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

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2024

OR

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

For the transition period from _____ to _____

Commission file number 001-41141

GLUCOTRACK, INC.

(Exact name of registrant as specified in its charter)

Delaware	**98-0668934**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
301 Route 17 North, Suite 800 **Rutherford, NJ**	**07070**
(Address of Principal Executive Offices)	(Zip Code)

(201) 842-7715
Registrant's telephone number, including area code

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.001 per share	GCTK	The Nasdaq Stock Market LLC

Securities registered pursuant to section 12(g) of the Act: None

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

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

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

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

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

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

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

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

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

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

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

As of June 28, 2024, the last business day of the registrant's last completed second quarter, the aggregate market value of the common stock held by non-affiliates of the registrant was approximately $8.6 million based on the closing price per share of the registrant's common stock, par value $0.001 per share (the "Common Stock"), on June 28, 2024, as reported by the Nasdaq Stock Market. For the purposes of this disclosure, shares of Common Stock held by each executive officer, director and affiliate based on public filings and other information known to the registrant have been excluded since such persons may be deemed affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

As of March 31, 2025, there were 25,585,853 shares of Common Stock, par value $0.001 per share, of the registrant issued and outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

None.

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Cautionary Note Regarding Forward-Looking Statements

This Annual Report on Form 10-K (the "Annual Report") includes statements that express our opinions, expectations, beliefs, plans, objectives, assumptions or projections regarding future events or future results and therefore are, or may be deemed to be, "forward-looking statements." All statements other than statements of historical facts contained in this Annual Report may be forward-looking statements. These forward-looking statements can generally be identified by the use of forward-looking terminology, including the terms "believes," "estimates," "continues," "anticipates," "expects," "seeks," "projects," "intends," "plans," "may," "will," "would" or "should" or, in each case, their negative or other variations or comparable terminology. They appear in a number of places throughout this Annual Report, and include statements regarding our intentions, beliefs or current expectations concerning, among other things, our results of operations, financial condition, liquidity, prospects, growth, strategies, future acquisitions and the industry in which we operate.

By their nature, forward-looking statements involve risks and uncertainties because they relate to events and depend on circumstances that may or may not occur in the future. We believe that these risks and uncertainties include, but are not limited to, those described in the "*Risk Factors*" section of this Annual Report, which include, but are not limited to, risks related to the following:

- our ability to manufacture, market and sell our products;
- our ability to launch and penetrate markets;
- our dependency upon effective operation with operating systems, devices, networks and standards that we do not control and on our continued relationships with mobile operating system providers, device manufacturers and mobile software application stores on commercially reasonable terms or at all;
- our ability to hire and retain key personnel;
- the possibility of security and privacy breaches in our systems and in the third-party software and/or systems that we use, damaging client relations and inhibiting our ability to grow;
- our ability to internally develop new inventions and intellectual property;
- the existence of undetected software defects in our products and our failure to resolve detected defects in a timely manner;
- our ability to remain a going concern;
- our ability to raise additional capital and the risk of such capital not being available to us at commercially reasonable terms or at all;
- our ability to be profitable;
- interpretations of current laws and the passages of future laws;
- acceptance of our business model by investors;
- intense competition in our industry and the markets in which we operate, and our ability to successfully compete;
- the risks inherent with international operations;
- the impact of evolving information security and data privacy laws on our business and industry;
- the impact of governmental regulations on our business and industry;
- our ability to protect our intellectual property and our ability to operate our business without infringing on the rights of others;
- the risk of being delisted from Nasdaq Capital Market ("Nasdaq") if we fail to meet any of its applicable listing requirements;
- the difficulty of predicting our revenues and operating results and the chance of such revenues and results falling below analyst or investor expectations, which could cause the price of our Common Stock to fall
- the other factors described in the "*Risk Factors*" section of this Annual Report.

These factors should not be construed as exhaustive and should be read with the other cautionary statements in this Annual Report.

Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date this report is filed with the Securities and Exchange Commission ("SEC"). We cannot guarantee the accuracy of any such forward-looking statements contained in this Annual Report, and we do not intend to publicly update or revise any forward-looking statements, whether as a result of new information, future events, or otherwise. For further information regarding risks and uncertainties associated with our business, and important factors that could cause our actual results to vary materially from those expressed or implied in such forward-looking statements, please refer to the factors listed and described in this Annual Report and in our other SEC filings.

PART I

Item 1. Business

Unless the context otherwise requires, the terms "we", "our", "ours" "us", "Company" and "Glucotrack" refer to Glucotrack, Inc., a Delaware corporation.

Overview

The Company was incorporated on May 18, 2010 under the laws of the State of Delaware. We are a medical device company focused on the development of an implantable continuous blood glucose monitor ("CBGM") for persons with Type 1 diabetes and insulin-dependent Type 2 diabetes (the "Glucotrack CBGM").

The Company was founded with a mission to develop Glucotrack®, a non-invasive glucose monitoring device designed to help people with diabetes and pre-diabetics obtain glucose level readings without the pain, inconvenience, cost and difficulty of conventional (invasive) spot finger stick devices. The first generation Glucotrack, which successfully received CE Mark approval, obtained glucose measurements via a small sensor clipped onto one's earlobe. A limited release beta test in Europe and the Middle East demonstrated the need for an updated product with improved accuracy and human factors. As the glucose monitoring landscape has since rapidly moved away from point-in-time measurement to continuous measurement, the Company recently determined that it would focus its efforts on developing the Glucotrack CBGM. As such, we have since withdrawn our CE Mark for Glucotrack and are no longer pursuing commercialization of this product or development of any further iterations.

On October 7, 2022, the Company acquired certain intellectual property related to the Glucotrack CBGM from Paul V. Goode, the Company's Chief Executive Officer and intends to develop the technology to address the growing Type 1 and insulin-dependent Type 2 diabetes market.

The Company is currently developing the Glucotrack CBGM for use by Type 1 diabetes patients as well as insulin-dependent Type 2 patients. Implant longevity is key to the success of such a device. We have continued to evolve our sensor chemistry following our successful in-vitro feasibility study demonstrating that a minimum two-year implant life is highly probable with the current sensor design. Recently we announced that a 3-year longevity is feasible leveraging both in-vitro and in-silico test results. We have also completed multiple animal studies with initial prototype systems which demonstrated a simple implant procedure with good safety and functionality. The results of both were presented in poster form at the 2024 American Diabetes Association annual conference.

Further to the above progress on the Glucotrack CBGM, we have also successfully demonstrated continuous glucose sensing in the epidural space. This latter approach is of importance for patients with diabetes already contemplating spinal cord stimulation therapy for their condition. We believe our technology, if successful, has the potential to be more accurate, more convenient and have a longer duration than other implantable glucose monitors that are either in the market or currently under development.

The Company has recently completed a first in human study. This study was an acute study intended to demonstrate device performance and safety, as well as safety of the implant and removal procedures. The study used the planned commercial version of the implantable sensor connected to an externalized prototype electronics device. Patients were monitored in hospital for 4 days. Results of the study were positive, meeting the endpoints of no serious safety events while demonstrating similar performance and accuracy as observed in longer-term animal studies.

A regulatory submission has recently been made for a first in human study of the planned commercial version of the Glucotrack CBGM system: fully implantable sensor and electronics with no on-body wearable. This will be a long-term study intended to demonstrate device performance and safety over a period of at least one year. Most of the preparatory clinical activities are complete and the study is expected to initiate late in the second quarter of 2025, pending regulatory approval. In parallel, the Company is also preparing for pre-submission discussions with the U.S. Food and Drug Administration (FDA) regarding our planned multi-center United States ("U.S.") clinical trial we hope to launch before the end of 2025.

As part of this effort, the Company has recently obtained ISO13485 certification, an internationally agreed-upon standard of quality system requirements for the design, production, distribution, and sale of medical devices. The Company has successfully completed all necessary audits without any major nonconformities. Certification of compliance to the standard is recognized and accepted by the FDA, the European Medicines Agency (EMA), and many other regulatory authorities worldwide.

Our executive management team consists of our Chief Executive Officer and President, Paul V. Goode PhD, an experienced executive with a 25+ year career developing innovative medical technologies, including at Dexcom, Inc. ("Dexcom") and MiniMed (now Medtronic Diabetes) and Chief Financial Officer, Peter C. Wulff, who has over 35 years of experience as a chief financial officer and chief operating officer in both public and private entities. Our senior management team consists of: Mark Tapsak PhD, Chief Scientific Officer, a medical research scientist who brings over 25 years of experience in the diabetes industry, including previous senior roles at Dexcom and Medtronic; James P. Thrower PhD, Vice President of Advanced Technologies, a seasoned engineering executive with 20 years' experience formerly of Sterling Medical Devices, Mindray DS USA and Dexcom.; Drinda Benjamin, Vice President of Marketing, a medical device professional with over 20 years of experience in the medical device and diabetes industry with senior roles at Intuity Medical, Senseonics, Incorporated, Abbott Diabetes, and Medtronic Diabetes; Vincent Wong, Vice President of Operations, a medical device professional with 15 years of experience in quality system for implantable medical device manufacturing with senior roles at Cirtec Medical and TOMZ Corporation ("TOMZ"); Sandie Martha, Vice President Clinical Operations, a medical device professional with over 20 years of experience in the medical device and diabetes industry with senior roles at Dexcom and GlySens Incorporated ("GlySens"); and Ted Williams, Vice President Regulatory, a medical device professional with over 20 years of experience in the biotech and diabetes industry with a senior role at GlySens.

Our Board of Directors (the "Board" or "Board of Directors") includes the Chairman Luis J. Malavé, formerly of Insulet Corp, Medtronic and MiniMed (now Medtronic Diabetes); Andy Balo, formerly of Dexcom and St Jude Medical (now Abbott), Erin Carter, formerly of Medtronic and Boston Scientific; John Ballantyne, formerly of Aldeveron; Robert Fischell, formerly of Pacesetter (now Abbott), NeuroPace, and IsoStent, Inc.; and Allen Danzig, formerly of L3-Harris Technologies and Celanese.

Market Opportunity

Diabetes

Diabetes is a chronic, life-threatening disease for which there is no known cure. Diabetes is caused by the body's inability to produce or effectively utilize the hormone insulin. This inability prevents the body from adequately regulating blood glucose levels. Glucose, the primary source of energy for cells, must be maintained at certain concentrations in the blood in order to permit optimal cell function and health. Normally, the pancreas provides control of blood glucose levels by secreting the hormone insulin to decrease blood glucose levels when concentrations are too high. In people with diabetes, blood glucose levels fluctuate between very high levels, a condition known as hyperglycemia, and very low levels, a condition known as hypoglycemia. Hyperglycemia can lead to serious long-term complications, such as blindness, kidney disease, nervous system disease, amputations, stroke and cardiovascular disease. Hypoglycemia can lead to confusion, loss of consciousness or death.

Diabetes is typically classified into two major groups: Type 1 and Type 2. Type 1 diabetes is characterized by the body's inability to produce insulin, resulting from destruction of the insulin producing cells of the pancreas. Individuals with Type 1 diabetes must rely on frequent insulin injections in order to regulate and maintain blood glucose levels. Type 1 diabetes is frequently diagnosed during childhood or adolescence, although disease onset can occur at any age. Type 2 diabetes, the more common form of diabetes, is a metabolic disorder that is characterized by the body's inability to either properly utilize insulin or produce enough insulin. Type 2 diabetes is associated with older age, obesity, family history of diabetes, history of gestational diabetes, impaired glucose metabolism, physical inactivity and race or ethnicity. Depending on the severity of Type 2 diabetes, individuals may require diet and nutrition management, exercise, oral medications or insulin injections to regulate blood glucose levels.

According to the Diabetes Atlas (Ninth Edition) published by the International Diabetes Federation in 2021, approximately 537 million adults worldwide, between the ages of 20 and 79, or approximately 10% of the world's adult population, were estimated to suffer from diabetes in 2021 (not including those persons who suffer from impaired glucose tolerance or gestational diabetes, diabetic conditions first arising during pregnancy). The International Diabetes Federation estimates that this number will grow to approximately 784 million adults worldwide by 2045. The Centers for Disease Control and Prevention in its 2023 National Diabetes Statistics Report provided crude estimates for 2021 that there are approximately 38 million people with diabetes in the U.S., of which 29.7 million have diagnosed diabetes. Among US adults ages 18 years or older, there were 1.2 million new cases of diabetes diagnosed in 2021.

Glucose Monitoring

Blood glucose levels can be affected by many factors, including the carbohydrate and fat content of meals, exercise, stress, illness or impending illness, hormonal releases, medications, variability in insulin absorption and changes in the effects of insulin in the body. Given the many factors that affect blood glucose levels, maintaining glucose within a normal range can be difficult. People with diabetes generally manage their blood glucose levels by administering insulin or ingesting carbohydrates throughout the day to maintain blood glucose within normal ranges. Normal ranges vary from person to person. In order to maintain blood glucose levels within normal ranges, people with diabetes must first measure their blood glucose levels so that they can make the proper therapeutic adjustments. As adjustments are made, additional blood glucose measurements may be necessary to gauge the individual's response to the adjustments. More frequent testing of blood glucose levels provides these individuals with information that can be used to better understand and manage their diabetes. Testing of blood glucose levels should be performed (at a minimum) before meals, after meals and before going to sleep. People with diabetes who take insulin usually need to test more often than those who do not take insulin.

Until recently, spot finger stick devices known as blood glucose monitors ("BGM") have been the most prevalent devices for blood glucose monitoring. These devices require users to insert a strip into a glucose meter, take a blood sample with a finger stick and place a drop of blood on a test strip that yields a single point in time blood glucose measurement. Despite continued developments in the field of BGMs, the routine measurement of glucose levels remains invasive, painful, inconvenient, difficult and costly. Moreover, the American Diabetes Association updated guidelines (released 2023) indicated there is no clinical evidence of benefit for non-insulin dependent Type 2 diabetes patients; and recommended CGM as the standard of care for those patients.

Continuous glucose monitor ("CGM") systems involve the insertion of sensors into the body to measure glucose levels in the interstitial fluid throughout the day and night, providing real-time data that shows trends in glucose measurements. Many published clinical studies demonstrate that CGMs improve glycemic control in people with Type 1 diabetes or people with insulin-requiring Type 2 diabetes. As a result, CGM use is rapidly increasing and has become the clinically recommended standard of care for these patients.

Despite the benefits in glycemic control and significant insurance coverage, almost half of the people with diabetes still have not adopted CGM. We believe that a significant market opportunity exists for an innovative CGM device that addresses the remaining barriers to adoption. According to a 2017 Diabetes Care study, these barriers include the inconvenience of wearing devices all the time, discomfort and inconvenience of bi-weekly device replacement, dislike for having diabetes devices on the body, and dislike for how diabetes devices look on the body. Additionally, the study reported that reasons that people discontinued using a CGM included the device being uncomfortable or painful and the belief that the device is not accurate.[1] The Company conducted its own market research study in 2024 to validate these findings as still being relevant. The results on over 750 patients demonstrated that patients with diabetes still have the same issues as expressed in 2017.[2] We believe that improved CGM devices that address these barriers could provide significant benefits to patients, healthcare providers and payors, thereby increasing overall CGM adoption and ongoing satisfaction. The Company is developing a long-term implantable blood-based CGM that will allow continuous monitoring of blood glucose levels, which the Company believes is a significant improvement in quality compared to spot finger stick devices and CGM.

[1] Tanenbaum ML, Hanes SJ, Miller KM, Naranjo D, Bensen R, Hood KK. Diabetes device use in adults with type 1 diabetes: barriers to uptake and potential intervention targets. *Diabetes Care* **2017** Feb 1;40(2):181-7.

[2] "Evaluating Acceptance of a Continuous Blood Glucose Monitor for People with Insulin Requiring Diabetes", Presented at 2024 ADCES annual conference.

Our Product

The Company is currently developing a long-term implantable CBGM with no requirement for an additional wearable component with maintained calibration status (the "Glucotrack CBGM"). The Glucotrack CBGM utilizes an intravascular approach, in which the device is implanted subcutaneously and connected to a lead that is placed directly into a blood vessel. This facilitates continuous blood glucose measurements with zero lag time. In comparison, all other CGM systems of which we are aware measure glucose in the interstitial fluid, which lags behind blood glucose. Our approach is based on design elements, implant techniques, and implant tools commonly used for active implantable devices in the cardiovascular space. As a result, it employs a recognized, established, and widely utilized implant procedure and device form factor.

In the second quarter of 2023, we completed the laboratory-based feasibility study demonstrating that the CBGM sensor is capable of measuring glucose for at least two years post-implant. By the end of 2023 we completed our initial preclinical in vivo animal study. This initial preclinical study produced very strong results, demonstrating at least three months of well-sustained sensor life while also demonstrating that the sensor is safe for animals. The study also indicated the CBGM is capable of a high level of measurement accuracy as compared with conventional CGM technologies on the market.

In the fourth quarter of 2023, we initiated a human clinical device/system design and development program. The objective was to complete this effort in time to initiate regulatory filings for a first-in-human acute ("FIH-A") study in the second quarter of 2024.

In the first quarter of 2024, we advanced the program of the commercial device/system design and development program with our contract manufacturing partner, Cirtec Medical. The objective was to complete this effort in time to initiate regulatory filings for a first-in-human chronic ("FIH-C") study in the fourth quarter of 2024.

During the second quarter of 2024, we announced that the Glucotrack CBGM successfully completed 30 days of a 60-day long-term preclinical study on measuring glucose in the epidural space. The Glucotrack CBGM sensor, implanted in the epidural space of animals, closely tracked both blood glucose and a commercially available subcutaneous CGM throughout the 30-day period. The implantation procedure took approximately 20 minutes, and the animals recovered without complications. No abnormal clinical signs or findings in the spinal cord or surrounding tissues were observed at the 30-day mark. We subsequently announced that the 60-day long-term study was completed, demonstrating the feasibility of glucose monitoring in the epidural space. No abnormal clinical signs were observed throughout the study period, and no abnormal findings were observed in the spinal cord or surrounding tissues during post-explant analysis. The study also confirmed that the implanted sensor did not cause any delayed latent effects over the long-term period, which is particularly important as a complete healing process in animal studies with implanted devices may take several weeks. With the completion of this study, the durability of the epidural approach for continuous glucose monitoring has now been confirmed over the 60-day period.

Also in the second quarter of 2024, a regulatory submission was prepared and eventually submitted for the FIH-A study to be performed in Sao Paulo, Brazil. This study was a small cohort of up to 10 patients evaluated in-hospital for 4 days. The goals of the study were to prove the implant and removal procedures were safe and reasonable, the device was safe and functional, and the overall experience was well-tolerated. The trial began in December 2024 and was completed in late January 2025. The study successfully met all objectives.

During the third quarter of 2024, we presented data at the Diabetes Technology Society annual meeting that demonstrated a sensor longevity of 3 years. Using in silico modeling to iterate membrane parameter design changes and further validated by in vitro bench testing, we were able to improve our projected sensor longevity from 2 years to 3 years.

During the fourth quarter of 2024, a regulatory submission was prepared and eventually submitted for the FIH-C study to be performed in Melbourne, Australia. This study is to be up to 30 patients across up to 3 centers evaluated in daily life for one year, with the option to extend the study longer. The goals of the study are to collect data for sensor characterization and algorithm development, along with implant procedure characterization and refinement. These results will drive any necessary refinements to the system. Upon incorporation of any required refinements, we intend to conduct a U.S. Pilot Study. Initial regulatory feedback from the Australian regulatory body is expected in first quarter 2025 with trial start expected in second quarter 2025.

With respect to clinical trials, we are targeting the second quarter of 2025 for initiation of the FIH-C trial. This trial is expected to use the commercial version of the implantable system products (device and sensor), along with the scaled mobile app and cloud. Throughout 2025, we will identify potential clinical sites, obtain regulatory approval, and prepare the sites for trial initiation. We will also be working with key physician partners to refine the implant, explant, and replacement procedures

and associated tool set. We will also request our first pre-submission meeting with the FDA. The goal of this is to initiate discussions culminating in an Investigational Device Exemption ("IDE") submission in the third quarter of 2025. The IDE submission will be for a U.S. Pilot Study targeting up to 40 patients across up to 3 U.S. clinical centers; however, the FDA may limit number of patients and/or clinical centers. The primary goal of this study is to be a 'dry run' for the eventual FDA pivotal trial for FDA approval.

In the first quarter of 2025, we received ISO 13485:2016 certification from the British Standards Institute ("BSI"). We successfully completed Stage I and Stage II Assessments performed by the notified body, BSI, to verify the Company has established, and is maintaining, a quality management system that meets all requirements of the ISO 13485:2016 standard for design and development of our products.

We do not have commercial manufacturing facilities and do not intend to build commercial manufacturing facilities of our own in the foreseeable future. Our strategy has been to select leaders in the manufacturing of similar or complementary products. We recently announced a development and manufacturing agreement with Cirtec Medical (Brooklyn Park, MN), one of the leading medical device solutions providers of implantable therapies. We require our critical suppliers and their manufacturing facilities to comply with applicable regulations in the jurisdictions in which our devices are to be marketed (including ISO 13485 in the European Union ("EU")), current quality system regulations, which include current good manufacturing practices, and to the extent laboratory analysis is involved, current good laboratory practices. There can be no assurance that our manufacturing partners will perform as expected.

Research and Development

See "*Item 7 – Management's Discussion and Analysis of Financial Condition and Results of Operation – Results of Operation*" below for a discussion of the research and development expenses for the fiscal years ended December 31, 2024 and 2023.

Regulatory Considerations

Healthcare is heavily regulated by federal, state and local governments in the United States, and by similar authorities in other countries. Any product that we develop must receive all relevant regulatory approvals or clearances, as the case may be, before it may be marketed in a particular country. The laws and regulations affecting healthcare change regularly, thereby increasing the uncertainty and risk associated with any healthcare related venture. The United States government has in the past considered, is currently considering and may in the future consider healthcare policies and proposals intended to curb rising healthcare costs, including those that could significantly and adversely affect reimbursement for healthcare products such as our devices. These policies have included and may in the future include: basing reimbursement policies and rates on clinical outcomes, the comparative effectiveness and costs of different treatment technologies and modalities; imposing price controls and taxes on medical device providers; and other measures. Future significant changes in the healthcare systems in any jurisdiction in which our devices, may be cleared for sale could also have a negative impact on the demand for our devices. These include changes that may reduce reimbursement or payment rates for such products.

In the United States, the federal government regulates healthcare through various agencies, including but not limited to the following: (i) the FDA, which administers the Food, Drug, and Cosmetic Act (the "FDCA") as well as other relevant laws; (ii) the Centers for Medicare & Medicaid Services ("CMS"), which administers the Medicare and Medicaid programs; (iii) the Office of Inspector General, which enforces various laws aimed at curtailing fraudulent or abusive practices including, by way of example, the Anti-Kickback Law, the Anti-Physician Referral Law, commonly referred to as the Stark Law, the Anti-Inducement Law, the Civil Money Penalty Law, and the laws that authorize the Office of Inspector General to exclude health care providers and others from participating in federal healthcare programs; and (iv) the Office of Civil Rights which administers the privacy and security aspects of the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"). All of the aforementioned are agencies within the Department of Health and Human Services. Healthcare is also provided or regulated, as the case may be, by the Department of Defense through its TriCare program, the Department of Veterans Affairs under, among other laws, the Veterans Health Care Act of 1992, the Public Health Service within the Department of Health and Human Services under the Public Health Service Act, the Department of Justice through the federal False Claims Act (the "FCA") and various criminal statutes, and state governments under the Medicaid program and their internal laws regulating all healthcare activities. If and when we receive FDA approval to market our devices in the United States, we will be subject to regulation by some or all of the foregoing agencies.

The applicable regulatory schemes in the EU are significantly more diverse than those in the United States and do not lend themselves to similar summary. Although the CE Mark system and the Medical Device Regulation ("MDR") require a minimum level of harmonization in the EU, each EU member country may impose additional regulatory requirements. Because there are numerous EU member countries with distinct legal systems, the scope of potential regulatory requirements in each of the EU countries (additional to the harmonized EU requirements) is difficult to summarize or predict.

Regulation of the Design, Manufacture and Distribution of Medical Devices

Any product that we develop must receive all relevant regulatory clearances or approvals, as the case may be, before it may be marketed in a particular country.

Sales of medical devices outside the United States are subject to foreign regulatory requirements that vary widely from country to country. These laws and regulations range from simple product registration requirements in some countries to complex clearance and production controls in others. As a result, the processes and time periods required to obtain foreign marketing approval may be longer or shorter than those necessary to obtain FDA approval (as described below). These differences may affect the efficiency and timeliness of international market introduction of our devices. For countries in the EU, medical devices must display a CE Mark before they may be imported or sold and must comply with the requirements of the MDR. However, although the MDR is applicable throughout the EU, in practice it does not ensure uniform regulation throughout the EU. Rather, the MDR requires only a minimum level of harmonization in the EU. Accordingly, member countries may apply and enforce the MDR's terms differently, and certain EU member countries may request or require performance and/or safety data in addition to the MDR's requirements from time to time, on a case-by-case basis. The CE Mark also permits the sale in countries that have an MDR Mutual Recognition Agreement with the EU.

In the United States, under Section 201(h) of the FDCA, a medical device is an article which, among other things, is intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment or prevention of disease in man or other animals. We believe that our devices will be classified as medical devices and subject to regulation by numerous agencies and legislative bodies, including the FDA and its foreign counterparts. Devices are subject to varying levels of regulatory control, the most comprehensive of which requires that a clinical evaluation be conducted before a device receives approval for commercial distribution. The FDA classifies medical devices into one of three classes. Class I devices are relatively simple and can be manufactured and distributed with general controls. Class II devices are somewhat more complex and require greater scrutiny. Class III devices are new and frequently help sustain life.

In the United States, a company generally can obtain permission to distribute a new device in two ways – through a so-called "510(k)" premarket notification application or through a Section 515 premarket approval ("PMA") application. The 510(k) submission applies to any device that is substantially equivalent to a device first marketed prior to May 28, 1976 or to another device marketed after that date, but which was substantially equivalent to a pre-May 28, 1976 device. These devices are either Class I or Class II devices. Under the 510(k) submission process, the FDA will issue an order finding substantial equivalence to a predicate device (pre-May 28, 1976 or post-May 28, 1976 device that was substantially equivalent to a pre-May 28, 1976 device) and permitting commercial distribution of that device for its intended use. A 510(k) submission must provide information supporting its claim of substantial equivalence to the predicate device. The FDA permits certain low risk medical devices to be marketed without requiring the manufacturer to submit a premarket notification. In other instances, the FDA may require that a premarket notification not only be submitted, but also be accompanied by clinical data. If clinical data from human experiments are required to support the 510(k) submissions, these data must be gathered in compliance with investigational device exemption regulations for investigations performed in the United States. The FDA review process for premarket notifications submitted pursuant to section 510(k) should take about 90 days, but it can take substantially longer if the FDA has concerns, and there is no guarantee that the FDA will clear the device for marketing, in which case the device cannot be lawfully distributed in the United States. If the FDA finds that the device subject to the premarket notification is substantially equivalent to a proper predicate device, then the FDA may "clear" that device for marketing. These devices are not "approved" by the FDA. It is very unlikely, however, that the FDA will deem our Glucotrack CBGM subject to the 510(k) process, as opposed to the more time-consuming, resource intensive and problematic PMA application process described below.

The more comprehensive PMA process applies to a new device that either is not substantially equivalent to a pre-May 28, 1976 product or is to be used in supporting or sustaining life or preventing impairment. These devices are normally Class III devices and can only be marketed following approval of a PMA application. For example, most implantable devices are subject to the PMA approval process. Two steps of FDA approval generally are required before a company can market a product in the U.S. that is subject to Section 515 PMA approval, as compared to a Section 510(k) clearance. First, a company must comply with investigational device exemption regulations in connection with any human clinical investigation of the device; however, those regulations permit a company to undertake a clinical study of a "non-significant risk" device without formal FDA

approval. Prior express FDA approval is required if the device is a significant risk device. If there is any doubt as to whether a device is a "non-significant risk" device, companies normally seek prior approval from the FDA. Normally, clinical studies of new diagnostic products are conducted in tandem with a cleared or approved device and treatment decisions are based on the results from the existing diagnostic device. In such a setting, the FDA may consider the clinical trial as one not posing a significant risk. However, FDA action is always uncertain and dependent on the contours of the design of the clinical trial and the device and there is no assurance that the FDA would consider any proposed clinical trial as one posing a non-significant risk. Moreover, before undertaking any clinical trial, the company sponsoring the trial and the investigator conducting the trial are required by federal law to seek and obtain the approval of institutional review boards ("IRB"). An IRB weighs the risks and benefits of a proposed trial to ensure that the human subjects are not exposed to unnecessary risk and reviews the informed consent form to ensure that it meets federal requirements and accurately describes the risks and benefits, if any, of the clinical trial. IRB review occurs annually, and annual re-approval is required. University medical centers as well as other entities maintain and operate IRB. Second, the FDA must review a company's PMA, which contains, among other things, clinical information acquired under the investigational device exemption. The FDA will approve the PMA if it finds there is reasonable assurance that the device is safe and effective for its intended use. The premarket approval process takes substantially longer than the 510(k) process.

The Glucotrack CBGM is still under development and has not yet been approved for commercial sale in or outside the United States. Given the implantable nature of our CBGM, it is most likely that the device will be assigned a Class III designation and need to follow the PMA process for regulatory approval. We are preparing for this approach.

Even when a clinical study has been approved or cleared by the FDA or a notified body or deemed approved, the study is subject to factors beyond a manufacturer's control, including, but not limited to the fact that the IRB at a given clinical site might not approve the study, might decline to renew approval which is required annually, or might suspend or terminate the study before the study has been completed. Also, the interim results of a study may not be satisfactory, in which case the sponsor may terminate or suspend the study on its own initiative or the FDA or a notified body may terminate or suspend the study. There is no assurance that a clinical study at any given site will progress as anticipated; there may be an insufficient number of patients who qualify for the study or who agree to participate in the study, or the investigator at the site may have priorities other than the study. Also, there can be no assurance that the clinical study will provide sufficient evidence to assure the FDA or a notified body that the product is safe and effective, a prerequisite for FDA approval of a PMA. Even if the FDA or a notified body approves or clears a device, it may limit its intended uses in such a way that manufacturing and distributing the device may not be commercially feasible.

After approval to market is given, the FDA and foreign regulatory agencies, upon the occurrence of certain events, are authorized under various circumstances to withdraw the clearance or approval or require changes to a device, its manufacturing process or its labeling or additional proof that regulatory requirements have been met.

A manufacturer of a device approved through the PMA process is not permitted to make changes to the device which affects its safety or effectiveness without first submitting a supplement application to its PMA and obtaining FDA approval for that supplement. In some instances, the FDA may require clinical trials to support a supplement application. Any change in the intended uses of a PMA device or a 510(k) device requires an approval supplement. Exported devices are subject to the regulatory requirements of each country to which the device is exported, as well as certain FDA export requirements.

The Company plans to leverage the De Novo/PMA clinical trial data, if successful, along with the associated development and manufacturing information, for CE Mark certification. The Company will choose a notified body and submit via the MDR regulations to obtain this necessary clearance for marketing in EU member states. Upon approval, if granted, the Company may consider alternative markets that can leverage both the FDA and CE Mark approvals.

Reimbursement Considerations

In the U.S. market, coverage and reimbursement from Medicare, Medicaid or other governmental healthcare programs or systems, and private third-party healthcare payors is critical to the success of a medical device company. CGM systems have been broadly accepted by Medicare and commercial third-party payors. Currently, Medicare covers CGM systems, which includes supplies necessary for the use of the device under the Durable Medical Equipment (DME), benefit category. Previously, Medicare coverage for CGM was only available to Medicare patients who take at least three doses of insulin a day. The Local Coverage Determination (LCD), that the Medicare Administrative Contractors (MACs) released in April 2023 extended Medicare CGM coverage to all patients using insulin. The LCD also allows coverage for patients not taking insulin if the patient has a history of problematic hypoglycemia.

There is currently one commercially available implantable CGM product and the current reimbursement landscape includes coverage for the product itself, coverage for the implantation process and coverage for the removal and reinsertion process. Additionally, an LCD was recently released (NGS ICGM LCD - Effective 4/1/2024) allowing for expanded access of this product to include all people with diabetes using insulin, removing the previous requirement for at least three doses of insulin a day. Like non-implantable CGM, the LCD also allows coverage for patients not taking insulin if the patient has a history of problematic hypoglycemia.

Even though CGM coverage is broad, we anticipate that sales volumes and prices of the Glucotrack CBGM will depend in large part on the availability of adequate reimbursement from Medicare and third-party payors. Medicare reimburses medical devices in a variety of ways depending on where and how the device is used. However, Medicare only provides reimbursement if CMS determines that the device should be covered and that the use of the device is consistent with the coverage criteria. A coverage determination can be made at the national level by CMS or at the local level by the Medicare administrative contractor (formerly called carriers and fiscal intermediaries) or a private contractor that processes and pays claims on behalf of CMS for the geographic area where the services were rendered. Obtaining a coverage determination, whether local or national, is a time-consuming, expensive and highly uncertain proposition, especially for a new technology, and inconsistent local determinations are possible. Our inability to obtain a favorable coverage determination for our CBGM product may adversely affect our ability to market the product and thus, the commercial viability of the product.

Additionally, we believe that the overall escalating cost of medical products and services has led to and will continue to lead to increased pressures on the healthcare industry to reduce the costs of products and services. There can be no assurance that third-party reimbursement and coverage will be available or adequate, or that future legislation, regulation, or reimbursement policies of third-party payors will not adversely affect the demand for our products or our ability to sell these products on a profitable basis. The unavailability or inadequacy of third-party payor coverage or reimbursement could have a material adverse effect on our business, operating results, and financial condition. Until adequate reimbursement or insurance coverage is established, patients may have to bear the financial cost of our products.

To mitigate these risks, we are starting our reimbursement planning process early, well in advance of obtaining regulatory approval. We have engaged a leading reimbursement consultancy to complete an analysis of the current landscape for CGM technologies. Additionally, since our product is an implantable device and very similar in form factor and procedure to commercially available cardiovascular devices, we are also assessing the current reimbursement landscape for those technologies. This will enable us to craft a reimbursement strategy that is best suited to our Glucotrack CBGM and reflects the different healthcare providers that may be involved in utilizing the product.

Our reimbursement strategy also incorporates coverage for the product, the implantation procedure, and the removal and reinsertion procedures. While we are proactively preparing our reimbursement strategy, some activities such as coding applications, if needed, are not able to be executed until FDA approval is obtained.

Outside the United States, availability of reimbursement from third parties varies widely from country to country. Within the EU member countries, healthcare reimbursement, coverage regulations, and systems differ significantly. An EU reimbursement analysis and strategy may begin if and when we decide to enter the EU market.

Anti-Fraud and Abuse Rule

There are extensive United States federal and state laws and regulations prohibiting fraud and abuse in the healthcare industry that can result in significant criminal and civil penalties that can materially affect us, if and when we receive FDA approval to market our products in the United States. These federal laws include, by way of example, the following:

- The anti-kickback statute (Section 1128B(b) of the Social Security Act), which prohibits certain business practices and relationships that might affect the provision and cost of healthcare services reimbursable under Medicare, Medicaid and other federal healthcare programs, including the payment or receipt of remuneration for the referral of patients whose care will be paid by Medicare or other governmental programs;
- The physician self-referral prohibition (Ethics in Patient Referral Act of 1989, as amended, commonly referred to as the Stark Law, Section 1877 of the Social Security Act), which prohibits referrals by physicians of Medicare or Medicaid patients to providers of a broad range of designated healthcare services in which the physicians (or their immediate family members) have ownership interests or with which they have certain other financial arrangements;
- The anti-inducement provisions of the Civil Monetary Penalties Law (Section 1128A(a)(5) of the Social Security Act), which prohibit providers from offering anything to a Medicare or Medicaid beneficiary to induce that beneficiary to use items or services covered by either program;

- The FCA (31 U.S.C. § 3729 et seq.), which prohibits any person from knowingly presenting or causing to be presented false or fraudulent claims for payment to the federal government (including the Medicare and Medicaid programs); and
- The Civil Monetary Penalties Law (Section 1128A of the Social Security Act), which authorizes the United States Department of Health and Human Services to impose civil penalties administratively for fraudulent or abusive acts.

Sanctions for violating these federal laws include criminal and civil penalties that range from punitive sanctions, damage assessments, monetary penalties, imprisonment and/or denial of Medicare and Medicaid payments or exclusion from the Medicare and Medicaid programs, or both. These laws also impose an affirmative duty on those receiving Medicare or Medicaid funding to ensure that they do not employ or contract with persons excluded from the Medicare and other government programs.

Many states have adopted or are considering legislative proposals similar to the federal fraud and abuse laws, some of which extend beyond the Medicare and Medicaid programs, to prohibit the payment or receipt of remuneration for the referral of patients and physician self-referrals regardless of whether the service was reimbursed by Medicare or Medicaid. Many states have also adopted or are considering legislative proposals to increase patient protections, such as limiting the use and disclosure of patient specific health information. These state laws also impose criminal and civil penalties similar to the federal laws.

Similarly, the EU and EU member countries may have similar fraud and abuse laws which would regulate our business in those jurisdictions. However, given the diversity of legal systems within the EU, it is difficult to predict with specificity what anti-fraud legislation and regulations may be implemented and the penalties that they impose.

In the ordinary course of their business, medical device manufacturers and suppliers have been and are subject regularly to inquiries, investigations and audits by federal and state agencies that oversee these laws and regulations. Recent federal and state legislation has greatly increased funding for investigations and enforcement actions, which have increased dramatically over the past several years. This trend is expected to continue. Private enforcement of healthcare fraud also has increased due in large part to amendments to the civil FCA that were designed to encourage private persons to sue on behalf of the government. These whistleblower suits by private persons, known as qui tam relators, may be filed by almost anyone, including present and former patients or nurses and other employees, as well as competitors. HIPAA, in addition to its privacy provisions, created a series of new healthcare-related crimes.

As federal and state budget pressures continue, federal and state administrative agencies may also continue to escalate investigation and enforcement efforts to root out waste and to control fraud and abuse in governmental healthcare programs. A violation of any of these federal and state fraud and abuse laws and regulations could have a material adverse effect on a supplier's liquidity and financial condition. An investigation into the use of a device by physicians may dissuade physicians from recommending that their patients use the device. This could have a material adverse effect on our ability to commercialize our products.

The Privacy Provisions of HIPAA

In the United States, HIPAA, among other things, protects the privacy and security of individually identifiable health information by limiting its use and disclosure. HIPAA directly regulates "covered entities," such as healthcare providers, insurers and clearinghouses, and regulates "business associates," with respect to the privacy of patients' medical information. All entities that receive and process protected health information are required to adopt certain procedures to safeguard the security of that information. It is uncertain whether we would be deemed to be a covered entity under HIPAA and, owing to changes in the law, it is uncertain, based on our current business model, whether we would be a business associate. Nevertheless, we will likely be contractually required to physically safeguard the integrity and security of any patient information that we receive, store, create or transmit in the United States. If we fail to adhere to our contractual commitments, then our physician, hospital or insurance customers may be subject to civil monetary penalties, which could adversely affect our ability to market our devices. Changes in the law wrought by the provisions of Health Information Technology for Economic and Clinical Health ("HITECH") Act, enacted as part of the American Recovery and Reinvestment Act of 2009 ("ARRA"), increase the duties of business associates and covered entities with respect to protected health information that thereby subject them to direct government regulation, increasing its compliance costs and exposure to civil monetary penalties and other government sanctions. While HITECH does not alter the definition of a business associate, it makes it more likely that covered entities with whom we are likely to do business in the United States, if and when we receive FDA approval to market the Glucotrack CBGM in the United States, will require us to enter into business associate agreements.

Intellectual Property

We are pursuing a proactive intellectual property strategy, which includes patent filings in multiple jurisdictions, including the United States and other commercially significant markets. We understand the importance of obtaining patent and trade secret protection for new technologies, products and processes. Our success will depend in large part on our ability to file for and obtain patent protection of our principal products and procedures, to defend existing or future patents, to maintain trade secrets and to operate without infringing upon the proprietary rights of others.

The Company's U.S. patent application, US20230079720A1, titled 'Methods and Systems for Continuously Monitoring the Glucose Level of a Patient,' is currently under review. Two related international applications, EP4401635A1 and WO2023044347A1, have been published and are also pending review. Additionally, the Company has filed during 2024 four new provisional patent applications: US63/563,880, 'Systems and Methods for Integrated Spinal Cord Stimulation and Glucose Monitoring'; US63/633,647, 'Methods and Systems for Continuously Monitoring the Glucose Level of a Patient'; US63/661,648, 'Methods and Systems for Continuously Monitoring the Glucose Level of a Patient' ; and US63/661,526, 'Amperometric Electrochemical Enzyme Oxidase Sensor'. We have trademark registrations for Glucotrack® in the U.S. and Europe and various other jurisdictions.

We believe that our intellectual property and products do not and will not infringe patents or violate proprietary rights of others, although it is possible that our existing patent rights may not be valid or that infringement of existing or future patents or proprietary rights may occur. Litigation may be necessary to defend or enforce our patent rights or to determine the scope and validity of the proprietary rights of others. Defense and enforcement of patent claims can be expensive and time consuming, even in those instances in which the outcome is favorable and could result in the diversion of substantial resources and management time and attention from our other activities. An adverse outcome could subject us to significant liability to third parties, require us to obtain licenses from third parties, require us to alter our products or processes, or require that we cease altogether any related research and development activities or product sales.

Patent protection is highly uncertain and involves complex legal and factual questions and issues. The patent application and issuance process can be expected to take several years and entails considerable expense. There can be no assurance that patents will be issued as a result of any applications or that any patents resulting from such applications, or our existing patents will be sufficiently broad to afford protection against competitors with similar or competing technology. Patents that we obtain may be challenged, invalidated or circumvented, or the rights granted under such patents may not provide us with any competitive advantages.

Competition

The market for CGM devices is intensely competitive, subject to rapid change and significantly affected by new product introductions. Three companies, Abbott Laboratories ("Abbott"), DexCom and Medtronic currently account for substantially all of the worldwide sales of CGM systems. These products are all transcutaneous systems with sensor longevities of 7-15 days. These systems have a sensor that is worn on the back of the upper arm or the abdomen, depending on the system. The sensor measures glucose in the interstitial fluid, which lags glucose in the blood, so the CGM readings may lag about 15-20 minutes behind blood glucose readings. Depending on the system, the sensor provides glucose readings every one to five minutes and streams directly to the users' compatible smartphone. Following the insertion of a new Abbott FreeStyle Libre 3 or DexCom G7 sensor, there is a warm-up period of 30-60 minutes, depending on the system, during which time no readings are available. After that period, both systems are factory-calibrated, which means that no fingersticks (blood glucose measurements using a glucometer) are required for calibration. For the Medtronic Guardian 4 system, there is a 2-hour warm-up period; after that period, no fingersticks are required for calibration when using as a part of the MiniMed 780G insulin pump system.

There is currently one implantable CGM that is commercially available in the US and Europe: Senseonics Holdings, Inc. The sensor is inserted by a doctor under the skin of the upper arm and lasts up to 365 days. The wearable smart transmitter provides on-body vibe alerts and is worn over the sensor using a daily adhesive. There is a 24-hour warm up period with this system and, after that period, fingersticks are required for calibration twice a day for the 1st 21 days and then once daily. Similar to the transcutaneous systems, this system also measures glucose in the interstitial fluid. All four competitors are either publicly traded or are divisions of publicly traded companies, and they enjoy several competitive advantages, including:

- significantly greater name recognition;
- established relations with healthcare professionals, customers and third-party payors;

- established distribution networks;

- additional lines of products, and the ability to offer rebates or bundle products to offer higher discounts or incentives to gain a competitive advantage;

- greater experience in conducting research and development, manufacturing, clinical trials, obtaining regulatory approval for products and marketing approved products; and

- greater financial and human resources for product development, sales and marketing, and patent litigation.

As a result, we cannot ensure that we will be able to compete effectively against these companies or their products.

There are several new and smaller players that have obtained clearance to market in EU or Asia. Their systems are transcutaneous systems with similar form factors and longevity as the Abbott, DexCom and Medtronic systems. None of these companies has yet achieved a significant user base.

Additionally, Medtronic and other companies have developed or are developing, insulin pumps integrated with CGM systems that provide, among other things, the ability to suspend insulin administration while the user's glucose levels are low and to automate basal or bolus insulin dosing. Both Abbott and DexCom have received FDA clearance to integrate certain versions of their sensors into automated insulin delivery systems.

Although we face potential competition from many different sources, we believe that our technology, experience and scientific knowledge provide us with competitive advantages of accuracy, longevity, discretion and usability, though our technology is not in any way integrated with an automatic insulin delivery system.

Corporate Information

Our principal offices are located at 301 17 North, Suite 800, Rutherford NJ 07070, and our telephone number is 201-842-7715. Our website address is http://www.glucotrack.com; the reference to such website address does not constitute incorporation by reference of the information contained on the website and such information should not be considered part of this Annual Report.

Board and Committees

We have seven members on our Board, five of whom are independent. The Board has an audit committee (the "Audit Committee"), a compensation committee and a nominating and corporate governance committee. Each of our committees consist solely of independent directors.

Employees

As of December 31, 2024, we had eleven full-time employees. None of our employees are represented by a collective bargaining agreement. In addition, as of December 31, 2024, we had three significant consultants.

Item 1A. Risk Factors

An investment in our Common Stock involves a high degree of risk. You should carefully consider the following risks and all of the other information contained in this Annual Report before deciding whether to invest in our Common Stock. If any of the following risks are realized, our business, financial condition and results of operations could be materially and adversely affected. In that event, the trading price of our Common Stock could decline, and you could lose all or part of your investment in our Common Stock. Additional risks of which we are not presently aware or that we currently believe are immaterial may also harm our business and results of operations. Some statements in this Annual Report, including such statements in the following risk factors, constitute forward-looking statements. See the section entitled "Cautionary Note Regarding Forward-Looking Statements."

Risks Related to our Business and Industry

We have a history of operating losses, and there is no assurance that we will generate material revenues or become profitable in the near future.

We are a medical device company with a limited operating history. We are not profitable and have incurred losses since our inception. To date we have not generated material revenue from the sale of products, and we do not anticipate that we will report operating income in the foreseeable future. Our initial product, Glucotrack CBGM, has not been approved for marketing in the United States and is currently under preclinical development. We continue to incur research and development and selling, marketing and general and administrative expenses related to our operations, development and commercialization of our first product. Our operating losses for the years ended December 31, 2024 and 2023 were approximately $22.6 million and $7.1 million, respectively, and we had an accumulated deficit of approximately $132.0 million as of December 31, 2024. We expect to continue to incur losses for the foreseeable future, and these losses will likely increase as we develop and prepare to commercialize Glucotrack CBGM. If we are not successful in developing, manufacturing and distributing Glucotrack CBGM, or if Glucotrack CBGM does not achieve market acceptance, we may never become profitable. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods.

As we continue to evolve from a company primarily involved in development to a company also involved in commercialization, we may encounter difficulties in managing our growth and expanding our operations successfully.

We anticipate that, as our operations expand and, assuming that our development, testing, studies and trials are successful, we will need to expand our manufacturing, marketing and sales capabilities by contracting with third parties. Maintaining these relationships and managing our future growth will impose significant added responsibilities on members of our management team. We must be able to manage our development efforts effectively; manage our clinical trials effectively; hire, train and integrate additional management, development, administrative and sales and marketing personnel; improve managerial, development, operational and finance systems; and expand our facilities, all of which may impose a strain on our administrative and operational infrastructure.

We may have future capital needs and may not be able to obtain additional financing on acceptable terms.

Economic and credit market conditions, the performance of our industry and our financial performance, as well as other factors, may constrain our financing abilities. Our ability to secure additional financing, if available, and to satisfy our financial obligations under indebtedness outstanding from time to time will depend upon our future operating performance, the availability of credit, economic conditions and financial, business and other factors, many of which are beyond our control.

We may require additional financing to fund our operations and growth. The failure to secure additional financing could have an adverse effect on our continued development or growth. None of our officers, directors or stockholders is required to provide any financing to us.

Raising additional capital may cause dilution to our existing stockholders and investors, restrict our operations, or require us to relinquish rights to our products and/or product candidates on unfavorable terms to us.

We will seek additional capital through a variety of means, including through private and public equity offerings and debt financings, collaborations, strategic alliances and marketing, distribution or licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, or through the issuance of shares under other types of contracts, or upon the exercise or conversion of outstanding options, warrants, convertible debt or other similar securities, the ownership interests of our stockholders will be diluted, and the terms of such financings may include liquidation or other preferences, anti-dilution rights, conversion and exercise price adjustments and other provisions that adversely affect the rights of our stockholders, including rights, preferences and privileges that are senior to those of our holders of Common Stock in terms of the payment of dividends or in the event of a liquidation. In addition, debt financing, if available, could include covenants limiting or restricting our ability to take certain actions, such as incurring additional debt, making capital expenditures, entering into licensing arrangements or declaring dividends and may require us to grant security interests in our assets. If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, product or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financing when needed, we may need to curtail or cease our operations.

Our independent registered public accounting firm's report contains an explanatory paragraph that expresses substantial doubt about our ability to continue as a "going concern."

We may not have sufficient liquidity to meet our anticipated obligations over the next year from the issuance of the financial statements contained in this Annual Report. We have incurred net losses and negative cash flows from our operations and comprehensive loss since our inception and as of December 31, 2024, we had an accumulated deficit of $132.5 million. These conditions raise substantial doubt about the Company's ability to continue as a going concern.

Economic crises and market instability may materially and adversely affect the demand for our products, as well as our ability to obtain credit or secure funds through sales of our stock, which may materially and adversely affect our business, financial condition and ability to fund our operations.

Economic crises may reduce the demand for new and innovative medical devices, resulting in delayed market acceptance of our products, if and when they are approved. Such a delay could have a material adverse impact on our business, expected cash flows, results of operations and financial condition. Additionally, we have funded our operations to date primarily through public and private sales of securities, including Common Stock and other securities convertible into or exercisable for shares of our Common Stock. Economic turmoil and instability in the world's equity and credit markets may materially adversely affect our ability to sell additional securities and/or borrow cash. There can be no assurance that we will be able to raise additional working capital on acceptable terms or at all, and any failure to do so may materially adversely affect our ability to continue operations.

Glucotrack CBGM is not approved for sale in the United States or other jurisdictions.

We will likely be required to undertake significant clinical trials to demonstrate to the FDA that Glucotrack CBGM is safe and effective for its intended use (refer to "*Business – Regulatory Considerations*"). We may also be required to undertake similar clinical trials by non-U.S. regulatory agencies, particularly for the European Union (CE Mark). Clinical trials for implantable medical devices are expensive and uncertain processes that take years to complete. Failure can occur at any point in the process and early positive results do not ensure that the entire clinical trial will be successful. Product candidates in clinical trials may fail to show desired efficacy and safety traits despite early promising results. A number of companies in the medical device industry have suffered significant setbacks in advanced clinical trials, even after their product candidates demonstrated promising results at earlier points.

Positive results from the limited safety and performance pre-clinical trials and first-in-human acute clinical studies that we have conducted should not be relied upon as evidence that early-stage or large-scale clinical trials will succeed. Despite efforts to choose the proper animal model reflecting our intended use, our pre-clinical animal trials and first-in-human acute clinical studies cannot be a guarantee of clinical trial success because human physiology and anatomy are different. Because of the sample size, possible variation in methodology or differences in physiology, the results of these pre-clinical trials may not be indicative of future results. We will be required to demonstrate through well-controlled clinical trials that Glucotrack CBGM or future product candidates, if any, are safe and effective for their intended uses.

Further, the Glucotrack CBGM or our future product candidates, if any, may not be cleared or approved, as the case may be, even if the clinical data are satisfactory and support, in our view, its or their clearance or approval. The FDA or other non-U.S. regulatory authorities may disagree with our trial design or interpretation of the clinical data. In addition, any of these regulatory authorities may change requirements for the clearance or approval of a product candidate even after reviewing and providing comment on a protocol for a pivotal clinical trial that has the potential to result in FDA approval. In addition, any of these regulatory authorities may also clear or approve a product candidate for fewer or more limited uses than we request or may grant clearance or approval contingent on the performance of costly post-marketing clinical trials. In addition, the FDA or other non-regulatory authorities may not approve the labeling claims necessary or desirable for the successful commercialization of Glucotrack CBGM or our future product candidates, if any.

We are highly dependent on the success of our product candidate, Glucotrack CBGM, and cannot give any assurance that it will receive regulatory approval or clearance or be successfully commercialized.

We are highly dependent on the success of our product candidate, Glucotrack CBGM. We cannot give any assurance that the FDA will permit us to clinically test the device, nor can we give any assurance that the clinical trials will be successful or that Glucotrack CBGM will receive regulatory clearance or approval or be successfully commercialized, for a number of reasons, including, without limitation, the potential introduction by our competitors of more clinically-effective or cost-effective alternatives, failure in our sales and marketing efforts, or the failure to obtain positive coverage determinations or reimbursement. Any failure to obtain approval to conduct clinical trials, favorable clinical data, clearance or approval of or to successfully commercialize Glucotrack CBGM would have a material adverse effect on our business.

If our competitors develop and market products that are more effective, safer or less expensive than Glucotrack CBGM or our future product candidates, if any, our commercial opportunities will be adversely affected.

The life sciences industry is highly competitive, and we face significant competition from many medical device companies that are researching and marketing products designed to address the needs of people suffering from diabetes. We are currently developing medical devices that will compete with other medical devices that currently exist or are being developed. Some of our competitors have significantly greater financial, manufacturing, marketing and product development resources than we do. Large medical device companies, in particular, have extensive experience in clinical testing and in obtaining regulatory clearances or approvals for medical devices. These companies also have significantly greater research and marketing capabilities than us. Some of the medical device companies that we expect to compete with include Abbott Laboratories, DexCom, Medtronic, and Senseonics. In addition, many universities and private and public research institutions are or may become active in research involving blood glucose measurement devices.

We believe that our ability to successfully compete will depend on, among other things:

- our ability to have partners manufacture and sell commercial quantities of any approved products to the market;
- acceptance of product candidates by physicians and other health care providers;
- the results of our clinical trials;
- our ability to recruit and enroll patients for our clinical trials;
- the efficacy, safety, performance and reliability of our product candidates;
- the speed at which we develop product candidates;
- our ability to obtain prompt and favorable IRB review and approval at each of our clinical sites;
- our ability to commercialize and market any of our product candidates that may receive regulatory clearance or approval;
- our ability to design and successfully execute appropriate clinical trials;
- the timing and scope of regulatory clearances or approvals;
- appropriate coverage and adequate levels of reimbursement under private and governmental health insurance plans, including Medicare; and
- our ability to protect intellectual property rights related to our products.

If our competitors market products that are more effective, safer, easier to use or less expensive than Glucotrack CBGM or our future product candidates, if any, or that reach the market sooner than Glucotrack CBGM or our future product candidates, if any, we may not achieve commercial success. In addition, the medical device industry is characterized by rapid technological change. It may be difficult for us to stay abreast of the rapid changes in each technology. If we fail to stay at the forefront of technological change, we may be unable to compete effectively. Technological advances or products developed by our competitors may render our technologies or product candidates obsolete or less competitive.

A number of medical device companies, medical researchers and pharmaceutical companies are also pursuing new delivery technologies, procedures, drugs and other therapies for the monitoring, treatment and prevention of diabetes. If successful, these technologies could render glucose monitoring devices, like the Glucotrack CBGM, obsolete. Technological breakthroughs in diabetes treatment or prevention could reduce the potential market for Glucotrack CBGM, making it less competitive or obsolete altogether.

The diabetes market is currently seeing increasing use of GLP-1 drugs for the treatment of obesity and Type 2 diabetes. While we believe that GLP-1s are a companion product and can be used in conjunction with CGM systems, such drugs could potentially compete with the Glucotrack CBGM and impact successful commercialization.

Our product development activities could be delayed or stopped.

We do not know whether our future clinical trials will begin on time, or at all, and whether ongoing and/or future clinical trials will be completed on schedule, or at all.

The commencement of future clinical trials could be substantially delayed or prevented by several factors, including:

- the failure to obtain sufficient funding to pay for all necessary clinical trials;
- limited number of, and competition for, suitable patients that meet the protocol's inclusion criteria and do not meet any of the exclusion criteria;
- limited number of, and competition for, suitable sites to conduct the clinical trials, and delay or failure to obtain FDA approval, if necessary, to commence a clinical trial;
- delay or failure to obtain sufficient supplies of the product candidate for clinical trials;
- requirements to provide the medical device required in clinical trials at cost, which may require significant expenditures that we are unable or unwilling to make;
- delay or failure to reach agreement on acceptable clinical trial agreement terms or clinical trial protocols with prospective sites or investigators; and
- delay or failure to obtain IRB approval or renewal of such approval to conduct a clinical trial at a prospective or accruing site, respectively.

The completion of clinical trials in connection with our application for FDA approval could also be substantially delayed or prevented by several factors, including:

- slower than expected rates of patient recruitment and enrollment;
- failure of patients to complete the clinical trial;
- unforeseen safety issues;
- lack of efficacy evidenced during clinical trials;
- termination of clinical trials by one or more clinical trial sites;
- inability or unwillingness of patients or medical investigators to follow clinical trial protocols; and
- inability to monitor patients adequately during or after treatment.

Our clinical trials may be suspended or terminated at any time by the FDA, other regulatory authorities, the IRB for any given site or us. Any failure or significant delay in completing clinical trials for Glucotrack® or future product candidates, if any, could materially harm our financial results and the commercial prospects for our product candidates.

The regulatory approval process is expensive, time-consuming and uncertain and may prevent us from obtaining approvals for the commercialization of Glucotrack CBGM or our future product candidates, if any.

The research, testing, manufacturing, labeling, approval, selling, marketing and distribution of medical devices are subject to extensive regulation by the FDA and other non-U.S. regulatory authorities, with regulations that differ from country to country. We are not permitted to market our product candidates in the United States until we receive a clearance letter under Section 515 premarket approval from the FDA. We have not submitted an application or premarket notification for or received marketing clearance or approval for our current product candidate. Obtaining approval of any premarket approval can be a lengthy, expensive and uncertain process, particularly for Class III devices under which our product candidate falls. In lieu of acting on a premarket notification, the FDA may seek additional information or additional data which would further delay our ability to market the product candidate. In addition, failure to comply with FDA, non-U.S. regulatory authorities or other applicable U.S. and non-U.S. regulatory requirements may, either before or after product clearance or approval, if any, subject us to administrative or judicially imposed sanctions, including:

- restrictions on the products, manufacturers or manufacturing process;

- adverse inspectional observations (Form 483), warning letters or non-warning letters incorporating inspectional observations, i.e., so-called "untitled letter";
- civil and criminal penalties;
- injunctions;
- suspension or withdrawal of regulatory clearances or approvals;
- product seizures, detentions or import bans;
- voluntary or mandatory product recalls and publicity requirements;
- total or partial suspension of production;
- imposition of restrictions on operations, including costly new manufacturing requirements; and
- refusal to clear or approve pending applications or premarket notifications.

Regulatory approval of a PMA or PMA supplement is not guaranteed, and the approval will take several years when factoring in clinical trial timelines. The FDA also has substantial discretion in the medical device clearance or approval processes. Despite the time and expense exerted, failure can occur at any stage, and we could encounter problems that cause us to abandon clinical trials or to repeat or perform additional pre-clinical studies and clinical trials. The number of pre-clinical studies and clinical trials that will be required for FDA clearance or approval varies depending on the medical device candidate, the disease or condition that the medical device candidate is designed to address and the regulations applicable to any particular medical device candidate. The FDA can delay, limit or deny clearance or approval of a medical device candidate for many reasons, including:

- a medical device candidate may not be deemed safe or effective;
- FDA officials may not find the data from the clinical trials sufficient;
- the FDA might not approve our third-party manufacturer's processes or facilities; or
- the FDA may change its clearance or approval policies or adopt new regulations.

Failure to recruit and enroll patients for clinical trials may cause the development of our product candidates to be delayed.

We may encounter delays if we are unable to recruit, enroll and retain enough patients to complete clinical trials. Patient enrollment depends on many factors, including the size of the patient population, the nature of the protocol, the proximity of patients to clinical sites and the eligibility criteria for the trial. Delays in patient enrollment are not unusual. Any such delays in planned patient enrollment may result in increased costs, which could harm our ability to develop products.

The terms of clearances or approvals and ongoing regulation of our products may limit how we manufacture and market our product candidates, which could materially impair our ability to generate anticipated revenues.

Once regulatory clearance or approval has been granted, the cleared or approved product and its manufacturer are subject to continual review. Any cleared or approved product may only be promoted for its indicated uses. In addition, if the FDA or other non-U.S. regulatory authorities clear or approve Glucotrack CBGM or our future product candidates, if any, the labeling, packaging, adverse event reporting, storage, advertising and promotion for the product will be subject to extensive regulatory requirements. We, and the manufacturers of our products also will be required to comply with the FDA's Quality System Regulation, which includes requirements relating to quality control and quality assurance, as well as the corresponding maintenance of records and documentation. Moreover, device manufacturers are required to report adverse events by filing Medical Device Reports with the FDA, which are publicly available. Further, regulatory agencies must approve our manufacturing facilities before they can be used to manufacture products, and these facilities are subject to ongoing regulatory inspection. If we fail to comply with the regulatory requirements of the FDA and other non-U.S. regulatory authorities, or if previously unknown problems with our products, manufacturers or manufacturing processes are discovered, we could be subject to administrative or judicially imposed sanctions, including:

- restrictions on the products, manufacturers or manufacturing process;
- adverse inspectional observations (Form 483), warning letters, or non-warning letters incorporating inspectional observations;

- civil or criminal penalties or fines;
- injunctions;
- product seizures, detentions or import bans;
- voluntary or mandatory product recalls and publicity requirements;
- suspension or withdrawal of regulatory clearances or approvals;
- total or partial suspension of production;
- imposition of restrictions on operations, including costly new manufacturing requirements; and
- refusal to clear or approve pending applications or premarket notifications.

In addition, the FDA and other non-U.S. regulatory authorities, including the EU and each of the EU member countries individually, may change their policies and enact additional regulations that could prevent or delay regulatory clearance or approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are not able to maintain regulatory compliance, we will likely not be permitted to market future product candidates and may not achieve or sustain profitability.

Even if we receive regulatory clearance or approval to market Glucotrack CBGM or our future product candidates, if any, the market may not be receptive to our products.

Even if Glucotrack CBGM or our future product candidates, if any, obtain regulatory clearance or approval, resulting products may not gain market acceptance among physicians, patients, health care payors or the medical community. We believe that the degree of market acceptance will depend on a number of factors, including:

- timing of market introduction of competitive products;
- safety and efficacy of our product;
- prevalence and severity of any side effects;
- potential advantages or disadvantages over alternative treatments;
- strength of marketing and distribution support;
- price of our product candidates, both in absolute terms and relative to alternative treatments; and
- availability of coverage and reimbursement from government and other third-party payors.

If the Glucotrack CBGM or our future product candidates, if any, fail to achieve market acceptance, we may not be able to generate significant revenue or achieve or sustain profitability.

The coverage and reimbursement status of newly cleared or approved medical devices is uncertain, and failure to obtain adequate coverage and adequate reimbursement could limit our ability to market Glucotrack CBGM or future product candidates, if any, and may inhibit our ability to generate revenue from Glucotrack CBGM or our future product candidates, if any, that may be cleared or approved.

There is significant uncertainty related to the third-party coverage and reimbursement of newly cleared or approved medical devices. The commercial success of Glucotrack CBGM or our future product candidates, if any, in both domestic and international markets will depend in part on the availability of coverage and adequate reimbursement from third-party payors, including government payors, such as the Medicare and Medicaid programs, managed care organizations and other third-party payors. Government and other third-party payors are increasingly attempting to contain health care costs by limiting both coverage and the level of reimbursement for new products and, as a result, they may not cover or provide adequate payment

for Glucotrack CBGM or our future product candidates, if any. These payors may conclude that our products are not as safe or effective as existing devices or that the overall cost of using one of our devices exceeds the overall cost of the competing device, and third-party payors may not approve Glucotrack CBGM or our future product candidates, if any, for coverage and adequate reimbursement. Furthermore, deficit reduction and austerity measures in the United States and abroad may put further pressure on governments to limit coverage of, and reimbursement for, our products. The failure to obtain coverage and adequate reimbursement for Glucotrack CBGM or our future product candidates, if any, or health care cost containment initiatives that limit or restrict reimbursement for such products, may reduce any future product revenue.

We may not obtain insurance coverage to adequately cover all significant risk exposures.

We will be exposed to liabilities that are unique to the products we provide. We currently maintain commercial general liability and property insurance, but there can be no assurance that we will acquire or maintain insurance for certain risks, that the amount of our insurance coverage will be adequate to cover all claims or liabilities or that we will not be forced to bear substantial costs resulting from risks and uncertainties of business. It is also not possible to obtain insurance to protect against all operational risks and liabilities. The failure to obtain adequate insurance coverage on terms favorable to us, or at all, could have a material adverse effect on our business, financial condition and results of operations.

If product liability lawsuits are brought against us, we may incur substantial liabilities.

We face a potential risk of product liability as a result of any of the products that we offer for sale. For example, we may be sued if any product we sell allegedly causes injury or is found to be otherwise unsuitable during product testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability and a breach of warranties. Claims could also be asserted under state or federal consumer protection laws or regulations. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities. Even successful defense would require significant financial and managerial resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for products that we may offer for sale;
- injury to our reputation;
- costs to defend the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions; and
- a decline in our stock price.

Our inability to obtain and retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of products we develop. We currently maintain product liability insurance up to $5,000 per claim and in the aggregate. Although we have product liability coverage, we may have to pay amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts.

If we fail to attract and retain key management and scientific personnel, we may be unable to successfully develop or commercialize Glucotrack CBGM or our future product candidates, if any.

We will need to expand and effectively manage our managerial, operational, financial, development and other resources in order to successfully pursue our research, development and commercialization efforts for Glucotrack CBGM or our future product candidates, if any. Our success depends on our continued ability to attract, retain and motivate highly qualified management and pre-clinical and clinical personnel. The loss of the services of any of our executive and senior management could delay or prevent the development or commercialization of Glucotrack CBGM or our future product candidates, if any. At present, we do not have executive insurance policies with respect to any of our employees. We will need to hire additional personnel as we continue to expand our research and development activities and build a sales and marketing function.

We may not be able to attract or retain qualified management and scientific personnel in the future due to the intense competition for qualified personnel among medical device and other businesses. If we are not able to attract and retain the necessary personnel to accomplish our business objectives, we may experience constraints that will significantly impede the achievement of our research and development objectives, our ability to raise additional capital and our ability to implement our business strategy. In particular, if we lose any members of our executive or senior management teams, we may not be able to find suitable replacements in a timely fashion or at all and our business may be harmed as a result.

We rely on third parties to manufacture and supply our product.

We do not own or operate manufacturing facilities for clinical or commercial production of Glucotrack CBGM, other than a prototype lab. We have no experience in medical device manufacturing and lack the resources and the capability to manufacture the Glucotrack CBGM on a commercial scale.

If our manufacturing partners are unable to produce our products in the amounts, timing or pricing that we require, we may not be able to establish a contract and obtain a sufficient alternative supply from another supplier on a timely basis and in the quantities or pricing we require. We expect to depend on third-party contract manufacturers for the foreseeable future.

Glucotrack CBGM does, and our future product candidates, if any, likely will require precise, high quality manufacturing. Any of our contract manufacturers will be subject to ongoing periodic unannounced inspections by the FDA and other non-U.S. regulatory authorities to ensure strict compliance with quality system regulations, including current good manufacturing practices and other applicable government regulations and corresponding standards. If our contract manufacturers fail to achieve and maintain high manufacturing standards in compliance with quality system regulations, we may experience manufacturing errors resulting in patient injury or death, product recalls or withdrawals, delays or interruptions of production or failures in product testing or delivery, delay or prevention of filing or approval of marketing applications for our products, cost overruns or other problems that could seriously harm our business.

Any performance failure on the part of our third-party manufacturers could delay clinical development or regulatory clearance or approval of our product candidates or commercialization of our future product candidates, if any, depriving us of potential product revenue and resulting in additional losses. In addition, our dependence on a third-party for manufacturing may adversely affect our future profit margins. Our ability to replace an existing manufacturer may be difficult because the number of potential manufacturers is limited and the FDA must approve any replacement manufacturer before it can begin manufacturing our product candidates. Such approval would require additional non-clinical testing and compliance inspections. It may be difficult or impossible for us to identify and engage a replacement manufacturer on acceptable terms in a timely manner, or at all.

Independent clinical investigators and contract research organizations that we may engage to conduct our clinical trials may not be diligent, careful or timely.

We will depend on independent clinical investigators to conduct our clinical trials. Contract research organizations may also assist us in the collection and analysis of data. These investigators and contract research organizations will not be our employees and we will not be able to control, other than by contract, the amount of resources spent on our endeavors, including time that they devote to products that we develop. If independent investigators fail to devote sufficient resources to the clinical trials, or if their performance is substandard, it will delay the approval or clearance and commercialization of any products that we develop. Further, the FDA requires that we comply with standards, commonly referred to as good clinical practice, for conducting, recording and reporting clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial subjects are protected. If our independent clinical investigators and contract research organizations fail to comply with good clinical practice, the results of our clinical trials could be called into question and the clinical development of our product candidates could be delayed. Failure of clinical investigators or contract research organizations to meet their obligations to us or comply with federal regulations could adversely affect the clinical development of our product candidates and harm our business.

Our business may become subject to economic, political, regulatory and other risks associated with international operations, which could harm our business.

Our business is subject to risks associated with conducting business internationally. Accordingly, our future results could be harmed by a variety of factors, including:

- difficulties in compliance with non-U.S. laws and regulations;

- changes in non-U.S. regulations and customs;
- changes in non-U.S. currency exchange rates and currency controls;
- changes in a specific country or region's political or economic environment;
- trade protection measures, import or export licensing requirements or other restrictive actions by U.S. or non-U.S. governments;
- negative consequences from changes in tax laws; and
- difficulties associated with staffing and managing foreign operations, including differing labor relations.

The funding that we received through the Israeli Innovation Authority ("IIA") for research and development activities restricts our ability to manufacture products or to transfer technology outside of Israel.

On March 4, 2004, the IIA agreed to provide us with a grant of 420 New Israeli Shekels ("NIS"), or approximately $93 at an exchange rate of 4.502 NIS/dollar (the exchange rate in effect on such date), for our plan to develop a non-invasive blood glucose monitor (the "development plan"). This grant constituted 60% of our research and development budget for the development plan at that time. Due to our acceptance of this grant, we are subject to the provisions of the Israeli Law for the Encouragement of Industrial Research and Development, 1984 (the "R&D Law"). Among other things, the R&D Law restricts the ability to sell or transfer rights in technology or know-how developed with IIA funding or transfer any Means of Control (as defined in the R&D Law) of us to non-Israeli entities. The Industrial Research and Development Committee at the IIA (the "research committee") may, under special circumstances, approve the transfer outside of Israel of rights in technology or know-how developed with IIA funding subject to certain conditions, including the condition that certain payments be made to the IIA. Additionally, products developed with IIA funding outside of Israel cannot be manufactured without the approval of a research committee. The restrictions regarding the sale or transfer of technology or manufacturing rights out of Israel could have a material adverse effect on the ability to enter into strategic alliances or enter into merger or acquisition transactions in the future that provide for the sale or transfer of technology or manufacturing rights.

In late 2023, the Company abandoned pursuit of its Israeli originated first generation product development programs top focus solely on its next generation CBGM product development efforts for FDA market approval.

Risks Related to Owning our Common Stock

We have never declared or paid any cash dividends on our Common Stock and do not anticipate paying any dividends on our Common Stock in the foreseeable future.

We have never declared or paid any cash dividends on our Common Stock and do not anticipate paying any dividends on our Common Stock in the foreseeable future. Any cash that might be available for payment of dividends will be used to expand our business. Payments of any cash dividends in the future will depend on our financial condition, results of operation and capital requirements, as well as other factors deemed relevant to our Board of Directors.

If we are unable to continue to satisfy the applicable continued listing requirements of Nasdaq, our Common Stock could be delisted, and we and our stockholders could face significant material adverse consequences.

In order to remain listed on Nasdaq, we must satisfy minimum financial and other continued listing requirements and standards, including those regarding director independence and independent committee requirements, minimum stockholders' equity, minimum share price, and certain corporate governance requirements.

For example, Nasdaq Listing Rule 5550(b)(1) requires companies listed on Nasdaq to maintain a minimum of $2,500,000 in stockholders' equity for continued listing (the "Minimum Stockholders' Equity Requirement"). On May 21, 2024, the Nasdaq Qualifications Listing Staff (the "Staff") notified us that our Form 10-Q for the period ended March 31, 2024, indicated that we no longer met the Minimum Stockholders' Equity Requirement. Failure to meet the Minimum Stockholders' Equity Requirement is a basis for delisting our Common Stock.

Because we were not in compliance with the requirement to maintain a minimum bid price of $1.00 per share for continued listing on Nasdaq as set forth in Nasdaq Listing Rule 5550(a)(2) (the "Bid Price Rule"), at the time we were notified about the non-compliance with the Minimum Stockholders' Equity Requirement, we were not eligible to submit a plan to regain compliance with the Staff. However, we timely requested a hearing before the Nasdaq Hearings Panel (the "Panel") and paid the fee, which resulted in a stay of any suspension or delisting action pending the hearing. The hearing took place on July 9, 2024, and on August 5, 2024, we received the decision of the Panel, and they granted us an extension until November 18, 2024 to regain compliance with the Minimum Stockholders' Equity Requirement.

On November 19, 2024, the Company received a compliance letter (the "Compliance Letter") from Nasdaq, informing the Company that it had regained compliance with the Minimum Stockholders' Equity Requirement. The Compliance Letter noted, that because the Company's bid price has closed below the minimum required by the Bid Price Rule following the November Offering (defined blow), the Panel has determined to impose on the Company a Discretionary Panel Monitor, pursuant to Listing Rule 5815(d)(4)(B), for a period of one year from the date of the Compliance Letter, to ensure that the Company maintains long-term compliance with the Minimum Stockholders' Equity Requirement, the Bid Price Rule, and all of Nasdaq's continued listing requirements.

There can be no assurance that we will be able to continue to maintain compliance with Nasdaq's continued listing requirements, the Bid Price Rule, or other Nasdaq listing requirements. If we are not able to comply with applicable listing standards, our shares of Common Stock will be subject to delisting.

If Nasdaq delists our Common Stock from trading on its exchange for failure to meet comply with the Bid Price Rule, or any other listing standards, we and our stockholders could face significant material adverse consequences including, but not limited to:

- a limited availability of market quotations for our securities;
- a reduction in liquidity and market price of our Common Stock;
- a reduction in the number of investors willing to hold or acquire our Common Stock, which could negatively impact our ability to raise equity financing;
- 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, possibly resulting in a reduced level of trading activity in the secondary trading market for our Common Stock;
- a limited amount of analyst coverage; and
- a decreased ability to issue additional securities or obtain additional financing in the future.

We had identified a material weakness in our internal control over financial reporting, and we may not be able to successfully implement remedial measures.

We identified material weaknesses related to our internal control over financial reporting as of December 31, 2024 and concluded that internal control over financial reporting as at December 31, 2024 were not effective. The ineffectiveness of the Company's internal control over financial reporting was due to identification of material weaknesses related to lack of sufficient internal accounting personnel, segregation of duties, and lack of sufficient internal controls (including IT general controls) that encompass the Company as a whole with respect to entity and transaction level controls in order to ensure complete documentation of complex and non-routine transactions and adequate financial reporting.

Further, there can be no assurance that we will not suffer from other material weaknesses or significant deficiencies in the future. If we fail to remediate these material weaknesses or fail to otherwise maintain effective internal controls over financial reporting in the future, such failure could result in a material misstatement of our annual or quarterly financial statements that would not be prevented or detected on a timely basis and which could cause investors and other users to lose confidence in our financial statements, limit our ability to raise capital and have a negative effect on the trading price of our Common Stock. Additionally, failure to remediate the material weakness or otherwise maintain effective internal controls over financial reporting may also negatively impact our operating results and financial condition, impair our ability to timely file our periodic and other reports with the SEC, subject us to additional litigation and regulatory actions and cause us to incur substantial additional costs in future periods relating to the implementation of remedial measures.

The market price of our Common Stock has been volatile and may continue to be volatile due to numerous circumstances beyond our control, and stockholders could lose all or part of their investment.

The market price of our Common Stock has been and may continue to be highly volatile. Our stock price could be subject to wide fluctuations in response to a variety of factors, including, without limitation:

- results of trials or studies;
- the announcement of new products or product enhancements by us or our competitors;
- developments concerning intellectual property rights and regulatory approvals;
- variations in our and our competitors' results of operations;
- changes in earnings estimates or recommendations by securities analysts, if the Common Stock is covered by analysts;
- developments in the medical device industry;
- the results of product liability or intellectual property lawsuits;
- sales, or the perception that future sales may occur, of equity securities or issuance of debt;
- future issuances of Common Stock or other securities;
- the addition or departure of key personnel;
- changes in state, provincial, or federal regulations affecting us and our industry;
- economic, political, and other external factors;
- announcements by us or our competitors of acquisitions, investments or strategic alliances; and
- general market conditions and other factors, including factors unrelated to our operating performance.

In addition, the stock market in general, and the market for medical device companies in particular, have experienced extreme price and volume fluctuations. Continued or renewed market fluctuations could result in extreme volatility in the price of our Common Stock, which could cause a decline in the value of the Common Stock.

Risks Related to Intellectual Property

If we are unable to obtain and enforce patent protection for our products, our business could be materially harmed.

Our success depends, among other things, on our ability to protect proprietary methods and technologies that we develop under the patent and other intellectual property laws of the United States and other countries, so that we can prevent others from unlawfully using our inventions and proprietary information. However, we may not hold proprietary rights to some patents required for us to commercialize proposed products. For this and other reasons, we may be unable to secure desired patent rights, thereby losing desired exclusivity. Although we do not believe that we need any licenses for Glucotrack CBGM, we may need to obtain licenses in the future for other products or in certain circumstances, such as if one of our patents were declared invalid in the future. If such licenses are not available to us on acceptable terms, we will not be able to market the affected products or conduct the desired activities, unless we successfully challenge the validity, enforceability or infringement of the third-party patent or otherwise circumvent the third-party patent.

Our strategy depends on our ability to rapidly identify and seek patent protection for our discoveries. The process of obtaining patent protection is expensive and time-consuming. Despite our efforts to protect our proprietary rights, unauthorized parties may be able to obtain and use information that we regard as proprietary.

The issuance of a patent does not guarantee that it is valid or enforceable. Any patents we have obtained, or which we may obtain in the future, may be challenged, invalidated, unenforceable or circumvented. Moreover, the United States Patent and Trademark Office (the "USPTO") may commence interference proceedings involving our patents or patent applications. Any challenge to, finding of unenforceability or invalidation or circumvention of our patents or patent applications would be costly, would require significant time and attention of our management and could have a material adverse effect on our business. In addition, court decisions may introduce uncertainty in the enforceability or scope of patents owned by medical device companies.

Our pending patent applications may not result in issued patents. The patent position of medical device companies, including us, is generally uncertain and involves complex legal and factual considerations. The standards that the USPTO and its foreign counterparts use to grant patents are not always applied predictably or uniformly and can change. There is also no uniform, worldwide policy regarding the subject matter and scope of claims granted or allowable in medical device patents. Accordingly, we do not know the degree of future protection for our proprietary rights or the breadth of claims that will be allowed in any patents issued to us or to others. The legal systems of certain countries do not favor the aggressive enforcement of patents, and the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. Therefore, the enforceability or scope of our patents in the United States or in foreign countries cannot be predicted with certainty, and, as a result, any patents that we own may not provide sufficient protection against competitors. We may not be able to obtain or maintain patent protection for our pending patent applications or those we may file in the future.

We cannot assure you that any patents that will issue, that may issue or that may be licensed to us will be enforceable or valid or will not expire prior to the commercialization of our product candidates, thus allowing others to more effectively compete with us. Therefore, any patents that we own may not adequately protect our product candidates or our future products.

If we are unable to protect the confidentiality of our proprietary information and know-how, the value of our technology and products could be adversely affected.

In addition to patent protection, we also rely on other proprietary rights, including protection of trade secrets, know-how and confidential and proprietary information. To maintain the confidentiality of trade secrets and proprietary information, we will seek to enter into confidentiality and non-disclosure agreements with our employees, consultants and collaborators upon the commencement of their relationships with us. These agreements generally require that all confidential information developed by the individual or made known to the individual by us during the course of the individual's relationship with us be kept confidential and not disclosed to third parties. Our agreements with employees also generally provide and will generally provide that any inventions conceived by the individual in the course of rendering services to us shall be our exclusive property. However, we may not obtain these agreements in all circumstances, and individuals with whom we have these agreements may not comply with their terms. In the event of unauthorized use or disclosure of our trade secrets or proprietary information, these agreements, even if obtained, may not provide meaningful protection, particularly for trade secrets or other confidential information. To the extent that our employees, consultants or contractors use technology or know-how owned by third parties in their work for us, disputes may arise between us and those third parties as to the rights in related inventions.

Adequate remedies may not exist in the event of unauthorized use or disclosure of our confidential information. The disclosure of trade secrets would impair our competitive position and may materially harm our business, financial condition and results of operations.

Our commercial success depends significantly on our ability to operate without infringing the patents and other proprietary rights of third parties.

Other entities may have or obtain patents or proprietary rights that could limit our ability to manufacture, use, sell, offer for sale or import products or impair our competitive position. In addition, to the extent that a third party develops new technology that covers our products, we may be required to obtain licenses to that technology, which licenses may not be available on commercially reasonable terms, if at all. If licenses are not available on acceptable terms, we will not be able to market the affected products or conduct the desired activities unless we successfully challenge the validity, enforceability or infringement of the third-party patent or circumvent the third-party patent, which would be costly and would require significant time and attention of our management. Third parties may have or obtain valid and enforceable patents or proprietary rights that could block us from developing products using our technology. Our failure to obtain a license to any technology that we require may materially harm our business, financial condition and results of operations.

If we become involved in patent litigation or other proceedings related to a determination of rights, we could incur substantial costs and expenses, substantial liability for damages or be required to stop our product development and commercialization efforts.

Third parties may sue us for infringing their patent rights. Likewise, we may need to resort to litigation to enforce a patent issued or licensed to us or to determine the scope and validity of proprietary rights of others. In addition, a third party may claim that we have improperly obtained or used our confidential or proprietary information. The cost to us of any litigation or other proceeding relating to intellectual property rights, even if resolved in our favor, could be substantial, and the litigation would divert management's efforts. Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. Uncertainties resulting from the initiation and continuation of any litigation could limit our ability to continue our operations.

If any parties successfully claim that our creation or use of proprietary technologies infringes upon their intellectual property rights, we might be forced to pay damages, potentially including treble damages, if we are found to have willfully infringed on such parties' patent rights. In addition to any damages we might have to pay, a court could require us to stop the infringing activity or obtain a license. Any license required under any patent may not be made available on commercially acceptable terms, if at all. In addition, such licenses are likely to be non-exclusive and, therefore, our competitors may have access to the same technology. If we fail to obtain a required license and are unable to design technology that does not infringe upon a patent belonging to a third party, we may be unable to effectively market some of our technology and products, which could limit our ability to generate revenues or achieve profitability and possibly prevent us from generating revenue sufficient to sustain operations.

Security threats to our information technology infrastructure could expose us to liability and damage our reputation and business.

It is essential to our business strategy that our technology and network infrastructure remain secure and are perceived by our customers and corporate partners to be secure. Despite security measures, however, any network infrastructure may be vulnerable to cyber-attacks by hackers and other security threats. We may face cyber-attacks that attempt to penetrate our network security, sabotage or otherwise disable our research, products and services, misappropriate our or our customers' and partners' proprietary information, which may include personally identifiable information, or cause interruptions of our internal systems and services.

Additionally, there are a number of state, federal and international laws protecting the privacy and security of health information and personal data. For example, HIPAA imposes limitations on the use and disclosure of an individual's healthcare information by healthcare providers, healthcare clearinghouses and health insurance plans, or, collectively, covered entities, and also grants individuals rights with respect to their health information. HIPAA also imposes compliance obligations and corresponding penalties for non-compliance on individuals and entities that provide services to healthcare providers and other covered entities. As part of the ARRA, the privacy and security provisions of HIPAA were amended. ARRA also made significant increases in the penalties for improper use or disclosure of an individual's health information under HIPAA and extended enforcement authority to state attorneys general. As amended by ARRA and subsequently by the final omnibus rule adopted in 2013, HIPAA also imposes notification requirements on covered entities in the event that certain health information has been inappropriately accessed or disclosed as well as notification requirements to individuals, federal regulators and in some cases, notification to local and national media. Notification is not required under HIPAA if the health information that is improperly used or disclosed is deemed secured in accordance with encryption or other standards developed by the U.S. Department of Health and Human Services. Most states have laws requiring notification of affected individuals and/or state regulators in the event of a breach of personal information, which is a broader class of information than the health information protected by HIPAA. Many state laws impose significant data security requirements, such as encryption or mandatory contractual terms, to ensure ongoing protection of personal information. Activities outside of the United States implicate local and national data protection standards, impose additional compliance requirements, and generate additional risks of enforcement for non-compliance. We may be required to expend significant capital and other resources to ensure ongoing compliance with applicable privacy and data security laws, to protect against security breaches and hackers or to alleviate problems caused by such breaches.

If we are not able to adequately prevent disclosure of trade secrets and other proprietary information, the value of our technology and product could be significantly diminished.

We also rely on trade secrets to protect our proprietary technologies, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. We rely in part on confidentiality agreements with our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to protect our trade secrets and other proprietary information. 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 our trade secrets and proprietary information. For example, the FDA, as part of its transparency initiative, is currently considering whether to make additional information publicly available on a routine basis, including information that we may consider to be trade secrets or other proprietary information, and it is not clear at the present time how the FDA's disclosure policies may change in the future, if at all. 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.

We may be subject to claims that our employees or consultants have wrongfully used or disclosed alleged trade secrets.

As is common in the biotechnology and pharmaceutical industries, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees and consultants do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or our employees or consultants have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. If we fail to defend any such claims, in addition to paying monetary damages, we could lose valuable intellectual property rights or personnel, which could adversely impact our business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

Item 1B. Unresolved Staff Comments

None.

Item 1C. Cybersecurity

Risk Management and Strategy

We recognize the critical importance of developing, implementing, and maintaining robust cybersecurity measures to safeguard our information systems and protect the confidentiality, integrity, and availability of our data. The Company considers its primary cybersecurity risks to be theft of intellectual property, theft of other business data, fraud or extortion, lack of access to its information systems, harm to employees, harm to business partners, violation of privacy laws, potential reputational risk, and litigation or other legal risk if a cybersecurity incident were to occur. It is difficult to assign a monetary materiality assessment to these risks or to the impact if the Company were to sustain a breach of its systems. The Company's approach to cybersecurity is based on the premise that any cybersecurity incident could result in material harm to the Company. We have a cybersecurity and risk management processes in place to oversee risks associated with cybersecurity and respond to emerging threats in a timely and effective manner. We monitor our systems to assess cybersecurity risks and threats.

Managing Material Risks & Integrated Overall Risk Management

We have integrated cybersecurity risk management into our broader risk management framework. This integration ensures that cybersecurity considerations are an integral part of our decision-making process. We conduct annual risk assessments and quarterly vulnerability scans of risks posed by cybersecurity threats in conjunction with our insurance renewal cycles. As a result of these assessments, we have implemented technical, administrative, and, where appropriate, physical controls and practices to proactively monitor our systems and user accounts including, but not limited to, deploying solutions to constantly monitor users accessing systems, implementation of two factor authentication for logins, and improved rules for password maintenance.

Like many companies, we make use of cloud-based solutions provided by several large service providers for critical information technology infrastructure such as email and file storage. We do not maintain stand-alone servers for our email, file storage or other business applications. In the normal course of our relationships with the providers of these services, we regularly monitor their message boards and other formal and informal communications channels for signs of breaches of their systems. We also survey available public information for indications that they have suffered a breach of their systems.

Engage Third Parties on Risk Management

Our Audit Committee has been designated with oversight responsibility for cybersecurity risks and our Chief Financial Officer is responsible for managing our efforts in this area. Neither the Chief Financial Officer nor any member of the Audit Committee has relevant expertise in cybersecurity. Recognizing the complexity and evolving nature of cybersecurity threats, the Company has retained an third-party technical expert to support its information technology systems including addressing cybersecurity risks. This relationship enables us to leverage specialized knowledge and insights, to ensure our cybersecurity strategies and processes are aligned with industry best practices.

Oversee Third Party Risk

We utilize various third-party software applications in the functioning of our core business. We conduct assessments of all third-party providers and maintain ongoing reviews to ensure compliance with our cybersecurity standards. Our assessment of risks associated with the use of third-party providers is part of our overall cybersecurity framework. In addition, some of our business partners also maintain data related to our trials and ongoing product development on servers they maintain. We require these partners to comply with all HIPAA standards for maintaining security of their systems where this data resides.

Risks from Cybersecurity Threats

We face risk from cybersecurity threats that could have a material adverse effect on our business, financial condition, results of operations, cash flows or reputation. For more information about the cybersecurity risks we face, see the risk factor entitled "*Security threats to our information technology infrastructure could expose us to liability and damage our reputation and business*." in *Item 1A., Risk Factors*.

Governance

Our Board of Directors is aware of the critical nature of managing risks associated with cybersecurity threats, and recognizes the significance of these threats to our operational integrity and stockholder confidence.

Risk Management Personnel

We utilize an out-sourced information technology (IT) network and cybersecurity compliance service provider, Windstar Technologies, Inc. ("Windstar") Windstar, under the supervision of our Chief Financial Officer, is responsible for developing and implementing our information security program. Windstar provides managed IT network and cloud services, network, cyber and web security services, cyber risk audits and compliance and penetration testing assessments.

Board of Directors Oversight

Our Board is aware of the critical nature of managing risks associated with cybersecurity threats, and recognizes the significance of these threats to our operational integrity and stockholder confidence. The Audit Committee is central to the Board's oversight of cybersecurity risks and bears the primary responsibility for this domain.

Management's Role Managing Risk and Reporting to the Board

We do not currently have an employee who has significant and demonstrated professional IT management experience. Presently, our Chief Financial Officer with assistance from our third-party IT services provider, Windstar, are primarily responsible for informing the Audit Committee regarding cybersecurity risks. They provide briefings to the Audit Committee on a regular basis, with a minimum frequency of once per year.

In addition to scheduled meetings, the Audit Committee and the Chief Financial Officer maintain an ongoing dialogue regarding emerging or potential cybersecurity risks. Together, they receive updates on any significant developments in the cybersecurity domain, ensuring the Board's oversight is proactive and responsive. This involvement ensures that cybersecurity considerations are integrated into the Company's broader strategic objectives and helps in identify areas for improvement, ensuring the alignment of cybersecurity efforts with the overall risk management framework.]

To date, we have not experienced any previous cybersecurity incidents that have materially affected or are reasonably likely to materially affect our business strategy, results of operations, or financial condition.

Item 2. Properties

The following table describes our principal property leased as of the date of this Annual Report. We believe the facility described below is adequate for our current needs.

Purpose	Location	Square Footage
Office and Research Laboratory[(1)]	Front Royal, Virginia	2,700

(1) Monthly rental payments of $2,500 per month on a month-to-month basis. The lease expires on March 31, 2027.

Item 3. Legal Proceedings

We are not presently a party to any material litigation. From time to time, may however, become involved in litigation matters arising in the ordinary course of our business.

Item 4. Mine Safety Disclosures

Not applicable.

PART II

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

Market Information

Our Common Stock is listed on the Nasdaq Capital Market under the symbol "GCTK."

Holders

As of March 31, 2025, there were 313 holders of record of our Common Stock. A substantially greater number of holders are "street name" or beneficial holders, whose shares of record are held by banks, brokers, and other financial institutions.

Dividends

Since our inception, we have not paid any dividends on our Common Stock, and we currently expect that, for the foreseeable future, all earnings, if any, will be retained for use in the development and operation of our business. In the future, our Board may decide, at its discretion, whether dividends may be declared and paid to holders of our Common Stock.

Securities Authorized for Issuance under Equity Compensation Plans

The information required by Item 5 of Form 10-K regarding equity compensation plans is incorporated herein by reference to Item 12 of Part III of this Annual Report.

Unregistered Sales of Equity Securities

Issuance Under Intellectual Property Purchase Agreement

On October 7, 2022, the Company entered into the Intellectual Property Purchase Agreement (the "IP Purchase Agreement") with Paul Goode, which is the Company's Chief Executive Officer, pursuant to which Dr. Goode sold, assigned, transferred, conveyed and delivered to the Company, all of his right, title and interest in and to the following assets, properties and rights (collectively, the "Purchased Assets"): (a) all rights, title, interests in all current and future intellectual property, including, but not limited to patents, trademarks, trade secrets, industry know-how and other IP rights relating to an implantable continuous glucose sensor (collectively, the "Conveyed Intellectual Property"); and (b) all the goodwill relating to the Purchased Assets.

In consideration for the sale by Dr. Goode of the Purchased Assets to the Company, the Company paid to Dr. Goode cash in the amount of one dollar and became obligated to issue up to 10,000 shares of Common Stock based upon specified performance milestones as set forth in the IP Purchase Agreement (the "Purchase Price"). In addition, if upon the final issuance of Common Stock under the IP Purchase Agreement, the aggregate 10,000 shares represent less than 1.5% of the then outstanding Common Stock of the Company, the final issuance will include such number of additional shares so that the total aggregate issuance equals 1.5% of the outstanding shares (the "True-Up Shares") of Common Stock of the Company. All shares of Common Stock to be issued under the IP Purchase Agreement shall be (i) restricted over a limited period as defined in the IP Purchase Agreement and issued in transactions exempt from registration under Section 4(a)(2) of the Securities Act of 1933, as amended and (ii) subject to the lockup provisions.

On December 29, 2023, 1,000 shares of Common Stock were earned under the terms of the IP Purchase Agreement and were issued to Dr. Goode on February 6, 2024. On May 1, 2024, 1,500 shares of Common Stock were earned under the terms of the IP Purchase Agreement. On March 26, 2025, the Board determined that the third milestone was met and that an additional 2,500 shares of Common Stock have been earned under the terms of the IP Purchase Agreement.

February 2024 Exchange

On February 13, 2024, the Company entered into an exchange agreement (the "February Exchange Agreement") with certain shareholders (the "February Holders"), pursuant to which the Company and the February Holders agreed to exchange (the "February Exchange") Common Stock purchase warrants (the "February Warrants") owned by the Holders for shares of Common Stock to be issued by the Company.

On February 13, 2024, the Company closed the Exchange and issued to the February Holders an aggregate of 35,932 shares of Common Stock in exchange for 43,820 February Warrants.

The issuance of the Common Stock to the February Holders was made pursuant to the exemption from registration contained in Section 3(a)(9) of the Securities Act and Regulation D promulgated thereunder.

April Private Placement

On April 22, 2024, the Company entered into a private placement agreement under which the Company issued 3,968 shares of its Common Stock at a price of $126.0 per share for aggregate gross proceeds of $500. The Offering included participation of certain members of the Company's executive management, Board of Directors and existing shareholders. The shares were issued in reliance on the exemption from registration requirements thereof provided by Section 4(a)(2) of the Securities Act and Regulation D promulgated under the Securities Act. The Company relied on this exemption from registration based in part on representations made by the investors.

June 27 Private Placement

On July 27, 2024, the Company entered into note and warrant purchase agreements with certain officers, directors, and existing investors (the "June 27 Investors"), providing for the private placement of unsecured promissory notes in the aggregate principal amount of $100,000 (the "June 27 Notes") and warrants (the "June 27 Warrants") to purchase up to an aggregate of 15,000 shares of Common Stock. The closing of the private placement occurred on July 1, 2024.

The June 27 Notes bore simple interest at the rate of three percent (3%) per annum and were due and payable in cash on the earlier of: (a) twelve (12) months from the date of the June 27 Note; or (b) the date the Company raised third-party equity capital in an amount equal to or in excess of $1,000,000 (the "June 27 Maturity Date"). The Company could prepay the June 27 Notes at any time prior to the June 27 Maturity Date without penalty.

Each June 27 Warrant has an exercise price of $99.0 per share. The June 27 Warrants are immediately exercisable and have a five-year term.

The June 27 Notes and the June 27 Warrants were issued in reliance on the exemption from registration requirements thereof provided by Section 4(a)(2) of the Securities Act and Regulation D promulgated thereunder. The Company relied on this exemption from registration based in part on representations made by the June 27 Investors.

July 18 Private Placement

On July 18, 2024, the Company entered into a series of convertible promissory notes with certain officers and directors (the "July 18 Investors"), providing for the private placement of unsecured convertible promissory notes in the aggregate principal amount of $360,000 (the "July 18 Notes" and each a "July 18 Note").

The July 18 Notes bore simple interest at the rate of eight percent (8%) per annum and were due and payable in cash on the earlier of: (a) the twelve (12) month anniversary of the July 18 Note, or (b) the date of closing of a Qualified Financing (defined below) (the "July 18 Maturity Date").

Except with regard to conversion of the July 18 Notes as discussed below, the Company could not prepay the July 18 Notes without the written consent of the holder. If not sooner repaid, all outstanding principal and accrued but unpaid interest on the July 18 Notes (the "Note Balance"), as of the close of business on the day immediately preceding the date of the closing of the next issuance and sale of capital stock of the Company, in a single transaction or series of related transactions, to investors resulting in gross proceeds to the Company of at least $500,000 (excluding indebtedness converted in such financing) (a "Qualified Financing"), would automatically be converted into that number of shares of equity securities of the Company sold in the Qualified Financing equal to the number of shares calculated by dividing (X) the Note Balance by (Y) an amount equal to the price per share or other unit of equity securities issued in such Qualified Financing, and otherwise on the same terms as the security issued in the Qualified Financing, provided that the conversion price per share shall not be lower than $31.20 (the "Floor Price").

The July 18 Notes were issued in reliance on the exemption from registration requirements thereof provided by Section 4(a)(2) of the Securities Act and Regulation D promulgated thereunder. The Company relied on this exemption from registration based in part on representations made by the July 18 Investors.

July 30 Private Placement

On July 30, 2024, the Company entered into a convertible promissory note and three warrant agreements (the "July 30 Warrants") with an existing investor (the "July 30 Holder"), providing for the private placement of a secured convertible promissory note in the aggregate principal amount of $4,000,000 (the "July 30 Note"). The July 30 Note was not convertible until and unless approved at a meeting of the Company's stockholders ("Stockholder Approval"). Stockholder Approval was obtained on September 26, 2024. The July 30 Note bore simple interest at the rate of eight percent (8%) per annum and was due and payable in cash on the earlier of: (a) the twelve (12) month anniversary of July 30 Note, or (b) the date of closing of a Sale Transaction (defined below) (the "July 30 Maturity Date"). The July 30 Note was secured by a first-priority security interest on all Company assets.

Except with regard to conversion of the July 30 Note or a Sale Transaction as discussed below, the Company could not prepay the July 30 Notes without the written consent of the July 30 Holder. The July 30 Note (i) was convertible at the discretion of the July 30 Holder at a price equal to the closing price of the Common Stock on the date of conversion and, (ii) if the closing price of the Common Stock exceeds $100.00 per share for a period of five (5) consecutive trading days, would automatically convert at a price equal to the five-day (5) VWAP (subject to adjustment for any stock split, stock dividend, reverse stock split, combination or similar transaction). "VWAP" means the daily volume weighted average price of the Common Stock.

In the event of a Sale Transaction on or prior to the Maturity Date, the Company would repay the July 30 Holder, at the July 30 Holder's election, as follows: (a) cash equal to 200% of the Note balance, or (b) transaction consideration in the amount to be received by the July 30 Holder in such Sale Transaction if the July 30 Note was converted pursuant to an optional conversion. "Sale Transaction" means a merger or consolidation of the Company with or into any other entity, or a sale of all or substantially all of the assets of the Company, or any other transaction or series of related transactions in which the Company's stockholders immediately prior to such transaction(s) receive cash, securities or other property in exchange for their shares and, immediately after such transaction(s), own less than 50% of the equity securities of the surviving corporation or its parent.

Each July 30 Warrant becomes exercisable 12 months after its issuance and has term of 10 years. The July 30 Warrants are exercisable for cash only and have no price-based antidilution. The first July 30 Warrant is for 106,667 shares at $37.50 per share. The second July 30 Warrant is for 76,191 shares at $52.50 per share. The third July 30 Warrant is for 59,260 shares at $67.50 per share.

The July 30 Note and the July 30 Warrants were issued in reliance on the exemption from registration requirements thereof provided by Section 4(a)(2) of the Securities Act and Regulation D promulgated under the Securities Act. The Company relied on this exemption from registration based in part on representations made by the July 30 Holder

August 23 Conversion

On August 23, 2024, two of the June 27 Investors entered into conversion agreements (each an "August Conversion Agreements") with the Company, pursuant to which the Company agreed to convert the principal amount, plus any accrued but unpaid interest pursuant to each of the June 27 Notes, totaling $20,076 each (the "August Conversion Debt"), held by the Investors to Common Stock at a conversion price of $20.40 per share.

Also in satisfaction of the August Conversion Debt and pursuant to the August Conversion Agreements, the Company issued to each of the two June 27 Investors three warrants (each an "August 23 Warrant"). Each August 23 Warrant becomes exercisable on August 16, 2025 and has term of 10 years. The August 23 Warrants are exercisable for cash only and have no price-based antidilution. The first August 23 Warrant is for 535 shares of Common Stock and is exercisable at $37.50 per share. The second August 23 Warrant is for 382 shares of Common Stock, exercisable at $52.50 per share. The third August 23 Warrant is for 297 shares of Common Stock, exercisable at $67.50 per share.

The August 23 Warrants and the shares issued in satisfaction of the Debt were issued in reliance on the exemption from registration requirements thereof provided by Section 4(a)(2) of the Securities Act and Regulation D promulgated thereunder. The Company relied on this exemption from registration based in part on representations made by the investors.

September 5 Conversion

On September 5, 2024, another June 27 Investor entered into a Conversion Agreement with the Company (the September Conversion Agreement"), pursuant to which the Company agreed to convert the principal amount, plus any accrued but unpaid interest pursuant to the June 27 Investor's June 27 Note, totaling $259,310.67 (the "September Conversion Debt"), held by the June 27 Investor to Common Stock at a conversion price of $20.40 per share.

Also in satisfaction of the September Conversion Debt and pursuant to the September Conversion Agreement, the Company issued to the June 27 Investor three warrants (each an "September 5 Warrant"). Each September 5 Warrant becomes exercisable on August 16, 2025 and has term of 10 years. The September 5 Warrants are exercisable for cash only and have no price-based antidilution. The first September 5 Warrant is for 6,915 shares of Common Stock and is exercisable at $37.50 per share. The second September 5 Warrant is for 4,940 shares of Common Stock, exercisable at $52.50 per share. The third September 5 Warrant is for 3,842 shares of Common Stock, exercisable at $67.50 per share.

The September 5 Warrants and the shares issued in satisfaction of the Debt were issued in reliance on the exemption from registration requirements thereof provided by Section 4(a)(2) of the Securities Act and Regulation D promulgated thereunder. The Company relied on this exemption from registration based in part on representations made by the investor.

Concurrent Private Offering

In a private placement offering completed concurrently with the November 2024 Offering (the "Concurrent Private Offering"), the July 30 Holder, which is an existing investor controlled by a director of the Company, converted approximately $4,093,112 of debt, which represented the then outstanding principal and accrued interest under the July 30 Note (the "July 30 Note Debt"). The July 30 Note Debt was converted to Common Stock and Common Warrants on substantially the same terms as the November 2024 Offering, resulting in the issuance of 132,036 shares of Common Stock, 132,036 accompanying Series A common warrants to purchase Common Stock (the "Series A Common Warrants"), and 132,036 accompanying Series B common warrants to purchase Common Stock (the "Series A Common Warrants", and together with the Series A Common Warrants, the "Common Warrants"), based on a conversion price of $31.0 per share, which is equal to the consolidated closing bid price of the Common Stock on the Nasdaq Capital Market on November 12, 2024.

July 18 Note Conversion

In addition, concurrently with the November 2024 Offering, the Company converted on substantially the same terms as the November Offering, the three outstanding July 18 Notes, with an aggregate outstanding principal and accrued interest in the amount of $304,494. As previously disclosed in the Form 8-K filed by the Company with the SEC on July 22, 2024, that disclosed the entry into the July 18 Notes, the July 18 Notes were to automatically convert upon a Qualified Financing, into a number of equity securities of the Company sold in the Qualified Financing, equal to a number of shares calculated by dividing (X) the Note Balance by (Y) an amount equal to the price per share or other unit of equity securities issued in such Qualified Financing, and otherwise on the same terms as the security issued in the Qualified Financing, provided that the conversion price per share shall not be lower than the Floor Price. The three outstanding July 18 Notes automatically converted in connection with the closing of the November 2024 Offering at a conversion price of $31.20, which is equal to the Floor Price as defined in the July 18 Notes, for an aggregate of 9,760 shares of Common Stock, 9,760 Series A Common Warrants, and 9,760 Series B Common Warrants (the "July 18 Note Conversion").

The Common Stock and the Common Warrants issued in connection with the Concurrent Private Offering and the July 18 Note Conversion were not registered under the Securities Act and were offered pursuant to the exemption from registration provided in Section 4(a)(2) under the Securities Act and Rule 506(b) promulgated thereunder. The Company relied on this exemption from registration based in part on representations made by the investors.

Item 6. [Reserved]

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

The discussion in this section contains forward-looking statements. These statements relate to future events, our future operations or our future financial performance. We have attempted to identify forward-looking statements by terminology such as "anticipate," "believe," "can," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "should," "would" or "will" or the negative of these terms or other comparable terminology, but their absence does not mean that a statement is not forward-looking. These statements are only predictions and involve known and unknown risks, uncertainties and other factors, which could cause our actual results to differ from those projected in any forward-looking statements we make. Several risks and uncertainties we face are discussed in more detail under "Risk Factors" in Part I, Item 1A of this Annual Report or in the discussion and analysis below. You should, however, understand that it is not possible to predict or identify all risks and uncertainties and you should not consider the risks and uncertainties identified by us to be a complete set of all potential risks or uncertainties that could materially affect us. You should not place undue reliance on the forward-looking statements we make herein because some or all of them may turn out to be wrong. We undertake no obligation to update any of the forward-looking statements contained herein to reflect future events and developments, except as required by law. The following discussion should be read in conjunction with the consolidated financial statements and the notes to those statements included elsewhere in this Annual Report.

Unless otherwise noted, all information in this Item 7 regarding share amounts of our Common Stock and prices per share of our Common Stock has been adjusted to reflect the application of the one-for-five reverse stock split of our Common Stock that we effected on May 27, 2024 and the one-for-twenty reverse stock split of our Common Stock that we effected on February 3, 2025, as further described below, on a retroactive basis.

Overview

The Company was incorporated on May 18, 2010 under the laws of the State of Delaware. We are currently developing an implantable CBGM, the Glucotrack CBGM, for persons with Type 1 diabetes and insulin-dependent Type 2 diabetes.

The Company was founded with a mission to develop Glucotrack®, a non-invasive glucose monitoring device designed to help people with diabetes and pre-diabetics obtain glucose level readings without the pain, inconvenience, cost and difficulty of conventional (invasive) spot finger stick devices. The first generation Glucotrack, which successfully received CE Mark approval, obtained glucose measurements via a small sensor clipped onto one's earlobe. A limited release beta test in Europe and the Middle East demonstrated the need for an updated product with improved accuracy and human factors. As the glucose monitoring landscape rapidly moved away from point-in-time measurement to continuous measurement since then, the Company recently determined that it would focus its efforts on developing its Glucotrack CBGM. As such, we have since withdrawn our CE Mark for Glucotrack and are no longer pursuing commercialization of this product or development of any further iterations.

The Company is currently developing the Glucotrack CBGM for use by Type 1 diabetes patients as well as insulin-dependent Type 2 patients. Implant longevity is key to the success of such a device. We have continued to evolve our sensor chemistry following our successful in-vitro feasibility study demonstrating that a minimum two-year implant life is highly probable with the current sensor design. Recently we announced a 3-year longevity is feasible leveraging both in-vitro and in-silico test results. We have also completed four animal studies with evolving prototype systems, all four of which consistently demonstrated a simple implant procedure, good functionality, and safety. The Company has also successfully demonstrated continuous glucose sensing in the epidural space via two additional animal trials, both of which demonstrated a simple implant procedure, good functionality, and safety. This latter approach is of importance for patients with painful diabetic neuropathy contemplating spinal cord stimulation therapy for their condition. The results of these animal trials were recently presented in poster form at the American Diabetes Association, the Diabetes Technology Society, and the DiabetesMine annual conferences.

A regulatory submission has been made for a first in human study outside of the United States. This will be an acute study intended to demonstrate device performance and safety. All preparatory clinical activities and applicable regulatory approvals are complete. In parallel, the Company is also preparing for a long-term clinical trial outside the United States that is expected to begin in the second quarter of 2025.

We believe our technology, if successful, has the potential to be more accurate, more convenient and have a longer duration than other implantable glucose monitors that are either in the market or currently under development.

Our executive management team consists of our Chief Executive Officer and President, Paul V. Goode PhD, an experienced executive with a 25+ year career developing innovative medical technologies, including at Dexcom and MiniMed (now Medtronic Diabetes) and Chief Financial Officer, Peter C. Wulff, who has over 35 years of experience as a chief financial officer and chief operating officer in both public and private entities. Our senior management team consists of: Mark Tapsak PhD, Chief Scientific Officer, a medical research scientist who brings over 25 years of experience in the diabetes industry, including previous senior roles at Dexcom and Medtronic ; James P. Thrower PhD, Vice President of Advanced Technologies, a seasoned engineering executive with 20 years' experience formerly of Sterling Medical Devices, Mindray DS USA and Dexcom; Drinda Benjamin, Vice President of Marketing, a medical device professional with over 20 years of experience in the medical device and diabetes industry with senior roles at Intuity Medical, Senseonics, Abbott Diabetes, and Medtronic Diabetes; Vincent Wong, Vice President of Operations, a medical device professional with 15 years of experience in quality system for implantable medical device manufacturing with senior roles at Cirtec Medical and TOMZ; Sandie Martha, Vice President Clinical Operations, a medical device professional with over 20 years of experience in the medical device and diabetes industry with senior roles at Dexcom and GlySens; and Ted Williams, Vice President Regulatory, a medical device professional with over 20 years of experience in the biotech and diabetes industry with a senior role at GlySens.

Recent Developments

Research and Development

Completion of Preclinical Study

On May 16, 2024, we announced that our implantable continuous glucose monitor successfully completed 30 days of a 60-day long-term preclinical study on measuring glucose in the epidural space. The Glucotrack sensor, implanted in the epidural space of animals, closely tracked both blood glucose and a commercially available subcutaneous CGM throughout the 30-day period. The implantation procedure took approximately 20 minutes, and the animals recovered without complications. No abnormal clinical signs or findings in the spinal cord or surrounding tissues were observed at the 30-day mark. On June 13, 2024, we announced that the 60-day long-term study was completed, demonstrating the feasibility of glucose monitoring in the epidural space. No abnormal clinical signs were observed throughout the study period, and no abnormal findings were observed in the spinal cord or surrounding tissues during post-explant analysis. The study also confirmed that the implanted sensor did not cause any delayed latent effects over the long-term period, which is particularly important as a complete healing process in animal studies with implanted devices may take several weeks. With the completion of this study, the durability of the epidural approach for continuous glucose monitoring has now been confirmed over the 60-day period. These developments mark another potential use of the Glucotrack technology by combining the technology with a conventional spinal cord stimulator for treating patients who have chronic lower back and lower limb pain, a significant proportion of which have diabetes.

On February 4, 2025, we announced the successful completion of our first in-human clinical study, marking a significant milestone in continuous glucose monitoring. This study represents the first real-time CBGM placed in the subclavian vein, offering the potential for direct blood glucose measurement without the limitations often seen with traditional continuous glucose monitors that measure glucose levels in interstitial fluid.

The prospective single arm study was a short-term in-hospital study over a period of four days, focusing on the safety and procedural aspects of the Glucotrack CBGM sensor lead placement, use, and removal. The sensor lead was placed intravascularly via a percutaneous procedure and connected to a prototype sensor electronics component that was placed on the skin. The six study participants had been previously diagnosed with diabetes mellitus requiring glucose monitoring and intensive insulin therapy.

The results established safety of the placement, usage and removal of the CBGM sensor lead. While neither the study nor prototype system was designed to evaluate sensor accuracy, the system performed as expected with similar accuracy results as previously seen in our animal studies.

The study met its primary endpoint with no procedure or device related serious adverse events reported from implant through seven days post-removal of the CBGM sensor lead. The study also confirmed the function of the CBGM sensor lead in the subclavian vein. Placement and removal procedures were successfully performed by interventional cardiologists.

ISO 13485:2016 Certification

On January 21, 2025, we announced that we received ISO 13485:2016 certification from the British Standards Institute ("BSI"). We successfully completed Stage I and Stage II Assessments performed by the notified body, BSI, to verify the Company has established, and is maintaining, a quality management system that meets all requirements of the ISO 13485:2016 standard for design and development of its products. ISO 13485 is an internationally recognized standard for quality management systems, created by the International Organization for Standardization to ensure the safety and effectiveness of medical devices. It builds on the ISO 9001 standard with additional regulatory requirements specific to medical devices. In 2024, the FDA issued the Quality Management System Regulation Final Rule, which harmonizes U.S. requirements with global standards through the adoption of ISO 13485 for medical devices. ISO 13485 is also strongly recommended and widely used in the European Union.

Corporate and Regulatory

Nasdaq Listing Status

Nasdaq Listing Rule 5550(b)(1) requires companies listed on Nasdaq to maintain a minimum of $2,500,000 in stockholders' equity for continued listing. On May 21, 2024, Nasdaq notified us that our Quarterly Report on Form 10-Q for the period ended March 31, 2024, indicated that we no longer met the Minimum Stockholders' Equity Requirement. Failure to meet the Minimum Stockholders' Equity Requirement was a basis for delisting our Common Stock.

Because we were not in compliance with the Bid Price Rule at the time we were notified about the non-compliance with the Minimum Stockholders' Equity Requirement, we were not eligible to submit a plan to regain compliance with the Staff. However, we timely requested a hearing before the Nasdaq Hearings Panel and paid the fee, which resulted in a stay of any suspension or delisting action pending the hearing. The hearing took place on July 9, 2024, and on August 5, 2024, we received the decision of the Panel, and they granted us an extension until November 18, 2024 to regain compliance with the Minimum Stockholders' Equity Requirement.

On November 19, 2024, the Company received a Compliance Letter from Nasdaq, informing the Company that it had regained compliance with the Minimum Stockholders' Equity Requirement. The Compliance Letter noted, that because the Company's bid price has closed below the minimum required by the Bid Price Rule following the 2024 November Offering (defined below), the Panel had determined to impose on the Company a Discretionary Panel Monitor, pursuant to Listing Rule 5815(d)(4)(B), for a period of one year from the date of the Compliance Letter, to ensure that the Company maintains long-term compliance with the Minimum Stockholders' Equity Requirement, the Bid Price Rule, and all of Nasdaq's continued listing requirements.

On December 31, 2024, we received a notification from Nasdaq that for at least the last 30 consecutive business days, the Company was not in compliance with the Bid Price Rule and, in accordance with Nasdaq Listing Rule 5810(c)(3)(A), we have a compliance period of 180 calendar days, or until June 30, 2025, to regain compliance with the Bid Price Rule. If at any time before June 30, 2025, the bid price of our Common Stock closes at $1.00 per share or more for a minimum of ten consecutive business days, Nasdaq will provide us with a written confirmation of compliance with the Bid Price Rule and the matter will be deemed closed.

If we do not regain compliance with the Bid Price Rule by June 30, 2025, we may be eligible for an additional 180-day compliance period. To qualify, we would be required to meet the continued listing requirement for market value of publicly held shares and all other initial listing standards for the Nasdaq Capital Market, with the exception of the Bid Price Rule, and would need to provide written notice of our intention to cure the bid price deficiency during the second compliance period by effecting a reverse stock split, if necessary.

There can be no assurance that we will be able to continue to maintain compliance with Nasdaq's continued listing requirements, the Bid Price Rule, or other Nasdaq listing requirements. See "*Risk Factors — Our failure to maintain compliance with Nasdaq's continued listing requirements could result in the delisting of our Common Stock*."

Reverse Stock Splits

2024 Reverse Stock Split

We filed with the Delaware Secretary of State a Certificate of Amendment (the "May Certificate of Amendment"), to our Certificate of Incorporation, as amended (the "Certificate of Incorporation"), which became effective at 4:30 p.m. on May 17, 2024 (the "First Effective Time") to implement a one-for-five (1:5) reverse stock split (the "2024 Reverse Stock Split") of the shares of our Common Stock. The 2024 Reverse Stock Split was approved by our stockholders at the 2024 annual meeting of the stockholders on April 26, 2024.

As a result of the 2024 Reverse Stock Split, every five (5) shares of issued and outstanding Common Stock were automatically combined into one (1) issued and outstanding share of Common Stock, without any change in the par value per share. No fractional shares were issued as a result of the 2024 Reverse Stock Split, and any person who would otherwise be entitled to a fractional share of Common Stock as a result of the 2024 Reverse Stock Split was entitled to receive a cash payment equal to the fraction of a share of Common Stock to which such holder would otherwise be entitled, multiplied by the closing price per share of the Common Stock on Nasdaq at the close of business on the date prior to the First Effective Time.

Following the 2024 Reverse Stock Split, the number of shares of Common Stock outstanding was proportionally reduced. The shares of Common Stock underlying the outstanding stock options and warrants were similarly adjusted along with corresponding adjustments to their exercise prices. The 2024 Reverse Stock Split also proportionally reduced the total number of authorized shares of Common Stock from 500,000,000 shares to 100,000,000 shares.

2025 Reverse Stock Split

We filed with the Delaware Secretary of State a Certificate of Amendment to our Certificate of Incorporation (the "2025 Certificate of Amendment") which became effective at 4:30 p.m. on February 3, 2025 (the "Second Effective Time"), to implement a reverse stock split at a ratio of 1-for-20 (the "2025 Reverse Stock Split") of the shares of our Common Stock. The 2025 Reverse Stock Split was approved by our stockholders at the special meeting of our stockholders held on January 3, 2025 (the "Special Meeting").

As a result of the 2025 Reverse Stock Split, every twenty (20) shares of issued and outstanding Common Stock were automatically combined into one (1) issued and outstanding share of Common Stock, without any change in the par value per share. No fractional shares were issued as a result of the 20254 Reverse Stock Split, and instead, stockholders who otherwise would have been entitled to receive fractional shares because they held a number of shares not evenly divisible by the Reverse Stock Split ratio were entitled to receive an additional fraction of a share of Common Stock to round up to the next whole share.

In addition, the stockholders approved at the Special Meeting an increase in our authorized shares of Common Stock from 100,000,000 to 250,000,000, as well as the full issuance of shares of Common Stock issuable by us upon the exercise of Series A Warrants and Series B Warrants (further described below).

Increase in Authorized Common Stock

On January 3, 2025, the Company filed an amendment to the Company's Certificate of Incorporation, as to increase the Company's authorized shares of Common Stock from 100,000,000 to 250,000,000.

Financing

February 2024 Exchange

On February 13, 2024, we entered into the February Exchange Agreement with the February Holders, pursuant to which the Company and the February Holders agreed to exchange the February Warrants owned by the February Holders for shares of Common Stock to be issued by the Company.

On February 13, 2024, the Company closed the February Exchange and issued to the February Holders an aggregate of 35,932 shares of Common Stock in exchange for 43,820 February Warrants.

April Private Placement

On April 22, 2024, we entered into a private placement agreement under which the Company issued 3,968 shares of its Common Stock at a price of $126.0 per share for aggregate gross proceeds of $500,000. The Offering included participation of certain members of the Company's executive management, Board of Directors and existing shareholders.

June 27 Private Placement

On June 27, 2024, we entered into note and warrant purchase agreements with the June 27 Investors, providing for the private placement of unsecured promissory notes in the aggregate principal amount of $100,000 and to purchase up to an aggregate of 15,000 shares of Common Stock. The closing occurred on June 27, 2024.

July 18 Private Placement

On July 18, 2024, we entered into a series of convertible promissory notes with the July 18 Investors, providing for the private placement of unsecured convertible promissory notes in the aggregate principal amount of $360,000.

On August 23, 2024, two of the June 27 Investors entered into conversion agreements with the Company, pursuant to which the Company agreed to convert the principal amount, plus any accrued but unpaid interest, of each of the June 27 Notes, totaling $20,076 each, held by the investors into Common Stock at a conversion price of $20.40 per share. On September 5, 2024, another June 27 Investor entered into a separate conversion agreement with the Company, under which the Company agreed to convert the principal amount, plus any accrued but unpaid interest, of the June 27 Note held by the investor, totaling $259,310, into Common Stock at the same conversion price of $20.40 per share.

Also in satisfaction of the debt and pursuant to the August Conversion Agreement, the Company issued to each of the two June 27 Investors that converted their notes in August, three August 23 Warrants. Each August 23 Warrant becomes exercisable on August 16, 2025 and has term of 10 years. The August 23 Warrants are exercisable for cash only and have no price-based antidilution. The first August 23 Warrant is for 535 shares of Common Stock and is exercisable at $37.50 per share. The second August 23 Warrant is for 382 shares of Common Stock, exercisable at $52.50 per share. The third August 23 Warrant is for 297 shares of Common Stock, exercisable at $67.50 per share. The June 27 Investor that converted his note in September was issued three September 5 Warrants on the same terms as the August 23 Warrants. The first September 5 Warrant is for 6,915 shares of Common Stock and is exercisable at $37.50 per share. The second September 5 Warrant is for 4,940 shares of Common Stock, exercisable at $52.50 per share. The third September 5 Warrant is for 3,842 shares of Common Stock, exercisable at $67.50 per share.

July 30 Private Placement

On July 30, 2024, we entered into the July 30 Note and three July 30 Warrants with the July 30 Holder, providing for the private placement of a secured convertible promissory note in the aggregate principal amount of $4,000,000. The July 30 Note bore simple interest at the rate of eight percent (8%) per annum and is due and payable in cash on the earlier of: (a) the twelve (12) month anniversary of July 30 Note, or (b) the date of closing of a Sale Transaction. The July 30 Note was secured by a first-priority security interest on all Company assets.

$10.0 Million Public Offering and Concurrent Private Placement

On November 13, 2024, the Company entered into a Securities Purchase Agreement (the "Purchase Agreement") with certain purchasers identified on the signature pages therein, pursuant to which the Company sold in a "best efforts" public offering (the "2024 November Offering"), pursuant to an effective registration statement on Form S-1 (File No. 333- 282158) under the Securities Act, an aggregate of (i) 121,867 shares of its Common Stock (the "Shares"), (ii) 237,845 pre-funded warrants to purchase up to an aggregate of 237,845 shares of Common Stock in lieu of Shares (the "Pre-Funded Warrants"), (iii) 359,712 Series A Common Warrants, and (iv) 359,712 Series B Common Warrants. The public offering price for each Share and accompanying Common Warrants was $27.80, and the public offering price for each Pre-Funded Warrant and accompanying Common Warrants was $27.78 (the "Offering Price").

In a private placement offering completed concurrently with the Offering (the "Concurrent Private Offering"), the July 30 Holder, converted approximately $4,093,112 of debt, which represented the then outstanding principal and accrued interest under a convertible promissory note dated July 30, 2024 (the "July 30 Note Debt"). The July 30 Note Debt was converted to Common Stock and Series A Common Warrants and Series B Common Warrants on substantially the same terms as the

November 2024 Offering, resulting in the issuance of 132,036 shares of Common Stock, 132,036 accompanying Series A Common Warrants, and 132,036 accompanying Series B Common Warrants, based on a conversion price of $31.00 per share, which is equal to the consolidated closing bid price of the Common Stock on the Nasdaq Capital Market on November 12, 2024.

In addition, concurrently with the November 2024 Offering, the Company completed the July 18 Note Conversion of the outstanding July 18 Notes. The July 18 Notes, which represented an aggregate outstanding principal and accrued interest in the amount of $304,494 were converted at a conversion price of $31.20, which is equal to the Floor Price as defined in the July 18 Notes, for an aggregate of 9,760 shares of Common Stock, 9,760 Series A Common Warrants, and 9,760 Series B Common Warrants.

ATM Sales Agreement

On December 17, 2024, we entered into an ATM sales agreement (the "Sales Agreement") with Dawson James Securities, Inc. ("Dawson James"), pursuant to which we have agreed to issue and sell shares of Common Stock, having an aggregate offering price of up to $8.23 million, from time to time, through an "at-the-market" equity offering program under which Dawson James will act as sales agent (the "Agent"). As of December 31, 2024, no sales of Common Stock had been made pursuant to the Sales Agreement.

On March 21, 2025, we sold 12,377,967 shares of Common Stock at an average offering price of $0.304 per share pursuant to the Sales Agreement (the "March ATM Sale"). We received net proceeds of approximately $3,643,000, after deducting fees owed to the placement agent from such sale.

February 2025 Registered Direct Offering

On February 4, 2025, we entered into a securities purchase agreement with certain institutional investors, relating to the registered direct offering and sale of an aggregate of 2,638,042 shares of Common Stock at an offering price of $1.15 per share. The shares of Common Stock were offered by the Company pursuant to a prospectus supplement dated February 4, 2025, and accompanying prospectus dated October 3, 2024, in connection with a takedown from the Company's shelf registration statement on Form S-3 (Registration No. 333-282297), which was declared effective by the SEC, on October 3, 2024 (the "February 2025 Offering" and, together with the March ATM Sale, the "2025 Offerings"). Dawson James acted as the placement agent for the offering pursuant to a placement agency agreement, dated February 4, 2025, by and between the Company and Dawson James. The net proceeds to the Company from the offering were approximately $2,706,000, after deducting fees owed to Dawson James and other offering expenses. The February 2025 Offering closed on February 5, 2025.

Warrant Exchange

Beginning on January 6, 2025, through March 13, 2025, the Company received exchange notices from certain holders of the Series B Warrants, with respect to an aggregate of 359,612 of the Series B Warrants, requiring the delivery of 9,721,782 shares of Common Stock. The remaining 100 Series B Warrants are exchangeable for an aggregate of approximately 1,940 shares of Common Stock (subject to adjustment in the event of any stock dividend and split, reverse stock split, recapitalization, reorganization or similar transaction).

Pro Forma Impact of Registered Direct Offerings, Warrant Exchange, and Series A Warrant Revaluation

The following financial information has been developed by application of pro forma adjustments to the historical financial statements of the Company appearing elsewhere in this Annual Report. The unaudited pro forma information gives effect to the 2025 Offerings, the exchange of Series B Warrants to common stock, and the revaluation of Series A Warrants.

The unaudited pro forma financial information is presented for informational purposes only and does not purport to represent what the results of operations or financial position of the Company would have been had the transactions described above actually occurred on the dates indicated, nor do they purport to project the financial condition of the Company for any future period or as of any future date. The unaudited pro forma financial information should be read in conjunction with the Company's financial statements and notes thereto included elsewhere in this Annual Report.

Unaudited Pro Forma Balance Sheet

	Year Ended December 31, 2024				
		Adjustments			
	As Reported	Series B Warrant Exercise	2025 Offerings	Revaluation of Series A Warrants	Pro Forma as Adjusted
Current Assets					
Cash and cash equivalents	5,617		6,300		11,917
Other current assets	151				151
Total current assets	5,768				12,068
Operating lease right-of-use asset, net	59				59
Property and equipment, net	95				95
Restricted cash	10				10
TOTAL ASSETS	5,932				12,232
LIABILITIES AND STOCKHOLDERS' (DEFICIT) EQUITY					
Current Liabilities					
Accounts payable	992				992
Operating lease liability	26				26
Convertible promissory notes	5				5
Other current liabilities	252				252
Total current liabilities	1,275				1,275
Non-Current Liabilities					
Derivative financial liabilities	17,421	(14,877)		(2,452)	92
Operating lease liability, non-current	33				33
Loans from stockholders	203				203
Total liabilities	18,932				1,603
Commitments and contingent liabilities					
Stockholders' (Deficit) Equity					
Common Stock of $0.001 par value 100,000,000 shares authorized as of December 31, 2024 and 2023; 791,609 and 208,914 shares issued and outstanding as of December 31, 2024 and 2023, respectively	1				1
Additional paid-in capital	119,229	14,877	6,300	2,452	142,858
Receipts on account of shares	228				228
Accumulated other comprehensive income	(8)				(8)
Accumulated deficit	(132,450)				(132,450)
Total stockholders' (deficit) equity	(13,000)				10,629
TOTAL LIABILITIES AND STOCKHOLDERS' (DEFICIT) EQUITY	5,932				12,232

Financial Overview

Operating Expenses

Research and Development

Research and development expenses consist primarily of salaries and other personnel-related expenses, including stock-based compensation expenses, materials, travel expenses, clinical trials and other expenses. We expect research and development expenses to increase in 2025 and beyond, primarily due to expanding clinical trial activities, hiring additional personnel, as well the development of Glucotrack CBGM; however, we may adjust or allocate the level of our research and development expenses based on available financial resources and based on our commercial needs, including the FDA registration process, specific requirements from customers, development of new Glucotrack CBGM models and other product candidates.

General and Administrative

General and administrative expenses consist primarily of professional services, salaries, travel expenses and other related expenses for executive, finance and administrative personnel, including stock-based compensation expenses. Other general and administrative costs and expenses include facility-related costs not otherwise included in research and development costs and expenses, and professional fees for legal and accounting services.

Other (Income) Expense

Other income expense, consist primarily of the change in fair value of derivatives liabilities, loss on the issuance of equity, loss on settlement of debt to equity and finance income.

Results of Operations – Comparison of the Years Ended December 31, 2024 and 2023

All information below is stated in thousands of US dollars.

The following discussion of our operating results explains material changes in our results of operations for the years ended December 31, 2024 and December 31, 2023. The discussion should be read in conjunction with the financial statements and related notes included elsewhere in this Annual Report.

Research and Development Expense

Research and development expenses were $9,499 for the year ended December 31, 2024, as compared to $4,704 for the prior-year period. The increase of $4,795 was primarily attributable to increased expenses related to product design, development and manufacturing activities and pre-clinical animal studies.

General and Administrative Expense

General and administrative expenses were $4,655 for the year ended December 31, 2024, as compared to $2,278 for the prior-year period. The increase of $2,377 is primarily attributable to increased legal and professional fees, personnel costs and placement agent fees.

Share-based compensation expense included in research and development and general and administrative expense, for the fiscal years ended December 31, 2024 and 2023, was comprised as follows:

	December 31, 2024	December 31, 2023
Research and development	307	176
General and administrative	364	159
	671	335

The increase in share-based compensation expense is attributable to the current year vesting of equity awards granted to employees, directors and consultants supporting our research and development and general and administrative functions.

Other (Income) Expense, net

Other expense was $8,050 for the year ended December 31, 2024, as compared to other income $7 for the prior-year period. The increase in other expense is primarily attributed to recognized losses on the settlement of debt and the issuance of warrants containing derivative features.

Net Loss

Net loss was $22,597 for the year ended December 31, 2024, as compared to a net loss of $7,097 for the prior-year period. The increase in net loss is attributable primarily to the expense classifications discussed above.

Liquidity and Capital Resources

As of December 31, 2024, we had $5,617 in cash and cash equivalents compared with $4,492 in cash and cash equivalents as of December 31, 2023. The net increase in cash and cash equivalents was attributable to the $13,743 received from financing activities offset by cash used in operating and investing activities of $12,594.

We have a history of recurring losses, and as of December 31, 2024, we have a stockholders' deficiency of $13,000. During the fiscal year ended December 31, 2024, we recorded a net loss of $22,597. Our primary requirements for liquidity have been to fund product and clinical development activities and to satisfy our general corporate and working capital needs.

Subsequent to December 31, 2024, we received approximately $6,349 through the February 2025 Offering and the March ATM Sale. In addition, as noted above, the impact of the subsequent financings, the exercise of Series B Warrants and the revaluation of Series A warrants has resulted in Stockholders' Equity of $10,629 as of December 31, 2024, on a pro forma basis.

Based on our operating plans, we do not expect that our current cash and cash equivalents as of December 31, 2024, will be sufficient to fund our operating, investing, and financing cash flow needs for at least the next twelve months, assuming our programs advance as currently contemplated. Based upon this review and our current financial condition, the Company has concluded that substantial doubt exists as to our ability to continue as a going concern. We have raised and believe we will continue to be able to raise additional capital through debt financing, private or public equity financings, license agreements, collaborative agreements or other arrangements with other companies, or other sources of financing. However, there can be no assurances that such financing will be available or will be at terms acceptable to us, or at all. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, reduce, or eliminate our clinical trials or other operations. If any of these events occur, our ability to achieve our operational goals would be adversely affected. Our future capital requirements and the adequacy of available funds will depend on many factors, including those described in the section titled "*Risk Factors*." Depending on the severity and direct impact of these factors on us, we may be unable to secure additional financing to meet our operating requirements on commercially acceptable terms favorable to us, or at all.

Going Concern Uncertainty

To date, we have not yet commercialized the Glucotrack CBGM. Further development and commercialization efforts are expected to require substantial additional expenditure. Therefore, we are dependent upon external sources for financing our operations. As of December 31, 2024, we have incurred a stockholders' deficiency of $13,000, which includes an accumulated deficit of $132,450. In addition, we have generated operating losses and negative operating cash flow for all reported periods. As of December 31, 2024, the balance of cash and cash equivalents amounted to $5,617.

During the year ended December 31, 2024, we received approximately $13,734 through public offerings and debt issuances which were subsequently converted to equity. In addition, subsequent to the balance sheet date, we received $6,349 through the sale of shares of Common Stock. We plan to finance our operations through the sale of debt or equity securities (including the shelf registration statement on Form S-3 that was declared effective on October 3, 2024 by the SEC which allows us to register up to $30,000 of certain equity and/or debt securities of the Company through prospectus supplement). There can be no assurance that we will succeed in obtaining the necessary financing or generating sufficient revenue from sale of the Glucotrack CBGM in order to continue our operations as a going concern.

Management has considered the significance of such conditions in relation to our ability to meet current obligations and to achieve our business targets and determined that these conditions raise substantial doubt about our ability to continue as a going concern.

Critical Accounting Policies and Estimates

The discussion and analysis of our financial condition and results of operations are based on our audited consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States, or GAAP. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues, expenses, and related disclosures. We evaluate our estimates on an ongoing basis. We base our estimates on historical experience and on other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

We believe the following accounting policies and estimates are critical to aid you in understanding and evaluating our reported financial results.

Share-Based Compensation

We grant equity-based awards under share-based compensation plans. We estimate the fair value of share-based payment awards using the Black-Scholes option valuation model. This fair value is then amortized over the requisite service periods of the awards. The Black-Scholes option valuation model requires the input of subjective assumptions, including price volatility of the underlying stock, risk-free interest rate, dividend yield, and expected life of the option. Share-based compensation expense is based on awards ultimately expected to vest and therefore is reduced by expected forfeitures. Changes in assumptions used under the Black-Scholes option valuation model could materially affect our net loss and net loss per share.

Derivative Financial Instruments

We review the terms of the Common Stock, warrants and convertible debt we issue to determine whether there are derivative instruments, including embedded conversion options that are required to be bifurcated and accounted for separately as derivative financial instruments. In circumstances where the host instrument contains more than one embedded derivative instrument, including a conversion option, that is required to be bifurcated, the bifurcated derivative instruments are accounted for as a single, compound derivative instrument.

Derivatives are initially recorded at fair value and are then revalued at each reporting date with changes in the fair value reported as non-operating income or expense. When the equity or convertible debt instruments contain embedded derivative instruments that are to be bifurcated and accounted for as liabilities, the total proceeds received are first allocated to the fair value of all the bifurcated derivative instruments. The remaining proceeds, if any, are then allocated to the host instruments themselves, usually resulting in those instruments being recorded at a discount from their face value.

Recent Accounting Pronouncements

Information regarding recent accounting pronouncements is contained in Note 2 to the Consolidated Financial Statements, included elsewhere in this report.

Off Balance Sheet Arrangements

We do not have any off-balance sheet arrangements.

Item 7A. Quantitative and Qualitative Disclosure About Market Risk

As a smaller reporting company, we have elected not to provide the disclosure required by this item.

Item 8. Financial Statements and Supplementary Data

Reference is made to pages F-1 through F-31 comprising a portion of this Annual Report on Form 10-K, which are incorporated by reference under this Item.

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

None.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Management, under the supervision and with the participation of the Chief Executive Officer and Chief Financial Officer, have conducted an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act). Disclosure controls and procedures are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by

a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to our management, including our principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Based on that evaluation, our Chief Executive Officer and our Chief Financial Officer, concluded that as of the end of the period covered by this Annual Report, (i) the Company's disclosure controls and procedures were not effective to ensure that material information relating to the Company is recorded, processed, summarized, and reported within the time periods specified in the rules and forms of the SEC, and (ii) the Company's controls and procedures have not been designed to ensure that information required to be disclosed by the Company in the reports that it files or submits under the Exchange Act, is accumulated and communicated to the Company's management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

Management's Report on Internal Controls Over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rules 13a-15(f) and 15d-15(f). Under the supervision and with the participation of management including our Chief Executive Officer and our Chief Financial Officer, the Company conducted an evaluation of the effectiveness of its internal control over financial reporting based principally on the framework and criteria established in Internal Control - Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission as of the end of the period covered by this Annual Report. Based on the foregoing evaluation, management concluded that the Company's internal controls over financial reporting were not effective because of the material weaknesses discussed below.

This Annual Report does not include an attestation report of the Company's registered public accounting firm regarding internal control over financial reporting because the attestation report requirement has been removed for "smaller reporting companies" under the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010.

The Company has identified material weaknesses in its internal control over financial reporting. As defined in Regulation 12b-2 under the Exchange Act, a "material weakness" is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented, or detected on a timely basis. The Company identified material weaknesses in its internal controls in the following areas: general IT controls; lack of sufficient accounting personnel and inadequate segregation of duties consistent with control objectives. None of these deficiencies resulted in a material misstatement to the Company's annual or interim Consolidated Financial Statements for the year ended December 31, 2024.

Management's Remediation Measures

Management has identified corrective actions to remediate such material weaknesses, which includes the implementation of proper IT system access controls and the proper backup of the Company's IT architecture. In addition, the Company has outsourced certain accounting functions to ensure proper segregation of duties over financial reporting and hired additional accounting personnel. Management intends to continue the implementation of procedures to remediate such material weaknesses during the fiscal year 2025; however, the implementation of these initiatives may not fully address any material weaknesses that we may have in our internal control over financial reporting.

The Company will continue to review and improve its internal controls over financial reporting to address the underlying causes of the material weaknesses and control deficiencies. Such material weaknesses and control deficiencies will not be remediated until the Company's remediation plan has been fully implemented, and it has concluded that its internal controls are operating effectively for a sufficient period of time.

Changes in Internal Control over Financial Reporting

Except for the material weaknesses and the remediation efforts described above, no other change in our internal control over financial reporting (as defined by Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the quarter ended December 31, 2024, that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

Item 9B. Other Information

None.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

Information Regarding Directors and Executive Officers

The following table sets forth information regarding our executive officers and non-employee directors.

Name	Age	Position
Paul V. Goode	57	Chief Executive Officer, President, and Director
Peter C. Wulff	65	Chief Financial Officer
Luis Malave	63	Director
Erin Carter	55	Director
Dr. Robert Fischell	96	Director
Andrew K. Balo	77	Director
Allen Danzig	69	Director
John Ballantyne	55	Director

Paul V. Goode, PhD – Chief Executive Officer, President and Director

Dr. Goode has served as the Company's Chief Executive Officer since November 2021. He most recently served as Vice President of Product Development at Orchestra Biomed where he oversaw development of its implantable cardiac stimulator system for hypertension. Prior to Orchestra, from 2010 until July 2019 Dr. Goode served in several executive roles at EndoStim, including Senior Vice President of R&D, Chief Technology Officer, and Interim Chief Executive Officer. From 2006 through 2010 he served as Vice President of Research and Development at Metacure and from 2004 through 2006 Mr. Goode served as Director of Engineering at Impulse Dynamics. Prior to that, Mr. Goode was employed as Director of Engineering at DexCom and as Senior Engineer at MiniMed. Dr. Goode received his BS, MS and PhD degrees from North Carolina State University. Dr. Goode's extensive experience in the medical device space qualifies him to serve on our Board of Directors.

Peter C. Wulff – Chief Financial Officer, Treasurer and Corporate Secretary

Mr. Wulff has served as the Company's Chief Financial Officer since January 2025. Mr. Wulff has over 40 years' experience in financial and operating management in the emerging growth life sciences industry, having served most recently as Chief Financial Officer of Biological Dynamics, Inc., a life science research organization focused on early cancer detection, from January 2023 to June 2024. Prior to his time at Biological Dynamics, Inc., he served as the Chief Financial Officer at JenaValve Technology, Inc., a heart valve technology medical device company, from August 2015 to April 2022. Mr. Wulff has served as the executive financial officer of various other medical technology companies, including PURE Bioscience, Inc. from November 2012 to July 2015, Alphatec Spine Holdings from June 2008 to April 2011, Artes Medical Inc. from January 2005 to May 2008, and CryoCor, Inc. from May 2001 to May 2004. In these roles, he directed and managed accounting and finance and investor relations. Mr. Wulff earned his MBA in Finance and his bachelor's degree in Economics and Germanic Languages from Indiana University.

Luis Malavé – Director

Mr. Malavé has served as a director of the Company since June 22, 2021 and serves on our Audit Committee and Nominating, Governance and Compensation Committee. Mr. Malavé brings more than 30 years of leadership experience in the MedTech industry, primarily in diabetes management, spanning all company stages, from private startups to large-cap publicly listed companies. He has extensive expertise in product development, operations, marketing, strategic partnerships, and US FDA regulatory strategy. Since October 2017, Mr. Malavé has served as President of EOFLOW CO. Ltd., a company listed on the Korea Stock Exchange that has developed a wearable disposable insulin pump. From October 2014 to June 2016, he was COO of Mikroscan Technologies. Prior to that, Mr. Malavé was the President and CEO of Palyon Medical, maker of an implantable drug-delivery system that spun out from German medical-technology giant Fresenius SE. Prior to Palyon, he spent nearly a decade at insulin pump maker Insulet Corp., including as its Senior Vice President of Research, Development and Engineering, and as Chief Operating Officer. He also held various senior positions at Medtronic and MiniMed, overseeing product development of various diabetes management devices. Mr. Malavé earned his Bachelor's degree in Mathematics and Computer Science from the University of Minnesota, a Master's degree in Software Engineering from the University of St. Thomas, and an MBA from the University of Maryland. Mr. Malavé's extensive experience in the medical device space and public company experience qualify him to serve on our Board of Directors.

Erin Carter – Director

Ms. Carter has served as a director of the Company since August 25, 2023, and is the Chair of its Audit Committee. Ms. Carter brings 30 years of executive level finance experience in the medical device industry. Ms. Carter (since July of 2024) currently serves as the Chief Financial Officer for the Mayo Collaborative Services, at the Mayo Clinic. Mayo Collaborative Services facilitates access to the Mayo Clinic diagnostic expertise and services with revenues exceeding $1B. From 2012 until March of 2023, she held various senior roles with Medtronic, most recently serving as Chief Financial Officer and Vice President of Finance for their $9B Neuroscience division. In addition, during her tenure at Medtronic she grew the Gastrointestinal Solutions division from early tech start-up acquisition of $36M to revenue of $450M in 5 years through organic growth and multiple acquisitions. Prior to Medtronic, Ms. Carter served as Director of Finance at Boston Scientific and as VP of Accounting and Reporting at UnitedHealth Group. Prior to that, she served as Assistant Controller for Arterial Vascular Engineering, where she was instrumental in guiding the rapid growth of the company from 200 employees to over 4,000 in under five years. During this time, she managed the integration of two acquisitions and subsequently that company's sale to Medtronic. Ms. Carter holds a B.S. in Business Administration from California Polytech State University and is a Certified Public Accountant (inactive) in the State of California. Ms. Carter's extensive executive finance experience, including leadership roles in the medical device space, makes her qualified to serve on our Board of Directors.

Dr. Robert Fischell –Director

Dr. Fischell has served as a director of the Company since 2010. He also serves on the Company's Nominating, Governance and Compensation Committee and on the Audit Committee. Dr. Fischell is an inventor and serial entrepreneur with over 160 issued U.S. patents. Starting in 1959, Dr. Fischell spent over 30 years with the Johns Hopkins University Applied Physics Laboratory, which resulted in 53 patents in both aerospace and biomedical technology. His interests at Johns Hopkins then turned to the invention of new medical devices such as pacemakers and implantable heart defibrillators. Starting in 1969, Dr. Fischell began the formation of 14 private companies that licensed his patents on medical devices. These companies include Pacesetter Systems, Inc. (purchased by Siemens and now part of St. Jude Medical, Inc.), IsoStent, Inc. (merged with Cordis Company, a Johnson and Johnson Company), NeuroPace, Inc., Neuralieve, Inc., Angel Medical Systems, Inc., and Svelte Medical Systems, Inc. As it relates to diabetes management devices, he was the inventor of the first implantable insulin pump (which became Minimed, which was sold to Medtronic). Dr. Fischell's honors include Inventor of the Year for the USA in 1984, election to the National Academy of Engineering in 1989, the Distinguished Physics Alumnus Award of the University of Maryland, and several medals for distinguished accomplishments in science, engineering and innovation. In 2004, Discover magazine gave Dr. Fischell their annual Technology for Humanity award. In 2008, Dr. Fischell received the honorary degree of Doctor of Humane Letters from the Johns Hopkins University in recognition of his many lifesaving inventions. From June 2009 until March 2011, Dr. Fischell was a director of InspireMD, Inc. (OTCBB: NSPR), a medical device company focusing on the development and commercialization of its proprietary stent system, MGuard. Dr. Fischell received his BSME degree from Duke University and MS and Sc.D. degrees from the University of Maryland. At the White House on May 16, 2016, President Obama presented to Dr. Fischell the National Medical of Technology and Innovation, the highest award in the USA for achievements in innovative technology. Dr. Fischell is suited to serve as a member of the Board of Directors due to his extensive diabetes and medical device experience.

Andrew K. Balo – Director

Mr. Balo has served as a director of the Company since June 2024. Mr. Balo joined DexCom International, Ltd. as part of the original executive team in 2002 and played a critical role in shaping the company's future. During his tenure, he was responsible for numerous glucose monitoring regulatory submissions and clinical trials worldwide and coordinated quality activities across multiple manufacturing facilities. From February 2022 until his retirement on March 24, 2024, Mr. Balo served as Executive Vice President of Clinical, Global Access, and Medical Affairs. Prior to joining Dexcom, Mr. Balo held several leadership positions at St. Jude Medical, including Corporate Vice President of Regulatory, Clinical, and Quality, and also served in executive roles at Baxter, Pacesetter and Endocardial Solutions. Mr. Balo's extensive leadership experience in clinical and regulatory affairs makes him qualified to serve on the Board of Directors.

Allen Danzig – Director

Mr. Danzig has served on our Board since October 31, 2019 and is the Chair of our Nominating, Governance and Compensation Committee. Mr. Danzig most recently served as Vice President, Assistant General Counsel and Assistant Secretary of L3Harris Technologies, Inc., a global aerospace and defense technology contractor, with $17 billion in annual revenue. Prior to its merger with Harris Corporation in June 2019, Mr. Danzig served as Vice President, Assistant General Counsel and Assistant Secretary at L3 Technologies, Inc. where he had been employed since 2006. Prior to his employment at

L3, Mr. Danzig served in management positions with Celanese Corporation, a global chemical and specialty materials company, and The Hertz Corporation, one of the world's largest vehicle and equipment rental companies. He received his undergraduate degree from Adelphi University and law degree from Pace University School of Law and is a member of the New York State Bar. Mr. Danzig's extensive legal and corporate governance experience makes him qualified to serve on the Board of Directors.

John Ballantyne – Director

Mr. Ballantyne has served on our Board since September 2024. Mr. Ballantyne brings over 20 years of experience on the executive team at the global biotechnology contract development and manufacturing organization, Aldevron. He co-founded the company in 1998 and served as its Chief Science Officer through its acquisition by Danaher, and until December 2021. A leader in advancing biological science, Aldevron's custom development and manufacturing services have provided scientists around the world with the essential components to accelerate research within their laboratories for groundbreaking science and breakthrough discoveries. Due to Aldevron's significant presence in the biotechnology sector, Mr. Ballantyne has developed relationships across a continuum of focus areas maintained through investments, Board and Scientific Advisory Board roles and co-founding of multiple companies. Mr. Ballantyne holds undergraduate degrees in Pharmacy from the Central Institute of Technology (Heretaunga, NZ) and University of Otago (Dunedin, NZ) and his Doctorate in Pharmaceutical Sciences from North Dakota State University (Fargo, ND). Mr. Ballantyne's extensive experience in healthcare research and innovation, strategic growth, and other key business functions makes him a valuable addition to the Board.

Compliance with Section 16(a) of the Exchange Act

Section 16(a) of the Securities Exchange Act of 1934, requires our directors, executive officers and persons who own more than 10% of our common stock to file with the SEC initial reports of ownership and reports of changes in ownership of common stock and other of our equity securities.

Based solely upon a review of those reports and written representations provided to us by all of our directors and executive officers, we believe that during the year ended December 31, 2024, our directors, executive officers and greater than 10% stockholders did not report the following transactions on a timely basis: a Form 3 filing for Luis Malave that was due on June 22, 2021, which was filed on March 28, 2025; a Form 3 filing for Andrew Balo that was due on June 14, 2024, which was filed on March 28, 2025; a Form 3 filing for the John A. Ballantyne Revocable Trust 08/01/2017 (the "Ballantyne Trust") that was due on July 30, 2024, which was filed on March 28, 2025; Forms 4 for Allen Danzig reporting the acquisition of Common Stock on each of October 4, 2022 and April 8, 2024, both of which were not filed (both of the aforementioned acquisitions by Allen Danzig were subsequently reported on a Form 4 filed on March 28, 2025); Forms 4 for Robert Fischell reporting the acquisition of Common Stock on each of August 24, 2021 and April 8, 2024, each of which were not filed (both of the aforementioned acquisitions by Robert Fischell were subsequently reported on a Form 4 filed on March 28, 2025); a Form 4 for Paul Goode disclosing an option grant that was made on June 14, 2024, was not filed; a Form 4 for Paul Goode disclosing the purchase of a warrant on July 1, 2024, was not filed; a Form 4 for Paul Goode reporting the purchase of a convertible promissory note on July 18, 2024, was not filed; a Form 4 for Paul Goode reporting the conversion of a promissory note on November 14, 2024, was not filed; a Form 4 for Paul Goode reporting the acquisition of Series A Common Warrants and Series B Common Warrants on November 14, 2024, was not filed; a Form 4 for Paul Goode reporting the acquisition of Common Stock pursuant to the IP Purchase Agreement, was not filed (each of the aforementioned transactions by Paul Goode were subsequently reported on a Form 4 filed on March 28, 2025); Forms 4 for Erin Carter reporting the acquisition of Common Stock on each of December 31, 2023 and April 8, 2024, both of which were not filed; a Form 4 for Erin Carter reporting the purchase of a convertible promissory note on July 18, 2024, was not filed; a Form 4 for Erin Carter reporting the conversion of a promissory note on November 14, 2024, was not filed; a Form 4 for Erin Carter reporting the acquisition of Series A Common Warrants and Series B Common Warrants on November 14, 2024, was not filed (each of the aforementioned transactions by Erin Carter were subsequently reported on a Form 4 filed on March 28, 2025); a Form 4 for John Ballantyne reporting the purchase of three warrants on July 30, 2024, was not filed; a Form 4 for John Ballantyne reporting the conversion of a promissory note on November 14, 2024, was not filed; a Form 4 for John Ballantyne reporting the acquisition of Series A Common Warrants and Series B Common Warrants on November 14, 2024, was not filed; (each of the aforementioned transactions by John Ballantyne were subsequently reported on a Form 4 filed on March 31, 2025); a Form 4 for the Ballantyne Trust reporting the purchase of three warrants on July 30, 2024, was not filed; a Form 4 for the Ballantyne Trust reporting the conversion of a promissory note on November 14, 2024, was not filed; a Form 4 for the Ballantyne Trust reporting the acquisition of Series A Common Warrants and Series B Common Warrants on November 14, 2024, was not filed (each of the aforementioned transactions by the Ballantyne Trust were subsequently reported on a Form 4 filed on March 31, 2025); Forms 4 for Luis Malave reporting the acquisition of Common Stock on each of August 31, 2021, December 31, 2021, March 31, 2022, June 30, 2022, October 4, 2022, January 9, 2023, August 20, 2023, December 31, 2024 and April 8, 2024, each of which

were not filed; a Form 4 for Luis Malave reporting the purchase of a convertible promissory note on July 18, 2024, was not filed; a Form 4 for Luis Malave reporting the conversion of a promissory note on November 14, 2024, was not filed; and a Form 4 for Luis Malave reporting the acquisition of Series A Common Warrants and Series B Common Warrants on November 14, 2024, was not filed; (each of the aforementioned transactions by Luis Malave were subsequently reported on a Form 4 filed on March 31, 2025).

Code of Ethics and Business Conduct

In accordance with the information required by this Item 10 relating to the code of ethics required by Item 406 of Regulation S-K, the Company has a Code of Ethics and Business Ethics (the "Code of Ethics"), which applies to its directors, officers, and employees, including its principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions (collectively, the "Covered Persons" and each a "Covered Person"). The full text of the Code of Ethics is available on the "Investors" section of our website, which is located at *www.glucotrack.com*. The Company intends to satisfy the SEC's requirements regarding amendments to, or waivers from, the Code of Ethics by posting such information on its website or by filing a Current Report on Form 8-K to disclose such information.

Procedures for Stockholders to Recommend Director Nominees

There have been no material changes to the procedures by which security holders may recommend nominees to our Board.

Audit Committee Information

The Company's Board has a standing Audit Committee. Our Audit Committee is chaired by Erin Carter and its other members are Luis Malave and Dr. Robert Fischell. Our Board has determined that each of these directors is "independent" as defined by the rules of the SEC and the Nasdaq Listing Rules. The Board has determined that Ms. Carter is an "audit committee financial expert" as that term is defined in Item 407(d)(5)(ii) of Regulation S-K.

Insider Trading Policy

The Company has an insider trading policy (the "Insider Trading Policy") which prohibits Covered Persons from buying or selling the Company's securities while the Covered Person is aware of material nonpublic information about the Company. The Company believes that its Insider Trading Policy is reasonably designed to promote compliance with insider trading laws, rules and regulations, and any applicable listing standards. A copy of the Insider Trading Policy is filed as Exhibit 19.1 to this Annual Report.

Item 11. Executive Compensation

The following discussion contains forward-looking statements that are based on our current plans, considerations, expectations and determinations regarding future compensation programs. The actual amount and form of compensation and the compensation policies and practices that we adopt in the future may differ materially from currently planned programs as summarized in this discussion.

We are currently considered a "smaller reporting company" within the meaning of the Securities Act for purposes of the SEC's executive compensation disclosure rules. Accordingly, we are required to provide a Summary Compensation Table, as well as limited narrative disclosures regarding executive compensation for our last two completed fiscal years and an Outstanding Equity Awards at Fiscal Year End Table for our last completed fiscal year. These reporting obligations extend only to "named executive officers." Individuals we refer to as our "named executive officers" include (i) all individuals serving as our Chief Executive Officer during the fiscal year ended December 31, 2024 and (ii) our two most highly compensated executive officers, as defined in Exchange Act Rule 3b-7, other than our Chief Executive Officer, who were serving as executive officers at the end of the fiscal year ended December 31, 2024, whose salary and bonus for services rendered in all capacities exceeded $100,000 during the fiscal year ended December 31, 2024.

This section discusses material components of the executive compensation programs for the Company's "named executive officers" who area named in the "Summary Compensation Table" below. In 2024, the Company's "named executive officer" was Paul V. Goode, the Company's Chief Executive Officer. No other executive officer of the Company received total compensation during the fiscal year ended December 31, 2024 in excess of $100,000, and thus disclosure is not required for any other person.

Summary Compensation Table

The following table sets forth total compensation paid to our named executive officer for the years ended December 31, 2024, and 2023.

Name and Position	Year	Salary ($)	Bonus ($)	Stock Awards ($)	Option Awards ($)[1]	Non-Equity Incentive Plan Compensation ($)	Non-qualified Deferred Compensation Earnings ($)	All Other Compensation ($)	Total ($)
Paul V Goode	2024	350,000	—	—	2,096	—	—	—	352,096
Chief Executive Officer	2023	225,000	—	—	258,243	—	—	—	356,237

Narrative to the Summary Compensation Table

Annual Base Salary

We pay our named executive officer a base salary to compensate him for services rendered to our company. The base salary payable to our named executive officers is intended to provide a fixed component of compensation reflecting the executive's skill set, experience, role and responsibilities.

Equity Compensation

We have granted stock options to our employees, including our named executive officer, in order to attract and retain them, as well as to align their interests with the interests of our shareholders. In order to provide a long-term incentive, these stock options vest over three years subject to continued service.

Executive Compensation Arrangements

Employment Agreement

Set forth below is a summary of the material terms of the employment agreement of our current named executive officer.

Paul Goode

On October 19, 2021, Paul V. Goode was appointed as President and Chief Operating Officer of the Company, effective November 1, 2021 (the "Goode Effective Date") and currently serves as the Chief Executive Officer.

In this role, Goode leads the Company's operations, overseeing strategy, design, manufacturing, business and product development and helps to build the U.S. infrastructure in preparation for the U.S. clinical trials of the Company. He devotes such time as necessary to perform his duties but is able to pursue other professional opportunities at the same time. His base salary shall be $175,000 per year, and he is entitled to a cash bonus of up to 20% of his annual base salary as determined by the Company's Compensation Committee and was granted options to purchase up to one-and-a-half percent (1.5%) of the fully diluted Common Stock as of the Goode Effective Date, with a per share exercise price equal to $49.00 per share, which vests in equal monthly installments over a three-year period following the Goode Effective Date.

The bonus and equity incentives are subject to clawback rights if there is a misstatement of financials which changes any metrics upon which a bonus or incentives are based and the clawback will be pro rata based upon the changes in the financials with respect to the effect on any underlying metrics.

Outstanding Equity Awards as of December 31, 2024

The following table sets forth for the Company's named executive officer certain information regarding unexercised options as of December 31, 2024:

Name	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price	Option Expiration Date
Paul V. Goode	3,277	—	$ 49.00	10/31/31

Director Compensation

Decisions regarding the compensation to be paid to the members of our Board of Directors, if any, are determined and/or ratified by the Board with recommendations given by the Compensation Committee. Non-employee directors are compensated with a combination of cash and shares. Additionally, we provide reimbursement to our non-employee directors for their reasonable expenses incurred in attending meetings of our Board of Directors and its committees. Directors may also receive equity awards from time to time. The directors who also serve as an employee of the Company do not receive additional compensation for their service as a director.

The following table sets forth information with respect to the compensation of our directors as of December 31, 2024:

Name	Fees Earned or Paid in Cash	Stock Awards ($)	Options Awards ($)	All Other Compensation ($)	Total
Allen Danzig	$ 70,000	$ 30,000	$ —	$ —	$ 100,000
Luis Malave	$ 64,750	$ 55,250	$ —	$ —	$ 120,000
Dr. Robert Fischell	$ 70,000	$ 30,000	$ —	$ —	$ 100,000
Erin Carter	$ 45,000	$ 55,000	$ —	$ —	$ 100,000
John Ballantyne	$ —	$ 34,783	$ —	$ —	$ 34,783
Andrew Balo	$ —	$ 53,022	$ —	$ —	$ 53,022
Shimon Rapps[(1)]	$ 43,333	$ 15,000	$ —	$ —	$ 58,333
Andrew Sycoff[(1)]	$ —	$ 58,333	$ —	$ —	$ 58,333
	$ 293,083	$ 331,388	$ —	$ —	$ 624,471

(1) On July 29, 2024, the director resigned from the board of directors.

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

Securities Authorized for Issuance under Share-Based Compensation Plans

Equity Compensation Plan Information

The following table sets forth, as of December 31, 2024, information regarding awards previously granted and outstanding, and securities authorized for future issuance, under the Company's equity compensation plans.

Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants or Rights	Weighted-Average Exercise Price of Outstanding Options, Warrants or Rights	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Outstanding Options, Warrants, or Rights)
Equity compensation plans approved by shareholders	16,436	$ 49.72	10,321
Equity compensation plans not approved by shareholders	-	-	-

Summary of Material Terms of the 2024 Equity Incentive Plan

The following is a summary of the material features of the Glucotrack, Inc. 2024 Equity Incentive Plan (the "2024 Plan"), which was adopted by the stockholders on April 26, 2024. This summary is qualified in its entirety by the full text of the 2024 Plan, a copy of which is filed as an exhibit to this Annual Report.

Purpose

The purpose of the 2024 Plan is to provide employees, directors, and consultants with opportunities to acquire the Company's shares, or to receive monetary payments based on the value of such shares. Equity awards and equity-linked compensatory opportunities are intended to assist in further aligning the interests of directors, employees, and consultants with those of our stockholders.

Eligibility

Persons eligible to participate in the 2024 Plan will be employees, directors, and consultants of the Company and its subsidiaries as selected from time to time by the plan administrator in its discretion, including prospective officers, employees, non-employee directors and consultants. Any awards granted to such a prospect before the individual's start date may not become vested or exercisable, and no shares may be issued to such individual, before the date the individual first commences performance of services with the Company. As of the date of this Annual Report, approximately 13 individuals are eligible to participate in the 2024 Plan.

Administration

The 2024 Plan will be administered by the Compensation Committee of our Board of Directors, our Board of Directors, or such other similar committee pursuant to the terms of the 2024 Plan. The plan administrator, which initially will be the Compensation Committee of our Board of Directors, will have full power to select, from among the individuals eligible for awards, the individuals to whom awards will be granted, to make any combination of awards to participants, and to determine the specific terms and conditions of each award, subject to the provisions of the 2024 Plan. The plan administrator may delegate to one or more officers of the Company, the authority to grant awards to individuals who are not subject to the reporting and other provisions of Section 16 of the Exchange Act.

Share Reserve

Up to 26,756 shares of our Common Stock may be issued under the 2024 Plan. Following stockholder approval of the 2024 Plan, no new awards will be made under the 2010 Plan.

Shares issuable under the 2024 Plan may be authorized, but unissued, or reacquired shares of Common Stock. Shares underlying any awards under the 2024 Plan that are forfeited, cancelled, held back upon exercise of an option or settlement of an award to cover the exercise price or tax withholding satisfied without the issuance of stock or otherwise terminated (other than by exercise) will be added back to the shares available for issuance under the 2024 Plan, although shares shall not again become available for issuance as incentive stock options.

Annual Limitation on Awards to Non-Employee Directors

The 2024 Plan contains a limitation whereby the value of all awards under the 2024 Plan and all other cash compensation paid by the Company to any non-employee director may not exceed $750,000 for the first calendar year a non-employee director is initially appointed to the Company's Board of Directors, and $500,000 in any other calendar year.

Types of Awards

The 2024 Plan provides for the grant of stock options, stock appreciation rights, restricted stock, restricted stock units, and other stock-based awards (collectively, "awards"). Unless otherwise set forth in an individual award agreement, each award shall vest over a three (3) year period, with one-third (1/3) of the award vesting on the first annual anniversary of the date of grant and the remaining portion of the award vesting monthly thereafter.

Stock Options.

The 2024 Plan permits the granting of both options intended to qualify as incentive stock options under Section 422 of the Internal Revenue Code of 1986, as amended (the "Code") and options that do not so qualify. Options granted under the 2024 Plan will be nonqualified options if they fail to qualify as incentive stock options or exceed the annual limit on incentive stock options. Incentive stock options may only be granted to employees of the Company and its subsidiaries. Nonqualified options may be granted to any persons eligible to receive awards under the 2024 Plan.

The exercise price of each option will be determined by the plan administrator, but such exercise price may not be less than 100% of the fair market value of one share of Common Stock on the date of grant or, in the case of an incentive stock option granted to a 10% or greater stockholder, 110% of such share's fair market value. The term of each option will be fixed by the plan administrator and may not exceed ten (10) years from the date of grant (or five years for an incentive stock option granted to a 10% or greater stockholder). The plan administrator will determine at what time or times each option may be exercised, including the ability to accelerate the vesting of such options.

Upon exercise of an option, the exercise price must be paid in full either in cash, check or, with approval of the plan administrator, by delivery (or attestation to the ownership) of the shares of Company Common Stock that are beneficially owned by the optionee free of restrictions or were purchased in the open market. Subject to applicable law and approval of the plan administrator, the exercise price may also be made by means of a broker-assisted cashless exercise. In addition, the plan administrator may permit nonqualified options to be exercised using a "net exercise" arrangement that reduces the number of shares issued to the optionee by the largest whole number of shares with fair market value that does not exceed the aggregate exercise price.

Stock Appreciation Rights.

The plan administrator may award stock appreciation rights subject to such conditions and restrictions as it may determine. Stock appreciation rights entitle the recipient to shares of Common Stock or cash, equal to the value of the appreciation in the Company's stock price over the exercise price, as set by the plan administrator. The term of each stock appreciation right will be set by the plan administrator and may not exceed ten years from the date of grant. The plan administrator will determine at what time or times each stock appreciation right may be exercised, including the ability to accelerate the vesting of such stock appreciation rights.

Restricted Stock.

A restricted stock award is an award of shares of Common Stock that vests in accordance with the terms and conditions established by the plan administrator. The plan administrator will determine the persons to whom grants of restricted stock awards are made, the number of restricted shares to be awarded, the price (if any) to be paid for the restricted shares, the time or times within which awards of restricted stock may be subject to forfeiture, the vesting schedule and rights to acceleration thereof, and all other terms and conditions of restricted stock awards. Unless otherwise provided in the applicable award agreement, a participant generally will have the rights and privileges of a stockholder as to such restricted shares, including without limitation the right to vote such restricted shares and the right to receive dividends, if applicable.

Restricted Stock Units.

Restricted stock units are the right to receive shares of Common Stock at a future date in accordance with the terms of such grant upon the attainment of certain conditions specified by the plan administrator. Restrictions or conditions could include, but are not limited to, the attainment of performance goals, continuous service with the Company or its subsidiaries, the passage of time or other restrictions or conditions. The plan administrator determines the persons to whom grants of restricted stock units are made, the number of restricted stock units to be awarded, the time or times within which awards of restricted stock units may be subject to forfeiture, the vesting schedule, and rights to acceleration thereof, and all other terms and conditions of the restricted stock unit awards. The value of the restricted stock units may be paid in shares of Common Stock, cash, other securities, other property, or a combination of the foregoing, as determined by the plan administrator.

The holders of restricted stock units will have no voting rights. Prior to settlement or forfeiture, restricted stock units awarded under the 2024 Plan may, at the plan administrator's discretion, provide for a right to dividend equivalents. Such right entitles the holder to be credited with an amount equal to all dividends paid on one share of Common Stock while each restricted stock unit is outstanding. Dividend equivalents may be converted into additional restricted stock units. Settlement of dividend equivalents may be made in the form of cash, shares of Common Stock, other securities, other property, or a combination of the foregoing. Prior to distribution, any dividend equivalents shall be subject to the same conditions and restrictions as the restricted stock units to which they are payable.

Other Stock-Based Awards.

Other stock-based awards may be granted either alone, in addition to, or in tandem with, other awards granted under the 2024 Plan and/or cash awards made outside of the 2024 Plan. The plan administrator shall have authority to determine the persons to whom and the time or times at which other stock-based awards will be made, the amount of such other stock-based awards, and all other conditions, including any dividend and/or voting rights.

Repricing

The 2024 Plan authorizes the plan administrator to take the following repricing actions without stockholder approval: (i) modify the purchase price or the exercise price of any outstanding award or (ii) cancel any award in exchange for cash or another award.

Tax Withholding

Participants in the 2024 Plan are responsible for the payment of any federal, state, or local taxes that the Company or its subsidiaries are required by law to withhold upon the exercise of options or stock appreciation rights or vesting of other awards. The plan administrator may cause any tax withholding obligation of the Company or its subsidiaries to be satisfied, in whole or in part, by the applicable entity withholding from the shares of Common Stock to be issued pursuant to an award a number of shares with an aggregate fair market value that would satisfy the withholding amount due. The plan administrator may also require any tax withholding obligation of the Company or its subsidiaries to be satisfied, in whole or in part, by an arrangement whereby a certain number of shares issued pursuant to any award are immediately sold and proceeds from such sale are remitted to the Company or its subsidiaries in an amount that would satisfy the withholding amount due.

Equitable Adjustments

In the event of a merger, consolidation, recapitalization, stock split, reverse stock split, reorganization, split-up, spin-off, combination, repurchase or other change in corporate structure affecting shares of Common Stock, the maximum number and kind of shares reserved for issuance or with respect to which awards may be granted under the 2024 Plan will be adjusted to reflect such event, and the plan administrator will make such adjustments as it deems appropriate and equitable in the number, kind, and exercise price of shares of Common Stock covered by outstanding awards made under the 2024 Plan.

Change in Control

In the event of any proposed change in control (as defined in the 2024 Plan), the plan administrator will take any action as it deems appropriate, which action may include, without limitation, the following: (i) the continuation of any award, if the Company is the surviving corporation; (ii) the assumption of any award by the surviving corporation or its parent or subsidiary; (iii) the substitution by the surviving corporation or its parent or subsidiary of equivalent awards; (iv) accelerated vesting of the award, with all performance objectives and other vesting criteria deemed achieved at targeted levels, and a limited period during which to exercise the award prior to closing of the change in control, or (v) settlement of any award for the change in control price (less, to the extent applicable, the per share exercise price). Unless determined otherwise by the plan administrator, in the event that the successor corporation refuses to assume or substitute for the award, a participant shall fully vest in and have the right to exercise the award as to all shares of Common Stock, including those that would not otherwise be vested or exercisable, all applicable restrictions will lapse, and all performance objectives and other vesting criteria will be deemed achieved at targeted levels.

Transferability of Awards

Unless determined otherwise by the plan administrator, an award may not be sold, pledged, assigned, hypothecated, transferred, or disposed of in any manner, except to a participant's estate or legal representative, and may be exercised, during the lifetime of the participant, only by the participant. If the plan administrator makes an award transferable, such award will contain such additional terms and conditions as the plan administrator deems appropriate.

Term

The 2024 Plan became effective when approved by our shareholders, and, unless terminated earlier, the 2024 Plan will continue in effect for a term of ten (10) years.

Amendment and Termination

Our Board may amend or terminate the 2024 Plan at any time. Any such termination will not affect outstanding awards. No amendment or termination of the 2024 Plan will materially impair the rights of any participant, unless mutually agreed otherwise between the participant and the Company. Approval of the stockholders shall be required for any amendment, where required by applicable law, as well as (i) to increase the number of shares available for issuance under the 2024 Plan and (ii) to change the persons or class of persons eligible to receive awards under the 2024 Plan.

Recoupment Policy

All awards granted under the 2024 Plan, all amounts paid under the 2024 Plan, and all shares of Common Stock issued under the 2024 Plan shall be subject to reduction, recoupment, clawback, or recovery by the Company in accordance with applicable laws and with Company policy.

Form S-8

The Company intends to file with the SEC a registration statement on Form S-8 covering the shares of Common Stock issuable under the 2024 Plan.

Material United States Federal Income Tax Considerations

The following is a general summary under current law of the material U.S. federal income tax considerations related to awards and certain transactions under the 2024 Plan, based upon the current provisions of the Code and regulations promulgated thereunder. This summary deals with the general federal income tax principles that apply and is provided only for general information. It does not describe all federal tax consequences under the 2024 Plan, nor does it describe state, local, or foreign income tax consequences or federal employment tax consequences. The rules governing the tax treatment of such awards are quite technical, so the following discussion of tax consequences is necessarily general in nature and is not complete. In addition, statutory provisions are subject to change, as are their interpretations, and their application may vary in individual circumstances. This summary is not intended as tax advice to participants, who should consult their own tax advisors.

The 2024 Plan is not qualified under the provisions of Section 401(a) of the Code and is not subject to any of the provisions of the Employee Retirement Income Security Act of 1974, as amended. The Company's ability to realize the benefit of any tax deductions described below depends on the Company's generation of taxable income as well as the requirement of reasonableness and the satisfaction of the Company's tax reporting obligations.

Incentive Stock Options.

No taxable income is generally realized by the optionee upon the grant or exercise of an incentive stock option. If shares of Common Stock issued to an optionee pursuant to the exercise of an incentive stock option are sold or transferred after two years from the date of grant and after one year from the date of exercise, then generally (i) upon sale of such shares, any amount realized in excess of the option exercise price (the amount paid for the shares) will be taxed to the optionee as a long-term capital gain, and any loss sustained will be a long-term capital loss, and (ii) neither the Company nor its subsidiaries will be entitled to any deduction for federal income tax purposes; provided that such incentive stock option otherwise meets all of the technical requirements of an incentive stock option. The exercise of an incentive stock option will give rise to an item of tax preference that may result in alternative minimum tax liability for the optionee.

If the shares of Common Stock acquired upon the exercise of an incentive stock option are disposed of prior to the expiration of the two-year and one-year holding periods described above (a "disqualifying disposition"), generally (i) the optionee will realize ordinary income in the year of disposition in an amount equal to the excess (if any) of the fair market value of the shares of Common Stock at exercise (or, if less, the amount realized on a sale of such shares of Common Stock) over the option exercise price thereof, and (ii) the Company or its subsidiaries will be entitled to deduct such amount. Special rules will apply where all or a portion of the exercise price of the incentive stock option is paid by tendering shares of Common Stock.

If an incentive stock option is exercised at a time when it no longer qualifies for the tax treatment described above, the option is treated as a nonqualified option. Generally, an incentive stock option will not be eligible for the tax treatment described above if it is exercised more than three months following termination of employment (or one year in the case of termination of employment by reason of disability). In the case of termination of employment by reason of death, the three-month rule does not apply.

Nonqualified Options.

No income is generally realized by the optionee at the time a nonqualified option is granted. Generally, (i) at exercise, ordinary income is realized by the optionee in an amount equal to the difference between the option exercise price and the fair market value of the shares of Common Stock issued on the date of exercise, and the Company or its subsidiaries receive a tax deduction for the same amount, and (ii) at disposition, appreciation or depreciation after the date of exercise is treated as either short-term or long-term capital gain or loss depending on how long the shares of Common Stock have been held. Special rules will apply where all or a portion of the exercise price of the nonqualified option is paid by tendering shares of Common Stock. Upon exercise, the optionee will also be subject to Social Security taxes on the excess of the fair market value of the shares of Common Stock over the exercise price of the option.

Stock Appreciation Rights, Restricted Stock, Restricted Stock Units, and Other Stock-Based Awards.

The current federal income tax consequences of other awards authorized under the 2024 Plan generally follow certain basic patterns: (i) stock appreciation rights are taxed and deductible in substantially the same manner as nonqualified options; (ii) nontransferable restricted stock subject to a substantial risk of forfeiture results in income recognition equal to the excess of the fair market value of the shares of Common Stock over the price paid, if any, only at the time the restrictions lapse (unless the recipient elects to accelerate recognition as of the date of grant through a Section 83(b) election); and (iii) restricted stock units, dividend equivalents, and other stock or cash based awards are generally subject to tax at the time of payment. The Company or its subsidiaries generally should be entitled to a federal income tax deduction in an amount equal to the ordinary income recognized by the participant at the time the participant recognizes such income.

The participant's basis for the determination of gain or loss upon the subsequent disposition of shares of Common Stock acquired from a stock appreciation right, restricted stock, restricted stock unit, or other stock-based award will be the amount paid for such shares plus any ordinary income recognized when the shares were originally delivered, and the participant's capital gain holding period for those shares will begin on the day after they are transferred to the participant.

Parachute Payments.

The vesting of any portion of an award that is accelerated due to the occurrence of a change in control (such as a sale event) may cause all or a portion of the payments with respect to such accelerated awards to be treated as "parachute payments" as defined in the Code. Any such parachute payments may be non-deductible to either the Company or its subsidiaries, in whole or in part, and may subject the recipient to a non-deductible 20% federal excise tax on all or a portion of such payment (in addition to other taxes ordinarily payable).

Section 409A.

The foregoing description assumes that Section 409A of the Code does not apply to an award under the 2024 Plan. In general, stock options and stock appreciation rights are exempt from Section 409A if the exercise price per share is at least equal to the fair market value per share of the underlying stock at the time the option or stock appreciation right was granted. Restricted stock awards are not generally subject to Section 409A. Restricted stock units are subject to Section 409A unless they are settled within two and one-half months after the end of the later of (1) the end of the Company's fiscal year in which vesting occurs or (2) the end of the calendar year in which vesting occurs. If an award is subject to Section 409A and the provisions for the exercise or settlement of that award do not comply with Section 409A, then the participant would be required

to recognize ordinary income whenever a portion of the award vested (regardless of whether it had been exercised or settled). This amount would also be subject to a 20% federal tax and premium interest in addition to the federal income tax at the participant's usual marginal rate for ordinary income.

Security Ownership of Certain Beneficial Owners and Management

The following table provides information regarding the beneficial ownership of our common stock as of March 31, 2025, or the Evaluation Date, by: (i) each of our current directors, (ii) each of our named executive officers as set forth in Item 11 of this Annual Report, (iii) all such directors and executive officers as a group and (iv) our five percent or greater stockholders. The table is based upon information supplied by our officers, directors and principal stockholders and a review of Schedules 13D and 13G, if any, filed with the SEC. Unless otherwise indicated in the footnotes to the table and subject to community property laws where applicable, we believe that each of the stockholders named in the table has sole voting and investment power with respect to the shares indicated as beneficially owned.

Applicable percentages are based on 25,585,853 shares outstanding as of the Evaluation Date, adjusted as required by rules promulgated by the SEC. These rules generally attribute beneficial ownership of securities to persons who possess sole or shared voting power or investment power with respect to those securities. In addition, the rules include shares of our common stock issuable pursuant to the exercise of stock options or warrants or settlement of shares issued for services that are either immediately exercisable or exercisable within 60 days of the Evaluation Date. These shares are deemed to be outstanding and beneficially owned by the person holding those securities for the purpose of computing the percentage ownership of that person, but they are not treated as outstanding for the purpose of computing the percentage ownership of any other person. Unless otherwise noted, the business address of each of the following entities or individuals is 301 Rte. 17 North, Ste. 800, Rutherford, NJ 07070.

Name of Beneficial Owner	Number of Shares Beneficially Owned	Percent of Common Stock
***Named Executive Officers* and Directors**		
Paul V. Goode	27,662(1)	*
Peter C. Wulff	—	*
Luis Malave	150,502(2)	*
Erin Carter	47,710(3)	*
Dr. Robert Fischell	2,077(4)	*
Andrew K. Balo	4,490(5)	*
Allen Danzig	1,922(6)	*
John A. Ballantyne	3,121,871(7)	12.02%
All of our named executive officers and directors as a group (8 individuals)	3,356,234(8)	12.91%
5% or Greater Stockholders		
John A. Ballantyne Rev Trust 08/01/2017	3,117,745(9)	11.82%

* Indicates less than one percent of the outstanding shares of the Company's common stock.

(1) Includes (i) 3,277 shares of common stock subject to options currently exercisable or exercisable within 60 days of the Evaluation Date, (ii) 2,896 warrants currently exercisable, (iii) 2,500 shares earned under the IP Purchase Agreement and issuable within 60 days of the Evaluation Date and (iv) 18,989 shares of common stock held directly by Mr. Goode.

(2) Includes (i) 6,886 warrants currently exercisable, (ii) 2,076 unissued shares earned in connection with Board service and issuable within 60 days of the Evaluation Date and (iii) 141,540 shares of common stock held directly by Mr. Malave.

(3) Includes (i) 2,078 warrants currently exercisable, (ii) 1,896 unissued shares earned in connection with Board service and issuable within 60 days of the Evaluation Date and (iii) 43,736 shares of common stock held directly by Ms. Carter.

(4) Includes (i) 32 shares of common stock subject to options currently exercisable or exercisable within 60 days of the Evaluation Date, (ii) 1,498 unissued shares earned in connection with Board service and issuable within 60 days of the Evaluation Date and (iii) 547 shares of common stock held directly by Dr. Fischell.

(5) Includes 4,490 unissued shares earned in connection with Board service and issuable within 60 days of the Evaluation Date.

(6) Includes (i) 1,498 unissued shares earned in connection with Board service and issuable within 60 days of the Evaluation Date and (ii) 424 shares of common stock held directly by Mr. Danzig.

(7) Includes (i) 4,126 unissued shares earned in connection with Board service and issuable within 60 days of the Evaluation Date, (ii) 2,743,591 shares owned by the John A. Ballantyne Revocable Trust 08/01/2017, and (iii) 374,154 warrants currently exercisable and owned by John A. Ballantyne Revocable Trust 08/01/2017.

(8) Includes (i) an aggregate of 3,309 shares of common stock subject to options currently exercisable or exercisable within 60 days of the Evaluation Date, (ii) 386,014 warrants currently exercisable, (iii) 15,584 unissued shares earned in connection with Board service and issuable within 60 days of the Evaluation Date, (iv) 2,500 shares earned under the IP Purchase Agreement and issuable within 60 days of the Evaluation Date and (v) 2,948,827 shares of common stock, held by all directors and executive officers as a group.

(9) Includes 2,743,591 shares owned by the John A. Ballantyne Revocable Trust 08/01/2017 and 374,154 warrants currently exercisable and owned by John A. Ballantyne Revocable Trust 08/01/2017. The address of John A. Ballantyne Rev Trust 08/01/2017 is 7410 Claire Drive South, Fargo ND 58104. John A. Ballantyne has voting and investment control over the shares held by John A. Ballantyne Rev Trust 08/01/2017.

Changes in Control

Management of the Company knows of no arrangements, including any pledge by any person or securities of the Company, the operation of which may at a subsequent date result in a change in control of the registrant.

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

Other than as listed below, during 2024 and 2023, we were not a participant in any transaction or series of transactions in which the amount involved did exceed or may exceed the lesser of $120,000 or 1% of the average of our total assets at year-end for 2024 and 2023 in which any directors, director nominees, executive officers, greater than 5% beneficial owners and their respective immediate family members (each, a "Related Person") had or will have a direct or indirect material interest, other than the compensation arrangements (including with respect to equity compensation) described in "*Executive Compensation*" beginning on page 50 and "*Director Compensation*" on page 51.

We intend to ensure that in accordance with the Audit Committee charter, that the Audit Committee shall conduct reasonable prior review and oversight of all related party transaction for potential conflicts of interest, except for transactions involving the compensation of executive officers or directors, which shall be overseen by the compensation committee.

Issuance Under IP Purchase Agreement

On October 7, 2022, the Company entered into the IP Purchase Agreement with Paul Goode, which is the Company's Chief Executive Officer, pursuant to which Dr. Goode sold, assigned, transferred, conveyed and delivered to the Company the Purchased Assets: (a) the Conveyed Intellectual Property and (b) all the goodwill relating to the Purchased Assets.

In consideration for the sale by Dr. Goode of the Purchased Assets to the Company, the Company paid to Dr. Goode cash in the amount of one dollar and became obligated to issue up to 10,000 shares of Common Stock based upon specified performance milestones as set forth in the IP Purchase Agreement. In addition, if upon the final issuance of Common Stock under the IP Purchase Agreement, the aggregate 10,000 shares represent less than 1.5% of the then outstanding Common Stock of the Company, the final issuance will include such number of additional shares so that the total aggregate issuance equals 1.5% of the outstanding shares (the "True-Up Shares") of Common Stock of the Company. All shares of Common Stock to be issued under the IP Purchase Agreement shall be (i) restricted over a limited period as defined in the IP Purchase Agreement and issued in transactions exempt from registration under Section 4(a)(2) of the Securities Act of 1933, as amended and (ii) subject to the lockup provisions.

On December 29, 2023, 1,000 shares of Common Stock were earned under the terms of the IP Purchase Agreement and were issued to Dr. Goode on February 6, 2024. On May 1, 2024, 1,500 shares of Common Stock were earned under the terms of the IP Purchase Agreement. On March 26, 2025, the Board determined that the third milestone was met and that an additional 2,500 shares of Common Stock have been earned under the terms of the IP Purchase Agreement.

April Private Placement

On April 22, 2024, the Company entered into a private placement agreement under which the Company issued 3,969 shares of its Common Stock at a price of $126.0 per share for aggregate gross proceeds of $500. The Offering included participation of certain members of the Company's executive management, Board of Directors and existing shareholders.

June 27 Private Placement

On June 27, 2024, the Company entered into note and warrant purchase agreements with certain officers, directors, and existing investors (the "June 27 Investors"), providing for the private placement of unsecured promissory notes in the aggregate principal amount of $100,000 (the "June 27 Notes") and warrants (the "June 27 Warrants") to purchase up to an aggregate of 15,000 shares of Common Stock. The closing of the private placement occurred on June 27, 2024.

The June 27 Notes bore simple interest at the rate of three percent (3%) per annum and were due and payable in cash on the earlier of: (a) twelve (12) months from the date of the June 27 Note; or (b) the date the Company raised third-party equity capital in an amount equal to or in excess of $1,000,000 (the "June 27 Maturity Date"). The Company could prepay the June 27 Notes at any time prior to the June 27 Maturity Date without penalty.

Each June 27 Warrant has an exercise price of $99.0 per share. The June 27 Warrants are immediately exercisable and have a five-year term.

July 18 Private Placement

On July 18, 2024, the Company entered into a series of convertible promissory notes with the July 18 Investors, providing for the private placement of unsecured convertible promissory notes in the aggregate principal amount of $360,000.

The July 18 Notes bore simple interest at the rate of eight percent (8%) per annum and were due and payable in cash on the earlier of: (a) the twelve (12) month anniversary of the July 18 Note, or (b) the date of closing of a Qualified Financing (defined below) (the "July 18 Maturity Date").

Except with regard to conversion of the July 18 Notes as discussed below, the Company could not prepay the July 18 Notes without the written consent of the holder. If not sooner repaid, all outstanding principal and accrued but unpaid interest on the July 18 Notes (the "Note Balance"), as of the close of business on the day immediately preceding the date of the closing of the next issuance and sale of capital stock of the Company, in a single transaction or series of related transactions, to investors resulting in gross proceeds to the Company of at least $500,000 (excluding indebtedness converted in such financing) (a "Qualified Financing"), would automatically be converted into that number of shares of equity securities of the Company sold in the Qualified Financing equal to the number of shares calculated by dividing (X) the Note Balance by (Y) an amount equal to the price per share or other unit of equity securities issued in such Qualified Financing, and otherwise on the same terms as the security issued in the Qualified Financing, provided that the conversion price per share shall not be lower than $31.20 (the "Floor Price").

July 30 Private Placement

On July 30, 2024, the Company entered into the July 30 Notes and the July 30 Warrants with the July 30 Holder, providing for the private placement of a secured convertible promissory note in the aggregate principal amount of 4,000,000. The July 30 Note was not convertible until and Stockholder Approval was obtained, which occurred on September 26, 2024. The July 30 Note bore simple interest at the rate of eight percent (8%) per annum and was due and payable in cash on the July 30 Maturity Date. The July 30 Note was secured by a first-priority security interest on all Company assets.

Except with regard to conversion of the July 30 Note or a Sale Transaction as discussed below, the Company could not prepay the July 30 Notes without the written consent of the July 30 Holder. The July 30 Note (i) was convertible at the discretion of the July 30 Holder at a price equal to the closing price of the Common Stock on the date of conversion and, (ii) if the closing price of the Common Stock exceeds $100.00 per share for a period of five (5) consecutive trading days, would automatically convert at a price equal to the five-day (5) VWAP (subject to adjustment for any stock split, stock dividend, reverse stock split, combination or similar transaction). "VWAP" means the daily volume weighted average price of the Common Stock.

In the event of a Sale Transaction on or prior to the Maturity Date, the Company would repay the July 30 Holder, at the July 30 Holder's election, as follows: (a) cash equal to 200% of the Note balance, or (b) transaction consideration in the amount to be received by the July 30 Holder in such Sale Transaction if the July 30 Note was converted pursuant to an optional conversion. "Sale Transaction" means a merger or consolidation of the Company with or into any other entity, or a sale of all or substantially all of the assets of the Company, or any other transaction or series of related transactions in which the Company's stockholders immediately prior to such transaction(s) receive cash, securities or other property in exchange for their shares and, immediately after such transaction(s), own less than 50% of the equity securities of the surviving corporation or its parent.

Each July 30 Warrant becomes exercisable 12 months after its issuance and has term of 10 years. The July 30 Warrants are exercisable for cash only and have no price-based antidilution. The first July 30 Warrant is for 106,667 shares at $37.50 per share. The second July 30 Warrant is for 76,191 shares at $52.50 per share. The third July 30 Warrant is for 59,260 shares at $67.50 per share.

Concurrent Private Offering

In the Concurrent Private Offering, the July 30 Holder, which is an existing investor controlled by a director of the Company, converted the July 30 Note Debt, equaling approximately $4,093,112 of debt, which represented the then outstanding principal and accrued interest under the July 30 Note. The July 30 Note Debt was converted to Common Stock and Common Warrants on substantially the same terms as the November 2024 Offering, resulting in the issuance of 132,036 shares of Common Stock, 132,036 accompanying Series A Common Warrants, and 132,036 accompanying Series B Common Warrants, based on a conversion price of $31.0 per share, which is equal to the consolidated closing bid price of the Common Stock on the Nasdaq Capital Market on November 12, 2024.

July 18 Note Conversion

In addition, concurrently with the November 2024 Offering, the Company converted on substantially the same terms as the November Offering, the three outstanding July 18 Notes, with an aggregate outstanding principal and accrued interest in the amount of $304,494. As previously disclosed in the Form 8-K filed by the Company with the SEC on July 22, 2024, that disclosed the entry into the July 18 Notes, the July 18 Notes were to automatically convert upon a Qualified Financing, into a number of equity securities of the Company sold in the Qualified Financing, equal to a number of shares calculated by dividing (X) the Note Balance by (Y) an amount equal to the price per share or other unit of equity securities issued in such Qualified Financing, and otherwise on the same terms as the security issued in the Qualified Financing, provided that the conversion price per share shall not be lower than the Floor Price. The three outstanding July 18 Notes automatically converted in connection with the closing of the November 2024 Offering at a conversion price of $31.20, which is equal to the Floor Price as defined in the July 18 Notes, for an aggregate of 9,760 shares of Common Stock, 9,760 Series A Common Warrants, and 9,760 Series B Common Warrants (the "July 18 Note Conversion").

Item 14. Principal Accountant Fees and Services

Fahn Kanne & Co. Grant Thornton Israel has served as the independent registered public accounting firm for the Company for 2024 and 2023. The following table sets forth the fees billed to the Company by Fahn Kanne & Co. Grant Thornton Israel for 2024 and 2023.

		2024	2023
(in thousands)			
Audit Fees (1)	$	113,152	145,000
Audit-Related Fees		71,000	-
All Other Fees		-	-
Total Fees	$	184,152	145,000

(1) Represents, for each year, fees for services related to the Company's annual financial statement audit and quarterly reviews.

Under its charter, the Company's Audit Committee must review and pre-approve both audit and permitted non-audit services provided by the Company's independent registered public accounting firm and shall not engage the independent registered public accounting firm to perform any non-audit services prohibited by law or regulation. The independent registered public accounting firm's retention to audit the Company's financial statements, including the associated fee, is subject to approval each year by the Audit Committee. The Audit Committee does not regularly evaluate potential engagements of the independent registered public accounting firm and approve or reject such potential engagements. At each Audit Committee meeting, the Audit Committee receives updates on the services actually provided by the independent registered public accounting firm, and management may present additional services for pre-approval.

PART IV

Item 15. Exhibits and Financial Statement Schedules

(a) Documents filed as part of this Annual Report

(1) All financial statements

Report of Independent Registered Public Accounting Firm* F-2
Consolidated Balance Sheets as of December 31, 2024 and 2023 ..... F-5
Consolidated Statements of Operations for the Years Ended December 31, 2024, 2023, and 2022 ..... F-6
Consolidated Statements of Changes in Stockholders' Equity for the Years Ended December 31, 2024, 2023, and 2022 F-7
Consolidated Statements of Cash Flows for the Years Ended December 31, 2024, 2023, and 2022 ..... F-8
Notes to Consolidated Financial Statements F-9

* Fahn Kanne & Co., PCAOB Firm ID No. 1375

(2) Financial Statement Schedules

All financial statement schedules are omitted because they are either inapplicable or not required, or because the required information is included in the Consolidated Financial Statements or notes thereto contained in this Annual Report.

(3) Exhibits required by Item 601 of Regulation S-K

The following documents are filed as exhibits to this registration statement:

Exhibit Number	Description of Exhibit
2.1	Merger Agreement and Plan of Reorganization, dated as of May 25, 2010, by and among Integrity Applications, Inc., Integrity Acquisition Ltd. and A.D. Integrity Applications Ltd. (incorporated by reference to Exhibit 2.1 to the Registration Statement on Form S-1 filed by Integrity Applications, Inc. on August 22, 2011)
3.1	Certificate of Incorporation of Integrity Applications, Inc. (incorporated by reference to Exhibit 3.1 to the Registration Statement on Form S-1 filed by Integrity Applications, Inc. on August 22, 2011)
3.2	Certificate of Amendment to Certificate of Incorporation of Integrity Applications, Inc. (incorporated by reference to Exhibit 3.2 to the Registration Statement on Form S-1 filed by Integrity Applications, Inc. on August 22, 2011)
3.3	Bylaws of Integrity Applications, Inc. (incorporated by reference to Exhibit 3.3 to the Registration Statement on Form S-1 filed by Integrity Applications, Inc. on August 22, 2011)
3.4	Certificate of Amendment to Certificate of Incorporation of Integrity Applications, Inc. (incorporated by reference to Exhibit 99.1 to the Current Report on Form 8-K filed by Integrity Applications, Inc. on April 23, 2020)
3.5	Amendments to The Company's Certificate of Incorporation (incorporated by reference to Exhibit 3.5 to the Annual Report on Form 10-K filed by Glucotrack, Inc. on March 28, 2024)
3.6	First Amendment to Bylaws dated June 14, 2024 (incorporated by reference to Exhibit 3.01 to the Current Report on Form 8-K filed by Glucotrack, Inc. on June 20, 2024)
3.7	Certificate of Amendment to Amended and Restated Certificate of Incorporation, as filed with the Secretary of State of the State of Delaware on May 17, 2024 (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed by Glucotrack, Inc. on May 20, 2024)
3.8	Certificate of Amendment of Certificate of Incorporation of Glucotrack, Inc., dated January 3, 2025 (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed by Glucotrack, Inc. on January 7, 2025)
3.9	Certificate of Amendment to Certificate of Incorporation, as filed with the Secretary of State of the State of Delaware on February 3, 2025 (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed by Glucotrack, Inc. on February 4, 2025)
4.1*	Description of Registrant's Securities
4.2	Specimen Certificate Evidencing Shares of Common Stock (incorporated by reference to Exhibit 4.1 to the Registration Statement on Form S-1 filed by Integrity Applications, Inc. on August 22, 2011)

Exhibit Number	Description of Exhibit
4.3	Form of Warrant (incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K filed by Glucotrack, Inc. on July 1, 2024)
4.4	Form of Warrant (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K filed by Glucotrack, Inc. on July 31, 2024)
4.5	Form of Pre-Funded Warrant (incorporated by reference to Exhibit 4.3 to the Current Report on Form 8-K filed by Glucotrack, Inc. on November 14, 2024)
4.6	Form of Series A Common Warrant (incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K filed by Glucotrack, Inc. on November 14, 2024)
4.7	Form of Series B Common Warrant (incorporated by reference to Exhibit 4.2 to the Current Report on Form 8-K filed by Glucotrack, Inc. on November 14, 2024)
10.1+	Integrity Applications, Inc. 2010 Incentive Compensation Plan (incorporated by reference to Exhibit 10.1 to the Registration Statement on Form S-1 filed by Integrity Applications, Inc. on August 22, 2011)
10.2+	Amendment No. 1 to Integrity Applications, Inc. 2010 Incentive Compensation Plan (incorporated by reference to Exhibit 10.3 to the Current Report on Form 8-K filed by Integrity Applications, Inc. on March 23, 2016)
10.3+	Amendment No. 2 to Integrity Applications, Inc. 2010 Incentive Compensation Plan (incorporated by reference to Exhibit 10.4 to the Current Report on Form 8-K filed by Integrity Applications, Inc. on April 13, 2017)
10.4+	Form of Stock Option Agreement (incorporated by reference to Exhibit 10.14 to the Registration Statement on Form S-1 filed by Integrity Applications, Inc. on August 22, 2011)
10.5+	Form of Stock Option Agreement (ESOP) (incorporated by reference to Exhibit 10.15 to the Registration Statement on Form S-1 filed by Integrity Applications, Inc. on August 22, 2011)
10.6	Letter of Approval, addressed to Integrity Applications Ltd. from the Ministry of Industry, Trade and Employment of the State of Israel (incorporated by reference to Exhibit 10.16 to the Registration Statement on Form S-1 filed by Integrity Applications, Inc. on November 10, 2011)
10.7	Letter of Undertaking, addressed to the Ministry of Industry, Trade and Employment of the State of Israel - Office of the Chief Scientist from Integrity Applications Ltd. (incorporated by reference to Exhibit 10.17 to the Registration Statement on Form S-1 filed by Integrity Applications, Inc. on November 10, 2011)
10.8+	Consulting Agreement, dated October 11, 2023, by and between GlucoTrack, Inc. and James S. Cardwell (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed by Glucotrack, Inc. on October 12, 2024)
10.9†	Form of Exchange Agreement, dated February 13, 2024, by and among GlucoTrack, Inc. and certain holders thereof (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed by Glucotrack, Inc. on February 16, 2024)
10.10+	Employment Agreement, dated October 19, 2021, by and between Integrity Applications, Inc. and Paul V. Goode (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed by Integrity Applications, Inc. on October 25, 2021)
10.11+	Employment Agreement, dated January 29, 2025, by and between Glucotrack, Inc. and Peter Wulff (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed by Glucotrack, Inc. on January 29, 2025)
10.12	Form of Note and Warrant Purchase Agreement (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed by Glucotrack, Inc. on July 1, 2024)
10.13	Form of Promissory Note (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K filed by Glucotrack, Inc. on July 1, 2024)
10.14	Form of Convertible Promissory Note (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed by Glucotrack, Inc. on July 22, 2024)
10.15	Form of Convertible Promissory Note (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed by Glucotrack, Inc. on July 31, 2024)
10.16	Placement Agent Agreement, dated November 13, 2024, between the Company and Dawson James Securities, Inc. (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed by Glucotrack, Inc. on November 14, 2024)
10.17	Form of Securities Purchase Agreement (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K filed by Glucotrack, Inc. on November 14, 2024)
10.18+	Glucotrack, Inc. 2024 Equity Incentive Plan (incorporated by reference to Appendix A of Glucotrack, Inc.'s DEF 14A filed with the Commission on April 1, 2024)
10.19	Form of Lock-up Agreement (incorporated by reference to Exhibit 10.3 to the Current Report on Form 8-K filed by Glucotrack, Inc. on November 14, 2024)

Exhibit Number	Description of Exhibit
10.20	Securities Purchase Agreement, dated November 13, 2024, by and between the Company and John A. Ballantyne Revocable Trust DTD 8/1/2017 (incorporated by reference to Exhibit 10.4 to the Current Report on Form 8-K filed by Glucotrack, Inc. on November 14, 2024)
10.21	Form of Support Agreement (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed by Glucotrack, Inc. on November 18, 2024)
10.22	At-the-Market Sales Agreement, dated December 17, 2024, by and between Glucotrack, Inc. and Dawson James Securities, Inc. (incorporated by reference to Exhibit 1.1 to the Current Report on Form 8-K filed by Glucotrack, Inc. on December 17, 2024)
19.1	Insider Trading Policies and Procedures, adopted March 22, 2024 (incorporated by reference to Exhibit 19 to the Annual Report on Form 10-K filed by Glucotrack, Inc. on March 28, 2024)
21.1*	Subsidiaries of the Registrant
23.1*	Consent of Fahn Kanne & Co., an Independent Public Accounting Firm
97.1	Policy Related to Recovery of Erroneously Awarded Compensation, adopted November 30, 2023 (incorporated by reference to Exhibit 97.1 to the Annual Report on Form 10-K filed by Glucotrack, Inc. on March 28, 2024)
31.1*	Certification of Principal Executive Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2*	Certification of Principal Financial Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1*	Certification of Principal Executive Officer, pursuant to 18 U.S.C. Section 1350, as created by Section 906 of the Sarbanes-Oxley Act of 2002
32.2*	Certification of Principal Financial Officer, pursuant to 18 U.S.C. Section 1350, as created by Section 906 of the Sarbanes-Oxley Act of 2002
99.1*	Code of Ethics
101.INS	Inline XBRL Instance Document - the instance document does not appear in the Interactive Data File because its Inline XBRL tags are embedded within the Inline XBRL document
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (formatted as inline XBRL and contained in Exhibit 101)

+ Denotes a management contract or compensatory plan or arrangement.

* Filed or furnished herewith

† Certain of the exhibits and schedules to this Exhibit have been omitted in accordance with Regulation S-K Item 601(a)(5). The Registrant agrees to furnish a copy of all omitted exhibits and schedules to the SEC upon its request.

Item 16. Form 10-K Summary

None.

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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Report of Independent Registered Public Accounting Firm
Board of Directors and the Stockholders of
GLUCOTRACK INC.

Opinion on the financial statements

We have audited the accompanying consolidated balance sheets of Glucotrack Inc. a Delaware corporation (the "Company") as of December 31, 2024, and 2023, the related consolidated statements of operations and comprehensive loss, changes in stockholders' equity and cash flows for each of the two years in the period ended December 31, 2024, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2024, and 2023, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2024, in conformity with accounting principles generally accepted in the United States of America.

Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1B to the consolidated financial statements, the Company has incurred operating losses and negative cash flows from its operations and comprehensive loss since its inception and as of December 31, 2024, there is an accumulated deficit of $132,450. These conditions, along with other matters as set forth in Note 1B, raise substantial doubt about the Company's ability to continue as a going concern. Management's plans regarding these matters are also described in Note 1B. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for opinion

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

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

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

Critical Audit Matters

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

The accounting and valuation of warrant derivative liability

As described further in Notes 4F, 4G and 4J to the consolidated financial statements, the Series A warrants, and Series B warrants issued by the Company in November 2024, as part of a package issuance (hereinafter – "the Warrants"), include certain features that management has determined to preclude such financial instruments from being considered as indexed to the company's own stock and accordingly, the Warrants are accounted for as warrant derivative liability. In evaluating whether the Warrants are deemed indexed to the company's own equity, the management used the assistance of a third-party accounting expert. The Warrants were recognized upon initial recognition and on each reporting date at fair value with changes in fair value reported in earnings. As the Warrants are not traded on a public exchange, the Company is required to estimate their fair value based on a valuation technique.

Upon initial recognition and at each reporting date, management, with the assistance of a third-party appraiser, performs a fair value measurement using option pricing model with inputs that include the exercise price, share prices risk-free interest rates, term to expiration and volatility. Because certain inputs used to determine the fair value of option contracts are unobservable (principally implied volatility) and require the management to use Judgments and assumptions, the Company has categorized the warrant derivative liability as Level 3 fair value measure.

On December 31, 2024, the fair value of the Company's warrant derivative liability was $17,421 thousands and, in the year, ended December 31, 2024, the company recognized loss from changes in fair value in earnings in the amount of $798 thousands.

We identified the accounting and the valuation of the Warrants as a critical audit matter. The principal considerations for our determination that the accounting and the valuation of the Warrants is a critical audit matter are due to the high degree of auditor judgment, effort and subjectivity in performing procedures and evaluating management's accounting analysis and the estimates and assumptions. Given the complexity of the accounting of financial instruments involved, the subjective nature and judgment applied by management, auditing these accounting treatment and estimates required a high degree of auditor judgment and an increased extent of effort including the use of specialists.

Our audit procedures related to the accounting and the valuation of the warrant derivative liability included the following, among others. We evaluated the appropriateness of the option pricing model; tested the completeness, accuracy and relevance of underlying data used in the model; and evaluated the reasonableness of significant assumptions used by management, including mainly implied volatility. Our evaluation involved evaluating whether the assumptions used by management were reasonable. We utilized a valuation specialist and an accounting expert to assess the accounting analysis and the appropriateness of the option pricing model used by the company and to assist us with testing the assumptions in the model.

Going Concern

As described further in Note 1B to the consolidated financial statements, the Company has not yet generated significant revenues from its previous product and the development and commercialization of its current product is expected to require substantial additional expenditures. Thus, it was determined by Company's management that the Company is dependent upon external sources for financing its operations. As of December 31, 2024, the Company has incurred an accumulated deficit of $132,450. Furthermore, the Company has generated recurring operating losses and negative operating cash flow. As of December 31, 2024, the remaining balance of cash was determined by the Company's management as insufficient for the Company to realize its business plans for the twelve-month period subsequent to the reporting period. Accordingly, the Company's management has determined that these conditions raise substantial doubt about the Company's ability to continue as a going concern.

The Company plans to finance its operations through the sale of equity and/or debt securities. However, Company's management has concluded that such plans do not alleviate the substantial doubt regarding to the Company's ability to continue as a going concern as it was determined by management that there can be no assurance that the Company will succeed in obtaining the necessary financing or generating sufficient revenues from sales of its current product in order to continue its operations as a going concern.

We identified the assessment of the Company's ability to continue as a going concern as a critical audit matter. The principal considerations for our determination are due to significant judgment required by management when assessing the Company's ability to continue as a going concern, taking into consideration management plans, the Company's available funds, the ability of the Company to generate revenues from sales of its current product and the risk of bias in management's judgments and assumptions in their determination.

Our audit procedures related to this matter included the following, among others. We reviewed and evaluated management's plans for dealing with the adverse effect of these conditions and events. We inquired Company management and reviewed the company records to assess whether there are additional factors that might contribute to the uncertainties disclosed. We evaluated the reasonableness of significant assumptions used by management in its determination. We assessed whether the Company's determination that there is substantial doubt about its ability to continue as a going concern was adequately disclosed.

/s/ FAHN KANNE & CO. GRANT THORNTON ISRAEL

Certified Public Accountants (Isr.)
We have served as the Company's auditor since 2010.

Tel-Aviv, Israel
March 31, 2025

GLUCOTRACK INC.

CONSOLIDATED BALANCE SHEETS

	In thousands of US dollars (except stock data)	
	December 31, 2024	**December 31, 2023**
Current Assets		
Cash and cash equivalents (Note 2D)	5,617	4,492
Other current assets	151	376
Total current assets	5,768	4,868
Operating lease right-of-use asset, net (Note 6)	59	-
Property and equipment, net	95	27
Restricted cash (Note 2D)	10	10
TOTAL ASSETS	5,932	4,905
LIABILITIES AND STOCKHOLDERS' (DEFICIT) EQUITY		
Current Liabilities		
Accounts payable	992	839
Operating lease liability, current (Note 6)	26	-
Convertible promissory notes (Note 4E)	5	-
Other current liabilities	252	673
Total current liabilities	1,275	1,512
Non-Current Liabilities		
Derivative financial liabilities (Note 4F, 4G and Note 4J)	17,421	-
Operating lease liability, non-current (Note 6)	33	-
Loans from stockholders (Note 3)	203	196
Total liabilities	18,932	1,708
Commitments and contingent liabilities (Note 5)		
Stockholders' (Deficit) Equity (Note 8)		
Common Stock of $0.001 par value ("Common Stock"):		
100,000,000 shares authorized as of December 31, 2024 and 2023; 791,609 and 208,914 shares issued and outstanding as of December 31, 2024 and 2023, respectively	1	-
Additional paid-in capital	119,229	112,986
Receipts on account of shares	228	48
Accumulated other comprehensive income	(8)	16
Accumulated deficit	(132,450)	(109,853)
Total stockholders' (deficit) equity	(13,000)	3,197
TOTAL LIABILITIES AND STOCKHOLDERS' (DEFICIT) EQUITY	5,932	4,905

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

GLUCOTRACK INC.

CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

	In thousands of US dollars (except stock and per stock amounts)	
	2024	**2023**
Research and development expenses (Note 9)	9,499	4,704
Marketing expenses	393	122
General and administrative expenses (Note 10)	4,655	2,278
Total operating expenses	14,547	7,104
Operating loss	14,547	7,104
Other (income) expense	(14)	-
Change in fair value of derivative liability	798	-
Loss on equity issuance	1,925	-
Loss on settlement of liabilities	4,758	-
Finance expense (income), net (Note 7)	583	(7)
Loss for the year	22,597	7,097
Other comprehensive loss:		
Foreign currency translation adjustment	(24)	1
Comprehensive loss for the year	22,573	7,098
Basic and diluted loss per share (Note 2O)	68.44	34.18
Weighted average number of Common Stock outstanding used in computing basic and diluted net loss per share	330,171	207,603

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

GLUCOTRACK INC.

CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' (DEFICIT) EQUITY

	In thousands of US Dollars (except share data)						
	Common Stock						
	Numbers of Shares	Amount	Additional Paid-in Capital	Receipts on account of shares	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' (Deficit) Equity
Balance as of January 1, 2023	154,999	-	103,110	4	17	(101,901)	1,230
Loss for the year	-	-	-	-	-	(7,097)	(7,097)
Other comprehensive loss	-	-	-	-	(1)	-	(1)
Net proceeds received from underwritten U.S. public offering	53,765	-	8,730	-	-	-	8,730
Deemed dividend resulted from trigger of down round protection feature of certain warrants granted	-	-	855	-	-	(855)	-
Stock-based compensation	-	-	281	-	-	-	281
Issuance of restricted shares as compensation to directors	150	(*)	10	44	-	-	54
Balance as of December 31, 2023	208,914	-	112,986	48	16	(109,853)	3,197
Loss for the year	-	-	-	-	-	(22,597)	(22,597)
Other comprehensive loss	-	-	-	-	(24)	-	(24)
Stock-based compensation	-	-	173	-	-	-	173
Issuance of restricted shares as compensation to directors	4,343	-	126	(48)	-	-	78
Restricted shares to be issued as compensation towards directors	-	-	-	228	-	-	228
Issuance of restricted shares as payment for achievement of milestone pursuant to purchase agreement (Note 5B)	2,500	-	192	-	-	-	192
Issuance of Common Stock upon private placement transaction (Note 4C)	3,968	-	500	-	-	-	500
Exercise of prefunded warrants into shares	19,765	-	-	-	-	-	-
Issuance of Ordinary Shares upon completion of public offering, net of offering expenses	121,867	-	-	-	-	-	-
Issuance of detachable warrants through private placement transactions	237,845	-	-	-	-	-	-
Exchange of warrants into shares	35,932	1	(1)	-	-	-	-
Issuance of shares and warrants as settlement of financial liabilities	156,475	-	2,618	-	-	-	2,618
Issuance of detachable warrants through private placement transactions	-	-	2,635	-	-	-	2,635
Balance as of December 31, 2024	791,609	1	119,229	228	(8)	(132,450)	(13,000)

(*) Less than 1.

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

GLUCOTRACK INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

	2024	2023
Cash flows from operating activities:		
Loss for the year	(22,597)	(7,097)
Adjustments to reconcile loss for the year to net cash used in operating activities:		
Depreciation	36	13
Equity issuance costs	1,217	-
Stock-based compensation	173	281
Issuance of restricted shares as compensation to directors	306	54
Shares issued to CEO for achieving of IP Agreement milestones	192	-
Loss on settlement of liabilities	4,758	-
Loss on equity issuance	1,925	-
Change in fair value of derivative liability	798	-
Discount amortization and interest expenses related to promissory notes	628	-
Linkage difference on principal of loans from stockholders	7	1
Changes in assets and liabilities:		
Decrease (increase) in other current assets	225	(309)
Increase in accounts payable	263	167
Increase (decrease) in other current liabilities	(421)	332
Net cash used in operating activities	(12,490)	(6,558)
Cash flows from investment activities:		
Purchase of property and equipment	(104)	-
Net cash used in investment activities	(104)	-
Cash flows from financing activities		
Issuance of promissory notes and detachable warrants through private placement Transaction (Note 4E)	100	-
Net proceeds received from underwritten U.S. public offering (Note 4J)	8,783	-
Issuance of convertible promissory notes - related parties (Note 4G)	4,000	-
Issuance of convertible promissory notes and bifurcated conversion feature through private placement transaction (Note 4F)	360	-
Net proceeds received from underwritten U.S. public offering (Note 4C)	500	8,730
Net cash provided by financing activities	13,743	8,730
Effect of exchange rate changes on cash and cash equivalents	(24)	(1)
Change in cash, cash equivalents, and restricted cash	1,125	2,171
Cash, cash equivalents, and restricted cash at beginning of the year	4,502	2,331
Cash, cash equivalents, and restricted cash at end of the year	5,627	4,502
Supplemental disclosure of cash flow activities:		
(a) Net cash (received) paid during the year for:		
Interest	$ (62)	$ -
(b) Non-cash investment and financing activities:		
Deemed dividend upon trigger of down round protection	$ -	$ 855
Recognition of right for use asset against a lease liability (Note 6)	$ 79	$ -
Settlement of liabilities with equity (Note 4H and 4I)	$ 1,743	$ -
Derivative liability (Note 4G)	$ 35	$ -
Conversion of debt into equity (Note 4F and 4G)	$ 2,284	$ -

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

NOTE 1 – GENERAL

A. The Company was incorporated on May 18, 2010 under the laws of the State of Delaware. The Company is currently developing an implantable CBGM, the Glucotrack CBGM, for persons with Type 1 diabetes and insulin-dependent Type 2 diabetes.

The Glucotrack CBGM is being developed for use by Type 1 diabetes patients as well as insulin-dependent Type 2 patients. Implant longevity is key to the success of such a device. The Company has continued to evolve its sensor chemistry following the successful in-vitro feasibility study demonstrating that a minimum two-year implant life is highly probable with the current sensor design. Recently the Company announced that a 3-year longevity is feasible leveraging both in-vitro and in-silico test results. The Company has also completed multiple animal studies with initial prototype systems which demonstrated a simple implant procedure with good safety and functionality. The results of both were presented in poster form at the 2024 American Diabetes Association annual conference.

Further to the above progress on the Glucotrack CBGM, the Company has also successfully demonstrated continuous glucose sensing in the epidural space. This latter approach is of importance for patients with diabetes already contemplating spinal cord stimulation therapy for their condition.

A regulatory submission has been made for a first in human study outside of the United States. This will be an acute study intended to demonstrate device performance and safety. All preparatory clinical activities and applicable regulatory approvals are complete. In parallel, the Company is also preparing for a long-term clinical trial outside the United States that is expected to begin in the second quarter of 2025.

The Company believes its technology, if successful, has the potential to be more accurate, more convenient and have a longer duration than other implantable glucose monitors that are either in the market or currently under development.

B. Liquidity and capital resources

To date, the Company has not yet commercialized the Glucotrack CBGM Product. Further development and commercialization efforts are expected to require substantial additional expenditure. Therefore, the Company is dependent upon external sources for financing its operations. As of December 31, 2024, the Company has incurred an accumulated deficit of $132,450. In addition, the Company has generated operating losses and negative cash flow from operations since inception. As of December 31, 2024, the balance of cash and cash equivalents amounted to $5,617.

During the year ended December 31, 2024, the Company raised approximately $15 million through public offerings and debt issuances which were subsequently converted to equity. In addition, subsequent to the balance sheet date, the Company raised $6.3 million through the sale of shares of Common Stock. See Note 4 and 14. The Company plans to finance its operations through the sale of equity securities (and/or debt securities). There can be no assurance that the Company will succeed in obtaining the necessary financing or generating sufficient revenue from sale of its Glucotrack CBGM Product in order to continue its operations as a going concern.

Management has considered the significance of such conditions in relation to the Company’s ability to meet its current obligations and to achieve its business targets and determined that these conditions raise substantial doubt about the Company’s ability to continue as a going concern.

The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

NOTE 2 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

The consolidated financial statements were prepared in accordance with accounting principles generally accepted in the United States of America (US GAAP).

A. Use of estimates in the preparation of financial statements

The preparation of the consolidated financial statements in conformity with US GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the dates of the financial statements, and the reported amounts of expenses during the reported periods. Actual results could differ from those estimates. As applicable to these financial statements, the most significant estimates and assumptions relate to evaluation of going concern, the classification of financial instruments as equity or liability, share based compensation and the determination of the fair value of derivative liabilities.

B. Functional currency

The functional currency of the Company is the US dollar, which is the currency of the primary economic environment in which it operates. In accordance with ASC 830, "Foreign Currency Matters" (ASC 830), balances denominated in or linked to foreign currency are stated on the basis of the exchange rates prevailing at the applicable balance sheet date. For foreign currency transactions included in the statement of operations, the exchange rates applicable on the relevant transaction dates are used. Gains or losses arising from changes in the exchange rates used in the translation of such transactions are carried as financing income or expenses. The functional currency of the Israeli subsidiary is the New Israeli Shekel ("NIS") and its financial statements are included in consolidation, based on translation into US dollars. Accordingly, assets and liabilities were translated from NIS to US dollars using year-end exchange rates, and expense items were translated at average exchange rates during the year. Gains or losses resulting from translation adjustments are reflected in stockholders' equity, under "accumulated other comprehensive income".

	2024	2023
Official exchange rate of NIS 1 to US dollar	0.274	0.272
Increase (Decrease) of the official exchange rate of NIS 1 to US dollar during the year:	0.74%	(8.86)%

C. Principles of consolidation

The consolidated financial statements include the accounts of the Company and its subsidiary. All intercompany balances and transactions have been eliminated in consolidation.

D. Cash and cash equivalents and restricted cash

The Company considers all short-term investments, which are highly liquid investments with original maturities of three months or less at the date of purchase, to be cash equivalents.

Restricted cash is invested in certificates of deposit, which are used to secure Integrity Israel's obligations in respect of its credit card.

For presentation of statement of cash flows purposes, restricted cash balances are included with cash and cash equivalents, when reconciling the reported period total amounts.

The Company's cash is held with financial institutions in the United States and Israel. Management believes that the financial institutions that hold the Company's cash are financially sound and, accordingly, minimal credit risk exists with respect to these investments. Account balances held in the Unites States may, at times, exceed the Federal Deposit Insurance Corporation (FDIC) insurance limit. As of December 31, 2024 and 2023, the Company had $4,968 and $3,942, respectively, in excess of the FDIC insurance limit.

	In thousands of US dollars	
	December 31, 2024	December 31, 2023
Cash and cash equivalents	$ 5,617	$ 4,492
Restricted cash	$ 10	$ 10
Total cash, cash equivalents, and restricted cash shown in the statement of cash flows	$ 5,627	$ 4,502

E. Property and equipment, net

1. Property and equipment are stated at cost, net of accumulated depreciation. Depreciation is calculated using the straight-line method over the estimated useful lives of the assets. When an asset is retired or otherwise disposed of, the related carrying value and accumulated depreciation are removed from the respective accounts and the net difference less any amount realized from disposition is reflected in the statements of operations and comprehensive loss.

2. Rates of depreciation:

	Years
Computers and equipment	3
Furniture and office equipment	7-15

F. Impairment of long-lived assets

The Group's long-lived assets are reviewed for impairment in accordance with ASC 360, "Property, Plant and Equipment", whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to the future undiscounted cash flows expected to be generated by the asset. If such asset is considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the asset exceeds its fair value. To date the Group did not incur any material impairment losses related to long lived assets.

G. Modification of equity-classified contracts

The modification or exchange of equity-classified contracts, such as warrants that were classified as equity before the modification or exchange and remained eligible for equity classification after the modification, was accounted for in a similar manner to a modification of stock-based compensation. Accordingly, the incremental fair value from the modification or exchange (the change in the fair value of the instrument before and after the modification or exchange), due to the characteristics of the modification, was recognized as a reduction of retained earnings (or an increase of accumulated deficit) as a deemed dividend. Modifications or exchanges that result in a decrease in the fair value of an equity-classified share-based payment awards are not recognized. In addition, the amount of the deemed dividend is also recognized as an adjustment to earnings available to common shareholders for purposes of calculating earnings per share.

H. Convertible Promissory Notes

Upon initial recognition of convertible promissory notes and similar instruments, the Company considers the provisions of ASC 815-40, "Derivatives and Hedging - Contracts in Entity's Own Equity" ("ASC 815-40") in order to determine whether the conversion features embedded within the convertible instrument should be separated from the host instrument.

When it is determined that an embedded derivative required to be bifurcated (such as embedded conversion feature that does not qualify for equity classification), the Company recognizes the embedded derivative bifurcated as a separate derivative liability upon initial recognition and on subsequent periods at fair value. The remaining consideration amount received or allocated to the entire convertible instrument is allocated to the host debt instrument. The difference between the face value of the host and the allocated amount represents a discount which is amortized as finance expense to profit or loss using the effective interest method over the term of the note until its stated maturity.

When it is determined that the embedded conversion feature qualifies for equity classification (such when the embedded conversion option, if it were freestanding, is not qualified as a derivative in accordance with the provisions of ASC 815-10, "Derivatives and Hedging" since its terms did not require or permit net settlement or when the embedded conversion option is indexed to the entity's own stock), the conversion option is not bifurcated. When bifurcation is not required, the Company considers whether the debt instrument involves a significant premium (i.e. when the proceeds received or allocated upon issuance exceed the principal amount that will be paid at maturity). When it is determined that a substantial premium exists, the entire premium is allocated to paid-in capital and when it is determined, otherwise no additional accounting is required and the convertible promissory note is accounted for at amortized cost using the effective interest method over the term of the note until its stated maturity.

I. Allocation of proceeds and related issuance costs

When multiple instruments are issued in a single transaction (package issuance), the total gross proceeds from the transaction are allocated among the individual freestanding instruments identified. The allocation occurs after identifying all freestanding instruments and the subsequent measurement basis for those instruments.

Financial instruments that are required to be subsequently measured at fair value (such as derivative liabilities) are measured at fair value and the remaining consideration is allocated to other financial instruments that are not required to be subsequently measured at fair value (such as liabilities measured at amortized cost, common shares and warrants eligible for equity classification), based on the relative fair value basis for such instruments.

Issuance costs allocated to financial instruments that are required to be subsequently measured at fair value are immediately expensed. Issuance costs allocated to shares and warrants classified as equity components and are recorded as a reduction of additional paid-in capital. Issuance costs allocated to financial liabilities measured at amortized cost are recorded as a discount and accreted over the contractual term of the financial instrument using the effective interest method.

J. Warrants

Equity classified warrants

Certain warrants that were determined to be freestanding financial instruments that are legally detachable and separately exercisable, do not embody an obligation for the Company to repurchase its own shares, and permit the holders to receive a fixed number of Ordinary Shares upon exercise for a fixed exercise price and thus, are considered as indexed to the Company's own shares, were classified as equity instruments. As such warrants were issued together with financial instruments that are not subsequently measured at fair value, the warrants were measured based on allocation of the proceeds received by the Company in accordance with the relative fair value basis. Direct issuance expenses that were allocated to such warrants were deducted from additional paid-in capital.

Warrants classified as derivative liabilities

Upon initial recognition of Series A Warrants and Series B Warrants that were issued in November 2024 as part of an equity issuance and debt conversions, management considered the provisions of ASC 815-40, Derivatives and Hedging — Contracts in Entity's Own Equity and determined that the settlement amount of Series A Warrants and Series B Warrants might not be based on an exchange of a fixed number of shares for a fixed amount of consideration and thus such Warrants are not eligible to be considered as indexed to the Company's own shares. Accordingly, the Series A Warrants and Series B Warrants were accounted for as warrant derivative liability at fair value and the changes in fair values are carried to profit or loss. In accordance with ASC 210-10-20, the warrant derivative liability is presented as a noncurrent liability since its settlement will require the issuance of shares and not the use of any resources that are properly classified as current assets.

K. Leases

The Company applies ASC Topic 842, "Leases" ("ASC 842") under which the Company determines if an arrangement is a lease at inception.

Leases are classified as either finance leases or operating leases. A lease is classified as a finance lease if any one of the following criteria are met: (i) the lease transfers ownership of the asset by the end of the lease term, (ii) the lease contains an option to purchase the asset that is reasonably certain to be exercised, (iii) the lease term is for a major part of the remaining useful life of the asset, (iv) the present value of the lease payments equals or exceeds substantially all of the fair value of the asset, or (v) the underlying asset is of such a specialized nature that it is expected to have no alternative use to the lessor at the end of lease term. A lease is classified as an operating lease if it does not meet any one of these criteria. Since all the Company's lease contracts for premises do not meet any of the criteria above, the Company concluded that all its lease contracts should be classified as operating leases.

Right of Use ("ROU") assets and liabilities are recognized on the commencement date based on the present value of remaining lease payments over the lease term. For this purpose, the Company considers only payments that are fixed and determinable at the time of commencement. As most of the Company's leases do not provide an implicit rate, the Company uses its Incremental Borrowing Rate ("IBR") based on the information available on the commencement date in determining the present value of lease payments. The Company's IBR is estimated to approximate the interest rate for collateralized borrowing with similar terms and payments and in economic environments where the leased asset is located. The ROU asset also includes any lease payments made prior to commencement and is recorded net of any lease incentives received. Moreover, the ROU asset may also include initial direct costs, which are incremental costs of a lease that would not have been incurred if the lease had not been obtained. The Company uses the long-lived assets impairment guidance in ASC 360-10, "Property, Plant, and Equipment - Overall", to determine whether a ROU asset is impaired, and if so, the amount of the impairment loss to recognize. Certain leases include options to extend or terminate the lease. An option to extend the lease is considered in connection with determining the ROU asset and lease liability when it is reasonably certain that the Company will exercise that option. An option to terminate is considered unless it is reasonably certain that the Company will not exercise the option.

L. Income tax

The Company accounts for income taxes in accordance with ASC 740, "Income Taxes". Accordingly, deferred income taxes are determined utilizing the asset and liability method based on the estimated future tax effects of differences between the financial accounting and the tax bases of assets and liabilities under the applicable tax law. Deferred tax balances are computed using the enacted tax rates expected to be in effect when these differences reverse. Valuation allowances in respect of deferred tax assets are provided for, if necessary, to reduce deferred tax assets to amounts more likely than not to be realized.

The Company accounts for uncertain tax positions in accordance with ASC Topic 740-10, which prescribes detailed guidance for the financial statement recognition, measurement and disclosure of uncertain tax positions recognized in an enterprise's financial statements. According to ASC Topic 740-10, tax positions must meet a more-likely-than-not recognition threshold. The Company's accounting policy is to classify interest and penalties relating to uncertain tax positions under income taxes, however the Company did not recognize such items in its fiscal 2024 and 2023 financial statements and did not recognize any liability with respect to unrecognized tax position in its balance sheet.

M. Research and development expenses

Research and development expenses are charged to operations and comprehensive loss, as incurred.

N. Royalty-bearing grants

Royalty-bearing grants from the Israeli Innovation Authority (IIA) to fund approved research and development projects are recognized at the time Integrity Israel is entitled to such grants, on the basis of the costs incurred and reduce research and development costs. To date, the cumulative research and development grants received by Integrity Israel from IIA amounted to $93. See also Note 5A below.

O. Basic and diluted loss per share

Basic loss per share for the year ended December 31, 2024 is computed by dividing the loss for the period applicable for Common Stockholders and the holders of the pre-funded warrants divided by the weighted average number of shares of Common Stock outstanding and shares of Common Stock to be issued upon the exercise of prefunded warrants during the period. Basic loss per share for December 31, 2023 is computed by dividing the loss for the period applicable (after considering the effect of deemed dividend related to trigger of down round protection feature) for Common Stockholders and the holders of the pre-funded warrants divided by the weighted average number of shares of Common Stock outstanding and shares of Common Stock to be issued upon achievement of first performance milestone (see Note 5B below) and upon exercise of pre-funded warrants (see Note 8B below) during the period.

In computing, diluted loss per share, basic earnings per share are adjusted to reflect the potential dilution that could occur upon the exercise of options or warrants issued or granted using the "treasury stock method", and using the if-converted method for other financial instruments such as convertible liabilities and other share settled derivative liabilities, if the effect of each of such financial instruments is dilutive.

In computing diluted loss per share, the average stock price for the period is used in determining the number of Common Stock assumed to be purchased from the proceeds to be received from the exercise of stock options or stock warrants.

Shares that will be issued upon exercise of all stock options and stock warrants, have been excluded from the calculation of the diluted net loss per share for all the reported periods for which net loss was reported because the effect of the common shares issuable as a result of the exercise or conversion of these instruments was anti-dilutive

	In thousands of US dollars (except share data)	
	Year ended December 31,	
	2024	2023
Numerator:		
Net loss	$ 22,597	$ 7,097
Deemed dividend related to trigger of down round protection feature (see Note 8C3 below)	-	855
Net loss attributable to common stockholders	$ 22,597	$ 7,952
Denominator:		
Shares of Common Stock used in computing basic and diluted net loss per common stock	330,171	193,131
Shares of Common Stock to be issued upon exercise of pre-funded warrants (see Note 8B1 below)	-	13,971
Shares of Common Stock to be issued upon achievement of first performance milestone (see Note 5B below)	-	501
Weighted average number of Common Stock outstanding used in computing basic and diluted net loss per share	330,171	207,603
Basic and diluted net loss per common stock	$ 68.44	$ 34.18

See Note 14 regarding a significant issuance of shares as part of the exercise of the Series B Warrants subsequent to the balance sheet date.

P. Stock-based compensation

The Company measures and recognizes the compensation expense for all equity-based payments to employees based on their estimated fair values in accordance with ASC 718, "Compensation-Stock Compensation". Share-based payments including grants of stock options are recognized in the consolidated statement of operations and comprehensive loss as an operating expense based on the fair value of the award at the date of grant. The fair value of stock options granted is estimated using the Black-Scholes option-pricing model. The Company has expensed compensation costs, net of estimated forfeitures, applying the accelerated vesting method, over the requisite service period or over the implicit service period when a performance condition affects the vesting, and it is considered probable that the performance condition will be achieved. Share-based payments to non-employees are accounted for in accordance with ASC 718.

Q. Fair value of financial instruments

ASC Topic 825-10, "Financial Instruments" defines financial instruments and requires disclosure of the fair value of financial instruments held by the Company. The Company considers the carrying amount of cash and cash equivalents, restricted cash, accounts receivable, other current assets, accounts payable and other current liabilities balances, to approximate their fair values due to the short-term maturities of such financial instruments. ASC Topic 825-10, establishes the following fair value hierarchy, which prioritizes the inputs used in the valuation methodologies in measuring fair value:

Level 1 - Quoted prices (unadjusted) in active markets that are accessible at the measurement date for assets or liabilities. The fair value hierarchy gives the highest priority to Level 1 inputs.
Level 2 - Observable prices that are based on inputs not quoted on active markets but corroborated by market data.
Level 3 - Unobservable inputs are used when little or no market data is available. Level 3 inputs are considered as the lowest priority under the fair value hierarchy.

The fair value of the financial instruments included in the working capital of the Company (cash and cash equivalents, accounts payable and other current assets and liabilities) approximates their carrying value.

The Company did not estimate the fair value of the loans received from stockholders since their repayment schedule has not yet been determined.

There were no Level 3 assets or liabilities for the year ended December 31, 2023. The following table presents changes in Level 3 assets and liabilities measured at fair value for the year ended December 31, 2024:

	Liability
Balance – November 14, 2024 – Warrant issuance date	$ 16,626
Fair value adjustments – Derivative financial liability	795
Balance – December 31, 2024	$ 17,421

The following table sets forth the Company's assets and liabilities which are measured at fair value on a recurring basis by level within the fair value hierarchy:

	Fair Value Measurements as of December 31, 2024			
	Level I	Level II	Level III	Total
Liability:				
Warrant derivative liability	$ -	$ -	$ 17,421	$ 17,421

R. Segment reporting

Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision maker, or ("CODM"). The Company has identified its Chief Executive Officer, Paul V. Goode, as the CODM who is responsible for making decisions regarding resource allocation and assessing performance. The Company views its operations and manages its business as one operating segment. The Company's long-lived assets consist primarily of property and equipment, net, which are all held in the United States.

S. Concentrations of credit risk

Financial instruments that potentially subject the Company to concentrations of credit risk consist primarily of cash and cash equivalents, and restricted cash. Cash and cash equivalents and restricted cash are deposited with a major bank in the United States. Management believes that such financial institutions are financially sound, accordingly, minimal credit risk exists with respect to these financial instruments. The Company does not have any significant off-balance-sheet concentration of credit risk, such as foreign exchange contracts, option contracts or other foreign hedging arrangements.

T. Contingencies

The Company records accruals for loss contingencies arising from claims, litigation and other sources when it is probable that a liability has been incurred and the amount can be reasonably estimated. These accruals are adjusted periodically as assessments change or additional information becomes available. Legal costs incurred in connection with loss contingencies are expensed as incurred.

U. Warrants with down-round protection

The Company disregards the down round feature when assessing whether the instrument is indexed to its own stock, for purposes of determining liability or equity classification in accordance with the provisions of ASU 2017-11, "Earnings Per Share" (ASU 2017-11). Based on its evaluation, management has determined that such warrants with down-round protection feature are eligible for equity classification.

Accordantly, upon the occurrence of an event that triggers a down round protection feature (i.e., when the exercise price of the warrants is adjusted downward because of the down round feature), the effect is accounted for as a deemed dividend and as a reduction of income available to common shareholders for purposes of basic earnings per share calculation. See also Note 2P above.

V. Recently adopted accounting pronouncements

In November 2023, the FASB issued ASU No. 2023-07, Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures ("ASU 2023-07"). This standard requires a public entity to disclose significant segment expenses and other segment items on an interim and annual basis. Additionally, it requires a public entity to disclose the title and position of the Chief Operating Decision Maker. ASU 2023-07 is effective for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024, with early adoption permitted. A public entity should apply the amendments in this ASU retrospectively to all prior periods presented in the financial statements. The Company adopted ASU 2023-07 for the fiscal year ended December 31, 2024 and interim financial statements thereafter, on a retrospective basis for all prior periods presented in the financial statements. The adoption of ASU 2023-07 did not change the way that the Company identifies its reportable segments and, as a result, did not have a material impact on the Company's financial position or results of operations. See (Note 13) - Segment Reporting for further information.

W. Recently issued accounting pronouncements, not yet adopted

In November 2024, the FASB issued ASU 2024-03, "Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures" to require more detailed information about specified categories of expenses (purchases of inventory, employee compensation, depreciation, amortization, and depletion) included in certain expense captions presented on the face of the income statement. ASU 2024-03 is effective for fiscal years beginning after December 15, 2026 and for interim periods within fiscal years beginning after December 15, 2027. Early adoption is permitted. The amendments may be applied either (1) prospectively to financial statements issued for reporting periods after the effective date of this ASU or (2) retrospectively to all prior periods presented in the financial statements. The Company is currently evaluating the impact of adopting this guidance on its consolidated financial statements and related disclosures. The adoption of this pronouncement is not expected to have a material impact on the Company's consolidated financial statements.

In December 2023, the FASB issued ASU No. 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures related to improvements to income tax disclosures. The amendments in this update require enhanced jurisdictional and other disaggregated disclosures for the effective tax rate reconciliation and income taxes paid. The amendments in this update are effective for fiscal years beginning after December 15, 2024. The adoption of this pronouncement is not expected to have a material impact on the Company's consolidated financial statements.

NOTE 3 – LOANS FROM STOCKHOLDERS

During the years 2003-2004, Integrity Israel received loans from stockholders (four separate lenders) in a total amount of approximately $400. However, following the repayment of the entire balance to certain lender in 2015, the remaining balance as of December 31, 2024 is approximately $203. The loans are indexed to the Israeli consumer price index from their origination date and bear no interest.

The Company will be required to pay the loans, in quarterly installments, commencing on the first quarter following the first fiscal year in which the Company reports net profit in its annual report. At such time, the Company will be required to make quarterly payments equal to 10% of its total sales for each quarter until the loans have been repaid in full. Notwithstanding the repayment mechanism, the Company will not be required to repay the loans during any period in which such payment would cause a deficit in the Company's working capital.

As of December 31, 2024, the Company does not expect to make any material repayments during the following 12-month period, if any, and accordingly the entire remaining balance of the loans from stockholders have been presented as non-current liability.

NOTE 4 – SIGNIFICANT TRANSACTIONS

A. Exercise of pre-funded warrants

On January 3, 2024, 19,765 pre-funded warrants granted through underwritten public offering in April 2023 have been fully exercised into the same number of shares of Common Stock of the Company.

B. Exchange Agreement

On February 13, 2024, the Company entered into an Exchange Agreement with certain warrant holders (the "Holders"), pursuant to which the Company and the Holders agreed to exchange (the "Exchange") warrants with down round protection feature exercisable to common shares (the "Warrants") owned by the Holders for shares of Common Stock to be issued by the Company. On February 15, 2024, 35,932 shares of Common Stock have been issued in exchange for 43,820 Warrants (the "Shares").

It was also agreed that the Holders will not, during the period ("Lock-Up Period") (i) offer, pledge, announce the intention to sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, or otherwise transfer or dispose of, directly or indirectly, any Shares, (ii) enter into any swap or other agreement that transfers, in whole or in part, any of the economic consequences of ownership of the Shares of, whether any such transaction described in clause (i) or (ii) above is to be settled by delivery of Shares or such other securities, in cash or otherwise, (iii) make any demand for or exercise any right with respect to, the registration of any Shares or any security convertible into or exercisable or exchangeable for shares of common stock, or (iv) publicly announce an intention to effect any transaction specific in clause (i), (ii) or (iii) above, provided that the Holder, during the Lock-Up Period, may (a) sell or contract to sell Shares at a price higher than $0.5 per Share on any trading day up to 10% of the daily volume of Shares or (b) sell or contract to sell Shares at a price higher than $0.8 per Share on any trading day with no volume limitation.

The Lock-Up Period shall expire at the earliest of (i) 365 days after the date hereof or (ii) until the Shares traded above $100.00 per Share for five consecutive trading days.

The Company accounted for the Exchange of the aforesaid warrants with shares in a similar manner of a modification of shares-based payment as a deemed dividend which was calculated at the closing date by the management using the assistance of external appraiser as the excess of fair value of the shares to be issued after taking into consideration a discount for lack of marketability at a rate of 16.81% over the Lock-Up Period over the fair value of the original equity instrument (i.e. warrants which included down round protection feature). However, since the fair value of the shares was estimated as less than the fair value of the replaced equity instrument, deemed dividend was not recorded.

C. Private Placement Agreement

On April 22, 2024, the Company entered into a private placement agreement under which the Company issued 3,968 shares of its common stock at a price of $126 per share for aggregate gross proceeds of $500 (the "Offering"). The Offering included participation of certain members of the Company's executive management, Board of Directors and existing shareholders.

D. Adoption of 2024 Equity Incentive Plan and Reverse Share Split

On April 26, 2024, the Company held its Annual Meeting of Shareholders (the "Annual Meeting") under which the Company's stockholders approved, inter alia, the following proposals: (i) adoption of the Company's 2024 Equity Incentive Plan and (ii) an amendment to Article IV of the Company's Certificate of Incorporation, to effect a reverse stock split of the Company's Common Stock at a ratio of between one-for-five and one-for-thirty, with such ratio to be determined at the sole discretion of the Board of Directors. Following the Annual Meeting, on April 30, 2024, the Company's Board of Directors approved a one-for-five reverse stock split of the Company's issued and outstanding shares of common stock. On May 17, 2024, the Company filed a Certificate of Amendment to the Company's Certificate of Incorporation with the Secretary of State of the State of Delaware which effected the reverse stock split.

On February 3, 2025, subsequent to the balance sheet date on December 31, 2024, the Company approved to effect an additional reverse stock split of twenty-for-one (20 to 1). The reverse split did not impact the total number of authorized shares of common stock or the par value per share.

For accounting purposes, all shares, options and warrants to purchase shares of common stock and loss per share amounts have been adjusted to give retroactive effect to both of the reverse splits for all periods presented in these consolidated financial statements. Any fractional shares resulting from the reverse splits were rounded up to the nearest whole share.

E. Note and Warrant Purchase Agreements

On June 27, 2024, the Company entered into note and warrant purchase agreements (the "Purchase Agreement") with certain investors (the "June 27 Investors"), providing for the private placement of unsecured promissory notes in the aggregate principal amount of $100 (the "June 27 Notes" and each a "June 27 Note") and warrants to purchase up to an aggregate of 15,000 shares of the Company's Common Stock (the "June 27 Warrants").

The June 27 Notes bear simple interest at a rate of 3% per annum and are due and payable in cash on the earlier of: (a) 12 months from the date of the June 27 Note; or (b) the date the Company raises third-party equity capital in an amount equal to or in excess of $1,000 (the "Maturity Date"). The Company may prepay the June 27 Notes at any time prior to the Maturity Date without penalty. If an event of default occurs, the then-outstanding principal amount of the June 27 Notes plus any unpaid accrued interest will accelerate and become immediately payable in cash.

Each of June 27 Warrants has a fixed exercise price of $99 per share. The June 27 Warrants are immediately exercisable and have a 5-year term.

Upon initial recognition, the management allocated the gross cash proceeds received based on the relative fair value of the June 27 Notes and the detachable June 27 Warrants in total amount of $15 and $85, respectively. The fair value of the June 27 Note was determined based on a rating model using a debt discount rate of 28.65% which represented the Company's applicable rate of risk. The fair value of the June 27 Warrants was determined by using Black-Scholes pricing model taking into account, inter alia, expected stock price volatility of 245% and risk-free interest rate of 4.52%. The amount allocated to June 27 Warrants was classified as a component of equity (as their terms permit the holders to receive a fixed number of shares of common stock upon exercise for a fixed exercise price).

The June 27 Notes were accounted for as a financial liability measured at amortized cost. In subsequent periods, the Company recognized a discount and interest expense over the economic life of the June 27 Notes based on the effective interest rate method.

The following tabular presentation reflects the reconciliation of the carrying amount of the June 27 Notes during the period of years ended December 31, 2024:

	Year ended December 31, 2024
Opening balance	$ -
Total proceeds received	100
Total proceeds allocated to June 27 Warrants at initial recognition	(85)
Discount amortization and interest expenses related to June 27 Notes (Note 7 below)	16
Partial conversion June 27 Notes and accrued Interest (Note 4H and Note 4I below)	(26)
Balance December	$ 5

During the period commencing the issuance date through December 31, 2024, none of the June 27 Warrants have been exercised.

F. Convertible Promissory Notes

On July 18, 2024, the Company entered into a series of convertible promissory notes with three directors, and one member of the Company's executive management (the "July 18 Investors"), providing for the private placement of unsecured convertible promissory notes in the aggregate principal amount of $360 (the "July 18 Notes" and each a "July 18 Note").

The July 18 Notes bore simple interest at a rate of 8% per annum. Upon initial date, the management measured the fair value of the embedded conversion feature which is accounted for as embedded derivative liability. The difference between the total gross cash proceeds received and the fair value of the embedded conversion feature is allocated to the host component of the July 18 Notes that are measured at amortized cost under which in subsequent periods the Company recognizes a discount expense over the economic life of the July 18 Notes based on the effective interest rate method. However, the fair value of the embedded derivative liability related to the conversion feature was determined by the management at an insignificant amount since upon closing of a Qualified Financing, the loan will convert based on market conditions (i.e. conversion price will be equal to the fair value of the share upon conversion) and thus all proceeds received of $360 were allocated to the July 18 Notes.

On September 5, 2024, the Company and one of July 18 noteholders entered into a conversion agreement, under which the Company agreed to convert his portion of the outstanding principal nominal amount plus any accrued but unpaid interest pursuant to the July 18 Note, totaling $101 into 4,955 shares of Common Stock at a conversion price of $20.4 per share. Please see note 4I.

In November 2024, the Company and the remaining July 18 noteholders entered into a conversion agreement under which the Company agreed to convert their portion of the outstanding principal nominal amount plus any accrued but unpaid interest pursuant to the July 18 Note, totaling $305 to Common Stock and warrants at a conversion price of $31.2 per share. The July 18 noteholders received 9,760 shares of Common Stock, 9,760 Series A Warrants and 9,760 Series B Warrants. The fair value of the shares of Common Stock received was $60. The Series A and Series B Warrants are treated as derivative liabilities and at grant date were valued at $43 and $279, respectively. As a result, the Company recorded a loss on the settlement of debt in the amount of $79 in the Statement of Operations. Please see Note 4J for the terms and valuation methodology of the Series A and Series B Warrants.

G. Convertible Promissory Note and Warrant Agreements

On July 30, 2024, the Company entered into a convertible promissory note and three warrant agreements (the "July 30 Warrants") with an existing investor (the "July 30 Holder"), providing for the private placement of a secured convertible promissory note in the aggregate principal amount of $4,000 (the "July 30 Note"). The July 30 Note bore simple interest at a rate of 8% per annum and is due and payable in cash on earlier of: (i) 12 months anniversary of July 30 Note, or (ii) closing date of a Sale Transaction (defined below) (the "Maturity Date"). The July 30 Note is secured by a first-priority security interest on all Company's assets.

Each July 30 Warrant becomes exercisable 12 months after its issuance and has term of 10 years. The July 30 Warrants are exercisable for cash only and have no price-based antidilution. The first July 30 Warrant is for 106,667 shares at $37.50 per share. The second July 30 Warrant is for 76,191 shares at $52.50 per share. The third July 30 Warrant is for 59,259 shares at $67.50 per share. Management has determined that the warrants are eligible to be classified as a component of equity as their terms permit the holders to receive a fixed number of shares of common stock upon exercise for a fixed exercise price.

At the initial date, the Company has issued four freestanding instruments that include (i) a financial instrument that is considered as "host" which comprised of July 30 Note and two embedded derivative financial instruments (i.e. an embedded conversion feature and an embedded redemption feature to receive cash equals to 200% of July 30 Note balance upon the occurrence of a Sale Transaction) and (ii) three series of detachable warrants. At the initial date, the Company is required to estimate the fair value of the freestanding instruments and allocate the total gross proceeds received between them based on that relative fair value identified. The fair value of the embedded derivative financial instruments (i.e. the conversion right and the redemption right) should be bifurcated from the host instrument and remeasured on recurring basis at each reporting period under marked to market approach, the July 30 Note was accounted for at amortized cost whereby discount and interest expenses are recorded over the economic life of the July 30 Note based on the effective interest rate method and the July 30 Warrants are classified into equity without any further subsequent measurement.

Upon initial recognition, the management by using the assistance of an external appraiser allocated the gross cash proceeds received based on the relative fair value of the July 30 Note and the detachable July 30 Warrants in total amount of $1,450 and $2,550, respectively. The fair value of the convertible note was determined by using hybrid method that includes conversion scenario and liquidation scenario taking into account, inter alia, a debt discount rate of 28.65%. The fair value of the July 30 Warrants was determined by using Black-Scholes pricing model taking into account, inter alia, expected stock price volatility of 122.8% and risk-free interest rate of 4.78%. The amount allocated to July 30 Warrants was classified as a component of equity.

Furthermore, it was determined that the embedded conversion feature and embedded redemption feature are required to be bifurcated from the host loan instrument. The fair value of the bifurcated derivatives was determined by the management using the assistance of an external appraiser in a total amount of $35 upon initial recognition and in subsequent periods as derivative liability at fair value through profit and loss. The remaining amount of $1,415 was allocated to the host loan instrument which in subsequent periods was accounted for using the effective interest method over the term of the loan, until its stated maturity.

On September 24, 2024, the Company held a special meeting of its stockholders under which shares of common stock issuable by the Company upon conversion of the July 30 Note and exercise of the July 30 Warrants was approved. The July 30 Holder has not elected to trigger the exercise of the July 30 Warrants into shares of common stock.

On November 12, 2024, the Company and the July 30 Holder entered into an agreement for the settlement of the July 30 Note plus any accrued but unpaid interest totaling $4,093 to Common Stock and warrants at a conversion price of $31.0 per share. The July 30 Holder received 132,036 shares of Common Stock, 132,036 Series A Warrants and 132,036 Series B Warrants. The fair value of the shares of Common Stock received was $813. The Series A and Series B Warrants are treated as derivative liabilities and at grant date were valued at $609 and $3,768, respectively. As of the settlement date, the carrying amount of the July 30 Note under the effective interest method was $1,978 and the fair value of the derivative liability relating to the conversion feature was $37. Upon settlement, the total fair value of the warrant related derivatives of $4,377 and the equity received of $813 exceeded the net book value of the July 30 Note of $1,978 and the value of the debt conversion derivative that was settled of $37. As a result, the Company recorded a loss on extinguishment of debt in the amount of $3,175 in the Statement of Operations. Please see Note 4J for the terms and valuation methodology of the Series A and Series B Warrants.

H. August 23 Conversion

On August 23, 2024 (the "Commitment Date"), the Company and two of June 27 Investors entered into conversion agreement, under which the Company agreed to convert the principal nominal amount plus any accrued but unpaid interest pursuant to each of June 27 Notes, with a face value of $20 each (the "Debt"), held by the Investors to Common Stock at a conversion price of $20.4 per share. On October 15, 2024, the Company issued 985 shares of common stock for each of the two of the June 27 Investors in respect of each respective Debt converted.

In satisfaction of the Debt, the Company also issued to each of the two June 27 Investors three warrants (each an "August 23 Warrant"). Each August 23 Warrant becomes exercisable on August 16, 2025 and has term of 10 years. The August 23 Warrants are exercisable for cash only and have no price-based antidilution. The first August 23

Warrant is for 535 shares of Common Stock and is exercisable at $37.5 per share. The second August 23 Warrant is for 382 shares of Common Stock, exercisable at $52.5 per share. The third August 23 Warrant is for 297 shares of Common Stock, exercisable at $67.5 per share.

The above transaction was accounted for as a settlement of financial liabilities under which the instruments issued or to be issued to the June 27 Investors (i.e. shares of common stock and August 23 Warrants) are eligible for equity classification and thus both have been recorded as part of equity based on the total fair value of $238 at the Commitment Date. The difference between the fair value of these equity instruments and the carrying amount of each of the respective Debt at the Commitment Date amounted to $11 was charged immediately to the finance expenses (see also Note 7 below). Due to the above settlement, the Company recorded a loss on the settlement on the amount of $216.

During the period commencing the issuance date through December 31, 2024, none of the August 23 Warrants have been exercised.

I. September 5 Conversion

On September 5, 2024 (the "Commitment Date"), the Company and one of June 27 Investors and July 18 Investors entered into a conversion agreement, under which the Company agreed to convert outstanding board fees amounted $113 and the principal nominal amount plus any accrued but unpaid interest pursuant to June 27 Note and July 18 Note, totaling $146 (referring together as a "Debt"), held by the Investor to Common Stock at a conversion price of $20.4 per share. On October 15, 2024, the Company issued 12,712 shares of common stock for the June 27 Investor in respect of the Debt converted.

In satisfaction of the Debt, the Company also issued to June 27 Investor and July 18 Investor three warrants (each an "September 5 Warrant"). Each September 5 Warrant becomes exercisable on August 16, 2025 and has term of 10 years. The September 5 Warrants are exercisable for cash only and have no price-based antidilution. The first September 5 Warrant is for 6,915 shares of Common Stock and is exercisable at $37.5 per share. The second September 5 Warrant is for 4,940 shares of Common Stock, exercisable at $52.5 per share. The third September 5 Warrant is for 3,842 shares of Common Stock, exercisable at $67.5 per share.

The above transaction was accounted for as settlements of financial liabilities under which the instruments issued or to be issued to the July 18 Investor (i.e. shares of common stock and September 5 Warrants) are eligible for equity classification and thus both have been recorded as part of equity based on the total fair value of $1,505 at the Commitment Date. The carrying amount of the Debt at the Commitment Date amounted to $227 and the difference was recorded as loss on settlement of debt in the Statement of Operations in the amount of $1,278 (see also Note 7 below).

During the period commencing the issuance date through December 31, 2024, none of the September 5 Warrants have been exercised.

J. November 12 Issuance

On November 12, 2024, the Company completed a public offering (the "Offering") under which the Company received gross proceeds of $10,000 in exchange for issuance of an aggregate of (i) 121,867 shares (the "Shares") of its Common Stock, (ii) 237,845 pre-funded warrants (the "Pre-Funded Warrants") to purchase up to an aggregate of 237,845 shares of Common Stock (the "Pre-Funded Warrant Shares") in lieu of Shares, (iii) Series A Warrants (the "Series A Warrants") to purchase up to 359,712 shares of Common Stock (the "Series A Warrant Shares") and (iv) Series B Warrants (the "Series B Warrants" and, together with the Series A Warrants, the "Common Warrants") to purchase up to 359,712 shares of Common Stock ("the "Series B Warrant Shares" together with the Series A Warrant Shares, the "Warrant Shares"). Each Share or Pre-Funded Warrant, as applicable, was sold together with one Series A Warrant to purchase one share of Common Stock and one Series B Warrant to purchase one Common Share. The public offering price for each Share and accompanying Common Warrants was $27.80, and the public offering price for each Pre-Funded Warrant and accompanying Common Warrants was $27.78 (the "Offering Price").

The Pre-Funded Warrants have an exercise price of $0.02 per share, are exercisable immediately and expire when exercised in full. Each Series A Common Warrant will have an exercise price per share of $36.2 and will be exercisable beginning on the date on which Stockholder Approval (as defined below) is received and deemed effective (the "Initial

Exercise Date" or the "Stockholder Approval Date"). The Series A Warrants will expire on the five-year anniversary of the Initial Exercise Date. The Series B Warrants will have an exercise price per share of $36.2 and will be exercisable beginning on the Initial Exercise Date. The Series B Warrants will expire on the two and one-half year anniversary of the Initial Exercise Date. The issuance of Common Warrant Shares upon exercise of the Common Warrants is subject to stockholder approval under applicable rules and regulations of The Nasdaq Stock Market LLC ("Nasdaq") ("Stockholder Approval" and the date on which Stockholder Approval is received and deemed effective, the "Stockholder Approval Date").

The exercise price of Series A Warrants and Series B Warrants is subject to certain adjustments. If at the time of exercise there is no effective registration statement registering, or the prospectus is not available for the issuance of the Series A Warrants Shares and Series B Warrant Shares to the holders, then the Series A Warrants and Series B Warrants may also be exercised, in whole or in part, at such time by means of a "cashless exercise". In addition, the holders are entitled to an option to require the Company to purchase the Series A Warrants and Series B Warrants for cash in an amount equal to their Black-Scholes Option Pricing Model value, in the event that certain fundamental transactions (which some of them are not considered solely within the control of the Company) as defined in the Series B Warrants agreement, occur. Additionally, holders of Series B Warrants may also effect an "alternative cashless exercise" at any time while the Series B Warrants are outstanding following the Initial Exercise Date. Under the alternate cashless exercise option, the holder of the Series B Warrant has the right to receive an aggregate number of shares equal to the product of (i) the aggregate number of shares of Common Stock that would be issuable upon a cashless exercise of the Series B Warrant and (ii) 3.0. The Company analyzed the terms of the warrants in accordance with Accounting Standards Codification No. 480, *Distinguishing Liabilities from Equity* ("ASC 480") and determined that the Series A and Series B Warrants are not eligible for equity classification and thus would be classified as derivative liabilities and recorded at fair value, with changes in fair value recorded through profit or loss. The Company used the Monte Carlo Simulation method for determining the fair value of the warrants. The Series A Warrant assumptions used in the Monte Carlo simulations are an expected term of 5 years, exercise price of $36.2, comparable company volatility of 96.3%, risk-free interest rate of 4.32% and share price of $6.17. The Series B Warrant assumptions used in the Monte Carlo simulations are an expected term of 2.5 years, exercise price of $36.2, company historical volatility of 378.6%, risk-free interest rate of 4.30% and share price of $6.17.

Upon initial recognition, the management allocated the gross cash proceeds to the detachable instruments included in the issuance, firstly to Series A Warrants and Series B Warrants which were classified as financial instruments that are required to be subsequently measured at fair value. The fair value at the issuance date of the Series A and Series B Warrants received was $1,659 and 10,266, respectively. Accordingly, there were no remaining proceeds to allocate to the equity instruments (the Shares and the Pre-Funded Warrants). Issuance costs in the amount of $1,217 were recorded as expenses in the Statement of Operations.

In addition, as the total fair value of the derivative liabilities amounting to $11,925 exceeded the $10,000 of cash raised in the issuance, the Company recorded an immediate loss from the issuance of equity in the amount of $1,925 in the Statement of Operations.

See Note 14 regarding a significant issuance of shares as a settlement of Series B Warrants subsequent to the balance sheet date.

The following tabular presentation reflects the reconciliation of the fair value of the Warrants during the period from their issuance through December 31, 2024:

	Common Warrants	Series A Warrants	Series B Warrants	Total
Opening balance				
July issuance	$ 34	-	-	$ -
Settlement of July warrants	(37)	-	-	-
November issuance	-	1,659	10,266	11,925
Settlement of July 30 Convertible Promissory Note	-	609	3,768	4,377
Settlement of July 18 Convertible Promissory Note	-	45	279	324
Change in fair value	3	230	565	798
Balance as of December 31, 2024	**$ -**	**2,544**	**14,877**	**$ 17,421**

NOTE 5 - COMMITMENTS AND CONTINGENT LIABILITIES

A. In 2004, the Israeli Innovation Authority (IIA) provided Integrity Israel with a grant of approximately $93 (NIS 420,000), for develop a non-invasive blood glucose monitor (the "Development Plan"). Integrity Israel is required to pay royalties to IIA at a rate ranging between 3-5% of the proceeds from sale of the Company's products arising from the Development Plan up to an amount equal to $93, plus interest at LIBOR from the grant date. Until December 31,2023 the Liability was subject to LIBOR interest rate and commencing January 1,2024 the interest rate was replaced with Term SOFR (Secured Overnight Financing Rate). As of December 31, 2024, the remaining contingent liability with respect to royalty payment on future sales equals approximately $93, excluding interest. Such contingent obligation has no expiration date.

B. On October 7, 2022 ("the Closing Date"), the Company entered into Intellectual Property Purchase Agreement (the "Agreement") with Paul Goode, which is the Company's Chief Executive Officer (the "Seller"), under which it was agreed that on and subject to the terms and conditions of the Agreement, at the Closing Date, Seller sold and assigned to the Company, all of Seller's right, title and interest in and to the following assets, properties and rights (collectively, the "Purchased Assets"): (i) all rights, title, interests in all current and future intellectual property, including, but not limited to patents, trademarks, trade secrets, industry know-how and other IP rights relating to an implantable continuous glucose sensor (collectively, the "Conveyed Intellectual Property"); and (ii) all the goodwill relating to the Purchased Assets.

In consideration for the sale of the Purchased Assets to the Company, at the Closing Date, the Company paid to Seller cash in the amount of one dollar and obligated to issue up to 10,000 shares of Common Stock to be issued based upon specified performance milestones as set forth in the Agreement (the "Purchase Price"). In addition, if upon the final issuance, the aggregate 10,000 shares represent less than 1.5% of the then outstanding Common Stock of the Company, the final issuance will include such number of additional shares so that the total aggregate issuance equals 1.5% of the outstanding shares (the "True-Up Shares"). All shares of Common Stock of the Company that will be issued under the agreement shall be (i) restricted over a limited period as defined in the Agreement and (ii) subject to the lockup provisions.

When the Company acquires net assets that do not constitute a business, as defined under ASU 2017-01 Business Combinations (Topic 805) Clarifying the Definition of a Business (such when there is no substantive process in the acquired entity) the transaction is accounted for as asset acquisition and no goodwill is recognized. The acquired In-Process Research and Development intangible asset ("IPR&D") to be used in research and development projects which have been determined not to have alternative future use at the acquisition date, is expensed immediately.

At the Closing Date, it was determined that the asset acquisition represents the purchase of IPR&D with no alternative future use. However, the achievement of each of the performance milestones is considered as a contingent event outside the Company's control and thus the contingent consideration which is equal to the fair value of the Purchase Price as measured at the Closing Date will be recognized when and if it becomes probable that each target will be achieved within the reasonable period. Such additional contingent consideration will be recognized in subsequent periods if and when the contingency (the achievement of targets) is resolved.

In June 2023, the Company achieved the first performance milestone out of the five performance milestones outlined in the Agreement executed between the Company and the Seller as of the Closing Date. As a result, upon the date of the fulfilment of the first performance milestone the Company was committed to issue 1,000 restricted shares to the Seller. Accordingly, the Company recorded an amount of $131 as research and development expenses with a similar amount as an increase to additional paid-in capital. The first performance milestone shares were issued on February 6, 2024.

In May 2024, the Company achieved the second performance milestone out of the five performance milestones outlined in the Agreement executed between the Company and the Seller as of the Closing Date. As result, the Company is committed to issue 1,500 restricted shares to the Seller. Accordingly, the Company recorded stock-based compensation expenses amounted to $192 which represents the quoted price of its Common Stock at the Closing Date, after taking into consideration a discount for lack of marketability in a rate of 30% over the applicable restriction period. The second performance milestone shares were issued on November 20, 2024, excluding 11,000 shares that were issued erroneously and were returned to the Company subsequent to the balance sheet date.

As of December 31, 2024, the achievement of all other remaining performance milestones was not considered probable and thus no stock-based compensation expenses were recorded with respect to thereof.

NOTE 6 - LEASE AGREEMENT

On February 19, 2024, the Company entered into Lease Agreement (the "Agreement") with Tapsak Enterprises LLC dba Virginia Analytical (the "Landlord") under which it was agreed that the Company will lease from the Landlord a premises located in Front Royal, Virginia area for a monthly rental fee of $2.5 over a period of 3-years commencing March 1, 2024 through February 28, 2027 (the "Initial Lease Period"). Security deposit of $2.5 which represents payment of one month is held by the Landlord which will be return to the Company at the end of the Initial Lease Period.

In addition, the Company has an option to renew the Initial Lease Period for another two additional periods of 3-years each following the Initial Lease Period (the "Option Term"), following advanced notice as defined in the Agreement. The monthly rental fee over the Option Term shall be the fair market rate determined as what is a comparable cost for similar property in Front Royal, Virginia area.

In accordance with the provision of ASC 842, Leases, at the commencement date of the Agreement, the Company recognized the right to use asset equals to lease liability in total amount of $79. The lease liability was measured at the present value of the future lease payments, which are discounted based on an estimate of the incremental interest rate that the Company would be required to pay to borrow a similar amount for a similar period in order to obtain a similar amount on the initial recognition date of the lease.

As part of the leasing period, the Company considered only the Initial Lease Period as the realization of the option to extend the period was not considered as reasonably certain.

Operating lease:

	December 31, 2024
Operating right-of-use asset	$ 59
Current operating lease liability	$ 26
Non-Current operating lease liability	$ 33

Maturity analysis of the Company's lease liability:

	December 31, 2024
Less than one year	$ 30
Between 1-2 years	30
More than 2 years	5
Total operating lease payments	$ 65
Less: imputed interest	$ 6
Present value of lease liabilities	$ 59

Additional information on lease

The following is a summary of the weighted average remaining lease terms and discount rate for the lease:

	December 31, 2024
Lease term (years)	2.17
Weighted average discount rate	9.03%

NOTE 7 - FINANCE (INCOME) EXPENSES, NET

	Year ended December 31,	
	2024	2023
	Unaudited	
Discount amortization and interest expenses related to June 27 Notes.....	$ 21	$ -
Interest expenses related to July 18 Notes	44	-
Interest expense and debt discount amortization related to July 30 Notes	563	
Interest on bank deposits.....	(62)	(17)
Exchange rate differentials, bank commissions and miscellaneous.....	17	10
	$ 583	$ (7)

NOTE 8 – COMMON STOCK AND WARRANTS WITH-DOWN ROUND PROTECTION

A. Description of the rights attached to the Common Stock

Each share of Common Stock entitles the holder to one vote, either in person or by proxy, on each matter submitted to the approval of the Company's stockholders. The holders of Common Stock are not permitted to vote their shares cumulatively.

B. Equity Issuances

1. 2023 Equity Issuances

On April 13, 2023, the Company completed an underwritten public offering under which the Company received gross proceeds of approximately $10 million for issuance of (i) 53,765 shares of common stock and (ii) 19,765 pre-funded warrants at a price to the public of $136 per share. The pre-funded warrants are exercisable for the same number of shares of common stock and may be exercised at any time until exercised in full at an exercise price of $0.001.

Upon satisfaction of customary closing conditions, the closing date of the above underwritten public offering was April 17, 2023 (the "Closing Date"). The Company received substantially all the pre-funded warrant's proceeds upfront (without any conditions) as part of the pre-funded warrant's purchase price and in return the Company is obligated to issue fixed number of 19,765 shares of Common Stock to the holders. Thus, pre-funded warrants were accounted for and were classified as additional paid-in capital as part of the Company's stockholders' equity.

Total incremental and direct issuance costs amounted to $1,270 thousand. These expenses were deducted from additional paid-in capital as they were allocated to shares of Common Stock and pre-funded warrants.

On January 3, 2024, the above pre-funded warrants have been fully exercised to 19,765 shares of Common Stock of the Company.

2. 2024 Equity Issuances

See Notes 4H, 4I and 4J relating to the issuances of shares during 2024.

3. Subsequent event issuances

See Note 14 regarding a significant issuance of shares as a settlement of Series B Warrants subsequent to the balance sheet date.

C. Stock-based compensation

1. Plan

On January 11, 2010, the Company's Board of Directors approved and adopted the 2010 Share Incentive Plan (the "Plan"), pursuant to which the Company's Board of Directors may award share options to purchase the Company's Common Stock as well as restricted shares, Restricted Stock Units (the "RSU") and other share-based awards to designated participants. Subject to the terms and conditions of the Plan, the Company's Board of Directors has full authority in its discretion, from time to time and at any time, to determine (i) the designate participants; (ii) the terms and provisions of the respective award agreements, including, but not limited to, the number of share options to be granted to each optionee, the number of shares to be covered by each share option, provisions concerning the time and the extent to which the share options may be exercised and the nature and duration of restrictions as to the transferability or restrictions constituting substantial risk of forfeiture and to cancel or suspend awards, as necessary; (iii) determine the fair market value of the shares covered by each award; (iv) make an election as to the type of approved 102 Option under Israeli tax law; (v) designate the type of share options; (vi) take any measures, and to take actions, as deemed necessary or advisable for the administration and implementation of the Plan; (vii) interpret the provisions of the Plan and to amend from time to time the terms of the Plan.

2. Grant of equity awards to employees

A. In August 2023, the Company granted Ms. Drinda Benjamin, the Vice President, Marketing of the Company, 2,220 options estimated at fair value of $51, to purchase the same number of Common Stock, with an exercise price per share equals to the greater of (A) $136 per share or (B) the closing price of a share of Common Stock on the grant date, as reported by Bloomberg L.P., which shall vest in equal monthly installments over a period of 3-years following the grant date.

B. On June 14, 2024, the Board of Directors approved the cancellation of all outstanding stock options previously granted to employees, directors, and officers of the Company. Concurrently, the Board authorized the issuance of new stock options to the relevant parties. The new stock options were issued in replacement with exercise price $245.

C. During the years ended December 31, 2024 and 2023, the Company recorded stock-based compensation expenses of $173 and $281, respectively.

D. The following table presents the Company's stock options (excluding RSU) activity for employees and members of the Board of Directors of the Company under the Plan, for the years ended December 31, 2024 and 2023:

	Number of Share Options	Weighted Average Exercise Price $	Weighted average remaining contractual life (years)	Intrinsic value $
Outstanding as of December 31, 2022	8,046	152	2.1	-
Granted	2,221	28	9.7	-
Forfeited or expired	(269)	1290	1.7	-
Outstanding as of December 31, 2023	9,998	90	8.0	-
Granted	6,438	49.72	9.37	-
Cancelled	-	-	-	-
Forfeited or expired	-	-	-	-
Outstanding as of December 31, 2024	16,436	49.72	9.37	-
Exercisable as of December 31, 2024	11,249	*49.11	9.41	

*After modification of exercise price

The aggregate intrinsic value in the table above represents the total intrinsic value (the difference between the deemed fair value of the Company's Ordinary Shares on the last day of each of the applicable reported period and the exercise price, multiplied by the number of in-the-money share options) that would have been received by the share option holders had all share options holders exercised their share options on December 31 of each of the reported period. This amount is impacted by the changes in the fair market value of the Company's Ordinary Share.

E. During the years ended December 31, 2024 and 2023, stock options have not been exercised into Common Stock.

F. The following table presents the assumptions used to estimate the fair values of the share options granted in the reported periods presented:

	Years ended December 31	
	2024	**2023**
Volatility (%)	207-288%	220%
Risk-free interest rate (%)	3.51-4.64%	4.7%
Dividend yield (%)	-	-
Expected life (years)	3	3
Exercise price ($)	41-58	140
Share price ($)	49.0	30

G. As of December 31, 2024, there was $298 of unrecognized compensation expense related to unvested stock options. The Company recognizes compensation expense on an accelerated vesting basis over the requisite service periods, which results in a weighted average period of approximately 1.9 years over which the unrecognized compensation expense is expected to be recognized.

3. Grant of equity awards to non-employees

A. Upon closing of underwritten U.S. public offering in 2023 as noted in Note 8B above, a down round protection feature of certain previously granted warrants, was triggered through the reduction of their original exercise prices from a price in a range of $335 -$7,020 to a price of $136 which represented the public offering price. Such reduction was accounted for in accordance with the provisions of ASU 2017-11 as a deemed dividend estimated at a total amount of $855 thousand which was recorded as part of the additional paid-in capital versus increase of accumulated deficit. Regarding the effect of the loss per share, see also Note 2O above.

B. The following table presents the Company's warrants activity for the years ended December 31, 2024 and 2023:

	Number of Share Warrants	**Weighted Average Exercise Price $**	**Weighted average remaining contractual life (years)**	**Intrinsic value $**
Outstanding as of December 31, 2023	-	-	-	-
Granted	1,278,259	39.66	9.31	-
Cancelled	-	-	-	-
Forfeited or expired	-	-	-	-
Outstanding as of December 31, 2024	1,278,259	39.66	9.31	-
Exercisable as of December 31, 2024	1,278,259	39.66	9.31	-

The total compensation cost related to all of the Company's equity-based awards recognized during the years ended December 31, 2024 and 2023 was comprised as follows:

	In thousands of US dollars	
	December 31, 2024	December 31, 2023
Research and development	307	176
General and administrative	364	159
	671	335

NOTE 9 – RESEARCH AND DEVELOPMENT EXPENSES

	In thousands of US dollars	
Research and Development	December 31, 2024	December 31, 2023
Salaries and related expenses	1,881	930
Professional fees	7,363	3,709
Depreciation	14	10
Other	241	55
	9,499	4,704

NOTE 10 – GENERAL AND ADMINISTRATIVE EXPENSES

	In thousands of US dollars	
General and Administrative	December 31, 2024	December 31, 2023
Salaries and related expenses	476	340
Professional fees (including directors' fees)	3,724	1,527
Depreciation	22	3
Insurance	313	336
Other	120	72
	4,655	2,278

NOTE 11 – INCOME TAX

A. Measurement of results for tax purposes under the Israeli Income Tax (Inflationary Adjustments) Law, 1985 (the "Inflationary Adjustment Law")

Commencing January 1, 2008, the results of operations of Integrity Israel for tax purposes have been measured on a nominal basis.

B. Tax assessments

For federal, state and local income tax purposes the Company remains open for examination by the tax authorities for the tax years from 2019 through 2022 under the general statute of limitations.

Notwithstanding, pursuant and subject to the provisions of article 145 of the Income Tax Ordinance, Integrity Israel's tax returns that were filed with the tax authority up to and including 2018 are considered final.

C. Loss for the years ended December 31, 2024 and 2023 consists of the following:

	Year ended December 31	
	2024	2023
Domestic	$ 22,502	$ 6,945
Foreign entity (Integrity Israel)	95	152
	22,597	7,097

D. Net Operating Losses (NOL) carryforward

As of December 31, 2024, the Company had cumulative Net Operating Losses (NOL) carry forward for US federal purposes of approximately $31.6 million to offset against future taxable income for an indefinite period of time. Integrity Israel has cumulative NOL carry forward for Israeli income tax purposes of approximately $38.5 million to offset against future taxable income for an indefinite period of time.

E. For the years ended December 31, 2024 and 2023, the main reconciling item is the recognition of valuation allowance in respect of deferred taxes relating to accumulated net operating losses carried forward and other permanent and temporary differences due to the uncertainty of the realization of such deferred taxes.

F. Deferred taxes result principally from temporary differences in the recognition of certain revenue and expense items for financial and income tax reporting purposes. Significant components of the Company's future tax assets are as follows:

	As of December 31	
Composition of deferred tax assets:	**2024**	**2023**
Vacation accrual	208	66
Research and development credits	3,276	1,033
Net operating losses carry forwards	16,981	12,368
Net deferred tax asset before deferred tax liabilities and valuation allowance	20,465	13,467
Valuation allowance	(20,465)	(13,467)
Net deferred tax assets	-	-

NOTE 12 – RELATED PARTIES

A. For more information regarding the intellectual property purchase agreement from the company's CEO - See Note 5B above.

B. For more information regarding loans received from certain Stockholders - See Note 3 above.

C. Tapsak Enterprises LLC, dba Virginia Analytical

On October 25, 2022, the Company entered into agreement with Tapsak Enterprises LLC dba Virginia Analytical, which fully owned by Mark Tapsak, who serves as the Vice President of Sensor Science of the Company, under which, Tapsak Enterprises LLC dba Virginia Analytical, is providing laboratory space, equipment and materials to support the Company sensor development activities. During the years ended December 31, 2024 and 2023, a total amount of $25 and $162 were recorded as part of the Company's research and development expenses, respectively.

For more information regarding execution of lease agreement with Tapsak Enterprises LLC dba Virginia Analytical, see Note 6.

D. Regarding the issuances of notes, shares, warrants and settlement of notes, ee Note 4 above.

NOTE 13 – SEGMENT REPORTING:

ASC 280, "Segment Reporting" establishes standards for reporting information about operating segments on a basis consistent with the Company's internal organization structure as well as information about services categories, business segments and major customers in financial statements. The Company has only one reportable segment, the Glucotrack CBGM Product Segment, as all their research and development activities are related the development of the Glucotrack CBGM Product. Since the Company operates in one operating segment, all required financial segment information can be found in the consolidated financial statements.

The Company adheres to the provisions of ASC 280, Segment Reporting, which establishes standards for the way public business enterprises report information about operating segments in annual financial statements and requires that those enterprises report selected information about operating segments in financial statements issued to shareholders. As the Company is currently involved in the development of one product, the Platform, the Company has determined that it operates in a single reportable segment. The Company's Chief Operating Decision Maker (CODM), its Chief Executive Officer (CEO), reviews the consolidated results of operations when making decisions about allocating resources and assessing the performance of the Company as a whole and, hence, the Company has only one reportable segment. The Company's assets are located in the United States of America.

NOTE 14 – SUBSEQUENT EVENTS

2025 Reverse Stock Split and Increase in Authorized Common Stock

The Company filed with the Delaware Secretary of State a Certificate of Amendment to its Certificate of Incorporation which became effective at 4:30 p.m. on February 3, 2025, to implement a reverse stock split at a ratio of 1-for-20 (the "2025 Reverse Stock Split") of the shares of its Common Stock. The 2025 Reverse Stock Split was approved by the Company's stockholders at the special meeting of stockholders held on January 3, 2025 (the "Special Meeting"). All shares and per share numbers in the consolidated financial statements have been retroactively adjusted and are reflected on a post-reverse share split basis.

On January 3, 2025, the Company filed an amendment to the Company's Certificate of Incorporation, as to increase the Company's authorized shares of Common Stock from 100,000,000 to 250,000,000. On February 3, 2025, the stockholders approved at the Special Meeting the increase in the Company's authorized shares of Common Stock from 100,000,000 to 250,000,000, as well as the full issuance of shares of Common Stock issuable by the Company upon the exercise of Series A Warrants and Series B Warrants (see below).

ATM Sales Agreement

On December 17, 2024, the Company entered into an ATM sales agreement (the "Sales Agreement") with Dawson James Securities, Inc. ("Dawson James"), pursuant to which the Company have agreed to issue and sell shares of Common Stock, having an aggregate offering price of up to $8.23 million, from time to time, through an "at-the-market" equity offering program under which Dawson James will act as sales agent (the "Agent").

On March 21, 2025, the Company sold 12,377,967 shares of Common Stock at an average offering price of $0.304 per share pursuant to the Sales Agreement. for net proceeds of $3.6 million, after deducting fees owed to the Agent from such sale. The shares of Common Stock were offered by the Company pursuant to a prospectus supplement dated December 17, 2024, and accompanying prospectus dated October 3, 2024, which forms a part of the Company's registration statement on Form S-3 (Registration No. 333-282297), which was declared effective by the Securities and Exchange Commission, on October 3, 2024.

Registered Direct Offering

On February 4, 2025, the Company entered into a securities purchase agreement with certain institutional investors, relating to the registered direct offering and sale of an aggregate of 2,638,042 shares of Common Stock at an offering price of $1.15 per share. The net proceeds to the Company from the offering were approximately $2.7 million, after deducting fees owed to placement agent and other offering expenses. The February 2025 offering closed on February 5, 2025.

The shares of Common Stock from the February 2025 registered direct offering was offered by the Company pursuant to a prospectus supplement dated February 4, 2025, and accompanying prospectus dated October 3, 2024, which forms a part of the Company's registration statement on Form S-3 (Registration No. 333-282297), which was declared effective by the Securities and Exchange Commission, on October 3, 2024. Dawson James acted as the placement agent for the offerings pursuant to a placement agency agreement, dated February 4, 2025, by and between the Company and Dawson James.

Warrant Exchange

Beginning on January 6, 2025, through March 15, 2025, the Company received exchange notices from certain holders of the Series B Warrants, with respect to an aggregate of 359,612 of the Series B Warrants, requiring the delivery of 9,721,782 shares of Common Stock according to the alternative cashless exercise, as applicable to the Series B Warrants under the November 2024 offering. The remaining 100 Series B Warrants are exchangeable for an aggregate of approximately 1,940 shares of Common Stock (subject to adjustment in the event of any stock dividend and split, reverse stock split, recapitalization, reorganization or similar transaction).

Appointment of Peter C. Wulff as Chief Financial Officer

In connection with Mr. Cardwell's resignation, on January 28, 2025, the Board appointed Peter C. Wulff as Chief Financial Officer of the Company.

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

GLUCOTRACK, INC.

Date: March 31, 2025

By: */s/ Paul Goode*
Name: Paul Goode
Title: Chief Executive Officer
(Principal Executive Officer)

Date: March 31, 2025

By: */s/ Peter Wulff*
Name: Peter Wulff
Title: Chief Financial Officer
(Principal Financial and Accounting Officer)

Pursuant to the requirements of the Securities Exchange Act of 1934, this Report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ *Paul Goode* Paul Goode	Chief Executive Officer and Director (*Principal Executive Officer)*	March 31, 2025
/s/ *Peter Wulff* Peter Wulff	Chief Financial Officer *(Principal Financial and Accounting Officer)*	March 31, 2025
/s/ *Erin Carter* Erin Carter	Director	March 31, 2025
/s/ *Luis Malave* Luis Malave	Director	March 31, 2025
/s/ *Robert Fischell* Dr. Robert Fischell	Director	March 31, 2025
/s/ *Andrew Balo* Andrew Balo	Director	March 31, 2025
/s/ *Allen Danzig* Allen Danzig	Director	March 31, 2025
/s/ *John Ballantyne* John Ballantyne	Director	March 31, 2025