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

FORM 20-F

☐ REGISTRATION STATEMENT PURSUANT TO SECTION 12(b) or 12(g) OF THE *SECURITIES EXCHANGE ACT OF 1934*

OR

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

For the fiscal year ended **December 31, 2023**

OR

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

For the transition period from _____ to _____

OR

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

Date of event requiring this shell company report _____

Commission file number **001-41010**

Mainz Biomed N.V.
(Exact name of Registrant specified in its charter)

Not Applicable
(Translation of Registrant's name into English)

The Netherlands
(Jurisdiction of incorporation or organization)

Mainz Biomed N.V.
Robert Koch Strasse 50
55129 Mainz
Germany
(Address of principal executive offices)

Mr. Guido Baechler
Chief Executive Officer
+49 (0) 6131 / 55428-60
info@mainzbiomed.com
(Name, Telephone, Email and/or Facsimile number and Address of Company Contact Person)

Securities registered or to be registered pursuant to Section 12(b) of the Act.

Title of Each Class	Trading symbol(s)	Name of each exchange on which registered
Ordinary Shares	**MYNZ**	**The Nasdaq Stock Market LLC**

Securities registered or to be registered pursuant to Section 12(g) of the Act.

None
(Title of Class)

Securities for which there is a reporting obligation pursuant to Section 15(d) of the Act.

Ordinary Shares
(Title of Class)

Number of outstanding shares of each of the issuer's classes of capital or common stock as of the close of business of the period covered by the annual report.

21,165,482 Ordinary Shares

Indicate by check mark if the Registrant is a well-known seasoned issuer as defined in Rule 405 of the Securities Act.

Yes ☐ No X

If this report is an annual or transition report, indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or 15(d) of the *Securities Exchange Act of 1934*

Yes ☐ No X

Indicate by check mark whether 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 Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes X No ☐

Indicate by check mark whether the registrant has submitted electronically on its corporate Web site, if any, 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 X No ☐

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

Large Accelerated Filer	☐	Accelerated Filer	☐
Non Accelerated Filer	X	Emerging Growth Company	X

If an emerging growth company that prepares its financial statements in accordance with U.S. GAAP, 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 pursuant to Section 13(a) of the Exchange Act. ☐

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

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

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

Indicate by check mark which basis of accounting the registrant has used to prepare the financial statements included in this filing:

U.S. GAAP ☐	International Financial Reporting Standards as issued by the International Accounting Standards Board X	Other ☐

If "Other" has been checked in response to the previous question, indicate by check mark which financial statement item the registrant has elected to follow: Item 17 ☐ Item 18 ☐

If this is an annual report, indicate by check mark whether the Registrant is a shell company (as defined in Rule 12b 2 of the Exchange Act):

Yes ☐ No X

(APPLICABLE ONLY TO ISSUERS INVOLVED IN BANKRUPTCY PROCEEDINGS DURING THE PAST FIVE YEARS)

Indicate by check mark whether Registrant has filed all documents and reports required to be filed by Sections 12, 13 or 15(d) of the *Securities Exchange Act of 1934* subsequent to the distribution of securities under a plan confirmed by a court.

Not applicable.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This annual report contains statements that constitute "forward-looking statements". Any statements that are not statements of historical facts may be deemed to be forward-looking statements. These statements appear in a number of different places in this annual report and, in some cases, can be identified by words such as "anticipates", "estimates", "projects", "expects", "contemplates", "intends", "believes", "plans", "may", "will", or their negatives or other comparable words, although not all forward-looking statements contain these identifying words. Forward-looking statements in this annual report may include, but are not limited to, statements and/or information related to: strategy, future operations, projected production capacity, projected sales or rentals, projected costs, expectations regarding demand and acceptance of our products, availability of material components, trends in the market in which we operate, plans and objectives of management.

We believe that we have based our forward-looking statements on reasonable assumptions, estimates, analysis and opinions made in light of our experience and our perception of trends, current conditions and expected developments, as well as other factors that we believe to be relevant and reasonable in the circumstances at the date that such statements are made, but which may prove to be incorrect. Although management believes that the assumption and expectations reflected in such forward-looking statements are reasonable, we may have made misjudgments in preparing such forward-looking statements. Assumptions have been made regarding, among other things: our expected production capacity; labor costs and material costs, no material variations in the current regulatory environment and our ability to obtain financing as and when required and on reasonable terms. Readers are cautioned that the foregoing list is not exhaustive of all factors and assumptions which may have been used.

The forward-looking statements, including the statements contained in Item 3.D "Risk Factors". In particular, without limiting the generality of the foregoing disclosure, the statements contained in Item 4.B. – "Business Overview", Item 5 – "Operating and Financial Review and Prospects" and Item 11 – "Quantitative and Qualitative Disclosures About Market Risk" and elsewhere in this annual report, are subject to known and unknown risks, uncertainties and other factors that may cause actual results to be materially different from those expressed or implied by such forward-looking statements.

Although management has attempted to identify important factors that could cause actual results to differ materially from those contained in forward-looking statements, there may be other factors that cause results not to be as anticipated, estimated or intended. Forward-looking statements might not prove to be accurate, as actual results and future events could differ materially from those anticipated in such forward-looking statements or we may have made misjudgments in the course of preparing the forward-looking statements. Accordingly, readers should not place undue reliance on forward-looking statements. We wish to advise you that these cautionary remarks expressly qualify, in their entirety, all forward-looking statements attributable to our company or persons acting on our company's behalf. We do not undertake to update any forward-looking statements to reflect actual results, changes in assumptions or changes in other factors affecting such statements, except as, and to the extent required by, applicable securities laws. You should carefully review the cautionary statements and risk factors contained in this annual report and other documents that we may file from time to time with the securities regulators.

OTHER STATEMENTS IN THIS ANNUAL REPORT

Unless the context otherwise requires, in this annual report, the term(s) "we", "us", "our", "Company", "our company", "our business" and "Mainz Biomed" refer to Mainz Biomed N.V. together with its two wholly-owned subsidiaries.

PART I

ITEM 1. IDENTITY OF DIRECTORS, SENIOR MANAGEMENT AND ADVISERS

Not Applicable.

ITEM 2. OFFER STATISTICS AND EXPECTED TIMETABLE

Not Applicable.

ITEM 3. KEY INFORMATION

A. [Reserved]

B. Capitalization and Indebtedness

Not applicable.

C. Reasons for the offer and use of proceeds

Not applicable.

D. Risk Factors

An investment in our ordinary shares carries a significant degree of risk. You should carefully consider the following risks, as well as the other information contained in this annual report, including our historical financial statements and related notes included elsewhere in this annual report, before you decide to purchase our ordinary shares. Any one of these risks and uncertainties has the potential to cause material adverse effects on our business, prospects, financial condition and operating results which could cause actual results to differ materially from any forward-looking statements expressed by us and a significant decrease in the value of our ordinary shares. Refer to "Special Note Regarding Forward-Looking Statements".

We may not be successful in preventing the material adverse effects that any of the following risks and uncertainties may cause. These potential risks and uncertainties may not be a complete list of the risks and uncertainties facing us. There may be additional risks and uncertainties that we are presently unaware of, or presently consider immaterial, that may become material in the future and have a material adverse effect on us. You could lose all or a significant portion of your investment due to any of these risks and uncertainties.

Risks Related to Our Business Generally

We are an early revenue stage company and have incurred operating losses since inception, and we do not know when we will attain profitability. An investment in our securities is highly risky and could result in a complete loss of your investment if we are unsuccessful in our business plans.

We are an early-stage company. Since inception, we have incurred operating losses and negative cash flow, and we expect to continue to incur losses and negative cash flow in the future. Our net losses for the years ended December 31, 2023 and December 31, 2022 were approximately $26,295,727 and $26,387,336, respectively. Ultimately, our ability to generate sufficient operating revenue to earn a profit depends upon our success in developing and marketing or licensing our diagnostic tests and technology. Any failure to do so could result in the possible closure of our business or force us to seek additional capital through loans or additional sales of our equity securities to continue business operations, which could dilute the value of any securities you hold or could result in the loss of your entire investment. Until we earn a profit (and even if we earn a profit, until we earn a sufficient profit), our ability to continue and grow our operations depend on our ability to raise additional capital through debt and equity financings. If we are unable to raise additional capital through debt and equity financings, we could be forced to curtail or cease our operations, including in the near term.

Terms of subsequent financings may adversely impact your investment.

We have primarily funded our operations through in common equity, debt, or preferred stock financing and intend to engage in such financings in the future. Your rights and the value of your investment in our securities could be reduced as a result of any such future financing. Interest on debt securities could increase costs and negatively impact operating results. Preferred shares could be issued in series from time to time with such designation, rights, preferences, and limitations as needed to raise capital. The terms of preferred shares could be more advantageous to those investors than to the holders of ordinary shares. In addition, if we need to raise more equity capital from the sale of ordinary shares, institutional or other investors may negotiate terms at least as, and possibly more, favorable than the terms of your investment. Ordinary shares which we sell could be sold into the public market for our ordinary shares which could adversely affect the market price of our ordinary shares. As of the date of this annual report, we are subject to the "baby shelf" restrictions for the use of a shelf registration statement, meaning that we can only offer one-third of our public float through a shelf registration statement in any 12-month period. If we intend to register securities for sale that are equal to more than one-third of our public float in any 12-month period, we would have to do so through a registration statement on Form F-1, and any such financing could require less favorable terms or have a lesser chance of success.

Our inability to manage growth could harm our business.

We have added, and expect to continue to add, additional personnel in the area of research and development (where the approximate $4.6 million increase in our research and development expenses between our 2023 and 2022 fiscal years was primarily attributable to the increase in headcount in our employees working on research and development) and elsewhere in our company. We expect to continue to add additional personnel in the areas of sales and marketing, research & development, laboratory operations, finance, quality assurance and compliance. As we build our commercialization efforts and expand research and development activities, our operating expenses and capital requirements have also increased, and we expect that they will continue to increase, significantly. Our ability to manage our growth effectively requires us to forecast expenses accurately, and to properly forecast and expand operational and testing facilities, if necessary, to expend funds to improve our operational, financial and management controls, reporting systems and procedures. As we move forward in commercializing our tests and developing our test portfolio, we will also need to effectively manage our growing manufacturing, laboratory operations and sales and marketing needs. If we are unable to manage our anticipated growth effectively, our business could be harmed.

Risks that we face in undertaking this expansion include:

- training new personnel;
- forecasting production and revenue;
- expanding our marketing efforts;
- controlling expenses and investments in anticipation of expanded operations;
- establishing and maintaining relationships with new customers and partners;
- implementing and enhancing administrative infrastructure, systems and processes;
- unforeseen delays in the development of new products;
- unforeseen delays in regulatory approvals;
- unforeseen test performance that we may experience performing FDA studies; and
- addressing new markets.

We intend to continue to hire additional personnel. Competition for individuals with relevant experience can be intense, and we may not be able to attract, assimilate, train or retain additional highly qualified personnel in the future. The failure to attract, integrate, train, motivate and retain these additional employees could seriously harm our business and prospects.

We substantially depend upon our management.

Our success depends largely on the skills, experience and performance of key members of our management who are critical to directing and managing our growth and development in the future. Our success substantially depends upon our senior management's ability to lead our company, implement successful corporate strategies and initiatives, develop key relationships, including relationships with collaborators and business partners, and successfully commercialize products and services. While our management has significant experience developing diagnostic products, we have considerably less experience in commercializing these products or services. The efforts of our management will be critical as we develop our technologies and seek to commercialize our tests and other products and services.

Failure of our internal controls over financial reporting could harm our business and financial results.

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting for external purposes in accordance with accounting principles generally accepted in the United States. Internal control over financial reporting includes maintaining records that in reasonable detail accurately and fairly reflect our transactions; providing reasonable assurance that transactions are recorded as necessary for preparation of our financial statements; providing reasonable assurance that receipts and expenditures of our assets are made in accordance with management authorization; and providing reasonable assurance that unauthorized acquisition, use or disposition of our assets that could have a material effect on the financial statements would be prevented or detected on a timely basis. Because of its inherent limitations, internal control over financial reporting is not intended to provide absolute assurance that a misstatement of our financial statements would be prevented or detected. Our growth and entry into new diagnostic tests, technologies and markets will place significant additional pressure on our system of internal control over financial reporting. Any failure to maintain an effective system of internal control over financial reporting could limit our ability to report our financial results accurately and timely or to detect and prevent fraud.

Our financial statements for the fiscal year ended December 31, 2023 include an explanatory paragraph from our auditor indicating that there is substantial doubt about our ability to continue as a going concern.

Since inception, we have devoted substantially all of our resources to developing our in-vitro diagnostic tests, establishing partnerships and sales channels to distribute such tests and operating a clinical diagnostic laboratory. We have recurring losses, accumulated deficit totaling $69,328,021 and negative cash flows used in operating activities of $21,938,845 as of and for the year ended December 31, 2023, and we expect to continue to have recurring losses and negative cash flows in operating activities in the near future as we seek to gain regulatory approval for our principal product in certain jurisdictions. These factors led management to conclude that there is a substantial doubt as to our ability to continue as a going concern for a period that is one year from the date of our financial statements, and we prepared out financial statements on that basis. In addition, the auditor's opinion accompanying our audited financial statements for the year ended December 31, 2023 includes an explanatory paragraph indicating that there is substantial doubt about our ability to continue as a going concern as a result of recurring losses from operations and negative cash flows. We expect our financial condition and operating results to fluctuate significantly from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. If we are unable to obtain funding, we could be forced to delay, reduce, or eliminate our research and development, regulatory, and commercial efforts which could adversely affect our future business prospects and our ability to continue as a going concern.

You may face difficulties protecting your interests, and your ability to protect your rights through the U.S. federal courts may be limited because we are incorporated under the laws of the Netherlands, a substantial portion of our assets are in the European Union and substantial portion of our directors and executive officers reside outside the United States.

We are constituted under the laws of the Netherlands. A substantial portion of our officers, and directors, reside outside the United States. In addition, a substantial portion of their assets and our assets are located outside of the United States. As a result, you may have difficulty serving legal process within the United States upon us or any of these persons. You may also have difficulty enforcing, both in and outside of the United States, judgments you may obtain in U.S. courts against us or these persons in any action, including actions based upon the civil liability provisions of U.S. Federal or state securities laws. Furthermore, there is substantial doubt as to the enforceability in the Netherlands against us or against any of our directors, officers and the expert named in this annual report who are not residents of the United States, in original actions or in actions for enforcement of judgments of U.S. courts, of liabilities based solely upon the civil liability provisions of the U.S. federal securities laws. In addition, shareholders in Dutch corporations may not have standing to initiate a shareholder derivative action in U.S. federal courts.

As a result, our public shareholders may have more difficulty in protecting their interests through actions against us, our management, our directors or our major shareholders than would shareholders of a corporation incorporated in a jurisdiction in the United States.

Global economic conditions could materially adversely impact demand for our products and services.

Our operations and performance depend significantly on economic conditions. Global financial conditions continue to be subject to volatility arising from international geopolitical developments, such as the ongoing wars in Ukraine and the Middle East, and global economic phenomenon, as well as general financial market turbulence and natural phenomena, such as the COVID-19 pandemic. Uncertainty about global economic conditions could result in:

- customers postponing purchases of our products and services in response to tighter credit, unemployment, negative financial news and/or declines in income or asset values and other macroeconomic factors, which could have a material negative effect on demand for our products and services; and
- third-party suppliers being unable to produce components for our products in the same quantity or on the same timeline or being unable to deliver such parts and components as quickly as before or subject to price fluctuations, which could have a material adverse effect on our production or the cost of such production; and accordingly, on our business, results of operations or financial condition.

Access to public financing and credit can be negatively affected by the effect of these events on German, Dutch, European, U.S. and global credit markets. The health of the global financing and credit markets may affect our ability to obtain equity or debt financing in the future and the terms at which financing or credit is available to us. These instances of volatility and market turmoil could adversely affect our operations and the trading price of our ordinary shares.

Changes to trade policy, tariffs, and import/export regulations may have a material adverse effect on our business, financial condition, and results of operations.

Changes in laws and policies governing foreign trade could adversely affect our business. As a result of recent and future policy changes, there may be greater restrictions and economic disincentives on international trade. Such changes have the potential to adversely impact the global and local economies, our industry and global demand for our products and, as a result, could have a material adverse effect on our business, financial condition and results of operations.

Fluctuations in currency exchange rates may significantly impact our results of operations.

A substantial percentage of our operations are conducted in Europe. As a result, we are exposed to an exchange rate risk between the U.S. and the Euro. The exchange rates between these currencies in recent years have fluctuated significantly and may continue to do so in the future. An appreciation of the Euro against the U.S. dollar could increase the relative cost of our products outside of Europe, which could lead to decreased sales. Conversely, to the extent that we are required to pay for goods or services in U.S. dollars, the depreciation of the Euro dollar against the U.S. dollar would increase the cost of such goods and services.

We do not hedge our currency exposure and, therefore, we incur currency transaction risk whenever we enter into either a purchase or sale transaction using a currency other than the Euro. Given the volatility of exchange rates, we might not be able to effectively manage our currency transaction risks, and volatility in currency exchange rates might have a material adverse effect on our business, financial condition or results of operations.

Risks Related to Our Technology and Business Strategy

We may fail to generate sufficient revenue from our relationships with our clients or laboratory partners to achieve and maintain profitability.

We believe our commercial success depends upon our ability to successfully market and sell our products and solutions, to continue to expand our current relationships and to develop new relationships with customers, physicians, and laboratories. The demand for our existing and future services may decrease for a number of reasons, including, but is not limited to, the development by competitors of new products, and increased competition from companies that offer similar products and solutions. In addition to reducing our revenue, if our laboratory partners or clients decide to decrease or discontinue their partnerships or relationships with us, and their use of our knowledge and interpretation-based solutions, this may reduce our access to research and patient data that facilitates the incorporation of newly developed information about rare diseases into our data repository.

Our success depends heavily on our ColoAlert screening tests.

For the foreseeable future, our ability to generate revenues depends almost entirely on the commercial success of ColoAlert, our colon cancer screening test. The commercial success and our ability to generate revenues depends on a variety of factors, including the following:

- patient acceptance of and demand for our tests;
- acceptance of our test in the medical community;
- successful sales, marketing, and educational programs;
- the amount and nature of competition from other colon cancer screening products and procedures;
- the ease of use of our ordering process for physicians;
- maintaining and defending intellectual property and trade secrets, and our ability to establish and maintain adequate commercial manufacturing, distribution, sales and laboratory testing capabilities; and
- The potential of being sued by competitors to avoid or delay market entry in certain geographic markets.

If we are unable to develop and maintain substantial sales of our tests or if we are significantly delayed or limited in doing so, our business prospects, financial condition and results of operation would be adversely affected.

Sales of our diagnostic tests could be adversely impacted by the reluctance of physicians to adopt the use of our tests and by the availability of competing diagnostic tests.

Physicians and hospitals may be reluctant to try a new diagnostic test due to the high degree of risk associated with the application of new technologies and diagnostic test in the field of human medicine, especially if the new test differs from the current standard of care for detecting cancer in patients. For example, CRC prevention strategies, such as FIT and colonoscopies, are well known in the patient group aged over 50 years, while ColoAlert and similar diagnostic tests are not vastly known by physicians or patients. We will need to expend significant sums of money to market our products to increase the public's awareness. If our products do not achieve an adequate level of acceptance, we may not generate enough revenues to become profitable or profitability may occur much later.

Competing tests for the initial diagnosis, reoccurrence diagnosis and optimal treatment of cancer are being manufactured and marketed by other companies. To compete with other diagnostic tests, particularly any that sell at lower prices, our tests will have to provide medically significant advantages or be more cost effective. Even if we can overcome physician reluctance and compete with products that are currently on the market, our competitors may succeed in developing new, safer, more accurate or more cost-effective diagnostic tests that could render our diagnostic tests and technologies obsolete or non-competitive.

We may not succeed in establishing, maintaining and strengthening ColoAlert and other brands associated with our products, which would materially and adversely affect acceptance of our diagnostic tests, and our business, revenues and prospects.

Our business and prospects heavily depend on our ability to develop, maintain and strengthen the ColoAlert brand and the brands of our future products. Any failure to develop, maintain and strengthen these brands may materially and adversely affect our ability to sell our products. Most of our sales are to clinical reference laboratories or routine diagnostic laboratories. Those laboratories are generally more focused on taking orders than on marketing the products that they sell. We need to educate these reference laboratories and the general public as to why we believe our products are superior. If we are not able to establish, maintain and strengthen our brands, we may lose the opportunity to build our customer base.

We expect that our ability to develop, maintain and strengthen our brands will depend heavily on the success of our marketing efforts. We intend to use current cash assets to market our products, but we might not be successful in such expanded marketing. Due to the specifics of the market in which we operate, the investment in customer acquisition will be high and the uptake is likely slow until a critical mass is reached. To further promote our brand, we may be required to change our marketing practices, which could result in substantially increased advertising expenses, including the need to use traditional media such as television, radio and print. If we do not develop and maintain strong brands, our business, prospects, financial condition and operating results will be materially and adversely impacted.

We might decide not to incorporate the UdeS Biomarkers after we conclude additional studies on such biomarkers.

On February 15, 2023 we acquired a portfolio of novel mRNA biomarkers developed at the Université de Sherbrooke (the "UdeS Biomarkers"). We are in the process conducting an international multi-center clinical study in the United States and Europe (such study called "eAArly DETECT") to assess the potential to integrate the UdeS Biomarkers into ColoAlert. If we conclude the eAArly DETECT study and decide not to integrate the UdeS Biomarkers, we will have expended significant time and funds in connection with the acquisition and the study without improving our ColoAlert product.

Product liability, warranty, personal injury, property damage and recall claims may materially affect our financial condition and damage our reputation.

We are engaged in a business that exposes us to claims for product liability and warranty claims in the event our products actually or allegedly fail to perform as expected or the use of our products results, or is alleged to result, in property damage, personal injury or death. Any judgment or settlement for personal injury or wrongful death claims could be more than our assets and, even if not justified, could prove expensive to contest.

Although we maintain product and general liability insurance of the types and in the amounts that we believe are customary for the industry, we are not fully insured against all such potential claims. We may experience legal claims in excess of our insurance coverage or claims that are not covered by insurance, either of which could adversely affect our business, financial condition and results of operations. Adverse determination of material product liability and warranty claims made against us could have a material adverse effect on our financial condition and harm our reputation. In addition, if any of our products or components in our products are, or are alleged to be, defective, we may be required to participate in a recall of that product or component. Any such recall and other claims could be costly to us and require substantial management attention.

We may face technology transfer challenges and expenses in adding new tests to our portfolio and in expanding our reach into new geographical areas.

Our plan for expanding our business includes developing and acquiring additional tests or additional biomarkers that can be transferred into our current and future diagnostic product portfolio and distributed in our target markets. Due to differences in the hardware and software platforms available at different laboratories for running molecular tests, we may need to adjust the configuration of the reagents and there may be changes to the related software in order for the tests to be performed on particular hardware platforms. Making any such adjustments could take a considerable amount of time and expense, and we might not succeed in running our tests on the hardware and software that we may encounter in different laboratories. To manage this issue, we may license or acquire our own instrument system and software from another company that has a platform that will be compatible with our tests. This may include additional licenses and license fees needed for reagents or components required hereto as well.

If third party payors do not provide reimbursement, breach, rescind or modify their contracts or reimbursement policies or delay payments for our tests, or we are unable to successfully renegotiate reimbursement contracts, our commercial success could be compromised.

Physicians and patients might not order our tests unless third party payors, such as managed care organizations as well as government payors, pay a substantial portion of the test price. Reimbursement by a payor may depend on a number of factors, including a payor's determination that tests using our technologies are not experimental or investigational, and that they are medically necessary, cost-effective, supported by peer-reviewed publications and included in clinical practice guidelines. There is uncertainty concerning third-party payor reimbursement of any test incorporating new technology.

Reimbursement is based in most countries on reimbursement codes, which differ from country to country. Currently, ColoAlert is reimbursed as a polymerase chain reaction ("PCR") test in Germany for privately insured patients if an authorized medical care center is performing the analysis. For statutory and/or privately insured patients in Germany and in other countries, we may need to apply for a specific reimbursement code, which may call for a new clinical study and additional CE-IVD approvals.

We believe that it may take several years to achieve reimbursement with a majority of third-party payors for our tests. If we fail to establish and maintain broad adoption of and reimbursement for all of our current tests and any future tests that we may develop, our reputation could be harmed and our future prospects, revenue and our business could suffer. Additionally, we have in the past experienced, and anticipate further experiencing, delays and temporary interruptions in the receipt of payments from third-party payors due to modifications in existing contracts or arrangements, contract implementation matters, documentation requirements and other issues, which could cause our revenues to fluctuate from period to period.

We will need to make significant inroads with general practitioners in Europe. In most European countries, health care is considered a public responsibility, and the main payer is public health insurance. This implies that the private pay market is limited, and that general practitioners are the main gate keepers to market penetration. If we cannot convince general practitioners in Europe that our products are the superior choice, we cannot grow there as quickly as we need, if at all.

We may depend on possible future collaborations to develop and commercialize many of our diagnostic test candidates and to provide the manufacturing, regulatory compliance, sales, marketing and distribution capabilities required for the success of our business.

We may enter into various collaborative research and development, manufacturing, and diagnostic test marketing agreements to develop and commercialize our diagnostic tests. Any future milestone payments and cost reimbursements from collaboration agreements could provide an important source of financing for our research and development programs, thereby facilitating the application of our technology to the development and commercialization of our diagnostic tests, but there are risks associated with entering into collaboration arrangements.

There is a risk that we could become dependent upon one or more collaborative arrangements for diagnostic test development or manufacturing or as a source of revenues from the sale of any diagnostic tests that may be developed by us alone or through one of the collaborative arrangements. A collaborative arrangement upon which we might depend might be terminated by our collaboration partner or they might determine not to actively pursue the development or commercialization of our diagnostic tests. A collaboration partner also may not be precluded from independently pursuing competing diagnostic tests or technologies.

There is a risk that a collaboration partner might fail to perform its obligations under the collaborative arrangements or may be slow in performing its obligations. In addition, a collaboration partner may experience financial difficulties at any time that could prevent it from having available funds to contribute to the collaboration. If a collaboration partner fails to conduct its diagnostic test development, manufacturing, commercialization, regulatory compliance, sales and marketing or distribution activities successfully and in a timely manner, or if it terminates or materially modifies its agreements with us, the development and commercialization of one or more diagnostic test candidates could be delayed, curtailed or terminated because we may not have sufficient financial resources or capabilities to continue diagnostic test development, manufacturing, and commercialization on our own.

If we are unable to obtain and enforce patents and to protect our trade secrets, others could use our technology to compete with us, which could create undue competition and pricing pressures. There is no certainty that any future patent applications will result in the issuance of patents or that issued patents, if we receive any, will be deemed enforceable.

The success of our business depends significantly on our ability to operate without infringing patents and other proprietary rights of others. If the technology that we use infringes a patent held by others, we could be sued for monetary damages by the patent holder or its licensee, or we could be prevented from continuing research, development, and commercialization of diagnostic tests that rely on that technology, unless we are able to obtain a license to use the patent. The cost and availability of a license to a patent cannot be predicted, and the likelihood of obtaining a license at an acceptable cost would be lower if the patent holder or any of its licensees is using the patent to develop or market a diagnostic test with which our diagnostic test would compete. If we cannot obtain a necessary license, we would need to develop or obtain rights to alternative technologies, which could prove costly and could cause delays in diagnostic test development, or we could be forced to discontinue the development or marketing of any diagnostic tests that were developed using the technology covered by the patent.

Our success depends in part on our ability to obtain and enforce intellectual property protection. In February 2023, we acquired the UdeS Biomarkers, and we are now responsible for prosecuting and maintaining any patents on such biomarkers, including the patent application filed with the U.S. PTO (application no. 68/108,510 filed November 2, 2020 and the corresponding International Application Serial No: PCT/CA2021/051548 filed November 2, 2021) and the International Patent System. We currently rely on trade secrets, know-how and technology to protect our intellectual property and, except as discussed above, do not have any patents or any pending patent applications. If the intellectual property that is the subject of our patent application is not granted a patent or we are otherwise unsuccessful in obtaining or maintaining such intellectual property protection and our trade secrets and know-how are revealed to our competitors, they could use our intellectual property and create diagnostic tests that compete with our diagnostic tests, without paying license fees or royalties to us.

Confidentiality agreements with employees and others may not adequately prevent disclosure of trade secrets and other proprietary information.

We rely on trade secrets, know-how and technology, which are not protected by patents and do not have any patent applications pending (apart from our patent application related to the UdeS Biomarkers), to protect the intellectual property behind our diagnostic tests. We do not yet use confidentiality agreements with our collaborators, employees, consultants, outside scientific collaborators and sponsored researchers and other advisors to protect our proprietary technology and processes. We intend to use such agreements in the future, but these agreements may not effectively prevent disclosure of confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. In addition, others may independently discover trade secrets and proprietary information, and in such cases, we cannot assert any trade secret rights against such party. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights, and failure to obtain or maintain trade secret protection could adversely affect our competitive business position.

Results of FDA required studies may not create desired clinical performance resulting in follow-on studies delaying the launch of the product in the US.

We will be required to undertake a clinical study to achieve U.S. Food and Drug Administration ("FDA") market authorization that will be significantly larger than the study used to receive CE-IVD certification under the IVD-D. The clinical performance of the ColoAlert test for the FDA study might not meet the current product performance. As a result, we may need to undertake additional studies or abandon the study altogether. Additional studies would be costly and delay or prevent our rollout of ColoAlert in the United States.

Risks Related to Regulations

Our global operations expose us to numerous and sometimes conflicting legal and regulatory requirements, and violations of these requirements could harm our business.

We are subject to numerous, and sometimes conflicting, legal regimes in the countries in which we operate, including on matters as diverse as health and safety standards, marketing and promotional activities, anticorruption, import/export controls, content requirements, trade restrictions, tariffs, taxation, sanctions, immigration, internal and disclosure control obligations, securities regulation, anti-competition, data privacy and labor relations. This includes in emerging markets where legal systems may be less developed or familiar to us. We strive to abide by and maintain compliance with these laws and regulations. Compliance with diverse legal requirements is costly and time-consuming. Violations of one or more of these regulations in the conduct of our business could result in significant fines, criminal sanctions against us or our board of directors or officers, prohibitions on doing business and damage to our reputation. Violations of these regulations in connection with the performance of our obligations to our clients or partners also could result in liability for significant monetary damages, fines and/or criminal prosecution, unfavorable publicity and other reputational damage, restrictions on our ability to process information and allegations by our clients or partners that we have not performed our contractual obligations. Due to the varying degrees of development of the legal systems of the countries in which we operate, local laws might be insufficient to protect our rights.

Our international operations could be affected by changes in laws, trade regulations, labor and employment regulations, and procedures and actions affecting approval, products and solutions, pricing, reimbursement and marketing of our products and solutions, as well as by inter-governmental disputes. Any of these changes could adversely affect our business. The imposition of new laws or regulations, including potential trade barriers, may increase our operating costs, impose restrictions on our operations or require us to spend additional funds to gain compliance with the new rules, if possible, which could have an adverse impact on our financial condition.

Our business is subject to various complex laws and regulations. We could be subject to significant fines and penalties if we or our partners fail to comply with these laws and regulations.

As a manufacturer of clinical diagnostic products and clinical diagnostic services, we and our partners are subject to extensive and frequently changing federal, state and local laws and regulations governing various aspects of our business. In particular, the clinical laboratory industry is subject to significant governmental certification and licensing regulations, as well as federal and state laws regarding:

- test ordering and billing practices;
- marketing, sales and pricing practices;
- health information privacy and security, including the Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and comparable state and local laws;
- anti-markup legislation; and
- consumer protection.

We expect to be required to comply with U.S. Food and Drug Administration, or FDA, regulations, including with respect to our labeling and promotion activities. In addition, advertising of our tests is subject to regulation by the Federal Trade Commission, or FTC. Violation of any FDA requirement could result in enforcement actions, such as seizures, injunctions, civil penalties and criminal prosecutions, and violation of any FTC requirement could result in injunctions and other associated remedies, all of which could have a material adverse effect on our business. Most states also have similar regulatory and enforcement authority for devices. Additionally, most foreign countries have authorities comparable to the FDA and processes for obtaining marketing approvals. Obtaining and maintaining these approvals, and complying with all laws and regulations, may subject us to similar risks and delays as those we could experience under FDA and FTC regulation. We incur various costs in complying and overseeing compliance with these laws and regulations.

Healthcare policy has been a subject of extensive discussion in many national, regional and local governments, and healthcare laws and regulations are subject to change. Development of the existing commercialization strategy for our tests have been based on existing healthcare policies. We cannot predict what additional changes, if any, will be proposed or adopted or the effect that such proposals or adoption may have on our business, financial condition, and results of operations. If we or our partners, including independent sales representatives, fail to comply with these laws and regulations, we could incur significant fines and penalties and our reputation and prospects could suffer. Additionally, our partners could be forced to cease offering our products and services in certain jurisdictions, which could materially disrupt our business.

We will have to maintain facilities, or maintain relationships with third party laboratories, for the manufacture and use of diagnostic tests. Our ability to provide services and pursue our research and development and commercialization efforts may be jeopardized if these facilities were to be harmed or rendered inoperable.

Our facilities and equipment could be harmed or rendered inoperable by natural or man-made disasters, including fire, flooding and power outages, which may render it difficult or impossible for us to perform our tests or provide laboratory services for some period of time. The inability to perform our tests or the backlog of tests that could develop if any of our facilities is inoperable for even a short period of time may result in the loss of customers or harm to our reputation or relationships with key researchers, collaborators, and customers, and we may be unable to regain those customers or repair our reputation in the future. Furthermore, our facilities and the equipment we use to perform our research and

development work could be costly and time-consuming to repair or replace.

Additionally, a key component of our research and development process involves using biological samples and the resulting data sets and medical histories, as the basis for our diagnostic test development. In some cases, these samples are difficult to obtain. If the parts of our laboratory facilities where we store these biological samples are damaged or compromised, our ability to pursue our research and development projects, commercialization of our diagnostic tests, as well as our reputation, could be jeopardized. We carry insurance for damage to our property and the disruption of our business, but this insurance may not be sufficient to cover all of our potential losses and may not continue to be available to us on acceptable terms, if at all.

We anticipate being required to obtain regulatory approval of our diagnostic test products to enter new markets.

If our products enter new markets, they will need to satisfy the regulatory rules in that market. Given the nature of our products and product candidates, we believe that our entry into the U.S. market will require FDA market authorization through pre-market review. This may also be the case for corresponding foreign regulatory authorities. Our products and product candidates may not be cleared or approved on a timely basis, if at all. The regulatory approval process may involve, among other things, successfully completing additional clinical trials and filing a pre-market approval application (PMA) with the FDA. Similar review and approval processes may be applicable for corresponding foreign regulatory authorities.

We are required to comply with national, regional and local laws governing the privacy of health information, and any failure to comply with these laws could result in material criminal and civil penalties.

National, regional and local laws set forth security regulations that establish administrative, physical and technical standards for maintaining the confidentiality, integrity and availability of protected health information in electronic form. If protected health information is breached, additional laws, require us to provide certain health information security breach notifications to those individuals whose protected health information is breached.

We may incur significant compliance costs related to varying national and state privacy regulations and varying national and state privacy and security laws. Given the complexity of such laws and their overlap with national and state privacy and security laws, and the fact that these laws are rapidly evolving and are subject to changing and potentially conflicting interpretation, our ability to comply with such laws and requirements is uncertain and the costs of compliance are significant. The costs of complying with any changes to the national and state privacy restrictions may have a negative impact on our operations. Noncompliance could subject us to criminal penalties, civil sanctions and significant monetary penalties as well as reputational damage.

We are subject to cybersecurity risks to operational systems, security systems, infrastructure and personal data processed by us or third-party vendors or suppliers and any material failure, weakness, interruption, cyber event, incident or breach of security could prevent us from effectively operating our business or subject us to liability for mishandling sensitive data.

We may become exposed to actual and attempted cyber-attacks of our IT networks, such as through phishing scams and ransomware. For example, we are at risk for interruptions, outages and breaches of: operational systems, including business, financial, accounting, product development, data processing, and production processes, owned by us or our third-party vendors or suppliers; facility security systems, owned by us or our third-party vendors or suppliers; in-product technology owned by us or our third-party vendors or suppliers; the integrated software in our solutions; or personal data that we process or our third-party vendors or suppliers process on our behalf. Such cyber incidents could materially disrupt operational systems; result in loss of intellectual property, trade secrets or other proprietary or competitively sensitive information; compromise certain information of customers, employees, suppliers, drivers or others; jeopardize the security of our facilities; or affect the performance of in-product technology and the integrated software solutions. A cyber incident could be caused by disasters, insiders (through inadvertence or with malicious intent) or malicious third parties (including nation-states or nation-state supported actors) using sophisticated, targeted methods to circumvent firewalls, encryption and other security defenses, including hacking, fraud, trickery or other forms of deception. The techniques used by cyber attackers change frequently and may be difficult to detect for long periods of time. Although we maintain information technology measures designed to protect us against intellectual property theft, data breaches and other cyber incidents, such measures require constant updates and improvements, and we cannot guarantee that such measures will be adequate to detect, prevent or mitigate cyber incidents. The implementation, maintenance, segregation and improvement of these systems requires significant management time, support and cost. Moreover, there are inherent risks associated with developing, improving, expanding and updating current systems, including the disruption of our data management, procurement, production execution, finance, supply chain and sales and service processes. These risks may affect our ability to manage our data and inventory, procure parts or supplies or produce, sell, deliver and service our solutions, adequately protect our intellectual property or achieve and maintain compliance with, or realize available benefits under, applicable laws, regulations and contracts. We cannot be sure that the systems upon which we rely, including those of our third-party vendors or suppliers, will be effectively implemented, maintained or expanded as planned. If we do not successfully implement, maintain or expand these systems as planned, our operations may be disrupted, our ability to accurately and timely report our financial results could be impaired, and deficiencies may arise in our internal control over financial reporting, which may impact our ability to certify our financial results. Moreover, our proprietary information or intellectual property could be compromised or misappropriated, and our reputation may be adversely affected. If these systems do not operate as we expect them to, we may be required to expend significant resources to make corrections or find alternative sources for performing these functions.

A significant cyber incident could impact production or laboratory capability, harm our reputation, cause us to breach our contracts with other parties or subject us to regulatory actions or litigation, any of which could materially affect our business, prospects, financial condition and operating results. In addition, our insurance coverage for cyber-attacks may not be sufficient to cover all the losses we may experience as a result of a cyber incident. Any problems with our third-party cloud hosting providers, whether due to cyber security failures or other causes, could result in lengthy interruptions in our business.

We are subject to national and regional healthcare fraud and abuse laws and regulations and could face substantial penalties if we are unable to fully comply with such laws.

We are subject to healthcare fraud and abuse regulation and enforcement by both national governments and the regions in which we conduct our business. In the United States, where we intend to seek approval to rollout our ColoAlert product, these health care laws and regulations include the following:

- The federal Anti-Kickback Statute;
- The federal physician self-referral prohibition, commonly known as the Stark Law;
- The federal false claims and civil monetary penalties laws;
- The federal Physician Payment Sunshine Act requirements under the Affordable Care Act; and
- State law equivalents of each of the federal laws enumerated above.

Any action brought against us for violation of these laws or regulations, even if we are in compliance and successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. If our operations are found to be in violation of any of these laws and regulations, we may be subject to applicable penalties associated with the violation, including, among others, administrative, civil and criminal penalties, damages and fines, and/or exclusion from

participation in Medicare, Medicaid programs, including the California Medical Assistance Program (Medi-Cal — the California version of the Medicaid program) or other state or federal health care programs. Additionally, we could be required to refund payments received by us, and we could be required to curtail or cease our operations.

Risks Related to Our Ordinary Shares

The market price of our ordinary shares may be volatile and may fluctuate in a way that is disproportionate to our operating performance.

The public market for our ordinary shares has a limited history. Our ordinary shares began trading on the Nasdaq Capital Market on November 5, 2021, and since that date they have had a high closing price of $27.76 per share and a low closing price of $0.875 per share. The daily trading volume and our per ordinary share market price may decrease significantly after the date of this annual report. The value of our ordinary shares could decline due to the impact of any of the following factors upon the market price of our ordinary shares:

- sales or potential sales of substantial amounts of our ordinary shares;
- announcements about us or about our competitors;
- litigation and other developments relating to our intellectual property or other proprietary rights or those of our competitors;
- conditions in the diagnostic test industry;
- governmental regulation and legislation;
- variations in our anticipated or actual operating results;
- change in securities analysts' estimates of our performance, or our failure to meet analysts' expectations;
- change in general economic trends; and
- investor perception of our industry or our prospects.

Many of these factors are beyond our control. These fluctuations often have been unrelated or disproportionate to the operating performance of these companies. As a consequence, there may be periods of several days or more when trading activity in our shares is minimal or non-existent, as compared to a seasoned issuer which has a large and steady volume of trading activity that will generally support continuous sales without an adverse effect on share price. A broad or active public trading market for our ordinary shares may not develop or be sustained.

You may experience dilution of your ownership interests if we issue additional ordinary shares or preferred shares.

In the future, we may issue our authorized but previously unissued equity securities, resulting in the dilution of the ownership interests of our present shareholders. We are authorized to issue an aggregate of 45,000,000 ordinary shares. As of March 26, 2024, we had 21,886,575 ordinary shares outstanding, approximately 45% of the ordinary shares that we are authorized to issue. In addition as of March 26, 2024, we had 6,957,500 warrants exercisable into ordinary shares outstanding, 2,749,650 options exercisable into ordinary shares outstanding and $5,185,772 of convertible debt outstanding, which is convertible into 2,576,776 ordinary shares using the lowest permitted conversion price.

We may issue additional ordinary shares or other securities that are convertible into or exercisable for ordinary shares in order to raise additional capital, or in connection with hiring or retaining employees, directors, or consultants, or in connection with future acquisitions of licenses to technology or diagnostic tests in connection with future business acquisitions, or for other business purposes. The future issuance of any such additional ordinary shares or other securities, including those underlying the warrants and options we have issued and granted, would dilute the voting power of our current stockholders, could dilute the net tangible book value per share at the time of such future issuance and may create downward pressure on the trading price of our ordinary shares.

We may also issue preferred shares having rights, preferences, and privileges senior to the rights of our ordinary shares with respect to dividends, rights to share in distributions of our assets if we liquidate our company, or voting rights. Any preferred shares may also be convertible into ordinary shares on terms that would be dilutive to holders of ordinary shares.

We do not intend to pay dividends, and there will thus be fewer ways in which you are able to make a gain on your investment.

We have never paid any cash or stock dividends, and we do not intend to pay any dividends for the foreseeable future. To the extent that we require additional funding currently not provided for in our financing plan, our funding sources may prohibit the payment of any dividends. Because we do not intend to declare dividends, any gain on your investment will need to result from an appreciation in the price of our ordinary shares. There will therefore be fewer ways in which you will be able to make a gain on your investment. Our articles of association prescribe that any profits in any financial year will be distributed first to holders of preferred shares, if outstanding.

FINRA sales practice requirements may limit your ability to buy and sell our ordinary shares, which could depress the price of our shares.

FINRA rules require broker-dealers to have reasonable grounds for believing that an investment is suitable for a customer before recommending that investment to the customer. Prior to recommending speculative low-priced securities to their non-institutional customers, broker-dealers must make reasonable efforts to obtain information about the customer's financial status, tax status and investment objectives, among other things. Under interpretations of these rules, FINRA believes that there is a high probability such speculative low-priced securities will not be suitable for at least some customers. Thus, FINRA requirements may make it more difficult for broker-dealers to recommend that their customers buy our ordinary shares, which may limit your ability to buy and sell our shares, have an adverse effect on the market for our shares and, thereby, depress their market prices.

Volatility in our ordinary shares price may subject us to securities litigation.

The market for our ordinary shares may have, when compared to seasoned issuers, significant price volatility, and we expect that our share price may continue to be more volatile than that of a seasoned issuer for the indefinite future. In the past, plaintiffs have often initiated securities class action litigation against a company following periods of volatility in the market price of its securities. We may, in the future, be the target of similar litigation. Securities litigation could result in substantial costs and liabilities and could divert management's attention and resources.

We are a foreign private issuer within the meaning of the rules under the Exchange Act, and as such we are exempt from certain provisions applicable to U.S. domestic public companies.

We are a foreign private issuer within the meaning of the rules under the Securities Exchange Act of 1934, as amended (the "Exchange Act"). As such, we are exempt from certain provisions applicable to U.S. domestic public companies. For example:

- we are not required to provide as many Exchange Act reports, or as frequently, as a domestic public company;
- for interim reporting, we are permitted to comply solely with our home country requirements, which are less rigorous than the rules that apply to domestic public companies;
- we are not required to provide the same level of disclosure on certain issues, such as executive compensation;
- we are exempt from provisions of Regulation FD aimed at preventing issuers from making selective disclosures of material information;
- we are not required to comply with the sections of the Exchange Act regulating the solicitation of proxies, consents or authorizations in respect of a security registered under the Exchange Act; and
- we are not required to comply with Section 16 of the Exchange Act requiring insiders to file public reports of their share ownership and trading activities and establishing insider liability for profits realized from any "short-swing" trading transaction.

Our shareholders may not have access to certain information they may deem important and are accustomed to receiving from U.S. reporting companies.

We may lose our foreign private issuer status in the future, which could result in significant additional cost and expense.

While we currently qualify as a foreign private issuer, the determination of foreign private issuer status is made annually based on the last business day of an issuer's most recently completed second fiscal quarter and, accordingly, our next determination will be made based on information as of June 30, 2023. In the future, we would lose our foreign private issuer status if we fail to meet the requirements necessary to maintain our foreign private issuer status as of the relevant determination date. For example, if 50% or more of our securities are held by U.S. residents and more than 50% of (i) our assets are located in the United States or (ii) our senior management or directors are residents or citizens of the United States, we could lose our foreign private issuer status. We believe that it is possible that when we analyze whether we are a foreign private issuer as of June 30, 2024 we will conclude that we are not.

The regulatory and compliance costs to us under U.S. securities laws as a U.S. domestic issuer may be significantly higher. If we cease to be a foreign private issuer, we will be required to file periodic reports and registration statements on U.S. domestic issuer forms with the SEC, which are more detailed and extensive in certain respects than the forms available to a foreign private issuer. We would be required under current SEC rules to prepare our financial statements in accordance with U.S. GAAP, rather than IFRS, and modify certain of our policies to comply with corporate governance practices required of U.S. domestic issuers. Such conversion of our financial statements to U.S. GAAP would involve significant time and cost. In addition, we may lose our ability to rely upon exemptions from certain corporate governance requirements on U.S. stock exchanges (including the Nasdaq Capital Market) that are available to foreign private issuers such as the ones described above and exemptions from procedural requirements related to the solicitation of proxies.

As an "emerging growth company" under applicable law, we will be subject to lessened disclosure requirements. Such reduced disclosure may make our ordinary shares less attractive to investors.

For as long as we remain an "emerging growth company", as defined in the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act"), we will elect to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not "emerging growth companies", including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports, and exemptions from the requirements of holding a non-binding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved. Because of these lessened regulatory requirements, our shareholders would be left without information or rights available to shareholders of more mature companies. If some investors find our ordinary shares less attractive as a result, there may be a less active trading market for such securities and their market prices may be more volatile.

We will incur significant costs after we cease to qualify as an "emerging growth company."

The Sarbanes-Oxley Act, as well as rules subsequently implemented by the SEC and the Nasdaq Capital Market, impose various requirements on the corporate governance practices of public companies. We are an "emerging growth company," as defined in the JOBS Act and will remain an emerging growth company until the earlier of (1) (a) December 31, 2026, (b) the last day of the fiscal year in which we have total annual gross revenue of at least $1.07 billion, or (c) the last day of the fiscal year in which we are deemed to be a large accelerated filer, which means the market value of our ordinary shares that is held by non-affiliates exceeds $700 million as of the prior June 30th, and (2) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period. An emerging growth company may take advantage of specified reduced reporting and other requirements that are otherwise applicable generally to public companies. These provisions include exemption from the auditor attestation requirement under Section 404 in the assessment of the emerging growth company's internal control over financial reporting and permission to delay adopting new or revised accounting standards until such time as those standards apply to private companies. After we are no longer an emerging growth company, we expect to incur significant expenses and devote substantial management effort toward ensuring compliance with the requirements of Section 404 and the other rules and regulations of the SEC.

If we are, or were to become, a passive foreign investment company (a "PFIC") for U.S. federal income tax purposes, U.S. investors in our ordinary shares would be subject to certain adverse U.S. federal income tax consequences.

In general, a non-U.S. corporation will be a PFIC for any taxable year if (i) 75% or more of its gross income consists of passive income or (ii) 50% or more of the average quarterly value of its assets consists of assets that produce, or are held for the production of, passive income. We do not expect to be a PFIC for our current taxable year or in the foreseeable future. However, there can be no assurance that we will not be considered a PFIC for any taxable year. If we were a PFIC for any taxable year during which a U.S. investor held ordinary shares, such investor would be subject to certain adverse U.S. federal income tax consequences, such as ineligibility for any preferred tax rates on capital gains or on actual or deemed dividends, an additional interest charge on certain taxes treated as deferred, and additional reporting requirements under U.S. federal income tax laws and regulations. If we are characterized as a PFIC, a U.S. investor may be able to make a "mark-to-market" election with respect to our ordinary shares that would alleviate some of the adverse consequences of PFIC status. Although U.S. tax rules also permit a U.S. investor to make a "qualified electing fund" election with respect to the shares of a non-U.S. corporation that is a PFIC if the non-U.S. corporation provides certain information to its investors, we do not currently intend to provide the information that would be necessary for a U.S. investor to make a valid "qualified electing fund" election with respect to our ordinary shares.

Nasdaq maintains certain standards which Nasdaq requires listed companies meet for their respective securities to continue to be listed and traded on its exchange, and if we are unable to continue to meet such continued listing requirements, Nasdaq may choose to delist our ordinary shares from its exchange, which may adversely affect the liquidity and trading price of our ordinary shares.

Our ordinary shares are currently listed on Nasdaq. Nasdaq requires that companies that have securities listed with it continue to meet certain requirements to maintain such listing. Failure to meet these requirements would result in a delisting of the securities from Nasdaq. One such requirement is that securities listed on Nasdaq do not have a 30 consecutive trading day period in which the minimum bid price of such securities is less than $1.00 per share. As of March 26, 2024, the closing price of our common stock was $1.01, and we recently had a six-consecutive day trading day period where the minimum bid price was below $1.00 shortly followed by a 13-consecutive day trading day period where the minimum bid price was below $1.00.

Generally, if a company falls afoul of a Nasdaq continued listing requirement, there is an automatic grace period to regain compliance and Nasdaq may, upon request, grant additional periods for the company to regain compliance. In the future, we may cease to be compliant with Nasdaq's continued listing requirement, and if that occurs we may not be able to regain compliance within the periods allotted to us. If our ordinary shares are delisted and we are not able to list our securities on another national securities exchange, we expect our ordinary shares could be quoted on the OTCQB or the "pink sheets." If this occurs, we could face material adverse consequences, including:

- a limited availability of market quotations for our securities;
- reduced liquidity for our securities;
- a determination that our common stock is a "penny stock" which will require brokers trading in our common stock to adhere to more stringent rules and possibly result in a reduced level of trading activity in the secondary trading market for our securities;
- a limited amount of news and analyst coverage; and
- a decreased ability to issue additional securities or obtain additional financing in the future.

If we are delisted and are unable to have our ordinary share quoted on the OTCQB or "pink sheets" or similar bulletin board, our shareholders would not be able to resell their securities in a public market.

ITEM 4. INFORMATION ON THE COMPANY

A. History and development of the Company

We are a public company under Dutch law. We were incorporated on March 8, 2021 as a private limited liability company (*besloten vennootschap met beperkte aansprakelijkheid*) under Dutch law. We were formed to acquire PharmGenomics GmbH ("PharmGenomics"), a German company with limited liability, and we acquired PharmGenomics on September 20, 2021. On November 9, 2021, we converted into a Dutch public company with limited liability (*naamloze vennootschap*). The address for our principal place of business is Robert Koch Strasse 50, 55129 Mainz, Germany, and the telephone number is +49 6131 5542860.

We have registered our ordinary shares under the Exchange Act, and we intend to make our current and periodic reports and other information (including interactive data files) filed with or furnished to the SEC, pursuant to Section 13(a) or 15(d) of the Exchange Act, available free of charge through our website as soon as reasonably practicable after those reports and other information are electronically filed with, or furnished to, the SEC. The SEC maintains a website at *http://www.sec.gov* that contains reports and other information regarding issuers that file electronically with the SEC, and all of our reports and other information filed or submitted publicly with the SEC may also be found there.

Information on our website or any other website is not incorporated by reference into this annual report and does not constitute a part of this annual report. We have included our website address as an inactive textual reference only.

B. Business Overview

General

We develop and sell in-vitro diagnostic ("IVD") tests for the early detection of cancer. Our flagship ColoAlert product is being marketed and sold in European markets. We are currently developing our next generation colorectal cancer screening product and intend to launch that product in the future in the United States and in Europe. We additionally operate a clinical diagnostic laboratory and distribute our IVD kits to third-party laboratories in Europe and through our on-line store in Germany.

In addition, we conduct research and development to increase and diversify our product portfolio. Currently, we are managing our government funded research and development project called PancAlert, which provide us non-refundable grant income that covers a percentage of the individual project-related costs.

About the Industry

The cancer industry can be divided into a diagnostics segment focused on detecting cancers, and a therapeutic segment focused on treating them. We are focused on the diagnostic aspect of the cancer industry.

For most cancer, early detection can be lifesaving and for CRC, in particular, the symptoms are unclear and removal of cancer by surgery in the early stage is easy compared to treatment at a late stage. Screening of CRC is both lifesaving and cost saving. We compete with other entities developing and offering diagnostic tests to detect the presence of cancers. Our core product is a CRC screening stool DNA test, and we are in the early stages of researching a similar test for pancreatic cancer.

CRC are malignant tumors in the colon or rectum. These tumors usually develop from benign polyps, which over time degenerate and become cancerous. Between 5 and 15 years may elapse between the development of CRC and the formation of metastases. One method for the categorization of cancer stages of CRC is that used by the Surveillance, Epidemiology, and End Results ("SEER") program of the U.S. National Cancer Institute. SEER categorizes CRC on whether the cancer is localized (there is no sign that the cancer has spread outside of the colon or rectum), regional (the cancer has spread outside the colon or rectum to nearby structures or lymph nodes) or distant (the cancer has spread to distant parts of the body such as the liver, lungs, or distant lymph nodes). According to a 2023 report from the American Cancer Society, patients in the United States diagnosed with CRC between 2012 and 2018 had approximate 5-year survival rates for colon and rectal cancer as set out below:

	Colon Cancer	Rectal Cancer
Localized	91%	90%
Regional	72%	74%
Distant	13%	17%

According to the American Cancer Society, CRC is the third most-commonly diagnosed cancer and the third leading cause of cancer death in men and women in the United States. According to the International Agency for Research on Cancer, the distribution of CRC cases varies widely, with more than two-thirds of all cases and about 60% of all deaths occurring in countries with a high or very-high human development index. According to an article in BMJ Journals, global cases of CRC are expected to increase by 60% to more than 2.2 million new cases and 1.1 million deaths by 2030. Across Europe, 378,445 new CRC cases were diagnosed in 2018, with more than 170,000 deaths. Therefore, in 2020 CRC was the second most common gender-unspecific cancer in Europe according to the European Commission. SEER estimated that there were 151,030 new cases of CRC in the United States in 2022 (accounting for 7.9% of all new cancer diagnoses in the United States that year) and that 52,580 people died of CRC in the United States in 2022 (accounting for 8.6% of all cancer deaths in the United States that year).

In Europe, there are more than 194 million people over the age of 50 years. According to a report from the Digestive Cancers Europe group, less than 15% of adults aged 45 to 74 in the European Union participate in colorectal screening programs. The European Council of Health Ministers recommended that all Member States implement population-wide screening for colorectal cancer. The European Council set a 65% participation rate as a desirable target for the defined target population. Some countries such as the Netherlands have a very high participation rate of 70% and many other European countries are striving for the same participation numbers. With a 65% participation rate, the total available market in Europe would be around 126 million individuals.

Approximately 15 million colonoscopies were performed in 2020 in the United States, according to Harvard Health. According to the U.S. Center for Disease Control and Prevention, in 2020 approximately 20% of U.S. adults aged 50–75 years have never been screened for colorectal cancer. With the new US Preventative Services Task Force (USPSTF) guidelines recommending the core screening target group drops to age 45 there are now 117 million individuals within our addressable market growing to over 160 million within the next 10 years, we believe that our addressable market in the United States alone will increase from $3.7 billion to over $5.2 billion annually.

Products and Product Candidates

We strive to make the diagnosis of various diseases more effective by using the latest genetic diagnostic technologies. Enabling earlier detection of these diseases allows for earlier and better therapy for affected individuals. In addition to offering the CRC screening test, ColoAlert, we are currently developing our product candidate PancAlert for the detection of pancreatic cancer. We aim to use proprietary, known and existing biomarkers in applicable and reliable diagnostic tools.

ColoAlert and Our Next Generation Colorectal Cancer Screening Test

We offer a CE-IVD certified CRC diagnostic test, ColoAlert. We believe that molecular genetic stool tests like ColoAlert increase the participation rate in CRC screening and shift the detection of CRC to an earlier point of time which increases the likelihood of successful treatment of the cancer.

In the human intestines, epithelial skin cells are continuously shed into the stool. In addition to healthy cells, cells from polyps and colon cancer are also released. Using state-of-the-art genetic diagnostic methods, such as PCR analysis (a process used to rapidly make millions to billions of copies of a specific DNA sample, allowing for the amplification of a small sample of DNA to a large enough amount to study in detail), these shed cells can be isolated and examined for genetic changes.

ColoAlert is a multitarget test in which the stool sample is analyzed for genetic anomalies as well as for the presence of hidden blood, often called occult blood. The genetic analysis consists of the quantification of human DNA, the analysis of somatic point mutations in the KRAS (codon 12/13) and BRAF (codon 600) genes. An independent clinical test lead by Professor Matthias Dollinger and conducted with 566 patients by the University Hospitals in Leipzig and Halle-Wittenberg, Germany showed ColoAlert to have a sensitivity of 85% and a specificity of 92% while being as non-invasive as other stool tests and showing a very high patient satisfaction of 98%. Compared to the FITs reimbursed in Germany, this meant up to 60% less overseen CRCs. The genetic markers were chosen to complement the diagnostic accuracy of the occult blood test and lead to an increased clinical added value. Since the independent clinical study, we have updated the occult blood test component of ColoAlert to what we believe is a more accurate occult blood test in terms of sensitivity and specificity.

We target individuals covered by national CRC screening programs. Most screening programs recommend CRC screening starting at age 50. However, a trend exists to further lower the screening age. For example, the FDA recently recommended CRC screening starting at age 45. In 2023, the American Cancer Society released a statement that CRC "is swiftly shifting to more advanced disease and younger individuals" and noting that diagnoses of CRC in people under 55 years of age increased from 11% in 1995 to 20% in 2019. Due to the increasing prevalence of the disease in the younger population, we anticipate a further decrease in the screening age, especially for test methods such as ColoAlert that are, in principle, capable of detecting cancer at early stages. In addition to age, other personal characteristics in favor of CRC screening include a family predisposition to CRC, risk factors such as obesity, irritable bowel syndrome ("IBS"), inflammatory bowel disease ("IBD"), excessive meat, alcohol and nicotine consumption, and pre-existing conditions such as breast cancer or type 2 diabetes mellitus.

Prior to February 2023, we had licensed the ColoAlert test from a Norwegian research and development company, ColoAlert AS, and we acquired the test and related intellectual property from ColoAlert in February 2023. We acquired the ColoAlert test and related intellectual property in exchange for (i) $2 million cash, to be paid out over the next four years, (ii) 300,000 ordinary restricted shares and (iii) a revenue share limited to $1 per test sold for a period of 10 years.

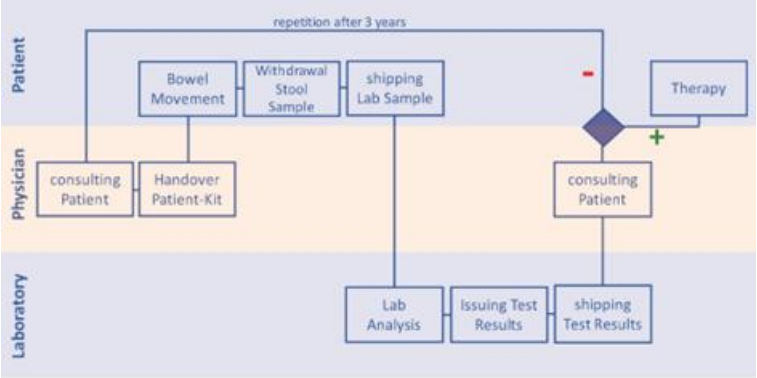
In the European Union, the ColoAlert PCR kit ("ColoAlert Lab Kit Core II") is a CE-IVD registered product under the current In-Vitro Diagnostics Directive 98/79 /EC ("IVD-D"). Starting on May 26, 2022, IVD products in the European Union are regulated by the In-Vitro Diagnostics Regulation, EU 2017/746 ("IVD-R"), which replaces the IVD-D. The ColoAlert sample collection kit has already been registered successfully under the IVD-R. We are currently evaluating the necessary steps to meet the upcoming regulations for our ColoAlert PCR kit as well. ColoAlert is currently validated on the Roche LightCycler 480 II. Mainz BioMed is planning to validate the test on additional real time PCR instruments used in many laboratories worldwide to allow a potential faster market penetration. We manufacture the ColoAlert PCR kits at our facility in Mainz, Germany.

In January 2022, we entered into a Technology Rights Agreement related to a portfolio of novel mRNA biomarkers developed at the Université de Sherbrooke (the "UdeS Biomarkers". Pursuant to the agreement, we acquired an exclusive unilateral option to acquire an exclusive license to the UdeS Biomarkers. We exercised the option on February 15, 2023 when we entered into an Assignment Agreement to acquire the intellectual property rights associated with the UdeS Biomarkers. In exchange for the UdeS Biomarkers, we are to (i) pay €25,000 in cash and (ii) pay a profit share of 2% of the net sales of any products that we sell using the UdeS biomarkers.

The UdeS Biomarkers are five gene expression biomarkers which have demonstrated a high degree of effectiveness in detecting CRC lesions including advanced adenomas ("AA"), a type of pre-cancerous polyp often attributed to this deadly disease. In a UdeS sponsored study evaluating these biomarkers, study results achieved overall sensitivities of 75% for AA and 95% for CRC, respectively, with a 96% specificity outcome.

In connection with the Udes Biomarkers, we have initiated two feasibility studies to evaluate the Udes Biomarkers, as well as the DNA biomarkers and FIT tests that comprise our current ColoAlert test. The first of these two studies, ColoFuture, is an international multi-center clinical study to evaluate the effectiveness of the UdeS biomarkers to enhance ColoAlert's technical profile to expand its capability to identify AA while increasing ColoAlert's rates of diagnostic sensitivity and specificity. ColoFuture is designed to evaluate 662 subjects, including patients with average risk of colon cancer and subjects suspected or known to have colon cancer or advanced adenoma. Enrollment in ColoFuture is expected to be completed by late 2023. We are also performing a U.S. multi-center study under the label "eAArly DETECT" designed to measure both feasibility and stability, evaluating 450 subjects, including patients with average risk of colon cancer and subjects suspected or known to have colon cancer or advanced adenoma. eAArly DETECT is expected to complete enrollment for the feasibility analysis during the first half of 2023 and stability by the end of 2023. These studies are intended to evaluate the optimal combination of biomarkers, both which may include DNA and mRNA and DNA biomarkers and a FIT test, to be included our next generation of product, to be evaluated in our pivotal FDA PMA study, labeled "reconAAsense".

In October 2023, we announced results from the ColoFuture study which included a sensitivity for CRC of 94% with a specificity of 97% and a sensitivity for advanced adenoma (AA) of 80%. In December 2023, we announced topline results from our eAArly DETECT U.S. clinical study which reported a sensitivity for colorectal cancer of 97% with a specificity of 97% and a sensitivity for advanced adenoma of 82%. These topline results confirm the positive results from ColoFuture, its European counterpart which reported data in October 2023. The eAArly DETECT study enrolled 254 evaluable subjects across 21 sites in the United States with a similar design to that of ColoFuture, its European counterpart. Patients aged 45 years and older were invited to participate when referred for a colonoscopy to either screen for CRC (average risk), to follow up on a positive non-invasive test, imaging or symptoms, or if a subject was already identified as having colorectal cancer but before any treatment had been administered. Those who agreed to provide a stool sample in advance of the colonoscopy (or treatment in the case of subjects with already identified colorectal cancer) were eligible for participation. Subjects were classified into groups following central pathology review: CRC, advanced adenoma, non-advanced adenoma, no findings, or non-colorectal cancer. Each subject outcome was compared to the results from the ColoAlert® test incorporating the novel biomarkers.



Above is a typical process flow for the use of ColoAlert for Germany.

Typical process flow:

1. The patient is informed about the risk of CRC.
2. The physician discusses with the patient the need for a CRC test.
3. The physician provides the kit to the patient or the patient receives the kit shipped from the laboratory partner.
4. The patient collects the sample and ships the collected sample to the testing clinical laboratory.
5. The clinical laboratory tests the sample and provides the result to the ordering physician.
6. The ordering physician informs patient about the results and decides on next steps.

PancAlert

We are in the early stages of developing PancAlert, a stool-based screening test for the detection of pancreatic cancer. According to the Global Cancer Observatory, pancreatic cancer was diagnosed in over 460,000 patients worldwide in 2018. Due to the asymptomatic early stages, in most cases this disease is detected too late, making pancreatic cancer one of the most lethal malignant neoplasms with over 430,000 annual deaths according to the Global Cancer Observatory. SEER estimated that in the United States alone there were 62,210 new cases of pancreatic cancer and 49,830 deaths from pancreatic cancer. SEER estimated that between 2012 and 2018, the 5-year survival rate was approximately 44% if the cancer was localized, 15% if it was regional and 3% if it was distant. Studies have shown that the prognosis in asymptomatic patients, when who were diagnosed by chance during other examinations, is significantly better than in patients with characteristic symptoms such as rapid weight loss or back pain.

The mean age of onset is 71 years for men and 75 years for women. Similar to other cancers, age is an essential risk factor. Most patients are over 50, with most diagnoses occurring between the ages of 60 and 80. The fact that pancreatic cancer is the European Union's third biggest cancer killer, despite being the seventh most common cancer, highlights the extremely poor outlook for patients. Although, the survival rate of pancreatic cancer patients has improved in the last few decades, there is still the urgent need for early diagnostic optimization.

A definitive diagnosis is currently made through a series of investigations, including imaging scans, blood tests and biopsy, which are usually only performed in symptomatic patients. However, recent research suggests that the disease can persist for a longer period of time without patients becoming symptomatic; providing an important opportunity for early detection. Because the initiation of pancreatic cancer occurs on a molecular level, genetic diagnostic methods can be a promising approach for early detection. The biomarkers associated with pancreatic cancer reach the stool, amongst other ways by the pancreatic juice, which enables a user-friendly sample collection. The development approach includes the selection and verification of a specific biomarker panel with the establishment of a suitable method for sample preparation, the establishment and validation of the detection and measurement technology with purchased or clinically defined samples (biopsies, pancreatic juice, stool and others), the transfer to routine diagnostics (stool) and the optimization and clinical evaluation as a potential screening tool for the early detection of pancreatic cancer.

Our goal is to make PancAlert the world's first pancreatic cancer screening test based on Real-Time PCR-based multiplex detection of molecular-genetic biomarkers in stool samples. The most promising candidates for disease-specific biomarkers to date are KRAS, mBMP3, NDRG4, and GNAS codon 201. In addition, the platform technology used will enable simple integration of further biomarkers if indicated. The analysis of the results will be additionally facilitated by a specialized artificial intelligence solution. Based on the research progress in this project, we plan to initiate an initial pilot study with one or more selected clinical sites. We do not expect to conclude such studies prior to 2024. If the clinical pilot studies show promising results, we intend to start developing an IVD-R and FDA approvable product for the European and U.S. markets.

Competitive Advantages & Operational Strengths

We face competition from providers of more traditional CRC screening diagnostics, such as colonoscopies, as well as other manufacturers of non-invasive stool- or blood-based tests. We believe the primary competitive factors for ColoAlert and our next generation colorectal cancer screening test include but are not limited to:

- **Accuracy:** End-users want as accurate a result as possible without worrying about costs, hassle and time associated with false-negative and false-positive results. A report by Professor Dollinger found the current ColoAlert product to have a specificity of 92%, above the 90% specificity requirement set by the European CRC screening guidelines, and has a sensitivity of 85%. Sensitivity defines how often a test correctly generates a positive result for the condition being tested. Specificity is the ability of the test to correctly identify those without the disease (true negative rate). Since that report, we have updated the occult blood test component of ColoAlert in a way that we believe increases sensitivity and specificity. In January 2022, we entered into a Technology Rights Agreement to exclusively license certain biomarkers developed ay the Université de Sherbrooke with the goal of further increasing the sensitivity and specificity of ColoAlert, and we acquired the intellectual property in connection with those biomarkers in February 2023.

- **Time-to-result:** The faster the results of a diagnostic test are known; the sooner treatment may begin or the end user can gain ease of mind. Due to ColoAlert's simplicity of the testing procedure, the resultant turn-around time between the patient's decision and delivery of the test report can be as low as three days in Germany, which we believe is significantly shorter than most other tests.

- **Ease of use:** As many people will delay or avoid getting an invasive diagnostic test, such as a colonoscopy, the easier it is to take such a test, the higher the participation rates will be, which could mean more detection of cancer at earlier stages and higher rates of survival. ColoAlert is less invasive than traditional colonoscopies, requiring neither the drinking of barium (oral or suppository) the night prior to the test, nor prior fasting, and does not require a trip to a clinic or the administration of anesthesia. Compared to blood-based tests, stool tests can be performed at home and do not require the patient to visit their physician.

- **Executive team:** Our leadership team and advisors have extensive experience developing and commercializing innovative diagnostic products globally. We have strong relationships with government organizations and universities in Europe.

- **Research and Development:** We are confident that we have organized a strong team to front our research and development. Our research and development efforts have been supported by a grant of up to approximately €440,000 from the German Federal Ministry of Research and Education for the development of PancAlert, a non-invasive product candidate to detect pancreatic cancers.

Strategy

We intend to make the next generation ColoAlert the global CRC screening market leader by providing the best performance at an affordable cost. To fulfil this goal efficiently, our sales strategy is primarily based on collaborations with large laboratory chains. This distribution strategy is chosen because laboratories typically have a large customer base of physicians as well as a strong sales team. This can increase awareness of ColoAlert within the physician community in a cost-effective manner. At the same time, it offers the opportunity for accelerated product rollouts in foreign markets, as large laboratory chains operate across Europe or worldwide and successful products are often distributed within the laboratory chain. Laboratory partners benefit from the introduction and distribution of ColoAlert especially from the increased medical added value, the positioning as innovation leaders and from, we believe, significantly higher margins compared to conventional stool tests such as FIT. We believe that this distribution approach also provides a strong business differentiation in the United States from the Cologuard, a test offered by Exact Sciences Corporation. Cologuard is performed exclusively in Exact Sciences' in-house laboratories and therefore other laboratories currently do not have access to a multitarget stool test. By providing the ColoAlert test kits, other laboratories can also offer highly sensitive, non-invasive CRC screening to their affiliated physicians and their patients.

To introduce ColoAlert into the United States and potentially other markets like China, extensive regulatory studies are required. We are actively exploring the required regulatory path for the United States.

Therefore, we intend to focus much of near-term efforts on:

- expanding the commercial opportunity of our ColoAlert product in Europe by expanding our commercial team and partnerships;

- preparing and executing a comprehensive clinical and regulatory strategy to achieve market authorization from the FDA to use ColoAlert as a screening test for CRC in the United States; and

- continuing research and development of PancAlert.

Expansion of ColoAlert in Europe and Other Select European Markets

We have advanced ColoAlert's commercial presence in Germany, leveraging our proximity to Frankfurt where our headquarters are located. In 2024, Germany will remain our focal market, as we aim to enlarge our footprint through a combination of direct sales, channel partnerships, and heightened product visibility. We are implementing a dual distribution model: a centralized system via our laboratory and a decentralized approach through associated lab partners.

ColoAlert is directly offered to medical professionals overseeing colorectal cancer (CRC) screening in Germany. This group is not limited to the 1,800 gastroenterologists who primarily conduct colonoscopies but extends to 55,000 general practitioners and over 7,000 specialized practices in gynecology and urology, who customarily initiate CRC screening, predominantly through the FIT stool test. For individuals covered by statutory health insurance, ColoAlert is a supplementary expense, whereas it is reimbursable for those with private insurance. Out of Germany's 84 million populace, approximately 10 million have private health coverage. To facilitate sales, we are developing targeted marketing resources and planning to engage physicians and healthcare providers at medical conferences.

Our strategy also includes partnering with laboratories that have a stronghold in CRC screening. These partnerships enable us to reach broader physician networks affiliated with these labs. Approximately 12 lab chains in Germany process about 64% of the FIT tests, amounting to roughly 3 million tests annually. By partnering with significant lab chains and independent laboratories, we aim to amplify ColoAlert's market penetration.

Furthermore, we have pioneered a direct-to-consumer channel allowing patients to acquire ColoAlert via an online portal, bypassing the need for a doctor to prescribe the test. This access point is particularly beneficial for individuals below the typical screening age, in light of the rising incidence of CRC among the under-50 demographic.

We are not currently seeking statutory reimbursement for ColoAlert, as we believe our next-generation test, currently under development, is more attuned to the stringent criteria set by German regulatory and reimbursement agencies. With enhanced sensitivity and specificity for detecting early-stage colorectal cancer and advanced adenomas, this forthcoming product is poised for inclusion in statutory reimbursement schemes, thereby establishing a solid market presence in anticipation of its release.

Other European Markets

Mainz Biomed is progressively extending its operations to additional German-speaking territories and selected international markets that are accustomed to personal health expenditures, as ColoAlert is not included in statutory health insurance programs in these regions. Currently, our reach includes established connections in the United Kingdom, Spain, Poland, Austria, Romania, Italy, and Israel.

While we broaden our reach within other European markets, particularly those accustomed to out-of-pocket payments for medical tests, we will fortify our commercial team with individuals who possess robust local expertise in marketing cutting-edge diagnostic products. Our growth strategy is to target medical practices and clinical labs directly, bolstering our sales efforts with specialized training for sales reps, educational seminars for physicians, and joint marketing initiatives to heighten ColoAlert's profile.

As we pursue these expansions, we remain committed to adapting our commercial strategies to align with the healthcare payment practices prevalent in each locale. We recognize the importance of catering to markets with a predisposition towards out-of-pocket payments for health services, which presents a favorable environment for ColoAlert's integration and acceptance in the near term, while pursuing statutory reimbursement for our next generation product.

Entry into the U.S. Market

We plan to employ decentralized product and marketing strategy in the United States ; we will seek to sell the ColoAlert test as a test kit to clinical laboratories that are certified by the Secretary of the Department of Health and Human Services under the Clinical Laboratory Improvement Amendments of 1988 ("CLIA labs") requiring FDA market authorization. The top five laboratory chains in the United States had revenues of nearly $38 billion in 2020. Alternatively or in addition, we could offer ColoAlert, or as a laboratory developed test offered by the Mainz BioMed clinical laboratory governed under US Centers for Medicare and Medicaid Services ("CMS").

We are exploring the required clinical and regulatory path to submit ColoAlert to the FDA to achieve a CRC screening claim for asymptomatic patients who are at average risk for CRC, aged 45 to 80.

In December 2022, we received approval from an independent Institutional Review Board (IRB) for the protocol reconAAsense, our U.S. pivotal study to evaluate the clinical performance of ColoAlert. We plan to initiate the study, which will form the basis of the data package to be submitted for review by the U.S. Food and Drug Administration (FDA) to achieve marketing authorization, during the second half of 2023. reconAAsense is a prospective clinical study that envision including approximately 15,000 subjects from 150 sites across the United States. The study objectives include calculating sensitivity, specificity, positive predictive value and negative predictive value in average-risk subjects for CRC and advanced adenomas.

Integral to our development strategy concerning the evolution of the product's specifications is the potential to upgrade its technical profile to achieve a transformational advancement in self-administered CRC screening. To this end, we have also initiated eAArly DETECT, our U.S. extension of ColoFuture, our European feasibility study evaluating the integration of a portfolio of novel gene expression (mRNA) biomarkers into our next-generation product. These biomarkers have demonstrated a unique ability to identify precancerous colonic polyps and early-stage CRC (Herring et al., 2021). The eAArly DETECT study was initiated in November of 2022 and is evaluating the effectiveness of these biomarkers to enhance product specifications to extend its capability to include the detection of advanced adenomas while increasing rates of diagnostic sensitivity and specificity for colorectal cancer. Based on the study's outcome, we will decide whether to integrate the biomarkers evaluated in ColoFuture's eAArly DETECT into the reconAAsense study. In December 2023, we announced topline results from our eAArly DETECT U.S. clinical study which reported a sensitivity for colorectal cancer of 97% with a specificity of 97% and a sensitivity for advanced adenoma of 82%.

During this market preparation period market conditions may change, existing competitors may improve their products or new competitors may become commercially active which may force us to adjust our future commercial strategy if the FDA eventually authorizes the product. We may consider manufacturing our next generation ColoAlert test kits as private label products to be sold to labs. In this case, we likely would not undertake any marketing efforts in the United States to promote it to physicians and patients but expect our business partner to take on this obligation.

Research and Development

Our research and development strategy has been centered on

- developing our product candidate PancAlert, a proposed stool-based screening test for pancreatic cancer that is in the early stages of development and might never become a product, and
- running our ColoFuture study, an international multi-center clinical study to evaluate the effectiveness of the UdeS biomarkers to enhance ColoAlert's technical profile to expand its capability to identify AA while increasing our next generation prodcut's rates of diagnostic sensitivity and specificity. Our ColoFuture Study has been expanded into the United States under the label "eAArly DETECT".

Our research and development team is located at our facilities in Mainz, Germany, and consisted of 26 employees and independent contractors as of December 31, 2023. We have patent applications pending relating to the UdeS Biomarkers, as well as trade secrets. If our research and development efforts are successful for our next generation colorectal cancer screening test or PancAlert, we intend to file patent applications to protect the intellectual property derived from such research and development.

We have received government grants as part of our research and development programs, including approximately $28,000 in our fiscal year ended December 31, 2023 and $151,000 in our fiscal year ended December 31, 2022.

Government Regulation

In-vitro diagnostic (IVD) devices are regulated by government agencies in countries where such products are sold there is no uniform set of regulations governing our product portfolio. Following is a summary of governmental regulations in Europe (EU), our principal market, and the United States, the next country that we seek to market.

Europe

Until May 26, 2022, medical devices such as ColoAlert were regulated by the IVD Directive (IVDD) (98/79/EC), requiring CE-Mark through self-certification process due to the lowest risk classification. Under the IVDD, developers and manufacturers were required to operate according to a Quality System and validate medical devices in a limited clinical trial to demonstrate the manufacturer has met analytical and clinical performance criteria. We have implemented an International Organization for Standardization standard — ISO 13485 — quality management system for the design and manufacture of medical devices. ISO 13485 addresses managerial awareness of regulatory requirements, control systems, inspection and traceability, device design, risk and performance criteria as well as verification for corrective and preventative measures for device failure. Medical device companies such as ours are subject to pre-market compliance assessments from Notified Bodies, a certification organization which the national authority (the competent authority) of a European Union member state designates to conduct one or more of the conformity assessment procedures. ISO 13485 certification establishes conformity to specific European Union directives related to medical devices and allows CE Marking and sale of the device.

The European In Vitro Diagnostic Regulation (EU 2017/746), or the IVDR, became effective as of May 25, 2017, marking the beginning of a five-year transition period for manufacturers selling IVD devices into Europe. The IVDR, which replaced the IVDD, has been fully implemented, and new IVDD applications will not be accepted by notified bodies. During the transition period manufacturers had to update their technical documentation and processes to fulfill the new, more stringent EU regulatory requirements. We believe that the most challenging areas under the IVDR regard the classification of products, which brings the majority of IVDs under the direct review and approval of Notified Bodies, and the performance evaluation of IVDs, which will not only include the classic clinical performance and analytical performance but also scientific validity, the role and responsibilities of the economic actors of the supply chain, the traceability and the transparency of the devices with, in particular, the introduction of the UDI-system and an expanded EUDAMED database.

Notified Bodies began auditing to the IVDR once they were designated as a Notified Body under the IVDR by their Competent Authority. Mainz has selected TÜV SÜD as the designated Notified Body under the IVDR. For Class C devices (such as ColoAlert), the conformity assessment procedure will be a combination of the Quality Management System audits and Technical Documentation assessments. The assumed assessment time needed for a Technical Documentation assessment of a Class C device currently is expected to be quite lengthy due to the limited number of Notified bodies and the major increase of submissions requiring NB review/approval. We have already begun discussions with the TÜV SÜD in order to ensure compliance with the IVDR as soon as possible.

We believe that we have structured our business operations to comply with applicable legal requirements. However, it is possible that governmental entities or other third parties could interpret these laws differently and assert otherwise, which could have a material adverse impact on our business.

United States

U.S. Food and Drug Administration

Obtaining FDA market authorization for our ColoAlert test is critical to our business strategy. We have started activities in order to achieve premarket approval (PMA) for our ColoAlert test.

Under the FDA's regulatory framework, *in vitro* diagnostic devices (IVDs), including tests that can be used in the diagnosis or detection of cancer such as ColoAlert, are a type of medical device. The FDA categorizes medical devices into one of three classes — class I, II, or III — based on the risks presented by the device and the regulatory controls necessary to provide a reasonable assurance of the device's safety and effectiveness. Devices deemed by FDA to pose the greatest risks, such as life sustaining, life supporting or some implantable devices, or devices that have a new intended use, or use advanced technology that is not substantially equivalent to that of a legally marketed device, are designated in Class III, requiring approval of a PMA and the ColoAlert test would be a Class III IVD, as this is consistent with the prior FDA approval of similar devices. Some pre-amendment devices are unclassified, but are subject to FDA's premarket notification and clearance process in order to be commercially distributed.

Class III devices require PMA approval before they can be marketed. Obtaining PMA approval requires the submission of "valid scientific evidence" to FDA to support a finding of a reasonable assurance of the safety and effectiveness of the device. A PMA must provide complete analytical and clinical performance data and also information about the device and its components regarding, among other things, device design, manufacturing, and labeling. Following receipt of a PMA, FDA determines whether the application is sufficiently complete to permit a substantive review. If FDA accepts the application for review, it has 180 days under the FDC Act to complete its review of a PMA, although in practice, FDA's review often takes significantly longer, and can take up to several years.

An advisory panel of experts from outside FDA may be summoned to review and evaluate the application and provide recommendations to FDA as to the approvability of the device. FDA may or may not accept the panel's recommendation. As part of FDA's review of a PMA, FDA will typically inspect the manufacturer's facilities for compliance with Quality System Regulation (QSR) requirements, which impose requirements related to design controls, manufacturing controls, documentation, and other quality assurance procedures.

FDA will approve the new device for commercial distribution when it determines that the data and information in the PMA constitute valid scientific evidence and that there is reasonable assurance that the device is safe and effective for its intended use(s). FDA may approve a PMA with post-approval conditions intended to ensure the safety and effectiveness of the device, including, among other things, restrictions on labeling, promotion, sale and distribution, and collection of long-term follow-up data from patients in the clinical study that supported PMA approval or requirements to conduct additional clinical studies post-approval. FDA may grant PMA approval on some form of post-market surveillance when deemed necessary to protect the public health or to provide additional safety and efficacy data for the device in a larger population or for a longer period of use. In such cases, the manufacturer might be required to follow certain patient groups for a number of years and to make periodic reports to FDA on the clinical status of those patients. Failure to comply with the conditions of approval can result in material adverse enforcement action, including withdrawal of the approval.

Certain changes to an approved device, such as changes in manufacturing facilities, methods, or quality control procedures, or changes in the design performance specifications, which affect the safety or effectiveness of the device, require submission of an amendment to the PMA prior to approval and if after the initial PMA approval, a supplement to the PMA. PMA supplements require information needed to support any changes from the device covered by the original PMA and may not require as extensive clinical data or the convening of an advisory panel. Certain other changes to an approved device require the submission of a new PMA, such as when the design change causes a different intended use, mode of operation, and technical basis of operation, or when the design change is so significant that a new generation of the device will be developed, and the data that were submitted with the original PMA are not applicable for the change in demonstrating a reasonable assurance of safety and effectiveness.

The studies required in connection with our seeking FDA approval of our technologies will be costly and lengthy. FDA might not ultimately approve any PMA submitted by us in a timely manner or at all.

Clinical Trials

Clinical trials are usually required to achieve PMA approval. If the device presents a "significant risk," as defined by the FDA, to human health, the FDA requires the device sponsor to file an Investigational Device Exemption (IDE) application with the FDA and obtain IDE approval prior to commencing the human clinical trials. The investigational device exemption application must be supported by appropriate data, such as animal and laboratory testing results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. The IDE application must be approved in advance by the FDA for a specified number of patients, unless the product is deemed a "non-significant risk" device and eligible for more abbreviated investigational device exemption requirements. Clinical trials for a significant risk device may begin once the investigational device exemption application is approved by the FDA and the appropriate institutional review boards at the clinical trial sites. Our clinical trials must be conducted in accordance with FDA regulations and federal and state regulations concerning human subject protection, including informed consent and healthcare privacy. A clinical trial may be suspended by the FDA or the investigational review board at any time for various reasons, including a belief that the risks to the study participants outweigh the benefits of participation in the study. Even if a study is completed, the results of our clinical testing may not demonstrate the safety and efficacy of the device or may be equivocal or otherwise not be sufficient to obtain approval of our product.

Laboratory Certification, Accreditation and Licensing

If we operate clinical laboratories in the United States, we will also be subject to U.S. and state laws and regulations regarding the operation of clinical laboratories. Federal Clinical Laboratory Improvement Amendments (CLIA) requirements and laws of certain other states impose certification requirements for clinical laboratories, and establish standards for quality assurance and quality control, among other things. Clinical laboratories are subject to inspection by regulators, and to sanctions for failing to comply with applicable requirements. Sanctions available under CLIA include prohibiting a laboratory from running tests, requiring a laboratory to implement a corrective plan, and imposing civil monetary penalties. If we fail to meet any applicable requirements of CLIA or state law, that failure could adversely affect any future CMS consideration of our technologies,

prevent their approval entirely, and/or interrupt the commercial sale of any products and otherwise cause us to incur significant expense.

HIPAA and Other Privacy Laws

The Health Insurance Portability and Accountability Act of 1996, or HIPAA, established for the first time comprehensive protection for the privacy and security of health information. The HIPAA standards apply to three types of organizations, or "Covered Entities": health plans, healthcare clearinghouses, and healthcare providers that conduct certain healthcare transactions electronically. Covered Entities and their business associates must have in place administrative, physical, and technical standards to guard against the misuse of individually identifiable health information. If we are able to commercialize our ColoAlert test, we might perform activities that may implicate HIPAA, such as providing clinical laboratory testing services or entering into specific kinds of relationships with a Covered Entity or a business associate of a Covered Entity.

Federal and State Billing and Fraud and Abuse Laws

Antifraud Laws/Overpayments. If our ColoAlert test is successfully accepted by federal and state healthcare programs, we will be subject to numerous federal and state antifraud and abuse laws. Many of these antifraud laws are broad in scope, and neither the courts nor government agencies have extensively interpreted these laws. Prohibitions under some of these laws include:

- the submission of false claims or false information to government programs;
- deceptive or fraudulent conduct;
- excessive or unnecessary services or services at excessive prices; and
- prohibitions in defrauding private sector health insurers.

We could be subject to substantial penalties for violations of these laws, including denial of payment and refunds, suspension of payments from Medicare, Medicaid or other federal healthcare programs and exclusion from participation in the federal healthcare programs, as well as civil monetary and criminal penalties and imprisonment. Numerous federal and state agencies enforce the antifraud and abuse laws. In addition, private insurers may also bring private actions. In some circumstances, private whistleblowers are authorized to bring fraud suits on behalf of the government against providers and are entitled to receive a portion of any final recovery.

Federal and State "Self-Referral" and "Anti-kickback" Restrictions

If we or our operations are found to be in violation of applicable laws and regulations prohibiting improper referrals for healthcare services or products, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from participation in U.S. federal or state health care programs, and the curtailment or restructuring of our operations.

Anti-Kickback Statute. The federal Anti-Kickback Statute prohibits persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce either the referral of an individual, or the furnishing, recommending, or arranging for a good or service, for which payment may be made under a federal healthcare program, such as the Medicare and Medicaid programs. The term "remuneration" is not defined in the federal Anti-Kickback Statute and has been broadly interpreted to include anything of value, including for example, gifts, discounts, the furnishing of supplies or equipment, credit arrangements, payments of cash, waivers of payment, ownership interests and providing anything at less than its fair market value. Sanctions for violations of the federal Anti-Kickback Statute may include imprisonment and other criminal penalties, civil monetary penalties and exclusion from participation in federal healthcare programs. Many states have also adopted laws similar to the federal Anti-Kickback Statute, some of which apply to the referral of patients for healthcare items or services reimbursed by any source, not only the Medicare and Medicaid programs, and do not contain identical safe harbors.

Self-Referral law. The federal "self-referral" law, commonly referred to as the "Stark" law, provides that physicians who, personally or through a family member, have ownership interests in or compensation arrangements with a laboratory are prohibited from making a referral to that laboratory for laboratory tests reimbursable by Medicare, and also prohibits laboratories from submitting a claim for Medicare payments for laboratory tests referred by physicians who, personally or through a family member, have ownership interests in or compensation arrangements with the testing laboratory. The Stark law contains a number of specific exceptions which, if met, permit physicians who have ownership or compensation arrangements with a testing laboratory to make referrals to that laboratory and permit the laboratory to submit claims for Medicare payments for laboratory tests performed pursuant to such referrals. We are subject to comparable state laws, some of which apply to all payors regardless of source of payment, and do not contain identical exceptions to the Stark law.

Any action against us for violation of these or similar foreign 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 applicable federal and state privacy, security and fraud laws may prove costly.

Sunshine Act

In 2010, Congress enacted a statute commonly known as the Sunshine Act, which aims to promote transparency. The Sunshine Act requires manufacturers of drugs, devices, biologics and medical supplies covered by Medicare, Medicaid or the Children's Health Insurance Program, or CHIP, to report annually to CMS any payments or other transfers of value made to physicians and teaching hospitals, with limited exceptions. Manufacturers must also disclose to CMS any physician ownership or investment interests.

Competition

Our principal product, ColoAlert, competes with other methods of CRC screening, such as the colonoscopy or the FIT test. The current standard for CRC screening test is the colonoscopy, although we also compete with non-invasive CRC screening tests. In addition to these widespread, traditional screening tests, we also compete with companies that provide or are developing novel CRC screening tests.

Colonoscopy

The colonoscopy was established over 50 years ago and is used by countless physicians worldwide. The colonoscopy is an invasive procedure in which the inner wall of the intestine is examined by a physician using an endoscope. Preparation requires patients to undergo bowel cleansing at least the day prior to the procedure. Colonoscopy is a painful process and associated with the risk of punctuating the colon. An experienced scopeist will perform the process with less pain and a higher detection rate. The average detection rate of colonoscopy is approximately 95%.

The compliance rate for colonoscopy in Germany even after a consultation with a physician is a mere 16%. The occurrence of false-positive results is not possible due to the nature of the method. Usually, national screening programs suggest a screening interval of 10 years for this method. Because of the invasive procedure and the prior bowel cleansing, this method has a patient acceptance rate of less than 20%..

Any developments that result in the reduction of the cost of colonoscopies, the accuracy of their results or the ease of use may not be transferable to IVD tests.

Occult blood tests

With Fecal Immunochemical Tests ("FITs"), a patient's stool sample can be examined for hidden, or occult, blood in a laboratory which can be a symptom of CRC. Unfortunately, occult blood is often only present in the later stages of the disease. There is no need for patients to prepare prior to sample collection, which leads to a higher patient acceptance. According to IKK Südwest, when coordinated by a centralized invitation to screening, participation rates can get as high as 73%. Since this method can only provide an indirect indication of CRC via fecal blood, the sensitivity normally hovers around 65% with a false-positive rate around 5% per an article published by the American Gastroenterological Association. Since this method depends on the presence of a blood signal and many tumors do not bleed in the early stages, many affected individuals are diagnosed in later stages of the disease which leads to lower than 5-year survival rates and higher treatment costs. This current state of international screening programs suggests a need for more sensitive non-invasive screening tools. The recommended screening interval for FITs is normally yearly.

Entities Providing Screening Tests

We compete with other entities that offer other non-invasive screening tests. Most of our current and potential competitors in Europe and the United States have significantly greater financial, technical, manufacturing, marketing, and other resources than we have and consequently may have better and more competitive products, services, marketing or distribution. Most of our competitors have more extensive customer bases and broader customer and industry relationships than we do. In addition, many of these companies have longer operating histories and greater name recognition than we do. Our competitors may be in a stronger position to respond quickly to new technologies and may be able to design, develop, market and sell their products more effectively.

As we continue to innovate within the non-invasive colorectal cancer (CRC) screening market, Mainz Biomed competes against a spectrum of entities offering alternative screening tests. Notably, many of our contemporaries in both Europe and the United States have considerably more robust financial backing and superior capabilities in areas such as technical development, manufacturing, and marketing. These organizations often enjoy more comprehensive customer networks, deeper industry connections, and greater brand recognition, with a history that may enable them to adapt more swiftly to emergent technologies and market shifts.

We are in competition with several key players in the CRC screening landscape:

- Exact Sciences: This leading molecular diagnostics firm specializes in the early detection of various cancers, producing Cologuard, a fecal DNA-based CRC screening test. Cologuard boasts a sensitivity of 92% and specificity of 87%, with an average reimbursement rate of $500, as reported in a New England Journal of Medicine study. Exact Sciences is actively expanding its U.S. market share, strengthening healthcare provider relationships, and diversifying its oncology screening portfolio through strategic acquisitions.

- Freenome Holdings, Inc.: Aiming to enhance early cancer detection, Freenome Holdings is pioneering a blood-based CRC screening test that employs a multimodal data approach, with pivotal FDA study results and clearance anticipated in the next 12 months.

- Geneoscopy Inc.: Focusing on gastrointestinal health, Geneoscopy's stool RNA test "ColoSense" has shown promising sensitivity and specificity rates in detecting CRC and advanced adenomas during clinical trials. An FDA decision on pre-marketing approval is expected in 2024.

- Guardant Health, Inc.: Known for its liquid biopsy technology, Guardant Health's "Shield" blood test detects colorectal cancer signals, including circulating tumor DNA, with high sensitivity and specificity, as demonstrated in clinical validation studies. Guardant are also targeting a commercial launch of the product in the US sometime in 2024.

- GRAIL, Inc.: Leveraging next-generation sequencing technology, GRAIL's "Galleri" blood test can detect over 50 types of cancer, intended for use alongside traditional screening methods, priced at $959.

- Universal DX: This Spanish entity is developing "Signal-C," a liquid biopsy screening test for CRC, currently undergoing validation to demonstrate sensitivity and specificity metrics, with FDA approval in process.

Despite not being the earliest entrant into the market, we believe that our strategic emphasis on decentralized laboratory testing, leveraging well-established PCR methodology allows us to position competitively against many firms adopting centralized testing models with costlier technologies like next-generation sequencing and mass spectrometry. We anticipate the commercial availability of various developmental screening tests in the United States by the time we seek FDA approval for our next-generation product. Nonetheless, there remains a gap within the large reference laboratory and health network sectors for CRC screening options, which we aim to fill.

We might not be able to compete successfully in our market, particularly as we seek to enter the United States and commercialize ColoAlert. We expect that some of the screening tests currently being developed will be commercially available in the United States by the time we obtain FDA approval for ColoAlert, if we receive it at all. If our competitors introduce new diagnostic tests that compete with or surpass the accuracy, price or ease of use of our products, we may be unable to satisfy existing customers or attract new customers at the prices and levels that would allow us to generate attractive rates of return on our investment. Increased competition could result in price reductions and revenue shortfalls, loss of customers and loss of market share, which could harm our business, prospects, financial condition and operating results.

Customers

Our current customers are primarily laboratories in Germany, including some of the largest chains in Germany, that offer our ColoAlert test to physicians for use with their patients. For the year ended December 31, 2023, 2022 and 2021, we had revenue from one, two and four customers that accounted for approximately 21%, 38% and 56% of revenue, respectively. We are actively seeking to expand our customer base in Europe, and we intend to further expand it into the United States depending upon the progress of an application with the FDA for approval of ColoAlert.

Suppliers and Raw Material

We purchase most of our supplies "off-the-shelf" and at market rates and have normally second source suppliers available in case we experience supply issues with the primary supplier. We are planning to establish a safety stock from the primary suppliers to allow enough time for the necessary valuation to be performed if a secondary supplier is required.

Legal Proceedings

We are not involved in, or aware of, any legal or administrative proceedings contemplated or threatened by any governmental authority or any other party. As of the date of this annual report, no director, officer or affiliate is a party adverse to us in any legal proceeding or has an adverse interest to us in any legal proceeding.

C. Organizational structure

We have three wholly-owned subsidiaries, Mainz Biomed Germany GmbH (f/k/a PharmGenomics GmbH), Mainz Biomed USA, Inc. and European Oncology Lab GmbH (which is a wholly owned subsidiary of Mainz Biomed Germany GmbH).

D. Property, plant and equipment

Our principal premises are located at Robert Koch Strasse 50, Mainz, Germany. In 2013, we entered into a fifteen-year lease agreement for these premises with a monthly minimum rent of approximately €5,730 plus ancillary rental costs of approximately €1,500 per month. The leased premises is approximately 7,300 sq. ft. in size. During 2022, we entered into three additional lease agreements (i) starting January with additional rent of €2,307 and ancillary costs of €621 until December 2028 (2,228 sq. ft.), (ii) starting July with additional rent of €7,024 and ancillary costs of €1,012 until December 2026 (3,631 sq. ft.) and (iii) starting August with additional rent of €385 and ancillary costs of €187 until December 2026 (476 sq. ft). During 2023, we entered into two additional contracts for (i) lab space, starting in February 2023 until the end of December 2030 with rent of €8,200 and ancillary cost of €2,580 (7,883 sq.ft) and (ii) office space, starting April 2023 with rent of €1,250 and ancillary cost of €280 until December 2018 (860 sq.ft). Total rented space on our principal location amounts to approximately 22,400 sq. ft with a monthly rent of approx. €24,300 and ancillary costs of approximately €7,000.

We use these facilities for administrative purposes, research and development, manufacturing of our products and analysis by our laboratories. We believe that these facilities will satisfy our manufacturing and research and development needs in the next 12 months.

Some members of our management work outside of these premises in office space that we do not rent.

We do not own any real property and do not lease any other properties.

ITEM 4A. UNRESOLVED STAFF COMMENTS

Not Applicable.

ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS

You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and the related notes to those statements included elsewhere in this annual report on Form 20-F. This discussion and analysis contains forward-looking statements based upon current beliefs, plans and expectations related to future events and our future financial performance that involve risks, uncertainties and assumptions, such as statements regarding our intentions, plans, objectives, expectations, forecasts and projections. Our actual results and the timing of selected events could differ materially from those anticipated in these forward-looking statements as a result of several factors, including those set forth under the section titled "Risk Factors" and elsewhere in this annual report on Form 20-F. You should carefully read the "Risk Factors" to gain an understanding of the important factors that could cause actual results to differ materially from our forward-looking statements. Please also see the section titled "Special Note Regarding Forward-Looking Statements."

Organization and Overview of Operations

We develop and sell in-vitro diagnostic ("IVD") tests for the early detection of cancer. Our flagship ColoAlert product is being marketed and sold in European markets. We are currently developing our next generation colorectal cancer screening product and intend to launch that product in the future in the United States and in Europe. We additionally operate a clinical diagnostic laboratory and distribute our IVD kits to third-party laboratories in Europe and through our on-line store in Germany.

In addition, we conduct research and development to increase and diversify our product portfolio. Currently, we are managing our government funded research and development project called PancAlert, which provide us non-refundable grant income that covers a percentage of the individual project-related costs.

Results of Operations

Comparison of the Year Ended December 31, 2023 and 2022

The following table provides certain selected financial information for the periods presented:

	Year Ended December 31,			
	2023	2022	Change	% Change
Revenue	$ 895,479	$ 529,877	$ 365,602	69%
Cost of revenue	$ 385,820	$ 347,726	$ 38,094	11%
Gross profit	$ 509,659	$ 182,151	$ 327,508	180%
Gross profit percentage	57%	34%		
Research and Development	$ 9,590,393	$ 5,019,366	$ 4,571,027	91%
Sales and Marketing	$ 6,158,477	$ 6,396,906	$ (238,429)	(4)%
General and Administrative	$ 11,405,471	$ 15,209,919	$ (3,804,448)	(25)%
Total operating expenses	$ 27,154,341	$ 26,626,191	$ 528,150	2%
Loss from operations	$ (26,644,682)	$ (26,444,040)	$ 91,609	1%
Other income (expense)	$ 348,955	$ 56,094	$ 292,251	515%
Net loss	$ (26,295,727)	$ (26,387,336)	$ 91,609	0%
Total Comprehensive Loss	$ (26,800,221)	$ (26,337,633)	$ (462,588)	(2)%
Basic and dilutive loss per common share	$ (1.62)	$ (1.86)	$ 0.24	13%
Weighted average number of common shares outstanding – basic and diluted	16,242,334	14,157,492	2,084,842	15%

Revenue

Revenue for the year ended December 31, 2023 was $895,479 compared to $529,877 in the prior year, which represented a 69% year over year increase compared to the prior year. This increase was the result of an increase in the sale of our ColoAlert product, primarily in Germany. We sell our ColoAlert directly to lab partners, who in turn provide the tests to patients and perform the tests and deliver results to those patients; we also market directly to patients through our online platform, where we deliver and perform the test, and

provide reports directly to those patients. As we gain access to reimbursed markets in Europe, we expect our revenue to grow, led by our lab partner channel. We plan to launch our FDA pivotal study in the next twelve months for our next generation product; that product, if approved by the FDA, will be launched in the United States and in Europe.

Cost of Revenue

Cost of Revenue for the year ended December 31, 2023 increased by $38,094, or 11%, compared to the year ended December 31, 2022, as the result of increased costs associated with the increase in ColoAlert sales.

Gross profit

Gross profit increased from $182,151 for the year ended December 31, 2022, to $509,659for the year ended December 31, 2023, with gross margins increasing from 34% to 57%. The increased gross margins were the result of revenue growth from sales performed in our diagnostic lab, where our margins are higher than in sales to lab partners.

Research and Development Expenses

Research and development expenses for the year ended December 31, 2023 were $9,590,393 compared to $5,019,366 for the year ended December 31, 2022. This increase of $4,571,027 was primarily attributable to the increase in headcount in our employees working on research and development, resulting in an increase in compensation (salary, benefits and consulting related to our clinical studies) costs of $1.5 million and an increase of $3.0 million related to our ColoFuture and eAArly DETECT clinical studies in Europe and the United States, respectively.

Sales and Marketing Expenses

Sales and marketing expenses for the year ended December 31, 2023, were $6,158,477 compared to $6,396,906 for the year ended December 31, 2022, a decrease of $238,429. This decrease was attributable to a $1.2 million decrease in advertising and marketing expenses after our initial marketing launch expenses in 2022, net of a $0.9 million increase in salaries and benefits resulting from increased headcount in our sales and marketing department.

General and Administrative Expenses

General and administrative expenses for the year ended December 31, 2023 were $11,405,471 compared to $15,209,919 for the year ended December 31, 2022, a decrease of $3,804,448. This decrease was attributable to a $5.6 million decrease in stock option expense (a non-cash expense), net of an increase of $1.7 million for consulting and professional fees primarily related to costs associated with raising capital and increasing brand and company awareness.

Other income (expense)

Other income for the year ended December 31, 2023 was $348,955 compared to $56,704 for the year ended December 31, 2022. This increase in other income was primary related to a fair value adjustment (income) of $0.6 million related to our convertible debt financing in November 2023, net of increased financing fees and foreign currency translation losses.

Comparison of the Year Ended December 31, 2022 and 2021

For a discussion of our results for the year ended December 31, 2022 compared to the year ended December 31, 2021, please see "Operating and Financial Review and Prospects – Results of Operations – Comparison of the Year Ended December 31, 2022 and 2021" contained in our annual report on Form 20-F filed with the U.S. Securities and Exchange Commission on April 7, 2023 and incorporated herein by reference.

Liquidity and Capital Resources

Our principal liquidity requirements are for working capital and capital expenditures. Historically, we have funded our liquidity requirements primarily through cash on hand, cash flows from operations, and equity and debt financing.

We have recurring losses, accumulated deficit totaling $69,328,021 and negative cash flows used in operating activities of $21,938,845 as of and for the year ended December 31, 2023. We also had $7,070,925 of cash on hand at December 31, 2023. These factors raise a substantial doubt as to the Company's ability to continue as a going concern for a period that is one year from the date these financial statements are published. If we are unable to obtain funding, we could be forced to delay, reduce, or eliminate our research and development, regulatory, and commercial efforts which could adversely affect its future business prospects and our ability to continue as a going concern.

We plan to fund our cash flow needs through current cash on hand and future debt and/or equity financings which it may obtain through one or more public or private equity offerings, debt financings, government or other third-party funding, strategic alliances, or collaboration agreements. During 2022 we raised $24.2 million of net proceeds from common stock sales and warrant proceeds. During 2023 we raised $16.5 million from a combination of sale of shares and warrants as well as the issuance of convertible debt. During 2024 and beyond we believe that we will be able to raise additional funds through a combination of the sale of ordinary shares, the sale and/or conversion of warrants, and use of our access to capital through our Controlled Equity Offering (see Note 16) and our Pre-Paid Advance Agreement (see Note 13). We also have the ability to defer certain costs, especially those related to clinical studies, to match financing inflows. We believe that with currently available cash on hand, including additional financing described above, will be sufficient to meet our planned expenditures and to meet the our obligations for at least the one-year period following its consolidated financial statement issuance date.

The following table summarizes our cash flows from operating, investing and financing activities:

	Year Ended December 31,		
	2023	2022	Change
Cash used in operating activities	$ (21,938,845)	$ (14,769,590)	$ (7,169,255)
Cash provided by (used in) investing activities	$ (1,898,841)	$ (658,483)	$ (1,240,358)
Cash provided by financing activities	$ 14,226,692	$ 23,943,418	$ (9,716,726)

Cash Flow from Operating Activities

For the year ended December 31, 2023, net cash flows used in operating activities was $21,938,845, an increase of $7,169,255 from the year ended December 31, 2022. This increase was primarily from the increase of our net loss, net of stock-based compensation, depreciation, amortization and change in fair value of convertible debt. Operating activities also included $500,187 of increased expenditures related to inventories in support of our commercial efforts.

Cash Flows from Investing Activities

During the year ended December 31, 2023, cash used in investing activities was $1,898,841, including $1.2 million for the capital expenditure and $700 thousand for the purchase of intellectual property to support our ColoAlert product. For the year ended December 31, 2022 we had capital expenditures of $0.7 million.

Cash Flows from Financing Activities

During the year ended December 31, 2023, we raised $6.4 million from the sale of ordinary shares and warrants and $9.0 million (net) from our Pre-Paid Advance agreement, in the form of convertible debt. During 2023 we also made principal payments of $1.2 million for silent partnerships and lease obligations. During the year ended December 31, 2022 we raised $23.9 million and the sale of ordinary shares and warrants and made principal payments of $300 thousan for silent partnerships and lease obligations.

Critical Accounting Policies and Significant Judgments and Estimates

This discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with International Financial Reporting Standards, or IFRS, as issued by the International Accounting Standards Board. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. While our significant accounting policies are described in more detail in the notes to our financial statements included elsewhere in this annual report, we believe that the following accounting policies are critical to understanding our historical and future performance, as these policies relate to the more significant areas involving management's judgments and estimates.

We believe our most critical accounting policies and estimates relate to the following:

- Revenue Recognition,
- Foreign Currency Translation,
- Stock Option Compensation,
- Impairment of Long-Lived Assets Including Intangibles,
- Lease Accounting, and
- Financial Instruments.

Revenue Recognition

Our revenue is primarily derived through providing genetic diagnostic tests to customers. We recognize revenue in accordance with International Financial Reporting Standards ("IFRS") 15 "Revenue from Contracts with Customers".

In accordance with IFRS 15, revenue is recognized upon the satisfaction of performance obligations. Performance obligations are satisfied at the point at which control of the promised goods or services are transferred to customers, in an amount that reflects the consideration we expect to be entitled to receive for those goods and services.

We sell our genetic diagnostic testing kits to both laboratory partners and directly to patients who are the end users of the product. Upon the delivery of our products to laboratory partners, we have completed our performance obligations and as such revenue is recorded upon delivery. Sales to patients, or end users, where samples are sent to our diagnostic lab for testing and evaluation, are recognized when they are delivered to the end user, returned to our laboratory, and testing results have been delivered. Revenue from these sales is deferred on our Statement of Financial Position until recognition.

We also receive income from government sponsored R&D grants. Income is recognized on these programs when funds are received and all performance obligations, as defined in the grant, are completed. This income is included in the Statements of Comprehensive Loss as Other Income.

Foreign Currency Translation

The functional currency is determined using the currency of the primary economic environment in which that entity operates. The functional currency, as determined by our management, is the Euro (EUR).

Foreign currency transactions are translated into functional currency using the exchange rates prevailing at the date of the transaction. Foreign currency monetary items are translated at the period-end exchange rate. Non-monetary items measured at historical cost continue to be carried at the exchange rate at the date of the transaction. Non-monetary items measured at fair value are reported at the exchange rate at the date when fair values were determined.

Exchange differences arising on the translation of monetary items or on settlement of monetary items are recognized in the statement of comprehensive loss in the period in which they arise, except where deferred in equity as a qualifying cash flow or net investment hedge.

Exchange differences arising on the translation of non-monetary items are recognized in other comprehensive income to the extent that gains and losses arising on those non-monetary items are also recognized in other comprehensive income. Where the non-monetary gain or loss is recognized in profit or loss, the exchange component is also recognized in profit or loss.

Our presentation currency is the US dollar. For presentation purposes, all amounts are translated from the Euro functional currency to the US dollar presentation currency for each period using the exchange rate at the end of each reporting period for the statement of financial position. Revenues and expenses are translated on the basis of average exchange rates during the year.

Exchange gains and losses arising from translation to our presentation currency are recorded as exchange differences on translation to reporting currency, which is included in other comprehensive income (loss).

Stock Option Compensation

We have adopted our 2021 Omnibus Incentive Plan and the 2022 Omnibus Incentive Plan (the "Plans"). Under the Plans, we are authorized to issue equity incentives in the form of incentive stock options, non-statutory stock options, restricted shares, restricted share units, share appreciation rights, performance units or performance shares under separate award agreements. Under the Plans, the aggregate number of shares underlying awards that we could issue cannot exceed 2,300,000 ordinary shares.

On November 4, 2021, we awarded 1,484,650 stock options under the Plan, with a strike price of $5.00, the per share price in our November 2021 initial public offering. Such stock options were granted to all of our current employees, directors, advisors and senior management team. Such stock options for our non-senior management team, independent directors and advisors will begin vesting on November 4, 2022 and stop vesting on November 4, 2025 at the latest. Such stock options for the four members of our senior management team will begin vesting in portions equal to 25% of such options granted if, prior to November 4, 2025, the four-year anniversary of our initial public offering, for ten consecutive trading days (with at least 100,000 shares traded per trading day) the volume-weighted average price of the ordinary shares on the principal market is at least:

- $7.50;
- $10.00;
- $12.50, provided that such options could not vest until the twelve-month anniversary of the initial public offering; and
- $15.00, provided that such options could not vest until the twelve-month anniversary of the initial public offering.

We value our stock options as follows: (a) for those options that have time-based vesting, we use the Black Scholes method to value the stock options at the time of award and record the compensation expense in our Statement of Operations over the vesting period, and (b) for options issued with milestone based vesting criteria, we use a Monte Carlo simulation to value the options at the time of issuance and each subsequent reporting date until fully vested or expired, with any change in compensation expense measured by such method to be recorded in our Statement of Operations.

The Black Scholes option pricing model considers, among other factors, the expected term of the award and the expected volatility of our stock price. Due to the lack of an adequate history of a public market for the trading of our ordinary shares, we have based our estimate of expected volatility on the historical volatility of a group of similar companies that are publicly traded with historical share price information sufficient to meet the expected life of the stock-based awards. The Monte Carlo simulation approach is a class of computational algorithms that rely on repeated random sampling to compute their results. This approach allows the calculation of the value of such stock options based on a large number of possible stock price path scenarios. Expense for the market-condition stock options will be recognized over the derived service period as determined through the Monte Carlo simulation model.

Impairment of Long-Lived Assets Including Intangibles

We continually evaluate whether events or circumstances have occurred that indicate the remaining estimated useful lives of our long-lived assets including intangible assets may warrant revision or that the remaining balance of such assets may not be recoverable. We use an estimate of the related undiscounted cash flows over the remaining life of the asset in measuring whether the asset is recoverable.

Lease Accounting

We assess at contract inception whether a contract is, or contains, a lease. That is, if the contract conveys the right to control the use of an identified asset for a period of time in exchange for consideration. We apply a single recognition and measurement approach for all leases, except for short-term leases and leases of low-value assets. We recognize lease liabilities to make lease payments and right-of-use assets representing the right to use the underlying assets.

At the commencement date of the lease, we recognize lease liabilities measured at the present value of lease payments to be made over the lease term. Lease payments include fixed payments (including in-substance fixed payments) less any lease incentives receivable, variable lease payments that depend on an index or a rate, and amounts expected to be paid under residual value guarantees. Lease payments also include the exercise price of a purchase option reasonably certain to be exercised by us and payments of penalties for terminating the lease, if the lease term reflects us exercising the option to terminate. Variable lease payments that do not depend on an index or a rate are recognized as expenses in the period in which the event or condition that triggers the payment occurs. In calculating the present value of lease payments, we use our incremental borrowing rate at the lease commencement date because the interest rate implicit in the lease is not readily determinable. After the commencement date, the amount of lease liabilities is increased to reflect the accretion of interest and reduced for the lease payments made. In addition, the carrying amount of lease liabilities is remeasured if there is a modification, a change in the lease term, a change in the lease payments (e.g., changes to future payments resulting from a change in an index or rate used to determine such lease payments) or a change in the assessment of an option to purchase the underlying asset.

We recognize right-of-use assets at the commencement date of the lease (i.e., the date the underlying asset is available for use). Right-of-use assets are measured at cost, less any accumulated depreciation and impairment losses, and adjusted for any remeasurement of lease liabilities. The cost of right-of-use assets includes the amount of lease liabilities recognized, initial direct costs incurred, and lease payments made at or before the commencement date less any lease incentives received. Right-of-use assets are depreciated on a straight-line basis over the shorter of the lease term and the estimated useful lives of the assets.

Financial Instruments

(a) Classification

We classify our financial instruments in the following categories: at fair value through profit and loss ("FVTPL"), at fair value through other comprehensive income (loss) ("FVTOCI") or at amortized cost. We determine the classification of financial assets at initial recognition. The classification of debt instruments is driven by our business model for managing the financial assets and their contractual cash flow characteristics. Equity instruments that are held for trading are classified as FVTPL. For other equity instruments, on the day we acquire them, we can make an irrevocable election (on an instrument-by-instrument basis) to designate them as at FVTOCI. Financial liabilities are measured at amortized cost, unless they are required to be measured at FVTPL (such as instruments held for trading or derivatives) or if we have opted to measure them at FVTPL.

(b) Measurement

Financial assets and liabilities at amortized cost

Financial assets and liabilities at amortized cost are initially recognized at fair value plus or minus transaction costs, respectively, and subsequently carried at amortized cost less any impairment.

Financial assets and liabilities at FVTPL

Financial assets and liabilities carried at FVTPL are initially recorded at fair value and transaction costs are expensed in the statements of loss and comprehensive loss. Realized and unrealized gains and losses arising from changes in the fair value of the financial assets and liabilities held at FVTPL are included in the statements of loss and comprehensive loss in the period in which they arise.

Debt investments at FVTOCI

These assets are subsequently measured at fair value. Interest income calculated using the effective interest method, foreign exchange gains and losses and impairment are recognized in profit or loss. Other net gains and losses are recognized in OCI. On derecognition, gains and losses accumulated in OCI are reclassified to profit or loss.

Equity investments at FVTOCI

These assets are subsequently measured at fair value. Dividends are recognized as income in profit or loss unless the dividend clearly represents a recovery of part of the cost of the investment. Other net gains and losses are recognized in OCI and are never reclassified to profit or loss.

Disclosure of Contractual Arrangements

On December 31, 2023, we were committed to minimum lease payments as follows:

Contractual Obligation	Less than One Year	1 – 3 Years	3 – 5 Years	Over 5 Years
Office Rent	$ 278,563	$ 633,018	$ 453,050	$ 358,513
Laboratory Equipment	$ 27,317	$ 37,558	$ 14,784	$ 9,856
Automobiles	$ 54,794	$ 39,531	$ -	$ -
Office Equipment	$ 6,359	$ 6,840	$ 788	$ -
TOTAL	**$ 367,033**	**$ 716,947**	**$ 468,622**	**$ 368,369**

The amounts above are undiscounted and include the total amounts due, including the interest component.

ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES

A. Directors and Senior Management

The following table sets forth the names and ages of all of our directors and executive officers.

Name, Region/State and Country of Residence	Age	Position	Director/Officer Since
Guido Baechler *California, USA*	58	Chief Executive Officer, Executive Director	July 2021
William Caragol *Florida, USA*	57	Chief Financial Officer	July 2021
Dr. Moritz Eidens *Ingelheim, Germany*	41	Chief Scientific Officer, Executive Director	June 2008
Dr. Heiner Dreismann *Florida, USA*	70	Non-Executive Director	December 2022
Darin Leigh *Florida, USA*	56	Chief Commercial Officer	March 2022
Dr. Chris von Toerne *Mainz, Germany*	52	Chief Operating Officer	June 2022
Dr. Frank Kreig-Schneider *Mainz, Germany*	62	Chief Technology Officer	August 2022
Dr. Alberto Libanori *California, USA*	34	Non-Executive Director	November 2021
Hans Hekland *Bergen, Norway*	65	Non-Executive Director	November 2021
Philipp Freese *Grevenbroich, Germany*	42	Chief Business Officer	February 2015
Nicole Holden *Virginia, USA*	51	Non-Executive Director	November 2021
Gregory Tibbitts *California, USA*	56	Non-Executive Director	December 2022

Business Experience

The following summarizes the occupation and business experience for our directors, and executive officers as of the date of this annual report:

Guido Baechler, our Chief Executive Officer and an executive director, has global experience in private and public companies specializing in the life science and medical diagnostics fields. Mr. Baechler founded Berkeley Life Science Advisors, a diagnostic and life science start-up consulting business, in 2019. He was the Chief Executive Officer of SummerBio, a leading COVID testing CLIA laboratory in California, from July 2020 to February 2021 and Chief Executive Officer and Chief Operating Officer of Singulex, Inc. from November 2008 to June 2019.

Mr. Baechler previously held several leadership positions at Roche Molecular Systems, including serving as a member of its executive team. He held various leadership positions at Roche Diagnostics within Research, Development, and Marketing in Switzerland and California during his almost twenty years with the company.

Since 2020, Mr. Baechler is the chairman of the board of Telo Genomics, a publicly traded Canadian biotech company and an advisor to other life science companies.

Mr. Baechler holds a Bachelor's Degree in Electrical Engineering and completed a series of executive finance and management classes at the London School of Business and at the Haas Business School at the University of California, Berkeley.

William Caragol, our Chief Financial Officer, has over thirty years of experience working with growth stage technology companies. In 2018, he founded and is the Managing Director of Quidem LLC, a corporate strategic and financial advisory firm. Since 2015, Mr. Caragol has been Chairman of the Board of Thermomedics, Inc., a privately held medical diagnostic equipment company. Since February 2021, Mr. Caragol is also on the Board of Directors and is Chairman of the Audit Committee of RYVYL, Inc. (NASDAQ: RVYL) a financial technology company leveraging proprietary blockchain security to build customized payment solutions, and since July 2021 is on the Board of Directors of Worksport Ltd. (Nasdaq: WKSP), an emerging electric vehicle company. Since November 2021, Mr. Caragol has served as the Chief Operating Officer for Iron Horse Acquisitions Corp. (NASDAQ: IROH), a special purpose acquisition corporation. Mr. Caragol earned a B.S. in business administration and accounting from Washington & Lee University and is a member of the American Institute of Certified Public Accountants.

Dr. Moritz Eidens, our Chief Scientific Officer and an executive director, received his Masters Degree at the international oriented University of Applied Sciences in Rheinbach near Bonn, Germany in 2006 with a focal point on human genetics and genetic diseases. In 2019, Dr. Eidens graduated from the University-Medicine Hospital of the Johannes Gutenberg University in Mainz, Germany, and was awarded with a Ph.D. from the medical faculty.

In 2008, Dr. Eidens founded PharmGenomics and has served since then as an executive of the organization. Dr. Eidens has been involved in PharmGenomics' development and distribution of several innovative products, managed and coordinated several national and international grant projects with large industrial or academic partners process development, technology transfer, supply chain management as well as internal and external audits. In September 2021, Dr. Eidens was appointed as Chief Scientific Officer at Mainz Biomed N.V. He also serves as Managing Director of Mainz Biomed Germany GmbH and the European Oncology Lab GmbH in St. Ingbert, Germany our wholly-owned subsidiaries. Dr. Eidens heads the Company's research department, where our product candidate PancAlert, a stool based pancreatic cancer screening tool is under development.

Dr. Heiner Dreismann, Ph.D., a non-executive director, had a successful career at the Roche Group from 1985 to 2006 where he held several senior positions, including President and CEO of Roche Molecular Systems, Head of Global Business Development for Roche Diagnostics and as a member of Roche's Global Diagnostic Executive Committee. During the past five years, Dr. Dreismann served on the Board of Directors of Myriad Genetics, Inc., Med BioGene, Inc. and Ignyta, Inc. He earned a M.S. degree in biology and his Ph.D. in microbiology/molecular biology (summa cum laude) from Westfaelische Wilhelms University (The University of Münster) in Germany.

Darin Leigh, our Chief Commercial Officer, has over 30 years of global life sciences and in-vitro diagnostics experience. Mr. Leigh founded Simeon Global Consulting LLC in 2017 focused on implementing commercialization strategies for small startup and early-stage diagnostic companies. From December 2020 to April 2022, he was Chief Commercial Officer for CDR Maguire, an emergency management company based in Florida who were responsible for the state's response to the COVID pandemic including operationalizing testing and vaccination sites across Florida. He was Chief Commercial Officer for Chromacode Inc, from July 2019 to December 2020, and Chief Commercial Officer for Singulex, Inc from August 2018 to June 2019.

Mr. Leigh previously held leadership positions at Metabolon, Inc, Asuragen, Inc, Luminex Corporation and Abbott Diagnostics. During his time at Luminex, he grew the company revenues from $26 million in 2005 to $183 million in 2011 and oversaw significant global commercial growth and formation of international operations in Japan, China and Europe.

Mr. Leigh holds a Degree in Medical Laboratory Sciences from the University College London and completed several MBA management classes at the University of Chicago Booth School of Business.

Dr. Chris von Toerne, our Chief Operating Officer, has over 15 years of experience in the development and global commercialization of IVD products. During this time, Mr. von Toerne has obtained significant technical experience in various diagnostic technologies (PCR, sequencing, immuno-assays, AST), alliance management, and key account management. Successful registration of several products with the FDA fall into this timeframe.

Before his position at Mainz Biomed, Dr. von Toerne has held program management and functional leadership positions at Siemens (2009-2013), Novartis and Grifols (2013-2019) in the United States, and more recently at Eppendorf SE where he co-led the OEM business through the COVID pandemic (2019-2022).

Dr. von Toerne holds a Masters's Degree and a Doctorate in Applied Mathematics from Bonn University, Germany. He also holds a Project Management Professional (PMP) certificate and has undergone Six Sigma Green Belt training.

Frank Krieg-Schneider, our Chief Technology Officer, has over 30 years of experience in private, public and startup companies in the life sciences and in-vitro diagnostics field. Dr. Krieg-Schneider founded KS Management Consulting in 2019 focused on connecting startup and IVD companies. Prior to joining Mainz Biomed, he was responsible for sales and marketing of the diagnostic products at r-biopharm, a privately owned company and market leader in stool-based diagnostics based in Germany.

Dr. Krieg-Schneider previously held leadership positions at Qiagen and r-biopharm. During his time at Qiagen, he developed the QIAamp product line and several automated sample preparation systems. Furthermore, he built the company's OEM business and grew the revenues significantly. At r-biopharm he oversaw the transition of the product portfolio to meet the requirements of the IVDR and positioned the company as one of the leading COVID PCR test providers in several countries in Europe, Latin America and Canada during the pandemic.

Dr. Krieg-Schneider graduated from Johannes Gutenberg University in Mainz, Germany, and was awarded with a Ph.D. from the faculty of Biology for his thesis conducted at the German Cancer Research Center in Heidelberg, Germany.

Philipp Freese, our Chief Business Officer, received his Diploma in Business Administration with focus on marketing, business law and production technology at Excellence University RWTH in Aachen/Germany in 2008. Until 2015 he worked in project, product, process, quality and key account management as well as business development for the German Economic Institute. In 2014, he successfully finished his postgraduate studies in IT-related business administration.

Mr. Freese served as the Interim Head of Marketing at PharmGenomics from 2013 to 2015, and in 2015 he became its Commercial Managing Director responsible for marketing, sales, operations, legal affairs and Finance/IR. He was the major driver for ColoAlert's product-market-fit, brand, customer-facing processes and marketing strategies, established relationships with reference laboratories and assisted in our capital raises. In September 2021, Mr. Freese was appointed as Chief Operating Officer at Mainz Biomed N.V. In July 2023, he transitioned into the commercial role of our Chief Business Officer. He also serves as Managing Director of Mainz Biomed Germany GmbH and European Oncology Lab GmbH, our wholly owned subsidiaries.

Hans Hekland, a non-executive director, graduated Siviløkonom (MBA) from Norwegian School of Economics and Business Administration in Bergen, Norway in 1983. He has had several executive positions in international Banking and Industry until 2001 when he established Sarsia Innovation as the tech-transfer-office for University of Bergen. He has during his career developed Sarsia into a venture fund management company, established three venture funds. He holds board positions in several healthcare and biotech companies, and since 2021, he has been on the board of Lifecare AS (Euronext Growth: LIFE), a company developing a continuous glucose measurement implant.

In 2013 he established ColoAlert AS together with Dr. Dagfinn Øgreid and Dr Roger Løvlie and engaged PharmGenomics to develop the ColoAlert test, which led to the current license agreement.

Dr. Alberto Libanori, a non-executive director, serves as Managing Director to Boustead Securities, LLC. Alberto has 10 years' work experience at the science-business interface in venture capital, BD&L, M&A and IPOs, focusing in life-sciences, med-tech and cosmeceuticals, having worked with L'Oréal Research and Innovation, M-Ventures, and

Novartis Venture Funds (NVF). Previously Alberto founded and helped with the strategic exits of a number of technology start-ups including Atelier Mnemist SAS and Cutech (acquired by Symrise). He is currently an Independent Director on the Board of Nasdaq-listed Brera Holdings PLC (BREA), a multi-club ownership company in global football, and The RoyaLand Company Limited, a Bermuda company focused on royal themed multiplayer online role-playing game. A prolific scientist, Alberto has published more than 40 peer-reviewed articles in journals including Nature Electronics, Advanced Materials, and ACS Nano, and is the holder of two patents. Alberto Libanori holds a PhD and MS in Bioengineering from UCLA, with focus on wearable and implantable bioelectronics and biomaterials for regenerative medicine, an MPhil in Bioscience Enterprise from Cambridge University, and a Bachelor's in Bimolecular Sciences (Hons) from St Andrews University. Raised internationally, Alberto is fluent in English, French, Spanish, Mandarin Chinese and Portuguese, alongside his native Italian.

Nicole Holden, CPA, a non-executive director, has more than 20 years of accounting advisory experience for large publicly traded and privately held clients. Ms. Holden advises clients in matters involving SEC reporting, complex financial transactions, initial public offerings, acquisitions and divestiture accounting, restructuring, discontinued operations, and various technical accounting matters. From 2018 to 2023, Ms. Holden was the Audit Committee Chair for Nerds On Site, Inc. (CSE: NERD). Prior to joining our Board, Ms. Holden had a broad professional career. She is currently the Vice President, Client Advisory in the Advisory Service practice for The Alliance Group. Ms. Holden was also an Assistant Controller for Enviva LP (NYSE: EVA). She was a Director in the Professional practice for the Center for Audit Quality (The CAQ). She also served as a Senior Manager in the Office of Research and Analysis and Assistant Chief Auditor in the Office of the Chief Auditor for the Public Company Accounting Oversight Board (PCAOB). She was a Director in the Transaction Services practice at KPMG LLP. She also served as a Senior Manager in the Assurance practice at Stonefield Josephson, Inc. She was a Staff Accountant in the Corporate Finance division of the U.S. Securities and Exchange Commission (SEC). She also worked on the Internal Audit team for Computer Sciences Corp (NYSE: DXC). She began her career first as an Assurance associate for Arthur Andersen, then as an Assurance associate for Ernst & Young, LLP. Ms. Holden is a licensed Certified Public Accountant in Washington, DC (Active). She received a Master of Accounting from the American University, Kogod School of Business.

Gregory Tibbitts, a non-executive director, is a Certified Public Accountant with over 30 years of professional experience as a senior financial executive and as a board member of publicly traded and privately held companies. His expertise includes multiple debt and equity transactions, restructure of complex manufacturing operations, resolution of technical accounting issues and direct interactions with the U.S. Securities and Exchange Commission. He worked as a Chief Financial Officer for both public and private companies, primarily in the medical diagnostics and life sciences sectors. He served as a board member for CoImmune Inc, a biotechnology company, through March 2024, and served as a board member for IDMI Pharma, Inc., a NASDAQ listed biotech company prior to its acquisition. He obtained a B.B.A. at University of San Diego and an M.B.A. at San Diego State University.

Family Relationships

There are no family relationships among any of our directors and executive officers.

Arrangements

We are not aware of any arrangement among shareholders regarding the nomination or approval of directors or senior management.

Term of Office

Each director is to serve until his successor is elected and qualified or until his death, resignation or removal. Our Board of Directors appoints our officers and each officer is to serve until his successor is appointed and qualified or until his or her death, resignation or removal.

Involvement in Certain Legal Proceedings

During the past ten years, none of our directors or executive officers have been the subject of the following events:

1. a petition under the Federal bankruptcy laws or any state insolvency law was filed by or against, or a receiver, fiscal agent or similar officer was appointed by a court for the business or property of such person, or any partnership in which he was a general partner at or within two years before the time of such filing, or any corporation or business association of which he was an executive officer at or within two years before the time of such filing;

2. convicted in a criminal proceeding or is a named subject of a pending criminal proceeding (excluding traffic violations and other minor offenses);

3. the subject of any order, judgment, or decree, not subsequently reversed, suspended or vacated, of any court of competent jurisdiction, permanently or temporarily enjoining him from, or otherwise limiting, the following activities;

    i) acting as a futures commission merchant, introducing broker, commodity trading advisor, commodity pool operator, floor broker, leverage transaction merchant, any other person regulated by the Commodity Futures Trading Commission, or an associated person of any of the foregoing, or as an investment adviser, underwriter, broker or dealer in securities, or as an affiliated person, director or employee of any investment company, bank, savings and loan association or insurance company, or engaging in or continuing any conduct or practice in connection with such activity;

    ii) engaging in any type of business practice; or

    iii) engaging in any activity in connection with the purchase or sale of any security or commodity or in connection with any violation of Federal or State securities laws or Federal commodities laws;

4. the subject of any order, judgment or decree, not subsequently reversed, suspended or vacated, of any Federal or State authority barring, suspending or otherwise limiting for more than 60 days the right of such person to engage in any activity described in paragraph 3.i in the preceding paragraph or to be associated with persons engaged in any such activity;

5. was found by a court of competent jurisdiction in a civil action or by the SEC to have violated any Federal or State securities law, and the judgment in such civil action or finding by the SEC has not been subsequently reversed, suspended, or vacated;

6. was found by a court of competent jurisdiction in a civil action or by the Commodity Futures Trading Commission to have violated any Federal commodities law, and the judgment in such civil action or finding by the Commodity Futures Trading Commission has not been subsequently reversed, suspended or vacated;

7. was the subject of, or a party to, any Federal or State judicial or administrative order, judgment, decree, or finding, not subsequently reversed, suspended or vacated, relating to an alleged violation of:

    i) any Federal or State securities or commodities law or regulation; or

    ii) any law or regulation respecting financial institutions or insurance companies including, but not limited to, a temporary or permanent injunction, order of disgorgement or restitution, civil money penalty or temporary or permanent cease-and-desist order, or removal or prohibition order, or

iii) any law or regulation prohibiting mail or wire fraud or fraud in connection with any business entity; or

8. was the subject of, or a party to, any sanction or order, not subsequently reversed, suspended or vacated, of any self-regulatory organization (as defined in Section 3(a)(26) of the Exchange Act (15 U.S.C. 78c(a)(26))), any registered entity (as defined in Section 1(a)(29) of the Commodity Exchange Act (7 U.S.C. 1(a)(29))), or any equivalent exchange, association, entity or organization that has disciplinary authority over its members or persons associated with a member.

Director Independence

We have five non-executive directors who qualify as "independent" according to the rules of the Nasdaq Stock Market, LLC. Our Board has determined that the following non-executive directors are "independent" as such directors do not have a direct or indirect material relationship with our company: Dr. Alberto Libanori, Nicole Holden, Hans Hekland, Dr. Heiner Driesmann and Gregory Tibbits.

A material relationship is a relationship which could, in the view of our Board of Directors, be reasonably expected to interfere with the exercise of a director's independent judgment.

Code of Ethics and Business Conduct

We have adopted a Code of Ethics and Business Conduct that applies to our directors, officers and other employees.

B. Compensation

Compensation Discussion and Analysis

This section sets out the objectives of our company's executive compensation arrangements, our company's executive compensation philosophy and the application of this philosophy to our company's executive compensation arrangements. It also provides an analysis of the compensation design, and the decisions that the Board intends to make with respect to our executive officers. When determining the compensation arrangements for our executive officers, our Compensation Committee considers the objectives of: (i) retaining an executive critical to our success and the enhancement of shareholder value; (ii) providing fair and competitive compensation; (iii) balancing the interests of management and our shareholders; and (iv) rewarding performance, both on an individual basis and with respect to the business in general.

Benchmarking

Our Compensation Committee handles matters relating to compensation, including benchmarking. The Compensation Committee considers a variety of factors when designing and establishing, reviewing and making recommendations for executive compensation arrangements for all our executive officers. The Compensation Committee does not intend to position executive pay to reflect a single percentile within the industry for each executive. Rather, in determining the compensation level for each executive, the Compensation Committee will look at factors such as the relative complexity of the executive's role within the organization, the executive's performance and potential for future advancement and pay equity considerations.

Elements of Compensation

The compensation paid to executive officers in any year consists of two primary components:

(a) base salary; and

(b) long-term incentives in the form of stock options.

The key features of these two primary components of compensation are discussed below:

Base Salary

Base salary recognizes the value of an individual to our company based on his or her role, skill, performance, contributions, leadership and potential. It is critical in attracting and retaining executive talent in the markets in which we compete for talent. Base salaries for the Named Executive Officers are intended to be reviewed annually. Any change in base salary of a Named Executive Officer is generally determined by an assessment of such executive's performance, a consideration of competitive compensation levels in companies similar to our company and a review of our performance as a whole and the role such executive officer played in such corporate performance.

Stock Option Awards

We provide long-term incentives to executive officers in the form of stock options as part of our overall executive compensation strategy. Our Compensation Committee believes that stock option grants serve our executive compensation philosophy in several ways: firstly, it helps attract, retain, and motivate talent; secondly, it aligns the interests of the executive officers with those of the shareholders by linking a specific portion of the officer's total pay opportunity to the share price; and finally, it provides long-term accountability for executive officers.

Risks Associated with Compensation Policies and Practices

The oversight and administration of our executive compensation program requires the Compensation Committee to consider risks associated with our compensation policies and practices. Potential risks associated with compensation policies and compensation awards are considered at annual reviews and also whenever it is deemed necessary by the Compensation Committee.

Our executive compensation policies and practices are intended to align management incentives with the long-term interests of the Corporation and its shareholders. In each case, the Corporation seeks an appropriate balance of risk and reward. Practices that are designed to avoid inappropriate or excessive risks include (i) financial controls that provide limits and authorities in areas such as capital and operating expenditures to mitigate risk taking that could affect compensation, (ii) balancing base salary and variable compensation elements and (iii) spreading compensation across short and long-term programs.

Compensation Governance

The Compensation Committee intends to conduct a yearly review of directors' compensation having regard to various reports on current trends in directors' compensation and compensation data for directors of reporting issuers of comparative our size. Director compensation is currently limited to the grant of stock options pursuant to the Stock Option Plan. It is anticipated that the Chief Executive Officer will review the compensation of our executive officers for the prior year and in comparison to industry standards via information disclosed publicly and obtained through copies of surveys. The Board expects that the Chief Executive Officer will make recommendations on compensation to the Compensation Committee. The Compensation Committee will review and make suggestions with respect to compensation proposals, and then make a recommendation to the Board.

The Compensation Committee is comprised of independent directors.

The Compensation Committee's responsibility is to formulate and make recommendations to our directors in respect of compensation issues relating to our directors and executive officers. Its responsibilities are more fully described under the section of this annual report entitled "Item 6.B Compensation — Compensation Governance".

Summary Compensation Table

We set out below certain disclosure on compensation paid to our seven executives on an aggregate basis for the year ended December 31, 2023, as disclosure of compensation on an individual basis is not required in our home country and is not otherwise publicly disclosed by us.

(U.S. dollars in thousands)	All executive officers
Base compensation	$ 1.859
Bonuses	452
Additional benefit payments	124
Total cash compensation	$ 2,435

Executive Compensation Agreements

Guido Baechler, Chief Executive Officer

On July 1, 2021, we entered into a management services agreement with Guido Baechler (as amended, the "Baechler Agreement"). Pursuant to the Baechler Agreement: (a) Mr. Baechler is appointed as our Chief Executive Officer and will undertake and perform the duties and responsibilities normally and reasonably associated with such office; (b) we paid Mr. Baechler annual base remuneration of $240,000 that increased to $350,000 upon the filing of the Form F-1 for our initial public offering, and to $450,000 in the year after the initial public offering provided we make satisfactory progress in Board-approved goals (the "Base Remuneration"); (c) we shall reimburse Mr. Baechler for one U.S. health plan and one U.S. dental plan (if not included in the health plan) amounting up to $3,500 per month; (d) we shall provide to Mr. Baechler any benefits plan, if and when we have adopted such benefits; (e) our Board of Directors shall, in good faith, consider the payment of an annual bonus equal to 50% of that year's Base Remuneration based upon our performance and upon the achievement of mutually agreed-upon milestones (the "Annual Bonus"); and (e) Mr. Baechler will be entitled to twenty days paid annual vacation per calendar year as well as the reimbursement of reasonable and necessary business expenses. Furthermore, our Board of Directors granted Mr. Baechler 467,850 stock options exercisable into ordinary shares under the 2021 Omnibus Incentive Plan. Such options shall vest in quarterly amounts on each of those dates when for the ten prior trading days the volume-weighted average price of the ordinary shares on the principal market is at least $7.50, $10.00, $12.50 and $15.00, provided that on each of those ten prior trading days at least 100,000 shares traded per trading day. During 2022, all of these options vested.

We or Mr. Baechler may terminate the Baechler Agreement at any time for any reason by providing not less than ten calendar days' notice in writing, provided that (a) we shall have the option to provide a lump sum payment equal to ten (10) days' Base Remuneration in lieu of such notice if terminating without cause; and (b) we may waive all or any part of the notice period for no consideration by giving written notice to Mr. Baechler if terminating with cause.

In the event we terminate the Baechler Agreement for cause or if Mr. Baechler's terminates the Baechler Agreement without good reason, Mr. Baechler is entitled to (i) any accrued but unpaid Base Remuneration and payment for any accrued but unused vacation; (ii) reimbursement for unreimbursed business expenses properly incurred by Mr. Baechler; and (iii) such benefits (including equity compensation), if any, to which Mr. Baechler may be entitled under our benefit plans as of termination; provided that, in no event shall Mr. Baechler be entitled to any payments in the nature of severance or termination payments except as specifically provided in the Baechler Agreement (collectively the "Accrued Amounts").

If we terminate the Baechler Agreement without good cause or Mr. Baechler resigns with good reason in compliance with the relevant terms and conditions of the Baechler Agreement, we shall be obligated to provide a severance package to Mr. Baechler that includes: (i) the Accrued Amounts (ii) equal installment payments payable under the our normal payroll practices, but no less frequently than monthly, which are in the aggregate equal to the Mr. Baechler's Base Remuneration for the year in which termination occurs; (iii) an amount equal to the Annual Bonus for the year in which the termination takes place; (iv) vesting of an additional 12 months (removing any cliff) under all time-based vesting schedules for equity-based incentives held by Mr. Baechler; and (v) reimbursement for up to $3,500 of the monthly U.S. health insurance premium paid by Mr. Baechler for himself and his dependents until the earliest date set forth by the Baechler Agreement.

The Baechler Agreement will terminate upon the death of Mr. Baechler. We may terminate Mr. Bachelor upon disability as defined by the Baechler Agreement. If Mr. Baechler is terminated on account of death or disability, we will provide Mr. Baechler, his estate, or, if applicable, Mr. Baechler's beneficiaries with the Accrued Amounts.

As discussed in further detail below, we have also granted Mr. Baechler a carve-out percentage under our Carve-Out Plan equal to 30% of the carve-out pool amount.

William Caragol, Chief Financial Officer

On April 29, 2022, effective May 1, 2022, we entered into an Employment Contract with Mr. Caragol (the "Caragol Contract"). Pursuant to the Caragol Contract: (a) Mr. Caragol has an annual salary of $350,000; (b) Mr. Caragol is eligible to receive an annual bonus of up to 50% of his salary as determined by the Compensation Committee of the Board of Directors; (c) Mr. Caragol is to have his healthcare expensed paid, and a monthly office allowance, not to exceed $1,500 per month; and (d) Mr. Caragol will be entitled to receive 80,000 options to purchase our ordinary shares subject to a the 2021 Omnibus Incentive Plan.

If we elect to terminate the Caragol Contract without good cause or Mr. Caragol resigns with good reason in compliance with the relevant terms and conditions of the Caragol Agreement, we shall be obligated to provide a severance package to Mr. Caragol that includes: (i) any amounts due to him under the Caragol Agreement that have not yet been paid, (ii) the amounts due to Mr. Caragol for a year subsequent to the date when the termination occurs; (iii) an amount equal to Mr. Caragol's target annual bonus for the year in which the termination takes place, with all criterion for such annual bonus deemed to have been achieved; and (iv) the vesting of an additional twelve months under all time-based vesting schedules for equity-based incentives held by Mr. Caragol.

Prior to the Employment agreement, effective on July 16, 2021, we entered into a consulting agreement with William Caragol (as amended, the "Caragol Agreement"). Pursuant to

the Caragol Agreement: (a) Mr. Caragol was paid a monthly salary of $15,000; and (b) Mr. Caragol received 155,950 options to purchase our ordinary shares subject to our 2021 Omnibus Incentive Plan. Such options shall vest in quarterly amounts on each of those dates when for the ten prior trading days the volume-weighted average price of the ordinary shares on the principal market is at least $7.50, $10.00, $12.50 and $15.00, provided that on each of those ten prior trading days at least 100,000 shares traded per trading day. During 2022 all of these options vested.

As discussed in further detail below, we have also granted Mr. Caragol a carve-out percentage under our Carve-Out Plan equal to 15% of the carve-out pool amount.

Dr. Moritz Eidens, Chief Scientific Officer

On September 20, 2021, we entered into a Management Services Agreement with Dr. Moritz Eidens with a term of three years (as amended, the "Eidens Agreement"). The Eidens Agreement is subject to automatic renewal on a three-year term basis unless either party provides written notice not to renew the Eidens Agreement with six months' notice before the end of the current or renewal term.

Pursuant to the terms and provisions of the Eidens Agreement: Dr. Eidens shall remain an executive of PharmGenomics GmbH and was appointed as an Executive Director of Mainz Biomed N.V.

As an Executive Director, Dr. Eidens is expected to undertake and perform the duties and responsibilities normally and reasonably associated with such office. For his services, Dr. Eidens will (a) receive a fixed gross annual salary of €164,000, payable monthly; (b) Dr. Eidens will be entitled to receive 233,925 options to purchase our ordinary shares subject to our 2021 Omnibus Incentive Plan; and (c) be granted, up to the amount of the statutory income threshold applicable at the time, an amount equal to the employer's share of the contributions to his private health and nursing care insurance (collectively the "Eidens Remuneration"). The options in the Eidens Remuneration shall vest in quarterly amounts on each of those dates when for the ten prior trading days the volume-weighted average price of the ordinary shares on the principal market is at least $7.50, $10.00, $12.50 and $15.00, provided that on each of those ten prior trading days at least 100,000 shares traded per trading day. During 2022 all of these options vested.

Furthermore, we will provide Dr. Eidens with (a) paid annual vacation time of 30 working days; (b) a company car for business and private use upon request; (c) a monthly budget of €400 a month alongside a one-time €2,000 budget for work equipment; (d) an annual budget of €5,000 for health care not covered by insurance; (e) an annual training budget; and (f) a company credit card.

If we terminate the Eidens Agreement, Dr. Eidens is entitled upon request to be released from his duties until the end of the relationship. He will also receive a severance payment equal to three months of Remuneration for each year of service under the Eidens Agreement.

If Dr. Eidens is unable to work due to reasons beyond his control, he is entitled to the Remuneration minus any benefits granted by the statutory health insurance fund institutions or a private health insurance fund for the lesser of six months or the end of the current three-year term. In addition, in the event of Dr. Eidens' death, his spouse and dependents will be entitled to receive Remuneration for the month of death and the lesser of twelve months or the end of the current three-year term after the month of death.

In the event of a change of control, Dr. Eidens may resign and terminate the Eidens Agreement with written notice until the last day of the sixth month after the change of control has occurred.

Philipp Freese, Chief Business Officer

On September 20, 2021, we entered into a Management Services Agreement with Mr. Phillip Freese with a three-year term (as amended, the "Freese Agreement"). The Freese Agreement is subject to automatic renewal on a three-year term basis unless either party provides written notice not to renew the Freese Agreement with six months' notice before the end of the current or renewal term.

Pursuant to the terms and provisions of the Freese Agreement: Mr. Freese shall remain an executive of PharmGenomics GmbH and serve as one of our Non-Executive Directors. Mr. Freese was appointed as our Chief Operations Officer.

As a Non-Executive Director, Mr. Freese is expected to undertake and perform the duties and responsibilities normally and reasonably associated with such office. For his services, Mr. Freese will (a) receive a fixed gross annual salary of €164,000, payable monthly; (b) Mr. Freese will be entitled to receive 233,925 options to purchase our ordinary shares subject to the 2021 Omnibus Incentive Plan (collectively the "Freese Remuneration"). Such options shall vest in quarterly amounts on each of those dates when for the ten prior trading days the volume-weighted average price of the ordinary shares on the principal market is at least $7.50, $10.00, $12.50 and $15.00, provided that on each of those ten prior trading days at least 100,000 shares traded per trading day. During 2022 all of these options vested.

Furthermore, we will provide Mr. Freese with (a) paid annual vacation time of 30 working days; (b) a company car for business and private use upon request; (c) a monthly budget of €400 a month alongside a one-time €2,000 budget for work equipment; (d) an annual budget of €5,000 for health care not covered by insurance; (e) an annual training budget; and (f) a company credit card.

If we terminate the Freese Agreement, Mr. Freese is entitled upon request to be released from his duties until the end of the relationship. He will also receive a severance payment equal to three months of the Freese Remuneration for each year of service under the Freese Agreement.

If Mr. Freese is unable to work due to reasons beyond his control, he is entitled to the Freese Remuneration minus any benefits granted by the statutory health insurance fund institutions or a private health insurance fund for the lesser of six months or the end of the current three-year term. In addition, in the event of Mr. Freese's death his spouse and dependents will be entitled to receive Freese Remuneration for the month of death and the lesser of twelve months or the end of the current three-year term after the month of death.

In the event of a change of control, Mr. Freese may resign and terminate the Freese Agreement with written notice until the last day of the sixth month after the change of control has occurred.

Stock Option Plans and Stock Options

We have adopted our 2021 Omnibus Incentive Plan and our 2022 Omnibus Incentive Plan, as amended (the "Plans"). Under the Plans, we are authorized to issue equity incentives in the form of incentive stock options, non-statutory stock options, restricted shares, restricted share units, share appreciation rights, performance units or performance shares under separate award agreements. Under the Plans, the aggregate number of shares underlying awards that we could issue cannot exceed 3,175,000 ordinary shares.

As of March 26, 2024, we had awarded 2,727,150 stock options under the Plans, with strike prices ranging from $1.99 to $20.87, the per share with a weighted average strike price of $6.25. Such stock options have been granted to our current employees, directors, advisors and senior management team. All stock options for our non-senior management team, independent directors and advisors began or will begin vesting one year from the date of grant and will continue vesting over a four year period at the latest, except for the stock options granted at the time of our IPO to four members of our senior management team. Such stock options for the four members of our senior management team, totaling 1,091,650 options with a strike price of $5.00 per share began vesting in portions equal to 25% pursuant to various metrics, all of which were met prior to December 31, 2022. As of December 31, 2022, all such options were fully vested.

Of the 2,727,150 stock options granted as of March 26, 2024, we granted 1,969,650 to our directors and executive officers as follows (i) 547,850 to Guido Baechler, (ii) 238,925 to Dr. Moritz Eidens, (iii) 238,925 to Philipp Freese, (iv) 315,950 to William Caragol, (v) 295,000 to Darin Leigh, (vi) 88,000 to Dr. Heiner Dreismann, (vii) 40,000 to Hans Hekland, (viii) 35,000 to Dr. Alberto Libanori, (ix) 35,000 to Nicole Holden, (x) 35,000 to Gregory Tibbitts, and (xi) 100,000 to Christopher von Toerne.

Carve-Out Plan

On February 22, 2024, our Compensation Committee approved the *carve-out plan* (the "COP") of Mainz Biomed USA, Inc. ("Mainz USA") and the Board of Directors of Mainz USA approved the COP. The purpose of the COP is to promote the interests of Mainz USA by providing a payment opportunity to individuals providing services to Mainz USA upon the consummation of a corporate transaction or series of transactions resulting in a change of control of Mainz USA or our Company (a "Change of Control" and the completion of a Change of Control, the "Closing").

Payment under the COP is based principally upon the carve-out pool amount which is equal to 13% of the aggregate pre-tax consideration (cash and fair market value of any securities or other consideration) payable in connection with a Change of Control that would be legally available for payment or distribution to Mainz USA, our Company or their respective shareholders in connection with a Change of Control (the "Consideration"). The COP provides for a carve-out pool equal to 13% of the Consideration less the aggregate severance payments contractually owed to all COP participants who have been informed on or before the Closing that their employment with Mainz USA will terminate on or within three months after the Closing. The carve-out pool will be allocated and paid to participants in the COP based on the product of the participant's applicable carve-out percentage as defined in the COP.

Under the COP, participants may receive transaction carve-out equal to the carve-out pool amount multiplied by each participant's carve-out percentage specified in such participant's participation acknowledgment less that participant's equity offset, as defined under the COP. Subject to the terms of the COP, payments under the COP will generally be paid in the same form (or forms) as the consideration received by shareholder of our Company in respect of their Company equity securities due to the change of control.

In connection with the approval of the COP, the Compensation Committee also approved a *noncompete agreement.* Each service provider to Mainz USA designated to participate in the COP and who executes a participation acknowledgment is eligible for awards under the COP, provided that he or she (i) remains in continuous service as defined in the COP until the Closing, and (ii) if so required of the participant, entry into a noncompete agreement with Mainz USA as outlined in the COP, or (iii) is (a) not terminated from employment by Mainz USA for cause, or (b) terminated without cause within 90 days of the Closing.

The Compensation Committee also recommended and adopted awards under the COP to Guido Bächler, the Company's Chief Executive Officer, with a carve-out percentage equal to 30% of the carve-out pool amount, and William Caragol, the Company's chief financial officer, with a carve-out percentage equal to 15% of the carve-out pool amount. Each award was made pursuant to a COP participation acknowledgement form. Future awards of carve-out percentages may be made at the discretion of our Compensation Committee.

Director Compensation for Fiscal 2023

In addition to salaries and other compensation that we paid to our directors for services that they provided as officers, we paid each of our independent directors a quarterly fee of $10,500 for their services as directors (with the retainer for the Board Chairman at $15,000 per quarter). In our fiscal 2023, we paid our directors an aggregate of $228,000 for their services as directors.

Pension Benefits

We do not have any defined benefit pension plans or any other plans requiring us to make retirement payments or pay comparable benefits.

Termination of Employment and Change of Control Benefits

Details with respect to termination of employment and change of control benefits for our directors and executive officers is reported above under the section titled "*Executive Compensation Agreements*."

C. Board Practices

Board of Directors

We have seven directors, five of whom satisfy the "independence" requirements of Rule 5605(a)(2) of the Listing Rules of the Nasdaq Stock Market and meet the independence standards under Rule 10A-3 under the Exchange Act. Our directors are elected annually at each annual meeting of our shareholders as well, if applicable, at any duly called extraordinary general meeting. The Nominating Committee assesses potential director candidates for required skills, expertise, independence and other factors.

Our Board of Directors is responsible for appointing our company's officers.

Board Committees

We established three committees under the board of directors: an Audit Committee, a Compensation Committee and a Nominating Committee. Each committee is governed by a charter approved by our Board of Directors. In addition, we have an informal Strategic Advisory Board that will assist the board in setting strategies, achieving goals and analyzing opportunities.

Audit Committee

We appointed to our Audit Committee three non-executive directors, Nicole Holden, Dr. Alberto Libanori, and Gregory Tibbitts, that satisfy the "independence" requirements of Rule 5605(a)(2) of the Listing Rules of the Nasdaq Stock Market and meet the independence standards under Rule 10A-3 under the Exchange Act. Nicole Holden is the Chair of the Audit Committee and is an "audit committee financial expert" within the meaning of the SEC rules and possesses financial sophistication within the meaning of the Listing Rules of the Nasdaq Stock Market. The Audit Committee oversees our accounting and financial reporting processes and the audits of the financial statements of our company. The Audit Committee is responsible for, among other things:

- selecting our independent registered public accounting firm and pre-approving all auditing and non-auditing services permitted to be performed by our independent registered public accounting firm;
- reviewing with our independent registered public accounting firm any audit problems or difficulties and management's response and approving all proposed related-party transactions, as defined in Item 404 of Regulation S-K;
- discussing the annual audited financial statements with management and our independent registered public accounting firm;

- annually reviewing and reassessing the adequacy of our Audit Committee charter;

- meeting separately and periodically with the management and our independent registered public accounting firm;
- reporting regularly to the full board of directors;
- reviewing the adequacy and effectiveness of our accounting and internal control policies and procedures and any steps taken to monitor and control major financial risk exposure; and
- such other matters that are specifically delegated to our Audit Committee by our board of directors from time to time.

Compensation Committee

We appointed to our Compensation Committee three non-executive directors, Dr. Heiner Dreismann, Hans Hekland, and Gregory Tibbitts, that satisfy the "independence" requirements of Rule 5605(a)(2) of the Listing Rules of the Nasdaq Stock Market and meet the independence standards under Rule 10A-3 under the Exchange Act. Dr. Heiner Dreismann is the Chair of the Compensation Committee. Our Compensation Committee assists the board in reviewing and approving the compensation structure, including all forms of compensation, relating to our directors and executive officers. No officer may be present at any committee meeting during which such officer's compensation is deliberated upon. The Compensation Committee is responsible for, among other things:

- reviewing and approving to the board with respect to the total compensation package for our most senior executive officers;
- approving and overseeing the total compensation package for our executives other than the most senior executive officers;
- reviewing and recommending to the board with respect to the compensation of our directors;
- reviewing periodically and approving any long-term incentive compensation or equity plans;
- selecting compensation consultants, legal counsel or other advisors after taking into consideration all factors relevant to that person's independence from management; and
- programs or similar arrangements, annual bonuses, employee pension and welfare benefit plans.

Nominating Committee

We appointed to our Nominating Committee three non-executive directors, Gregory Tibbitts, Nicole Holden and Dr. Alberto Libanori, that satisfy the "independence" requirements of Rule 5605(a)(2) of the Listing Rules of the Nasdaq Stock Market and meet the independence standards under Rule 10A-3 under the Exchange Act. Gregory Tibbits is the Chair of the Nominating Committee. The Nominating Committee is responsible for overseeing the selection of persons to be nominated to serve on our board of directors. The Nominating Committee considers persons identified by its members, management, shareholders, investment bankers and others.

Strategic Advisory Board

We have appointed a Strategic Advisory Board. Although the Strategic Advisory Board has no formal powers, our Board of Directors plans to consult it in setting strategies, achieving goals and analyzing opportunities. Our Strategic Advisory Board currently has three members;

Dr. Soren Thestrup-Nielsen. Dr. Thestrup-Nielsen has spent over 25 years in the medical device industry, first at Boston Scientific and later at Danaher Corporation where he led the inorganic growth of Danaher's acute care and laboratory diagnostics portfolio. He has previously held a series of notable executive roles including Chairman of Althea Group, as well as board member at numerous companies including lung cancer screening company Oncimmune. During his career, Dr. Thestrup-Nielson has overseen IPOs, trade-sales, acquisitions, and a variety of investment transactions with medical companies in both North America and Europe. He received a M.D. from the University of Copenhagen, School of Medicine, practiced five years as a general & vascular surgeon, and received an MBA from the IMD in Lausanne, Switzerland.

Dr. Michele Pedrocchi. Dr. Pedrocchi is a seasoned healthcare executive with over 25 years of international experience at Roche spanning in vitro diagnostics, digital health, and personalized medicine. During his tenure at Roche, Dr. Pedrocchi held senior leadership positions across corporate strategy, commercial and business development including, serving as Global Head of Strategy and Business Development for Diagnostics. Under his leadership, the division pioneered the entry into digital health and executed more than 20 acquisitions and 500 licensing deals. Prior leadership positions held at Roche included multiple international roles where Dr. Pedrocchi served as in-country and regional general manager and consistently built a track record of profitably growing businesses in emerging and mature markets. Moreover, he had an instrumental role in introducing patient selection through Companion Diagnostics (CDx) and establishing polymerase chain reaction (PCR) as a routine diagnostics methodology. Dr. Pedrocchi is currently an Independent Strategic Advisor and Non-Executive Director to private and public healthcare companies.

Dr. Rainer Metzger. Dr. Metzger is a solution-driven leader with significant achievement record in the development, leadership and execution of successful organizational and product development programs for pharmaceutical and diagnostics companies paired with insightful managerial and executive experience gained with venture-based start-up and mid-cap companies. Dr. Metzger's career includes senior management roles at Medicover, Qiagen, Danaher, Roche and Genentech. Dr. Metzger received his Ph.D. in Biology and a Masters' Degree in Biology from the University of Heidelberg.

Board Diversity Matrix (As of March 26, 2024)

Country of Principal Executive Offices	Germany
Foreign Private Issuer	Yes
Disclosure Prohibited Under Home Country Law	No
Total Number of Directors	7

	Female	Male	Non- Binary	Did Not Disclose Gender

Part I: Gender Identity				
Directors	1	6	0	0
Part II: Demographic Background				
Underrepresented Individual in Home Country Jurisdiction			0	
LGBTQ+			0	

D. Employees

As of March 26, 2024, the breakdown of employees by main category of activity is as follows:

Activity	Number of Full-Time Employees	Number of Part-Time Employees
Manufacturing and Clinical Laboratory	16	1
Research & Development	26	2
Sales & Marketing	10	2
Finance & Administration	11	1
Executives	2	0
Total:	65	6

None of our employees are covered by a collective bargaining agreement.

E. Share Ownership

Shares

The shareholdings of our officers and directors are set out in Item 7 below.

Options, Warrants and Other Convertible Securities

The stock options, exercisable into our ordinary shares, held by our officers and directors are set out in Item 6 B above. Our officers and directors do not hold any other securities convertible into our ordinary shares.

ITEM 7. MAJOR SHAREHOLDERS AND RELATED PARTY TRANSACTIONS

A. Major Shareholders

Security Ownership of Certain Beneficial Owners and Management

The following table sets forth certain information regarding the beneficial ownership of our ordinary shares as of March 26, 2024 by (a) each shareholder who is known to us to own beneficially 5% or more of our outstanding ordinary shares; (b) all directors; (c) our executive officers and (d) all executive officers and directors as a group. Except as otherwise indicated, all persons listed below have (i) sole voting power and investment power with respect to their ordinary shares, except to the extent that authority is shared by spouses under applicable law, and (ii) record and beneficial ownership with respect to their ordinary shares.

Name	Ordinary Shares Beneficially Owned[1]	Percentage of Ordinary Shares Beneficially Owned[1]
Directors and Executive Officers:		
Guido Baechler, *Chief Executive Officer, Executive Director*	752,357	3.4%
William Caragol, *Chief Financial Officer*	212,677	1.0%
Dr. Moritz Eidens, *Chief Scientific Officer, Executive Director*	1,126,348	5.1%
Philipp Freese, *Chief Business Officer*	361,972	1.6%
Darin Leigh, *Chief Commercial Officer*	115,417	0.5%
Dr. Chris von Toerne, *Chief Operating Officer*	6,771	0.0%
Dr. Frank Kreig-Schneider, *Chief Technology Officer*	11,771	0.1%
Dr. Heiner Dreismann, *Non-Executive Director*	88,000	0.4%
Dr. Alberto Libanori, *Non-Executive Director*	35,000	0.2%
Hans Hekland, *Non-Executive Director*[2]	717,081	3.3%
Nicole Holden, *Non-Executive Director*	35,000	0.2%
Gregory Tibbits, *Non-Executive Director*	35,000	0.2%
Directors and Executive Officers as a Group (Ten Persons)	3,497,394	14.9%
Other 5% or more Shareholders:		
Kreditanstalt für Wiederaufbau[3]	1,237,501	5.7%

(1) Based on 21,886,575 ordinary shares outstanding.
(2) Hans Hekland has dispositive and voting control over the shares held by Hannibal Invest AS and Unitargeting Research AS. The balance for Hans Hekland includes 208 ordinary shares underlying options that may be exercised within the next 60 days
(3) Kreditanstalt für Wiederaufbau (known as KfW) is a public law institution (*Anstalt des öffentlichen Rechts*) serving domestic and international public policy objectives of the Federal Government of the Federal Republic of Germany.

Our ordinary shares are held by 31 holders of record, of which 8 have registered addresses in the United States. Together such shareholders hold approximately 17,557,165 ordinary shares which account for approximately 80% of our ordinary shares outstanding as of April 8, 2024. We note that one of these shareholders is Cede & Co. which, as nominee for The Depository Trust Company, is the record holder of 17,115,211 ordinary shares. Accordingly, we believe that the shares held by Cede & Co. include ordinary shares beneficially owned by both holders in the United States and non-United States beneficial owners. As a result, these numbers may not accurately represent the number of beneficial owners in

the United States.

Transfer Agent

We have appointed Transhare Corporation as the transfer agent for our ordinary shares. Transhare Corporation's telephone number and address is (303) 662-1112 and 17755 US Hwy 19 N, Clearwater, FL 33764.

B. Related Party Transactions

Apart from the employment and consulting agreements described elsewhere in this annual report and the agreements with ColoAlert AS (one of our directors is a director and controlling shareholder of ColoAlert AS) described below under "Material Agreements", we have not entered into any material transactions with our directors, officers, promoters and shareholders or who beneficially own more than 10% of our ordinary shares (or their immediate family members). We have the following arrangements with immediate family members of related parties that we consider to be arms'-length and immaterial: we have an employment agreement with the wife of our Chief Scientific Officer whereby we pay her approximately €42,000 per year.

C. Interests of Experts and Counsel

Not Applicable.

ITEM 8. FINANCIAL INFORMATION

A. Consolidated Statements and Other Financial Information

Financial Statements

Our financial statements for the year ended December 31, 2023 have been prepared in accordance with IFRS, as issued by the International Accounting Standards Board, or IASB, and are included under Item 18 of this annual report. Such financial statements have been so included in reliance on the report of Reliant CPA PC, an independent registered public accounting firm, given on the authority of said firm as experts in accounting and auditing. Reliant CPA PC has offices at 895 Dove Street, Suite 300, #300180, Newport Beach, CA. Their telephone number is (949) 929-1932.

Legal Proceedings

As of the date of this annual report, in the opinion of our management, we are not currently a party to any litigation or legal proceedings which are material, either individually or in the aggregate, and, to our knowledge, no legal proceedings of a material nature involving us currently are contemplated by any individuals, entities or governmental authorities.

Dividends

We have not paid any dividends on our ordinary shares since incorporation. Our management anticipates that we will retain all future earnings and other cash resources for the future operation and development of our business. We do not intend to declare or pay any cash dividends in the foreseeable future. Payment of any future dividends will be at the Board's discretion, subject to applicable law, after taking into account many factors including our operating results, financial condition and current and anticipated cash needs.

B. Significant Changes

We have not experienced any significant changes since the date of the consolidated financial statements included with this Form 20-F except as disclosed in this Form 20-F.

ITEM 9. THE OFFER AND LISTING

A. Offer and Listing

Our ordinary shares are traded on the Nasdaq Capital Market under the symbol "MYNZ".

B. Plan of Distribution

Not Applicable.

C. Markets

Please see Section 9.A above.

D. Selling Shareholders

Not Applicable.

E. Dilution

Not Applicable.

F. Expenses of the Issue

Not Applicable.

ITEM 10. ADDITIONAL INFORMATION

A. Share Capital

Not Applicable.

B. Memorandum and Articles of Association

The following description of our Articles of Association, as amended by our Deed of Amendment on December 15, 2022, is intended as a summary only and does not constitute legal advice regarding those matters and should not be regarded as such. The description is qualified in its entirety by reference to the complete text of the Articles of Association.

Overview

We were incorporated on March 8, 2021 as a private limited liability company (*besloten vennootschap met beperkte aansprakelijkheid*) under Dutch law, and on November 9, 2021 we converted into a Dutch public company with limited liability (*naamloze vennootschap*).

We are registered in the Commercial Register of the Chamber of Commerce (*Kamer van Koophandel*) in the Netherlands under number 82122571. We have our corporate seat is in Amsterdam, the Netherlands and our registered office is at Robert-Koch Strasse 50, 55129 Mainz, Federal Republic of Germany.

Our ordinary shares are subject to, and have been created under, Dutch law. Set forth below is a summary of relevant information concerning the material provisions of our articles of association and applicable Dutch law.

Board of Directors

We have a one-tier board structure. Our board of directors (the "Board of Directors") consists of two executive directors and five non-executive directors. The Board of Directors shall consist of such number of executive Directors as the Board of Directors may determine.

The Board of Directors is charged with our management. In fulfilling their duties, our directors will serve our interest and the business connected by us. The executive directors and the executive committee are charged with our day-to-day management. Supervision of the fulfilment of duties by the executive directors and of the general course of our affairs and the business connected with us will primarily be carried out by the non-executive directors. The executive directors must in due time provide the non-executive directors with the information they need to carry out their duties.

Our directors will be elected by the general meeting upon a binding nomination. The Board of Directors will be authorized to nominate one or more director candidates for appointment at the general meeting. The general meeting may at all times overrule the binding nature of each nomination by a resolution adopted by a majority of at least two thirds of the votes cast, representing more than half of the issued share capital.

The general meeting may at any time suspend and dismiss a non-executive director or executive director. The general meeting may only adopt a resolution to suspend or dismiss a non-executive director or executive director by a majority of at least two thirds of the votes cast, representing more than half of the issued share capital, unless the resolution is adopted on the basis of a proposal of the Board of Directors.

The following summary of the material terms of our securities is not intended to be a complete summary of the rights and preferences of such securities and is qualified by reference to the Certificate of Incorporation, the Bylaws and the warrant-related documents described herein, which are exhibits to the registration statement of which this prospectus is a part. We urge you to read each of the Certificate of Incorporation, the Bylaws and the warrant-related documents described herein in their entirety for a complete description of the rights and preferences of our securities.

Our authorized share capital consists of 45,000,000 ordinary shares with a nominal value of EUR 0.01 per share and 5,000,000 preferred shares with a nominal value of EUR 0.01 per share. The preferred shares are divided into five series, each consisting of 1,000,000 preferred shares. Currently there are no preferred shares outstanding.

The number of ordinary shares included in the authorized share capital may be decreased and the number of preferred shares included in the authorized share capital may be increased pursuant to a resolution of the Board of Directors by a number not exceeding the number of ordinary shares included in the authorized share capital which have not been issued and which are not subject to any rights to subscribe for ordinary shares.

The preferred shares may, at the request of the holder, be converted into ordinary shares. The conditions for conversion and the further terms and conditions related to the preferred shares will be determined by our Board of Directors, subject to the prior approval of our general meeting and the meeting of holders of the series of preferred shares concerned, if such series of preferred shares has been issued and are held by persons other than us. The preceding sentence applies by analogy to any adjustment to the conditions.

Issuance of shares

Under Dutch law, shares are issued and rights to subscribe for shares are granted pursuant to a resolution of our general meeting. Our articles of association provide that the general meeting may only resolve to issue shares upon the proposal of our Board of Directors. The general meeting may authorize the Board of Directors to issue new ordinary shares or grant rights to subscribe for ordinary shares. The authorization can be granted and extended, in each case for a period not exceeding five years. For as long as, and to the extent, that such authorization is effective, our general meeting will not have the power to issue ordinary shares.

A resolution of the general meeting has authorized our Board of Directors until November 9, 2026, to issue ordinary shares and preferred shares up to the amount of the authorized share capital (from time to time).

Pre-emptive Rights

Subject to restrictions in our articles of association, holders of ordinary shares have pre-emptive rights in relation to newly issued ordinary shares under Dutch law.

Under our articles of association, the pre-emptive rights in respect of newly issued ordinary shares may be restricted or excluded by a resolution of our general meeting, which resolution requires a two-thirds majority of the votes cast if less than half of the issued share capital is present or represented at the meeting. The general meeting may authorize

our Board of Directors to limit or exclude the pre-emptive rights in respect of newly issued ordinary shares. Such authorization for our Board of Directors can be granted and extended, in each case for a period not exceeding five years.

A resolution of the general meeting has authorized our Board of Directors until November 9, 2026 to limit or exclude pre-emptive rights on ordinary shares.

Pre-emptive rights do not exist with respect (a) to the issue of ordinary shares or grant of rights to subscribe for ordinary shares to our employees or a "group" company of ours, (b) the issue of ordinary shares against a contribution other than cash, and (c) preferred shares to be issued. A holder of preferred shares has no pre-emptive right to acquire newly issued ordinary shares.

Transfer of Ordinary Shares

Under Dutch law, transfers of ordinary shares (other than in book-entry form) require a written deed of transfer and, unless we are a party to the deed of transfer, and acknowledgement by or proper service upon us to be effective.

Our articles of association provide that, if one or more ordinary shares or preferred shares are admitted to trading on Nasdaq or any other regulated foreign stock exchange located in the United States the laws of the State of New York will apply to the property law aspects of the ordinary shares and preferred shares included in the part of the register of shareholders kept by the relevant transfer agent.

Form of Ordinary Shares

Pursuant to our articles of association, the ordinary shares and preferred shares are in registered form.

Purchase and Repurchase of Ordinary Shares

Under Dutch law, we may not subscribe for newly issued ordinary shares. We may acquire ordinary shares, subject to applicable provisions and restrictions of Dutch law and our articles of association, to the extent that:

- such ordinary shares are fully paid-up;
- such repurchase would not cause our shareholders' equity to fall below an amount equal to the sum of the paid-up and called-up part of the issued share capital and the reserves we are required to maintain pursuant to Dutch law or our articles of association; and
- immediately after the acquisition of such ordinary shares, we and our subsidiaries would not hold, or would not hold as pledgees, shares having an aggregate nominal value that exceeds 50% of our issued share capital.

Other than ordinary shares acquired for no valuable consideration or under universal title of succession (*onder algemene titel*) (*e.g.*, through a merger or spin off) under statutory Dutch or other law, we may acquire ordinary shares only if our general meeting has authorized our Board of Directors to do so. An authorization by our general meeting for the acquisition of ordinary shares can be granted for a maximum period of 18 months. Such authorization must specify the number of ordinary shares that may be acquired, the manner in which these shares may be acquired and the price range within which the shares may be acquired. No authorization of our general meeting is required if ordinary shares are acquired by us on Nasdaq with the intention of transferring such ordinary shares to our employees or employees of a group company pursuant to an arrangement applicable to them. For each annual general meeting, we expect that our Board of Directors, will place on the agenda a proposal to re-authorize our Board of Directors to repurchase shares for a period of 18 months from the date of the resolution. We cannot derive any right to any distribution from ordinary shares, or voting rights attached to ordinary shares acquired by it.

A resolution of the general meeting, dated June 28, 2023, has authorized our Board of Directors until December 27, 2024 to acquire fully paid-up ordinary shares up to the maximum number of ordinary shares permitted pursuant to the law and our articles of association from time to time, through privately negotiated repurchases, in self-tender offers, or through accelerated repurchase arrangements, at prices ranging from the nominal value of the ordinary shares up to one hundred and ten percent (110%) of the market price of ordinary shares, provided that (i) for open market or privately negotiated repurchases, the market price will be the last closing price for ordinary shares on the Nasdaq Stock Market prior to the transaction, (ii) for self-tender offers, the market price will be the volume weighted average price for the ordinary shares on the Nasdaq Capital Market during a period, determined by the Board of Directors, of no less than one and no more than five consecutive trading days immediately prior to the expiration of the tender offer, and (iii) for accelerated repurchase arrangements, the market price will be the volume weighted average price of the ordinary shares on the Nasdaq Capital Market over the term of the arrangement. The volume weighted average price for any number of trading days will be calculated as the arithmetic average of the daily volume weighted average price on those trading days.

Pursuant to a resolution of the general meeting, dated June 28, 2023, our Board of Directors is furthermore authorized until December 27, 2024 to acquire fully paid up preferred shares up to the maximum number of preferred shares permitted pursuant to the law and our articles of association from time to time and that preferred shares may be acquired through privately negotiated repurchases, in self-tender offers, or through accelerated repurchase arrangements, at prices ranging from the nominal value of the preferred shares up to the higher of (i) the amount that would be paid by us upon cancellation of such preferred shares in accordance with the relevant provisions of our articles of association and (ii) one hundred and ten percent (110%) of the market price of the ordinary shares into which the preferred shares may be converted in accordance with the applicable provisions of our articles of association, whereby the market price shall be determined in the manner as set out in our articles of association.

Capital Reduction

At a general meeting, our shareholders may resolve on the proposal of our Board of Directors to reduce our issued share capital by (i) cancelling ordinary shares and preferred shares or (ii) reducing the nominal value of the ordinary shares and preferred shares by amending our articles of association. In either case, this reduction would be subject to applicable statutory provisions. A resolution to cancel shares may only relate to (i) shares held by us or in respect of which we hold the depository receipts, or (ii) all preferred shares of a particular series. In order to be approved by our general meeting, a resolution to reduce the capital requires approval of a majority of the votes cast at a general meeting if at least half of the issued share capital is represented at such meeting or at least two thirds of the votes cast, if less than half of the issued share capital is represented at such meeting.

Reduction of the nominal value of shares without repayment shall be effected proportionally to all ordinary shares and preferred shares. The requirement of proportionality may be waived by agreement of all shareholders concerned.

A resolution that would result in a reduction of capital requires approval by a majority of the votes cast of each group of shareholders of the same class whose rights are prejudiced by the reduction. In addition, a reduction of capital involves a two-month waiting period during which creditors have the right to object to a reduction of capital under specified circumstances.

General Meeting

General meetings are held in Amsterdam, Rotterdam, The Hague, Arnhem, Utrecht, or in the municipality of Haarlemmermeer (Schiphol Airport), the Netherlands. All of our shareholders and others entitled to attend our general meetings are authorized to address the meeting and, in so far as they have such right, to vote, either in person or by proxy.

We will hold at least one general meeting each year, to be held within six months after the end of its financial year. A general meeting will also be held within three months after our Board of Directors has determined it to be likely that our equity has decreased to an amount equal to or lower than half of its paid up and called up capital, in order to discuss the measures to be taken if so required. If our Board of Directors fails to hold such general meeting in a timely manner, each shareholder and other person entitled to attend our general meeting may be authorized by the Dutch court to convene our general meeting.

Our Board of Directors may convene additional extraordinary general meetings at its discretion, subject to the notice requirements described below. Pursuant to Dutch law, one or more shareholders and/or others entitled to attend general meetings of shareholders, alone or jointly representing at least 10% of our issued share capital, may on their application be authorized by the Dutch court to convene a general meeting. The Dutch court will disallow the application if (i) the applicants have not previously requested in writing that our Board of Directors convenes a shareholders' meeting or (ii) our Board of Directors convenes a shareholders' meeting or (iii) our Board of Directors has not taken the necessary steps so that the shareholders' meeting could be held within six weeks after such request.

The general meeting is convened by a notice, which includes an agenda stating the items to be discussed and the location and time of our general meeting. For the annual general meeting the agenda will include, among other things, the adoption of our annual accounts, the appropriation of its profits or losses and proposals relating to the composition of and filling of any vacancies on Board of Directors. In addition, the agenda for a general meeting includes such additional items as determined by our Board of Directors. Pursuant to Dutch law, one or more shareholders and/or others entitled to attend general meetings of shareholders, alone or jointly representing at least 3% of the issued share capital, have the right to request the inclusion of additional items on the agenda of shareholders' meetings. Such requests must be made in writing, and may include a proposal for a shareholder resolution, and must be received by us no later than on the 60th day before the day the relevant shareholders' meeting is held. Under our articles of association, certain items can only be put on the agenda as a voting item by our Board of Directors. Shareholders meeting the relevant requirements may still request the inclusion of such items on the agenda as a discussion item.

We will give notice of each general meeting by publication on its website and, to the extent required by applicable law, in a Dutch daily newspaper with national distribution, and in any other manner that we may be required to follow in order to comply with Dutch law and applicable stock exchange and SEC requirements. We will observe the statutory minimum convening notice period for a general meeting. Holders of registered shares may further be provided with notice of the meeting in writing at their addresses as stated in its shareholders' register.

Pursuant to our articles of association and Dutch law, our Board of Directors may determine a record date (*registratiedatum*) of 28 calendar days prior to a general meeting to establish which shareholders and others with meeting rights are entitled to attend and, if applicable, vote at our general meeting. The record date, if any, and the manner in which shareholders can register and exercise their rights will be set out in the notice of our general meeting. Our articles of association provide that a shareholder must notify us in writing of his or her intention to attend (or be represented at) our general meeting, such notice to be received by us on the date set by our Board of Directors in accordance with our articles of association and as set forth in the convening notice.

Our general meeting will be presided over by the chairman of our Board of Directors, who, nevertheless, may charge another person to preside over the meeting in his place even if he or she is present at the meeting. If the chairman of our Board of Directors is absent and he or she has not charged another person to preside over the meeting in his or her place, the directors present at the meeting will appoint one of them to be chairman. In the absence of all directors, our general meeting will appoint its chairman.

Voting Rights and Quorum

In accordance with Dutch law and our articles of association, each ordinary share, irrespective of which class it concerns, confers the right on the holder thereof to cast one vote at our general meeting. The voting rights attached to any ordinary shares held by us or our direct or indirect subsidiaries are suspended, unless the ordinary shares were encumbered with a right of usufruct or a pledge in favor of a party other than us or a direct or indirect subsidiary before such ordinary shares were acquired by us or such a subsidiary, in which case, the other party may be entitled to exercise the voting rights on the ordinary shares. We may not exercise voting rights for ordinary shares in respect of which its or a direct or indirect subsidiary has a right of usufruct or a pledge.

Voting rights may be exercised by shareholders or by a duly appointed proxy holder (the written proxy being acceptable to the chairman of our general meeting) of a shareholder, which proxy holder need not be a shareholder. The holder of a usufruct or pledge on shares will have the voting rights attached thereto if so provided for when the usufruct or pledge was created.

Under our articles of association, blank votes (votes where no choice has been made), abstentions and invalid votes will not be counted as votes cast. However, shares in respect of which a blank vote or invalid vote has been cast and shares in respect of which the person with meeting rights who is present or represented at the meeting has abstained from voting are counted when determining the part of the issued share capital that is present or represented at a general meeting. The chairman of our general meeting will determine the manner of voting and whether voting may take place by acclamation.

Resolutions of the shareholders are adopted at a general meeting by an absolute majority of votes cast, except where Dutch law or our articles of association provide for a special majority in relation to specified resolutions. Our articles of association do not provide for a quorum requirement, subject to any provision of mandatory Dutch law.

Subject to certain restrictions in our articles of association, the determination during our general meeting made by the chairman of that general meeting with regard to the results of a vote will be decisive. Our Board of Directors will keep a record of the resolutions passed at each general meeting.

Amendment of Articles of Association

At a general meeting, at the proposal of our Board of Directors, our general meeting may resolve to amend the articles of association. A resolution by the shareholders to amend the articles of association requires an absolute majority of the votes cast.

Dissolution and liquidation

Our shareholders may at a general meeting, based on a proposal by our Board of Directors, by means of a resolution passed by an absolute majority of the votes cast resolve that we will be dissolved. In the event of our dissolution, the liquidation will be effected by our executive directors, under the supervision of our non-executive directors, unless our general meeting decides otherwise.

Certain Other Major Transactions

Our articles of association and Dutch law provide that resolutions of our Board of Directors concerning a material change in our identity, character or business are subject to the approval of our general meeting. Such changes include:

- a transfer of all or materially all of its business to a third party;
- the entry into or termination of a long-lasting alliance of the company or of a subsidiary either with another entity or company, or as a fully liable partner of a limited partnership or partnership, if this alliance or termination is of significant importance to the company; and
- the acquisition or disposition of an interest in the capital of a company by the company or by its subsidiary with a value of at least one third of the value of our assets, according to the balance sheet with explanatory notes or, if the company prepares a consolidated balance sheet, according to the consolidated balance sheet with explanatory notes in our most recently adopted annual accounts.

Dividends and Other Distributions

We may only make distributions to its shareholders if our equity exceeds the aggregate amount of the issued share capital and the reserves which must be maintained pursuant to Dutch law.

Under our articles of association, any profits or distributable reserves must first be applied to pay a dividend on the preferred shares, if outstanding. Any amount remaining out of distributable profits is added to our reserves as our Board of Directors determines. After reservation by our Board of Directors of any distributable profits, our general meeting will be authorized to declare distributions on the proposal of our Board of Directors. Our Board of Directors is permitted to declare interim dividends without the approval of the shareholders. Interim dividends may be declared as provided in our articles of association and may be distributed to the extent that the shareholders' equity, based on interim financial statements, exceeds the paid-up and called-up share capital and the reserves that must be maintained under Dutch law or our articles of association. We may reclaim any distributions, whether interim or not interim, made in contravention of certain restrictions of Dutch law from shareholders that knew or should have known that such distribution was not permissible. In addition, on the basis of Dutch case law, if after a distribution we are not able to pay its due and collectable debts, then our shareholders or directors who at the time of the distribution knew or reasonably should have foreseen that result may be liable to its creditors.

The general meeting may determine that distributions will be made in whole or in part in the form of shares or a currency other than the Euro, provided on the proposal of the Board of Directors. We shall announce any proposal for a distribution and the date when and the place where the distribution will be payable to all shareholders by electronic means of communication with due observance of the applicable law and stock exchange rules. Claims for payment of dividends and other distributions not made within five years from the date that such dividends or distributions became payable will lapse, and any such amounts will be considered to have been forfeited to us (*verjaring*).

C. Material Contracts

We set out below, other than those agreements discussed in the sections of this annual report entitled "Item 7.B – Related-Party Transactions," "Item 6.B – Compensation — Executive Compensation Agreements" and "Item 4.D — Property, Plant and Equipment", those material agreements that we have entered into outside of our ordinary course of business in the past three years.

Contribution Agreement

On September 20, 2021, we acquired PharmGenomics GmbH ("PharmGenomics") pursuant to the terms of a Contribution Agreement. Under the Contribution Agreement, we acquired all of the outstanding shares of PharmGenomics in exchange for 6,000,000 of our ordinary shares at a deemed valuation of $2.00 per share. The ordinary shares issued to the shareholders of PharmGenomics equaled approximately 62% of our outstanding shares on the date of issuance. Under the Contribution Agreement, we were to establish prior to the closing of our initial public offering an equity incentive plan for a number of shares not to exceed 12% of our issued and outstanding stock. Additionally, under the Contribution Agreement we agreed not to terminate or relocate the business without the consent of each subsidiary of S-Innovations-Beteiligungsfinanzierungsgesellschaft Rheinland-Pfalz mbH, a company with limited liability under German law, that is a currently a shareholder or creditor of PharmGenomics for so long as such subsidiary remains a shareholder or creditor.

Agreements relating to the ColoAlert Intellectual Property Acquisition

On January 1, 2019, we entered into a License and Development Agreement (as amended, the "License Agreement") with ColoAlert AS whereby we were granted an exclusive, global sub-license to manufacture, market, and sublicense the ColoAlert CRC screening test. In 2017, ColoAlert AS obtained an exclusive license for the ColoAlert CRC screening test from Norda ASA. Under the License Agreement, ColoAlert AS has also engaged us to co-operate and further develop ColoAlert AS's technology.

In consideration of the exclusive license, we will pay ColoAlert AS (i) a fee of €5 per sample analyzed, payable at the end of each quarter, and (ii) a quarterly profit split in which ColoAlert AS receives 50% of the profit from ColoAlert tests (the "Profit Split").

Either party has the right to terminate the Agreement in the event (i) a material breach is not cured within 30 days of notice; (ii) the other party enters into liquidation (other than for an amalgamation or reconstruction) or if a petition of bankruptcy is filed against either party and not dismissed within 60 days; and (iii) the other party is adjudicated bankrupt or insolvent. Furthermore, ColoAlert shall have the right to terminate the Agreement if the Profit Split is less than for each quarter (i) from January 1, 2020, to December 31, 2022, €25,000 and (ii) thereafter €250,000.

In February 2021, we entered into an Option to Purchase Intellectual Property Assets (the "Option Agreement") with ColoAlert and Norda ASA (together the "Optionors"), whereby we were granted the option to acquire the intellectual property related to ColoAlert (the "ColoAlert IP") within a three-year term. The intellectual property underlying the Option Agreement were trade secrets and no patents or patents pending existed in connection with such intellectual property.

Pursuant to the Option Agreement, we could purchase the ColoAlert IP in exchange for (i) €2,000,000 in cash or (ii) €4,000,000 to be paid in our ordinary shares. In the event that we exercised the option for cash, ColoAlert AS had the option to have us instead pay this amount in our ordinary shares.

On February 15, 2023, we entered into an Intellectual Property Asset Purchase Agreement ("IPA), which superseded the Licensing Agreement and the Option Agreement. Pursuant to the IPA we acquired the intellectual property for the ColoAlert test. Pursuant to the IPA, we were able to reduce the price paid for the intellectual property to (i) $2 million cash, to be paid out over the next four years, (ii) 300,000 ordinary restricted shares and (iii) a revenue share limited to $1 per test sold for a period of 10 years. Under the IPA, we are no longer required to pay the Profit Split.

Silent Partnership Agreements

We have entered into various silent partnership (loan) agreements with different investors as described below:

- In 2020, we entered into a Silent Partnership Agreement to borrow €499,400. Prior to December 31, 2020, we borrowed €299,400 and during the six months ended June 30, 2021, we borrowed the remaining €200,000 that we are to repay by December 31, 2025. We are required to a minimum of 3% interest per annum on the loans, and in addition, until maturity the lenders are entitled to 3% of our net income in each fiscal year that we are profitable. Upon the amounts coming due, the lenders have the option to demand an additional payment equal to 15% of the contribution as a final remuneration;

- In 2020, we borrowed €50,000 under silent partnership agreements that we are to repay by June 30, 2025. We are required to pay a minimum of 3.5% interest per annum on the loans, and in addition until maturity the lenders are entitled to 0.5% of our net income in each year that we are profitable;

- Between the years of 2013 to 2016, we entered into silent partnership agreements for loans totaling €798,694 (of which $398,634 matures by June 30, 2023 and $400,000 that matures on December 31, 2025). We must pay a minimum of 8.5% interest per annum on the loans, and in addition until maturity the lenders are entitled to 1.66% of our net income in each year that are profitable. At maturity, the lenders have the option to demand an additional payment equal to 30% of the principal of the loans;

- In 2010, we entered into a silent partnership agreement to borrow €300,000 that we are to repay January 31, 2023. We must pay a minimum of 8% interest per annum on the loan, and in addition until maturity the lender is entitled to 1.95% of our net income in each that we are profitable. At maturity, the lender has the option to demand an additional payment of up to 30% of the principal of the loan. This loan was repaid in January 2022.

Technology Rights Agreement for the UdeS Biomarkers

In January 2022, we entered into a Technology Rights Agreement with Socpra Sciences Santé Et Humaines S.E.C. ("TTS") related to the UdeS Biomarkers. Pursuant to the agreement, we acquired an exclusive unilateral option to acquire an exclusive license to the UdeS Biomarkers in exchange for a payment of €10,000,future royalties, and an agreement to pay for the prosecution and maintenance of certain intellectual property relating to the UdeS Biomarkers. The option to license the technology is for one year, which period can be extended at our sole discretion for six additional months (the "Option Period").

We have a license during the Option Period to use the UdeS Biomarkers to further analyze their sensitivity and specificity. Depending on positive results from these further studies, we intend to exercise the option to license the UdeS Biomarkers for future integration into ColoAlert.

We exercised the option on February 15, 2023 when we entered into an Assignment Agreement to acquire the intellectual property rights associated with the UdeS Biomarkers. In exchange for the UdeS Biomarkers, we are to (i) pay €25,000 in cash and (ii) pay a profit share of 2% of the net sales of any products that we sell using the UdeS biomarkers. We are responsible for the prosecution and maintenance of patents relating to the UdeS Biomarkers, which currently consists of a U.S. PTO patent application and its corresponding application with the World Intellectual Property Organization.

D. Exchange Controls

We are incorporated pursuant to the laws of the Netherlands. There is no law or governmental decree or regulation in the Netherlands that restricts the export or import of capital, or affects the remittance of dividends, interest or other payments to a non-resident holder of ordinary shares, other than withholding tax requirements, applicable restrictions under sanctions and measures, including those concerning export control, pursuant to applicable resolutions adopted by the United Nations, regulations of the European Union, the Sanctions Act 1977 (*Sanctiewet 1977*), national emergency legislation or other legislation, applicable anti-boycott regulations and similar rules. Pursuant to the Dutch Foreign Financial Relations Act 1994 (*Wet financiële betrekkingen buitenland 1994*) entities could be obliged to provide certain financial information to the Dutch Central Bank for statistical purposes only. Any such remittances to U.S. residents are generally subject to withholding tax, however no such remittances are likely in the foreseeable future. The European Directive Mandatory Disclosure Rules (2011/16/EU) in relation to cross-border tax arrangements can provide for future notification requirements.

E. Taxation

Material Dutch Tax Income Tax Considerations

The following are the material Dutch tax consequences of the acquisition, ownership and disposal of our ordinary shares. This does not purport to set forth all possible tax considerations or consequences that may be relevant to all categories of investors, some of which may be subject to special treatment under applicable law (such as trusts or other similar arrangements), and in view of its general nature, it should be treated with corresponding caution. **Holders or prospective holders of ordinary shares should consult with their tax advisors with regard to the tax consequences of investing in the ordinary shares in their particular circumstances.**

Please note that this section does not set forth the tax considerations for:

- Holders of ordinary shares if such holders, and in the case of individuals, his/her partner or certain relatives by blood or marriage in the direct line (including foster children), have a substantial interest (*aanmerkelijk belang*) or a deemed substantial interest (*fictief aanmerkelijk belang*) in us under the Dutch Income Tax Act 2001 (*Wet inkomstenbelasting 2001*). A holder of ordinary shares in a company is considered to hold a substantial interest in such company if such holder alone or, in the case of individuals, together with his/her partner (as defined in the Dutch Income Tax Act 2001), directly or indirectly holds (i) an interest of 5% or more of the total issued and outstanding capital of that company or of 5% or more of the issued and outstanding capital of a certain class of shares of that company; or (ii) rights to acquire, directly or indirectly, such interest; or (iii) certain profit sharing rights in that company that relate to 5% or more of the company's annual profits and/or to 5% or more of the company's liquidation proceeds. A deemed substantial interest may arise if a substantial interest (or part thereof) in a company has been disposed of, or is deemed to have been disposed of, on a non-recognition basis;

- A holder of ordinary shares that is not an individual for which its shareholdings qualify or qualified as a participation (*deelneming*) for purposes of the Dutch Corporate Income Tax Act 1969 (*Wet op de vennootschapsbelasting 1969*). A taxpayer's shareholding of 5% or more in a company's nominal paid-up share capital (or, in certain cases, in voting rights) qualifies as a participation. A holder may also have a participation if such holder does not have a shareholding of 5% or more but a related entity (*verbonden lichaam*) has a participation or if the company in which the shares are held is a related entity (*verbonden lichaam*);

- Holders of ordinary shares who are individuals for whom the ordinary shares or any benefit derived from the ordinary shares are a remuneration or deemed to be a remuneration for (employment) activities performed by such holders or certain individuals related to such holders (as defined in the Dutch Income Tax Act 2001); and

- Pension funds, investment institutions (*fiscale beleggingsinstellingen*), exempt investment institutions (*vrijgestelde beleggingsinstellingen*) and other entities that are, in whole or in part, not subject to or exempt from corporate income tax in the Netherlands, as well as entities that are exempt from corporate income tax in their country of residence, such country of residence being another state of the European Union, Norway, Liechtenstein, Iceland or any other state with which the Netherlands have agreed to exchange information in line with international standards.

Except as otherwise indicated, this section only addresses Dutch national tax legislation and published regulations, whereby the Netherlands and Dutch law means the part of the Kingdom of the Netherlands located in Europe and its law, respectively, as in effect on the date hereof and as interpreted in published case law until this date, without prejudice to any amendment introduced (or to become effective) at a later date and/or implemented with or without retroactive effect. The applicable tax laws or interpretations thereof may change, or the relevant facts and circumstances may change, and such changes may affect the contents of this section, which will not be updated to reflect any such changes.

Dividend Withholding Tax

Holders of ordinary shares are generally subject to Dutch dividend withholding tax at a rate of 15% on dividends distributed by us. We are required to withhold such Dutch dividend withholding tax at source (which dividend withholding tax will not be borne by us but will be withheld by us from the gross dividends paid on the ordinary shares). However, as long as we continue to have our place of effective management in Germany, and not in the Netherlands, we will be considered to be solely tax resident in Germany for purposes of the Convention between the Federal Republic of Germany and the Netherlands for the avoidance of double taxation and prevention of fiscal evasion with respect to taxes on income (the "German-Dutch tax treaty"), and we will in principle not be required to withhold Dutch dividend withholding tax. This exemption from withholding Dutch dividend withholding tax may not apply to dividends distributed by us to a holder who is resident or deemed to be resident in the Netherlands for Dutch income tax purposes or Dutch corporate income tax purposes or to holders of ordinary shares that are neither resident nor deemed to be resident of the Netherlands if the ordinary shares are attributable to a Dutch permanent establishment of such non-resident holder, in which case the following paragraph applies.

Dividends distributed by us to individuals and corporate legal entities who are resident or deemed to be resident in the Netherlands for Dutch (corporate) income tax purposes ("Dutch Resident Individuals" and "Dutch Resident Entities," as the case may be) or to holders of ordinary shares that are neither resident nor deemed to be resident of the Netherlands if the ordinary shares are attributable to a Dutch permanent establishment of such non-resident holder are generally subject to Dutch dividend withholding tax at a rate of 15%. The expression "dividends distributed" include, but are not limited to:

- Distributions in cash or in kind, deemed and constructive distributions and repayments of paid-in capital not recognized for Dutch dividend withholding tax purposes;

- Liquidation proceeds, proceeds of redemption of shares, or proceeds of the repurchase of shares by us or one of our subsidiaries or other affiliated entities to the extent such proceeds exceed the average paid-in capital of those shares as recognized for purposes of Dutch dividend withholding tax, unless, in case of a repurchase, a particular statutory exemption applies;

- An amount equal to the par value of shares issued or an increase of the par value of shares, to the extent that it does not appear that a contribution, recognized for purposes of Dutch dividend withholding tax, has been made or will be made; and

- Partial repayment of the paid-in capital, recognized for purposes of Dutch dividend withholding tax, if and to the extent that we have net profits (*zuivere winst*), unless the holders of shares have resolved in advance at a general meeting to make such repayment and the par value of the shares concerned has been reduced by an equal amount by way of an amendment of our articles of association. The term "net profits" includes anticipated profits that have yet to be realized.

Dutch Resident Individuals and Dutch Resident Entities may credit the Dutch dividend withholding tax against their income tax or corporate income tax liability (maximized to the amount of corporate income tax due in that financial year) or may under certain circumstances be entitled to an exemption. The same applies to holders of ordinary shares that are neither resident nor deemed to be resident of the Netherlands if the shares are attributable to a Dutch permanent establishment of such non-resident holder. Depending on their specific circumstances, holders of ordinary shares that are resident in a country other than the Netherlands, may be entitled to exemptions from, reduction of, or full or partial refund of, Dutch dividend withholding tax pursuant to Dutch law, EU law or treaties for avoidance of double taxation.

On November 2, 2021, the Dutch Parliament adopted a proposal of law to which an alternative withholding tax (the "Alternative Dividend Withholding Tax") will be imposed on dividends paid to related entities in designated low-tax jurisdictions and in certain abusive situations, effective January 1, 2024. The Alternative Dividend Withholding Tax may be imposed at the highest Dutch corporate income tax rate in effect at the time of the distribution (currently 25.8%), if the shareholder entitled to those dividend payments has such an interest in us, possibly as part of a cooperating group, that such party can exert such influence on our decisions as to determine our activities, while that shareholder is established in a jurisdiction that is included in the Regulation of low-taxing countries and non-cooperative jurisdictions for tax purposes (*Regeling laagbelastende staten en niet-coöperatieve rechtsgebieden voor belastingdoeleinden*), or has a relevant connection therewith.

However, as long as we continue to have our place of effective management in Germany, and not in the Netherlands, we will be considered to be solely tax resident in Germany for purposes of the German-Dutch tax treaty, and we will in principle not be required to withhold the Alternative Dividend Withholding Tax.

Pursuant to legislation to counteract "dividend stripping," a reduction, exemption, credit or refund of Dutch dividend withholding tax is not granted if the recipient of the dividend is not the beneficial owner (*uiteindelijk gerechtigde*) as described in the Dutch Dividend Withholding Tax Act 1965 (*Wet op de dividendbelasting 1965*) of such dividends. This legislation targets situations in which a shareholder retains its economic interest in shares but reduces the withholding tax costs on dividends by a transaction with another party. It is not required for these rules to apply that the recipient of the dividends is aware that a dividend stripping transaction took place. The Dutch State Secretary of Finance takes the position that the definition of beneficial ownership introduced by this legislation will also apply in the context of a double taxation convention.

Taxes on Income and Capital Gains

Dutch Resident Individuals

If a holder of ordinary shares is a Dutch Resident Individual, any benefit derived or deemed to be derived from the shares is taxable at the progressive income tax rates, if:

(i) the ordinary shares are attributable to an enterprise from which the Dutch Resident Individual derives a share of the profit, whether as an entrepreneur (*ondernemer*) or as a person who has a co-entitlement to the net worth (*medegerechtigd tot het vermogen*) of such enterprise, without being an entrepreneur or a shareholder in such enterprise, as defined in the Dutch Income Tax Act 2001; or

(ii) the holder of the shares is considered to derive benefits from the shares that are taxable as benefits from other activities (*resultaat uit overige werkzaamheden*), such as activities with respect to the shares that go beyond ordinary asset management (*normaal actief vermogensbeheer*).

If the above-mentioned conditions (i) and (ii) do not apply to the individual holder of ordinary shares, such Dutch Resident Individual holder will be subject to an annual income tax imposed on a deemed return on the net value of the ordinary shares under the regime for savings and investments (*inkomen uit sparen en beleggen*). Irrespective of the actual income and capital gains realized, the deemed annual return of the Dutch Resident Individual's net investment assets that are taxed under this regime, including the ordinary shares, is set at variable percentages of the value of the investment assets and liabilities. For 2024, the variable percentages are set at 1.03% for savings, at 6.04% for other investments (such as ordinary shares) and at 2.47% for liabilities. Such fictitious annual return deemed to be derived from the ordinary shares will be taxed at a flat rate of 36% in 2024.

The net value of the investment assets for the year are the fair market value of the investment assets less the allowable liabilities on January 1 of the relevant calendar year. The ordinary shares are included as investment assets. A tax-free allowance of €57,000 is available (2024). For the avoidance of doubt, actual income, capital gains or losses in respect of the ordinary shares are as such not subject to Dutch income tax under the regime for savings and investments (*inkomen uit sparen en beleggen*). The deemed variable return will be adjusted annually on the basis of historic market yields.

The Dutch Government issued a draft legislative proposal for internet consultation on September 8, 2023 to introduce a new system regarding the taxation of income from savings and investments as of the tax year 2027. Such new system will be based on actual returns realized (such as dividends) and the value development of assets (such as a capital gain on shares or capital loss on shares).

Dutch Resident Entities

Any benefit derived or deemed to be derived from the shares held by Dutch Resident Entities, including any capital gains realized on the disposal thereof, will be subject to Dutch corporate income tax at a rate of 19% with respect to taxable profits up to €200,000 and 25.8% with respect to taxable profits in excess of that amount (rates and brackets for 2024).

Non-residents of the Netherlands

A holder of ordinary shares that is neither a Dutch Resident Individual nor a Dutch Resident Entity will not be subject to Dutch taxes on income or on capital gains in respect of any payment under shares or any gain realized on the disposal or deemed disposal of the shares, provided that:

- such holder does not have an interest in an enterprise which, in whole or in part, is either effectively managed in the Netherlands or is carried out through a permanent establishment, or a permanent representative in the Netherlands and to which enterprise or part of an enterprise the shares are attributable; and
- in the event such holder is an individual, such holder does not derive benefits from the shares that are taxable as benefits from other activities in the Netherlands, such as activities in the Netherlands with respect to the shares that go beyond ordinary asset management.

Under certain specific circumstances, Dutch taxation rights may be restricted for a holder of ordinary shares that is neither a Dutch Resident Individual nor a Dutch Resident Entity pursuant to treaties for the avoidance of double taxation.

Gift and Inheritance Taxes

Residents of the Netherlands

Gift or inheritance taxes will arise in the Netherlands with respect to a transfer of the ordinary shares by way of a gift by, or on the death of, a holder of ordinary shares who is resident or deemed to be resident in the Netherlands at the time of the gift or the holder's death.

Non-residents of the Netherlands

No Dutch gift or inheritance taxes will arise on the transfer of the ordinary shares by way of gift by, or on the death of, a holder of ordinary shares who is neither resident nor deemed to be resident in the Netherlands, unless:

- in the case of a gift of ordinary shares by an individual who at the date of the gift was neither resident nor deemed to be resident in the Netherlands, such individual dies within 180 days after the date of the gift, while being resident or deemed to be resident in the Netherlands; or
- the transfer is otherwise construed as a gift, such as a gift that is made under a condition precedent, or inheritance made by, or on behalf of, a person who, at the time of the gift or death, is or is deemed to be resident in the Netherlands.

For purposes of Dutch gift and inheritance taxes, a person that holds the Dutch nationality will be deemed to be resident in the Netherlands if such person has been resident in the Netherlands at any time during the 10 years preceding the date of the gift or his/her death. Additionally, for purposes of Dutch gift tax, any person, irrespective of his nationality will be deemed to be resident in the Netherlands if such person has been resident in the Netherlands at any time during the 12 months preceding the date of the gift.

Other Taxes and Duties

No Dutch value-added tax (*omzetbelasting*) and no Dutch registration tax, stamp duty or any other similar documentary tax or duty will be payable by a holder of shares on any payment in consideration for the acquisition, ownership or disposal of the shares.

F. Dividends and Paying Agents

Not Applicable.

G. Statements by Experts

Not Applicable.

H. Documents on Display

The documents concerning us which are referred to in this annual report may be inspected at our offices located at Robert Koch Strasse 50, 55129 Mainz, Germany. The documents referred to in this annual report that have been filed as exhibits to other filings with the SEC may be inspected and copied at the public reference facility maintained by the SEC at 100F. Street NW, Washington, D.C. 20549. In addition, the SEC maintains a website at www.sec.gov that contains copies of documents that we have filed with the SEC using its EDGAR system.

I. Subsidiary Information

We have two wholly-owned subsidiaries, Mainz Biomed Germany GmbH (f/k/a PharmGenomics GmbH), and Mainz Biomed USA, Inc.

ITEM 11. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Market Risk, Hedging and Financial Instruments

Our activities expose us to a variety of financial risks, including foreign currency risk and interest rate risk. We analyze each of these risks individually, as well as on an interconnected basis, and define strategies to manage the economic impact on our performance in line with our financial risk management policy. Management meets on a frequent basis and is responsible for reviewing the results of the risk assessment, approving recommended risk management strategies, monitoring compliance with the financial risk management policy and reporting to the Audit Committee.

Foreign Currency Risk

We are exposed to foreign currency risk on borrowings, investments, (forecasted) sales, (forecasted) purchases, royalties, licenses, management fees and interest expense/income whenever they are denominated in a currency other than the functional currency of our subsidiary engaged in the relevant transaction. To manage this risk, we primarily make use of cash deposits held in both U.S. dollars and Euro, in such amounts that match our forward budgeted expenditures.

As far as foreign currency risk on firm commitments and forecasted transactions is concerned, our policy is, when material, to hedge operational transactions which are reasonably expected to occur (*e.g.*, cost of goods sold and selling, general and administrative expenses) within the forecast period determined in the financial risk management policy. Operational transactions that are certain may be hedged without any limitation in time. Non-operational transactions (such as acquisitions and disposals of subsidiaries) may be hedged as soon as they are certain.

Interest Rate Risk

In the future, we pay be exposed to interest rate risk on variable-rate interest-bearing financial liabilities. In such instances in the future, we will apply a dynamic interest rate hedging approach where the target mix between fixed and floating rate is reviewed periodically. The purpose of our policy is to achieve an optimal balance between cost of funding and volatility of financial results, while taking into account market conditions as well as our overall business strategy. In the future, we may enter into interest rate swap agreements and forward rate agreements to manage our interest rate risk or into cross-currency interest rate swap agreements to manage both our foreign currency risk and interest rate risk.

Interest rates have been subject to significant volatility in the recent past and may be again in the future.

Other Risks

See our audited consolidated financial statements as of December 31, 2023 and 2022, and for the three years ended December 31, 2023 and the Risk Factors section of this Form 20-F for a fuller quantitative and qualitative discussion on the credit and liquidity risks to which we are subject and our policies with respect to managing those risks.

ITEM 12. DESCRIPTION OF SECURITIES OTHER THAN EQUITY SECURITIES

Not Applicable.

PART II

ITEM 13. DEFAULTS, DIVIDEND ARREARAGES AND DELINQUENCIES

There have not been any defaults with respect to dividends, arrearages or delinquencies since incorporation.

ITEM 14. MATERIAL MODIFICATIONS TO THE RIGHTS OF SECURITY HOLDERS AND USE OF PROCEEDS

On December 15, 2022, we amended our Articles of Association as previously disclosed in a current report on Form 6-K filed with the U.S. Securities and Exchange Commission on December 20, 2022 by execution of the Deed of Amendment. Among other matters, the Deed of Amendment eliminated the right of one or more shareholders holding more than 20% of our outstanding shares from nominating a director. Apart from the Deed of Amendment, there have been no other material modifications to the rights of our holders of ordinary shares since the start of our last fiscal year.

Use of Proceeds

On November 9, 2021, we completed an initial public offering of 2,300,000 ordinary shares. The offering was registered with the US Securities and Exchange Commission on Form F-1 (File No. 333-260176). We received approximately $10,358,750 in net proceeds from this offering.

On January 28, 2022, we completed a public offering of 1,725,000 ordinary shares. The offering was registered with the US Securities and Exchange Commission on Form F-1 (File No. 333-262294). We received approximately $23,865,889 in net proceeds from this offering.

During the year ended December 31, 2023 we raised net proceeds of $16,512,751 from our Controlled Equity Offering, a sale of Units in November 2023, and our Pre-Paid Advance Agreement. Shares issued pursuant to these offerings totaled 5,787,479 and were registered with the US Securities and Exchange Commission on Form F-3 (File No. 333-269091).

The proceeds that we used from these offerings were primarily used for the design and structure of our European and U.S. based clinical studies for our next generation Colorectal Cancer Screening product under development, research and development, recruitment of commercial personnel, and general corporate purposes.

ITEM 15. CONTROLS AND PROCEDURES

A. Disclosure Controls and Procedures

Disclosure controls and procedures are defined in Rule 13a-15(e) and 15d-15(e) under the *Securities Exchange Act of 1934*, as amended (the "Exchange Act") to mean controls and other procedures of an issuer that are designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms and includes, without limitation, controls and procedures designed to ensure that such information is accumulated and communicated to the issuer's management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

As required by Rule 13a-15 or 15d-15 under the Exchange Act, we have carried out an evaluation of the effectiveness of our Company's disclosure controls and procedures as of the end of the period covered by this annual report on Form 20-F, being December 31, 2023. This evaluation was carried out by our Chief Executive Officer and Chief Financial Officer. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as December 31, 2023.

B. Management's Annual Report On Internal Control Over Financial Reporting

Our management, under the supervision of our Chief Executive Officer and Chief Financial Officer, is responsible for establishing and maintaining adequate internal control over our financial reporting, as defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act of 1934, as amended. 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. Internal control over financial reporting includes policies and procedures that:

- pertain to the maintenance of records that in reasonable detail accurately and fairly reflect our transactions and asset dispositions;
- provide reasonable assurance that transactions are recorded as necessary to permit the preparation of our financial statements in accordance with generally accepted accounting principles;
- provide reasonable assurance that receipts and expenditures are made only in accordance with authorizations of our management and board of directors (as appropriate); and
- provide reasonable assurance regarding the prevention or timely detection of unauthorized acquisition, use or disposition of assets that could have a material effect on our financial statements.

Due to its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. In addition, 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 our management, including our Chief Executive Officer and Chief Financial Officer, we assessed the effectiveness of our internal control over financial reporting as of December 31, 2023, based on the framework for Internal Control-Integrated Framework set forth by The Committee of Sponsoring Organizations of the Treadway Commission (COSO) (2013). Based on our assessment and this framework, our management concluded that our internal control over financial reporting was effective as of December 31, 2023.

C. Attestation report of the registered public accounting firm

Not applicable.

D. Changes In Internal Control Over Financial Reporting

No changes were made to our internal controls over financial reporting that occurred during the fiscal year ended December 31, 2023 that have materially affected, or are reasonably likely to materially affect, our internal controls over financial reporting.

ITEM 16. [RESERVED]

ITEM 16A. AUDIT COMMITTEE FINANCIAL EXPERT

As of the date hereof, our Audit Committee is comprised of three non-executive directors, Nicole Holden (Chair), Gregory Tibbits and Dr. Alberto Libanori; each of whom is independent under the listing standards regarding "independence" within the meaning of the Listing Rules of the Nasdaq Stock Market.

Our Board has determined that Nicole Holden qualifies as an audit committee financial expert pursuant to Items 16A(b) and (c) of Form 20-F.

ITEM 16B. CODE OF ETHICS

We adopted a code of ethics, a copy of which is attached as an exhibit to this annual report, as available on the U.S. Securities Exchange Commission's Edgar Website, on October 26, 2021.

ITEM 16C. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The following table sets forth information regarding the amount billed and accrued to us by each of Reliant CPA PC for the fiscal years ended December 31, 2023 and 2022:

	Period Ended December 31,	
	2023	2022
Audit Fees:	$ 80,000	$ 60,000
Audit Related Fees:	$ 50,000	$ 45,000
Tax Fees:	$ 0	$ 0
Total:	$ 140,000	$ 105,000

Audit Fees

This category includes the aggregate fees billed by our independent auditor for the audit of our annual financial statements, reviews of interim financial statements that are provided in connection with statutory and regulatory filings or engagements.

Audit Related Fees

This category includes the aggregate fees billed in each of the last two fiscal years for assurance and related services by the independent auditors that are reasonably related to the performance of the audits or reviews of the interim financial statements and are not reported above under "Audit Fees," and generally consist of fees for other engagements under professional auditing standards, accounting and reporting consultations.

Tax Fees

This category includes the aggregate fees billed in each of the last two fiscal years for professional services rendered by the independent auditors for tax compliance, tax planning and tax advice.

Policy on Pre-Approval by Audit Committee of Services Performed by Independent Auditors

The policy of our Audit Committee is to pre-approve all audit and permissible non-audit services to be performed by our independent auditors during the fiscal year.

ITEM 16D. EXEMPTIONS FROM THE LISTING STANDARDS FOR AUDIT COMMITTEES

Not Applicable.

ITEM 16E. PURCHASES OF EQUITY SECURITIES BY THE ISSUER AND AFFILIATED PURCHASERS

None.

ITEM 16F. CHANGE IN REGISTRANT'S CERTIFYING ACCOUNTANT

On January 17, 2023, Reliant CPA PC replaced BF Borgers CPA P.C. as our independent registered public accounting firm. We previously disclosed this change in our certifying accountant in a current report on Form 6-K filed with the U.S. Securities and Exchange Commission on January 20, 2023.

ITEM 16G. CORPORATE GOVERNANCE.

As a "foreign private issuer," as defined by the SEC, we are permitted to follow home country corporate governance practices, instead of certain corporate governance standards required by the Nasdaq for U.S. companies. Accordingly, we follow Dutch corporate governance rules in lieu of certain of the Nasdaq's corporate governance requirements. The significant differences between our Dutch corporate governance rules and the Nasdaq's corporate governance requirements are set forth below:

- *Quorum Requirements*. In accordance with Dutch law and generally accepted business practices, our Articles of Association do not provide quorum requirements generally applicable to general meetings of shareholders in the United States. To this extent, our practice varies from the requirement of Nasdaq Listing Rule 5620(c), which requires an issuer to provide in its bylaws for a generally applicable quorum, and that such quorum may not be less than one-third of the outstanding voting stock.

- *Solicitation of Proxies*. Although we must provide shareholders with an agenda and other relevant documents for the general meeting of shareholders, Dutch law does not have a regulatory regime for the solicitation of proxies, our practice will vary from the requirement of Nasdaq Listing Rule 5620(b).

- *Shareholder Approval*. We have opted out of shareholder approval requirements for the issuance of securities in connection with certain events such as the acquisition of stock or assets of another company, the establishment of or amendments to equity-based compensation plans for employees, a change of control of us and certain private placements. To this extent, our practice varies from the requirements of Nasdaq Rule 5635, which generally requires an issuer to obtain shareholder approval for the issuance of securities in connection with such events.

ITEM 16H. MINE SAFETY DISCLOSURE

Not Applicable.

ITEM 16I. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not Applicable

ITEM 16J. INSIDER TRADING POLICIES

On January 18, 2023, our Board of Directors adopted an Insider Trading Policy governing the purchase, sale, and other dispositions of our securities by directors, senior management, and certain employees (the "Insiders") that are reasonably designed to promote compliance with applicable insider trading laws, rules and regulations, and Nasdaq's

continued listing standards. Among other matters, this policy sets out that, with limited exceptions:

- No Insider may buy or sell our securities at any time when they have material non-public information relating to our Company;
- No Insider may buy or sell securities of another company at any time when they have material non-public information about that company, including, without limitation, any company that we conduct ordinary business with, such as customers, vendors or suppliers, when that information is obtained during the course of his/her employment with us;
- No Insider may disclose material non-public information to third parties, to any other person, including family members, or make recommendations or express opinions on the basis of material non-public information with regard to trading securities; and
- No Insider may buy or sell our securities during a time before and after a significant event involving our Company (including twenty days before the end of each of our fiscal quarters through to the second trading day following the public announcement of the financial results of such fiscal quarter).

ITEM 16G. CYBERSECURITY

Risk Management and Strategy

We are susceptible to cybersecurity risks not only related to our operations and our own proprietary information but also related to the data of those persons that choose to us our products, particularly those analyzed in our in-house laboratory. We have established policies, processes, and systems for assessing, identifying, and managing material risks from cybersecurity threats, and have integrated these processes into our overall risk management systems and processes. We routinely assess material risks from cybersecurity threats, including any potential unauthorized occurrence on or conducted through our information systems that may result in adverse effects on the confidentiality, integrity, or availability of our information systems or any information residing therein.

We conduct assessments in the event of a material change in our business practices that may affect information systems, products, services, and our broader enterprise IT environment. These assessments include identification of reasonably foreseeable internal and external risks, the likelihood and potential damage that could result from such risks, and the sufficiency of existing policies, procedures, systems, and safeguards in place to manage such risks.

Following these assessments, we design, implement, and maintain reasonable safeguards to minimize identified risks; reasonably address any identified gaps in existing safeguards; and regularly monitor the effectiveness of our safeguards.

Our overall cybersecurity management system includes:

- the Mainz Biomed IT team principally responsible for managing (1) our cybersecurity risk assessment processes, (2) our security controls, and (3) our response to cybersecurity incidents;
- A Data Protection Officer (DPO) responsible for identifying risks in the area of data security in line with currently regulatory policies, mapping of data processes and management in the event of a data breach;
- regular assessments and deployment technical safeguards to improve the protection of our information systems;
- the use of external service providers, where appropriate, to assess, test or otherwise assist with aspects of our security controls;
- cybersecurity awareness training of our employees, incident response personnel, and senior management; and
- entering into agreements with our third-party service providers that require them to implement and maintain appropriate security measures, consistent with all applicable laws, to implement and maintain reasonable security measures in connection with their work with us, and to promptly report any suspected breach of its security measures that may affect our Company.

We continue to make investments to enhance the protection of our information technology systems and our business from cybersecurity incidents, including maintaining a cybersecurity insurance policy.

For additional information regarding whether any risks from cybersecurity threats, including as a result of any previous cybersecurity incidents, have materially affected or are reasonably likely to materially affect our company, including our business strategy, results of operations, or financial condition, please refer to Item 3.D. "Risk Factors" in this Annual Report on Form 20-F, including the risk factor entitled "We are subject to cybersecurity risks to operational systems, security systems, infrastructure and personal data processed by us or third-party vendors or suppliers and any material failure, weakness, interruption, cyber event, incident or breach of security could prevent us from effectively operating our business."

Governance

Our board of directors, with the assistance of the audit committee, oversees the Company's cybersecurity programs and strategies.

The audit committee oversees the Company's guidelines and policies with respect to risk assessment and risk management, including risk exposures related to information security, cybersecurity and data protection, and the steps management has taken to monitor and control such exposures.

Our Vice President of Information Technology ("VP of IT")], who reports to our CEO, is primarily responsible for the assessment and management our material risks from cybersecurity threats. Our VP of IT oversees our cybersecurity policies and processes, including those described in "Risk Management and Strategy" above. Our IT Team manages day-to-day incident identification, assessment and management, leads our overall cybersecurity risk management program, including ongoing assessments of system vulnerabilities and mitigation efforts, and continuously updates our VP of IT on such matters. Our IT team includes external suppliers that specialize in cybersecurity for other large biotech and research companies. Our VP of IT escalates cybersecurity incidents to other members of the Company's leadership, as appropriate, including our CFO and CEO. The VP or IT is tasked with briefing the audit committee as needed regarding the Company's cybersecurity risks and activities, including any recent cybersecurity incidents and related responses, cybersecurity systems testing, activities of third parties, and the like.

PART III

ITEM 17. FINANCIAL STATEMENTS

Not Applicable.

ITEM 18. FINANCIAL STATEMENTS

Our financial statements were prepared in accordance with IFRS, as issued by the IASB.

Financial statements filed as part of this annual report:

Mainz Biomed N.V.
INDEX TO FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

To the shareholders and the board of directors of Mainz Biomed N.V.

Opinion on the Financial Statements

We have audited the accompanying consolidated statements of financial position of Mainz Biomed N.V. (the "Company"), as of December 31, 2023 and 2022, the related consolidated statements of comprehensive loss, consolidated statement of changes in shareholders' equity (deficit) and consolidated statements of cash flows for the years then ended, and related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2023 and 2022, and the results of its operations and its cash flows for each of the two years then ended, in conformity with the International Financial Reporting Standards as issued by the International Accounting Standards Board.

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's significant operating losses raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

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

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

/s/ Reliant CPA PC

Reliant CPA PC

Served as Auditor since 2023
Newport Beach, CA
April 8, 2024

Mainz Biomed N.V.
Consolidated Statements of Financial Position
(Expressed in US Dollars)

	Note	December 31, 2023	December 31, 2022
ASSETS			
Current Assets			
Cash		$ 7,070,925	$ 17,141,775
Trade and other receivables, net	5	93,555	66,984
Inventories	6	613,638	175,469
Prepaid expenses and other current assets	7	1,201,670	994,113
Total Current Assets		8,979,788	18,378,341
Property and equipment, net	8	1,702,317	661,692
Intangible assets	9	3,394,645	-
Right-of-use assets	10	1,332,170	1,177,695
Other assets		108	23,275
Total assets		**$ 15,409,028**	**$ 20,241,003**
LIABILITIES AND SHAREHOLDERS' EQUITY			
Current Liabilities			
Accounts payable and accrued liabilities	11	$ 3,451,615	$ 2,717,269
Accounts payable – related party	17	32,702	-
Deferred revenue	3	138,889	199,410
Convertible debt	13	4,903,310	43,057
Convertible debt - related party	12	33,118	32,181
Silent partnership	15	-	759,168
Silent partnership - related party	15	-	206,167
Intellectual property acquisition liability - related party	9	388,839	-
Lease liabilities	10	288,463	285,354
Total current liabilities		9,236,936	4,242,606
Silent partnerships	15	758,812	687,128
Silent partnerships - related party	15	271,354	256,086
Lease liabilities	10	1,165,723	959,116
Intellectual property acquisition liability - related party	9	726,977	-
Total Liabilities		12,159,802	6,144,936
Shareholders' equity			
Share capital	16	235,818	164,896
Share premium	16	51,507,526	38,831,542
Reserve	16	21,286,215	18,079,741
Accumulated deficit		(69,328,021)	(43,032,294)
Accumulated other comprehensive income		(452,312)	52,182
Total shareholders' equity		3,249,226	14,096,067
Total liabilities and shareholders' equity		**$ 15,409,028**	**$ 20,241,003**
Nature of operations and going concern (Note 1)			
Subsequent events (Note 23)			

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

Mainz Biomed N.V.
Consolidated Statements of Comprehensive Loss
(Expressed in US Dollars)

	Note	Years ended December 31, 2023	2022	2021
Revenue		$ 895,479	$ 529,877	$ 577,348
Cost of sales		385,820	347,726	399,726
Product margin		509,659	182,151	177,622
Operating expenses:				
Sales and marketing	22	6,158,477	6,396,906	962,664
Research and development	22	9,590,393	5,019,366	481,934

General and administrative	22	11,405,471	15,209,919	8,457,630
Total operating expenses		27,154,341	26,626,191	9,902,228
Loss from operations		(26,644,682)	(26,444,040)	(9,724,606)
Other income (expense)				
Other income		601,421	411,417	393,418
Change in fair value of convertible debt	13	661,000	-	-
Gain on debt forgiveness – related party	15	48,677	-	-
Finance expense		(250,000)	-	-
Accretion and interest expense		(559,581)	(289,324)	(339,171)
Other Expense		(152,562)	(65,389)	-
Acquisition expense		-	-	(2,019,739)
Total other income (expense)		348,955	56,704	(1,965,492)
Loss before income tax		(26,295,727)	(26,387,336)	(11,690,098)
Income taxes provision		-	-	-
Net loss		**$ (26,295,727)**	**$ (26,387,336)**	**$ (11,690,098)**
Foreign currency translation gain (loss)		(504,494)	49,703	204,969
Comprehensive loss		**$ (26,800,221)**	**$ (26,337,633)**	**$ (11,485,129)**
Basic and diluted loss per ordinary share		**$ (1.62)**	**$ (1.86)**	**$ (1.62)**
Weighted average number of ordinary shares outstanding		**16,242,334**	**14,157,492**	**7,210,889**

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

Mainz Biomed N.V.
Consolidated Statement of Changes in Shareholders' Equity (Deficit)
(Expressed in US Dollars)

	Note	Number of shares	Share Capital	Share Premium	Reserve	Accumulated Deficit	Accumulated Other comprehensive Income (loss)	Total Shareholders' Equity (Deficit)
Balance, January 1, 2021		5,607,243	$ 64,265	$ 41,846	$ 2,309,684	$ (4,954,860)	$ (202,490)	$ (2,741,555)
Issuance of ordinary shares for conversion of debt		392,757	4,784	3,115	507,973	-	-	515,872
Recapitalization transaction	4	3,710,001	45,380	3,154,315	16,954	-	-	3,216,649
Sale of ordinary shares and warrants		2,300,000	26,646	9,927,217	471,297	-	-	10,425,160
Stock option expense	16	-	-	-	6,430,158	-	-	6,430,158
Net loss		-	-	-	-	(11,690,098)	-	(11,690,098)
Currency translation		-	-	-	-	-	204,969	204,969
Balance, December 31, 2021		12,010,001	141,075	13,126,493	9,736,066	(16,644,958)	2,479	6,361,155
Sale of ordinary shares and warrants	16	1,725,000	15,525	23,850,364	-	-	-	23,865,889
Issuance of ordinary shares for exercise of warrants	16	821,456	7,620	962,591	(587,711)	-	-	382,500
Share based expense	16	73,000	676	892,094	14,150	-	-	906,920
Stock option expense	16	-	-	-	8,917,236	-	-	8,917,236
Net loss		-	-	-	-	(26,387,336)	-	(26,387,336)
Foreign currency translation		-	-	-	-	-	49,703	49,703
Balance, December 31, 2022		14,629,457	$ 164,896	$ 38,831,542	$ 18,079,741	$ (43,032,294)	$ 52,182	$ 14,096,067
Sale of ordinary shares	16	4,474,032	48,538	6,344,213	-	-	-	6,392,751
Issuance of ordinary shares for exercise of warrants	16	305,771	3,333	12,132	(15,465)	-	-	-
Issuance of ordinary shares for commitment fee	13, 16	54,428	593	249,407	-	-	-	250,000
Issuance of ordinary shares for acquisition of intangible asset	9, 16	300,000	3,270	2,051,730	-	-	-	2,055,000
Issuance of ordinary shares for conversion of debt	13, 16	1,259,019	13,638	3,486,362				3,500,000
Share based expense	16	142,775	1,550	532,140	14,150	-	-	547,840
Stock option expense	16	-			3,207,789	-	-	3,207,789
Net loss		-	-	-	-	(26,295,727)	-	(26,295,727)
Foreign currency translation		-	-	-	-	-	(504,494)	(504,494)
Balance, December 31, 2023		21,165,482	$ 235,818	$ 51,507,526	$ 21,286,215	$ (69,328,021)	$ (452,312)	$ 3,249,226

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

Mainz Biomed N.V.
Consolidated Statements of Cash Flows
(Expressed in US Dollars)

		Years ended December 31,		
	Note	2023	2022	2021
Cash Flows From Operating Activities				
Net loss		$ (26,295,727)	$ (26,387,336)	$ (11,690,098)

Adjustments to reconcile net loss to net cash provided by (used in) operating activities:				
Share based compensation	16	4,005,629	9,824,157	6,430,158
Depreciation and amortization		866,412	379,798	69,929
Bad debt expense		14,357	65,389	-
Inventory write down		76,682	-	
Accretion expense	12, 15	168,109	79,628	139,974
Government grant	18	-	(118,232)	(51,410)
Change in fair value of convertible debt		(661,000)	-	-
Debt forgiveness – related party	15	(48,677)	-	-
Acquisition expense		-	-	2,019,739
Changes in operating assets and liabilities:				
Trade and other receivables, net		15,544	(211,231)	24,215
Inventories		(500,187)	(172,377)	-
Prepaid expenses and other assets		(239,703)	(53,788)	(833,556)
Deferred revenue		(60,521)	173,902	11,080
Accounts payable and accrued liabilities		720,237	1,650,500	659,645
Net cash used in operating activities		(21,938,845)	(14,769,590)	(3,220,324)
Cash Flows From Investing Activities				
Reverse Acquisition		-	-	1,219,856
Purchase of intangible asset	9	(700,000)	-	
Purchase of property and equipment	8	(1,198,841)	(658,483)	(16,705)
Net cash used in investing activities		(1,898,841)	(658,483)	1,203,151
Cash Flows From Financing Activities				
Sale of units including ordinary shares and warrants	16	6,392,751	23,865,889	10,425,160
Warrant exercise proceeds	16	-	382,500	-
Proceeds from convertible debt	13	10,120,000	-	7,673
Repayments of convertible debt	13	(1,100,000)	-	-
Proceeds from loans payable		-	-	2,305
Proceeds from silent partnerships		-	-	236,636
Payments on silent partnerships	15	(771,495)	-	(11,832)
Payments on silent partnerships – related party	15	(162,255)	-	-
Payments on loan payable	14	-	(107,027)	-
Payments of lease obligations	10	(252,309)	(197,944)	(49,408)
Net cash provided by financing activities		14,226,692	23,943,418	10,610,534
Effect of changes in exchange rates		(459,856)	(101,112)	11,613
Net change in cash		(10,070,850)	8,414,233	8,604,974
Cash at beginning of period		17,141,775	8,727,542	122,568
Cash at end of period		$ 7,070,925	$ 17,141,775	$ 8,727,542
Supplemental Disclosure of Operating Cash Flows				
Interest paid		$ 153,580	$ 125,543	$ 46,240
Non-Cash Investing and Financing Activities				
Right of use asset additions	10	$ 1,009,638	$ 1,010,299	$ 32,353
Acquisition of intangible asset for payable and stock payable	9	$ 3,271,828	$ -	$ -
Issuance of ordinary shares for share exchange	16	$ -	$ -	$ 3,216,649
Issuance of ordinary shares for cashless exercise	16	$ 15,465	$ 6,472	$ -
Issuance of ordinary shares for conversion of debt	13, 16	$ 3,000,000	$ -	$ 508,237

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

Mainz Biomed N.V.
Notes to the Consolidated Financial Statements
(Expressed in US dollars)
December 31, 2023, 2022 and 2021

1. NATURE OF OPERATIONS AND GOING CONCERN

Mainz Biomed N.V. (the "Company") is domiciled in Netherlands. The Company's registered office is at Robert-Koch Strasse 50, 55129 Mainz, Germany with substantially all of its operations in Germany. The Company was formed to acquire the business of Mainz Biomed Germany GmbH (f/k/a PharmGenomics GmbH ("PharmaGenomics", "PG")). In September 2021, the Company completed a Contribution Agreement to effect such acquisition (see Note 4).

We develop and sell in-vitro diagnostic ("IVD") tests for the early detection of cancer. Our flagship ColoAlert product is being marketed and sold in European markets. We are currently developing our next generation colorectal cancer screening product and intend to launch that product in the future in the United States and in Europe. We additionally operate a clinical diagnostic laboratory and distribute our IVD kits to third-party laboratories in Europe and through our on-line store in Germany.

Throughout these consolidated financial statements, Mainz Biomed N.V. and its directly and indirectly wholly owned subsidiaries, Mainz Biomed USA, Inc, Mainz Biomed GmbH (f/k/a PharmGenomics GmbH) and European Oncology Lab GmbH are referred to, collectively and individually as "Mainz", "Mainz Biomed", or the "Company").

Share Exchange

On August 3, 2021, the Company entered into a contribution agreement (the "Contribution Agreement") between Mainz Biomed B.V. ("Mainz"), which was a private company with limited liability under Dutch law incorporated for the purpose of acquiring PharmGenomics. Under the Contribution Agreement, 100% of the shares of PharmGenomics were acquired in exchange for 6,000,000 shares of Mainz. Upon the closing of the Contribution Agreement, PharmGenomics became a wholly owned subsidiary of Mainz and the former shareholders of PharmGenomics held approximately 62% of the outstanding shares of Mainz prior to the Company's initial public offering. On September 20, 2021, PharmGenomics and Mainz closed the Contribution Agreement. In November 2021, Mainz completed its initial public offering of its ordinary shares on the Nasdaq Capital Market, selling 2,300,000 shares at $5.00 per share. Upon the IPO the Company converted from Mainz Biomed B.V. to Mainz Biomed N.V.

Going Concern

The Company has recurring losses, accumulated deficit totaling $69,328,021 and negative cash flows used in operating activities of $21,938,845 as of and for the year ended December 31, 2023. The Company also had $7,070,925 of cash on hand at December 31, 2023. These factors raise a substantial doubt as to the Company's ability to continue as a going concern for a period that is one year from the date these financial statements are published. If the Company is unable to obtain funding, the Company could be forced to delay, reduce, or eliminate its research and development, regulatory, and commercial efforts which could adversely affect its future business prospects and its ability to continue as a going concern.

Management plans to fund its cash flow needs through current cash on hand and future debt and/or equity financings which it may obtain through one or more public or private equity offerings, debt financings, government or other third-party funding, strategic alliances, or collaboration agreements. During 2022 the Company raised $24.2 million of net proceeds from common stock sales and warrant proceeds. During 2023 the Company raised $16.5 million from a combination of sale of shares and warrants as well as the issuance of convertible debt. During 2024 and beyond the Company believes that it will be able to raise additional funds through a combination of the sale of ordinary shares, the sale and/or conversion of warrants, and use of the Company's access to capital through its Controlled Equity Offering (see Note 16) and its Pre-Paid Advance Agreement (see Note 13). The Company also has the ability to defer certain costs, especially those related to clinical studies, to match financing inflows. The Company believes that its currently available cash on hand, including additional financing described above, will be sufficient to meet its planned expenditures and to meet the Company's obligations for at least the one-year period following its consolidated financial statement issuance date.

These consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the settlement of liabilities in the normal course of business. These consolidated financial statements do not reflect the adjustments to the carrying values of assets and liabilities, the reported revenues and expenses, and the statement of financial position classifications used, that would be necessary if the Company were unable to realize its assets and settle its liabilities as a going concern in the normal course of operations. Such adjustments could be material.

2. BASIS OF PRESENTATION

Basis of Presentation and Statement of Compliance

These consolidated financial statements have been prepared in accordance with International Financial Reporting Standards ("IFRS") as issued by the International Accounting Standards Board ("IASB") and interpretations of the International Financial Reporting Issues Committee ("IFRIC"). The principal accounting policies applied in the preparation of these financial statements are set out below. These policies have been consistently applied to all years presented, unless otherwise stated.

These financial statements have been prepared on a historical cost basis, modified where applicable. In addition, these financial statements have been prepared using the accrual basis of accounting except for cash flow information. They were authorized for issue by the Company's board of directors on April 8, 2024.

New Accounting Standards

Standards, interpretations and amendments to standards and interpretations in the reporting period not yet effective and not yet applied:

Amendment to IAS 1, Presentation of Financial Statements

IAS 1 was amended in January 2020 to address inconsistences with how entities apply the standard over classification of current and non-current liabilities. The amendment serves to address whether, in the statement of financial position, debt and other liabilities with an uncertain settlement should be classified as current or non-current. The amendment is effective for annual reporting periods beginning on or after January 1, 2024. Earlier adoption is permitted. The Company will adopt this amendment as of the effective date and does not anticipate any material impacts on adoption.

Amendment to IAS 12 Deferred Tax related to Assets and Liabilities arising from a Single Transaction

The amendment narrowed the scope of certain recognition exemptions so that it no longer applies to transactions that, on initial recognition, give rise to equal taxable and deductible temporary differences. An entity applies the amendments to transactions that occur on or after the beginning of the earliest comparative period presented. It also, at the beginning of the earliest comparative period presented, recognizes deferred tax for all temporary differences related to leases and decommissioning obligations and recognizes the cumulative effect of initially applying the amendments as an adjustment to the opening balance of retained earnings (or other component of equity, as appropriate) at that date. The amendment is effective for annual periods beginning on or after January 1, 2023. Adoption did not have a material impact on our consolidated financial statements.

3. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES AND USE OF ESTIMATES AND JUDGMENTS

Inventories

Inventories are measured at the lower of cost and net realizable value. The cost of inventories is based on a weighted average cost and includes expenditure incurred in acquiring the inventories, production or conversion costs and other costs incurred in bringing them to their existing location and condition. Net realizable value is the estimated selling price in the ordinary course of business, less the estimated costs of completion and selling expenses.

Property and Equipment

Property and equipment are recorded at cost less accumulated depreciation. Expenditures that extend the life of the asset are capitalized and depreciated. Depreciation is recorded using the straight-line method over the estimated useful lives of the assets. Management evaluates the useful lives and method of depreciation at least annually and accounts for any changes to the useful life or method prospectively. Maintenance and repairs are charged to expense as incurred; cost of major additions and betterments are capitalized.

The estimated useful lives are:

Laboratory equipment	5 – 10 years
Office equipment	3 – 10 years
Right-of-use assets	Lease terms

Impairment of Non-Financial Assets

The Company performs impairment tests on its long-lived assets, including property and equipment when new events or circumstances occur, or when new information becomes available relating to their recoverability. When the recoverable amount of each separately identifiable asset or cash generating unit ("CGU") is less than its carrying value, the asset or CGU's assets are written down to their recoverable amount with the impairment loss charged against profit or loss. A reversal of the impairment loss in a subsequent period will be charged against profit or loss if there is a significant reversal of the circumstances that caused the original impairment. The impairment will be reversed up to the amount of depreciated carrying value that would have otherwise occurred if the impairment loss had not occurred.

The CGU's recoverable amount is evaluated using fair value less costs to sell calculations. In calculating the recoverable amount, the Company utilizes discounted cash flow techniques to determine fair value when it is not possible to determine fair value from active markets or a written offer to purchase. Management calculates the discounted cash flows based upon its best estimate of a number of economic, operating, engineering, environmental, political and social assumptions. Any changes in the assumptions due to changing circumstances may affect the calculation of the recoverable amount. There was no impairment recognized in the consolidated financial statements for the years ended December 31, 2023 and 2022.

Leases

The Company assesses at contract inception whether a contract is, or contains, a lease. That is, if the contract conveys the right to control the use of an identified asset for a period of time in exchange for consideration, the Company has the right to obtain substantially all of the economic benefits from the use of the asset through the specified period, and the Company has the right to direct the use of the specified assets, which involves the right to make the decisions that are most relevant to its use. The Company applies a single recognition and measurement approach for all leases, except for short-term leases and leases of low-value assets, which are recognized in profit or loss as the expense is incurred.

At the commencement date of the lease, the Company recognizes lease liabilities measured at the present value of lease payments to be made over the lease term. Lease payments include fixed payments (including in-substance fixed payments) less any lease incentives receivable, variable lease payments that depend on an index or a rate, and amounts expected to be paid under residual value guarantees. Lease payments also include the exercise price of a purchase option reasonably certain to be exercised by the Company and payments of penalties for terminating the lease, if the lease term reflects the Company exercising the option to terminate. Variable lease payments that do not depend on an index or a rate are recognized as expenses in the period in which the event or condition that triggers the payment occurs. In calculating the present value of lease payments, the Company uses the rate implicit in the lease, or if not readily determinable, its incremental borrowing rate ("IBR"). After the commencement date, the amount of lease liabilities is increased to reflect the accretion of interest and reduced for the lease payments made. In addition, the carrying amount of lease liabilities is remeasured if there is a modification, a change in the lease term, a change in the lease payments (e.g., changes to future payments resulting from a change in an index or rate used to determine such lease payments) or a change in the assessment of an option to purchase the underlying asset. Upon a remeasurement of a lease liability, the Company records a proportionate adjustment to the corresponding right-of-use asset. If the remeasurement results in a reduction of the right-of-use asset to nil, the difference is recorded in the statements of profit or loss in the period of occurrence.

The Company recognizes right-of-use assets at the commencement date of the lease (i.e., the date the underlying asset is available for use). Right-of-use assets are measured at cost, less any accumulated depreciation and impairment losses, and adjusted for any remeasurement of lease liabilities. The cost of right-of-use assets includes the amount of lease liabilities recognized, initial direct costs incurred, and lease payments made at or before the commencement date less any lease incentives received. Right-of-use assets are depreciated on a straight-line basis over the shorter of the lease term and the estimated useful lives of the assets.

Revenue Recognition

The Company's revenue is primarily derived through providing genetic diagnostic tests to customers. The Company recognizes revenue in accordance with IFRS 15–- "Revenue from Contracts with Customers".

In accordance with IFRS 15, revenue is recognized upon the satisfaction of performance obligations. Performance obligations are satisfied at the point at which control of the promised goods or services are transferred to customers, in an amount that reflects the consideration the Company expects to be entitled to receive for those goods and services.

The Company sells its genetic diagnostic testing kits to both laboratory partners and directly to patients who are the end users of the product. Upon the delivery of our products to laboratory partners the Company has completed its performance obligations and as such revenue is recorded upon delivery. Sales to patients, or end users, where samples are sent to our diagnostic lab for testing and evaluation, are recognized when they are delivered to the end user, returned to our laboratory, and testing results have been delivered. Revenue from these sales is deferred on our Statement of Financial Position until recognition.

Cost of revenue

Cost of revenue consists of patient test kits and laboratory kits sold to laboratory partners and patients. In the case of test performed in our diagnostic laboratory Cost of Revenue also includes the labor and overhead related to the performance of those test.

Research and Development

Expenditure on research activities, undertaken with the prospect of gaining new technical knowledge and understanding, is recognized in profit or loss as incurred.

Development activities involve a plan or design for the production of new or substantially improved products and processes. Development expenditure is capitalized only if development costs can be measured reliably, the product or process is technically and commercially feasible, future economic benefits are probable, and the Company intends to and has sufficient resources to complete development and to use or sell the asset. The expenditure capitalized includes the cost of materials, direct labor, overhead costs that are directly attributable to preparing the asset for its intended use, and borrowing costs on qualifying assets. Other development expenditures are recognized in profit or loss as incurred.

Research and development costs incurred subsequent to the acquisition of externally acquired intangible assets and on internally generated intangible assets are accounted for as research and development costs.

Financial Instruments

a) Classification

The Company classifies its financial instruments in the following categories: at fair value through profit and loss ("FVTPL"), at fair value through other comprehensive income (loss) ("FVTOCI") or at amortized cost. The Company determines the classification of financial assets at initial recognition. The classification of debt instruments is driven by the Company's business model for managing the financial assets and their contractual cash flow characteristics. Equity instruments that are held for trading are classified as FVTPL. For other equity instruments, on the day of acquisition the Company can make an irrevocable election (on an instrument-by-instrument basis) to designate them as at FVTOCI. Financial liabilities are measured at amortized cost, unless they are required to be measured at FVTPL (such as instruments held for trading or derivatives) or if the Company has opted to measure them at FVTPL.

b) Measurement

Financial assets and liabilities at amortized cost

Financial assets and liabilities at amortized cost are initially recognized at fair value plus or minus transaction costs, respectively, and subsequently carried at amortized cost less any impairment. The Company's financial assets measured at amortized cost are comprised of its cash and trade and other receivables, net. The Company's financial liabilities measured at amortized cost are comprised of its accounts payable and accrued liabilities, loans payable, loans payable – related party, convertible debt, convertible debt – related parties, silent partnerships, silent partnerships – related party and lease liabilities.

Financial assets and liabilities at FVTPL

Financial assets and liabilities carried at FVTPL are initially recorded at fair value and transaction costs are expensed in the statements of loss and comprehensive loss. Realized and unrealized gains and losses arising from changes in the fair value of the financial assets and liabilities held at FVTPL are included in the statements of loss and comprehensive loss in the period in which they arise.

Debt instruments at FVTOCI

These assets are initially measured at fair value. Interest income calculated using the effective interest method, foreign exchange gains and losses and impairment are recognized in profit or loss. Other net gains and losses associated with changes in fair value are recognized in OCI. On derecognition, gains and losses accumulated in OCI are reclassified to profit or loss. The Company does not hold any debt instruments at FVTOCI.

Equity instruments at FVTOCI

These assets are initially measured at fair value. Dividends are recognized as income in profit or loss unless the dividend clearly represents a recovery of part of the cost of the investment. Other net gains and losses associated with changes in fair value are recognized in OCI and are never reclassified to profit or loss. The Company does not hold any equity instruments at FVTOCI.

c) Impairment of financial assets at amortized cost

The Company recognizes a loss allowance for expected credit losses on financial assets that are measured at amortized cost. At each reporting date, the Company measures the loss allowance for the financial asset at an amount equal to the lifetime expected credit losses if the credit risk on the financial asset has increased significantly since initial recognition. If at the reporting date, the financial asset has not increased significantly since initial recognition, the Company measures the loss allowance for the financial asset at an amount equal to the twelve month expected credit losses. The Company shall recognize in the statements of loss and comprehensive loss, as an impairment gain or loss, the amount of expected credit losses (or reversal) that is required to adjust the loss allowance at the reporting date to the amount that is required to be recognized.

d) Derecognition

Financial assets

The Company derecognizes financial assets only when the contractual rights to cash flows from the financial assets expire, or when it transfers the financial assets and substantially all of the associated risks and rewards of ownership to another entity.

Financial liabilities

The Company derecognizes a financial liability when its contractual obligations are discharged or cancelled or expire. The Company also derecognizes a financial liability when the terms of the liability are modified such that the terms and/or cash flows of the modified instrument are substantially different, in which case a new financial liability based on the modified terms is recognized at fair value.

Gains and losses on derecognition are generally recognized in profit or loss.

Convertible Debt

The Company evaluates at initial recognition of a convertible debt the different components and features of the hybrid instruments and determines whether these elements are equity instruments or embedded derivatives which require bifurcation. In subsequent periods, the liability component is accounted for using (i) the fair value method, or (ii) the effective interest method, based on the expected maturity of the debt. The equity component is not remeasured, while embedded derivatives unless closely related to the host instruments, are recorded at fair value through the Consolidated Statement of Operations unless the convertible debt falls under FVTPL.

Foreign Currency Translation

The functional currency is determined using the currency of the primary economic environment in which that entity operates. The functional currency, as determined by management, of the Company is the Euro (EUR).

Foreign currency transactions are translated into functional currency using the exchange rates prevailing at the date of the transaction. Foreign currency monetary items are translated at the period-end exchange rate. Non-monetary items measured at historical cost continue to be carried at the exchange rate at the date of the transaction. Non-monetary items measured at fair value are reported at the exchange rate at the date when fair values were determined.

Exchange differences arising on the translation of monetary items or on settlement of monetary items are recognized in the statement of comprehensive loss in the period in which

they arise, except where deferred in equity as a qualifying cash flow or net investment hedge.

Exchange differences arising on the translation of non-monetary items are recognized in other comprehensive income to the extent that gains and losses arising on those non-monetary items are also recognized in other comprehensive income. Where the non-monetary gain or loss is recognized in profit or loss, the exchange component is also recognized in profit or loss.

The Company's presentation currency is the US dollar. For presentation purposes, all amounts are translated from the Euro functional currency to the US dollar presentation currency for each period using the exchange rate at the end of each reporting period for the statement of financial position. Revenues and expenses are translated on the basis of average exchange rates during the year.

Exchange gains and losses arising from translation to the Company's presentation currency are recorded as exchange differences on translation to reporting currency, which is included in other comprehensive income (loss).

Income Taxes

Current income tax:

Current income tax assets and liabilities for the current period are measured at the amount expected to be recovered from or paid to taxation authorities. The tax rates and tax laws used to compute the amount are those that are enacted or substantively enacted, at the reporting date, in the countries where the Company operates and generates taxable income.

Current income tax relating to items recognized directly in other comprehensive income or equity is recognized in other comprehensive income or equity and not in profit or loss. Management periodically evaluates positions taken in the tax returns with respect to situations in which applicable tax regulations are subject to interpretation and establishes provisions where appropriate.

Deferred tax:

Deferred tax is recognized on temporary differences at the reporting date arising between the tax bases of assets and liabilities and their carrying amounts for financial reporting purposes.

The carrying amount of deferred tax assets is reviewed at the end of each reporting period and recognized only to the extent that it is probable that future taxable income will be available to allow all or part of the temporary differences to be utilized.

Deferred tax assets and liabilities are measured at the tax rates that are expected to apply to the year when the asset is realized or the liability is settled, based on tax rates (and tax laws) that have been enacted or substantively enacted and are expected to apply by the end of the reporting period. Deferred tax assets and deferred income tax liabilities are offset if a legally enforceable right exists to set off current tax assets against current income tax liabilities and the deferred taxes relate to the same taxable entity and the same taxation authority.

Government Grants

Government grants are recognized when there is reasonable assurance that the grant will be received and that the Company will comply with the conditions attached to them. When the grant relates to an expense item, it is recognized as income on a systematic basis over the periods that the related costs, for which it is intended to compensate, are expensed. When the grant relates to an asset, it is recognized as income in equal amounts over the expected useful life of the related asset.

Loans received with better than market terms from government programs are recognized initially at fair value, with the difference between the fair value of the loan based on prevailing market interest rates and the amount received recorded as a gain in the statements of loss and comprehensive loss.

Share-Based Compensation

Our stock option grants may contain time based or market-based vesting provisions. Time based options are expensed on a straight-line basis over the vesting period. Market based options ("MBOs") are expensed when the related service and market performance conditions are expected to be met, such that the expenses ultimately recognized is based on the number of awards that meet the related service and market performance conditions at the vesting date.

The fair value of the stock options is determined on the grant date and is affected by our stock price and other assumptions regarding a number of complex and subjective variables. These variables include our expected stock price volatility over the term of the awards, risk free interest rates, expected dividends, and the expected option exercise term. The Company estimates the fair value of time-based stock options using the Black-Scholes-Merton pricing model. The simplified method is used to estimate the expected term of stock options due to a lack of related historical data regarding exercise, cancellation, and forfeiture. For MBOs, the fair value is estimated using Monte Carlo simulation techniques.

Where an equity-settled award is cancelled, it is treated as if it vested on the date of the cancellation and any expense not yet recognized for the award (being the total expense as calculated at the grant date) is recognized immediately. This includes any awards where vesting conditions within the control of either the Company or the employee are not met. However, if a new award is substituted for the cancelled award and designated as a replacement award on the date that it is granted, the cancelled award and new awards are treated as if they were a modification of the original awards.

Loss per Share

Basic loss per share is calculated by dividing the loss attributable to common shareholders by the weighted average number of common shares outstanding in the period. For all periods presented, the loss attributable to common shareholders equals the reported loss attributable to owners of the Company. When calculating the diluted earnings (loss) per share, the Company adds to the average number of ordinary shares outstanding, that was used to calculate the basic earnings per share, the weighted average of the number of shares to be issued assuming that all shares that have a potentially dilutive effect would be converted into shares. Potential ordinary shares are only taken into account in cases where their effect is dilutive (reducing the earnings per share or increasing the loss per share). As the Company has recorded net losses from operations in all periods presented, it has excluded stock options and warrants from the diluted Loss per Share calculation as the exercise of such would be anti-dilutive.

Segment Report

The Company operates in one operating segment, genetic diagnostic testing.

Reclassifications

Certain prior year amounts have been reclassified for consistency with the current year presentation.

Critical Accounting Estimates and Significant Management Judgments

The preparation of financial statements in accordance with IFRS requires the Company to use judgment in applying its accounting policies and make estimates and assumptions about reported amounts at the date of the financial statements and in the future. The Company's management reviews these estimates and underlying assumptions on an ongoing basis, based on experience and other factors, including expectations of future events that are believed to be reasonable under the circumstances. Revisions to estimates are adjusted for prospectively in the period in which the estimates are revised.

Useful lives of property and equipment

Estimates of the useful lives of property and equipment and intangible assets are based on the period over which the assets are expected to be available for use. The estimated useful lives are reviewed annually and are updated if expectations differ from previous estimates due to physical wear and tear, technical or commercial obsolescence, not electing to exercise renewal options on Leases, and legal or other limits on the use of the relevant assets. In addition, the estimation of the useful lives of the relevant assets may be based on internal technical evaluation and experience with similar assets. It is possible, however, that future results of operations could be materially affected by changes in the estimates brought about by changes in the factors mentioned above. The amounts and timing of recorded expenses for any period would be affected by changes in these factors and circumstances. A reduction in the estimated useful lives of the property and equipment and intangible assets would increase the recorded expenses and decrease the non-current assets.

Provision for expected credit losses on trade receivables

The provision for expected credit losses on trade receivables are estimated based on historical information, customer concentrations, customer solvency, current economic and geographical trends, and changes in customer payment terms and practices. The Company will calibrate its provision matrix to adjust the historical credit loss experience with forward-looking information. The assessment of the correlation between historical observed default rates, forecast economic conditions and expected credit losses is a significant estimate. The amount of expected credit losses is sensitive to changes in circumstances and of forecast economic conditions. The Company's historical credit loss experience and forecast of economic conditions may also not be representative of the customer's actual default in the future.

Estimating the incremental borrowing rate on leases

The Company cannot readily determine the interest rate implicit in leases where it is the lessee. As such, it uses its incremental borrowing rate ("IBR") to measure lease liabilities. The IBR is the rate of interest that the Company would have to pay to borrow over a similar term, and with a similar security, the funds necessary to obtain an asset of comparable value to the right-of-use asset in a similar economic environment. IBR therefore reflects what the Company "would have to pay", which requires estimation when no observable rates are available or where the applicable rates need to be adjusted to reflect the terms and conditions of the lease. The Company estimates the IBR using observable inputs (such as market interest rates) when available and is required to make certain entity-specific estimates.

Estimating the fair value of share-based payment transactions

The Company utilizes a Black-Scholes model, or where appropriate, a Monte-Carlo Simulation to estimate the fair value of its share-based payments. In applying these models, management must estimate the expected future volatility of the Company's estimated share price and makes such assumptions based on a proxy of publicly listed entities under an expectation that historical volatility is representative of the expected future volatility. Additionally, estimates have been made by management, in respect of the performance warrants, regarding the length of the vesting period as well as the number of performance warrants that are likely to vest.

Estimating the fair value of financial instruments

When the Company recognizes a financial instrument, where there is no active market for such an instrument, the Company utilizes alternative valuation methods. The Company utilizes inputs from observable markets to the extent that an appropriate market can be identified, but when there is a lack of such a market, the Company applies judgment to determine a fair value. Such judgments require those such as risk and volatility, of which changes in such assumptions may impact the fair value of the financial instrument.

Other significant judgments

The preparation of these financial statements in accordance with IFRS requires the Company to make judgments, apart from those involving estimates, in applying accounting policies. The most significant judgments in applying the Company's financial statements include:

- The assessment of the Company's ability to continue as a going concern and whether there are events or conditions that may give rise to significant uncertainty;
- The determination of the lease term of contracts with renewal and termination options;
- Determination of the extent to which it is probable that future taxable income will be available to allow all or part of the temporary differences and net operating losses to be utilized;
- Whether there are indicators of impairment of the Company's long-lived assets, including its intangible assets;
- Development costs do not meet the conditions for capitalization in accordance with IAS 38 and therefore all research and development costs have been expensed as incurred.

4. CONTRIBUTION AGREEMENT

On August 3, 2021, Mainz Biomed N.V. (f/k/a Mainz Biomed B.V.) and Mainz Biomed Germany Gmbh (f/k/a Pharmgenomics GmbH ("PG")) entered into Contribution Agreement for the purpose of Mainz Biomed N.V. acquiring PG. Under the Contribution Agreement, 100% of the shares of PG were acquired in exchange for 6,000,000 shares of the Company. Upon the closing of the Contribution Agreement, PG became a wholly owned subsidiary of the Company with the former shareholders of PG holding approximately 62% of the outstanding shares of the Company, after the Contribution Agreement closing. On September 20, 2021, Mainz Biomed N.V. and PG closed the Contribution Agreement.

For accounting purposes, the acquisition was considered to be a reverse acquisition under IFRS 3 Business Combinations ("IFRS 3") as the shareholders of PG obtained control of the Company. However, as Mainz Biomed N.V. did not, prior to the Contribution Agreement, meet the definition of a business as defined by IFRS 3, it has been accounted for as a share-based payment transaction in accordance with IFRS 2. The accounting for this transaction resulted in the following:

1. The consolidated financial statements of the combined entity are considered a continuation of the financial statements of the legal subsidiary, PG.

2. As PG was deemed to be the acquirer for accounting purposes, its assets and liabilities were included in the consolidated financial statements at their historical carrying values.

3. Since the shares allocated to the former shareholders of PG on closing of the Contribution Agreement were considered within the scope of IFRS 2, and there were not specifically identified goods or service received in return for the issuance of the shares, the value in excess of the net identifiable assets (net of liabilities acquired) of Mainz Biomed, N.V. acquired on closing was expensed in the consolidated statement of loss and comprehensive loss as an Acquisition Expense. The fair value of the 6,000,000 common shares for all of the outstanding shares of PG was determined to be $3,216,649 or $0.54 per common share.

4. The fair value of all the consideration given and charged to acquisition expense was comprised of

Fair value of common stock at share exchange date	$ 3,216,649
Identifiable assets acquired at September 20, 2021	
Cash	1,219,855
VAT receivable	12,497
Accounts payable	(35,443)
	$ 1,196,910
Unidentified assets acquired	
Acquisition expense	$ 2,019,739
Total net identifiable assets and transaction costs	$ 3,216,649

5. TRADE AND OTHER RECEIVABLES

	December 31, 2023	December 31, 2022
Trade receivables	$ 121,735	$ 130,588
Less: allowance for doubtful accounts	(28,180)	(66,852)
Trade receivables, net	93,555	63,736
Other	-	3,248
	$ 93,555	$ 66,984

For the year ended December 31, 2023, the Company recorded a reduction in allowance for doubtful accounts of $38,672, for trade receivables.

6. INVENTORIES

	December 31, 2023	December 31, 2022
Raw materials	$ 430,004	$ 175,469
Finished goods	240,467	-
	670,471	175,469
Less: Reserve	(56,833)	-
	$ 613,638	$ 175,469

For the year ended December 31, 2023, the Company recorded an inventory write down of $76,682 due to expiration of raw materials.

7. PREPAID AND OTHER CURRENT ASSETS

	December 31, 2023	December 31, 2022
Prepaid insurance	$ 478,116	$ 624,033
Other prepaid expense	327,538	55,356
Security deposit	135,061	122,570
VAT receivable	260,955	192,154
	$ 1,201,670	$ 994,113

For the year ended December 31, 2023, the Company recorded bad debt reserve of $53,295 for VAT receivables.

8. PROPERTY AND EQUIPMENT

Property and equipment and the changes in property, equipment and accumulated depreciation for the years ended December 31, 2023 and 2022 are provided as follows:

	Laboratory equipment	Office equipment	Construction in progress	Total

Cost				
Balance at December 31, 2021	$ 78,691	$ 11,697	$ -	$ 90,388
Additions	496,077	162,405	-	658,482
Disposal/reclasses	-	-	-	-
Effects of currency translation	4,403	2,245	-	6,648
Balance at December 31, 2022	$ 579,171	$ 176,347	$ -	$ 755,518
Additions	932,125	236,427	58,722	1,227,274
Disposal/reclasses	(51,509)	10,619	-	(40,890)
Effects of currency translation	34,945	(4,713)	1,207	31,439
Balance at December 31, 2023	$ 1,494,732	$ 418,680	$ 59,929	$ 1,973,341
Accumulated depreciation				
Balance at December 31, 2021	$ 44,787	$ 7,717	$ -	$ 52,504
Depreciation	34,977	8,563	-	43,540
Disposal/reclasses	-	-	-	-
Effects of currency translation	(1,931)	(287)	-	(2,218)
Balance at December 31, 2022	$ 77,833	$ 15,993	$ -	$ 93,826
Depreciation	137,996	64,987	-	202,983
Disposal/reclasses	(36,039)	4,013	-	(32,026)
Effects of currency translation	4,359	1,882	-	6,241
Balance at December 31, 2023	$ 184,149	$ 86,875	$ -	$ 271,024
Net book value at December 31, 2022	$ 501,338	$ 160,354	$ -	$ 661,692
Net book value at December 31, 2023	$ 1,310,583	$ 331,805	$ 59,929	$ 1,702,317

For the year ended December 31, 2023, 2022 and 2021, the Company recorded deprecation of $202,983, $43,540 and $6,573, respectively.

During 2023, we have begun the expansion of our clinical laboratory in our headquarters facility. Expenditures related to that lab expansion are included in Construction in progress.

As of December 31, 2023 and 2022, management assessed that there were no events or changes in circumstances that would require impairment testing of its fixed assets.

9. INTANGIBLE ASSET

Our flagship product is ColoAlert, a colorectal cancer ("CRC") screening test. On January 1, 2019, we entered into an exclusive licensing agreement (the "Licensing Agreement") with ColoAlert AS to license the intellectual property related to the ColoAlert test. On February 11, 2021, we obtained an option exercisable for three years to acquire the intellectual property for the ColoAlert test for (i) either a one-time cash payment of €2,000,000 or a €4,000,000 payment in ordinary shares at the valuation of our most recent financing plus (ii) a lifetime royalty payment of €5 per ColoAlert test sold (the "Option"). Subsequent to February 11, 2021, ColoAlert AS assigned their interest in ColoAlert and in the Licensing Agreement and the Option to Uni Targeting Research AS.

On February 15, 2023, we entered into an Intellectual Property Asset Purchase Agreement ("IPA"), which supersedes the Licensing and Options Agreements. Pursuant to the IPA, we acquired the intellectual property underlying the ColoAlert test. Pursuant to the IPA, we were able to reduce the price paid for the intellectual property to (i) $2 million cash, to be paid out over the next four years, (ii) 300,000 ordinary restricted shares and (iii) a revenue share limited to $1 per test sold for a period of 10 years. The Company recognized an intangible asset from this purchase and assigned a 10-year useful life. The intangible assets were valued: (a) for the portion to be settled in stock of the Company at the value on the day of closing, or $6.85 per share, and (b) for the cash portion, at the present value of the future payments using a 10% discount. During the year ended December 31, 2023 the Company paid $700,000 to the seller. The Company recorded amortization of $377,183 and interest expense of $100,813 for the year ended December 31, 2023. As of December 31, 2023, the liability for remaining required payments of $1,115,816 is recorded as intellectual property acquisition liability – related party (current and non-current) on the Statement of Financial Position.

In January 2022 the Company licensed the right to a novel set of mRNA biomarkers, including the exclusive license under a patent pending. Upon completion of the Company's evaluation of those biomarkers it exercised its right to acquire the rights to those biomarkers including the rights under the patent pending on February 15, 2023. The Company plans to use several of these biomarkers in its next generation product. Pursuant to the technology assignment agreement with SOCPRA Sciences Sante et Humaines S.E.C., operating under the name Transfertech Sherbrooke ("Sherbrooke"), the Company will owe Sherbrooke a royalty payment of 2% of net sales for any product sold that incorporates the biomarkers.

The activity in the Intangible Asset account for the year ended December 31, 2023 is as follows:

	Intangible asset
Net book amount at December 31, 2022	$ -
Additions	3,771,828
Disposal	-
Amortization	(377,183)
Net book amount at December 31, 2023	$ 3,394,645

At December 31, 2023 the Company analyzed the recoverability of its intangible assets and determined that an instance of impairment did not exist.

10. LEASES

Right-of-Use Assets

The Company's leases certain assets under lease agreements.

	Office Equipment	Laboratory Equipment	Vehicle	Office	Total
Cost					
Balance as of January 1, 2022	$ 48,754	$ 22,076	$ -	$ 489,143	$ 559,973
Additions	17,936	336,127	92,352	563,885	1,010,300
Effects of currency translation	(2,464)	4,767	1,656	(17,828)	(13,869)
Balance as of December 31, 2022	$ 64,226	$ 362,970	$ 94,008	$ 1,035,200	$ 1,556,404
Additions	-	38,943	70,914	587,245	697,102
Reduction	(36,907)	(312,790)	-	-	(349,697)
Effects of currency translation	1,110	4,939	4,193	42,192	52,434
Balance at December 31, 2023	$ 28,429	$ 94,062	$ 169,115	$ 1,664,637	$ 1,956,243
Accumulated amortization					
Balance as of January 1, 2022	$ 9,594	$ 7,447	$ -	$ 149,230	$ 166,271
Depreciation	11,456	69,569	21,720	115,281	218,026
Effects of currency translation	(343)	822	389	(6,456)	(5,588)
Balance as of December 31, 2022	$ 20,707	$ 77,838	$ 22,109	$ 258,055	$ 378,709
Depreciation	4,684	17,015	50,925	223,776	296,400
Reduction	(8,000)	(58,776)	-	-	(66,776)
Effects of currency translation	536	1,408	1,690	12,106	15,740
Balance at December 31, 2023	$ 17,927	$ 37,485	$ 74,724	$ 493,937	$ 624,073

As of December 31, 2023 and 2022, management assessed that there were no events or changes in circumstances that would require impairment testing of our right of use assets.

The carrying amount of the right-of-use assets is depreciated on a straight-line basis over the life of the leases, which at December 31, 2023, had an average expected life of 5.15 years.

Lease Liabilities

The Company's lease liabilities consist of office and laboratory equipment and office space. The present value of future lease payments were measured using an weighted average incremental borrowing rate of 9.80% per annum as of December 31, 2023.

	Total
Balance as of January 1, 2022	$ 442,842
Additions	1,010,299
Interest expenses	94,376
Lease payments	(292,320)
Effects of currency translation	(10,727)
Balance as of December 31, 2022	$ 1,244,470
Additions	697,103
Interest expenses	147,107
Lease payments	(399,416)
Reduction	(274,790)
Effects of currency translation	39,710
As of December 31, 2023	$ 1,454,186

	December 31, 2023
Lease liabilities	
Current portion	$ 288,463
Long-term portion	1,165,723
Total lease liabilities	$ 1,454,186

At December 31, 2023, the Company is committed to minimum lease payments as follows:

	December 31, 2023
Maturity analysis	
Less than one year	$ 367,033
One to two years	374,185
Two to three years	342,763
Three to four years	234,705
Four to five years	233,917
More than five years	368,369
Total undiscounted lease liabilities	$ 1,920,972
Amount representing implicit interest	(466,786)
Lease obligations	$ 1,454,186

11. ACCOUNTS PAYABLE AND ACCRUED EXPENSES

	December 31, 2023	December 31, 2022
Accounts payable	$ 2,326,439	$ 1,333,044
Accrued expenses	992,442	1,037,532
Payroll liabilities	132,734	346,693
	$ 3,451,615	$ 2,717,269

12. CONVERTIBLE DEBT – RELATED PARTY

During the years ended December 31, 2019 and 2020, the Company entered into loan agreements with related parties totaling EUR417,133 (approximately $467,154) (the "2019 and 2020 Convertible Loans"). The 2019 and 2020 Convertible Loans bear interest at 3.5% and have a maturity date of September 30, 2022. One of the convertible loans has not been converted and is payable on demand (balance of EUR30,000 ($33,118) as of December 31, 2023). While the 2019 and 2020 Convertible Loans are outstanding, the lenders are entitled to 0.5% of the Company's net income each year should the Company be profitable and provided that the amount paid does not exceed the principal amount of the debt; the lenders do not partake in the Company's losses. At maturity, the 2019 and 2020 Convertible Loans are convertible into ordinary shares of the Company at EUR1 per share.

The 2019 and 2020 Convertible Loans were determined to be a financial instrument comprising an equity classified conversion feature with a host debt component. On initial recognition, the Company used the residual value method to allocate the principal amount of the 2019 and 2020 Convertible Loans between the two components. The host debt component was valued first, based on similar debt securities without an embedded conversion feature and the residual was allocated to the equity-classified conversion feature. The Company recognized debt discounts totaling EUR13,064 on issuance of the 2019 and 2020 Convertible Loans.

A continuity of the Company's Convertible Debt is as follows:

	2019 and 2020 Convertible Loans
Balance, December 31, 2021	**$ 32,221**
Accretion	1,768
Effects of currency translation	(1,808)
Balance, December 31, 2022	**$ 32,181**
Effects of currency translation	937
Balance, December 31, 2023	**$ 33,118**

13. CONVERTIBLE DEBT

Convertible Loan

In November 2017, the Company entered into loan agreements with two former shareholders of the Company for loans totaling EUR80,278 (approximately $92,007) (the "2017 Convertible Loans"). As of December 31, 2023, one of the 2017 Convertible Loans is outstanding and is payable on demand, with a balance of EUR40,139 ($44,310). The remaining loan is convertible at the option of the lender to shares totaling 4.25% of the Company's common shares outstanding at the time of conversion. The loan is non-interest bearing, are unsecured and are due on demand.

A continuity of the Company's Convertible loan is as follows:

	2017 Convertible Loans
Balance, December 31, 2021	**$ 45,666**
Effects of currency translation	(2,609)
Balance, December 31, 2022	**$ 43,057**
Effects of currency translation	1,253
Balance, December 31, 2023	**$ 44,310**

Convertible Promissory Notes

On June 28, 2023, we entered into a Pre-Paid Advance Agreement (the "PPA") with YA II PN, Ltd. ("Holder"). Pursuant to the PPA, we may request that the Holder purchase from us up to $50,000,000 (the "Commitment Amount") of promissory notes (each, a "Promissory Note"). The Holder will purchase each Promissory Note at 92% of the principal amount of that Promissory Note. On June 28, 2023, we sold the Holder a Promissory Note (the "Initial Promissory Note") in the principal amount of $5,500,000 and received $5,060,000, net of discount. The Holder is not obligated to purchase any additional Promissory Notes from us under the PPA. On September 26, 2023, the Company issued a second Promissory Note of $5,500,000 and received $5,060,000, net of discount (the "Second Promissory Note").

Each Promissory Note matures one year from the date of its issuance. The Promissory Notes do not carry any interest, except if there is an event of default in which case the interest is 15% per annum. We may prepay a Promissory Note with at an 8% premium with advance written notice ranging between five business days and thirty calendar days prior to such prepayment, depending on the market price of our ordinary shares at the time of the notice.

The Promissory Notes are convertible at the Holder's discretion into our ordinary shares at a conversion price (the "Conversion Price") equal to the lower of (a) (I) $4.9986 in respect of the Initial Promissory Note, (II) $3.5424 in respect of the Second Promissory Note, and (III) with respect to each subsequent Promissory Note, if any, 110% of the volume weighted average price ("VWAP") of our ordinary shares on the trading day immediately preceding the issuance of such Promissory Note (the "Fixed Price") or (b) 92% of the average of the two lowest daily VWAPs of the shares during the eight trading days immediately prior to such conversion. In no event, however, shall the conversion price be less than a floor price of $2.00, as may be adjusted for stock splits and other similar transactions (the "Floor Price").

Under the Promissory Notes, a "Trigger Event" occurs if the trading price of an ordinary share is lower than the applicable Floor Price for any five of seven consecutive trading days. Within five trading days of a Trigger Event, we must make a monthly cash payment to the Holder in connection with the Promissory Notes (the "Monthly Payment") equal to the lesser of (i) $550,000, plus an 8% redemption premium on any principal being repaid plus any accrued and unpaid interest and (ii) all principal outstanding under all outstanding

Promissory Notes, plus an 8% redemption premium on any principal being repaid plus any accrued and unpaid interest. Thereafter, we must pay the Holder a Monthly Payment every 30 calendar days after the due date of the initial Monthly Payment; provided that our monthly obligation hereunder will end with respect to a particular Trigger Event if (i) the daily VWAP of the ordinary shares for seven consecutive trading days immediately prior to the due date of the next Monthly Payment is 10% or greater than the Floor Price or (ii) we reduce the Floor Price for all outstanding Promissory Notes by 50%, unless a new Trigger Event occurs.

In connection with the execution of the PPA, we agreed to pay a commitment fee of $250,000. Such commitment fee was paid on the date of the PPA in the form of 54,428 ordinary shares, which was derived using a per ordinary share price equal to the average of the daily VWAPs of the Ordinary Shares during the three trading days prior to the PPA.

The Company elected to account for the Promissory Notes at fair value through FVTPL. Management believes that the fair value option appropriately reflects the underlying economics of the Promissory Notes. Under the fair value election in IFRS 9, changes in fair value of the Promissory Notes, will be reported in the Consolidated Statements of Operations, under change in fair value of debt instrument, in each reporting period subsequent to the issuance of the Promissory Note. The Initial Promissory Note had a face value of $5,500,000 and had an original issue discount of $440,000. The Company recorded the Initial Promissory Note at its fair value of $5,060,000, which was also the cash received and the Second Promissory Note at its fair value of $5,008,000.

In November 2023, there was both a Trigger Event and default under the PPA and Promissory Notes. As a result, beginning in November 2023 the Company is incurring default interest of 15% per annum and is required to amortize the Notes with monthly cash payments. During November and December 2023, the Company paid $1,100,000 in principal under the notes and associated 8% premium and 15% default interest. During the period from January 1, 2024 to March 26, 2024 we continued to make payments as scheduled in a combination of cash and ordinary shares (see Note 23). We had a scheduled payment to Holder on March 27, 2024. We and the Holder mutually agreed to defer that payment into April 2024, without penalty, and are currently in discussions as to the amount and timing of that payment.

During the year ended December 31, 2023, principal amounts of the Initial Promissory Note of $3,500,000 was converted into 1,259,019 ordinary shares, at conversion prices ranging from $2.00 to $4.17.

For the year ended December 31, 2023, the Company recorded a change in fair value of $661,000, resulting in a balance of $4,859,000 as of December 31, 2023.

Changes in the balance of the convertible notes are as follows:

	Face Value	Carrying Amount at Fair value
Balance at December 31, 2022	$ -	$ -
Issuance of convertible promissory notes	11,000,000	10,120,000
Repayments of convertible promissory notes	(1,100,000)	(1,100,000)
Conversion of notes with ordinary shares	(3,500,000)	(3,500,000)
Change in fair value of convertible promissory notes	-	(661,000)
Balance at December 31, 2023	$ 6,400,000	$ 4,859,000

We classified this fair value as a Level 3 fair value measurement and used a fair value pricing model to calculate the fair value for the year ended December 31, 2023. Key inputs for the fair value model are summarized below.

A summary of the Company's significant inputs into the fair value of the Promissory Notes is as follows:

	December 31, 2023
Stock price	$ 1.16– - 4.82
Expected life in years	0.49– - 1.00
Risk free rate	5.09% - 5.57%
Expected volatility	74.65% - 130.0%

14. LOANS PAYABLE

During the year ended December 31, 2020, the Company entered into a loan agreement for the principal amount of EUR20,000 (approximately $22,828) (the "0.1% Loan). The 0.1% Loan bears interest at 0.1% per month and is due on demand and is secured against the Company's trade receivables.

Between the years of 2011 to 2013, the Company received loans from related parties totaling EUR35,000 (approximately $40,144) (the "Related Party 6% Loans"). The Loans have a stated interest rate of at 6.0%. EUR10,000 (approximately $11,461) of the loans matures on July 31, 2020 and EUR25,000 (approximately $28,653) of the loan matures on December 31, 2021. As the Related Party 6% Loans were received at below market interest rates, the initial fair value of the 3% Loan was determined to be EUR21,936 (approximately $25,140), determined using an estimated effective interest rate of 11.5%.

In 2017, the Company obtained a line of credit of up to EUR200,000 (approximately $229,224) (the "LOC"). The LOC accrues interest of 4% on amounts drawn, and a 0.5% fee if no amounts are drawn. The LOC was fully repaid in early 2022.

A continuity of the Company's loans payable is as follows:

	0.1% Loan	Related party 6% Loans	Related party LOC	Total
Balance, December 31, 2021	**$ 22,754**	**$ 39,819**	**$ 52,973**	**$ 115,546**
Extinguished during the year	(21,076)	(36,883)	(50,866)	(108,825)
Effects of currency translation	(1,678)	(2,936)	(2,107)	(6,721)
Balance, December 31, 2022	**$ -**	**$ -**	**$ -**	**$ -**

15. SILENT PARTNERSHIPS

During the year ended December 31, 2020, the Company entered into silent partnership agreements whereby the lender agreed to lend a total of EUR299,400 (approximately $341,740) (the "3% SPAs"). The Company is to repay the amount by December 31, 2025. The Company must pay a minimum of 3% interest per annum on the loans. The lender is entitled to 3% of the Company's net income each year should the Company be profitable and provided that the amount paid does not exceed the principal amount of the debt; the lender does not partake in the Company's losses. Upon the amounts coming due, the lender of the 3% SPAs has the option to demand an additional payment equal to 15% of the contribution as a final remuneration (the "Final Renumeration"). The Final Remuneration is considered to be the cost of issuing debt. The 3% SPAs were received at below market interest rates as part of a government program for COVID-19 relief. The initial fair value of the 3% SPAs was determined to be EUR218,120 (approximately $248,966), which was determined using an estimated effective interest rate of 11.5%. The difference between the face value and the fair value of the 3% SPAs of EUR81,280 ($92,774) has been recognized as government grant income during the period. During the year ended December 31, 2021 the Company received the remaining EUR200,000 ($236,640). The initial fair value of the 3.0% SPAs received was determined to be EUR230,000 (approximately $272,136), determined using an estimated effective interest rate of 11.5%. The initial fair value of the 3.0% SPAs received in 2021 was determined to be EUR156,549 (approximately $185,229), which was determined using an estimated effective interest rate of 11.5%. The difference between the face value and the fair value of the 3.0% SPAs received in 2021 of EUR43,451 (approximately $51,410) has been recognized as government grant income during the period.

During the year ended December 31, 2020, the Company entered into silent partnership agreements whereby the lender agreed to lend a total of EUR50,000 (approximately $57,071) (the "3.5% SPAs"). The Company is to repay the amount by June 30, 2025. The Company must pay a minimum of 3.5% interest per annum on the loans. The lender is entitled to 0.5% of the Company's net income each year should the Company be profitable and provided that the amount paid does not exceed the principal amount of the debt; the lender does not partake in the Company's losses. The 3.5% SPAs are convertible to common shares of the Company at EUR1 per share in the event that the Company is involved in any of the following transactions: capital increases, a share or asset deal or a public offering. Pursuant to the silent partnership agreement, the Company notified the holder, at which point the holder declined the opportunity to convert their loan into common shares. The 3.5% SPAs were determined to be a financial instrument comprising an equity classified conversion feature with a host debt component. On initial recognition, the Company used the residual value method to allocate the principal amount of the 3.5% SPAs between the two components. The host debt component was valued first, based on similar debt securities without an embedded conversion feature and the residual was allocated to the equity-classified conversion feature.

Between the years of 2013 to 2016, the Company entered into silent partnership agreements for loans totaling EUR798,694 (approximately $915,383) (the "8.5% SPAs"). Under the 8.5% SPAs, the Company is to repay EUR398,634 (approximately $408,496) of the loans by June 30, 2023 (such amounts were paid between the end of June and the beginning of July 2023) and EUR400,000 (approximately $409,859) of the loans matures on December 31, 2025. The Company must pay a minimum of 8.5% interest per annum on the loans. The lenders are entitled to 1.66% of the Company's net income each year should the Company be profitable and provided that the amount paid does not exceed the principal amount of the debt; the lenders do not partake in the Company's losses. At maturity, the lenders of the 8.5% SPAs have the option to demand an additional payment equal to 30% of the principal of the loans as a Final Remuneration. The Final Remuneration is considered to be cost of issuing the debt and as such, the initial fair value of the 8.5% SPAs was determined to be EUR772,568 (approximately $85,440), determined using an estimated effective interest rate of 11.5%. Under the agreements, the lenders also agreed to invest in the Company and contributed EUR676,366 (approximately $775,183) to acquire 27,752 shares of the Company between the years of 2013 and 2016. During the year ended December 31, 2020, EUR80,000 (approximately $99,527) of the 8.5% SPAs was extinguished as the lender, who is also a customer of the Company, elected to offset the debt amount against amounts in trade receivables due to the Company.

In 2010, the Company entered into a silent partnership agreement whereby the lender agreed to lend the Company EUR300,000 (approximately $343,830) (the "8% SPA"). The Company repaid this loan in January 2023. The Company must pay a minimum of 8% interest per annum on the loan. The lender is entitled to 1.95% of the Company's net income each year should the Company be profitable and provided that the amount paid does not exceed the principal amount of the debt; the lender does not partake in the Company's losses. At maturity, the lender of the 8% SPA has the option to demand an additional payment of up to 30% of the principal of the loan as a Final Remuneration. The Final Remuneration is considered to be cost of issuing the debt and as such, the initial fair value of the 8% SPA was determined to be EUR289,900 (approximately $332,254), determined using an estimated effective interest rate of 11.5%.

Certain of the Silent Partnership agreements are with a German based bank, which also owns ordinary shares of the Company. Those debts are classified as "related party" in the statement of financial position. A continuity of the Company's silent partnerships is as follows:

	3% SPAs	3.5% SPAs	8.5% SPAs	8% SPAs	Total
Balance, December 31, 2021	**$ 528,849**	**$ 43,271**	**$ 935,081**	**$ 432,918**	**$ 1,940,119**
Accretion	38,037	3,083	27,544	9,196	77,860
Effects of currency translation	(29,527)	(2,416)	(52,922)	(24,565)	(109,430)
Balance, December 31, 2022	**$ 537,359**	**$ 43,938**	**$ 909,703**	**$ 417,549**	**$ 1,908,549**
Extinguished during the year	-	-	(507,959)	(418,626)	(926,585)
Gain on debt forgiveness – related party	-	-	(48,667)	-	(48,667)
Accretion	42,063	3,382	20,529	805	66,779
Effects of currency translation	16,835	1,375	11,608	272	30,090
Balance, December 31, 2023	**$ 596,257**	**$ 48,695**	**$ 385,214**	**$ -**	**$ 1,030,166**

During the year ended December 31, 2023, the repayment of EUR150,000 (approximately $161,010) of the 8.5% SPAs was a related party transaction, who is a major shareholder.

As at December 31, 2023, EUR 200,000 (approximately $220,784) with a carrying value of $271,354 of the 8.5% SPAs were owing to major shareholders of the Company. EUR 200,000 of the loan is due on December 31, 2025.

As at December 31, 2022, EUR 350,000 (approximately $375,445) with a carrying value of $462,252 (2021 – $498,972) of the 8.5% SPAs were owing to major shareholders of the Company. EUR 150,000 of the loan is due on June 30, 2023 and EUR 200,000 of the loan is due on December 31, 2025.

16. EQUITY

Ordinary shares

The Company has 45 million ordinary shares authorized. Holders of ordinary shares are entitled to dividends as declared from time to time and are entitled to one vote per share at general meetings of the Company. The par value of share capital is EUR0.01 per share.

Controlled Equity Offering

In December 2022, the Company entered into a Controlled Equity Offering, known as an "ATM" facility. Pursuant to the ATM, the Company at its discretion and subject to an effective registration statement with the U.S. Securities and Exchange Commission, may sell through its agent ordinary shares at market prices, for a fee of 3%. During the year ended December 31, 2023 the Company issued 307,365 ordinary shares pursuant to the ATM for net proceeds of $1,894,742, at an average price of $6.16 per share.

November 2023 Financing

On November 13, 2023, we entered into a securities purchase agreement with several institutional investors to purchase approximately $5.0 million of our ordinary shares (or pre-funded warrants to purchase ordinary shares in lieu thereof) and warrants to purchase ordinary shares in a registered direct offering (the "Units"). The combined effective purchase price for each Unit, including an ordinary share (or pre-funded warrant) and an associated warrant to purchase one ordinary share was $1.20. Under the terms of the securities purchase agreement, we have agreed to issue 4,166,667 ordinary shares (or pre-funded warrant in lieu thereof) and warrants (the "Warrants") to purchase up to an aggregate of 4,166,667 shares. The Warrants will be exercisable immediately on the date of issuance until the fifth anniversary of the issuance date at a price of $1.20 per share. The Company received $4,499,555, net of offering costs. All pre-funded warrants were exercised by December 31, 2023.

The proceeds from the issuance of the Units are allocated between ordinary shares and warrants based on the residual method. Under this method, the proceeds are allocated first to share capital and premium based on the fair value of the ordinary shares at the time the offering was priced, any residual value is allocated to the warrants reserve. The fair value of ordinary shares was deemed to be $1.20, the price of this offering, and no residual value has been allocated to the warrants.

In addition, during the year ended December 31, 2023, the Company issued ordinary shares as follows:

- 142,775 ordinary shares issued for services rendered which were valued at $547,840
- 305,771 ordinary shares issued for cashless exercise of warrants
- 54,428 ordinary shares issued for a commitment fee on a convertible promissory note valued at $250,000
- 300,000 ordinary shares issued for acquisition of intangible assets valued at $2,055,000
- 1,259,019 ordinary shares issued for conversion of debt of $3,500,000

During the year ended December 31, 2022, the Company issued ordinary shares as follows:

- 1,725,000 ordinary shares issued for gross proceeds of approximately $25.9 million (proceeds net of offering expenses was $23.9 million);
- 821,456 ordinary shares issued for exercise of warrants, including cashless exercises (proceeds from the cash exercises of warrants were $382,500); and
- 73,000 ordinary shares issued for services valued at $906,920

Warrants

During the year ended December 31, 2021, in conjunction with private sales units, which included ordinary shares and warrants, the Company issued 3,755,000 warrants and issued 161,000 underwriter warrants with its IPO, cumulatively valued at $754,286, which was recorded to Reserve in the Consolidated Statement of Financial Position. The warrants were valued using the Black-Scholes pricing model. The Black-Scholes model requires six basic data inputs, which were as follows: the exercise or strike price ($3.00), time to expiration (2 to 5 years), the risk-free interest rate (0.16% to 1.08%), the current stock price at time of issuance ($0.283 to $1.602), the estimated volatility of the stock price in the future (75% to 95%), and the dividend rate (0%). Changes to these inputs could produce a significantly higher or lower fair value measurement. Unexercised warrants were to expire in November 2023. On September 8, 2023 the Board of Directors approved an amendment to the outstanding warrant agreements, which all remaining warrant holders accepted. The amendment extended the remaining life of the warrants to November 9, 2024 and removed the option for cashless exercise. No other terms were changed.

On November 13, 2023, the Company issued 4,166,667 warrants, as a part of the Unit offering, valued using the residual method and an assigned value of $0. The Warrants were exercisable immediately on the date of issuance until the fifth anniversary of the issuance date at a price of $1.20 per share.

A summary of activity during the year ended December 31, 2023 and 2022 is as follows:

	Warrant Outstanding	Weighted-Average Exercise Price	Weighted-Average Life (years)
Balance as of December 31, 2021	3,916,000	$ 3.08	1.60
Grants	-	-	-
Exercised	(668,500)	3.48	2.03
Expired	-	-	-
Balance as of December 31, 2022	3,247,500	$ 3.00	0.44
Grants	4,166,667	1.20	5.00
Exercised	(816,667)	3.00	2.71
Expired	-	-	-
Balance as of December 31, 2023	6,597,500	$ 1.86	3.39

As of December 31, 2023, all outstanding warrants are exercisable and the intrinsic value of the warrants is $0.

Stock options

In 2021, our shareholders adopted our 2021 Omnibus Incentive Plan (the "2021 Plan"). Under the 2021 Plan, we are authorized to issue equity incentives in the form of incentive stock options, non-statutory stock options, restricted shares, restricted share units, share appreciation rights, performance units or performance shares under separate award agreements. Under the 2021 Plan, the aggregate number of shares underlying awards that we could issue cannot exceed 2,300,000 ordinary shares.

In 2022, our shareholders adopted our 2022 Omnibus Incentive Plan (the ("2022 Plan"). Under the 2022 Plan, we are authorized to issue equity incentives in the form of incentive stock options, non-statutory stock options, restricted shares, restricted share units, share appreciation rights, performance units or performance shares under separate award agreements. Under the 2022 Plan, the aggregate number of shares underlying awards that we could issue cannot exceed 500,000 ordinary shares. In 2023, we amended the 2022 Plan

to increase the aggregate number of shares underlying awards that we could issue to 875,000 ordinary shares.

During the year ended December 31, 2021, the Company granted 1,504,650 stock options valued at $13,968,627. Stock options with time-based vesting were valued using the Black-sholes pricing model, while stock options with market-based vesting were valued using the Monte Carlo simulation.

During the year ended December 31, 2022, the Company granted 894,500 stock options valued at $6,494,112. Stock options with time-based vesting were valued using the Black-Scholes pricing model.

During the year ended December 31, 2023, the Company granted 417,500 stock options valued at $1,407,766. Stock options with time-based vesting were valued using the Black-Scholes pricing model.

During the years ended December 31, 2023, 2022 and 2021, the Company recorded share-based compensation of $3,207,789, $8,917,237 and $6,430,158 and unamortized expense of $3,315,321 and $5,115,344 as of December 31, 2023 and 2022, respectively. Forfeitures are estimated at the time of grant and adjusted, if necessary, in subsequent periods if actual forfeitures differ from those estimates.

For the year ended December 31, 2023, 2022 and 2021, the estimated fair values of the stock options are as follows:

	December 31, 2023	December 31, 2022	December 31, 2021
Exercise price	$ 1.99– - 7.02	$ 6.98– - 20.87	$ 5.00– - 10.56
Expected term	5.00– - 7.00 years	5.55– - 6.75 years	5.5– - 10 years
Expected average volatility	84% - 89%	73% - 79%	70% - 79%
Expected dividend yield	-	-	-
Risk-free interest rate	3.48% - 4.83%	1.26% - 3.38%	1.10% - 1.51%

A summary of activity during the year ended December 31, 2023 and 2022 follows:

	Stock options Outstanding	Weighted-Average Exercise Price	Weighted-Average Life (years)
Balance as of December 31, 2021	1,504,650	$ 5.10	9.85
Grants	894,500	10.73	10.00
Exercised	-	-	-
Forfeited	(5,000)	15.28	-
Expiry	-	-	-
Balance as of December 31, 2022	2,394,150	$ 7.18	9.11
Grants	385,000	4.48	10.00
Exercised	-	-	-
Forfeited/Cancelled	(52,000)	6.97	-
Expiry	-	-	-
Balance as of December 31, 2023	2,727,150	$ 6.89	8.44
Vested and exercisable as of December 31, 2023	1,766,782	$ 6.25	7.99
Expected to Vest	960,368	$ 7.79	2.61

As of December 31, 2023, the intrinsic value of the stock options is $0.

17. RELATED PARTY TRANSACTIONS

Key management personnel include those persons having authority and responsibility for planning, directing and controlling the activities of the Company as a whole. The Company has determined that key management personnel consist of members of the Company's Board, its Chief Executive Officer, Chief Financial Officer, Chief Commercial Officer, Chief Business Officer and Chief Scientific Officer. The remuneration of directors and key management personnel during the year ended December 31, 2023, 2022 and 2021 was as follows:

	Years ended December 31,		
	2023	2022	2021
Salaries and benefits	$ 1,647,186	$ 1,291,058	$ 673,464

As of December 31, 2023 and 2022, the Company recorded accounts payable – related party of $32,702 and $0, and accrued management salaries of $267,234 and $260,000, respectively.

Remuneration paid to related parties other than key personnel during the year ended December 31, 2023, 2022, and 2021 was as follows:

	Years ended December 31,		
	2023	2022	2021
Salaries and benefits	$ 29,468	$ -	$ 943

During the years ended December 31, 2023, 2022, and 2021, the Company incurred interest expense of $26,469, $32,457, and $36,442 on balances owing to related parties, respectively.

During the years ended December 31, 2023, 2022, and 2021, the Company incurred accretion expense of $10,712, $14,847, and $17,489 on balances owing to related parties, respectively.

During the years ended 2023, 2022, and 2021, we recorded expenses of $57,039, $97,924, and $259,600, respectively, for the cost of royalties and other associated costs owed to ColoAlert AS (and its successor, Uni Targeting Research AS, collectively "ColoAlert AS"), the company from which we exclusively licensed the ColoAlert product. A non-

executive director of the Company is also an owner of ColoAlert AS. During the year ended December 31, 2023, 2022 and 2021, we paid ColoAlert AS $885,335, $97,924, and $173,844, respectively. As of December 31, 2023 and 2022, we had liabilities recorded for unpaid costs to ColoAlert AS of $0 and $0, respectively, recorded as Accounts payable – related party.

On February 15, 2023, we entered into an Intellectual Property Asset Purchase Agreement ("IPA"), which supersedes the Licensing and Options Agreements with ColoAlert AS. Pursuant to the IPA, we acquired the intellectual property underlying the ColoAlert test. Pursuant to the IPA, we were able to reduce the price paid for the intellectual property to (i) $2 million cash, to be paid out over the next four years, (ii) 300,000 ordinary restricted shares and (iii) a revenue share limited to $1 per test sold for a period of 10 years. The Company recognized an intangible asset from this purchase and assigned a 10-year useful life. The intangible assets were valued: (a) for the portion to be settled in stock of the Company at the value on the day of closing, or $6.85 per share, and (b) for the cash portion, at the present value of the future payments using a 10% discount. During the year ended December 31, 2023 the Company paid $700,000 to the seller. The Company recorded amortization of $377,183 and interest expense of $100,813 for the year ended December 31, 2023. As of December 31, 2023, the liability for remaining required payments of $1,133,589 is recorded on the Consolidated Statement of Financial Position.

18. GOVERNMENT GRANTS

The Company receives government grants related to its research and development activities. The amount of government grants received during the years ended December 31, 2023, 2022 and 2021 and recognized as other income were as follows:

	Years ended December 31,		
	2023	**2022**	**2021**
Research and Development Projects			
Rapid detection of antibody-based pathogens	$ -	$ 42,055	$ 102,780
Multi-marker test for the early detection of pancreatic cancer	27,741	108,999	196,217
	$ 27,741	$ 151,054	$ 298,997

As of December 31, 2023 and 2022, the grants for rapid detection of antibody-based pathogens and a multi-marker test for the early detection of pancreatic cancer had remaining grant balances of approximately $6,604 and $81,706, respectively.

19. FINANCIAL INSTRUMENT RISK MANAGEMENT

Basis of Fair Value

Financial instruments measured at fair value are classified into one of three levels in the fair value hierarchy according to the relative reliability of the inputs used to estimate the fair values. The three levels of the fair value hierarchy are:

- Level 1 — Unadjusted quoted prices in active markets for identical assets or liabilities;
- Level 2 — Inputs other than quoted prices that are observable for the asset or liability either directly or indirectly; and
- Level 3 — Inputs that are not based on observable market data.

The Company's financial instruments consist of cash, trade and other receivables, accounts payable and accrued liabilities, lease liabilities, convertible debentures, and loans payable. With the exception of convertible debentures and loans payable, the carrying value of the Company's financial instruments approximate their fair values due to their short-term maturities. The fair value of convertible debentures and notes payable approximate their carrying value, excluding discounts, due to minimal changes in interest rates and the Company's credit risk since issuance of the instruments.

The Company is exposed in varying degrees to a variety of financial instrument related risks. The Board of Directors approves and monitors the risk management processes, inclusive of documented investment policies, counterparty limits, and controlling and reporting structures.

Credit Risk

The Company's principal financial assets are cash and trade receivables. The Company's credit risk is primarily concentrated in its cash which is held with institutions with a high credit worthiness. Management believes that the Company is not exposed to any significant credit risk with respect to its cash.

The Company mitigates its credit risk on receivables by actively managing and monitoring its receivables. The Company has been determined that no credit loss provision is required, as all amounts outstanding are considered collectible. During the year ended December 31, 2023, the Company incurred $14,357 (related to Trade receivable and VAT receivable) in bad debt expense (2022 - $65,389). The Company mitigates credit risk by evaluating the creditworthiness of customers prior to conducting business with them and monitoring its exposure for credit losses with existing customers.

Liquidity Risk

Liquidity risk is the risk that the Company will not be able to meet its financial obligations as they fall due. The Company has a planning and budgeting process in place to help determine the funds required to support the Company's normal operating requirements on an ongoing basis. As at December 31, 2023 and 2022, the Company had an unrestricted cash balance of $7,070,925 and $17,141,775, excluding the Initial Promissory Note, which is expected to be settled in ordinary shares, of $4,859,000 and $0, respectively.

Historically, the Company's primary source of funding has been the sale of ordinary shares and borrowings. The Company's access to financing is always uncertain. There can be no assurance of continued access to significant equity funding.

The following is an analysis of the contractual maturities of the Company's financial liabilities as at December 31, 2023 and 2022:

At December 31, 2023:

	Within	**More than**	**More than**

	one year	one year	five years
Accounts payable and accrued liabilities	$ 3,451,615	$ -	$ -
Accounts payable – related party	$ 32,702	$ -	$ -
Deferred revenue	$ 138,889	$ -	$ -
Convertible promissory note	4,859,000	-	-
Convertible loans	77,428	-	-
Silent partnerships	-	1,030,166	-
Lease liabilities	288,463	812,910	352,813
Intellectual property acquisition liability - related party	238,839	726,977	-
	$ 9,236,936	$ 2,570,053	$ 352,813

At December 31, 2022:

	Within one year	More than one year	More than five years
Accounts payable and accrued liabilities	$ 2,717,269	$ -	$ -
Deferred revenue	199,410	-	-
Convertible debt	75,238	-	-
Silent partnerships	965,335	943,214	-
Lease liabilities	285,354	771,457	187,659
	$ 4,242,606	$ 1,714,671	$ 187,659

Foreign Exchange Risk

Foreign currency risk is the risk that the fair values of future cash flows of a financial instrument will fluctuate because they are denominated in currencies that differ from the respective functional currency. As the Company operates in Germany it holds a portion of its cash balances in Euro to approximate between three to twelve months estimated operating needs. The remainder of the Company's cash is held in U.S. Dollars, the Company's reporting currency, which is also the currency of the Company's largest cash outlays over the next twenty-four months.

Interest Rate Risk

Interest rate risk is the risk that the fair value of future cash flows of a financial instrument will fluctuate because of changes in market interest rates. The Company is not exposed to interest rate risk as its financial liabilities carry interest at fixed rates.

Capital Management

The Company aims to manage its capital resources to ensure financial strength and to maximize its financial flexibility by maintaining strong liquidity and by utilizing alternative sources of capital including equity, debt and bank loans or lines of credit to fund continued growth. The Company sets the amount of capital in proportion to risk and based on the availability of funding sources. The Company manages the capital structure and makes adjustments to it in light of changes in economic conditions and the risk characteristics of the underlying assets. As an early-stage growth company, the sale of ordinary shares has been the primary source of capital to date. Additional debt and/or equity financing may be pursued in future as deemed appropriate to balance debt and equity. To maintain or adjust the capital structure, the Company may issue new shares, take on additional debt or sell assets to reduce debt.

20. CONCENTRATIONS

Major customers are defined as customers that each individually account for greater than 10% of the Company's annual revenues. For the year ended December 31, 2023, 2022, and 2021, the Company had revenue from one, two, and four, customers that accounted for approximately 21%, 38% and 56% of revenue, respectively.

21. INCOME TAXES

The provision for income taxes differs from the amount that would have resulted in applying the combined federal statutory tax rate as follows:

	December 31, 2023	December 31, 2022	December 31, 2021
Net loss for the period	$ (26,295,727)	$ (26,387,336)	$ (11,690,098)
Statutory income tax rate	25.0%	25.0%	25.0%
Expected in tax recovery at statutory income tax rates	$ (6,574,000)	$ (6,597,000)	$ (2,923,000)
Permanent differences	904,000	2,342,000	1,601,000
Difference in tax rates, foreign exchange, and other	5,695,000	3,723,000	484,000
Change in deferred tax assets not recognized	(25,000)	532,000	838,000
Income tax recovery	$ -	$ -	$ -

Temporary differences that give rise to the following deferred tax assets and liabilities at are:

	December 31, 2023	December 31, 2022
Deferred tax assets		
Net operating loss carryforwards	$ 2,704,532	$ 2,717,532
Deferred tax assets not recognized	(2,704,532)	(2,717,532)
Net deferred tax asset	$ -	$ -

As of December 31, 2023 and 2022, the Company has approximately $36,269,000 and $21,440,000 of non-capital losses that may be used to offset future taxable income. These losses may be carried forward on an indefinite basis and do not expire. The Company has not recognized the deferred tax assets due to the uncertainty around utilizing all of the losses carry-forwards.

Tax attributes are subject to review, and potential adjustment, by tax authorities.

22. OPERATING EXPENSES

For the years ended December 31, 2023, 2022, and 2021, operating expenses consisted of the following:

	Years ended December 31,		
Sales and marketing	2023	2022	2021
Salaries and Benefits	$ 1,442,952	$ 585,393	$ 84,418
Professional and consulting fees	909,046	756,919	243,012
Office expenses	21,746	49,092	34,206
Travel and entertainment	84,082	40,038	5,142
Depreciation and amortization	3,128	35,866	8,868
Marketing and advertising	3,697,523	4,929,598	587,018
	$ 6,158,477	$ 6,396,906	$ 962,664

	Years ended December 31,		
Research and development	2023	2022	2021
Salaries and benefits	$ 3,415,784	$ 1,961,718	$ 250,266
Professional and consulting fees	4,323,406	1,316,861	26,290
Lab and office expenses	975,315	1,375,349	106,487
Travel and entertainment	198,998	118,695	15,245
Depreciation and amortization	524,009	106,327	83,646
Materials for clinical studies	152,881	140,416	-
	$ 9,590,393	$ 5,019,366	$ 481,934

	Years ended December 31,		
General and administrative	2023	2022	2021
Salaries and benefits	$ 2,310,835	$ 2,175,242	$ 816,027
Employee stock option expense	3,266,702	8,931,386	6,430,158
Professional and consulting fees	3,883,687	2,144,679	800,836
Office expenses	657,185	785,862	193,514
Insurance	817,181	920,121	170,464
Travel and entertainment	130,606	133,257	17,116
Depreciation and amortization	339,275	119,372	29,515
	$ 11,405,471	$ 15,209,919	$ 8,457,630

23. SUBSEQUENT EVENTS

Subsequent to December 31, 2023, pursuant to the PPA (see Note 12), we paid $858,415 in cash and issued 721,093 ordinary shares. These transactions reduced the outstanding principal by $1,246,449, and interest of $177,566 and premiums of $74,995.

On February 22, 2024, our Compensation Committee approved the *carve-out plan* (the "COP") of Mainz Biomed USA, Inc. ("Mainz USA") and the Board of Directors of Mainz USA approved the COP. The purpose of the COP is to promote the interests of Mainz USA by providing a payment opportunity to individuals providing services to Mainz USA upon the consummation of a corporate transaction or series of transactions resulting in a change of control of Mainz USA or our Company (a "Change of Control" and the completion of a Change of Control, the "Closing").

Payment under the COP is based principally upon the carve-out pool amount which is equal to 13% of the aggregate pre-tax consideration (cash and fair market value of any securities or other consideration) payable in connection with a Change of Control that would be legally available for payment or distribution to Mainz USA, our Company or their respective shareholders in connection with a Change of Control (the "Consideration"). The COP provides for a carve-out pool equal to 13% of the Consideration less the aggregate severance payments contractually owed to all COP participants who have been informed on or before the Closing that their employment with Mainz USA will terminate on or within three months after the Closing. The carve-out pool will be allocated and paid to participants in the COP based on the product of the participant's applicable carve-out percentage as defined in the COP.

Under the COP, participants may receive transaction carve-out equal to the carve-out pool amount multiplied by each participant's carve-out percentage specified in such participant's participation acknowledgment less that participant's equity offset, as defined under the COP. Subject to the terms of the COP, payments under the COP will generally be paid in the same form (or forms) as the consideration received by shareholder of our Company in respect of their Company equity securities due to the change of control.

In connection with the approval of the COP, the Compensation Committee also approved a noncompete agreement. Each service provider to Mainz USA designated to participate in the COP and who executes a participation acknowledgment is eligible for awards under the COP, provided that he or she (i) remains in continuous service as defined in the COP until the Closing, and (ii) if so required of the participant, entry into a noncompete agreement with Mainz USA as outlined in the COP, or (iii) is (a) not terminated from employment by Mainz USA for cause, or (b) terminated without cause within 90 days of the Closing.

The Compensation Committee also recommended and adopted awards under the COP to Guido Bächler, the Company's Chief Executive Officer, with a carve-out percentage equal to 30% of the carve-out pool amount, and William Caragol, the Company's Chief Financial Officer, with a carve-out percentage equal to 15% of the carve-out pool amount. Each award was made pursuant to a COP participation acknowledgement form. Future awards of carve-out percentages may be made at the discretion of our Compensation Committee.

ITEM 19. EXHIBITS

The following exhibits are filed as part of this annual report on Form 20-F:

2.1	Description of Securities registered under Section 12 of the Exchange Act***
3.1	Unofficial English translation of Deed of Conversion***
3.2	Unofficial English translation of Deed of Amendment, dated December 15, 2022***
4.1	Share Certificate—Ordinary Shares***
10.1	Management Services Agreement, dated July 1, 2020, between the Company and Guido Baechler***
10.2	Consulting Agreement, dated July 16, 2021, between the Company and William Caragol***
10.3	Management Services Agreement, dated January 1, 2019, between the Company and Dr. Moritz Eidens***
10.4	Management Services Agreement, dated January 1, 2019, between the Company and Philipp Freese***
10.5	Form of Silent Partnership Agreements***
10.6	Mainz Biomed N.V. 2021 Omnibus Incentive Plan***
10.7	Mainz Biomed N.V. Amended and Restated 2022 Omnibus Incentive Plan***
10.8	Amendment to Management Services Agreement between Guido Baechler and the Company***
10.9	Amendment to Consultant Agreement between William Caragol and the Company***
10.10	Amendment to Management Services Agreement between Dr. Moritz Eidens and the Company***
10.11	Amendment to Consultant Agreement between Philipp Freese and the Company***
10.12	Technology Rights Agreement, dated January 4, 2022, between the Company and Socpra Sciences Santé Et Humaines S.E.C. ***
10.13	Employment Contract with William Caragol, dated April 29, 2022***
10.14	Intellectual Property Asset Purchase Agreement, dated February 15, 2023, with Uni Targeting Research AS***
10.15	Assignment Agreement, dated February 15, 2023, with SOCPRA Sciences Santé et Humaines S.E.C. ***
10.16	Mainz Biomed USA, Inc. Carve-Out Plan***
11.1	Insider Trading Policy*
11.2	Code of Ethics and Business Conduct***
12.1	Section 302(a) Certification of CEO*
12.2	Section 302(a) Certification of CFO*
13.1	Section 906 Certifications of CEO and CFO**
15.1	Consent of Reliant CPA PC*
97.1	Executive Compensation Clawback Policy*
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 (formatted as Inline XBRL and contained in Exhibit 101).*

* Filed herewith.
** Furnished herewith.
*** Previously filed.

SIGNATURES

The registrant certifies that it meets all of the requirements for filing on Form 20-F and that it has duly caused and authorized the undersigned to sign this annual report on its behalf.

Mainz Biomed N.V.

Date: April 8, 2024

By: */s/ Guido Baechler*
Guido Baechler
Chief Executive Officer

Insider Trading Policy

This Insider Trading Policy describes the standards of Mainz Biomed N.V., a company incorporated under the laws of the Netherlands (the "**Company**") and its subsidiaries on trading, and causing the trading of, the Company's securities or securities of certain other publicly traded companies while in possession of confidential information. This Policy is divided into two parts: the first part prohibits trading in certain circumstances and applies to all directors, officers and employees and their respective immediate family members of the Company and the second part imposes special additional trading restrictions and applies to all (i) directors of the Company, (ii) executive officers of the Company (together with the directors, "**Company Insiders**"), and (iii) certain other employees that the Company may designate from time to time as "covered persons" because of their position, responsibilities or their actual or potential access to material information ("Covered Employees", together with the Company Insiders, "Covered Persons").

One of the principal purposes of the federal securities laws is to prohibit so-called "insider trading." Simply stated, insider trading occurs when a person uses material nonpublic information obtained through involvement with the Company to make decisions to purchase, sell, give away or otherwise trade the Company's securities or the securities of certain other companies or to provide that information to others outside the Company. The prohibitions against insider trading apply to trades, tips and recommendations by virtually any person, including all persons associated with the Company, if the information involved is "material" and "nonpublic." These terms are defined in this Policy under Part I, Section 3 below. The prohibitions would apply to any director, officer or employee who buys or sells securities on the basis of material nonpublic information that he or she obtained about the Company, its customers, suppliers, partners, competitors or other companies with which the Company has contractual relationships or may be negotiating transactions.

PART I

1. Applicability

This Policy applies to all trading or other transactions in (i) the Company's securities, including common stock, options and any other securities that the Company may issue, such as preferred stock, notes, bonds and convertible securities, as well as to derivative securities relating to any of the Company's securities, whether or not issued by the Company and (ii) the securities of certain other companies, including common stock, options and other securities issued by those companies as well as derivative securities relating to any of those companies' securities.

This Policy applies to all employees of the Company, all officers of the Company and all members of the Company's board of directors, officers, employees, and their respective family members.

2. General Policy: No Trading or Causing Trading While in Possession of Material Nonpublic Information

(a) No director, officer or employee or any of their immediate family members may purchase or sell, or offer to purchase or sell, any Company security, whether or not issued by the Company, while in possession of material nonpublic information about the Company. (The terms "material" and "nonpublic" are defined in Part I, Section 3(a) and (b) below.)

(b) No director, officer or employee or any of their immediate family members who knows of any material nonpublic information about the Company may communicate that information to ("**tip**") any other person, including family members and friends, or otherwise disclose such information without the Company's authorization.

(c) No director, officer or employee or any of their immediate family members may purchase or sell any security of any other publicly-traded company while in possession of material nonpublic information that was obtained in the course of his or her involvement with the Company. No director, officer or employee or any of their immediate family members who knows of any such material nonpublic information may communicate that information to, or tip, any other person, including family members and friends, or otherwise disclose such information without the Company's authorization.

(d) For compliance purposes, you should never trade, tip or recommend securities (or otherwise cause the purchase or sale of securities) while in possession of information that you have reason to believe is material and nonpublic unless you first consult with, and obtain the advance approval of, the Compliance Officer (which is defined in Part I, Section 3(c) below).

(e) Covered Persons must "pre-clear" all trading in securities of the Company in accordance with the procedures set forth in Part II, Section 3 below.

3. Definitions

(a) Material. Insider trading restrictions come into play only if the information you possess is "material." Materiality, however, involves a relatively low threshold. Information is generally regarded as "material" if it has market significance, that is, if its public dissemination is likely to affect the market price of securities, or if it otherwise is information that a reasonable investor would want to know before making an investment decision.

Information dealing with the following subjects is reasonably likely to be found material in particular situations:

(i) significant changes in the Company's prospects;

(ii) significant write-downs in assets or increases in reserves;

(iii) developments regarding significant litigation or government agency investigations;

(iv) liquidity problems;

(v) changes in earnings estimates or unusual gains or losses in major operations;

(vi) major changes in the Company's management or the board of directors;

(vii) changes in dividends;

(viii) extraordinary borrowings;

(ix) major changes in accounting methods or policies;

(x) award or loss of a significant contract;

(xi) cybersecurity risks and incidents, including vulnerabilities and breaches;

(xii) changes in debt ratings;

(xiii) proposals, plans or agreements, even if preliminary in nature, involving mergers, acquisitions, divestitures, recapitalizations, strategic alliances, licensing arrangements, or purchases or sales of substantial assets; and

(xiv) offerings of Company securities.

Material information is not limited to historical facts but may also include projections and forecasts. With respect to a future event, such as a merger, acquisition or introduction of a new product, the point at which negotiations or product development are determined to be material is determined by balancing the probability that the event will occur against the magnitude of the effect the event would have on a company's operations or stock price should it occur. Thus, information concerning an event that would have a large effect on stock price, such as a merger, may be material even if the possibility that the event will occur is relatively small. When in doubt about whether particular nonpublic information is material, you should presume it is material. **If you are unsure whether information is material, you should either consult the Compliance Officer before making any decision to disclose such information (other than to persons who need to know it) or to trade in or recommend securities to which that information relates or assume that the information is material.**

(b) Nonpublic. Insider trading prohibitions come into play only when you possess information that is material and "nonpublic." The fact that information has been disclosed to a few members of the public does not make it public for insider trading purposes. To be "public" the information must have been disseminated in a manner designed to reach investors generally, and the investors must be given the opportunity to absorb the information. Even after public disclosure of information about the Company, you must wait until the close of business on the second trading day after the information was publicly disclosed before you can treat the information as public.

Nonpublic information may include:

(i) information available to a select group of analysts or brokers or institutional investors;

(ii) undisclosed facts that are the subject of rumors, even if the rumors are widely circulated; and

(iii) information that has been entrusted to the Company on a confidential basis until a public announcement of the information has been made and enough time has elapsed for the market to respond to a public announcement of the information, normally two trading days.

As with questions of materiality, if you are not sure whether information is considered public, you should either consult with the Compliance Officer or assume that the information is nonpublic and treat it as confidential.

(c) Compliance Officer. The Company has appointed the Chief Financial Officer as the Compliance Officer for this Policy. The duties of the Compliance Officer include, but are not limited to, the following:

(i) assisting with implementation and enforcement of this Policy;

(ii) circulating this Policy to all employees and ensuring that this Policy is amended as necessary to remain up-to-date with insider trading laws;

(iii) pre-clearing all trading in securities of the Company by Covered Persons in accordance with the procedures set forth in Part II, Section 3 below; and

(iv) providing approval of any Rule 10b5-1 plans under Part II, Section 1(c) below and any prohibited transactions under Part II, Section 4 below.

(v) providing a reporting system with an effective whistleblower protection mechanism.

4. Exceptions

The trading restrictions of this Policy do not apply to exercising stock options granted under the Company's current or future equity incentive plans or option plans for cash or the delivery of previously owned Company stock. However, the sale of any shares issued on the exercise of Company-granted stock options and any cashless exercise of Company-granted stock options are subject to trading restrictions under this Policy.

5. Violations of Insider Trading Laws

Penalties for trading on or communicating material nonpublic information can be severe, both for individuals involved in such unlawful conduct and their employers and supervisors, and may include jail terms, criminal fines, civil penalties and civil enforcement injunctions. Given the severity of the potential penalties, compliance with this Policy is absolutely mandatory.

(a) Legal Penalties. A person who violates insider trading laws by engaging in transactions in a company's securities when he or she has material nonpublic information can be sentenced to a substantial jail term and required to pay a criminal penalty of several times the amount of profits gained or losses avoided.

In addition, a person who tips others may also be liable for transactions by the tippees to whom he or she has disclosed material nonpublic information. Tippers can be subject to the same penalties and sanctions as the tippees, and the SEC has imposed large penalties even when the tipper did not profit from the transaction.

The SEC can also seek substantial civil penalties from any person who, at the time of an insider trading violation, "directly or indirectly controlled the person who committed such violation," which would apply to the Company and/or management and supervisory personnel. These control persons may be held liable for up to the greater of $1 million or three times the amount of the profits gained or losses avoided. Even for violations that result in a small or no profit, the SEC can seek penalties from a company and/or its management and supervisory personnel as control persons.

(b) Company-Imposed Penalties. Employees who violate this Policy may be subject to disciplinary action by the Company, including dismissal for cause. Any exceptions to the Policy, if permitted, may only be granted by the Compliance Officer and must be provided before any activity contrary to the above requirements takes place.

6. Inquiries

If you have any questions regarding any of the provisions of this Policy, please contact the Compliance Officer.

PART II

1. Blackout Periods

All Covered Persons are prohibited from trading in the Company's securities during blackout periods as defined below.

(a) Quarterly Blackout Periods. Trading in the Company's securities is prohibited during the period beginning at the close of the market on two weeks before the end of each fiscal quarter and ending at the close of business on the second trading day following the date the Company's financial results are publicly disclosed. During these periods, Covered Persons generally possess or are presumed to possess material nonpublic information about the Company's financial results.

(b) Other Blackout Periods. From time to time, other types of material nonpublic information regarding the Company (such as negotiation of mergers, acquisitions or dispositions, investigation and assessment of cybersecurity incidents or new product developments) may be pending and not be publicly disclosed. While such material nonpublic information is pending, the Company may impose special blackout periods during which Covered Persons are prohibited from trading in the Company's securities. If the Company imposes a special blackout period, it will notify the Covered Persons affected.

(c) Exception. These trading restrictions do not apply to transactions under a pre-existing written plan, contract, instruction, or arrangement under Rule 10b5-1 under the Securities Exchange Act of 1934 (an "**Approved 10b5-1 Plan**") that:

(i) has been reviewed and approved at least one month in advance of any trades thereunder by the Compliance Officer (or, if revised or amended, such revisions or amendments have been reviewed and approved by the Compliance Officer at least one month in advance of any subsequent trades);

(ii) was entered into in good faith by the Covered Person at a time when the Covered Person was not in possession of material nonpublic information about the Company; and

(iii) gives a third party the discretionary authority to execute such purchases and sales, outside the control of the Covered Person, so long as such third party does not possess any material nonpublic information about the Company; or explicitly specifies the security or securities to be purchased or sold, the number of shares, the prices and/or dates of transactions, or other formula(s) describing such transactions.

2. Trading Window

Covered Persons are permitted to trade in the Company's securities when no blackout period is in effect. Generally, this means that Covered Persons can trade during the period beginning on DAY THAT BLACKOUT PERIOD UNDER SECTION 1(A) ENDS and ending on DAY THAT NEXT BLACKOUT PERIOD UNDER SECTION 1(A) BEGINS. However, even during this trading window, a Covered Person who is in possession of any material nonpublic information should not trade in the Company's securities until the information has been made publicly available or is no longer material. In addition, the Company may close this trading window if a special blackout period under Part II, Section 1(b) above is imposed and will re-open the trading window once the special blackout period has ended.

3. Pre-Clearance of Securities Transactions

(a) Because Company Insiders are likely to obtain material nonpublic information on a regular basis, the Company requires all such persons to refrain from trading, even during a trading window under Part II, Section 2 above, without first pre-clearing all transactions in the Company's securities.

(b) Subject to the exemption in subsection (d) below, no Company Insider may, directly or indirectly, purchase or sell (or otherwise make any transfer, gift, pledge or loan of) any Company security at any time without first obtaining prior approval from the Compliance Officer. These procedures also apply to transactions by such person's spouse, other persons living in such person's household and minor children and to transactions by entities over which such person exercises control.

(c) The Compliance Officer shall record the date each request is received and the date and time each request is approved or disapproved. Unless revoked, a grant of permission will normally remain valid until the close of trading two business days following the day on which it was granted. If the transaction does not occur during the two-day period, pre-clearance of the transaction must be re-requested.

(d) Pre-clearance is not required for purchases and sales of securities under an Approved 10b5-1 Plan. With respect to any purchase or sale under an Approved 10b5-1 Plan, the third party effecting transactions on behalf of the Company Insider should be instructed to send duplicate confirmations of all such transactions to the Compliance Officer.

4. Prohibited Transactions

(a) Company Insiders are prohibited from trading in the Company's equity securities during a blackout period imposed under an "individual account" retirement or pension plan of the Company, during which at least 50% of the plan participants are unable to purchase, sell or otherwise acquire or transfer an interest in equity securities of the Company, due to a temporary suspension of trading by the Company or the plan fiduciary.

(b) Covered Persons, including any person's spouse, other persons living in such person's household and minor children and entities over which such person exercises control, are prohibited from engaging in the following transactions in the Company's securities unless advance approval is obtained from the Compliance Officer:

(i) Short-term trading. Company Insiders who purchase Company securities may not sell any Company securities of the same class for at least six months after the purchase;

(ii) Short sales. Company Insiders/Covered Persons may not sell the Company's securities short;

(iii) Options trading. Covered Persons may not buy or sell puts or calls or other derivative securities on the Company's securities;

(iv) Trading on margin or pledging. Covered Persons may not hold Company securities in a margin account or pledge Company securities as collateral for a loan; and

(v) Hedging. Covered Persons may not enter into hedging or monetization transactions or similar arrangements with respect to Company securities.

5. Acknowledgment and Certification

All Covered Persons are required to sign the attached acknowledgment and certification.

ACKNOWLEDGMENT AND CERTIFICATION

The undersigned does hereby acknowledge receipt of the Company's Insider Trading Policy. The undersigned has read and understands (or has had explained) such Policy and agrees to be governed by such Policy at all times in connection with the purchase and sale of securities and the confidentiality of nonpublic information.

_____
(Signature)

_____
(Please print name)

Date: _____

Exhibit 12.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO EXCHANGE ACT RULE 13A-14(A)/15D-14(A) AS ADOPTED PURSUANT TO SECTION 302
OF THE SARBANES-OXLEY ACT OF 2002

I, Guido Baechler, certify that:

1. I have reviewed this annual report on Form 20-F of Mainz Biomed N.V.;

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 company as of, and for, the periods presented in this report;

4. The company's other certifying officer 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 company 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 company, 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 company'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 company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the company's internal control over financial reporting; and

5. The company's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the company's auditors and the audit committee of the company'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 company'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 company's internal control over financial reporting.

Date: April 8, 2024

/s/ Guido Baechler
Guido Baechler
Title: Chief Executive Officer

Exhibit 12.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER
PURSUANT TO EXCHANGE ACT RULE 13A-14(A)/15D-14(A) AS ADOPTED PURSUANT TO SECTION 302
OF THE SARBANES-OXLEY ACT OF 2002

I, William Caragol, certify that:

1. I have reviewed this annual report on Form 20-F of Mainz Biomed N.V.;

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 company as of, and for, the periods presented in this report;

4. The company's other certifying officer 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 company 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 company, 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 company'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 company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the company's internal control over financial reporting; and

5. The company's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the company's auditors and the audit committee of the company'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 company'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 company's internal control over financial reporting.

Date: April 8, 2024

/s/ William Caragol
William Caragol
Title: Chief Financial Officer

Exhibit 13.1

CERTIFICATION OF THE PRINCIPAL EXECUTIVE OFFICER AND PRINCIPAL FINANCIAL OFFICER
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 Mainz Biomed N.V., a company incorporated under the laws of the Netherlands (the "Company") on Form 20-F for the year ended December 31, 2023, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), we, Guido Baechler, Chief Executive Officer of the Company, and William Caragol, Chief Financial Officer of the Company, each certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(i) the Report fully complies with the requirements of section 13(a) or 15(d) as applicable, of the Securities Exchange Act of 1934, as amended; and

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

Date: April 8, 2024

/s/ Guido Baechler
Guido Baechler
Title: Chief Executive Officer

Date: April 8, 2024

/s/ William Caragol
William Caragol
Title: Chief Financial Officer

The foregoing certification is not deemed filed for purpose of Section 18 of the Exchange Act and not incorporated by reference with any filing under the Securities Act.

Exhibit 15.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors of

Mainz Biomed N.V.

We consent to the inclusion by reference in the Form F-3 Registration Statement of Mainz Biomed N.V. (the "Company") (File No. 333-269091), our report dated April 8, 2024, relating to our audits of the consolidated statements of financial position of Mainz Biomed N.V., as of December 31, 2023 and 2022, and the related consolidated statements of comprehensive loss, changes in shareholders' equity (deficit) and cash flows for the years then ended.

We also consent to the reference to us under the caption "Experts" in the Registration Statement.

/s/ Reliant CPA PC

Certified Public Accountants
Newport Beach, California
April 8, 2024

MAINZ BIOMED N.V

CLAWBACK POLICY

Introduction

The Board of Directors ("**Board**") of Mainz Biomed N.V. (the "**Company**") believes that it is in the best interests of the Company and its shareholders to adopt this policy, which provides for the recoupment of certain executive compensation in the event of an accounting restatement resulting from material noncompliance with financial reporting requirements under the federal securities laws (the "**Policy**"). This Policy is designed to comply with Section 10D of the Securities Exchange Act of 1934, as amended (the "**Exchange Act**"), Rule 10D-1 promulgated under the Exchange Act ("**Rule 10D-1**") and Listing Rule 5608 of The Nasdaq Stock Market LLC ("**Nasdaq**").

Administration

This Policy shall be administered by the Board or, if so designated by the Board, by the Compensation Committee of the Board (the "**Compensation Committee**") or the Audit Committee of the Board (the "**Audit Committee**"), or any special committee comprised of members of the Compensation Committee or Audit Committee (the "**Administrator**"). Any determinations made by the Administrator shall be final and binding on all affected individuals. Subject to any limitation at applicable law, the Administrator may authorize and empower any officer or employee of the Company to take any and all actions necessary or appropriate to carry out the purpose and intent of this Policy (other than with respect to any recovery under this Policy involving such officer or employee).

Covered Executives

This Policy applies to the Company's current and former executive officers, as determined by the Administrator in accordance with Section 10D of the Exchange Act, the listing standards of the Nasdaq and any national securities exchange on which the Company's securities are listed, and such other senior executives/employees who may from time to time be deemed subject to the Policy by the Administrator (each, a "**Covered Executive**").

For the purposes of this Policy, "executive officers" shall include persons subject to reporting and short-swing liability provisions of Section 16 under the Exchange Act. This shall include the Company's president, principal financial officer, principal accounting officer (or, if there is no such accounting officer, the controller), any vice president in charge of a principal business unit, division, or function (such as sales, administration, or finance), any other officer who performs a policy-making function, or any other person who performs similar policy-making functions for the Company and any person identified under Regulation S-K Rule 401(b) in the Company's annual reports and proxy statements. Executive officers of a parent or subsidiary are deemed executive officers of the listed company if they perform such policy-making functions for the listed company or such parent or subsidiary. The policy-making function is not intended to include policy-making functions that are not significant.

Recoupment; Accounting Restatement

In the event the Company is required to prepare an accounting restatement of its financial statements due to the Company's material noncompliance with any financial reporting requirement under the securities laws, including any required accounting restatement to correct an error in previously issued financial statements that is material to the previously issued financial statements, or that would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period, the Administrator will require, as promptly as it reasonably can, reimbursement or forfeiture of any Incentive Compensation, as defined below, received by any Covered Executive during the three completed fiscal years immediately preceding the date on which the Company is required to prepare an accounting restatement (the "Restatement Date"), so long as the Incentive Compensation received by such Covered Executive is in excess of what would have been awarded or vested after giving effect to the accounting restatement. The amount to be recovered will be the excess of Incentive Compensation paid to the Covered Executive based on the erroneous data in the original financial statements over the Incentive Compensation that would have been paid to the Covered Executive had it been based on the restated results without respect to any taxes paid.

The Restatement Date is defined as the earlier of (i) the date the Board, a Board committee, or management (if no Board action is required) concludes, or reasonably should have concluded, that the Company is required to prepare an accounting restatement or (ii) the date a court, regulator, or other legally authorized body directs the Company to prepare an accounting restatement.

Incentive Compensation

For purposes of this Policy, "**Incentive Compensation**" means any of the following, provided that such compensation is granted, earned, or vested based wholly or in part on the attainment of a financial reporting measure:

- Annual bonuses and other short- and long-term cash incentives.
- Stock options.
- Stock appreciation rights.
- Restricted stock.
- Restricted stock units.
- Performance shares.
- Performance units.
- Non-equity incentive plan awards.

Financial reporting measures include any measure that is determined and presented in accordance with the accounting principles used in preparing the Company's financial statements and any measure that is derived wholly or in part from such measure. The following examples (and any measures derived therefrom) are non-exhaustive:

- Company stock price.
- Total shareholder return.
- Revenues.

- Net income.
- Operating income.
- Earnings before interest, taxes, depreciation, and amortization (EBITDA).
- Funds from operations and adjusted funds from operations.
- Liquidity measures such as working capital or operating cash flow.
- Return measures such as return on invested capital or return on assets.
- Earnings measures such as earnings per share.
- Profitability of one or more reportable segments.
- Financial Ratios such as accounts receivable turnover and inventory turnover rates.

- Sales per square foot or same store sales, where sales is subject to an accounting restatement.
- Revenue per user or average revenue per user.
- Cost per employee, where cost is subject to any accounting restatement.
- Any of such financial reporting measures relative to a peer group, where the Company's financial reporting measure is subject to an accounting restatement and tax basis income.
- Capital raised through debt or equity financing.
- Reductions in accounts receivables.

For the avoidance of doubt, Incentive Compensation does not include annual salary, compensation awarded based on completion of a specified period of service, or compensation awarded based on subjective standards, strategic measures, or operational measures.

Incentive Compensation includes incentive-based compensation received by a person:

- after beginning service as an executive officer;
- who serves as an executive officer at any time during the performance period for the incentive-based compensation;
- who served as an executive officer while the Company has a class of securities listed on a national securities exchange and
- who serves as an executive officer during the three fiscal years preceding the Restatement Date).

For the avoidance of doubt, subsequent changes in a Covered Executive's employment status, including retirement or termination of employment, do not affect the Company's rights to recover Incentive-Based Compensation pursuant to this Policy.

Excess Incentive Compensation: Amount Subject to Recovery

The amount to be recovered will be the excess of the Incentive Compensation paid to the Covered Executive based on the erroneous data over the Incentive Compensation that would have been paid to the Covered Executive had it been based on the restated results, as determined by the Administrator. Incentive Compensation is deemed "received" during the fiscal period during which the financial reporting measure specified in the incentive-based compensation award is attained, even if payment or grant of the Incentive Compensation occurs after the end of the period.

If the Administrator cannot determine the amount of excess Incentive Compensation received by the Covered Executive directly from the information in the accounting restatement, then it will make its determination based on a reasonable estimate of the effect of the accounting restatement.

Method of Recoupment

The Administrator will determine, in its sole discretion, the method for recouping excess Incentive Compensation hereunder, which may include, without limitation:

(a) requiring reimbursement of cash Incentive Compensation previously paid;

(b) seeking recovery of any gain realized on the vesting, exercise, settlement, sale, transfer, or other disposition of any equity-based awards;

(c) offsetting the recouped amount from any compensation otherwise owed by the Company to the Covered Executive;

(d) cancelling outstanding vested or unvested equity awards; and/or

(e) taking any other remedial and recovery action permitted by law, as determined by the Administrator.

No Indemnification of Covered Executives

The Company shall not indemnify any current or former Covered Executive against the loss of any incorrectly awarded Incentive Compensation, and shall not pay, or reimburse any Covered Executive for premiums for any insurance policy to fund such executive's potential recovery obligations.

Indemnification of the Administrator

Any members of the Administrator who assist in the administration of this Policy, shall not be personally liable for any action, determination, or interpretation made with respect to this Policy and shall be fully indemnified by the Company to the fullest extent under applicable law and Company policy with respect to any such action, determination or interpretation. The foregoing sentence shall not limit any other rights to indemnification of the Administrator under applicable law or Company policy.

Interpretation

The Administrator is authorized to interpret and construe this Policy and to make all determinations necessary, appropriate, or advisable for the administration of this Policy. It is intended that this Policy be interpreted in a manner that is consistent with the requirements of Section 10D of the Exchange Act, Rule 10D-1, Nasdaq Listing Rule 5608, and any other applicable rules or standards adopted by the Securities and Exchange Commission or any national securities exchange on which the Company's securities are then listed.

Effective Date

This Policy shall be effective as of the date it is adopted by the Administrator (the "**Effective Date**") and shall apply to Incentive Compensation that is approved, awarded, or granted to any Covered Executive on or after that date.

Amendment; Termination

The Board may amend this Policy from time to time in its discretion and shall amend this Policy as it deems necessary to reflect final regulations adopted by the Securities and Exchange Commission under Section 10D of the Exchange Act, Rule 10D-1 and Nasdaq Listing Rule 5608 and to comply with any other rules or standards adopted by a national securities exchange on which the Company's securities are then listed. The Board may terminate this Policy at any time.

Other Recoupment Rights

The Administrator intends that this Policy will be applied to the fullest extent of the law. The Administrator may require that any employment agreement, equity award agreement, or similar agreement entered into on or after the Effective Date shall, as a condition to the grant of any benefit thereunder, require a Covered Executive to agree to abide by the terms of this Policy. Any right of recoupment under this Policy is in addition to, and not in lieu of, any other remedies or rights of recoupment that may be available to the Company pursuant to the terms of any similar policy in any employment agreement, equity award agreement, or similar agreement and any other legal remedies available to the Company.

Impracticability

The Administrator shall recover any excess Incentive Compensation in accordance with this Policy unless such recovery would be impracticable, as determined by the Administrator in accordance with Rule 10D-1 of the Exchange Act and the listing standards of the national securities exchange on which the Company's securities are listed.

Successors

This Policy shall be binding and enforceable against all Covered Executives and their beneficiaries, heirs, executors, administrators, or other legal representatives.

Exhibit Filing Requirement

A copy of this Policy and any amendments thereto shall be posted on the Company's website and filed as an exhibit to the Company's Annual Report on Form 20-F.