 1320a–7b(b) imposes criminal penalties on persons and entities for, among other things, knowingly and willfully soliciting, offering, receiving or providing remuneration (including any kickback, bribe or rebate), directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, lease or order of a good, facility, item or service for which payment may be made under a government healthcare program such as Medicare and Medicaid.

- False Claims Act: the U.S. federal false claims and civil monetary penalties laws, including the federal civil U.S. False Claims Act (31 USC. §§ 3729 – 3733), impose criminal and civil penalties, including through civil whistleblower or qui tam actions against individuals or entities for, among other things knowingly presenting or False Claims Act: the U.S. federal false claims and civil monetary penalties laws, including the federal civil U.S. False Claims Act (31 USC. §§ 3729 – 3733), impose criminal and civil penalties, including through civil whistleblower or qui tam actions against individuals or entities for, among other things knowingly presenting or causing to be presented false or fraudulent claims for payment by a federal healthcare program or making a false statement or record material to payment of a false claim or avoiding, decreasing, or concealing an obligation to pay money to the federal government, with potential liability including mandatory treble damages, significant per-claim penalties, and administrative penalties.

Transparency requirements

The U.S. Physician Payments Sunshine Act (known as Affordable Care Act Section 6002: Transparency Reports and Reporting of Physician Ownership or Investment Interests) requires certain manufacturers of drugs, devices, biologics, and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program, with specific exceptions, to report annually to the CMS information related to payments or transfers of value made to physicians and teaching hospitals, as well as information regarding ownership and investment interests held by physicians and their immediate family members. Any failure to report or providing incomplete or misleading information may subject the Company to penalties. Analogous state laws. Analogous state fraud and abuse laws and regulations, such as U.S. state antikickback and false claims laws, can apply to sales or marketing arrangements, and claims involving healthcare items or services reimbursed by governmental or non-governmental third-party payors. These laws are generally broad and are enforced by many different U.S. federal and state agencies as well as through private actions. Some state laws require adherence to compliance guidelines promulgated by the U.S. federal government and require device and drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures.

Data privacy and security

We are subject to a number of federal, state and foreign laws and regulations that govern the collection, use, disclosure, and protection of health-related and other personal information. In the United States, such laws and regulations include health information privacy, data protection and security laws, data breach notification laws, and consumer protection laws and regulations, such as Section 5 of the Federal Trade Commission Act. For example, HIPAA imposes obligations on "covered entities," including certain healthcare providers, such as us, health plans, and healthcare clearinghouses, and their respective "business associates" that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity, as well as their covered subcontractors with respect to safeguarding the privacy, security and transmission of individually identifiable protected health information, or PHI,. Entities that are found to be in violation of HIPAA, whether as the result of a breach of unsecured PHI, a complaint about privacy practices, or an audit by HHS, may be subject to significant civil, criminal, and administrative fines and penalties and/or additional reporting and oversight obligations if required to enter into a resolution agreement and corrective action plan with HHS to settle allegations of HIPAA non-compliance.

In addition, certain state and non-U.S. laws, such as the CCPA, the CPRA, the GDPR, the UK GDPR and the UK Data Protection Act 2018, govern the privacy and security of personal information, including health-related information in certain circumstances, some of which are more stringent than HIPAA and many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

Failure to comply with these laws, where applicable, can result in claims, litigations, regulatory investigations and other proceedings, and the imposition of significant civil and/or criminal penalties and private litigation. Privacy, data protection and security laws, regulations, and other obligations are constantly evolving, may conflict with each other to complicate compliance efforts, and can result in claims, investigations, proceedings, or actions that lead to significant civil and/or criminal penalties, other liabilities, and restrictions on data use, storage, and other processing.

Health Insurance Portability and Accountability Act of 1996 ("HIPAA")

The HIPAA imposes criminal and civil liability for, among other things, failing to protect the privacy of patient and security of patient data. Additionally, the HIPAA by the Health Information Technology for Economic and Clinical Health Act and its implementing regulations, also imposes obligations on covered entities and their business associates that perform certain functions or activities that involve the use or disclosure of protected health information on their behalf, including mandatory contractual terms as well as implementing reasonable and appropriate administrative, physical and technical safeguards with respect to maintaining the privacy, security and transmission of protected health information.

Federal Trade Commission ("FTC")

The FTC has taken an active role with regard to protection of personal information, relying on its broad consumer protection powers to seek substantial penalties where companies that have made deceptive or misleading statements regarding practices of collecting and safeguarding data or did not have adequate safeguards to protect information consistent with their claims regarding data security. State laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not pre-empted by HIPAA, thus complicating compliance efforts.

Government and Third-Party Payor Reimbursement and Billing for Clinical Laboratory Services

Medicare coverage is limited to items and services that are within the scope of a Medicare benefit category that are reasonable and necessary for the diagnosis or treatment of an illness or injury.

Under Medicare, payment for our tests would be made under the Clinical Laboratory Fee Schedule, or CLFS, with payment amounts assigned to specific procedure billing codes. In April 2014, Congress passed the Protecting Access to Medicare Act, or PAMA, which included substantial changes to the way in which clinical laboratory services will be paid under Medicare. Under PAMA, laboratories that receive the majority of their Medicare revenue from payments made under the CLFS or the Medicare Physician Fee Schedule are required to report to CMS, beginning in 2017 and every three years thereafter (or annually for "advanced diagnostic laboratory tests"), private payor payment rates and volumes for their tests. Laboratories that fail to report the required payment information may be subject to substantial civil monetary penalties. As required under PAMA, CMS uses the rates and volumes reported by laboratories to develop Medicare payment rates for laboratory tests equal to the volume-weighted median of the private payor payment rates for the tests.

PAMA also authorizes the adoption of new, temporary billing codes and unique test identifiers for FDA-cleared or approved tests, as well as advanced diagnostic laboratory tests. The AMA's CPT Editorial Panel created a new section of billing codes to supplement the AMA's existing Category I CPT code set and to facilitate implementation of this section of PAMA. These proprietary laboratory analyses codes, or PLA codes, may be requested by a clinical laboratory or manufacturer to specifically identify their test. If approved, the codes are issued by the AMA on a quarterly basis. While our testing products are not presently identified by any PLA codes, we may choose to seek a specific PLA code or codes to describe some of our testing products in the future.

Billing for testing is complicated. Depending on the billing arrangement and applicable law, we must bill various payors, such as insurance companies, Medicare, Medicaid, physicians, hospitals, employer groups and patients, all of which have different billing requirements. Additionally, compliance with applicable laws and regulations as well as internal compliance policies and procedures adds further complexity to the billing process. Changes in laws and regulations could negatively impact our ability to bill our clients or increase our costs. CMS also establishes new procedures and continuously evaluates and implements changes to the coverage criteria and reimbursement process for billing government programs. There is a potential that missing or incorrect information on test requisitions will add complexity to and slow the billing process, create backlogs of unbilled tests, or generally increase the aging of accounts receivable and bad debt expense. Failure to timely and correctly bill for testing services may lead to our not being reimbursed for our services or an increase in the aging of our accounts receivable, which could adversely affect our results of operations and cash flows.

Revenue from governmental and third-party payors can be retroactively adjusted after a new examination during the claims settlement process or as a result of post-payment audits. For example, Medicare reimbursement claims made by healthcare providers and suppliers are subject to audit from time to time by governmental and third-party payors and their agents. To ensure compliance with Medicare, Medicaid and other requirements and regulations, government agencies or their agents (including Recovery Audit Contractors, Unified Program Integrity Contractors and other contractors operating under the Medicare and Medicaid programs) often conduct audits and request customer records and other documents to support claims submitted for payment of services rendered and compliance with government program claim submission requirements. Private payors conduct similar audits to ensure claims align with coverage requirements and may take legal action to recover alleged overpayments. Negative audit findings or allegations of fraud or abuse may subject us to liability, including but not limited to overpayment liability, refunds or recoupments of previously paid claims, payment suspension, or the revocation of billing or payment privileges in governmental healthcare programs or termination of arrangements with third-party payors. Failure to comply with applicable laws relating to billing federal healthcare programs could also lead to various penalties, including but not limited to:

- overpayments and recoupments of reimbursement received;
- exclusion from participation in Medicare/Medicaid programs;

- asset forfeitures;
- civil and criminal fines and penalties; and
- the loss of various licenses, certificates and authorizations necessary to operate our business.

Any of these penalties or sanctions could have a material adverse effect on our results of operations or cash flows.

Healthcare Reform

In March 2010, the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010, collectively the Affordable Care Act, or ACA, was enacted in the United States The ACA made a number of substantial changes to the way healthcare is financed by governmental and private insurers. The ACA, among other things, included provisions governing enrollment in federal and state healthcare programs, reimbursement matters and fraud and abuse, which we expect will impact our industry and our operations in ways that we cannot currently predict.

Since its enactment, there have been judicial, executive and Congressional challenges to certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA without specifically ruling on the constitutionality of the ACA. Prior to the Supreme Court's decision, President Biden issued an executive order initiating a special enrollment period from February 15, 2021 through August 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare. It is unclear how other healthcare reform measures of the Biden administration or other efforts, if any, to challenge, repeal or replace the ACA will impact the ACA or our business.

Other legislative changes have been proposed and adopted since the ACA was enacted. These changes include aggregate reductions to Medicare payments to providers of 2% per fiscal year pursuant to the Budget Control Act of 2011, which went into effect on April 1, 2013, and due to subsequent legislative amendments to the statute, will remain in effect through 2030, with the exception of a temporary suspension from May 1, 2020 through December 31, 2021, unless additional Congressional action is taken. The American Taxpayer Relief Act of 2012, among other things, further reduced Medicare payments to several providers, including hospitals and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Additional state and federal health care reform measures may also be adopted in the future, any of which could have a material adverse effect on the clinical laboratory industry.

Regulation of Medical Devices in the European Union

The European Union, or EU, has adopted specific directives and regulations regulating the design, manufacture, clinical investigations, conformity assessment, labeling and adverse event reporting for medical devices (including in vitro diagnostic medical devices).

In the EU, there is currently no premarket government review of medical devices. However, the EU requires that all in vitro diagnostic medical devices placed on the market in the EU must meet the essential requirements of the EU In Vitro Diagnostic Medical Devices Directive, or Directive 98/79/EC, or the IVDD, including the requirement that an in vitro diagnostic medical device must be designed and manufactured in such a way that it will not compromise the clinical condition or safety of patients, or the safety and health of users and others. In addition, the device must achieve the performances intended by the manufacturer and be designed, manufactured, and packaged in a suitable manner. The European Commission has adopted various standards applicable to medical devices. There are also harmonized standards relating to design and manufacture. While not mandatory, compliance with these standards is viewed as the easiest way to satisfy the essential requirements as a practical matter as it creates a rebuttable presumption that the device satisfies that essential requirement.

Compliance with the essential requirements of the IVDD is a prerequisite for European Conformity Marking, or CE-Mark, without which in vitro diagnostic medical devices cannot be marketed or sold in the EU. To demonstrate compliance with the essential requirements laid down in Annex I to the IVDD, medical device manufacturers must undergo a conformity assessment procedure, which varies according to the type of medical device and its (risk) classification. As a general rule, demonstration of conformity of in vitro diagnostic medical devices and their manufacturers with the essential requirements must be based, among other things, on the evaluation of clinical data supporting the safety and performance of the products during normal conditions of use. Specifically, a manufacturer must demonstrate that the device achieves its intended performance during normal conditions of use, that the known and foreseeable risks, and any adverse events, are minimized and acceptable when weighed against the benefits of its intended performance, and that any claims made about the performance and safety of the device are supported by suitable evidence. Except for (general) in vitro diagnostic medical devices, where the manufacturer can self-declare the conformity of its products with the essential requirements, a conformity assessment procedure requires the intervention of a notified body. Notified bodies are independent organizations designated by EU member states to assess the conformity of devices before being placed on the market. A notified body would typically audit and examine a product's technical dossiers and the manufacturers' quality system (notified body must presume that quality systems which implement the relevant harmonized standards – which is ISO 13485:2016 for Quality Management Systems – conform to these requirements). If satisfied that the relevant product conforms to the relevant essential requirements, the notified body issues a certificate of conformity, which the manufacturer uses as a basis for its own declaration of conformity. The manufacturer may then apply the CE-Mark to the device, which allows the device to be placed on the market throughout the EU.

Throughout the term of the certificate of conformity, the manufacturer will be subject to periodic surveillance audits to verify continued compliance with the applicable requirements. In particular, there will be a new audit by the notified body before it will renew the relevant certificate(s).

All manufacturers placing in vitro diagnostic medical devices into the market in the EU must comply with the EU medical device vigilance system. Under this system, incidents must be reported to the relevant authorities of the EU member states, and manufacturers are required to take Field Safety Corrective Actions, or FSCAs, to reduce a risk of death or serious deterioration in the state of health associated with the use of an in vitro diagnostic medical device that is already placed on the market. An incident is defined as any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the labeling or the instructions for use which, directly or indirectly, might lead to or might have led to the death of a patient or user or of other persons or to a serious deterioration in their state of health. An FSCA may include the recall, modification, exchange, destruction or retrofitting of the device. FSCAs must be communicated by the manufacturer or its legal representative to its customers and/or to the end users of the device through Field Safety Notices.

The advertising and promotion of in vitro diagnostic medical devices is subject to some general principles set forth by EU directives. According to the IVDD, only devices that are CE marked may be marketed and advertised in the EU in accordance with their intended purpose. Directive 2006/114/EC concerning misleading and comparative advertising and Directive 2005/29/EC on unfair commercial practices, while not specific to the advertising of medical devices, also apply to the advertising thereof and contain general rules, for example requiring that advertisements are evidenced, balanced and not misleading. Specific requirements are defined at national level. EU member states laws related to the advertising and promotion of medical devices, which vary between jurisdictions, may limit or restrict the advertising and promotion of products to the general public and may impose limitations on promotional activities with healthcare professionals.

Many member states in the EU have adopted specific anti-gift statutes that further limit commercial practices for medical devices (including in vitro diagnostic medical devices), in particular vis-à-vis healthcare professionals and organizations. Additionally, there has been a recent trend of increased regulation of payments and transfers of value provided to healthcare professionals or entities. In addition, many EU member states have adopted national "Sunshine Acts" which impose reporting and transparency requirements (often on an annual basis), similar to the requirements in the United States, on medical device manufacturers. Certain countries also mandate implementation of commercial compliance programs.

In the EU, regulatory authorities have the power to carry out announced and, if necessary, unannounced inspections of companies, as well as suppliers and/or sub-contractors and, where necessary, the facilities of professional users. Failure to comply with regulatory requirements (as applicable) could require time and resources to respond to the regulatory authorities' observations and to implement corrective and preventive actions, as appropriate. Regulatory authorities have broad compliance and enforcement powers and if such issues cannot be resolved to their satisfaction can take a variety of actions, including untitled or warning letters, fines, consent decrees, injunctions, or civil or criminal penalties.

The EU regulatory landscape concerning medical devices is evolving. On April 5, 2017 Regulation (EU) 2017/746 of the European Parliament and of the Council on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU, or the IVDR, was adopted to establish a modernized and more robust EU legislative framework, with the aim of ensuring better protection of public health and patient safety. Unlike directives, the IVDR does not need to be transposed into national law and therefore reduces the risk of discrepancies in interpretation across the different European markets.

The IVDR will become applicable five years after publication (on May 26, 2022). Once applicable, the IVDR will among other things:

- strengthen the rules on placing devices on the market and reinforce surveillance once they are available;
- establish explicit provisions on manufacturers' responsibilities for the follow-up of the quality, performance and safety of devices placed on the market;
- establish explicit provisions on importers' and distributors' obligations and responsibilities;
- impose an obligation to identify a responsible person who is ultimately responsible for all aspects of compliance with the requirements of the new regulation;
- improve the traceability of medical devices throughout the supply chain to the end-user or patient through the introduction of a unique identification number, to increase the ability of manufacturers and regulatory authorities to trace specific devices through the supply chain and to facilitate the prompt and efficient recall of medical devices that have been found to present a safety risk;
- set up a central database (Eudamed) to provide patients, healthcare professionals and the public with comprehensive information on products available in the EU; and
- strengthen rules for the assessment of certain high-risk devices that may have to undergo an additional check by experts before they are placed on the market.

Regulations Related to Clinical Laboratories in the European Union

The EU does not have an overarching law or regulation that governs the legal framework surrounding the operations of clinical laboratories in a way that would be analogous to CLIA in the United States. However, EU member states' laws may affect how our business as a testing service provider is carried out.

Other laws and guidelines that impact clinical laboratories work include the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, the Declaration of Helsinki adopted by the World Medical Association and related codes of conduct and guidelines issued by the relevant research ethics committees.

Coverage and Reimbursement

In international markets, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific product lines and procedures. In the EU, member states impose controls on whether products are reimbursable by national or regional health service providers and on the prices at which devices are reimbursed under state-run healthcare schemes. More and more, local, product specific reimbursement law is applied as an overlay to medical device regulation, which has provided an additional layer of clearance requirement.

Intellectual Property

We consider the protection of our proprietary technologies and products, as well as our ability to maintain patent protection that covers the composition of matter of our product candidates, their methods of use, and other related technologies and inventions, to be a critical element in the success of our business. As of November 16, 2022, our licensed intellectual property included one issued patent in Europe; one allowed application in the United States; one pending application in Canada and one pending Patent Cooperation Treaty, or PCT, application.

Our licensed intellectual property portfolio comprises the following:

Title	Country	Application No	Publication No	Registration No	Status
METHODS AND KITS COMPRISING GENE SIGNATURES FOR STRATIFYING BREAST CANCER PATIENTS	United States	16308564	US20190161809A1		Allowed
METHODS AND KITS COMPRISING GENE SIGNATURES FOR STRATIFYING BREAST CANCER PATIENTS	Canada	3025860			Pending
METHODS COMPRISING GENE SIGNATURES FOR STRATIFYING BREAST CANCER PATIENTS	Europe	177320785	3472345	3472345	EP Granted
METHODS AND KITS FOR DETERMINING THE RISK OF BREAST CANCER RECURRENCE	PCT	PCTEP2021062176	WO2021224466		Published

We have licensed the rights to a patent family that discloses methods and kits for stratifying risk in breast cancer patients from IEO/University of Milan pursuant to the License. This patent family includes pending applications in Canada and an allowed application in the United States and a granted patent in Europe. Patents issued in this patent family will expire in June 2037, excluding any patent term extensions available in several jurisdictions.

We have licensed the rights to a second patent family that discloses methods and kits for determining the risk of breast cancer recurrence from IEO/University of Milan pursuant to the License. This patent family includes one pending PCT with a national phase entry in November 2022 in Europe. Patents issued in this patent family will expire in May 2041, excluding any patent term extensions available in several jurisdictions.

We are not aware of any third-party claims or contested proceedings in relation to our intellectual property portfolio.

IEO/University of Milan License Agreement

On June 24, 2014, Tiziana entered into an exclusive license agreement (the “License”) with IEO/University of Milan, pursuant to which it obtained a worldwide, royalty-bearing, exclusive license under certain patents and a worldwide, royalty-bearing, non-exclusive license under certain know-how of IEO/University of Milan to develop and commercialize licensed products in connection with a multi-gene prognostic tool. The License was assigned to us as part of the arrangements contained in the demerger agreement on October 30, 2020. Pursuant to the terms of the License, we are obliged to use reasonable efforts in connection with the development and commercialization of the licensed products, including in accordance with specified diligence milestones.

On November 9, 2022, AccuStem and the IEO/University of Milan amended the License to clarify the regulatory path and timeline for the commercialization of StemPrintER. Specifically, the regulatory requirement language has been modified to (i) extend the timeline for regulatory approval or clearance of a licensed product to 36 months from the date of the amendment, (ii) clarify that contractual regulatory requirements can be satisfied by the approval or clearance of the test as a Laboratory Developed Test (i.e., approval or clearance can be achieved via the CLIA regulatory path rather than the FDA) and (iii) the timeline for commercial launch has been extended for an additional 60 months from the date of the amendment. The amendment provides for a separate licensing payment of $175,000 to the IEO.

The License also provides additional payments by us of up to €300,000 (or $320,250 based on exchange rate of $1.0675: to €1.00) in development milestone payments and payment of single digit percentage royalties on net sales. The License remains in effect until the royalty term has expired with respect to all licensed products in all countries. The License may be terminated by either party in the event of a material breach and in addition, we may terminate the License at any time upon 30 days' notice.

Legal Proceedings

From time to time, we may become a party to various legal actions and complaints arising in the ordinary course of business. In addition to commitments and obligations in the ordinary course of business, we are subject to various claims, pending and potential legal actions for damages, investigations relating to governmental laws and regulations and other matters arising out of the normal conduct of our business. It is possible that cash flows or results of operations could be materially affected in any particular period by the unfavorable resolution of one or more of these contingencies.

Human Capital

As of December 31, 2022, we had four full time employees. These employees are not represented by a labor union or covered by a collective bargaining agreement, and we consider our relationship with our employees to be good.

Compensation, Benefits, and Development

We provide our employees with competitive salaries and bonuses, opportunities for equity ownership, and a robust employment package that promotes well-being across all aspects of our employees' lives, including health care and paid time off.

Diversity and Inclusion

We value the diversity of our employees and take pride in our commitment to diversity and inclusion across all levels of our organizational structure and with respect to our board of directors. We continue to focus on expanding our commitment to diversity and inclusion across our entire workforce, including working with managers to develop strategies for building diverse teams and promoting the advancement of employees from diverse backgrounds.

CORPORATE INFORMATION

Our legal name is AccuStem Sciences, Inc. Our registered office is situated at 5 Penn Plaza, 19th Floor, #1954 New York, NY, and our telephone number is +44 (0) 20 7495 2379. We have one wholly owned subsidiary: StemPrintER Sciences Limited, a private company incorporated in England and Wales with limited liability under the Companies Act. Our website address is www.AccuStem.com. The reference to our website is an inactive textual reference only and information contained in, or that can be accessed through, our website or any other website cited in this registration statement is not part of hereof.

Available Information

We file annual, quarterly, and current reports, proxy statements, and other documents with the Securities and Exchange Commission ("SEC") under the Securities Exchange Act of 1934, as amended (the "Exchange Act"). The SEC maintains an internet website, www.sec.gov, that contains reports, proxy and information statements, and other information regarding issuers, including us, that file electronically with the SEC.

Copies of each of our filings with the SEC on Form 10-K, Form 10-Q, and Form 8-K and all amendments to those reports, can be viewed and downloaded free of charge at our website, www.accustem.com, as soon as reasonably practicable after the reports and amendments are electronically filed with or furnished to the SEC.

Our code of ethics, other corporate policies and procedures, and the charters of our Audit Committee, Compensation Committee, and Nominating/Corporate Governance Committee are available through our website at www.accustem.com.

Item 1A. Risk Factors

The following risk factors may be important to understanding any statement in this Annual Report on Form 10-K or elsewhere. Our business, financial condition and operating results can be affected by a number of factors, whether currently known or unknown, including but not limited to those described below. Any one or more of such factors could directly or indirectly cause our actual results of operations and financial condition to vary materially from past or anticipated future results of operations and financial condition. Any of these factors, in whole or in part, could materially and adversely affect our business, financial condition, results of operations and stock price.

Risks Specific to the Development of the Business

We do not have collaborations in place with institutions for utility studies and there is no guarantee that we will be able to demonstrate prospective clinical utility of StemPrintER.

Following the completion of the initial retrospective validation studies with respect to StemPrintER, we are likely to run clinical utility studies to support applications for reimbursement, which are necessary for successful commercialization and to provide further evidence to support marketing claims. We have not yet identified which institutions will carry out the utility studies and have not yet entered into the relevant agreements with these institutions. There is a risk that we will not be able to secure these collaborations, which would impact our ability to proceed to the utility study stage.

Furthermore, we may not be able to demonstrate the clinical utility of StemPrintER in a real-world setting, which would impact our ability to secure reimbursement. If such reimbursement is not achieved, it will make commercialization of StemPrintER significantly more challenging and would impact our ability to generate revenue and, accordingly, result in a material adverse impact on our business, financial condition, and results of operations.

There are risks associated with the process of establishing a CLIA laboratory and in offering StemPrintER which are outside our control.

StemPrintER is a 20-gene test that was designed to indicate the risk of recurrence for patients with early-stage breast cancer, primarily intended for use in the ER+/HER2- population. We do not yet have a CLIA-certified laboratory that can run StemPrintER as a LDT.

Even if we eventually obtain CLIA certification for a laboratory that will run our assay and proceed to commercialization, there are inherent risks associated with offering the StemPrintER as a LDT that are outside our control, including test uptake, which would have an impact on the amount of revenue we could generate. Further, we may not be able to generate any meaningful revenue from offering StemPrintER as a LDT.

We will be dependent on third parties to provide certain resources and services to us, as we have limited resources

We plan to rely in part on external resources to conduct the research, development, supply of supplies and clinical testing of our StemPrintER test, including in relation to our laboratory systems which we expect to rely on software developed by external manufacturers. The future development of StemPrintER and other products will partly depend upon the performance of these third parties. We cannot guarantee that the relevant third parties will be able to carry out their obligations under the relevant arrangements. In the future, we may depend on external resources in marketing, sales and distribution of our products. We cannot guarantee that we will be able to assign competent partners to conduct these tasks or that these tasks can be completed on the basis of terms which are beneficial to us. Additionally, while management is responsible for making decisions on our behalf, management will rely to a certain extent on the advice of external professional advisors. There is no guarantee that we will receive the correct advice from such advisors.

Disagreements between us and any third parties could lead to delays in our R&D program and/or commercialization plans. If any third parties were to terminate their relationships with us, we would be required to obtain development and/or commercialization services from other third parties or develop the relevant functions internally, which could have an adverse effect on our business, results of operations and financial condition.

We are subject to research and product development risk

We may not be able to develop new products or to identify specific market needs that can be addressed by tests or solutions developed us. Product development will be a key ongoing activity for us. However, there can be no assurance that further products will be developed, successfully launched, or accepted by the market. All new product development has an inherent level of risk and can be a lengthy process and suffer unforeseen delays, cost overruns and setbacks, such as difficultly recruiting patients into clinical trials. The nature of the medical device industry may mean new products may become obsolete as a result of competition or regulatory changes which could have a material adverse effect on our business, results of operations and financial condition.

In addition, R&D may be subject to various requirements, such as research subject protection for individuals participating in clinical evaluations of new products, institutional review board oversight, regulatory authorizations, and design control requirements. Failure to comply with requirements could result in penalties, delay, or prevent commercialization of products.

We are subject to risks associated with medical and technological change and obsolescence

Demand for our products could be adversely impacted by the development of alternative technology and alternative medicines. There can be no assurance that the technology and products currently being developed by us will not be rendered obsolete. As a result, there is the possibility that new technology or products may be superior to, or render obsolete, the technology and products that we are currently developing. Any failure of ours to ensure that our products remain up to date with the latest advances may have a material adverse impact on our competitiveness and financial performance. Our success will depend, in part, on our ability to develop and adapt our products or acquire and integrate new technologies to meet these technological changes and industry trends and failure to do so could have a material adverse effect on our business, results of operations and financial condition.

Risks Relating to Intellectual Property

Our rights to develop and commercialize our product candidates are subject to the terms and conditions of licenses granted to us by others. If we fail to comply with our obligations under our existing and any future intellectual property licenses with third parties, we could lose license rights that are important to our business.

We are reliant upon licenses and sublicenses from Istituto Europeo di Oncologia, Fondazione FIRC per l'Oncologia Molecolare and the University of Milan ("IEO/University of Milan") to certain patent rights and proprietary technology that are important or necessary to the development of our technology and product candidates, including the patents and know-how relating to manufacture.

On June 24, 2014, Tiziana entered into an exclusive license agreement (the "License") with IEO/University of Milan, pursuant to which it obtained a worldwide, royalty-bearing, exclusive license under certain patents and a worldwide, royalty-bearing, non-exclusive license under certain know-how, respectively, of IEO/University of Milan to develop and commercialize licensed products in connection with a multi-gene prognostic tool. The License was assigned to us as part of the arrangements contained in the demerger agreement on October 30, 2020. Pursuant to the terms of the License, we are obliged to use reasonable efforts in connection with the development and commercialization of the licensed products, including in accordance with specified diligence milestones.

If we fail to meet our obligations under the License or if the License is terminated for any reason, we may be required to discontinue our R&D program or any future commercialization efforts of StemPrintER product candidate, be unable to expand our operations or be unable to otherwise capitalize on our business opportunities, as desired, which could harm our business and potentially cause a discontinuation of our operations.

The License may also be terminated for other reasons including breach and insolvency.

If we are unable to obtain and maintain patent protection for our product candidates and technology, or if the scope of our patent protection is not sufficiently broad, our competitors could develop and commercialize similar products and technology

Our success depends, in large part, on our ability to seek, obtain and maintain patent protection in the United States, U.K. and other countries with respect to our product candidates and technology. Our licensors have sought, and we intend to seek, to protect our proprietary position by filing patent applications in the United States, the U.K. and elsewhere, related to certain technologies and our product candidate, StemPrintER, that are important to our business.

Our current patent portfolio contains a limited number of patent applications, which are in-licensed from third parties. If we are unable to assert any such patents to prevent others from reproducing our technology and product candidates, or are unable to identify patentable aspects of our R&D output before it is too late to obtain patent protection, failure to do so could have a material adverse effect on our business, results of operations and financial condition.

Our intellectual property is open to challenge

No assurance can be given that any current or future trademark, design right or patent applications will result in registered trademarks, design rights or patents, that the scope of any patent, design or trademark protection or the protection provided by copyright or database rights or the right to bring actions for breach of confidentiality will exclude competitors or provide competitive advantages to us, that any of our licensed-in patents, design rights or trademarks will be held valid if challenged or that third parties will not claim rights or ownership of the patents, design rights, trademarks or other intellectual property rights held by us.

If we cannot successfully enforce our intellectual property rights, this could have a material adverse effect on our business, financial condition and prospects. We may be subject to claims in relation to the infringement of patents, design rights, trademarks or other intellectual property rights owned by third parties. Adverse judgments against us may give rise to significant liabilities in monetary damages, legal fees and/or an inability to manufacture, market or sell products either at all or in particular territories.

Our strategy involves generating commercially valuable intellectual property that can be protected

We intend to augment our intellectual property portfolio. No assurance can be given that any future patent applications will result in granted patents, that the scope of any patent protection will exclude competitors or provide competitive advantages to us, that any of our patents will be held valid if challenged or that third parties will not claim rights in or ownership of the patents and other proprietary rights held by us. Should we fail to successfully obtain additional patent protection in respect its technology and products could have a material adverse effect on our business, results of operations and financial condition.

Market and Competitive Risks

We operate in a competitive market and will face competition from competitors involved in multi-gene prognostic assay for the prediction of risk of recurrence in luminal (ER+/HER2-) breast cancer patients

We may face competition from competitors involved in developing a multi-gene prognostic assay for the prediction of risk of recurrence in luminal (ER+/HER2-) breast cancer patients. Many of our competitors will have access to greater research, development, marketing, financial and personnel resources which may provide commercial advantages to those competitors. New products may be more effective, cheaper or more effectively marketed than StemPrintER. A substantial increase in competition for any of these reasons could require us to, for example, increase our marketing or capital expenditure or require us to change our business model to remain competitive, which may have an adverse impact on our business including our profitability and/or financial condition.

The market opportunities for our product candidates may be smaller than we anticipate

We are focusing our R&D efforts on a multi-gene prognostic tool for predicting the recurrence of certain breast cancers. Our understanding of both the number of people who have these diseases, as well as the subset of people with these diseases who have the potential to benefit from our prognostic assay, is based on estimates. These estimates may prove to be incorrect and new studies may reduce the estimated incidence or prevalence of these diseases. The number of patients in the United States, the United Kingdom ("U.K."), the European Union ("EU") and elsewhere may turn out to be lower than expected, may not be otherwise amenable to assessment with our product candidates or patients may become increasingly difficult to identify and access, all of which would adversely affect our business, financial condition, results of operations and prospects.

Further, there are several factors that could contribute to making the actual number of patients who receive our potential products, if and when approved, less than the potentially addressable market, such as the lack of widespread availability of, and limited reimbursement for, new therapies in many underdeveloped markets.

The future commercial success of our product candidates will depend upon the degree of each product candidate's market acceptance by physicians, patients, third-party payors and others in the medical community

We have no product authorized for marketing; our product candidates are at the validation study stage of development, and we may never have a product available to be commercially sold or that becomes commercially successful. The commercial success of our product candidates will depend, in part, on their acceptance by physicians, patients and third-party payors as medically necessary, cost-effective and safe. If our future products do not achieve an adequate level of acceptance, we may not generate significant product revenue and may not become profitable. Even if some product candidates achieve market acceptance, the market may not prove to be large enough to generate significant revenues. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on several factors, including, but not limited to:

- the effectiveness and safety of our product candidates as demonstrated in clinical trials;
- the potential and perceived advantages of our product candidates over alternative prognostic tools;
- the availability and cost of use relative to alternative prognostic tools;
- changes in the standard of care for the targeted indications for any product candidate;

- the willingness of physicians to use, and the target patient population to try, new prognostic tools;
- product labelling or product insert requirements of the FDA, the U.K. Medicines and Healthcare products Regulatory Agency , the European Medicines Agency ("EMA") or other regulatory authorities, including any limitations or warnings contained in a product's approved labelling;
- the timing of market introduction of competitive products;
- sales, distribution and marketing support;
- publicity concerning our product candidates or competing products and treatments;
- potential product liability claims;
- any restrictions on the use of our products together with other medications; and
- favorable third-party payor coverage and adequate reimbursement.

Even if a potential product displays favorable clinical properties and safety profile in preclinical studies and clinical trials, market acceptance of the product will not be fully known until after it is launched.

The insurance coverage and reimbursement status of newly approved products is uncertain. Failure to obtain or maintain adequate coverage and reimbursement for our approved product candidates could limit our ability to market those products

We expect that coverage and adequate reimbursement by government and private payors will be essential for most patients to be able to afford our approved product candidates. Accordingly, sales of our product candidates will depend substantially, both domestically and abroad, on the extent to which the costs of our product candidates will be paid by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or will be reimbursed by government authorities, private health coverage insurers and other third-party payors. Coverage and reimbursement by a third-party payor may depend upon several factors, including the third-party payor's determination that use of a product is:

- a covered benefit under our health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

Obtaining coverage and reimbursement for a product from third-party payors is a time-consuming and costly process that could require us to provide to the payor supporting scientific, clinical and cost-effectiveness data. We may not be able to provide data sufficient to gain acceptance with respect to coverage and reimbursement. If coverage and reimbursement are not available or delayed, or are available only at limited levels, we may not be able to successfully commercialize our product candidates. Even if coverage is provided, the approved reimbursement amount may not be adequate to realize a sufficient return on our investment and less favorable coverage policies and reimbursement rates may be implemented in the future.

Market acceptance and sales of our products will depend significantly on the availability of adequate coverage and reimbursement from third-party payors and may be affected by existing and future healthcare reform measures.

Regulatory Risks

Complying with numerous regulations pertaining to our business is an expensive and time-consuming process, and any failure to comply could result in substantial penalties.

Once we have our CLIA certified lab, we will be subject to CLIA, a federal law that regulates clinical laboratories that perform testing on samples derived from humans for the purpose of providing information for the diagnosis, prevention or treatment of disease. CLIA regulations mandate specific standards in the areas of personnel qualifications, administration, and participation in proficiency testing, patient test management, quality control, quality assurance and inspections. We will be subject to survey and inspection every two years. Moreover, CLIA inspectors may make random inspections of our clinical reference laboratory.

Although we are required to hold a certificate of accreditation or compliance under CLIA that allows us to perform high complexity testing, we are not required to hold a certificate of accreditation through CAP. We could alternatively maintain a certificate of accreditation from another accrediting organization or a certificate of compliance through inspection by surveyors acting on behalf of the CLIA program.

The failure to comply with CLIA requirements can result in enforcement actions, including the revocation, suspension, or limitation of our CLIA certificate of accreditation, as well as a directed plan of correction, state on-site monitoring, civil money penalties, civil injunctive suit and/or criminal penalties. We must maintain CLIA compliance and certification to be eligible to bill for tests provided to Medicare beneficiaries. If we were to be found out of compliance with CLIA program requirements and subjected to sanctions, our business and reputation could be harmed. Even if it were possible for us to bring our laboratory back into compliance, we could incur significant expenses and potentially lose revenue in doing so.

We will be required to maintain a license to conduct testing in Arizona. Arizona laws establish standards for day-to-day operation of our clinical reference laboratory, including the training and skills required of personnel and quality control. Moreover, several other states require that we hold licenses to test samples from patients in those states. Other states may have similar requirements or may adopt similar requirements in the future. Although we plan to obtain licenses from states where we believe we are required to be licensed, we may become aware of other states that require out-of-state laboratories to obtain licensure in order to accept samples from the state, and it is possible that other states currently have such requirements or will have such requirements in the future.

If we were to lose our CLIA certificate of accreditation or Arizona license, whether as a result of a revocation, suspension or limitation, we would no longer be able to sell our testing products, which would limit our revenue and harm our business.

If we fail to comply with healthcare laws and regulations, we could face substantial penalties and our business, operations and financial condition could be adversely affected.

We are also subject to healthcare fraud and abuse regulation by both the federal government and the states in which we conduct our business and to similar foreign laws and regulations in the countries where we conduct our business. These laws include, without limitation, state and federal anti-kickback, self-referral, fraud and abuse, false claims, and transparency laws and regulations with respect to payments and other transfers of value made to physicians and other licensed health care professionals.

The Anti-Kickback Stature, or AKS, prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce or in return for purchasing, leasing, ordering or arranging for the purchase, lease or order of any good, facility, item or service, including laboratory services, reimbursable, in whole or in part, under Medicare, Medicaid or other federally financed healthcare programs. The term “remuneration” has been broadly interpreted to include anything of value. The AKS has been interpreted to apply to arrangements between manufacturers on one hand and prescribers, purchasers and formulary managers on the other. Although there are a number of statutory exceptions and regulatory safe harbors protecting certain common activities from prosecution, the exceptions and safe harbors are drawn narrowly. Our practices may not in all cases meet all of the criteria for safe harbor protection from anti-kickback liability. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor, however, does not make the conduct per se illegal under the AKS. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all of its facts and circumstances. Several courts have interpreted the statute’s intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the AKS has been violated. Further, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

On June 25, 2014, the Office of Inspector General, or OIG, released a Special Fraud Alert, expressing concern regarding laboratory payments made to referring physicians and physician group practices for blood sample collection, processing, and packaging. Specifically, the OIG expressed concern that such arrangements may implicate the AKS when laboratories make payments to physicians for services that are already covered and reimbursed by Medicare, or are not commercially reasonable or exceed fair market value, all in order to induce physicians to order tests from such laboratory. Because the choice of laboratory and the decision to order laboratory tests is made or strongly influenced by the physician, with little or no input from patients, such payment may induce physicians to order more laboratory tests than are medically necessary, particularly when the payments are tied to, or take into account, the volume or value of business generated by the physician. To the extent our arrangements with physicians and pathology medical groups for services related to sample collection, transporting and handling are found to be inconsistent with applicable laws, we may be subject to significant penalties, including criminal penalties, and exclusion from participation in U.S. federal or state health care programs.

We are also subject to the federal physician self-referral prohibitions, commonly known as the Stark Law, which prohibits, among other things, physicians who have a financial relationship, including an investment, ownership or compensation relationship with an entity, from referring Medicare patients for designated health services, which include clinical laboratory services, unless an exception applies. Similarly, entities may not bill Medicare or any other party for services furnished pursuant to a prohibited referral. In addition, the government may assert that a claim including items or services resulting from a violation of the Stark Law constitutes a false or fraudulent claim for purposes of the false claims laws.

The federal civil and criminal false claims law, including the False Claims Act, prohibit, among other things, any person from knowingly presenting or causing to be presented a false claim for payment to the federal government, or knowingly making or causing to be made a false statement to get a false or fraudulent claim paid by the federal government. A claim includes "any request or demand" for money or property presented to the U.S. government. In addition, the government may assert that a claim for items or services arising from a violation of the AKS or Stark Law constitutes a false or fraudulent claim for purposes of the false claims laws. Private individuals also have the ability to bring actions under these false claims laws in the name of the government alleging false and fraudulent claims presented to or paid by the government (or other violations of the statutes) and to share in any amounts paid by the entity to the government in fines or settlement. Such suits, known as qui tam actions, are pervasive in the healthcare industry.

HIPAA also established federal criminal statutes that prohibit, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the AKS, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

In addition, under the federal civil monetary penalties statute, a person is prohibited from offering or transferring to a Medicare or Medicaid beneficiary any remuneration, including waivers of co-payments and deductible amounts (or any part thereof), that the person knows or should know is likely to influence the beneficiary's selection of a particular provider, practitioner or supplier of Medicare or Medicaid payable items or services. Moreover, in certain cases, providers who routinely waive copayments and deductibles for Medicare and Medicaid beneficiaries can also be held liable under the AKS and civil False Claims Act. One of the statutory exceptions to the prohibition is non-routine, unadvertised waivers of copayments or deductible amounts based on individualized determinations of financial need or exhaustion of reasonable collection efforts. The OIG emphasizes, however, that this exception should only be used occasionally to address special financial needs of a particular patient. Although this prohibition applies only to federal healthcare program beneficiaries, the routine waivers of copayments and deductibles offered to patients covered by commercial payors may implicate applicable state laws related to, among other things, unlawful schemes to defraud, excessive fees for services, tortious interference with patient contracts and statutory or common law fraud. To the extent our patient assistance programs are found to be inconsistent with applicable laws, we may be required to restructure or discontinue such programs, or be subject to other significant penalties.

Under the Physician Payments Sunshine Act, manufacturers of certain devices, drugs and biologics are required to report to CMS certain payments and transfers of value by them and in some cases their distributors to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain other health care providers beginning in 2022, and teaching hospitals, as well as ownership and investment interests held by physicians (as defined by the statute) and their immediate family members. Because we plan to manufacture our own laboratory developed tests, or LDTs, solely for use by or within our own laboratory, we believe that we are currently exempt from these reporting requirements. We cannot assure, however, that our regulators, principally the federal government, will agree with our determination, and a determination that we have violated these laws and regulations, or a public announcement that we are being investigated for possible violations, could adversely affect our business, prospects, results of operations or financial condition.

Several states in which we plan to operate have also adopted similar fraud and abuse laws as described above. The scope of these laws and the interpretations of them vary from state to state and are enforced by state courts and regulatory authorities, each with broad discretion. Some state fraud and abuse laws apply to items or services reimbursed by any payor, including patients and commercial insurers, not just those reimbursed by a federally funded healthcare program.

It is possible that some of our business activities could be subject to challenge under one or more of such laws. Such a challenge, regardless of the outcome, could have a material adverse effect on our business, business relationships, reputation, financial condition and results of operations. Although an effective compliance program can mitigate the risk of investigation and prosecution for violations of these laws, the risks cannot be entirely eliminated. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. Moreover, achieving and sustaining compliance with these laws may prove costly.

If we or our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to significant penalties, including administrative, civil and/or criminal penalties, damages, fines, disgorgement, individual imprisonment, exclusion from participation in U.S. federal or state health care programs, such as Medicare and Medicaid in the United States and similar programs outside the United States, a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations, any of which could materially adversely affect our ability to operate our business and our financial results. To the extent that any of our testing products are sold in a foreign country, we may be subject to similar foreign laws and regulations, which may include, for instance, applicable post-marketing requirements, including safety surveillance, anti-fraud and abuse laws, and implementation of corporate compliance programs and reporting of payments or transfers of value to healthcare professionals. For instance, many member states in the European Union, or EU, have adopted specific anti-gift statutes that further limit commercial practices for medical devices (including in vitro diagnostic medical devices), in particular vis-à-vis healthcare professionals and organizations.

Additionally, there has been a recent trend of increased regulation of payments and transfers of value provided to healthcare professionals or entities. In addition, many EU member states have adopted national "Sunshine Acts" which impose reporting and transparency requirements (often on an annual basis), similar to the requirements in the United States, on medical device manufacturers.

Our products and operations are subject to extensive government regulation and oversight both in the United States and abroad, and our failure to comply with applicable requirements could harm our business.

Our product candidates are in vitro tests which can be regulated as medical devices in the United States and other jurisdictions. When applicable, the FDA and foreign regulatory agencies regulate, among other things, with respect to medical devices: design, development and manufacturing; testing, labeling, content and language of instructions for use and storage; clinical trials (to the extent applicable, clinical trials encompass the notion of clinical investigations in the EU); product safety; establishment registration and device listing; marketing, sales and distribution; premarket clearance, classification, approval, and certification; recordkeeping procedures; advertising and promotion; recalls and field safety corrective actions; post-market surveillance, including reporting of deaths or serious injuries and malfunctions that, if they were to recur, could lead to death or serious injury; post-market studies; and product import and export.

The regulations to which we may be subject are complex and have tended to become more stringent over time. Regulatory changes could result in restrictions on our ability to carry on or expand our operations, higher than anticipated costs or lower than anticipated sales. The FDA and its foreign counterparts enforce its regulatory requirements through, among other means, periodic unannounced inspections. We do not know whether we or any contract manufacturers or suppliers that we utilize will be found compliant in connection with any future FDA or foreign inspections. Failure to comply with applicable regulations could jeopardize our ability to sell our products and result in enforcement actions such as: warning letters; fines; injunctions; civil penalties; termination of distribution; recalls or seizures of products; delays in the introduction of products into the market; total or partial suspension of production; refusal to grant future marketing authorizations or certifications; withdrawals or suspensions of current marketing authorizations and certifications, resulting in prohibitions on sales of our products; and in the most serious cases, criminal penalties.

In order to sell our products in EU member states, our products must comply with the essential requirements of the EU In Vitro Diagnostic Medical Devices Directive (Directive 98/79/EC), or the IVDD. Compliance with these requirements is a prerequisite to be able to affix the European Conformity, or CE, mark to our products, without which they cannot be sold or marketed in the EU. All medical devices placed on the market in the EU must meet the essential requirements laid down in Annex I to the IVDD including the requirement that an in vitro diagnostic medical device must be designed and manufactured in such a way that it will not compromise the clinical condition or safety of patients, or the safety and health of users and others. In addition, the device must achieve the performances intended by the manufacturer and be designed, manufactured, and packaged in a suitable manner. The European Commission has adopted various standards applicable to medical devices. There are also harmonized standards relating to design and manufacture. While not mandatory, compliance with these standards is viewed as the easiest way to satisfy the essential requirements as a practical matter as it creates a rebuttable presumption that the device satisfies that essential requirement. To demonstrate compliance with the essential requirements we must undergo a conformity assessment procedure, which varies according to the type of medical device and its (risk) classification. As a general rule, demonstration of conformity of in vitro diagnostic medical devices and their manufacturers with the essential requirements must be based, among other things, on the evaluation of clinical data supporting the safety and performance of the products during normal conditions of use. Specifically, a manufacturer must demonstrate that the device achieves its intended performance during normal conditions of use, that the known and foreseeable risks, and any adverse events, are minimized and acceptable when weighed against the benefits of its intended performance, and that any claims made about the performance and safety of the device are supported by suitable evidence.

Except for (general) in vitro diagnostic medical devices, where the manufacturer can self-declare the conformity of its products with the essential requirements of the IVDD, a conformity assessment procedure requires the intervention of a notified body. Notified bodies are independent organizations designated by EU member states to assess the conformity of devices before being placed on the market. The notified body would typically audit and examine the product's technical file and the manufacturer's quality system (notified body must presume that quality systems which implement the relevant harmonized standards—which is ISO 13485:2016 for Quality Management Systems—conform to these requirements). If satisfied that the relevant product conforms to the relevant essential requirements, the notified body issues a certificate of conformity, which the manufacturer uses as a basis for its own declaration of conformity. The manufacturer may then apply the CE-Mark to the device, which allows the device to be placed on the market throughout the EU.

If we fail to achieve compliance with applicable European laws and directives, we would be unable to continue to affix the CE mark to our products, which would prevent us from selling them within the EU. In the EU, we must inform the notified body that carried out the conformity assessment of the devices that we market or sell in the EU and European Economic Area, or EEA, of any planned substantial changes to our quality system or substantial changes to our in vitro diagnostic medical devices that could affect compliance with the essential requirements laid down in Annex I to the IVDD or cause a substantial change to the intended use for which the device has been CE marked. The notified body will then assess the planned changes and verify whether they affect the product's ongoing conformity with the IVDD. If the assessment is favorable, the notified body will issue a new certificate of conformity or an addendum to the existing certificate attesting compliance with the essential requirements and quality system requirements laid down in the Annexes to the IVDD.

The aforementioned EU rules are generally applicable in the EEA (which consists of the 27 EU member states plus Norway, Liechtenstein and Iceland). Non-compliance with the above requirements would also prevent us from selling our products in these three countries.

The EU regulatory landscape concerning medical devices is evolving and a new regulation governing in vitro diagnostic medical devices became applicable on May 26, 2022 and these modifications may have an effect on the way we plan to conduct our business in the EU and the EEA.

The FDA may modify its enforcement discretion policy with respect to laboratory developed tests, or LDTs, in a risk-based manner, and we may become subject to extensive regulatory requirements and may be required to conduct additional clinical trials prior to continuing to sell our existing tests or launching any other tests in the United States we may develop, which may increase the cost of conducting, or otherwise harm, our business.

LDTs are in vitro tests that are intended for clinical use and are designed, manufactured, and used within a single laboratory. Although LDTs are classified as medical devices and the FDA has statutory authority to ensure that medical devices are safe and effective for their intended uses, the FDA has historically exercised enforcement discretion and has not enforced certain applicable FDA requirements, including premarket review, with respect to LDTs. In addition, in August 2020, HHS announced that the FDA will not require premarket review of LDTs absent notice-and-comment rulemaking. Although the Biden administration has not taken affirmative steps to rescind this August 2020 announcement issued by the previous administration, this 2020 policy statement is no longer posted on the HHS website.

Legislative and administrative proposals proposing to amend the FDA's oversight of LDTs have been introduced in recent years and we expect that new legislative and administrative proposals will continue to be introduced from time to time. It is possible that legislation could be enacted into law or regulations or guidance could be issued by the FDA which may result in new or increased regulatory requirements for us to continue to offer our LDTs or to develop and introduce new tests as LDTs in the United States.

For example, the FDA could modify its current approach to LDTs in a way that would subject our tests that we market in the United States as LDTs to the enforcement of additional regulatory requirements. In recent years, the FDA has stated its intention to modify its enforcement discretion policy with respect to LDTs. Specifically, on July 31, 2014, the FDA notified Congress of its intent to modify, in a risk-based manner, its policy of enforcement discretion with respect to LDTs. On October 3, 2014, the FDA issued two draft guidance documents entitled "Framework for Regulatory Oversight of Laboratory Developed Tests (LDTs)," or the Framework Guidance, and "FDA Notification and Medical Device Reporting for Laboratory Developed Tests (LDTs)". The FDA halted finalization of the guidance in November 2016 to allow for further public discussion on an appropriate oversight approach to LDTs and to give congressional authorizing committees the opportunity to develop a legislative solution, and FDA issued a discussion paper on possible approaches to LDT regulation in January 2017.

In addition, the FDA and Congress have, for over the past decade, considered a number of proposals to end the FDA's enforcement discretion policy for LDTs and subject LDTs to additional regulatory requirements. For example, Congress has recently worked on legislation to create an LDT and in vitro diagnostic regulatory framework for all in vitro clinical tests that would be separate and distinct from the existing medical device regulatory framework. In June 2021, members of the U.S. House of Representatives formally introduced the VALID Act (Verifying Accurate Leading-edge IVCT Development Act of 2021) and an identical version of the bill was introduced in the U.S. Senate. If passed in its current form, the VALID Act would create a new category of medical products separate from medical devices called "in vitro clinical tests," or IVCTs, and bring all such products within the scope of FDA's oversight. The VALID Act appears to contemplate that traditional LDTs would become subject to FDA regulation as IVCTs, and that all IVCTs would be categorized as either high-risk or low-risk, distinct from FDA's existing classification for medical devices into Class I, Class II, or Class III. As proposed, the risk classification for an IVCT would depend on certain factors, including the risk to the patient or public health of an inaccurate result, the extent to which, the test is well-understood and/or how well-characterized it is, the clinical circumstances under which the test is used, and the availability of other tests and any mitigating measures. Depending on the risk classification, new IVCTs, or certain modifications to existing IVCTs, could be subject to premarket review. Notably, the bill currently includes a provision that would "grandfather" certain tests that were commercialized before the enactment of the legislation, subject to certain requirements. It is unclear whether the VALID Act or any other legislative proposals would be passed by Congress or signed into law by the President.

Even if the FDA does not modify its policy of enforcement discretion, they may impose significant regulatory requirements, including the requirement for premarket review and subsequent marketing authorization at some point in the future. We may also be required to conduct clinical studies to support our planned product launches. If we are required to conduct such clinical trials, delays in the commencement or completion of clinical testing could significantly increase our test development costs and delay commercialization of any products.

If we do not obtain and maintain any required international regulatory registrations and marketing authorizations or certifications for our products, we will be unable to market and sell such products outside of the United States.

Sales of our products outside of the United States will remain subject to foreign regulatory requirements that vary widely from country to country. In addition, the FDA regulates exports of medical devices from the United States. While the regulations of some countries may not impose significant barriers to marketing and selling our products or only require notification to regulators or third parties, others require that we obtain affirmative marketing authorization from a specified regulatory body. Complying with foreign regulatory requirements, including obtaining registrations, marketing authorizations or certifications, can be expensive and time-consuming, and we may not receive necessary marketing authorizations in each country in which we plan to market our products or we may be unable to do so on a timely basis. The time required to obtain registrations and marketing authorizations, if required by other countries, may be longer than that required for FDA marketing authorizations, and requirements for such registrations or authorizations may significantly differ from FDA requirements. If we modify our products, we may need to apply for additional marketing authorizations before we are permitted to sell the modified product. In addition, we may not continue to meet the quality and safety standards required to maintain the authorizations that we have received. If we are unable to maintain our marketing authorizations in a particular country, we will no longer be able to sell the applicable product in that country.

Obtaining marketing authorization in the United States from the FDA does not ensure similar marketing authorization or certification by regulatory authorities or notified bodies in other countries, and registration, marketing authorization or certification by one or more foreign regulatory authorities or notified bodies does not ensure registration, marketing authorization, or certification by regulatory authorities or notified bodies in other foreign countries or by the FDA. However, a failure or delay in obtaining registration, marketing authorization or certification in one country may have a negative effect on the regulatory process in others.

Legislative or regulatory reforms in the United States or the EU may make it more difficult and costly for us to obtain marketing authorizations or certifications for any product candidate or to manufacture, market or distribute any product candidates after such authorizations have been obtained.

From time to time, legislation is drafted and introduced in Congress that could significantly change the statutory provisions governing the regulation of medical devices. In addition, the FDA may change its policies, adopt additional regulations or revise existing regulations, or take other actions, which may prevent or delay marketing authorization in the United States of our future products under development or impact our ability to modify any products for which we have already obtained marketing authorizations on a timely basis. Over the last several years, the FDA has proposed reforms to its 510(k) clearance process, and such proposals could include increased requirements for clinical data and a longer review period, or could make it more difficult for manufacturers to utilize the 510(k) clearance process for their products. For example, in November 2018, FDA officials announced steps that the FDA intended to take to modernize the premarket notification pathway under Section 510(k) of the FDCA. Among other things, the FDA announced that it planned to develop proposals to drive manufacturers utilizing the 510(k) pathway toward the use of newer predicates. These proposals included plans to potentially sunset certain older devices that were used as predicates under the 510(k) clearance pathway, and to potentially publish a list of devices that have been cleared on the basis of demonstrated substantial equivalence to predicate devices that are more than ten years old. These proposals have not yet been finalized or adopted, although the FDA may work with Congress to implement such proposals through legislation. Accordingly, it is unclear the extent to which any proposals, if adopted, could impose additional regulatory requirements on us that could delay our ability to obtain 510(k) clearances in the future, increase the costs of compliance, or restrict our ability to maintain any marketing authorizations that we may obtain, or otherwise create competition that may negatively affect our business.

More recently, in September 2019, the FDA issued revised final guidance describing an optional "safety and performance based" premarket review pathway for manufacturers of "certain, well-understood device types" to demonstrate substantial equivalence under the 510(k) clearance pathway by showing that such device meets objective safety and performance criteria established by the FDA, thereby obviating the need for manufacturers to compare the safety and performance of their medical devices to specific predicate devices in the clearance process. The FDA maintains a list of device types appropriate for the "safety and performance based" pathway and continues to develop product-specific guidance documents that identify the performance criteria for each such device type, as well as recommended testing methods, where feasible. The FDA may establish performance criteria for classes of devices similar to ours, and it is unclear the extent to which such performance standards, if established, could impact our ability to obtain marketing authorization or otherwise create competition that may negatively affect our business.

In addition, FDA regulations and guidance are often revised or reinterpreted by the FDA in ways that may significantly affect our business and our products. Any new statutes, regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of any product candidates or make it more difficult to obtain marketing authorizations for, manufacture, market or distribute any product candidate we are developing. We cannot determine what effect changes in regulations, statutes, legal interpretation or policies, when and if promulgated, enacted or adopted may have on our business in the future. Such changes could, among other things, require: additional testing prior to seeking marketing authorization, changes to manufacturing methods recalls, replacement or discontinuance of our products; or additional record keeping.

The FDA's and other regulatory authorities' policies may change and additional government regulations may be promulgated that could prevent, limit or delay marketing authorization of any product candidates we develop. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may be subject to enforcement action and we may not achieve or sustain profitability.

The EU regulatory landscape concerning medical devices is evolving. On April 5, 2017, Regulation (EU) 2017/746 of the European Parliament and of the Council on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU, or the IVDR, was adopted to establish a modernized and more robust EU legislative framework, with the aim of ensuring better protection of public health and patient safety. Unlike directives, the IVDR does not need to be transposed into national law and therefore reduces the risk of discrepancies in interpretation across the different European markets.

The IVDR will become applicable five years after publication (on May 26, 2022). Once applicable, the IVDR will among other things:

- strengthen the rules on placing devices on the market and reinforce surveillance once they are available;
- establish explicit provisions on manufacturers' responsibilities for the follow-up of the quality, performance and safety of devices placed on the market;
- establish explicit provisions on importers' and distributors' obligations and responsibilities;
- impose an obligation to identify a responsible person who is ultimately responsible for all aspects of compliance with the requirements of the new regulation;
- improve the traceability of medical devices throughout the supply chain to the end-user or patient through the introduction of a unique identification number, to increase the ability of manufacturers and regulatory authorities to trace specific devices through the supply chain and to facilitate the prompt and efficient recall of medical devices that have been found to present a safety risk;

- set up a central database (Eudamed) to provide patients, healthcare professionals and the public with comprehensive information on products available in the EU; and

- strengthen rules for the assessment of certain high-risk devices that may have to undergo an additional check by experts before they are placed on the market.

These modifications may have an effect on the way we conduct our business in the EEA.

Changes in funding for, or disruptions caused by global health concerns impacting, the FDA and other government agencies could hinder their ability to hire and retain key leadership and other personnel, or otherwise prevent new medical device products from being developed, authorized or commercialized in a timely manner, which could negatively impact our business.

The ability of the FDA, foreign regulatory agencies and notified bodies to review, authorize and certify the sale of new products can be affected by a variety of factors, including government budget and funding levels; its ability to hire and retain key personnel and accept the payment of user fees; statutory, regulatory, and policy changes; and other events that may otherwise affect the FDA's ability to perform routine functions. Average review times at the FDA have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for new devices, including in vitro diagnostics to be reviewed and/or authorized for marketing by necessary government agencies, which would adversely affect our business. For example, over the last several years, including for 35 days beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities.

On July 10, 2020, the FDA announced its intention to resume certain on-site inspections of domestic manufacturing facilities subject to a risk-based prioritization system which had been postponed previously due to the COVID-19 pandemic. The FDA intends to use this risk-based assessment system to identify the categories of regulatory activity that can occur within a given geographic area, ranging from mission critical inspections to resumption of all regulatory activities. Other regulatory authorities may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA, other regulatory authorities or notified bodies from conducting business as usual or conducting inspections, reviews or other regulatory activities, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

For instance, in the EU, notified bodies must be officially designated to certify products and services in accordance with the IVDR. Only a few notified bodies have been designated so far but the COVID-19 pandemic has significantly slowed down their designation process. Without IVDR designation, notified bodies may not yet start certifying devices in accordance with the new Regulation. As only a few notified bodies have been IVDR-designated they are facing a heavy workload and their review times have lengthened. This situation could impact the way we are conducting our business in the EU and the EEA.

If we are unable to effectively adapt to changes in the healthcare industry, including changes to laws and regulations regarding or affecting the U.S. healthcare reform, our business may be harmed.

Federal, state and local legislative bodies frequently pass legislation and promulgate regulations relating to healthcare reform or that affect the healthcare industry. We anticipate that there will continue to be increased government oversight and regulation of the healthcare industry in the future. We cannot predict the ultimate content, timing or effect of any new healthcare legislation or regulations, nor is it possible at this time to estimate the impact of potential new legislation or regulations on our business. It is possible that future legislation enacted by Congress or state legislatures, or regulations promulgated by regulatory authorities at the federal or state level, could adversely affect our business.

Our failure to maintain compliance of our future clinical laboratory operations with applicable laws could result in substantial civil or criminal penalties

The operation of a clinical laboratory by us will be in a highly regulated environment which, among other things, will require maintaining compliance with CLIA certification and state clinical laboratory licensing requirements. Failure to maintain compliance with these requirements may result in a range of enforcement actions, including certificate or license suspension, limitation, or revocation, directed plan of action, onsite monitoring, civil monetary penalties and criminal sanctions. Such failure may also result in significant adverse publicity. Any of these consequences could limit or entirely prevent our continued operation and therefore impact our financial performance.

Failure in, or security breaches or incidents impacting, our information technology, storage systems or our clinical laboratory equipment could significantly disrupt our operations and our research and development efforts.

Our ability to execute our business strategy will depend, in part, on the continued and uninterrupted performance of our information technology, or IT, systems, which support our operations, including at our proposed clinical laboratories, and our research and development efforts. We are dependent on our IT systems for many aspects of our business, including our needs to retain and store our confidential and proprietary business information and to receive and process test orders, securely store patient health records and deliver the results of our tests. The integrity and protection of our own data, and that of our customers and employees, is critical to our business. The regulatory environment governing information, security and privacy and data protection laws is increasingly demanding and continues to evolve. IT systems are vulnerable to damage from a variety of sources, including telecommunications or network failures, cyberattacks (including ransomware attacks) and other malicious human acts from criminal hackers, hacktivists, state-sponsored intrusions and other attacks, industrial espionage and employee malfeasance, breaches and incidents due to employee error or negligence, and natural disasters. Moreover, despite network security and back-up measures, some of our servers are potentially vulnerable to physical or electronic break-ins, computer viruses and other malicious code similar disruptive problems.

High-profile security breaches and incidents at other companies and in government agencies have increased in recent years, and security industry experts and government officials have warned about the risks of hackers and cyber-attacks targeting businesses such as ours. Cyber-attacks are becoming more sophisticated and frequent, and in some cases have caused significant harm. Computer hackers and others routinely attempt to breach the security of technology products, services and systems, and to fraudulently induce employees, customers, or others to disclosure information or unwittingly provide access to systems or data. Much of our workforce currently works remotely rather than in our offices, and we may be more susceptible to security breaches and incidents as a result. Our service providers may be more susceptible to security breaches and other security incidents while social distancing measures restrict the ability of their employees to work at offices to combat the COVID-19 pandemic.

We may in the future experience attempted or successful cyber-attacks of our IT systems or networks. To date, we have not experienced any material cyber-attacks. However, any security breach or incident impacting, or interruption could compromise our networks and the information stored therein, including algorithms relating to our products, could be accessed by unauthorized parties, publicly disclosed, lost, inaccessible or unavailable, corrupted, or stolen. Despite the precautionary measures we have taken to prevent unanticipated problems that could affect our IT systems, unauthorized access to our systems, or disruptions or other security breaches impacting our IT systems, and any unauthorized access to, or, loss, inaccessibility, unavailability, corruption, theft or disclosure could also disrupt our operations, including our ability to:

- process tests, provide test results, bill payors or patients;
- process claims and appeals;
- provide customer assistance services;
- conduct research and development activities;
- collect, process and prepare company financial information;
- provide information about our tests and other patient and healthcare provider education and outreach efforts through our website; and
- and manage the administrative aspects of our business and damage our reputation.

Any such breach, incident, or other compromise of IT systems or data, or the perception that any of these has occurred, could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, such as the Health Insurance Portability and Accountability Act of 1996, or HIPAA, similar U.S. state data protection regulations, including the California Consumer Privacy Act, or CCPA, the EU General Data Protection Regulation, or GDPR, and other regulations, the breach of which could result in claims, complaints, regulatory investigations and other proceedings, and significant fines, penalties, and other liability. We also may be required to incur significant costs in an effort to detect and prevent security breaches and other security-related incidents. Additionally, information obtained by third parties in connection with past or future cyberattacks or other security breaches or incidents could be used in ways that adversely affect our company or our stockholders.

Further, third-party service providers who support our operations, and our independent contractors (including CROs), consultants, collaborators, and service providers also may suffer interruptions and disruptions of systems and other breaches, incidents, or other compromises of or impacting their IT systems or data that they process or maintain for us, which may lead to any of the foregoing. We and our third-party service providers may not have the resources or technical sophistication to anticipate or prevent all cyberattacks or other sources of security breaches or incidents, and we or they may face difficulties or delays in identifying and responding to cyberattacks and data security breaches and incidents. In addition, the interpretation and application of consumer, health related and security, privacy and data protection laws in the United States, Europe and elsewhere are often uncertain, contradictory and in flux, such as in the area of international transfers of personal data. Complying with these various laws, and satisfying healthcare providers' and patients' evolving expectations with respect to data protection, could cause us to incur substantial costs or require us to change our business practices and compliance procedures in a manner adverse to our business.

We do not maintain insurance policies for cybersecurity-related matters, data handling or data security liabilities. The successful assertion of one or more large claims against us could have a material adverse effect on our business, including our financial condition, operating results, and reputation

Potential conflicts of interest between our management, Board of Directors, and significant stockholders and Tiziana could result in a divergence of interest between management and investors.

Certain directors, management personnel, and significant stockholders of Tiziana are also our directors, officers and significant stockholders. Additionally, a majority of the Board, as of the date hereof, consists of individuals who are also affiliated with Tiziana. For the year ended December 31, 2022 and 2021, Tiziana has received cash fees of approximately $0 and $12,434, respectively, from us in consideration for providing certain services to us including, but not limited to, management and administrative services. Conflicts of interest may arise between the best interest of our stockholders and Tiziana with respect to the performance of services by Tiziana by us. There can be no assurances that any such conflicts will be resolved in our favor or will not adversely affect our business, operations or operating results.

Certain members of our management do not devote their full time to our company and certain of our officers and directors may have conflicts of interest.

While our executive officers devote such time to us as they deem reasonable and necessary to discharge the business of our company, our officers have professional interests in a variety of activities other than those relevant to us and are not required to devote any minimum amount of time to our business. Keeren Shah, our Chief Financial Officer also serves as Chief Financial Officer of Tiziana Life Sciences, OKYO Pharma Ltd and Rasna Therapeutics Inc. Accordingly, conflicts may arise in the allocation of time between our company and one or more of these activities. While we expect that our board of directors and management will exercise their fiduciary obligation to our company, there are no assurances any conflicts of interest which may arise will be resolved in our favor.

Risks Specific to Our Financial Position and the Future Financing of the Business

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

We are a clinical stage diagnostic company with a limited operating history. Since our inception in May 2013, we have incurred significant net losses. Our net losses were $3,746,419 and $670,614 for the year ended December 31, 2022 and 2021, respectively. As of December 31, 2022, we had an accumulated deficit of $4,471,281. We expect that it could be several years, if ever, before we have a commercialized product candidate. We expect to continue to incur significant and increasing operating expenses and losses for the foreseeable future. These net losses will adversely impact our stockholders' equity and net assets and may fluctuate significantly from quarter to quarter and year to year. We anticipate that our expenses will increase substantially if, and as, we:

- manufacture our product candidates in accordance with current good manufacturing practices, or cGMP, for clinical trials or potential commercial sales;
- establish a sales, marketing and distribution infrastructure to commercialize any product candidate for which we may obtain marketing approval;
- develop, maintain, expand and protect our intellectual property portfolio;
- identify, assess, and acquire or in-license other product candidates and technologies;
- secure, maintain or obtain freedom to operate for any in-licensed technologies and products;
- address any competing technological and market developments; and
- expand our operations in the United States and Europe.

We may never succeed in any or all of these activities and, even if we do, we may never generate revenues that are significant or large enough to achieve profitability. If we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would decrease the value of our company and could impair our ability to raise capital, maintain our research and development, or R&D, efforts expand our business or continue our operations.

We need substantial additional funding to complete the development of its product candidates, which may not be available on acceptable terms, if at all. Failure to obtain this necessary capital when needed may force us to delay, limit or terminate certain of our product development, research operations or future commercialization efforts, if any

Our operations have consumed substantial amounts of cash since inception, and we expect our expenses to increase significantly in connection with our ongoing activities, particularly as we continue the R&D of, initiate further clinical trials of and seek marketing approval for, our product candidates. In addition, if we obtain marketing approval for our product candidates, we expect to incur significant expenses related to product sales, marketing, manufacturing and distribution.

Furthermore, we expect to incur additional costs associated with operating as a public reporting company in the United States.

If we are unable to obtain adequate funding on a timely basis, we may be required to significantly curtail, delay or discontinue our R&D programs of our product candidates or any future commercialization efforts, be unable to expand our operations or be unable to otherwise capitalize on our business opportunities, as desired, which could harm our business and potentially cause a discontinuation of operations.

Our financial condition and operating results have varied significantly in the past and losses are continuing and increasing due to a variety of factors, many of which are beyond our control.

Our financial condition and operating results have varied significantly in the past and losses are continuing and increasing due to a variety of factors, many of which are beyond our control. Factors relating to our business that may contribute to these fluctuations include:

- continuing our current research and development programs, including conducting preclinical and clinical studies for product candidates;
- initiating clinical trials for product candidates;
- the success of our clinical trials through all phases of clinical development;
- delays in the commencement, enrollment and timing of clinical trials;
- our ability to secure and maintain collaborations, licensing or other arrangements for the future development and/or commercialization of our product candidates, as well as the terms of those arrangements;
- our ability to obtain, as well as the timeliness of obtaining, additional funding to develop our product candidates;
- the results of clinical trials or marketing applications for product candidates that may compete with our product candidates;
- competition from existing products or new products that may receive marketing approval;
- potential side effects of our product candidates that could delay or prevent approval or cause an approved product to be taken off the market;
- any delays in regulatory review and approval of our product candidates;
- our ability to identify and develop additional product candidates;
- the ability of patients or healthcare providers to obtain coverage or sufficient reimbursement for our products;
- our ability, and the ability of third parties such as Clinical Research Organizations (“CROs”) to adhere to clinical study and other regulatory requirements;
- the ability of third-party manufacturers to manufacture our product candidates and key ingredients needed to conduct clinical trials and, if approved, successfully commercialize our products;
- the costs to us, and our ability as well as the ability of any third-party collaborators, to obtain, maintain and protect our intellectual property rights;
- costs related to and outcomes of potential intellectual property litigation;
- our ability to adequately support future growth;
- our ability to attract and retain key personnel to manage our business effectively; and
- our ability to build our finance infrastructure and, to the extent required, improve our accounting systems and controls.

Developing new products and services is a speculative and risky endeavor. Products or services that initially show promise may fail to achieve the desired results or may not achieve acceptable levels of analytical accuracy or clinical utility. We may need to alter our products in development and repeat clinical studies before we identify a potentially successful product or service. Product development is expensive, may take years to complete and can have uncertain outcomes. Failure can occur at any stage of the development. If, after development, a product or service appears successful, we may, depending on the nature of the product or service, still need to obtain U.S. Food and Drug Administration, or FDA, and other regulatory clearances, authorizations or approvals before we can market it. The FDA's clearance, authorization or approval pathways are likely to involve significant time, as well as additional research, development and clinical study expenditures. The FDA may not clear, authorize or approve any future product or service we develop. Even if we develop a product or service that receives regulatory clearance, authorization or approval, we would need to commit substantial resources to commercialize, sell and market it before it could be profitable, and the product or service may never be commercially successful. Additionally, development of any product or service may be disrupted or made less viable by the development of competing products or services.

New potential products and services may fail any stage of development or commercialization and if we determine that any of our current or future products or services are unlikely to succeed, we may abandon them without any return on our investment. If we are unsuccessful in developing additional products or services, our potential for growth may be impaired.

In cases where we are successful in obtaining regulatory approval to market one or more of our product candidates, our revenue will be dependent, in part, upon the size of the markets in the territories for which we gain regulatory approval, the accepted price for the product, the ability to obtain coverage and reimbursement, and whether we own the commercial rights for that territory. If the number of our addressable patients is not as significant as we estimate, the indication approved by regulatory authorities is narrower than we expect, or the treatment population is narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenue from sales of such products, even if approved.

We expect our research and development expenses to continue to be significant in connection with our continued investment in our ongoing and planned clinical trials for our current product candidates and any future product candidates we may develop. Furthermore, if we obtain regulatory approval for our product candidates, we expect to incur increased sales and marketing expenses. In addition, once we are a public company, we will incur additional costs associated with operating as a public company. As a result, we expect to continue to incur significant and increasing operating losses and negative cash flows for the foreseeable future. These losses have had and will continue to have a material adverse effect on our stockholders' equity, financial position, cash flows and working capital.

Our recurring losses from operations raise substantial doubt about our ability to continue as a going concern

Since inception, we have incurred cumulative losses from operations, negative cash flows from operating activities and have accumulated deficits of $4,471,281 and $724,862 as of December 31, 2022 and 2021, respectively. We expect to continue to generate significant operating losses for the foreseeable future. Based on our recurring losses from operations since inception and continued cash outflows from operating activities, in our audited consolidated financial statements for the years ended December 31, 2022 and 2021, we concluded that this circumstance raised substantial doubt about our ability to continue as a going concern within one year from the original issuance date of such financial statements. Similarly, in its report on the consolidated financial statements for the years ended December 31, 2022 and 2021, our independent registered public accounting firm included an emphasis of matter paragraph stating that our recurring losses from operations and continued cash outflows from operating activities raised substantial doubt about our ability to continue as a going concern. Our consolidated financial statements for the years ended December 31, 2022 and 2021 do not include any adjustments that may result from the outcome of this uncertainty.

Risks Related to our Business Operations

Risks relating to managing growth, employee matters and other risks relating to our business

As of December 31, 2022, we had four full-time employees. As we mature, we expect to expand our full-time employee base and hire more scientists, technicians and other skilled and experienced personnel. Our management may need to divert a disproportionate amount of its attention away from the day-to-day activities and devote a substantial amount of time toward managing these growth activities. We may not be able to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure, operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Our expected growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of additional products or technologies. If the management is unable to effectively manage our growth, our expenses may increase more than expected, the ability to generate and/or grow revenues could be reduced, and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize products and compete effectively will depend, in part, on our ability to effectively manage any future growth.

Challenges in identifying and retaining key personnel could impair our ability to conduct and grow our operations effectively

Our ability to compete in the highly competitive medical device industry depends upon our ability to attract and retain highly qualified management and sales teams. We are intending to recruit our own commercial team and expand our existing central infrastructure team. Many of the other pharmaceutical companies and academic institutions that we compete against for qualified personnel have greater financial and other resources, different risk profiles and a longer history in the industry than it does. We might not be able to attract or retain these key persons on conditions that are economically acceptable. Our inability to attract and retain these key persons could have a material adverse effect on our business, prospects, financial conditions and results of operation.

We are reliant upon the expertise and continued service of a small number of key individuals of our management, Board of Directors and scientific advisors

We rely on the expertise and experience of a small number of key individuals of our management, Directors and scientific advisors to continue to develop and manage our business. The retention of their services cannot be guaranteed. Accordingly, the departure of these key individuals could have a negative impact on our operations, financial condition, our ability to execute our business strategy and future prospects.

We intend to rely, in part, on the recruitment of appropriately qualified personnel, including personnel with a high level of scientific and technical expertise in the industry. We may be unable to find a sufficient number of appropriately highly trained individuals to satisfy its growth rate which could affects its ability to develop products as planned.

In addition, if we fail to succeed in pre-clinical or clinical studies, it may make it more challenging to recruit and retain appropriately qualified personnel. Our inability to recruit key personnel or the loss of the services of key personnel or consultants may impede the progress of our R&D objectives as well as the commercialization of our lead and other products, which could have a material adverse effect on our business, results of operations and financial condition. We do not have employment agreements with any of our executive officers, and they may voluntarily terminate their employment with us at any time.

We may become subject to product liability claims

We face an inherent risk of product liability and associated adverse publicity as a result of the clinical testing of our products and sales of our products once marketing approval is received from relevant regulatory authorities.

Criminal or civil proceedings might be filed against us by study subjects, patients, relevant regulatory authorities, pharmaceutical companies, and any other third party using or marketing our products. Any such product liability claims may include allegations of defects in manufacturing or design, negligence, strict liability, a breach of warranties and a failure to warn of dangers inherent in the product.

If we cannot successfully defend ourself against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our products, if approved. Even if we successfully defend ourself against such product liability claims it could require significant financial and management resources. Regardless of the merits or eventual outcome, product liability claims may result in:

- decreased demand for our products due to negative public perception;
- injury to our reputation;
- withdrawal of clinical study participants or difficulties in recruiting new study participants;
- initiation of investigations by regulators;
- costs to defend or settle the related litigation;
- diversion of management's time and our resources;
- substantial monetary awards to patients, study participants or subjects;
- product recalls, withdrawals or labelling, marketing or promotional restrictions;
- loss of revenues from product sales; or
- the inability to commercialize any our products, if approved.

Although we intend to maintain levels of insurance customary for our sector to cover our current and future business operations, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. Our insurance policies also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. In such cases, we would have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. Any such judgment could adversely affect our business, financial condition, results of operations, business reputation and could adversely affect the market for our products.

If we or our partners, licensees and subcontractors were unable to obtain and maintain appropriate insurance coverage at an acceptable cost, or to protect ourself or themselves in any way against actions for damages, this would seriously affect the marketing of our products and, more generally, be detrimental to our business, prospects, results of operations or financial condition.

The ongoing COVID-19 pandemic and actions taken in response to it may result in disruptions to our business operations, which would have a materially adverse effect on our business, financial position, operating results, and cash flows.

In December 2019, the strain of coronavirus, SARS-CoV-2, causing the disease known as COVID-19, was reported to have surfaced in Wuhan, China. In March 2020, the WHO declared the COVID-19 outbreak a global pandemic. Since being discovered, new variants of SARS-CoV-2 have emerged.

Moreover, we may experience additional disruptions that could severely impact our business and development activities, including, but not limited to, strain on our suppliers and other third parties, possibly resulting in supply disruptions of our product candidates for preclinical development and potential future clinical trials we expect to initiate, decrease in clinical enrollment in any clinical trials we initiate, and the ability to raise capital when needed on acceptable terms, if at all. The COVID-19 pandemic continues to impact the global supply chain, causing disruptions to service providers, logistics, and the flow and availability of supplies and products. Disruptions in our operations or supply chain, whether as a result of government intervention, restricted travel, quarantine requirements, or otherwise, could negatively impact our ability to proceed with our clinical trials, preclinical development, and other activities and delay our ability to receive product approval and generate revenue.

In addition, the continued spread of COVID-19 may lead to severe disruption and volatility in the global capital markets, which could increase our cost of capital and adversely affect our ability to access the capital markets. It is possible that the continued spread of COVID-19 could cause an economic slowdown or recession or cause other unpredictable events, each of which could adversely affect our business, results of operations, or financial condition.

Market and economic conditions may negatively impact our business, financial condition and share price.

Concerns over medical epidemics, energy costs, geopolitical issues, the U.S. mortgage market and a deteriorating real estate market, unstable global credit markets and financial conditions, and volatile oil prices have led to periods of significant economic instability, diminished liquidity and credit availability, declines in consumer confidence and discretionary spending, diminished expectations for the global economy and expectations of slower global economic growth, increased unemployment rates, and increased credit defaults in recent years. Our general business strategy may be adversely affected by any such economic downturns (including the current downturn related to inflation and the Russia-Ukraine conflict), volatile business environments and continued unstable or unpredictable economic and market conditions. If these conditions continue to deteriorate or do not improve, it may make any necessary debt or equity financing more difficult to complete, more costly, and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance, and share price and could require us to delay or abandon development or commercialization plans.

Clinical trials are expensive, time-consuming, and may not be successful.

Clinical trials are expensive, time-consuming, and may not be successful. They involve the evaluation of diagnostic tests to determine the safety and efficacy of the diagnostic tests necessary for an approved diagnostic technology. Many tests and products in human clinical trials fail to demonstrate the desired safety and efficacy characteristics. Even if our tests and products candidates progress successfully through initial or subsequent human testing, they may fail in later phases of development. We may engage others to conduct our clinical trials, including clinical research organizations and government-sponsored agencies. These trials may not start or be completed as we forecast or may not achieve desired results.

We may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to receive marketing authorization or commercialize our diagnostic technologies, including:

- regulators or institutional review boards may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we may experience delays in reaching, or fail to reach, agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites;
- clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product and test development programs;
- the number of patients required for clinical trials may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate, or participants may drop out of these clinical trials at a higher rate than we anticipate;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- we may have to suspend or terminate clinical trials for various reasons, including a finding that the participants are being exposed to unacceptable health risks;

- regulators or institutional review boards may require that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;

- the cost of clinical trials may be greater than we anticipate; or

- regulators may revise the requirements for approving our diagnostic technologies, or such requirements may not be as we anticipate.

If we are required to conduct additional clinical trials or other testing beyond those that we currently contemplate, if we are unable to successfully complete clinical trials or other testing, if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we may:

- be delayed in obtaining marketing approval;

- not obtain marketing approval at all, which would seriously impair our viability;

- obtain marketing approval in some countries and not in others;

- obtain approval for indications or patient populations that are not as broad as we intend or desire;

- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings;

- be subject to additional post-marketing testing requirements; or

- have the diagnostic test removed from the market after obtaining marketing approval.

Our product and test development costs will increase if we experience delays in clinical testing or marketing approvals. We do not know whether any of our preclinical studies or clinical trials will begin as planned, will need to be restructured, or will be completed on schedule or at all. Significant preclinical or clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our diagnostic technology or allow our competitors to bring diagnostic tests to market before we do, potentially impairing our ability to successfully commercialize our diagnostic technologies and harming our business and results of operations.

If testing of a particular diagnostic test or product candidate does not yield successful results, then we will be unable to commercialize that test or product candidate.

We must demonstrate that the product safety and efficacy of our candidates for diagnostic tests and product candidates in humans through extensive clinical testing. Our research and development programs are at an early stage of development. We may experience numerous unforeseen events during, or as a result of, the testing process that could delay or prevent commercialization of any test or product, including the following:

- the results of pre-clinical studies may be inconclusive, or they may not be indicative of results that will be obtained in human clinical trials;

- safety and efficacy results attained in early human clinical trials may not be indicative of results that are obtained in later clinical trials;

- after reviewing test results, we may abandon projects that we might previously have believed to be promising;

- we or our regulators may suspend or terminate clinical trials because the participating subjects or patients are being exposed to unacceptable health risks; and

- our test or product candidates may not have the desired effects or may include undesirable side effects or other characteristics that preclude regulatory approval or limit their commercial use if approved.

Even if our diagnostic tests or product candidates receive marketing approval, they may fail to achieve the degree of market acceptance by physicians, patients, third-party payers and others in the medical community necessary for commercial success.

Even if our products receive marketing approval, they may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payers, and others in the medical community. If we do not generate significant product revenues, we may not become profitable. The degree of market acceptance of our products and tests, if approved for commercial sale, will depend on a number of factors, including:

- their efficacy, safety and other potential advantages compared to alternative tests or products;
- our ability to offer them for sale at competitive prices;
- their convenience and ease of administration compared to alternative diagnostics or treatments;
- the willingness of the target patient population to try new diagnostic tests and of physicians to order these tests;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength of marketing and distribution support;
- the availability of governmental agencies and third-party medical insurance and adequate reimbursement for our diagnostic tests or product candidates;
- any restrictions on the use of our diagnostic tests or product candidates together with other diagnostic methods or therapeutic treatments;
- any restrictions on the use of our diagnostic tests or product candidates together with other medications;
- inability of certain types of patients to produce adequate samples for analysis in the use of our diagnostic tests; and
- inability of certain types of patients to use our diagnostic tests.

If we are unable to address and overcome these and similar concerns, our business and results of operations could be substantially harmed.

If we are unable to establish effective sales, marketing, and distribution capabilities or enter into agreements with third parties with such capabilities, we may not be successful in commercializing our diagnostic tests or product candidates if and when they are approved.

We do not have a sales or marketing infrastructure and have limited experience in the sale, marketing, or distribution of our diagnostic tests or product candidates. To achieve commercial success for any diagnostic test or product candidates for which we obtain marketing approval, we will need to successfully establish and maintain relationships directly and with third parties to perform sales and marketing functions.

Factors that may inhibit our efforts to commercialize our diagnostic tests or product candidates on our own include:

- our inability to recruit, train, and retain adequate numbers of effective sales, technical support, and marketing personnel;
- the inability of sales personnel to obtain access to or educate physicians on the benefits of our diagnostic tests or product candidates;

- the lack of complementary diagnostic tests or products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive diagnostic tests or product lines;

- unforeseen costs and expenses associated with creating an independent sales, technical support, and marketing organization; and

- the inability to obtain sufficient coverage and reimbursement from third-party payors and governmental agencies.

If we do not establish sales, marketing, and distribution capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our diagnostic tests or product candidates.

If we are unable to convince physicians as to the benefits of our proposed diagnostic tests or product candidates, we may incur delays or additional expense in our attempt to establish market acceptance.

Broad use of our proposed diagnostic tests and products may require pathology laboratories and physicians to be informed regarding our proposed diagnostic tests and products and the intended benefits. Inability to carry out this physician education process may adversely affect market acceptance of our proposed diagnostic tests or products. We may be unable to timely educate physicians regarding our proposed diagnostic tests or products in sufficient numbers to achieve our marketing plans or to achieve acceptance of our diagnostic tests or products. Any delay in physician education may materially delay or reduce demand for our diagnostic tests or products. In addition, we may expend significant funds toward physician education before any acceptance or demand for our proposed diagnostic tests or products is created, if at all.

We face substantial competition, which may result in others discovering, developing, or commercializing competing diagnostic tests or products before or more successfully than we do.

The development and commercialization of new diagnostic technologies is highly competitive. We face competition and will face competition with respect to any diagnostic technology that we may seek to develop or commercialize in the future, from major diagnostic and pharmaceutical companies, LDT laboratories, smaller diagnostic and pharmaceutical companies, and biotechnology companies worldwide. Potential competitors also include academic institutions, government agencies, and other public and private research organizations that conduct research, seek patent protection, and establish collaborative arrangements for research, development, manufacturing, and commercialization.

A substantial number of the companies against which we are competing have or, against which we may compete in the future may have, significantly greater financial resources, established presence in the market, and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals, and marketing approved diagnostic tests or products than we do. Mergers and acquisitions in the diagnostic, pharmaceutical, and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors.

Smaller and other early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific, sales, marketing, and management personnel, establishing clinical trial sites and patient registration for clinical trials, and acquiring technologies complementary to, or necessary for, our programs.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize diagnostic tests or products that are more accurate, more convenient, or less expensive than any diagnostic tests or products that we may develop. Our competitors also may obtain FDA or other regulatory approval for their diagnostic tests or products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a stronger market position. In addition, our ability to compete may be affected in many cases by insurers or other third-party payors.

We may be unable to compete in our target marketplaces, which could impair our ability to generate revenues, thus causing a material adverse impact on our results of operations.

If users of our proposed diagnostic tests or products are unable to obtain adequate reimbursement from third-party payers or governmental agencies or if new restrictive legislation is adopted, market acceptance of our proposed tests or products may be limited, and we may not achieve revenues.

The continuing efforts of government and insurance companies, health maintenance organizations ("HMOs") and other payers of healthcare costs to contain or reduce costs may affect our future revenues and profitability, as well as the future revenues and profitability of our potential customers, suppliers, and collaborative partners and the availability of capital. For example, in certain international markets, pricing or profitability of diagnostic tests and products is subject to government control. In the U.S., given recent federal and state government initiatives directed at lowering the total cost of healthcare, the U.S. Congress and state legislatures will likely continue to focus on healthcare reform, the cost of medical devices, tests and prescription pharmaceuticals, and Medicare and Medicaid reforms. While we cannot predict whether any such legislative or regulatory proposals will be adopted, the announcement or adoption of such proposals could materially harm our business, financial condition, and results of operations.

Our ability to commercialize our proposed tests or products will depend in part on the extent to which appropriate reimbursement levels for the cost of our tests or products are obtained by governmental authorities, private health insurers, and other organizations such as HMOs. Governmental agencies and third-party payers are increasingly challenging the prices charged for medical tests, drugs, and services. Also, the trend toward managed healthcare in the U.S. and the concurrent growth of organizations such as HMOs, which could control or significantly influence the purchase of healthcare services, diagnostics, and drugs, as well as legislative proposals to reform healthcare or reduce government insurance programs, may all result in lower prices for or rejection of our tests or products.

Our employees, independent contractors, consultants, commercial partners and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

Our business operations and current and future relationships with investigators, healthcare professionals, consultants, third-party payors and customers will be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws, health information privacy and security laws, and other healthcare laws and regulations. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties. We are exposed to the risk of employee fraud or other illegal activity by our employees, independent contractors, consultants, commercial partners, vendors and agents acting on behalf of us or our affiliates. Misconduct by these parties could include intentional, reckless and/or negligent conduct that fails to: comply with the regulations of the FDA or foreign health authorities; provide true, complete and accurate information to the FDA or foreign health authorities; comply with manufacturing standards we have established; comply with healthcare fraud and abuse laws in the United States and similar foreign fraudulent misconduct laws; or report financial information or data accurately or to disclose unauthorized activities to us.

The market for our proposed tests and products is competitive and rapidly changing, and new diagnostic technologies which may be developed by others could impair our ability to maintain and grow our business and remain competitive.

The diagnostic industry is subject to rapid and substantial technological change. Developments by others may render our proposed tests or products noncompetitive or obsolete, or we may be unable to keep pace with technological developments or other market factors. Technological competition from diagnostic, pharmaceutical and biotechnology companies, universities, governmental entities, and others diversifying into the field is intense and is expected to increase.

Our resources are limited, and we may experience technical challenges inherent in such technologies. Competitors have developed or are in the process of developing technologies that are, or in the future may be, the basis for competition. Some of these technologies may have an entirely different approach or means of accomplishing similar diagnostic efficacy compared to our proposed tests or products. Our competitors may develop diagnostic technologies that are more effective or less costly than our proposed tests or products and therefore present a serious competitive threat.

The potential widespread acceptance of diagnostic tests that are alternatives to ours may limit market acceptance of our proposed tests or products, even if commercialized. Many of our targeted diseases and conditions can also be detected by other tests or treated by other medications. These tests and treatments may be widely accepted in medical communities and have a longer history of use. The established use of these competitive technologies may limit the potential for our technologies, formulations, tests and products to receive widespread acceptance if commercialized.

Risks Related to Our Reliance on Third Parties

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

We have relied upon and plan to continue to rely upon third parties, including independent clinical investigators and third-party contract research organizations ("CROs"), to conduct our preclinical studies and clinical trials and to monitor and manage data for our ongoing preclinical and clinical programs. In engaging these third parties, we typically have to, and expect to have to, negotiate budgets and contracts, which may result in delays to our development timelines and increases costs. Additionally, there is a limited number of qualified third-party service providers that specialize or have the expertise required to achieve our business objectives, and so it may be challenging to find alternative investigators or CROs, or do so on commercially reasonable terms. We rely on these parties for execution of our preclinical studies and clinical trials, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our preclinical studies and clinical trials is conducted in accordance with the applicable protocol and legal, regulatory and scientific standards, and our reliance on these third parties does not relieve us of our regulatory responsibilities. We and our third-party contractors and CROs are required to comply with Good Clinical Practice ('GCP') requirements, which are regulations and guidelines enforced by the FDA, the Competent Authorities of the Member States of the European Economic Area and comparable foreign regulatory authorities for all of our product candidates in clinical development. Regulatory authorities enforce these GCP requirements through periodic inspections of trial sponsors, principal investigators and clinical trial sites. If we fail to exercise adequate oversight over any of our CROs or if we or any of our CROs fail to comply with applicable GCP requirements, the clinical data generated in our clinical trials may be deemed unreliable and the FDA, EMA or other regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon a regulatory inspection of us or our CROs or other third parties performing services in connection with our clinical trials, such regulatory authority will determine that any of our clinical trials complies with GCP regulations. In addition, our clinical trials must be conducted with product produced under applicable cGMP regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

Further, these investigators and CROs are not our employees and we will not be able to control, other than by contract, the amount of resources, including time, which they devote to our product candidates and clinical trials. If independent investigators or CROs fail to devote sufficient resources to the development of our product candidates, or if their performance is substandard, it may delay or compromise the prospects for approval and commercialization of our product candidates. These investigators and CROs may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical studies or other product development activities, which could affect their performance on our behalf. In addition, the use of third-party service providers requires us to disclose our proprietary information to these parties, which increases the risk that a competitor will discover them or that this information will be misappropriated or disclosed.

If any of our relationships with these third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs or to do so on commercially reasonable terms. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. As a result, our results of operations and commercial prospects would be harmed, our costs could increase and our ability to generate revenues could be delayed.

Repeating clinical trials or switching or engaging additional CROs involves additional cost and requires our management's time and focus. In addition, there is a natural transition period when a clinical trial has to be repeated or when a new CRO commences work. As a result, delays could occur, which could materially impact our ability to meet our desired clinical development timelines.

Our failure to find third party collaborators to assist or share in the costs of product development could materially harm our business, financial condition and results of operations.

Our strategy for the development and commercialization of our proprietary product candidates may include the execution of collaborative arrangements with third parties. Future collaborators will have significant discretion in determining the efforts and resources they apply and may not perform their obligations as expected. Potential third-party collaborators include biopharmaceutical, pharmaceutical and biotechnology companies, academic institutions and other entities. Third-party collaborators may assist us in:

- funding research, pre-clinical development, clinical trials and manufacturing;
- seeking and obtaining regulatory approvals; and
- successfully commercializing any future product candidates.

If we are not able to establish collaboration agreements, we may be required to undertake product development and commercialization at our own expense. Such an undertaking may limit the number of product candidates that we will be able to develop, significantly increase our capital requirements and place additional strain on our internal resources. Our failure to enter into additional collaborations could materially harm our business, financial condition and results of operations.

In addition, our dependence on licensing, collaboration and other agreements with third parties may subject us to a number of risks. These agreements may not be on terms that prove favorable to us and may require us to relinquish certain rights in our product candidates. To the extent we agree to work exclusively with one collaborator in a given area, our opportunities to collaborate with other entities could be curtailed. Lengthy negotiations with potential new collaborators may lead to delays in the research, development or commercialization of product candidates. The decision by our collaborators to pursue alternative technologies or the failure of our collaborators to develop or commercialize successfully any product candidate to which they have obtained rights from us could materially harm our business, financial condition and results of operations.

Risks Related to Commercialization of Our Product Candidates

Even if we are successful in completing all pre-clinical studies and clinical trials, we may not be successful in commercializing one or more of our product candidates.

Even if we complete the necessary pre-clinical studies and clinical trials, the marketing approval process is expensive, time-consuming and uncertain and may prevent us from obtaining approvals for the commercialization of some or all of our product candidates. If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals, we will not be able to commercialize our product candidates, and our ability to generate revenue will be materially impaired.

Our product candidates and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution, export and import are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by the EMA and similar regulatory authorities outside of the United States. Failure to obtain marketing approval for a product candidate will prevent us from commercializing the product candidate. We have not submitted an application for or received marketing approval for any of our product candidates in the United States or in any other jurisdiction.

We have only limited experience in filing and supporting the applications necessary to gain marketing approvals and expect to rely on third-party clinical research organizations or other third-party consultants or vendors to assist us in this process. Securing marketing approval requires the submission of extensive pre-clinical and clinical data and supporting information to regulatory authorities for each indication to establish the product candidate's safety and efficacy. Securing marketing approval also requires the submission of information about the drug manufacturing process to, and inspection of manufacturing facilities by, the regulatory authorities.

The process of obtaining marketing approvals, both in the United States and abroad, is expensive, may take many years, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted drug application, may cause delays in the approval or rejection of an application. Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data is insufficient for approval and require additional pre-clinical, clinical or other studies. In addition, varying interpretations of the data obtained from pre-clinical studies and clinical trials could delay, limit or prevent marketing approval of a product candidate. Any marketing approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved drug not commercially viable.

Risks Related to Our Common Stock

Further issuances of Common Shares may be dilutive

We may decide to offer additional shares in the future for capital raising or other purposes. Shareholders who do not take up or who are not eligible to take such an offer will find their proportionate ownership and voting interests in us to be reduced. An additional offering could also have a material adverse effect on the market price of the Common Shares as a whole.

Economic conditions and current economic weakness

Any economic downturn either globally or locally in any area in which we operate may have an adverse effect on the demand for our services. A more prolonged economic downturn may restrict our ability to generate a profit.

In addition, although signs of economic recovery have been perceptible in certain countries, the sustainability of a global economic upturn is not yet assured. If economic conditions remain uncertain this might have an adverse impact on our operations and business results.

We presently do not intend to pay cash dividends on our common stock.

We expect that no cash dividends will be paid on the common stock in the foreseeable future. While our dividend policy will be based on the operating results and capital needs of the business, it is anticipated that all earnings, if any, will be retained to finance the future expansion of our business.

Our principal shareholder has a significant holding in the company which may give them influence in certain matters requiring approval by shareholders, including approval of significant corporate transactions in certain circumstances

As of December 31, 2022, Gabriele Cerrone and Planwise Group Limited, a company in which Mr. Cerrone is the sole beneficial owner, held a beneficial ownership interest in aggregate of approximately 33.77% of our outstanding common stock. Accordingly, Mr. Cerrone will, as a practical matter, be able to significantly influence certain matters requiring approval by stockholders, including approval of significant corporate transactions in certain circumstances. Such concentration of ownership may also have the effect of delaying or preventing any future proposed change in control of the Company. The trading price of the common stock could be adversely affected if potential new investors are disinclined to invest in us because they perceive disadvantages to a large shareholding being concentrated in the hands of a single shareholder.

We are an "emerging growth company", and there are reduced disclosure requirements applicable to emerging growth companies

We are an "emerging growth company" as defined in the SEC's rules and regulations and we will remain an emerging growth company until the earlier to occur of (1) the last day of 2025, (2) the last day of the fiscal year in which we have total annual gross revenues of at least $1.07 billion, (3) the last day of the fiscal year in which we are deemed to be a "large accelerated filer", under the SEC's rules, which means the market value of our equity securities that is held by non-affiliates exceeds $700 million as of the prior June 30th, and (4) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period. For so long as we remain an emerging growth company, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include:

- not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act;
- reduced disclosure obligations regarding executive compensation; and
- an exemption from the requirement to seek nonbinding advisory votes on executive compensation or golden parachute arrangements.

We may choose to take advantage of some, but not all, of the available exemptions. We have taken advantage of reduced reporting burdens in this registration statement. In particular, we have not included all of the executive compensation information that would be required if we were not an emerging growth company.

In addition, the JOBS Act provides that an emerging growth company may take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We are considering whether we will take advantage of the extended transition period for complying with new or revised accounting standards.

We will incur increased costs as a result of operating as a U.S. public company, and our management will be required to devote substantial time to new compliance initiatives

As a U.S. public company, and particularly after we are no longer an emerging growth company, we will incur significant legal, accounting and other expenses that we will not incur as a private company. In addition, the Sarbanes-Oxley Act of 2002, and rules subsequently implemented by the SEC have imposed various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, we expect that these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance.

Pursuant to Section 404, we will be required to furnish a report by our management on our internal control over financial reporting, including an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. However, while we remain an emerging growth company, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with Section 404 within the prescribed period, we will be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk we will not be able to conclude within the prescribed timeframe that our internal control over financial reporting is effective as required by Section 404. This could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

If we are unable to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, shareholders could lose confidence in our financial and other public reporting, which would harm our business

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404, or any subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. Inferior internal controls could also cause you to lose confidence in our reported financial information.

Our management will be required to assess the effectiveness of these controls annually. However, for as long as we are an emerging growth company, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal controls over financial reporting pursuant to Section 404. We could be an emerging growth company for up to five years. An independent assessment of the effectiveness of our internal controls over financial reporting could detect problems that our management's assessment might not. Undetected material weaknesses in our internal controls over financial reporting could lead to financial statement restatements and require us to incur the expense of remediation.

We have been a private company with limited accounting personnel to adequately execute our accounting processes and limited supervisory resources with which to address our internal control over financial reporting. As a newly public company, we have designed a control environment as required of public companies under the rules and regulations of the SEC. The Company identified a material weakness as of December 31, 2022 over internal controls over financial reporting due to a lack of accounting resources. If we fail to remediate a material weakness, or if we experience material weaknesses in the future or otherwise fail to maintain an effective system of internal controls in the future, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect investor confidence in us and, as a result, the value of our common stock.

Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud

Our disclosure controls and procedures are designed to reasonably assure that information required to be disclosed by us in reports we file or submit under the Exchange Act is accumulated and communicated to management, recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements or insufficient disclosures due to error or fraud may occur and not be detected.

Future changes to tax laws could materially adversely affect our company and reduce net returns to our shareholders

Recently enacted U.S. tax legislation has significantly changed the U.S. federal income taxation of U.S. corporations, including by reducing the U.S. corporate income tax rate, limiting interest deductions, modifying or repealing many business deductions and credits (including reducing the business tax credit for certain clinical testing expenses incurred in the testing of certain drugs for rare diseases or conditions generally referred to as "orphan drugs"), adopting elements of a territorial tax system, imposing a one-time transition tax, or repatriation tax, on all undistributed earnings and profits of certain U.S.- owned foreign corporations, revising the rules governing net operating losses and the rules governing foreign tax credits, and introducing new anti-base erosion provisions. Many of these changes are effective immediately, without any transition periods or grandfathering for existing transactions.

While some of the changes made by the tax legislation may adversely affect us in one or more reporting periods and prospectively, other changes may be beneficial on a going forward basis.

Trading on the OTC Markets may be volatile and sporadic, which could depress the market price of our common stock and make it difficult for our stockholders to resell their shares.

Our common stock is quoted on the OTC Markets. Trading in stock quoted on the OTC Markets is often thin and characterized by wide fluctuations in trading prices, due to many factors that may have little to do with our operations or business prospects. This volatility could depress the market price of our common stock for reasons unrelated to operating performance. Moreover, the OTC Markets is not a stock exchange, and trading of securities on the OTC Markets is often more sporadic than the trading of securities listed on a quotation system like NASDAQ or a stock exchange like the NYSE MKT. Accordingly, shareholders may have difficulty reselling any of their shares and the lack of liquidity may negatively impact our ability to pursue strategic alternatives.

Climate change initiatives could materially and adversely affect our business, financial condition, and results of operations.

Both domestic and international legislation to address climate change by reducing greenhouse gas emissions and establishing a price on carbon could create increases in energy costs and price volatility. Considerable international attention is now focused on development of an international policy framework to address climate change. Consumers and businesses also may change their behavior on their own as a result of these concerns. We will need to respond to new laws and regulations as well as consumer and business preferences resulting from climate change concerns. We may face cost increases, asset value reductions and operating process changes. The impact on our business will likely vary depending on specific attributes, including reliance on or role in carbon intensive activities.

Item 1b. Unresolved Staff Comments

Not applicable.

Item 2. Properties

We do not own any property but utilize approximately 75 square feet of office space in London from Tiziana for which we reimburse Tiziana at cost through a shared services agreement. We believe that our existing facilities are adequate to meet our current needs for the foreseeable future, and that suitable additional alternative spaces will be available in the future on commercially reasonable terms if needed.

Item 3. Legal Proceedings

We are not party to any material legal matters or claims. In the future, we may become party to legal matters and claims arising in the ordinary course of business, the resolution of which we do not anticipate would have a material adverse impact on our financial position, results of operations or cash flows.

Item 4. Mine Safety Disclosures

Not applicable.

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

Market information

Our common stock has traded on the OTC QB under the symbol "ACUT" since March 23, 2022.

Number of Stockholders

As of February 15, 2023, we had approximately 522 holders of record of our common stock.

Dividend Policy

Historically, we have not paid any dividends to the holders of shares of our common stock, and we do not expect to pay any such dividends in the foreseeable future as we expect to retain our future earnings for use in the operation and expansion of our business.

Transfer Agent

Our transfer agent for our common stock is Pacific Stock Transfer Company.

Item 6: [Reserved]

Not applicable.

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

Overview

We are a clinical stage diagnostics company dedicated to improving quality of life and outcomes for the more than 18 million people worldwide who are diagnosed with cancer each year. Our plan is to develop and commercialize a suite of novel genomic tests that support decision making along the entire continuum of oncology care. Our focus will be the commercialization of our proprietary genomic test, StemPrintER, for patients with early-stage breast cancer, and we estimate this market opportunity represents more than $1.3 billion in annual revenue.

Our primary product candidate is StemPrintER, a 20-gene prognostic assay intended to predict the risk of distant recurrence ("DR") in luminal (ER+/HER2-negative) breast cancer patients. The assay was developed to measure the "stemness" of tumors, or how much a tumor behaves like stem cells which could indicate how likely a cancer is to recur or be resistant to standard treatments, ultimately impacting how patients are managed by their multi-disciplinary care team. StemPrintER has been validated in several clinical cohorts and studies, the largest of which are a consecutive series of approximately 2,400 patients from the European Institute of Oncology ("IEO") and approximately 800 patients from the TransATAC study. In the IEO cohort, StemPrintER High Risk patients ("SPRS High") were 1.85 times more likely to have a distant recurrence compared to Low Risk ("SPRS Low") patients (Figure 1) and in the TransATAC cohort, SPRS High patients were 4.27 times more likely to experience a distant recurrence compared to SPRS Low Risk patients (Figure 2). Together, these data confirm that StemPrintER is highly prognostic for outcomes in patients with breast cancer and indicate the potential utility of the test in the oncology clinic.

*SPRS- StemPrintER Recurrence Score; SPRS High- StemPrintER High Risk; SPRS Low- StemPrintER Low Risk

Beyond our initial plans for StemPrintER, we believe there is significant opportunity to expand our product portfolio. First, given the broad applicability of tumor "stemness", which has been evaluated in a multitude of different cancers, we believe the StemPrint platform will have meaningful clinical utility beyond breast cancer. As such, we will seek to validate and commercialize StemPrint for a variety of different tumor types. Each tumor type, where applicable, would also include ancillary testing to boost our value proposition to physicians and their patients. In addition, we plan to offer ancillary commodity testing (e.g., hereditary genetic testing, somatic mutation testing) that augments our proprietary assays and provides additional information and value to patients and physicians throughout the patient care continuum.

We plan to launch StemPrintER once we have achieved several key milestones. First, we plan to identify or build a laboratory that will be responsible for processing, testing and reporting StemPrintER results for all commercial samples. Further, we plan to transfer the StemPrintER assay from the laboratories in which they were developed to our commercial laboratory. Finally, upon establishing testing capabilities in our commercial laboratory, we will seek to obtain U.S. Clinical Laboratory Improvement Amendments of 1988 ("CLIA") certification so that we are able to report results for clinical use and to seek reimbursement from the Centers for Medicare and Medicaid Services. We anticipate that it will take at least 18 months to complete these milestones. Once those tasks are complete, we plan to initially launch StemPrintER in the US and then expand to other markets as we evaluate clinical need and revenue opportunity.

Since our inception, we have devoted substantially all of our resources to conducting research and development of our product candidate. Our revenue is expected to be derived from different sources including standard private third-party and government medical insurance coverage and reimbursement models.

Financial Operations Overview

We have no products approved for commercial sale and have not generated revenue to date. We have never been profitable and have incurred net losses in each year since inception. We incurred net losses of $3,746,419 and $670,614 for the year ended December 31, 2022 and 2021, respectively. As of December 31, 2022, we had an accumulated deficit of $4,471,281. Substantially all of our net losses resulted from expenses incurred in connection with our research and development programs and from general and administrative costs associated with our operations.

Segment Information

As of December 31, 2022, we viewed our operations and managed our business as one operating segment consistent with how our chief operating decision maker, our Chief Executive Officer, makes decisions regarding resource allocation and assessing performance. As of December 31, 2022, substantially all of our assets were located in the United States. Our headquarters and operations are located in New York, NY and London, UK.

Research and development expense

Research and development costs are expensed as incurred. These costs consist of internal and external expenses, as well as depreciation expense on assets used within our research and development activities. Internal expenses include the cost of salaries, benefits, and other related costs, including share-based compensation, for personnel serving in our research and development functions. External expenses include development, clinical trials, patent costs, and regulatory compliance costs incurred with research organizations, contract manufacturers, and other third-party vendors. License fees paid to acquire access to proprietary technology are expensed to research and development, unless it is determined that the technology is expected to have an alternative future use. All patent-related costs incurred in connection with filing and prosecuting patent applications are expensed as incurred to research and development expense due to the uncertainty about the recovery of the expenditure. We record costs for certain development activities, such as preclinical studies and clinical trials, based on our evaluation of the progress to completion of specific tasks. Payments for these activities are based on the terms of the individual arrangements, which may differ from the pattern of costs incurred, and are reflected in the consolidated financial statements as prepaid or accrued research and development expense, as applicable. Our recording of costs for certain development activities requires us to use estimates. We believe our estimates and assumptions are reasonable under the current conditions; however, actual results may differ from these estimates.

Research and development expenses account for a significant portion of our operating expenses. We plan to incur research and development expenses for the foreseeable future as we expect to continue the development of our product candidates. We anticipate that our research and development expenses will be higher in fiscal year 2023 and subsequent periods as compared to the prior periods presented herein as we prepare to establish a CLIA certified lab.

Our research and development expenses are not currently tracked on a program-by-program basis for indirect and overhead costs. We use our personnel and infrastructure resources across multiple research and development programs directed toward identifying, developing, and commercializing product candidates.

At this time, due to the inherently unpredictable nature of preclinical and clinical developments as well as regulatory approval (or authorization) and commercialization, we are unable to estimate with any certainty the costs we will incur and the timelines we will require in our continued development and commercialization efforts. As a result of these uncertainties, successful development and completion of clinical trials as well as regulatory authorization or approval and commercialization are uncertain and may not result in authorized or approved and commercialized products. Completion dates and completion costs can vary significantly for each product candidate and are difficult to predict. We will continue to make determinations as to which product candidates to pursue and how much funding to direct to each product candidate on an ongoing basis in response to our ability to enter into collaborations with respect to each product candidate, the scientific and clinical success of each product candidate as well as ongoing assessments as to the commercial potential of each product candidate.

General and administrative expense

General and administrative expense consists primarily of personnel expenses, including salaries, benefits, insurance, and share-based compensation expense, for employees in executive, accounting, commercialization, human resources, and other administrative functions. General and administrative expense also includes expenses related to pre-commercial activities, corporate facility costs, insurance premiums, legal fees related to corporate matters, and fees for auditing, accounting, and other consulting services.

We anticipate that our general and administrative expenses will increase in fiscal year 2023 as compared to the prior periods presented herein as a result of higher corporate infrastructure costs including, but not limited to accounting, legal, human resources, consulting, investor relations, and public company insurance fees.

Results of Operations

The following discussion and analysis of our results of operations includes a comparison of the years ended December 31, 2022 and 2021:

	December 31, 2022	December 31, 2021	$ Change	% Change
Revenue	$ —	$ —	$ —	—%
Research and development expenses	266,933	73,335	193,598	264%
General and administrative expenses	3,479,486	597,279	2,882,207	483%
Loss from operations	3,746,419	670,614	3,075,805	459%
Loss, before income tax	(3,746,419)	(670,614)	3,075,805	459%
Income tax benefit (expense)	—	—	—	—%
Net loss	$ (3,746,419)	$ (670,614)	$ (3,075,805)	459%

Research and development

Research and development expenses increased $193,598 in 2022 as compared to 2021 from $73,335 to $266,933, primarily due to increases in patent related expenses, and laboratory work and consulting.

General and administrative

General and administrative expenses increased $2,882,207 in 2022 as compared to 2021 from $597,279 to $3,479,486, primarily due to increase an increase of payroll related costs as a result of the new management team structure, as well as costs related to legal fees and other compliance expenses.

Liquidity and Capital Resources

Sources of Liquidity

Since our inception, we have not generated any revenue and have incurred significant operating losses. Our potential products are at various phases of development. We do not expect to generate significant revenue from product sales for several years, if at all. Pursuant to the demerger, Tiziana transferred $1,353,373 (£1,000,000) in cash in January 2022 to us. In addition, subject to the terms of the supplemental demerger agreement, Tiziana invested $2,675,940 (£2,000,000) in cash in March 2022 for additional shares of the Company. Our cash flows may fluctuate and are difficult to forecast and will depend on many factors. As of December 31, 2022, our cash balance is $733,978, which is adequate for our current planned level of operations, through at least March 2023.

Our cash flows may fluctuate and are difficult to forecast and will depend on many factors.

Cash Flows

The following table summarizes our cash flows:

	December 31, 2022	December 31, 2021
Cash flows used in operating activities	$ (1,806,053)	$ —
Cash flows used in investing activities	(10,999)	—
Cash flows from financing activities	2,551,030	—
Net increase in cash and cash equivalents	733,978	—
Cash and cash equivalents at beginning of period	—	—
Cash and cash equivalents at end of period	$ 733,978	$ —

We did not generate any cash flows through December 31, 2021 as cash was funded by a related party.

Operating Activities

There was an increase in cash flows from operating activities during the year ended December 31, 2022 due to the collection of a receivable from a related party. There were no cash flows from operating activities during the year ended December 31, 2021 since all cash activities were funded by a related party.

Investing Activities

The cash flow used in investing activities increased during the year ended December 31, 2022 due to the purchase of computer equipment. There were no cash flows from operating activities during the year ended December 31, 2021

Financing Activities

We generated cash flows from financing activities during the year ended December 31, 2022 due to proceeds from the issuance of common stock to Tiziana, as mentioned in the "Sources of Liquidity" section above. There was no net cash received in financing investing activities for the year ended December 31, 2021.

Market Capital Expenditure Commitments

We have no material commitment for capital expenditures.

Funding Requirements

We expect that our expenses will increase and operating losses will be generated for several years. We have an accumulated deficit of $4,471,281 as of December 31, 2022. Based on our current plans, we believe our existing cash and cash equivalents will not be sufficient to fund our operations and capital expenditure requirements beyond March 2023. We expect to incur substantial additional expenditures in the near term to support our acceleration of activities. We expect to incur net losses for the foreseeable future. Our ability to fund our product development and clinical operations as well as commercialization of our product candidates, will depend on the amount and timing of cash received from planned financings. Our future capital requirements will depend on many factors, including:

- the costs, timing and outcomes of clinical trials and regulatory reviews associated with our product candidates;
- the costs of commercialization activities, including product marketing, sales and distribution;
- the costs of preparing, filing and prosecuting patent applications and maintaining, enforcing and defending intellectual property-related claims;
- the emergence of competing technologies and products and other adverse marketing developments;
- the effect on our product development activities of actions taken by the FDA, EMA or other regulatory authorities;
- our degree of success in commercializing our product candidates, if and when approved; and
- the number and types of future products we develop and commercialize.

A change in the outcome of any of these or other variables with respect to the development of any of our product candidates could significantly change the costs and timing associated with the development of that product candidate. Further, our operating plans may change in the future, and we may need additional funds to meet operational needs and capital requirements associated with such operating plans.

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our operations through a combination of equity financings, debt financings, collaborations with other companies or other strategic transactions. We do not currently have any committed external source of funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making acquisitions or capital expenditures or declaring dividends. If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings or other arrangements when needed, we may be required to delay, limit, reduce or terminate our research, product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Further, our operating plans may change, and we may need additional funds to meet operational needs and capital requirements for clinical trials and other research and development activities. We currently have no credit facility or committed sources of capital. Because of the numerous risks and uncertainties associated with the development and commercialization of our product candidates, we are unable to estimate the amounts of increased capital outlays and operating expenditures associated with our current and anticipated product development programs.

Critical Accounting Policies

Our consolidated financial statements are prepared in accordance with US GAAP. The preparation of our consolidated financial statements and related disclosures requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, costs and expenses, and the disclosure of contingent assets and liabilities in our consolidated financial statements. We base our estimates on historical experience, known trends and events and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions or conditions.

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

Share-based Compensation

We account for share-based payment awards issued to employees and members of our Board by measuring the fair value of the award on the date of grant and recognizing this fair value as share-based compensation using a straight-line basis over the requisite service period, generally the vesting period.

Related parties

Parties are related to us if the parties, directly or indirectly, through one or more intermediaries, control, are controlled by, or are under common control with us. Related parties also include our principal owners, our management, members of the immediate families of our principal owners and our management and other parties with which we may deal with if one party controls or can significantly influence the management or operating policies of the other to an extent that one of the transacting parties might be prevented from fully pursuing its own separate interests.

Off-Balance Sheet Arrangements

We have no off-balance sheet arrangements that have had, or are reasonably likely to have, a material current or future effect on our consolidated financial statements or changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources.

Recent Accounting Pronouncements

For information on recent accounting pronouncements, see our consolidated financial statements - Note 2 and the related notes found elsewhere in this annual report.

Item 7A. Quantitative and Qualitative Disclosure About Market Risk

As of December 31, 2022, we are not subject to any material market risk, including interest rate risk and foreign currency exchange rate risk. We additionally do not have material commodity price or equity price risks.

Item 8. Financial Statements and Supplementary Data

Index to the Consolidated Financial Statements

ACCUSTEM SCIENCES INC. AND SUBSIDIARY

December 31, 2022

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and
Shareholders of AccuStem Sciences Inc.

Opinion on the Financial Statements

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

Explanatory Paragraph Regarding Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has incurred operating losses since inception. The Company also had an accumulated deficit of $4,471,281 at December 31, 2022. The Company is dependent on obtaining necessary funding from institutional investors or others, in order to continue their operations. These conditions raise substantial doubt about its ability to continue as a going concern. Management's plans regarding those matters also are described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

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

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

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

/s/ Mazars USA LLP

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

New York, NY

February 15, 2023

ACCUSTEM SCIENCES INC. AND SUBSIDIARY
CONSOLIDATED BALANCE SHEETS

	December 31, 2022	December 31, 2021
ASSETS		
Current Assets		
Cash	$ 733,978	$ -
Related party receivable	-	1,353,373
Prepaid expenses	168,430	-
Other Current Assets	29,603	-
Total Current Assets	$ 932,011	$ 1,353,373
Equipment, net	7,678	-
TOTAL ASSETS	$ 939,689	$ 1,353,373
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities		
Accounts payable	$ 311,834	$ 388,681
Related party payable	142,229	190,838
Accrued expenses	518,625	123,181
Note Payable	106,551	-
Total Current Liabilities	1,079,239	702,700
TOTAL LIABILITIES	1,079,239	702,700
Stockholders' Equity		
Preferred stock $.001 par value; 10,000,000 shares authorized; none issued and outstanding	$ -	$ -
Common stock $.001 par value; 150,000,000 shares authorized; 11,346,535 and 9,999,132 shares issued and outstanding as of December 31, 2022 and December 31, 2021, respectively	11,346	9,999
Additional paid-in capital	4,320,385	1,503,434
Related party subscription receivable	-	(204,879)
Accumulated other comprehensive loss	-	66,981
Accumulated deficit	(4,471,281)	(724,862)
TOTAL STOCKHOLDERS' EQUITY	(139,550)	650,673
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 939,689	$ 1,353,373

ACCUSTEM SCIENCES INC. AND SUBSIDIARY
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

	Year Ended December 31, 2022	Year Ended December 31, 2021
OPERATING EXPENSES		
Research and development expenses	$ 266,933	$ 73,335
General and administrative expenses	3,479,486	597,279
Total operating expenses	3,746,419	670,614
LOSS FROM OPERATIONS	(3,746,419)	(670,614)
LOSS, BEFORE INCOME TAX	(3,746,419)	(670,614)
Income tax benefit (expense)	—	—
NET LOSS	$ (3,746,419)	$ (670,614)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.34)	$ (0.07)
Weighted average common shares outstanding used in computing net loss per share attributable to common stockholders, basic and diluted	11,016,165	9,999,132
NET LOSS	$ (3,746,419)	$ (670,614)
Translation adjustments	—	(11,553)
COMPREHENSIVE LOSS	$ (3,746,419)	$ (682,167)

ACCUSTEM SCIENCES INC. AND SUBSIDIARY
CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY

	Common Stock		Additional Paid-in Capital	Related Party Subscription Receivable	Accumulated Other Comprehensive Income	Accumulated Deficit	Stockholders' Equity
	Number of Shares	Amount					
Balance at December 31, 2020	9,999,132	$ 9,999	$1,482,174	$ (206,663)	$ 78,534	$ (54,248)	$ 1,309,796
Share-based compensation	—	—	21,260	—	—	—	21,260
Foreign currency translation adjustment	—	—	—	1,784	(11,553)	—	(9,769)
Net loss	—	—	—	—	—	(670,614)	(670,614)
Balance at December 31, 2021	9,999,132	9,999	1,503,434	(204,879)	66,981	(724,862)	650,673
Share-based compensation	—	—	133,889	—	—	—	133,889
Issuance of common stock	1,337,970	1,338	2,674,602	—	—	—	2,675,940
Receipt of subscription receivable	—	—	—	204,879	—	—	204,879
Exercise of common stock options	9,433	9	8,460	—	—	—	8,469
Foreign currency translation adjustment	—	—	—	—	(66,981)	—	(66,981)
Net loss	—	—	—	—	—	(3,746,419)	(3,746,419)
Balance at December 31, 2022	11,346,535	$ 11,346	$4,320,385	$ —	$ —	$ (4,471,281)	$ (139,550)

ACCUSTEM SCIENCES INC. AND SUBSIDIARY
CONSOLIDATED STATEMENTS OF CASH FLOWS

	For the Year Ended December 31	
	2022	**2021**
Operating Activities		
Net loss	(3,746,419)	(670,614)
Adjustments to reconcile net loss to net cash provided by operating activities		
Foreign currency translation	(66,981)	-
Depreciation	3,321	-
Share-based compensation	133,889	21,260
Change in operating assets and liabilities:		
Related party receivable	1,353,373	-
Prepaid expenses	270,692	-
Other current assets	(29,603)	-
Accounts payable	(76,846)	394,666
Related party payable	(48,609)	172,966
Accrued expenses	401,130	81,722
Net cash used in operating activities	(1,806,053)	-
Investing Activities		
Purchases of equipment	(10,999)	-
Net cash used in investing activities	(10,999)	-
Financing Activities		
Proceeds from receipt of subscription receivable	204,879	-
Proceeds from issuance of common stock	2,675,940	-
Proceeds from exercise of options	8,469	-
Payments on note payable	(338,258)	-
Net cash provided by financing activities	2,551,030	-
Increase in cash	733,978	-
Cash, beginning of year	-	-
Cash, end of year	733,978	-
Supplemental disclosure of noncash investing and financing activities		
Issuance of Note Payable for payment of prepaid expense	439,122	-
Supplemental cash flow information		
Cash paid for interest	7,474	-

1. DESCRIPTION OF BUSINESS

AccuStem Sciences Inc. and its subsidiary ("the Company") is a clinical stage diagnostics company dedicated to improving quality of life and outcomes for the more than 18 million people worldwide who are diagnosed with cancer each year.

Liquidity and Going Concern

The consolidated financial statements have been prepared on the going concern basis, which contemplates the realization of assets and discharge of liabilities in the normal course of business.

The Company has financed its activities principally from support from a related party. The Company has incurred a net loss in every fiscal period since inception. For the year ended December 31, 2022, the Company incurred a net loss of $3,746,419. The Company has an accumulated deficit as of December 31, 2022 of $4,471,281. The Company anticipates operating losses to continue for the foreseeable future due to, among other things, costs related to research funding, further development of its technology and products, and expenses related to the commercialization of its products.

Management believes that the Company does not have sufficient cash and current assets to support its operations through at least 12 months from the issuance date of these consolidated financial statements, and will require significant additional cash resources to continue its planned research and development activities.

The Company will need additional funds for promoting new products and working capital required to support research and development activities and generate sales from its products. There can be no assurance, however, that such financing will be available when needed, if at all, or on favorable terms and conditions. The precise amount and timing of the funding needs cannot be determined accurately at this time, and will depend on a number of factors, including the quality of product development efforts, management of working capital, and the continuation of normal payment terms and conditions for purchase of services.

In order to address its capital needs, including its planned research and development activities and other expenditures, the Company is actively pursuing additional equity financing. The Company has been in ongoing discussions with institutional investors and other parties with respect to such possible offerings. Adequate financing opportunities might not be available to the Company, when and if needed, on acceptable terms or at all. If the Company is unable to obtain additional financing in sufficient amounts or on acceptable terms or if the Company fails to consummate the private placement or a public offering, the Company will be forced to delay, reduce or eliminate some or all of its research and development programs and product portfolio expansion, which could adversely affect its operating results or business prospects. Although management continues to pursue these plans, there is no assurance that the Company will be successful in obtaining sufficient funding in terms acceptable to the Company to fund continuing operations, if at all. After considering the uncertainties, management determined it is appropriate to continue to adopt the going concern basis in preparing the consolidated financial statements.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

The principal accounting policies applied in the preparation of these consolidated financial statements are set out below.

Basis of Presentation

The accompanying financial statements have been prepared in accordance with U.S. Generally Accepted Accounting Principles ("U.S. GAAP") and applicable rules and regulations of the U.S. Securities and Exchange Commission ("SEC"). Unless otherwise indicated, all references to "$" are to U.S. dollars, and all references to "£" or "GBP" are to Great Britain Pounds. The Company's reporting currency is U.S. dollars.

Basis of Consolidation

The accompanying audited consolidated financial statements include the accounts of AccuStem Sciences Inc. as well as its wholly-owned subsidiary after elimination of intercompany transactions and balances.

Comprehensive loss

Comprehensive loss of all periods presented is comprised primarily of net loss and foreign currency translation adjustments.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management of the Company to make estimates and assumptions that affect the reported amounts of assets and liabilities, and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenue and expenses during the reporting period. Actual results could differ from those estimates.

Risk and Uncertainties

The Company is subject to a number of risks similar to those of other companies of similar size in its industry, including but not limited to, the success of its exploration to research and development activities, need for additional capital (or financing) to fund operating losses, competition from substitute products and services from larger companies, protection of proprietary technology, patent litigation, dependence on key individuals, and risks associated with changes in information technology.

Cash

The Company considers all highly liquid investments purchased with an original maturity date of three months or less at the date of purchase and money market accounts to be cash equivalents. At December 31, 2022, the Company had no cash equivalents and all cash amounts consisted of cash on deposit.

Concentrations of Credit Risk

Financial instruments that potentially subject the Company to significant contribution of credit risk consist of cash. Periodically, the Company maintains deposits in financial institutions in excess of government insured limits. Management believes that the Company is not exposed to significant credit risk as the Company's deposits are held at financial institutions that management believes to be of high credit quality and the Company has not experienced any losses in these deposits.

Equipment, net

Equipment is stated at cost, less accumulated depreciation. The Company depreciates its equipment for financial reporting purposes using the straight-line method over the estimated useful lives of the assets. The Equipment consists of computer equipment, which has a useful life of 3 years. Maintenance and repairs are expensed when incurred. Additions and improvements that extend the economic useful life of the asset are capitalized and depreciated over the remaining useful lives of the assets. The cost and accumulated depreciation of assets sold or retired are removed from the respective accounts, and any resulting gain or loss is reflected in current earnings.

Income Taxes

The Company accounts for income taxes under ASC 740 - *Income Taxes*. For federal and state income taxes, deferred tax assets and liabilities are recognized based upon the differences between the financial statement and the tax basis of assets and liabilities. In addition, deferred tax assets are also recorded with respect to net operating losses and other tax attribute carryforwards. Deferred income taxes are based upon prescribed rates and enacted laws applicable to periods in which differences are expected to reverse. A valuation allowance is recorded when it is not more likely than not that the tax benefit from the deferred tax assets will be realized.

The Company intends to continue maintaining a full valuation allowance on its deferred tax assets until there is sufficient evidence to support reversal of all or a portion of the allowances. In establishing the full valuation allowance position, the Company considered all available evidence, including all potential sources of taxable income, future reversals of taxable temporary differences, projections of taxable income, and income from tax planning strategies, as well as any other available and relevant information. Existing valuation allowances are re-examined each period. If it were determined that it is more likely than not that a deferred tax asset will be realized, the appropriate amount of the valuation allowance, if any, would be released in the period this determination is made.

Tax positions not deemed to meet a more-likely-than-not threshold would be recorded as a tax expense in the current year. There were no uncertain tax positions that require accrual or disclosure to the financial statements as of December 31, 2022 and 2021. Tax positions taken or expected to be taken in the course of preparing the Company's tax returns are required to be evaluated to determine whether the tax positions are "more-likely-than-not" of being sustained by the applicable tax authority. As of December 31, 2022, open years related to federal and state jurisdictions are 2020 and 2021.

Research and Development Expenses

Research and product development costs are expensed as incurred under ASC 730 - *Research and Development*. Research and development expenses primarily consist of costs associated with the preclinical and clinical development of the Company's product candidate portfolio, including but not limited to payments to Clinical Research Organizations ("CROs"), the manufacturing of clinical trial material, preclinical research activities, consultants and personnel needed to perform research and development activities, intellectual property, as well as costs to license intellectual property that is an in-process research and development asset with no alternative future use.

Segment Information

The Company applies ASC 280, *Segment Reporting*, in determining reportable segments for its financial statement disclosure. Operating segments are defined as components of an entity for which separate financial information is available and that is regularly reviewed by the Chief Operating Decision Maker ("CODM") in deciding how to allocate resources to an individual segment and in assessing performance. The Company's CODM is its Chief Executive Officer ("CEO"). The Company has determined that it operates as a single operating segment and has one reportable segment.

Fair Value of Financial Instruments

The Company classifies a financial instrument, or its component parts, as a financial liability, a financial asset or an equity instrument in accordance with the substance of the contractual arrangement and the definitions of a financial liability, a financial asset and an equity instrument.

The Company evaluates the terms of the financial instrument to determine whether it contains an asset, a liability or an equity component. Such components shall be classified separately as financial assets, financial liabilities or equity instruments.

The Company's financial liabilities include trade and other payables. The carrying value of such amounts approximate fair value based on the short-term nature of the items. The Company does not hold any financial assets or liabilities at fair value through profit or loss or fair value through other comprehensive income

Share-based Compensation

The Company may award stock options, performance-based options and other equity-based instruments to its employees, directors and consultants. Compensation cost related to equity-based instruments is based on the fair value of the instrument on the grant date, and is recognized over the requisite service period on a straight-line basis over the vesting period except for performance-based options. Performance-based stock options vest based on the achievement of performance targets. Compensation costs associated with performance-based option awards are recognized over the requisite service period based on probability of achievement. Performance-based stock options require management to make assumptions regarding the likelihood of achieving performance targets.

The Company estimates the fair value of service based and performance-based stock option awards, including modifications of stock option awards, using the Black-Scholes option pricing model. This model derives the fair value of stock options based on certain assumptions related to expected stock price volatility, expected option life, risk-free interest rate and dividend yield.

Loss per Share

The Company computes loss per share in accordance with ASC 260 - *Earnings per Share*. Basic net loss per common share is computed by dividing net loss by the weighted average number of shares of common shares outstanding during the period. Diluted net loss per share of common stock is computed by giving effect to all potential dilutive shares of common stock, including options and performance awards. Basic and diluted net loss per share of common stock were the same for all periods presented as the impact of all potentially dilutive securities outstanding was anti-dilutive.

Foreign Currencies

The consolidated financial statements are presented in United States dollars which is the Company's reporting and functional currency as the Company's operating and capital costs are transacted in U.S. dollars. The Company's fully consolidated subsidiary functional currency continued to be GBP, which is the currency of the primary economic environment in which the entities operated.

The financial results and position of foreign operations whose functional currency was different from the Company's reporting currency were translated as follows:

- assets and liabilities were translated at year-end exchange rates prevailing at that reporting date;
- income and expenses were translated at average exchange rates for the period; and
- equity transactions including retained earnings/accumulated deficit were translated at the exchange rates prevailing at the date of the transaction.

Gains and losses arising from translations or settlements of foreign currency denominated transactions or balances were included in the determination of income. "Other comprehensive loss," in the consolidated statements of comprehensive loss, included foreign currency translation adjustments for the periods ended December 31, 2022 and 2021.

Recently Issued and Adopted Accounting Standards
None

Issued Accounting Standards Not Yet Adopted

In September 2022, the FASB issued *ASU No. 2022-04- Liabilities—Supplier Finance Programs,* an accounting standard update which will require that a company that uses a supplier finance program in connection with the purchase of goods or services disclose sufficient information about the program to allow a user of financial statements to understand the program's nature, activity during the period, changes from period to period, and potential magnitude. The standard is effective for fiscal years, including interim periods within those fiscal years, beginning after December 15, 2022, except for the rollforward of the supplier finance program obligations, which is effective for fiscal years beginning after December 15, 2023. The new accounting standard is not expected to have an impact on the Company's financial condition, results of operations or cash flows.

3. NOTE PAYABLE

On May 20, 2022, the Company entered into a one-year Directors and Officers Liability Insurance agreement for $439,122. Under the terms of the agreement, the Company made a down payment of $88,000, with the remaining balance financed over the remaining term at an annual percentage rate of 3.95%. The Company makes monthly payments of $35,751, with the last payment expected to be made in March 2023. At the end of December 31, 2022, the outstanding balance on the note payable was $106,551.

4. EQUIPMENT

Equipment consists of the following:

	December 31, 2022	December 31, 2021
Computer equipment	$ 10,999	-
Less: Accumulated depreciation	3,321	-
Equipment, net	$ 7,678	-

Depreciation expense was approximately $3,321 and $0, respectively, for the year ended December 31, 2022 and 2021, respectively.

Depreciation expense is included within General and Administrative expenses in the accompanying Consolidated Statement of Operations and Comprehensive Loss.

5. LICENSE

On November 9, 2022, AccuStem and the IEO/University of Milan amended the License to clarify the regulatory path and timeline for the commercialization of StemPrintER. Specifically, the regulatory requirement language has been modified to (i) extend the timeline for regulatory approval or clearance of a licensed product to 36 months from the date of the amendment, (ii) clarify that contractual regulatory requirements can be satisfied by the approval or clearance of the test as a Laboratory Developed Test (i.e., approval or clearance can be achieved via the CLIA regulatory path rather than the FDA) and (iii) the timeline for commercial launch has been extended for an additional 60 months from the date of the amendment. The amendment provides for a separate licensing payment of $175,000 to the IEO.

In addition, for the term of the license, the following milestone payments are required to be made (converted from EUROS to USD using exchange rate of €1:$1.0675)

- €50,000 ($53,375) within 30 days of completion of development of a commercial test;
- €100,000 ($106,750) within 30 days of the first commercial sale of a licensed product; and
- €150,000 ($160,125) within 30 days of first regulatory approval in the U.S. or any other major market.

The License may be terminated by either party in the event of a material breach and in addition, we may terminate the License at any time upon 30 days' notice.

For the year ended December 31, 2022 and 2021, the Company did not recognize any expense related to this license agreement as no milestones were reached.

6. LOSS PER SHARE

Basic and diluted net loss per common share were the same since the inclusion of common shares issuable pursuant to the exercise of options in the calculation of diluted net loss per common shares would have been antidilutive.

For the periods ended December 31, 2022 and 2021, loss per share of the Company are as follows:

	For the Year Ended December 31, 2022	For the Year Ended December 31, 2021
Numerator:		
Net Loss	$ (3,746,419)	$ (670,614)
Net loss attributable to common shareholders	$ (3,746,419)	$ (670,614)
Denominator:		
Weighted-average common shares outstanding, basic and diluted	11,016,165	9,999,132
Net loss per common share, basic and diluted	$ (0.34)	$ (0.07)

The Company's potentially dilutive securities, which include stock options and warrants, have been excluded from the computation of diluted net loss per common share as the effect would be to reduce the net loss per share. Therefore, the weighted-average number of common shares outstanding used to calculate both basic and diluted net loss per share attributable to common shareholders is the same.

The Company excluded the following from the computation of diluted net loss per share attributable to common stockholders for the years ended December 31, 2022 and 2021 because including them would have had an anti-dilutive effect:

	For the Year Ended December 31, 2022	For the Year Ended December 31, 2021
Stock options to purchase common stock outstanding	1,360,115	100,005
Warrants to purchase common stock outstanding	350,000	—
Total	1,710,115	100,005

7. SHARE-BASED COMPENSATION

In August 2021, Limited adopted the 2021 Omnibus Equity Incentive Plan (the "Incentive Plan"). The Incentive Plan provides that the Company may grant Options, Stock Appreciation Rights, Restricted Stock, Restricted Stock Units, and Other Share-Based Awards to selected employees, directors, and independent contractors of the Company.

Each Award shall be exercisable at such time or times and subject to such terms and conditions set forth in the Incentive Plan, as shall be determined by the administrator in the applicable award agreement. Total shares authorized by the plan was 2,500,000. Awards under the Incentive Plan are exercisable for up to 10 years from the date of issuance. There are 1,130,452 remaining available shares to be issued under the Incentive Plan at December 31, 2022. The number of shares of Common Stock that are reserved and available for issuance under the Incentive Plan shall be subject to an annual increase on the first day of each calendar year beginning with the first January 1 following the effective date and ending with the last January 1 during the initial ten-year term of the Plan as defined in Section 4(a) of the Incentive Plan.

Options

The Company issued 1,322,239 options during the year ended December 31, 2022 for employees, directors and non-employees under the Incentive Plan. The options granted have an exercise price ranging from $1.00 to $2.13 and expire on the ten-year anniversary of the grant date.

The Company granted 100,005 options for the year ended December 31, 2021.

For the year ended December 31, 2021, stock option activity of the Company are as follows:

	Number of Time-Based Share Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in years)	Aggregate Intrinsic Value
Outstanding at January 1, 2021	—	$ —	—	$ —
Issued	100,005	0.42	10	—
Exercised	—	—	—	—
Expired/Forfeited	—	—	—	—
Outstanding at December 31, 2021	100,005	0.42	9.72	—
Vested and exercisable December 31, 2021	100,005	$ 0.42	9.72	$ —

For the year ended December 31, 2022, stock option activity for time-based options of the Company are as follows:

	Number of Time-Based Share Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in years)	Aggregate Intrinsic Value
Outstanding at January 1, 2022	100,005	$ 0.42	9.72	$ —
Issued	378,239	2.03	9.20	—
Exercised	(9,433)	0.90	—	—
Expired/Forfeited	52,696	0.28	—	—
Outstanding at December 31, 2022	416,115	$ 1.86	9.13	$ 57,207
Vested and exercisable December 31, 2022	57,115	$ 0.44	8.68	$ 51,957

For the year December 31, 2022, stock option activity for performance-based options of the Company are as follows:

	Number of Performance-Based Share Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in years)	Aggregate Intrinsic Value
Outstanding at January 1, 2022	—	$ —	—	$ —
Issued	944,000	1.45	9.11	—
Exercised	—	—	—	—
Expired/Forfeited	—	—	—	—
Outstanding at December 31, 2022	944,000	$ 1.45	9.11	$ 174,000
Vested and exercisable December 31, 2022	—	—	—	—

The aggregate intrinsic value is calculated as the difference between the estimated fair value of the underlying common stock as of December 31, 2022 and the option exercise price.

Total share-based compensation was approximately $133,889 and $21,260, respectively, for the year ended December 30, 2022 and 2021, respectively.

Total share-based compensation expense is included in General and Administrative expenses on the Condensed Consolidated Statement of Operations and Other Comprehensive Income.

The weighted average grant date fair value for stock options granted was $0.76 and $0.42 during the year ended December 31, 2022 and 2021. The performance-based and time-based stock options are equity-classified. There was no performance -based stock option granted during the year ended December 31, 2021.

The Company uses the Black-Scholes option pricing model to estimate the fair value of the option awards. The table below summarizes the resulting weighted average inputs used to calculate the estimated fair value of options awarded for the year ended December 31, 2022 and 2021.

	2022	2021
Risk-free interest rate	1.54 - 4.2 0%	0.31%
Expected dividend yield	—%	—%
Expected term	5.00 – 8.50 years	5.00 years
Expected volatility	57.2 - 65.7%	59.00%

The risk-free interest rate assumption is determined using the yield currently available on U.S. Treasury zero- coupon issues with a remaining term commensurate with the expected term of the award. The Company has historically been a private company and lacks company-specific historical and implied volatility information. Management has estimated expected volatility based on similar public companies. Expected life of the option represents the period of time options are expected to be outstanding. The estimate for dividend yield is 0% because the Company has not historically paid, and does not intend to pay, a dividend on common stock in the foreseeable future.

As of December 31, 2022, there was $872,662 unrecognized compensation expense related to options. $179,324 of this cost is subject to time-based conditions, and is to be recognized over a period of approximately 3.3 years. The remaining $693,338 of unrecognized compensation expense relates to performance-based conditions for unvested options. These costs are expected to be recognized over the required service period once the performance condition has occurred or becomes probable. Compensation costs related to the performance stock options are evaluated at each reporting period and subsequently adjusted for changes in the expected outcomes of the performance conditions. There was no unrecognized compensation expense related to options at December 31, 2021.

Warrants

In March 2022, the Company issued 350,000 common stock warrants to a non-employee under the Incentive Plan. The common stock warrants are subject to vesting and, grantees become fully vested and exercisable when certain performance requirements are met.

The common stock warrants granted have an exercise price of $1.06. The common stock warrants expire on the ten-year anniversary of the grant date. There were no warrants issued during the year ended December 31, 2021.

A summary of the Company's warrants to purchase common stock activity is as follows:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in years)	Aggregate Intrinsic Value
Outstanding at January 1, 2022	—	$ —	—	$ —
Issued	350,000	1.06	9.07	—
Exercised	—	—	—	—
Expired/Forfeited	—	—	—	—
Outstanding at December 31, 2022	350,000	$ 1.06	9.07	$ —
Vested and exercisable December 31, 2022	—	—	—	—

The grant date fair value for these warrants of $0.66 per warrant for a total fair value of $232,490. The table below summarizes the resulting weighted average inputs used to calculate the estimated fair value of the common stock warrants options awarded for the year ended December 31, 2022.

	December 31,2022	December 31, 2021
Risk-free interest rate	1.75%	—
Expected dividend yield	—	—
Expected term	8.50 years	—
Expected volatility	63.9%	—

There was no share-based compensation expense recognized during the year ended December 31, 2022 and 2021 for warrants.

As of December 31, 2022, there was $232,490 of total performance-based unrecognized compensation costs related to unvested common stock warrants. These costs are expected to be recognized once the performance condition has occurred or becomes probable.

On October 10, 2022, our stockholders approved an amendment to our Amended and Restated Certificate of Incorporation (the "Charter"), to effect a reverse stock split of our outstanding shares of common stock by a ratio of any whole number between one-for-two and one-for-fifteen, at any time prior to October 10, 2023, the implementation and timing of which shall be subject to the discretion of our board of directors.

8. RELATED PARTY TRANSACTIONS

Tiziana is a related party as the entity is controlled by a person that has a significant influence over the group. The Company and Tiziana share some directors, an officer and significant shareholders. The Company has also been formed due to an acquisition of a subsidiary company from Tiziana. As of December 31, 2022, Tiziana owns approximately 11.8% of the Company.

As of December 31, 2022 and 2021, $0 and $1,558,252 respectively, was due from Tiziana in relation to the demerger and supplemental demerger of Limited and StemPrintER, which consists of the related party receivable and related party subscription receivable on the condensed consolidated balance sheet.

Effective with the demerger agreement, the Company entered into a shared services agreement, where the Company outsources certain limited management and administrative services. The Company notes that the fees consist of payroll costs associated with time spent providing services for the Company and are based on actual time spent and the allocated payroll costs. In addition, the Company is charged at cost, for utilization of certain office space. There was no mark-up associated with fees charged for these services. Total cost for the year ended December 31, 2022 and 2021 were $35,668 and $12,434, respectively.

As of December 31, 2022 and 2021, $76,229 and $190,838 respectively, was also due to Tiziana, as Tiziana had paid for expenses on behalf of the Company.

In January 2022, the Company and Gabriele Cerrone, who is the Chairman of the Board of Directors and the largest shareholder, entered into an agreement in which he will provide consulting services to the Company for a monthly fee of $5,500. As of December 31, 2022, $66,000 was due to Gabriele Cerrone.

9. INCOME TAXES

A reconciliation of the provision for income taxes to the amount computed by applying the statutory income tax rate of 21% to the net loss before income taxes for the year ended December 31, 2022 and 2021 are as follows:

Rate reconciliation	2022	2021
Pre-tax Book Income	21.00%	21.00%
Permanent differences	(0.96)%	0.00%
Foreign net operating loss write-off	(2.56)%	0.00%
Increase in valuation allowance	(18.84)%	(23.29)%
State taxes	1.36%	0.33%
Foreign rate differential	0.00%	1.96%
Total tax expense	0.00%	0.00%

Income Tax Expenses attributable to income for continuing operations consists of the following:

Income tax expense	Current	Deferred	Total
Federal	-	-	-
State	-	-	-
Foreign	-	-	-
Total taxes	-	-	-

Deferred income taxes reflect the net tax effects of temporary differences between the carrying value of the asset and liabilities for financial reporting purposes, and amounts used for income tax purposes.

The temporary differences resulted in the deferred tax assets and liabilities as follows:

	2022	2021
Net operating loss carryforwards	$ 731,909	$ 169,721
Compensation accruals	88,423	—
Fixed assets	252	—
Patents	25,998	—
R&D expenses	28,793	—
Total deferred tax assets	875,375	169,721
Less: valuation allowance	$ (875,375)	$ (169,721)
Net deferred tax asset	-	-

At December 31, 2022, the Company had net operating losses of approximately $3,276,370 for federal income tax purposes, and approximately $1,133,327 for state income tax purposes.

In assessing the realizability of the deferred tax assets, management determined whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. Management considers the scheduled reversal of deferred tax liabilities, projected future taxable income, net operating loss carryback potential and tax planning strategies in making these assessments.

Based on the above criteria, the Company believes that it is more likely than not that the full amount of the remaining net deferred tax assets will not be realized. Accordingly, the Company has recorded a full valuation allowance of approximately $875,375 against net deferred tax assets that is not expected to be realized for the period ended December 31, 2022 and approximately $169,721 for the period ended December 31, 2021.

The Company recognizes interest accrued to unrecognized tax benefits and penalties as income tax expense. The Company accrued no penalties or interest during the years ended December 31, 2022 and 2021.

The Company files tax returns as prescribed by the laws of the jurisdictions in which they operate. In the normal course of business, the Company is subject to examination by federal and state jurisdictions where applicable based on the statute of limitations that apply in each jurisdiction. As of December 31, 2022, open years related to federal and state jurisdictions are 2020 and 2021.

The Company has no open tax audits with any tax authority of December 31, 2022.

The federal net operating loss carryforward will be carried forward indefinitely, and the state net operating loss carryforward will expire beginning in 2041.

In accordance with Section 382 of the Internal Revenue code, the usage of the Company's net operating loss carryforwards may be limited in the event of a change in ownership. A full Section 382 analysis has not been prepared and NOLs could be subject to limitation under Section 382.

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

Not applicable.

Item 9A. Controls and Procedures

Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal controls over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles ("US GAAP").

Because of their inherent limitations, internal controls over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Under the supervision and with the participation of management, our Chief Executive Officer and the Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial over financial reporting based on the framework described in Internal Control-Integrated Framework issued by the Commission of Sponsoring Organizations of the Treadway Commission, as revised in 2013. Based on that evaluation, management has concluded that we did not maintain effective internal control over financial reporting as of the period ended December 31 2022 due to the existence of the material weaknesses in internal control over financial reporting described below.

Material Weaknesses in Internal Controls Over Financial Reporting

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

Management has determined that we did not maintain effective internal control over financial reporting as of the period ended December 31, 2022 due to a lack of accounting resources resulting in inadequate monitoring controls and other oversight procedures. Our management has determined that our disclosure controls and procedures and internal controls were ineffective due to weaknesses in our financial closing process, inadequate segregation of duties over authorization, review and recording of transactions, lack of accounting resources, as well as the financial reporting of such transactions.

Management's Plan to Remediate the Material Weakness

Management intends to remediate this item in the following manner:

i. Recruit appropriately skilled accounting resources (the "Remediation Plan")

Accordingly, management has determined that these control deficiencies constitute a material weakness. Management has begun implementing the Remediation Plan described herein and intends to continue working on it through the year ended December 31, 2023.

Changes in Internal Control over Financial Reporting

There have been no changes in our internal control over financial reporting during the year ended December 31, 2022 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

None

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

None

Item 10. Directors, Executive Officers and Corporate Governance

The information required by this Item 10 will be included in our definitive proxy statement to be filed with the SEC with respect to our 2023 Annual Meeting of the Stockholders and is included herein by reference.

Item 11. Executive Compensation

The information required by this Item 11 will be included in our definitive proxy statement to be filed with the SEC with respect to our 2023 Annual Meeting of the Stockholders and is included herein by reference.

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

The information required by this Item 12 will be included in our definitive proxy statement to be filed with the SEC with respect to our 2023 Annual Meeting of the Stockholders and is included herein by reference.

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

The information required by this Item 13 will be included in our definitive proxy statement to be filed with the SEC with respect to our 2023 Annual Meeting of the Stockholders and is included herein by reference.

Item 14. Principal Accountant Fees and Services

Our independent public accounting firm is Mazars USA, LLP, New York, NY, PCAOB Auditor Firm ID 339.

The information required by this Item 14 will be included in our definitive proxy statement to be filed with the SEC with respect to our 2023 Annual Meeting of the Stockholders and is included herein by reference.

Item 15. Exhibits, Financial Statement Schedules

3.1	**Amended and Restated Certificate of Incorporation of AccuStem Sciences Inc. (incorporated by reference to Exhibit 3.1 to Form 8-K filed December 3, 2021)**
3.2	**Bylaws of AccuStem Sciences Inc. (incorporated by reference to Exhibit 3.2 to Form 8-K filed December 2, 2021)**
4.1	**Form of common stock certificate (incorporated by reference to Exhibit 4.1 to Form S-1 filed November 17, 2022)**
4.2	**Demerger Agreement between Tiziana Life Sciences PLC and AccuStem Sciences Limited dated October 5, 2020 (incorporated by reference to Exhibit 4.3 to Form 20-F filed March 12, 2021)**
4.3	**Supplemental Demerger Agreement between Tiziana Life Sciences PLC and AccuStem Sciences Limited dated October 30, 2020 (incorporated by reference to Exhibit 4.4 to Form 20-F filed March 12, 2021)**
4.4	**Description of the Registrant's Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934**
10.1	**License Agreement dated June 24, 2014 by and between TTFactor Srl and Fondazione Firc per l'Oncologia Molecolare and Universita degli Studi di Milano and Tiziana Life Sciences plc (incorporated by reference to Exhibit 4.5 to Form 20-F filed May 7, 2021)**
10.2	**Form of Indemnification Agreement (incorporated by reference to Exhibit 10.1 to Form 8-K filed December 3, 2021)**
10.3	**AccuStem Sciences Inc. 2021 Omnibus Equity Incentive Plan (incorporated by reference to Exhibit 10.2 to Form 8-K filed December 3, 2021)**
10.4	**Shared Services Agreement by and between Accustem Sciences Ltd. and Tiziana Life Sciences plc dated as of January 1, 2021 (incorporated by reference to Exhibit 10.4 to Form S-1 filed November 17, 2022).**
10.5	**Offer Letter dated February 18, 2022 between Accustem Sciences, Inc. and Wendy Blosser (incorporated by reference to Exhibit 10.5 to Form S-1 filed November 17, 2022).**
10.6	**Offer Letter dated November 25, 2021 between Accustem Sciences, Inc. and Jeff Fensterer (incorporated by reference to Exhibit 10.6 to Form S-1 filed November 17, 2022)**
10.7	**Offer Letter dated December 6, 2021 between Accustem Sciences, Inc. and Joe Flanagan (incorporated by reference to Exhibit 10.7 to Form S-1 filed November 17, 2022)**
10.8	**Consulting Agreement dated March 21, 2021 between Keeren Shah and Accustem Sciences, Inc. (incorporated by reference to Exhibit 10.8 to Form S-1 filed November 17, 2022)**
10.9	**Consulting Agreement dated January 1, 2022 between Gabriele Cerrone and Accustem Sciences, Inc. (incorporated by reference to Exhibit 10.9 to Form S-1 filed November 17, 2022) .**
10.10	**First Amendment to License Agreement by and between AccuStem Sciences, Inc., Istituto Europeo di Oncologia Srl and Universita degli Studi di Milano, dated November 9, 2022 (incorporated by reference to Exhibit 10.10 to Form S-1 filed November 17, 2022) .**
10.11	**Amendment to Consulting Agreement dated July 22, 2021 between Keeren Shah and Accustem Sciences, Inc. (incorporated by reference to Exhibit 10.11 to Form S-1 filed November 17, 2022)**
21.1	**List of Subsidiaries (incorporated by reference to Exhibit 8.1 to Form 20-F filed May 7, 2021)**
24.1	**Power of Attorney (included on signature page)**
31.1	**Certification of Principal Executive Officer required under Rule 13a-14(a)/15d-14(a) under the Exchange Act.**
31.2	**Certification of Principal Financial Officer required under Rule 13a-14(a)/15d-14(a) under the Exchange Act.**
32.1	**Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.**
32.2	**Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.**

101.INS* Inline XBRL Instance Document

101.SCH* Inline XBRL Taxonomy Extension Schema Document

101.CAL* Inline XBRL Taxonomy Extension Calculation Linkbase Document

101.DEF* Inline XBRL Taxonomy Extension Definition Linkbase Document

101.LAB* Inline XBRL Taxonomy Extension Label Linkbase Document

101.PRE* Inline XBRL Taxonomy Extension Presentation Linkbase Document

104 Cover Page Interactive Data File (embedded within the Inline XBRL document)

Item 16. Form 10-K Summary

Not applicable.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized on February 15, 2023.

ACCUSTEM SCIENCES, INC.
(Registrant)

/s/ Keeren Shah
Keeren Shah
Chief Financial Officer

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below hereby constitutes and appoints Wendy Blosser and Keeren Shah as his or her attorney-in-fact, with full power of substitution and resubstitution, for him or her in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorney-in-fact full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorney-in-fact, or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

In accordance with the Securities Exchange Act of 1934, this Report has been signed below on February 15, 2023 by the following persons on behalf of the Registrant and in the capacities indicated.

/s/ Wendy Blosser
Wendy Blosser
Chief Executive Officer and Director

/s/ Keeren Shah
Keeren Shah
Chief Financial Officer

/s/ Gabriele Cerrone
Gabriele Cerrone
Director

/s/ Sean McDonald
Sean McDonald
Director

/s/ Willy Simon
Willy Simon
Director

/s/ John Brancaccio
John Brancaccio
Director

Exhibit 4.4

DESCRIPTION OF THE REGISTRANT'S SECURITIES REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934

As of December 31, 2022, AccuStem Sciences, Inc. had one class of securities registered under Section 12 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"): (i) common stock, $0.001 par value per share ("Common Stock").

Unless the context otherwise requires, all references to "we", "us", the "Company", or "AccuStem" in this Exhibit 4.1 refer to AccuStem Sciences, Inc.

DESCRIPTION OF CAPITAL STOCK

The following description of our securities is intended as a summary only and is qualified in its entirety by reference to our amended and restated certificate of incorporation and amended and restated bylaws, which are filed as exhibits to the annual report on Form 10-K of which this Exhibit 4.4 is a part.

Authorized Capitalization

Our authorized capital stock consists of 160,000,000 shares, consisting of 150,000,000 shares of common stock, par value $0.001 per share and 10,000,000 shares of preferred stock, par value $0.001 per share.

As of February 15, 2023, there were 11,346,535 shares of common stock and no shares of preferred stock issued and outstanding.

Transfer Agent and Registrar. The transfer agent for our common stock is Pacific Stock Transfer Company.

Listing. Our common stock is quoted on the OTCQB Venture Market under the symbol "ACUT."

Common Stock

Holders of shares of our common stock are entitled to one vote for each share held of record on all matters submitted to a vote of stockholders. Except as otherwise provided in our amended and restated certificate of incorporation or as required by law, all matters to be voted on by our stockholders other than matters relating to the election and removal of directors must be approved by a majority of the shares present in person or by proxy at the meeting and entitled to vote on the subject matter or by a written resolution of the stockholders representing the number of affirmative votes required for such matter at a meeting. The holders of our common stock do not have cumulative voting rights in the election of directors.

Holders of shares of our common stock are entitled to receive dividends when and if declared by our board of directors out of funds legally available therefor, subject to any statutory or contractual restrictions on the payment of dividends and to any restrictions on the payment of dividends imposed by the terms of any outstanding preferred stock.

Upon our dissolution or liquidation or the sale of all or substantially all of our assets, after payment in full of all amounts required to be paid to creditors and subject to any rights of preferred stockholders, the holders of shares of our common stock will be entitled to receive pro rata our remaining assets available for distribution.

Holders of shares of our common stock do not have preemptive, subscription, redemption, or conversion rights. There will be no redemption or sinking fund provisions applicable to the common stock.

Exhibit 31.1

CERTIFICATION BY PRINCIPAL EXECUTIVE OFFICER, PRINCIPAL FINANCIAL AND ACCOUNTING OFFICER

I, Wendy Blosser, certify that:

1. I have reviewed this Annual Report on Form 10-K of AccuStem Sciences Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

    a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

    c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

    a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

    b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: February 15, 2023

/s/ Wendy Blosser

Name: Wendy Blosser
Title: Chief Executive Officer

Exhibit 31.2

CERTIFICATION BY PRINCIPAL EXECUTIVE OFFICER, PRINCIPAL FINANCIAL AND ACCOUNTING OFFICER

I, Keeren Shah, certify that:

1. I have reviewed this Annual Report on Form 10-K of AccuStem Sciences Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

    a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

    c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

    a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

    b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: February 15, 2023

/s/ Keeren Shah

Name: Keeren Shah
Title: Chief Financial Officer

Exhibit 32.1

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

In connection with the Annual Report of AccuStem Sciences Inc. (the "Company") on Form 10-K for the year ended December 31, 2022 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Wendy Blosser, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Dated: February 15, 2023

/s/ Wendy Blosser
Name: Wendy Blosser
Title: Chief Executive Officer

Exhibit 32.2

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

In connection with the Annual Report of AccuStem Sciences Inc. (the "Company") on Form 10-K for the year ended December 31, 2022 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Keeren Shah, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Dated: February 15, 2023

/s/ Keeren Shah
Name: Keeren Shah
Title: Chief Financial Officer