Filed pursuant to Rule 424(b)(5)
Registration Statement No. 333-282297

Prospectus Supplement
(To Prospectus dated October 3, 2024)

Glucotrack, Inc.

169,388 shares of Common Stock
1,350,220 Pre-Funded Warrants to Purchase up to 1,350,220 shares of Common Stock
1,350,220 Shares of Common Stock Underlying Pre-Funded Warrants

We are offering an aggregate of (i) 169,388 shares (the "Shares") of our common stock, $0.001 par value per share (the "Common Stock"), and (ii) pre-funded warrants (the "Pre-Funded Warrants") to purchase up to an aggregate of 1,350,220 shares of Common Stock (the "Pre-Funded Warrant Shares" and, together with the Shares, the "Securities"), to certain institutional and accredited investors in a registered direct offering pursuant to this prospectus supplement and the accompanying prospectus, filed as part of our registration statement on Form S-3 (File No. 333-282297). The offering price per Share is $2.04.

We are offering Pre-Funded Warrants in lieu of Shares to those purchasers whose purchase of Shares in this offering would result in the purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% of our outstanding Common Stock following the consummation of this offering. Subject to limited exceptions, a holder of Pre-Funded Warrants will not have the right to exercise any portion of its Pre-Funded Warrants if the holder, together with its affiliates, would beneficially own in excess of 4.99% (or, at the election of the holder, such limit may be increased up to 9.99%) of the number of shares of Common Stock outstanding immediately after giving effect to such exercise. Each Pre-Funded Warrant will be exercisable for one share of Common Stock. The purchase price of each Pre-Funded Warrant will be equal to the price per Share, minus $0.001, and the exercise price of each Pre-Funded Warrant will equal $0.001 per share. The Pre-Funded Warrants will be immediately exercisable and may be exercised at any time until all of the Pre-Funded Warrants are exercised in full. This prospectus supplement and the accompanying prospectus also relate to the offering of the Common Stock issuable upon exercise of the Pre-Funded Warrants in this offering.

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

On September 23, 2026, the last reported sale price of our Common Stock on Nasdaq was $2.03 per share. We intend to use the net proceeds of this offering for general corporate purposes and working capital. See "*Prospectus Supplement Summary – Use of Proceeds*."

As of September 23, 2026, the aggregate market value of our outstanding common stock held by non-affiliates was approximately $9.45 million, which we calculated based on 848,629 shares of outstanding common stock, of which 807,325 shares were held by non-affiliates, and a price per share of $11.70 as of July 30, 2026, which is a date within 60 days prior to the date of this prospectus. Pursuant to General Instruction I.B.6 of Form S-3, in no event will we sell, pursuant to the registration statement of which this prospectus forms a part, securities in a public primary offering with a value exceeding one-third of the aggregate market value of our outstanding common stock held by non-affiliates in any 12-month period, so long as the aggregate market value of our outstanding common stock held by non-affiliates remains below $75 million. During the 12 calendar months prior to and including the date of this prospectus, we have not offered or sold any securities pursuant to General Instruction I.B.6 of Form S-3.

We have engaged Dawson James to act as placement agent (the "placement agent") in connection with the securities offered by this prospectus supplement and the accompanying prospectus. The placement agent has agreed to use its reasonable best efforts to arrange for the sale of the securities offered in this offering. The placement agent is not purchasing or selling any of the securities we are offering, and the placement agent is not required to arrange the purchase or sale of any specific number of securities or dollar amount. There is no required minimum number of securities that must be sold as a condition to completion of this offering, and there are no arrangements to place the funds in an escrow, trust, or similar account.

Investing in our securities involves a high degree of risk. Before making an investment decision, please read the information under the heading "Risk Factors" beginning on page S-12 of this prospectus supplement and page 5 of the accompanying prospectus, and in the documents incorporated by reference into this prospectus supplement and the accompanying prospectus. We are a "smaller reporting company" as defined by Rule 12b-2 of the Securities Exchange Act of 1934, as amended (the "Exchange Act") and as such are subject to reduced public company reporting requirements.

	Per Share	Per Pre-Funded Warrant	Total
Offering price	$ 2.04000	$ 2.03900	$ 3,100,000.00
Placement agent fees[(1)]	$ 0.16320	$ 0.16312	$ 248,000.00
Proceeds to us, before expenses[(2)]	$ 1.87680	$ 1.87588	$ 2,852,000.00

(1) We have agreed to pay the placement agent a cash fee equal to 8% of the aggregate gross proceeds of this offering. We have also agreed to reimburse the placement agent for certain of their expenses. See "Plan of Distribution" beginning on page S-51 of this prospectus supplement for a description of the compensation and expense reimbursements to be received by the placement agent.

Unless otherwise indicated, and other than the consolidated financial statements and the related notes incorporated by reference into this prospectus supplement, the number of our shares of Common Stock presented in this prospectus supplement is adjusted to reflect the 1-for-15 reverse stock split that was implemented on August 28, 2026. See the section entitled "*Prospectus Supplement Summary—Reverse Stock Split*" for more information.

Investing in our securities involves risks. See the section entitled "*Risk Factors*" on page S-12 of this prospectus supplement and in the accompanying prospectus and the documents that are incorporated by reference herein and therein.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense. The securities are not being offered in any jurisdiction where the offer is not permitted.

Delivery of the Shares and Pre-Funded Warrants is expected to be made on or about September 25, 2026, subject to the satisfaction of certain conditions.

Dawson James Securities, Inc.

The date of this prospectus supplement is September 24, 2026.

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Prospectus Supplement

Prospectus

ABOUT THIS PROSPECTUS SUPPLEMENT

This document is part of a registration statement that was filed with the Securities and Exchange Commission (the "SEC"), using a "shelf" registration process and consists of two parts. The first part is this prospectus supplement, which describes the specific terms of this offering and also supplements and updates information contained in the accompanying prospectus and the documents incorporated by reference into this prospectus supplement and the accompanying prospectus. The second part is the accompanying prospectus, which provides more general information, some of which may not apply to this offering. This prospectus supplement may add, update or change information contained in the accompanying prospectus. If the information contained in this prospectus supplement differs or varies from, or is inconsistent with, the information contained in the accompanying prospectus, or the information contained in any document incorporated by reference that was filed with the SEC before the date of this prospectus supplement, you should rely on the information set forth in this prospectus supplement.

You should rely only on the information contained or incorporated by reference in this prospectus supplement and the accompanying prospectus. We have not, and the placement agent has not, authorized anyone else to provide you with information that is in addition to or different from that contained or incorporated by reference in this prospectus supplement and the accompanying prospectus, along with the information contained in any permitted free writing prospectuses we have authorized for use in connection with this offering. We and the placement agent take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may provide.

The information contained in this prospectus supplement and the accompanying prospectus is accurate only as of the date of this prospectus supplement or the date of the accompanying prospectus, and the information in the documents incorporated by reference in this prospectus supplement and the accompanying prospectus is accurate only as of the date of those respective documents, regardless of the time of delivery of this prospectus supplement and the accompanying prospectus or of any sale of our Common Stock. Our business, financial condition, results of operations and prospects may have changed since those dates. It is important for you to read and consider all information contained or incorporated by reference in this prospectus supplement and the accompanying prospectus in making your investment decision. You should read both this prospectus supplement and the accompanying prospectus, as well as the documents incorporated by reference into this prospectus supplement and the accompanying prospectus and the additional information described under "Where You Can Find More Information" in this prospectus supplement and in the accompanying prospectus before investing in our Common Stock.

We further note that the representations, warranties, and covenants made by us in any agreement that is filed as an exhibit to any document that is incorporated by reference in this prospectus supplement and the accompanying prospectus were made solely for the benefit of the parties to such agreement, including, in some cases, for the purpose of allocating risk among the parties to such agreements, and should not be deemed to be a representation, warranty or covenant to you. Moreover, such representations, warranties or covenants were accurate only as of the date when made. Accordingly, such representations, warranties, and covenants should not be relied on as accurately representing the current state of our affairs.

We use various trademarks and trade names in our business, including without limitation our corporate name and logo. All other trademarks or trade names referred to in this prospectus supplement and the accompanying prospectus and the documents incorporated by reference herein or therein are the property of their respective owners. Solely for convenience, the trademarks and trade names in this prospectus supplement and the accompanying prospectus and the documents incorporated by reference herein or therein may be referred to without the ® and ™ symbols, but such references should not be construed as any indicator that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto.

You should not consider this prospectus supplement or the accompanying prospectus to be an offer or solicitation relating to the securities in any jurisdiction in which such an offer or solicitation relating to the securities is not authorized. Persons outside the United States who come into possession of this prospectus supplement and the accompanying prospectus must inform themselves about, and observe any restrictions relating to, the offering of the securities and the distribution of this prospectus supplement and the accompanying prospectus outside the United States. This prospectus supplement and the accompanying prospectus do not constitute, and may not be used in connection with, an offer to sell, or a solicitation of an offer to buy, any securities offered by this prospectus supplement or the accompanying prospectus supplement by any person in any jurisdiction if the person making the offer or solicitation is not qualified to do so, or if it is unlawful for you to receive such an offer or solicitation.

Unless otherwise indicated, information contained in or incorporated by reference into this prospectus supplement and the accompanying prospectus concerning our business and the industry and markets in which we operate, including with respect to our business prospects, our market position and opportunity, and the competitive landscape, is based on information from our management's estimates, as well as from industry publications, surveys and studies conducted by third parties. Our management's estimates are derived from publicly available information, their knowledge of our business and industry, and assumptions based on such information and knowledge, which they believe to be reasonable. In addition, while we believe that information contained in the industry publications, surveys and studies has been obtained from reliable sources, we have not independently verified any of the data contained in these third-party sources, and the accuracy and completeness of the information contained in these sources is not guaranteed. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances reflected in this information. Unless otherwise expressly stated, we obtained this industry, business, market, and other data from reports, research surveys, studies and similar data prepared by market research firms and other third parties, industry, medical, and general publications, government data and similar sources.

Unless otherwise stated, all references to "us," "our," "we," the "Company" and similar designations refer to Glucotrack, Inc. and its consolidated subsidiaries. Our logo, trademarks and service marks are the property of Glucotrack, Inc. and its consolidated subsidiaries. Other trademarks or service marks appearing in this prospectus supplement are the property of their respective holders.

PROSPECTUS SUPPLEMENT SUMMARY

This summary highlights, and is qualified in its entirety by, the more detailed information and financial statements included elsewhere or incorporated by reference in this prospectus supplement and the accompanying prospectus. This summary does not contain all of the information that may be important to you in making your investment decision. You should read this entire prospectus supplement and the accompanying prospectus and the information incorporated by reference herein carefully, including the sections entitled "Risk Factors" beginning on page S-12, "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements and the related notes incorporated by reference herein, as well as the risk factors contained in our Annual Report on Form 10-K for the year ended December 31, 2025, each of our Quarterly Reports on Form 10-Q, and in our other subsequent filings with the SEC, before making an investment decision. Some of the statements included in this prospectus supplement and the information incorporated by reference herein constitute forward-looking statements. See the section entitled "Cautionary Note Regarding Forward-Looking Statements" for more information. In this prospectus supplement, except as otherwise indicated, the terms "Glucotrack," "the Company," "we," "us," or "our" refer to Glucotrack, Inc., a Delaware corporation, and its wholly-owned subsidiaries.

About the Business Combination

On July 14, 2026 (the "Closing Date"), the Company entered into an Agreement and Plan of Merger (the "Merger Agreement") with Glucotrack Merger Sub, Inc., a Nevada corporation ("Merger Sub"), Lokahi Therapeutics, Inc., a Nevada corporation ("Lokahi"), Glucotrack Technologies Inc. ("Glucotrack Technologies"), and Paul V. Goode, solely in his capacity as representative for Glucotrack Technologies. The transactions contemplated by the Merger Agreement are referred to herein as the "Business Combination Transactions" and the closing of the Business Combination Transactions is referred to herein as the "Closing". Immediately prior to the Closing, articles of merger (the "Articles of Merger") were filed with the Secretary of State of the State of Nevada. Pursuant to the Articles of Merger, Merger Sub merged with and into Lokahi (the "Merger"), with Lokahi surviving as a direct wholly owned subsidiary of the Company. The Closing occurred simultaneously with the execution and delivery of the Merger Agreement on the Closing Date. For more information regarding the Business Combination, please refer to the section entitled "*Business Combination*" in this prospectus supplement.

At the effective time of the Merger (the "Effective Time"), each share of common stock of Lokahi issued and outstanding immediately prior to the Effective Time was canceled and converted into the right to receive a portion of the merger consideration (as defined in the Merger Agreement, the "Merger Consideration"), consisting of shares of Common Stock and shares of Series A convertible preferred stock, par value $0.001 per share, of the Company (the "Preferred Stock"). The Merger Consideration was allocated among the former holders of Lokahi common stock such that, immediately following the Effective Time, such holders collectively hold, on a fully-diluted and as-converted to Common Stock basis, 90.0% of the total issued and outstanding equity securities of the Company calculated on a fully diluted basis.

Immediately prior to the Closing, the Company transferred to Glucotrack Technologies all assets and liabilities relating to the Company's operating business, which is focused on the design, development, and commercialization of novel technologies for people with diabetes, including the development of the Glucotrack Continuous Blood Glucose Monitor, a long-term implantable system that continually measures blood glucose levels, featuring a sensor longevity of approximately three (3) years, no on-body wearable component, and minimal calibration requirements (the "CBGM Business"). The assets transferred to Glucotrack Technologies included (i) all intellectual property, know-how, and proprietary information used in or necessary to the CBGM Business, (ii) all employees of the Company prior to Closing, (iii) all operations of the CBGM Business, and (iv) all cash and cash equivalents of the Company on hand as of the Closing Date (collectively, the "Contributed Assets"). Following the Closing, each of Lokahi and Glucotrack Technologies are operating subsidiaries of the Company.

About Lokahi Therapeutics Inc.

References in this sub-section to the "Company," "we," "us," or "our" refer to Lokahi Therapeutics, Inc., a Nevada corporation. For more information relating to the business of Lokahi Therapeutics, Inc., please refer to the section entitled "Business of the Combined Company – About Lokahi Therapeutics Inc." herein.

We are a clinical stage biopharmaceutical company in the process of developing LT-100, an intradermally administered bee venom-based toxin. Our focus is primarily on developing innovative therapies that address inflammation and pain management symptoms associated with knee OA and, to a lesser extent, MS. LT-100 is currently marketed and sold by Apimeds Inc. ("Apimeds Korea") in South Korea as "Apitoxin" for the treatment of OA. Lokahi is not associated with the market, sale and revenues generated from Apitoxin in South Korea, and LT-100 has not yet been approved by the FDA for any indication.

LT-100

LT-100 is a purified, pharmaceutical grade venom (bee venom), of the Apis mellifera, or western honeybee, which is classified by the FDA as an active pharmaceutical ingredient ("API"). Bee venom has been used in Asia and Europe to treat pain for hundreds of years. While not FDA approved in a controlled, prescription based biologic environment for defined indications, the use of bee venom has been FDA approved as a "under the skin injection" to reduce the allergic reactions to bee stings. Apimeds Korea has developed a proprietary method and process for turning extracted bee venom into a lyophilized powder for reconstitution prior to intradermal dose injections, which they sell in South Korea as Apitoxin. We intend to use a similar process with respect to LT-100, pursuant to the Business Agreement, which gives us a license to utilize all prior clinical development data associated with Apitoxin. The advancement of extracted bee venom for treatment of inflammatory conditions, including but not limited to knee OA and MS is speculative but based on direction provided by prior clinical data.

ai2 Futures Lab

We have established the ai² platform to support business development, opportunity evaluation, and talent development activities. The platform is used to identify and assess therapeutic, biotechnology, medical device, and other healthcare-related opportunities that may be considered for acquisition, licensing, strategic partnership, development, or other business initiatives.

The ai² platform utilizes evaluation methodologies, research processes, academic collaborations, and analytical tools to support the review of potential opportunities. Evaluations may include assessments of scientific rationale, clinical development status, intellectual property, regulatory considerations, commercial opportunity, competitive landscape, and strategic fit. Findings generated through the platform may be reviewed as part of our business development activities through collaborations with universities and other academic institutions. Lokahi partners with universities to give students hands-on exposure to the strategic side of biopharma, from evaluating clinical assets to understanding intellectual property, market dynamics, and go-to-market strategies. The ai² Futures Lab™ functions as both a discovery engine for potential therapeutic assets and a training ground for the next generation of biotech and business leaders.

ai^2 Futures Lab is a program within the ai² platform that operates through collaborations with universities and academic institutions. Through the program, student teams participate in research and opportunity evaluation projects utilizing methodologies developed by us. Projects generally focus on the identification and assessment of therapeutic, biotechnology, medical device, and other healthcare-related opportunities that meet parameters established by us. Student teams may conduct analyses relating to clinical development, intellectual property, regulatory pathways, commercial opportunity, and competitive landscape. Findings generated through the program may be reviewed as part of our business development activities. The ai² Futures Lab program also supports recruiting and workforce development activities. Participants may be considered for internship, consulting, or employment opportunities with us.

About Glucotrack Technologies, Inc.

References in this sub-section to the "Company," "we," "us," or "our" refer to Glucotrack Technologies Inc., a Nevada corporation. For more information relating to the business of Glucotrack Technologies Inc., please refer to the section entitled "Business" in Glucotrack, Inc.'s Annual Report on Form 10-K for the fiscal year ended December 31, 2025, as filed with the SEC on March 30, 2026 (the "Annual Report"), which is incorporated by reference into this prospectus supplement.

The Company was incorporated on July 8, 2026 under the laws of the State of Nevada. The Company is medical device company focused on the development of an implantable continuous blood glucose monitor ("CBGM") for persons with Type 1 diabetes and Type 2 diabetes using insulin or at risk for hypoglycemia (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 determined in 2023 that it would focus its efforts on developing the Glucotrack CBGM. As such, the Company withdrew the CE Mark for Glucotrack and is 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 Type 2 diabetes market.

The Company is currently developing the Glucotrack CBGM for use by Type 1 diabetes patients as well as Type 2 diabetes using insulin or at risk for hypoglycemia. Implant longevity is key to the success of such a device. The Company has demonstrated 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. During the period, two peer-reviewed scientific articles were published related to the CBGM technology. One article, published in the IEEE Sensors Journal, characterized the long-term in-vitro stability of electrochemical glucose sensors of the type used in the CBGM system, including the first year-long measurements of glucose oxidase enzyme decay reported in the literature. A second peer-reviewed article, published in The Journal of Diabetes Research, evaluated the long-term accuracy and stability of the CBGM system in an in-vivo ovine model, providing externally validated evidence supporting the long-term performance of the technology. 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.

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. The Company believes this approach may enable integrated chronic disease management with one system that provides dual benefits of pain relief and glucose monitoring.

The Company completed a first in human study in 2025. 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. Initial results were presented in poster form at the 2025 Advanced Technologies & Treatments for Diabetes annual meeting and final results were presented in poster form at the 2025 American Diabetes Association annual conference.

The Company initiated a long-term, multicenter feasibility study in Australia to evaluate the CBGM product performance and safety. The first phase of the clinical study provided early product learnings about how the complexity of certain health conditions may impact study eligibility as well as identified certain product improvements. Following a reassessment of the study in light of planned product updates and anticipated protocol modifications, the Company determined that continuation of the study in its current form was no longer practical and elected to close the study.

Subsequent to March 31, 2026, the Company submitted an Investigational Device Exemption ("IDE") application to the U.S. Food and Drug Administration ("FDA") to initiate a U.S. clinical study of its CBGM technology. The IDE submission represents an important milestone for the Company and reflects progress in its preclinical development and underlying technical foundation. Following the FDA's initial review, the FDA provided feedback on the application, and the Company has elected to address that feedback through the FDA's Pre-Submission process before resubmitting its IDE application. The Company has also engaged a clinical research organization and identified trial sites in preparation for study commencement. The timing of any U.S. clinical study will depend on FDA approval of its resubmitted IDE.

The Company initially obtained ISO13485 certification in 2024 and successfully passed the 2025 annual audit, both efforts without any major nonconformities. ISO 13485 is an internationally agreed-upon standard of quality system requirements for the design, production, distribution, and sale of medical devices. Certification of compliance to the standard is recognized and accepted by the FDA, the European Medicines Agency (EMA), and many other regulatory authorities worldwide.

The Company's executive management team consists of its 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). The Company's 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; Vincent Wong, Chief Operating Officer, a medical device professional with over 15 years of experience in operations and quality systems for implantable medical device manufacturing with senior roles at Cirtec Medical and TOMZ Corporation ("TOMZ"); 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; 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.

The Company's board of directors includes 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; and Victoria Carr-Brendel, formerly of Dexcom, Boston Scientific, JenaValve Technology, and Advanced Bionics.

As of the date of this prospectus supplement, the Company had a total of 15 employees. The Company is not subject to any collective bargaining agreement, and it believes that its relationships with its employees are good.

Recent Developments

Corporate and Regulatory

Reverse Stock Split

We filed with the Delaware Secretary of State a Certificate of Amendment to our Certificate of Incorporation (the "Certificate of Amendment") which became effective at 4:30 p.m. on August 28, 2026, to implement a reverse stock split at a ratio of 1-for-15 (the "Reverse Stock Split") of the shares of our Common Stock. The Reverse Stock Split was approved by the Company's stockholders at the 2026 annual meeting of the stockholders on August 18, 2026. As a result of the Reverse Stock Split, every 15 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. The shares of Common Stock underlying the outstanding stock options and warrants were similarly adjusted along with corresponding adjustments to their exercise prices. There was no reduction in the total number of authorized shares of Common Stock.

Nasdaq Listing Status

On May 11, 2026, we received a letter (the "Staff Determination") from the Listing Qualifications Department of The Nasdaq Stock Market LLC ("Nasdaq") notifying us that we no longer complied with Nasdaq Listing Rule 5550(a)(2), which requires a minimum bid price of $1.00 per share (the "Bid Price Rule"), and that the staff of the Listing Qualifications Department ("Nasdaq Staff") had determined to delist our securities from The Nasdaq Capital Market. We timely requested a hearing before a Nasdaq Hearings Panel (the "Panel") to appeal, which stayed further delisting actions. On May 15, 2026, we received a second letter from Nasdaq notifying us that, based on our Form 10-Q for the period ended March 31, 2026, we no longer meet the $2,500,000 minimum stockholders' equity requirement under Listing Rule 5550(b)(1) (the "Equity Rule") or the alternatives of market value of listed securities or net income from continuing operations. This deficiency became an additional basis for delisting and was considered in the Panel's decision regarding our continued listing. At a hearing on June 18, 2026, we presented our plan to regain compliance with the Bid Price Rule and the Equity Rule. On August 14, 2026, the Panel determined that we had regained compliance with the Equity Rule and granted our request for continued listing on Nasdaq, subject to certain conditions, including that we (i) hold our annual meeting and obtain stockholder approval of a reverse stock split sufficient to achieve a closing bid price of at least $1.00 on or before August 18, 2026, (ii) effect the reverse stock split and achieve a closing bid price at or above $1.00 on or before August 31, 2026, and (iii) maintain a closing bid price at or above $1.00 for each trading day until November 9, 2026. On August 18, 2026, the Company held its annual meeting of stockholders, at which the stockholders approved a proposal to allow the Company to implement a reverse stock split. There can be no assurance that we will satisfy the remaining conditions or maintain compliance with applicable Nasdaq listing requirements. See the section entitled "*Risk Factors – Our failure to maintain compliance with Nasdaq's continued listing requirements could result in the delisting of our Common Stock*" for more information

Financings

Bridge Financing

In connection with the Business Combination, the Company entered into a securities purchase agreement, dated July 14, 2026, as supplemented by a joinder dated August 4, 2026 (the "Purchase Agreement"), with certain investors (the "Bridge Investors"), pursuant to which the Company agreed to issue senior secured convertible promissory notes (including the follow-on bridge notes issued on August 4, 2026, the "Bridge Notes") for aggregate gross proceeds of approximately $7.95 million and common stock purchase warrants (including the follow-on bridge warrants issued on August 4, 2026, the "Bridge Warrants" and, together with the Bridge Notes, the "Bridge Securities") (such transactions, the "Bridge Financing").

The Notes include an original issue discount of 22%, bear interest at a rate of 8% per annum, and mature nine (9) months from the date of issuance. The Notes are convertible, following stockholder approval, at a conversion price equal to the lower of (i) the Nasdaq Minimum Price (as defined in the Purchase Agreement) and (ii) 80% of the lowest daily volume weighted average price of the Common Stock during the fifteen (15) trading days immediately preceding the conversion notice, subject to a floor price equal to 20% of the Nasdaq Minimum Price as of the date of issuance of the Notes.

The Bridge Warrants provide 125% coverage of the principal amount of the Notes, are exercisable for a period of five (5) years from the date of issuance, and have an exercise price per share equal to $35,000,000 divided by the total number of outstanding shares of Common Stock as of the applicable date of exercise.

The Company will not issue Bridge Shares in excess of 19.99% of the shares of Common Stock outstanding as of the date of the Purchase Agreement pursuant to the Bridge Financing Documents unless the Company obtains stockholder approval in accordance with Nasdaq Listing Rule 5635(d) (the "Bridge Exchange Cap"). The Company obtained the Bridge Stockholder Approval at the special meeting of the Company's stockholders held on September 11, 2026 (the "Special Meeting").

ELOC Purchase Agreement

On July 14, 2026, the Company entered into a Common Stock Purchase Agreement (as amended by Amendment No. 1, dated August 7, 2026, the "ELOC Purchase Agreement") with White Lion Capital, LLC (the "ELOC Investor"), pursuant to which the Company has the right, but not the obligation, to require the ELOC Investor to purchase, from time to time over a three-year period, up to $50,000,000 of shares of Common Stock (the "Purchase Shares"), subject to certain limitations and conditions set forth in the ELOC Purchase Agreement. The Company also agreed to issue to the ELOC Investor 167,035 shares of Common Stock as a commitment fee (the "Commitment Shares") and a commitment warrant (the "Commitment Warrant") to purchase shares of Common Stock with an aggregate value of up to $10,000,000.

Under the ELOC Purchase Agreement, after the effectiveness of a registration statement registering the resale of shares that may be issued to the ELOC Investor, the Company may, at its discretion, direct the ELOC Investor to purchase shares of Common Stock by delivering a purchase notice. The ELOC Purchase Agreement provides for two types of purchase notices: (i) Rapid Purchase Notices, in which the purchase price is the lowest traded price of the Common Stock on the date of the notice (the "Rapid Purchase Notice Date"), with the number of shares that may be purchased limited to ten percent (10%) of the trading volume of the Common Stock on the Rapid Purchase Notice Date, with closing to occur no later than one (1) business day following the Rapid Purchase Notice Date; and (ii) VWAP Purchase Notices, in which the purchase price is ninety-seven percent (97%) of the lowest daily volume weighted average price of the Common Stock during the three (3) consecutive business days commencing on and including the date of the notice (the "VWAP Purchase Valuation Period"), with the number of shares that may be purchased limited to sixty percent (60%) of the average daily trading volume of the Common Stock over the five (5) business days immediately preceding receipt of the notice, with closing to occur no later than one (1) business day following the VWAP Purchase Valuation Period.

The Company may not require the ELOC Investor to purchase shares if such purchase would result in the ELOC Investor beneficially owning more than 4.99% of the outstanding shares of Common Stock (the "Beneficial Ownership Limitation"), which may be increased to 9.99% upon mutual written agreement. Prior to the Special Meeting, the Company could not issue more than 19.99% of the shares of Common Stock outstanding as of the date of the ELOC Purchase Agreement (the "ELOC Exchange Cap") under the ELOC Purchase Agreement and the Commitment Warrant (as defined below), unless (i) the Company obtained stockholder approval in accordance with Nasdaq Listing Rule 5635(d) (the "ELOC Stockholder Approval" and together with the Merger Stockholder Approval and the Bridge Stockholder Approval, the "Stockholder Approvals"), (ii) the average price paid for all shares of Common Stock issued under the ELOC Purchase Agreement and the Commitment Warrant equaled or exceeded $5.9868 (the "Minimum Price"), which is a price equal to the lower of (A) the Nasdaq Official Closing Price of the Common Stock immediately preceding the execution of the ELOC Purchase Agreement, or (B) the arithmetic average of the five (5) Nasdaq Official Closing Prices for the Common Stock immediately preceding the execution of the ELOC Purchase Agreement (such that, for purposes of Nasdaq, the transaction would not be "below market" and the ELOC Exchange Cap would not apply), or (iii) the Company was exempt from obtaining ELOC Stockholder Approval for the issuance of shares of Common Stock above the ELOC Exchange Cap under the rules of Nasdaq. The Company obtained the requisite stockholder approval at the Special Meeting and, accordingly, is no longer subject to the ELOC Exchange Cap.

Interim PIPE

On August 4, 2026, the Company entered into a Securities Purchase Agreement (the "Interim PIPE SPA") with an investor (the "PIPE Purchaser") for a private placement of securities (the "Interim PIPE"). At the closing, the Company issued 177,778 pre-funded warrants (the "Pre-Funded Warrants") to purchase 177,778 shares of Common Stock (the "Pre-Funded Warrant Shares"), at a purchase price of $11.25 per warrant less the exercise price per Pre-Funded Warrant of $0.0001 per share, and Common Stock purchase warrants (the "PIPE Common Warrants" and, together with the Pre-Funded Warrants, the "PIPE Warrants") to purchase 177,778 shares (the "PIPE Warrant Shares") of Common Stock, at an exercise price of $22.50 per PIPE Warrant Share, for aggregate gross proceeds to the Company of $2,000,000.

The Pre-Funded Warrants are exercisable at any time after their original issuance and will not expire until exercised in full. The PIPE Common Warrants are exercisable immediately upon issuance and have a term of exercise of five (5) years, and are subject to a floor price equal to 20% of the closing price of the Common Stock on the date of issuance of the PIPE Common Warrant.

The exercise of the PIPE Warrants is subject to a beneficial ownership limitation of 4.99% (or, at the election of the PIPE Purchaser, 9.99%) of the outstanding Common Stock. On September 14, 2026, the PIPE Warrants were amended to provide that the holder shall not be entitled to exercise a PIPE Warrant, in whole or in part, and the Company shall not effect any exercise of a PIPE Warrant or issue any shares pursuant thereto, unless and until the Company has obtained the approval of its stockholders for the issuance of all shares issuable pursuant to the PIPE Warrants in accordance with Nasdaq Listing Rule 5635(d) and any other applicable rules of Nasdaq. The Interim PIPE SPA contains customary representations, warranties and covenants of the Company and the PIPE Purchaser and customary indemnification provisions in favor of the PIPE Purchaser.

September PIPE

On September 10, 2026, the Company entered into a securities purchase agreement (the "September Purchase Agreement") with certain investors (the "September Investors"), pursuant to which the Company issued senior secured convertible promissory notes (the "September Notes") in the aggregate principal amount of $11,596,172.68, in exchange for (i) aggregate cash consideration of $4,500,000 and (ii) the surrender and exchange of $4,545,014.69 in aggregate principal amount of certain outstanding senior secured convertible promissory notes held by certain September Investors, reflecting an aggregate purchase price of $9,045,014.69 and a 22% original issue discount. The September Notes bear interest at the rate of 8% per annum on the outstanding principal amount and mature nine (9) months from September 10, 2026. The September Notes are secured by a security interest in substantially all of the assets of the Company and its subsidiaries pursuant to the Company's existing Security Agreement (defined below), and share in the collateral on an equal and ratable basis with the Company's other outstanding obligations secured thereunder.

The September Notes are convertible, in whole or in part, at any time on or after the issuance date, at a conversion price equal to the lower of (i) $3.12, representing the Nasdaq Minimum Price (as defined in the September Notes) and (ii) 80% of the lowest daily volume weighted average price of the common stock, par value $0.001 per share, of the Company (the "Common Stock") during the fifteen (15) trading days immediately preceding the applicable conversion notice, subject in each case to a floor price equal to 20% of the Nasdaq Minimum Price (the "September Conversion Price"). The shares of Common Stock issuable upon conversion of the September Notes are the "September Note Conversion Shares." The total cumulative number of September Note Conversion Shares may not exceed 19.99% of the Common Stock outstanding immediately prior to the execution of the September Purchase Agreement (the "Exchange Cap"), unless and until the Company obtains stockholder approval of the issuance of the underlying Common Stock in accordance with Nasdaq Listing Rule 5635(d) (the "September Financing Stockholder Approval"). If the volume weighted average price of the Common Stock is less than the Floor Price (as defined in the September Purchase Agreement, the "September Floor Price") then in effect on each of any ten (10) consecutive trading days, the Floor Price shall, subject to the Company's receipt of the September Financing Stockholder Approval, automatically reset to, and thereafter equal, the lowest volume weighted average price during such ten (10) trading day period. The September Conversion Price and September Floor Price are subject to adjustment for stock splits, stock combinations, stock dividends, reclassifications, dilutive issuances, share combination events, and reorganization or change of control transactions.

The sale of the September Notes and September Warrants (as described below) is referred to herein as the "September PIPE Financing." The September PIPE Financing closed on September 10, 2026 (the "Closing"), resulting in gross proceeds to the Company of $4,500,000, before deducting the Placement Agent's fees and other offering expenses.

On September 10, 2026, the Company also issued to the September Investors Common Stock purchase warrants (the "September Warrants" and, together with the September Notes, the "September PIPE Securities") to purchase 4,831,739 shares of Common Stock (the "September Warrant Shares" and, together with the September Note Conversion Shares, the "September PIPE Shares"), representing a number of shares equal to 125% of each September Investor's principal amount under its September Note divided by $3.00. The September Warrants are exercisable for a period of five (5) years from the date of issuance at an exercise price of $7.50 per share; provided that, in each case, the shares of Common Stock issuable upon exercise of the September Warrants are subject to the September Exchange Cap and may not be issued in excess thereof unless and until the Company obtains the September Financing Stockholder Approval. The exercise price and the number of shares of Common Stock issuable upon exercise of the September Warrants is subject to appropriate adjustments in the event of certain stock dividends and distributions, stock splits, stock combinations, reclassifications or similar events affecting the Common Stock.

Risks of Investing

Investing in our securities involves substantial risks. Potential investors are urged to read and consider the risk factors relating to an investment in our securities set forth under "*Risk Factors*" in this prospectus supplement as well as other information we include in or incorporated by reference into this prospectus supplement.

Implications of Being a Smaller Reporting Company

We are a "smaller reporting company," meaning that the market value of our stock held by non-affiliates is less than $700 million as of our most recently completed second fiscal quarter and our annual revenue was less than $100 million during our most recently completed fiscal year. We may continue to be a smaller reporting company if either (i) the market value of our stock held by non-affiliates is less than $250 million or (ii) our annual revenue was less than $100 million during the most recently completed fiscal year and the market value of our stock held by non-affiliates is less than $700 million as of our most recently completed second fiscal quarter. As a smaller reporting company, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not smaller reporting companies.

Corporate Information

Our principal offices are located at 301 Rte. 17 North, Suite 800, Rutherford NJ 07070, and our telephone number is 201-842-7715. Our website address is https://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 prospectus supplement. Our Common Stock is traded on the Nasdaq Capital Market under the symbol "GCTK."

THE OFFERING

The following summary contains basic information about this offering. The summary is not intended to be complete. You should read the full text and more specific details contained elsewhere in this prospectus supplement and the accompanying prospectus. Unless otherwise indicated, all information contained in this prospectus supplement reflects the Reverse Stock Split.

Issuer	Glucotrack, Inc., a Delaware corporation
Common Stock offered by us	169,388 shares of Common Stock.
Pre-Funded Warrants Offered by Us	Pre-Funded Warrants to purchase an aggregate of 1,350,220 Common Shares. The purchase price of each Pre-Funded Warrant will be equal to the price per Common Share, minus $0.001. Each Pre-Funded Warrant will have an exercise price of $0.001 per share, will be exercisable commencing on the date of issuance and will expire when it is exercised in full. The exercise price of the Pre-Funded Warrants and the number of shares into which the Pre-Funded Warrants may be exercised are subject to adjustment in certain circumstances. See "*Description of Securities*." This prospectus supplement also relates to the registration of the Common Shares issuable upon exercise of such Pre-Funded Warrants.
Common Stock outstanding after this offering	2,368,237 shares of Common Stock, assuming the full exercise of the Pre-Funded Warrants.
Use of proceeds	We estimate that the net proceeds to us from this offering, after deducting the estimated placement agent fees and estimated offering expenses payable by us, will be approximately $2.85 million. We currently intend to use the net proceeds from this offering to pay off existing debt, with the remainder to be used for general corporate and working capital purposes. See "*Use of Proceeds*" on page S-44 of this prospectus supplement.
Nasdaq Capital Market symbol	"GCTK".
Risk factors:	Investing in our Common Stock involves significant risks. See "*Risk Factors*" on page S-12 of this prospectus supplement and under similar headings in the documents incorporated by reference into this prospectus supplement and the accompanying prospectus for a discussion of the factors you should carefully consider before deciding to invest in our Common Stock.
Transfer agent and registrar	VStock Transfer, LLC

(1) The number of shares of our Common Stock to be outstanding immediately after this offering is based on 848,629 shares of Common Stock outstanding as of September 23, 2026, which excludes:

- 1,100 shares of Common Stock issuable upon the exercise of options outstanding at a weighted average exercise price of $866.25 per share;
- 146,554 shares of Common Stock issuable upon exercise of warrants;
- 6,503 shares of Common Stock issuable under the Glucotrack, Inc. 2024 Equity Incentive Plan (as amended, the "Plan").
- 4,631,200 shares of Common Stock issuable upon conversion of 46,312 shares of Preferred Stock (such conversion subject to stockholder and Nasdaq approval);
- All shares of Common Stock issuable upon conversion of the Bridge Notes and exercise of the Bridge Warrants (such issuances subject to stockholder approval);
- All shares of Common Stock issuable upon exercise of the Commitment Warrant; and
- 355,556 shares of Common Stock issuable upon exercise of the PIPE Warrants.

All references to shares of Common Stock and per share numbers give effect to the Reverse Stock Split. Unless otherwise indicated, all information in this prospectus supplement assumes (i) no exercise of the outstanding options or warrants described above, (ii) no conversion of the convertible notes or preferred stock described above, and (iii) no additional issuances under the Plan.

RISK FACTORS

Investing in our Common Stock involves a high degree of risk. Before making an investment decision, you should carefully consider the risks described below and in our most recent Annual Report on Form 10-K and subsequent Quarterly Reports on Form 10-Q or Current Reports on Form 8-K, as well as any amendments thereto reflected in subsequent filings, each of which are incorporated by reference in this prospectus supplement and the accompanying prospectus, and all of the other information in this prospectus supplement and the accompanying prospectus, including our financial statements and related notes incorporated by reference in this prospectus supplement and the accompanying prospectus. If any of these risks are realized, our business, financial condition, results of operations and prospects could be materially and adversely affected. In that event, the trading price of our Common Stock could decline, and you could lose part or all of your investment. Additional risks and uncertainties that are not yet identified or that we think are immaterial may also materially harm our business, operating results and financial condition and could result in a complete loss of your investment.

Risks Related to our Securities and this Offering

Purchasers in this offering will experience immediate and substantial dilution in the book value of their investment.

The price per share of our Common Stock being offered may be higher than the net tangible book value per share of our outstanding Common Stock prior to this offering. Based on an offering price of $2.04 per share, we estimate our as adjusted net tangible book value per share of Common Stock after this offering will be $(14.48). As a result, purchasers of Common Stock in this offering will experience an immediate decrease of $16.52 per share in net tangible book value of our Common Stock. For a more detailed discussion of the foregoing, see "*Dilution*" in this prospectus supplement. To the extent outstanding preferred stock, stock options, warrants, or RSUs, are converted, exercised or vested, as applicable, there will be further dilution to new investors. New investors may be further diluted in the event Common Stock is issued pursuant to the Plan. In addition, to the extent we need to raise additional capital in the future and we issue additional shares of Common Stock or securities convertible or exchangeable for our Common Stock, our then existing stockholders may experience dilution and the new securities may have rights senior to those of our Common Stock offered in this offering.

There is no public market for the Pre-Funded Warrants being offered in this offering.

There is no established public trading market for the Pre-Funded Warrants, and we do not expect a market to develop. We do not intend to apply for listing of the Pre-Funded Warrants on Nasdaq or any other securities exchange or nationally recognized trading system. Without an active trading market, the liquidity of the Pre-Funded Warrants will be limited.

Holders of the Pre-Funded Warrants will not be entitled to the rights of holders of our Common Stock until they exercise their Pre-Funded Warrants.

Until holders of the Pre-Funded Warrants acquire shares of our Common Stock upon exercise of the Pre-Funded Warrants, they will have no rights with respect to the shares of Common Stock underlying the Pre-Funded Warrants, except as provided in the Pre-Funded Warrants. Upon exercise, holders will be entitled to exercise the rights of holders of Common Stock only as to matters for which the record date occurs after the exercise date.

We will have broad discretion in how we use the net proceeds of this offering, if any. We may not use these proceeds effectively, which could affect our results of operations and cause our stock price to decline.

Although we currently intend to use the net proceeds from this offering, if any, in the manner described in the section entitled "*Use of Proceeds*" in this prospectus supplement, we will have considerable discretion in the application of the net proceeds of this offering. We may use the net proceeds for purposes that do not yield a significant return or any return at all for our stockholders. In addition, pending their use, we may invest the net proceeds from this offering in a manner that does not produce income or that loses value. If we do not invest or apply the net proceeds from this offering in ways that enhance stockholder value, we may fail to achieve expected financial results, which could cause our stock price to decline.

Risks Relating to our Common Stock and the Securities Market

If the price of our Common Stock fluctuates significantly, your investment could lose value.

Although our Common Stock is listed on the Nasdaq Capital Market, we cannot assure you that an active public market will continue for our Common Stock. If an active public market for our Common Stock does not continue, the trading price and liquidity of our Common Stock will be materially and adversely affected. If there is a thin trading market or "float" for our stock, the market price for our Common Stock may fluctuate significantly more than the stock market as a whole. Without a large float, our Common Stock would be less liquid than the stock of companies with broader public ownership and, as a result, the trading prices of our Common Stock may be more volatile. In addition, in the absence of an active public trading market, investors may be unable to liquidate their investment in us.

Furthermore, the stock market is subject to significant price and volume fluctuations, and the price of our Common Stock could fluctuate widely in response to several factors, including:

- our quarterly or annual operating results;
- changes in our earnings estimates;
- investment recommendations by securities analysts following our business or our industry;
- additions or departures of key personnel;
- success of competitors;
- changes in the business, earnings estimates or market perceptions of our competitors;
- our failure to achieve operating results consistent with securities analysts' projections;
- changes in industry, general market or economic conditions; and
- announcements of legislative or regulatory changes.

Broad market and industry factors may materially harm the market price of our securities irrespective of our operating performance. The stock market in general, and Nasdaq in particular, has experienced price and volume fluctuations that have significantly affected the quoted prices of the securities of many companies, including companies in our industry and have often been unrelated or disproportionate to the operating performance of the particular companies affected. The trading prices and valuations of these stocks, and of our Common Stock, may not be predictable, and the price of our Common Stock could fluctuate based upon factors that have little or nothing to do with our company and these fluctuations could materially reduce our stock price.

A loss of investor confidence in the market for our Common Stock or the stocks of other companies which investors perceive to be similar to us could depress our stock price regardless of our business, prospects, financial condition or results of operations. A decline in the market price of our Common Stock also could adversely affect our ability to issue additional securities and our ability to obtain additional financing in the future.

If shares of our Common Stock become subject to the penny stock rules, it may be more difficult to sell such shares.

The SEC has adopted rules that regulate broker-dealer practices in connection with transactions in penny stocks. Penny stocks are generally equity securities with a price of less than $5.00 (other than securities registered on certain national securities exchanges or authorized for quotation on certain automated quotation systems, provided that current price and volume information with respect to transactions in such securities is provided by the exchange or system). The OTC Bulletin Board does not meet such requirements and if the price of shares of our Common Stock is less than $5.00 and such shares are no longer listed on a national securities exchange such as the Nasdaq, shares of our Common Stock may be deemed a penny stock. The penny stock rules require a broker-dealer, at least two business days prior to a transaction in a penny stock not otherwise exempt from those rules, to deliver to the customer a standardized risk disclosure document containing specified information and to obtain from the customer a signed and dated acknowledgment of receipt of such document. In addition, the penny stock rules require that prior to effecting any transaction in a penny stock not otherwise exempt from those rules, a broker-dealer must make a special written determination that the penny stock is a suitable investment for the purchaser and receive: (i) the purchaser's written acknowledgment of the receipt of a risk disclosure statement; (ii) a written agreement to transactions involving penny stocks; and (iii) a signed and dated copy of a written suitability statement. These disclosure requirements may have the effect of reducing the trading activity in the secondary market for shares of our Common Stock, and therefore, our stockholders may have difficulty selling their shares.

We will need to raise substantial additional capital in the future to fund our operations. To raise additional capital, we may in the future offer additional shares of our Common Stock or other securities convertible into or exchangeable for our Common Stock at prices that may not be the same as the price per share in this offering. We may sell shares or other securities in any other offering at a price per share that is less than the price per share paid by investors in this offering, and investors purchasing shares or other securities in the future could have rights superior to existing stockholders. The price per share at which we sell additional shares of our Common Stock, or securities convertible or exchangeable into Common Stock, in future transactions may be higher or lower than the price per share paid by investors in this offering. Further, the exercise of outstanding stock options and warrants may result in further dilution of your investment.

Our reverse stock splits may decrease the liquidity of the shares of our Common Stock.

Effective May 17, 2024, February 3, 2025, June 13, 2025, and August 28, 2026, we effected reverse stock splits of our Common Stock at ratios of 1-for-5, 1-for-20, 1-for-60, and 1-for-15, respectively, to regain compliance with the Bid Price Rule. The liquidity of the shares of our Common Stock may be affected adversely by these reverse stock splits given the reduced number of shares that are outstanding following such reverse stock splits. In addition, these reverse stock splits increased the number of stockholders who own odd lots (less than 100 shares) of our Common Stock, creating the potential for such stockholders to experience an increase in the cost of selling their shares and greater difficulty effecting such sales.

We may also effect additional reverse stock splits in the future in order to maintain compliance with applicable Nasdaq listing requirements or for other corporate purposes. Any such additional reverse stock splits could further reduce the number of outstanding shares of our Common Stock and exacerbate the adverse effects on liquidity described above.

Following a reverse stock split, the resulting market price of our Common Stock may not attract new investors, including institutional investors, and may not satisfy the investing requirements of those investors. Consequently, the trading liquidity of our Common Stock may not improve.

Although we believe that a higher market price of our Common Stock may help generate greater or broader investor interest, there can be no assurance that a reverse stock split, including our reverse stock splits, will result in a share price that will attract new investors, including institutional investors. In addition, there can be no assurance that the market price of our Common Stock will satisfy the investing requirements of those investors. As a result, the trading liquidity of our Common Stock may not necessarily improve.

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 June 30, 2026, we had an accumulated deficit of $159 million. These conditions raise substantial doubt about the Company's ability to continue as a going concern.

If securities or industry analysts do not publish research or reports, or if they publish negative, adverse, or misleading research or reports, regarding us, our business or our market, our Common Stock price and trading volume could decline.

The trading market for our Common Stock is influenced by the research and reports that securities or industry analysts publish about us, our business, or our market. We do not currently have a significant number of firms providing research coverage on the Company and may never obtain significant research coverage by securities or industry analysts. If no or few securities or industry analysts provide coverage of us, our Common Stock price could be negatively impacted. In the event we obtain significant securities or industry analyst coverage and such coverage is negative, or adverse or misleading regarding us, our business model, our intellectual property, our stock performance or our market, or if our operating results fail to meet the expectations of analysts, our Common Stock price would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our Common Stock price or trading volume to decline.

Our charter documents, Delaware law, and our commercial contracts may contain provisions that may discourage an acquisition of us by others and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our charter documents, as well as provisions of the Delaware General Corporation Law ("DGCL"), could have an impact on the trading price of our Common Stock by making it more difficult for a third party to acquire us at a price favorable to our stockholders. For example, our charter documents do not provide for the use of cumulative voting for the election of directors; authorize the issuance of "blank check" preferred stock, the terms of which may be established and shares of which may be issued by our Board without stockholder approval to defend against a takeover attempt; and establish advance notice requirements for nominations for election to our Board or for proposing matters that can be acted upon at stockholder meetings.

In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our Board or current management. We are subject to Section 203 of the DGCL, which generally prohibits a Delaware corporation from engaging in any of a broad range of business combinations with an interested stockholder for a period of three years following the date on which the stockholder became an interested stockholder, unless such transactions are approved by our Board. This provision could have the effect of delaying or preventing a change of control, whether or not it is desired by or beneficial to our stockholders, which could also affect the price that some investors are willing to pay for our Common Stock.

Finally, commercial contracts that we enter into with our vendors and customers in the course of our business operations may contain provisions with respect to changes in control that could provide for termination rights or otherwise have a negative impact on our business or results of operations if a stockholder were to acquire a significant percentage of our outstanding stock.

The issuance of additional stock in connection with acquisitions or otherwise will dilute all other stockholdings.

We are not restricted from issuing additional shares of our Common Stock, or from issuing securities that are convertible into or exchangeable for, or that represent the right to receive, Common Stock. As of the date of this prospectus supplement, we had an aggregate of 250.0 million shares of Common Stock authorized and of that approximately 121.5 million shares are not issued or outstanding. We may issue all of these shares without any action or approval by our stockholders. We may expand our business through complementary or strategic business combinations or acquisitions of other companies and assets, and we may issue shares of Common Stock in connection with those transactions. The market price of our Common Stock could decline as a result of our issuance of a large number of shares of Common Stock, particularly if the per share consideration we receive for the stock we issue is less than the per share book value of our Common Stock or if we are not expected to be able to generate earnings with the proceeds of the issuance that are as great as the earnings per share we are generating before we issue the additional shares. In addition, any shares issued in connection with these activities, the exercise of warrants or stock options or otherwise would dilute the percentage ownership held by our investors. As disclosed in our other filings with the SEC, we have certain outstanding securities that contain price reset provisions and anti-dilution mechanisms. The operation of these provisions may result in further dilution to our stockholders in connection with future issuances of our Common Stock or securities convertible into or exercisable for shares of our Common Stock. We cannot predict the size of future issuances or the effect, if any, that they may have on the market price of our Common Stock.

We have a history of losses, may not be able to achieve profitability going forward, and may not be able to raise additional capital necessary to continue as a going concern.

We have experienced losses since our inception on May 18, 2010 and, at June 30, 2026, had an accumulated deficit of approximately $159 million. We may incur additional losses in the future.

As of June 30, 2026, we had cash and cash equivalents of approximately $1.12 million. There are no assurances that we will be able to raise additional capital or do so on terms favorable to us. Our recurring losses from operations and projected future cash flow requirements raise substantial doubt about our ability to continue as a going concern without sufficient capital resources and we have included explanatory information in the notes to our financial statements for the year ended December 31, 2025, with respect to this uncertainty, and the report of our independent registered public accounting firm dated March 30, 2026 with respect to our audited financial statements for the year ended December 31, 2025 included an emphasis of matter for this as well. Our consolidated financial statements do not include any adjustments that might result from the outcome of this going concern uncertainty and have been prepared under the assumption that we will continue to operate as a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business.

Our ability to continue as a going concern is dependent on our available cash, how well we manage that cash, and our operating requirements. If we are unable to raise additional capital when needed, we could be forced to curtail operations or take other actions such as, implementing additional restructuring and cost reductions, disposing of one or more product lines and/or, selling or licensing intellectual property. If we are unable to continue as a going concern, we may be forced to liquidate our assets, which would have an adverse impact on our business and developmental activities. In such a scenario, the values we receive for our assets in liquidation or dissolution could be significantly lower than the values reflected in our financial statements.

Our failure to maintain compliance with Nasdaq's continued listing requirements could result in the delisting of our Common Stock.

Our Common Stock is currently listed for trading on the Nasdaq Capital Market. We must satisfy the continued listing requirements of Nasdaq, to maintain the listing of our Common Stock on the Nasdaq Capital Market.

On May 11, 2026, we received the Staff Determination letter from the Listing Qualifications Department of Nasdaq notifying us that Nasdaq Staff has determined to delist our Common Stock from the Nasdaq Capital Market.

The Staff Determination stated that the bid price of the Common Stock had closed at less than $1.00 per share over the previous 30 consecutive business days, from March 27, 2026 through May 8, 2026, and that, as a result, we are not in compliance with the Bid Price Rule.

The Staff Determination further stated that, although companies are typically afforded a 180-calendar day period to regain compliance with the Bid Price Rule, the Company is not eligible for any such compliance period pursuant to Nasdaq Listing Rule 5810(c)(3)(A)(iv). Nasdaq Staff cited the fact that we have effected a reverse stock split over the prior one-year period and have effected one or more reverse stock splits over the prior two-year period with a cumulative ratio of 250 shares or more to one.

On May 15, 2026, we received a second letter from Nasdaq notifying us that our Form 10-Q for the period ended March 31, 2026, indicates that we no longer meet the $2,500,000 minimum stockholders' equity requirement for continued listing set forth under Listing Rule 5550(b)(1) (the "Equity Rule"), and we do not meet the alternatives of market value of listed securities or net income from continuing operations. Accordingly, the failure to comply with the Equity Rule became an additional basis for delisting. The Nasdaq Staff further notified us that failure to meet the Equity Rule would be considered in its decision regarding our continued listing on the Nasdaq Capital Market. We presented our views with respect to this additional deficiency to the Panel at the hearing on June 18, 2026.

On August 14, 2026, the Panel determined that we had regained compliance with the Equity Rule and granted our request for continued listing on Nasdaq, subject to certain conditions, including that we (i) hold our annual meeting and obtain stockholder approval of a reverse stock split sufficient to achieve a closing bid price of at least $1.00 on or before August 18, 2026, (ii) effect the reverse stock split and achieve a closing bid price at or above $1.00 on or before August 31, 2026, and (iii) maintain a closing bid price at or above $1.00 for each trading day until November 9, 2026. On August 18, 2026, we held our annual meeting of stockholders, at which the stockholders approved a proposal to allow us to implement a reverse stock split. On August 28, 2026, we implemented the Reverse Stock Split. The Panel also stated that if we become non-compliant with any other Listing Rule during the term of the exception, we will be allowed seven (7) calendar days to advise the Panel on our plan to cure the listing deficiency, and the Panel will determine at that time whether to grant an exception to cure the deficiency or delist our Common Stock. There can be no assurance that we will satisfy the remaining conditions or maintain compliance with the Bid Price Rule or any other applicable Nasdaq listing requirements.

In addition to the foregoing requirements, Nasdaq has recently proposed a new listing requirement that would require each Nasdaq listed issuer to maintain a minimum market value of listed securities of at least $5 million. Under this proposal, if the value of an issuer's listed securities, as measured by each applicable trading day's closing price, continues to be less than $5 million for a period of 30 consecutive trading days, the issuer's securities would immediately be delisted, with no compliance or cure period. The proposed rule would also preclude an issuer's ability to seek stay of delisting during any appeals process, and would preclude Nasdaq hearings panels from reversing the delisting determination to situations where there was an error and the company never actually failed to satisfy the requirement. The panel would also not be able to consider any facts indicating that issuer subsequently regained compliance with the requirement or grant an issuer any additional time to regain compliance. The proposed rule is subject to review and approval by the SEC, and it is unknown whether the SEC will approve the proposal. If approved by the SEC, the rule could become effective on an imminent basis. Our Common Stock currently trades at levels that are below the $5 million aggregate market value threshold proposed by Nasdaq. As such, if this proposal is approved by the SEC, our Common Stock could be imminently delisted by Nasdaq on this basis.

We may be required to monitor our market value of listed securities closely and, if necessary, take actions such as issuing additional securities, raising additional capital or undertaking other corporate actions to seek to maintain compliance, any of which could dilute our existing shareholders, increase our costs, or divert management's attention. The risk of a rapid loss of Nasdaq listing, or an actual delisting, could adversely affect investor confidence, the liquidity and trading price of our Common Stock, and our ability to access the capital markets, and could have a material adverse effect on our business, financial condition and results of operations.

If our Common Stock were delisted from the Nasdaq Capital Market, trading of our Common Stock would most likely take place on an over-the-counter market established for unlisted securities, such as the OTCQB or the Pink Market maintained by OTC Markets Group Inc. An investor would likely find it less convenient to sell, or to obtain accurate quotations in seeking to buy, our Common Stock on an over-the-counter market, and many investors would likely not buy or sell our Common Stock due to difficulty in accessing over-the-counter markets, policies preventing them from trading in securities not listed on a national exchange or other reasons. In addition, as a delisted security, our Common Stock would be subject to SEC rules as a "penny stock," which impose additional disclosure requirements on broker-dealers. The regulations relating to penny stocks, coupled with the typically higher cost per trade to the investor of penny stocks due to factors such as broker commissions generally representing a higher percentage of the price of a penny stock than of a higher-priced stock, would further limit the ability of investors to trade in our Common Stock. In addition, delisting would materially and adversely affect our ability to raise capital on terms acceptable to us, or at all, and may result in the potential loss of confidence by investors, suppliers, customers and employees and fewer business development opportunities. For these reasons and others, delisting would adversely affect the liquidity, trading volume and price of our Common Stock, causing the value of an investment in us to decrease and having an adverse effect on our business, financial condition and results of operations, including our ability to attract and retain qualified employees and to raise capital.

We may be subject to claims arising from contractual restrictions in our financing agreements.

As disclosed in our other filings with the SEC, we are subject to certain variable rate transaction restrictions contained in agreements with certain investors. If we have failed to comply with such restrictions, we may be subject to claims by such investors, which could result in litigation and associated legal costs, damages, settlements, or other adverse consequences that could have a material adverse effect on our business, financial condition, and results of operations. We could be required to pay significant amounts of cash, including placement agent fees, legal expenses, and other amounts, and could be required to issue a significant number of shares of Common Stock or warrants to purchase shares of Common Stock. Any such payments or issuances could be material to our business and could result in significant dilution to our stockholders.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus supplement, the accompanying prospectus, and the documents incorporated by reference herein contain forward-looking statements that reflect our current expectations and views of future events. The forward-looking statements are contained principally in the sections included or incorporated by reference herein entitled "*Risk Factors*" and "*Management's Discussion and Analysis of Financial Condition and Results of Operations*." Readers are cautioned that known and unknown risks, uncertainties and other factors, including those over which we may have no control and others listed in the "*Risk Factors*" section of this prospectus supplement, may cause our actual results, performance or achievements to be materially different from those expressed or implied by the forward-looking statements.

These forward-looking statements involve numerous risks and uncertainties. Although we believe that our expectations expressed in these forward-looking statements are reasonable, our expectations may later be found to be incorrect. Our actual results of operations or the results of other matters that we anticipate could be materially different from our expectations. Important risks and factors that could cause our actual results to be materially different from our expectations are generally set forth in "*Risk Factors*," "*Management's Discussion and Analysis of Financial Condition and Results of Operations*," "*Business*," and other sections included or incorporated by reference in this prospectus supplement. You should thoroughly read this prospectus supplement and the documents incorporated herein by reference with the understanding that our actual future results may be materially different from and worse than what we expect. We qualify all of our forward-looking statements by these cautionary statements.

The forward-looking statements made in this prospectus supplement relate only to events or information as of the date on which the statements are made in or incorporated by reference in this prospectus supplement. Except as required by law, we undertake no obligation to update or revise publicly any forward-looking statements, whether as a result of new information, future events or otherwise, after the date on which the statements are made or to reflect the occurrence of unanticipated events. You should read this prospectus supplement, the documents incorporated by reference into this prospectus supplement and the documents we have filed as exhibits to the registration statement, of which this prospectus supplement forms a part, completely and with the understanding that our actual future results may be materially different from what we expect.

If information in this prospectus supplement is inconsistent with the accompanying prospectus or with any document incorporated by reference that was filed with the SEC before the date of this prospectus supplement, you should rely on this prospectus supplement. This prospectus supplement, the accompanying prospectus and the documents incorporated into each by reference include important information about us, the securities being offered and other information you should know before investing in our securities. You should also read and consider information in the documents we have referred you to in the sections of this prospectus supplement entitled "*Where You Can Find More Information*" and "*Incorporation by Reference*."

You should rely only on this prospectus supplement, the accompanying prospectus, the documents incorporated or deemed to be incorporated by reference herein or therein and any free writing prospectus prepared by us or on our behalf. We have not, and Dawson James has not, authorized anyone to provide you with information that is in addition to or different from that contained or incorporated by reference in this prospectus supplement and the accompanying prospectus. If anyone provides you with different or inconsistent information, you should not rely on it. We and Dawson James are not offering to sell these securities in any jurisdiction where the offer or sale is not permitted. You should not assume that the information contained in this prospectus supplement, the accompanying prospectus or any free writing prospectus, or incorporated by reference herein, is accurate as of any date other than as of the date of this prospectus supplement or the accompanying prospectus or any free writing prospectus, as the case may be, or in the case of the documents incorporated by reference, the date of such documents regardless of the time of delivery of this prospectus supplement and the accompanying prospectus or any sale of our securities. Our business, financial condition, liquidity, results of operations and prospects may have changed since those dates.

We further note that the representations, warranties and covenants made by us in any agreement that is filed as an exhibit to any document that is incorporated by reference in this prospectus supplement or the accompanying prospectus were made solely for the benefit of the parties to such agreement, including, in some cases, for the purpose of allocating risk among the parties to such agreements. Moreover, such representations, warranties or covenants were accurate only as of the date when made. Accordingly, such representations, warranties and covenants should not be relied on as accurately representing the current state of our affairs.

BUSINESS OF THE COMBINED COMPANY

General

The following section describes the business of the Company following the Closing of the Business Combination Transactions. Following the Closing, the Company operates as a holding company with two wholly owned operating subsidiaries: Lokahi Therapeutics, Inc. ("Lokahi"), a Nevada corporation focused on the clinical development of Apitox, a product candidate for the treatment of pain, and Glucotrack Technologies Inc. ("Glucotrack Technologies"), a Nevada corporation focused on the design, development, and commercialization of novel technologies for people with diabetes, including the development of the Glucotrack Continuous Blood Glucose Monitor.

About Lokahi Therapeutics Inc.

References in this sub-section to the "Company," "we," "us," or "our" refer to Lokahi Therapeutics, Inc., a Nevada corporation. For more information relating to the business of Lokahi Therapeutics, Inc., please refer to the section entitled "Business of the Combined Company" herein.

Overview

We are a clinical stage biopharmaceutical company in the process of developing LT-100, an intradermally administered bee venom-based toxin. Our focus is primarily on developing innovative therapies that address inflammation and pain management symptoms associated with knee OA and, to a lesser extent, MS. LT-100 is currently marketed and sold by Apimeds Inc. ("Apimeds Korea") in South Korea as "Apitoxin" for the treatment of OA. Lokahi is not associated with the market, sale and revenues generated from Apitoxin in South Korea, and LT-100 has not yet been approved by the FDA for any indication.

We have established the ai² platform to support business development, opportunity evaluation, and talent development activities. The platform is used to identify and assess therapeutic, biotechnology, medical device, and other healthcare-related opportunities that may be considered for acquisition, licensing, strategic partnership, development, or other business initiatives.

ai² Futures Lab

The ai² platform utilizes evaluation methodologies, research processes, academic collaborations, and analytical tools to support the review of potential opportunities. Evaluations may include assessments of scientific rationale, clinical development status, intellectual property, regulatory considerations, commercial opportunity, competitive landscape, and strategic fit. Findings generated through the platform may be reviewed as part of our business development activities through collaborations with universities and other academic institutions. Lokahi partners with universities to give students hands-on exposure to the strategic side of biopharma, from evaluating clinical assets to understanding intellectual property, market dynamics, and go-to-market strategies. The ai² Futures Lab™ functions as both a discovery engine for potential therapeutic assets and a training ground for the next generation of biotech and business leaders.

ai2 Futures Lab is a program within the ai² platform that operates through collaborations with universities and academic institutions. Through the program, student teams participate in research and opportunity evaluation projects utilizing methodologies developed by us. Projects generally focus on the identification and assessment of therapeutic, biotechnology, medical device, and other healthcare-related opportunities that meet parameters established by us. Student teams may conduct analyses relating to clinical development, intellectual property, regulatory pathways, commercial opportunity, and competitive landscape. Findings generated through the program may be reviewed as part of our business development activities. The ai² Futures Lab program also supports recruiting and workforce development activities. Participants may be considered for internship, consulting, or employment opportunities with us.

LT-100

LT-100 is a purified, pharmaceutical grade venom (bee venom), of the Apis mellifera, or western honeybee, which is classified by the FDA as an active pharmaceutical ingredient ("API"). Bee venom has been used in Asia and Europe to treat pain for hundreds of years. While not FDA approved in a controlled, prescription based biologic environment for defined indications, the use of bee venom has been FDA approved as a "under the skin injection" to reduce the allergic reactions to bee stings. Apimeds Korea has developed a proprietary method and process for turning extracted bee venom into a lyophilized powder for reconstitution prior to intradermal dose injections, which they sell in South Korea as Apitoxin. We intend to use a similar process with respect to LT-100, pursuant to the Business Agreement (defined below), which gives us a license to utilize all prior clinical development data associated with Apitoxin. The advancement of extracted bee venom for treatment of inflammatory conditions, including but not limited to knee OA and MS is speculative but based on direction provided by prior clinical data.

Apimeds Korea successfully completed Phase I, Phase II, and Phase III trials in OA in 2003, at which point Apitoxin was approved by the Korean Ministry of Food and Drug Safety ("MFDA") to treat pain and mobility in patients with OA. Since 2003, a post-marketing/approval safety study in South Korea followed 3,194 patients from 2003 through 2009, with no serious adverse events. The purpose of a Phase I trial is to test to determine whether a new treatment is safe and look for the best way to give the treatment. Phase II trials test to determine whether a condition or disease responds to the new treatment. Phase III trials test to determine whether a new treatment is better than a standard treatment.

In 2013, the first of two required U.S. Phase III clinical trials was authorized to enroll patients to study the use of Apitoxin to study the same indication as approved in South Korea in 2023 — treatment of pain and lack of mobility in patients with OA (the "Apimeds Korea Phase III OA Trial"). The Apimeds Korea Phase III OA Trial (330 patients) was completed in 2018, and displayed no serious adverse events.

Based on the results from the Apimeds Korea Phase III OA Trial, which demonstrated therapeutic (statistical and clinically significant improvements in all outcome measures of pain, physical function, and disease assessment) effect compared to the placebo group, but in combination with prior development by Apimeds Korea, did not meet the FDA's standards for approval, as the study population was too small and the methods for handling missing data were inadequate, resulting in a study that did not demonstrate a significant treatment effect. We will be pursuing appropriate trials to meet agreed upon FDA standards. Based on results from the Apimeds Korea Phase III OA Trial, we have evaluated the most appropriate population, defined as advanced knee OA patients, which will range from defined grade 2, 3 and 4 within this treatment group, to continue to progress our own Phase IIb trial. Pursuant to our previous correspondence with the FDA, we have designed and will first implement a Phase IIb trial to best address our patient population, appropriate dosing, and the most effective way to evaluate LT-100 in meeting the patient population's needs. As part of the Phase IIb trial, we are evaluating the effectiveness of subcutaneous delivery, to better reflect current clinical best practices, while reducing burden for patients and providers. We believe this positions the program well for continued progress.

We believe the progress we are making in clinical trials provides us support in our belief in the potential of LT-100 to be an innovative therapy. We aim to treat the inflammation and pain management symptoms associated with knee OA and to help manage the devastating symptoms of this disease. In the future, we also aim to leverage our research in knee OA to investigate how LT-100 may be used to treat similar symptoms associated with MS.

Treatment of OA

OA is typically treated with painkillers known as non-steroidal anti-inflammatory drugs (NSAIDs). These medications have an anti-inflammatory and pain-relieving effect. These medications include ibuprofen (Motrin, Advil) naproxen (Aleve) and diclofenac (Voltaren and others). All of these medications work by blocking enzymes that cause pain and swelling. The problem is that some of those enzymes also help blood to clot and protect the lining of your stomach. Without them, you can bruise easily, develop ulcers and may even bleed in your intestines. NSAIDs also increase your chance of heart attack, stroke and heart failure. The risk increases the longer you use them and the more you take. We believe LT-100 could be a successful alternative to NSAIDs in the treatment of the inflammation and pain management symptoms associated with OA without the harmful side effects.

According to Medical News Today, OA is the most common form of arthritis, affecting around 500 million people worldwide, or around 7% of the global population. Currently, in the United States, over 32 million people suffer from OA. As the 15th highest cause of years lived with disability (YLDs) worldwide, the burden OA poses to individuals is substantial, characterized by pain, activity limitations, and reduced quality of life. The economic impact of OA, which includes direct and indirect (time) costs, is also substantial, ranging from 1 to 2.5% of gross national product (GNP) in countries with established market economies, like the United States. Though trends in OA prevalence vary by geography, the prevalence of OA is projected to rise in regions with established market economies such as North America and Europe, where populations are aging and the prevalence of obesity is rising.

While OA can occur in any joint, it occurs most frequently in the knee, which, according to ScienceDirect, currently accounts for 365 million cases worldwide and 61% of YLDs lost due to OA, followed by the hand.

Our current efforts are focused on the development of LT-100 in the United States for the treatment of inflammation and pain management relating to OA in the knee.

Treatment of MS

Additionally, we believe the previous clinical trial success of Apimeds Korea with respect to the use of Apitoxin to treat symptoms associated with knee OA, and pending the success of our anticipated Phase III trial in knee OA, we will be in a position to further explore the use of LT-100 as a potential treatment for the symptoms of MS. MS is a chronic disease of the central nervous system. It is an autoimmune condition that is characterized by the body's own immune cells (macrophages and lymphocytes) attacking the myelin that coats nerve cells, which can lead to inflammation throughout the central nervous system. MS is an unpredictable disease that affects people differently. Some people with MS may have only mild symptoms. Others may lose their ability to see clearly, write, speak, or walk when communication between the brain and other parts of the body becomes disrupted.

MS is the most common progressive neurologic disease of young adults worldwide. A study funded by the National MS Society estimates that nearly one million individuals are currently affected by this disease in the United States. The total economic burden of MS in the United States is estimated to be $85.4 billion, with $63.3 billion in direct medical costs and $22.1 billion in indirect and nonmedical costs. MS typically affects patients at a young age, resulting in a greater loss of productivity and quality of life.

Beta interferon drugs are among the most common medications used to treat MS. Interferons are signaling molecules that regulate immune cells. Potential side effects of these drugs include flu-like symptoms (which usually fade with continued therapy), depression, or elevation of liver enzymes.

Pain from MS can be felt in different parts of the body. Trigeminal neuralgia (facial pain) is treated with anticonvulsant or antispasmodic drugs, or less commonly, painkillers. Central pain, a syndrome caused by damage to the brain and/or spinal cord, can be treated with gabapentin and nortriptyline. Treatments for chronic back or other musculoskeletal pain may include heat, massage, ultrasound, and physical therapy.

OA and the Current Standard of Care

OA is a degenerative joint disease in which the tissues in the joint break down over time. It is the most common type of arthritis and is more common in older people. People with osteoarthritis usually have joint pain and, after rest or inactivity, stiffness for a short period of time.

There are four stages of OA: (1) Minor — minor wear-and-tear in the joints and little to no pain in the affected area, (2) Mild — more noticeable bone spurs, the affected area feels stiff after sedentary periods and patients may need a brace, (3) Moderate — cartilage in the affected area begins to erode, the joint becomes inflamed and causes discomfort during normal activities, and (4) Severe — the patient is in a lot of pain, the cartilage is almost completely gone leading to an inflammatory response from the joint, and overgrowth of bony spurs may cause severe pain.

With the progression of OA of the knee, there is obvious joint inflammation which causes frequent pain when walking, running, squatting, extending or kneeling. Along with joint stiffness after sitting for long or when waking up in the morning, there may be popping or snapping sounds when walking.

The data from the Apimeds Korea Phase III OA Trial suggest that LT-100 would have the most potential in treating OA in stages 3 and 4.

MS and the Current Standard of Care

MS is increasingly recognized as a neurodegenerative disease triggered by an inflammatory attack of the central nervous system. There is no cure for multiple sclerosis. Treatment typically focuses on speeding recovery from attacks, reducing new radiographic and clinical relapses, slowing the progression of the disease, and managing MS symptoms.

MS is unpredictable and can vary substantially from person to person. MS is divided into four types: clinically isolated syndrome (CIS), relapsing-remitting MS (RRMS), secondary progressive MS (SPMS) and primary progressive MS (PPMS).

CIS refers to a first episode of neurologic symptoms caused by inflammation and demyelination in the central nervous system.

RRMS, the most common disease course, shows clearly defined attacks of new or increasing neurologic symptoms. These attacks are also called relapses or exacerbations. They are followed by periods of partial or complete recovery, or remission. In remissions, all symptoms may disappear or some symptoms may continue and become permanent. However, during those periods, the disease does not seem to progress.

SPMS follows the initial relapsing-remitting course. Some people diagnosed with RRMS eventually go on to have a secondary progressive course, in which neurologic function worsens progressively or disability accumulates over time.

With PPMS, neurologic function worsens or disability accumulates as soon as symptoms appear, without early relapses or remissions. PPMS can be further characterized as either active (with an occasional relapse and/or evidence of new MRI activity over a specified period of time) or not active, as well as with progression (evidence of disability accrual over time, with or without relapse or new MRI activity) or without progression.

Patients with MS tend to be more educated about their disease and better organized than patients with other diseases, resulting in patients that are aggressive in their approach to treatment. This is due to MS impacting otherwise healthy people in the prime of their lives.

MS treatment has undergone significant evolution in the last ten years with the development and approval of certain new drugs, including several oral agents such as Ocrevus, in the United States. These new agents not only give patients additional treatment options, but also have improved the efficacy and safety of treatment for MS overall. In general, these drugs are “disease modifying agents,” intended to slow down the immune mediated damage to the myelin sheaths that underlie symptoms in MS. However, they often do not adequately address the symptoms that MS patients experience such as walking problems, bladder control, dizziness, and especially pain. A 2022 study estimated that the average cost of treatment for patients with MS is approximately $88,000 annually. The out-of-pocket expense for patients can be significantly reduced through certain insurance plans. However, we believe there is the ability for LT-100 to be positioned as an important and cost-effective therapy.

We believe the data from the Apimeds Korea Phase III OA Trial suggest that LT-100 may have the potential as an adjunctive therapy for all four types of MS. We intend to explore LT-100 as a potential adjunctive therapy through non-registered corporate sponsorship studies to begin determining the appropriate MS patient populations.

Market Opportunity

We believe there is a significant market opportunity in the United States for LT-100 in the treatment of certain symptoms of knee OA and eventually MS. According to Precedence Research the osteoarthritis therapeutics market size accounted for $8.28 billion in 2022 and it is expected to hit around $20.24 billion by 2032, expanding at a CAGR of 9.4% from 2023 to 2032. Although OA can damage any joint, the disorder most commonly affects joints in your hands, knees, hips and spine. OA symptoms can usually be managed, although the damage to joints can’t be reversed. LT-100 has certain anti-inflammatory properties, which we believe give it significant potential to help treat the symptoms of certain chronic diseases that involve difficult to control pain and inflammation.

According to Pharmaceutical Technology the MS market size in the United States accounted for $10.73 billion in 2022 and is expected to hit $24.4 billion by 2030, expanding at a CAGR of 10.32%. Starting in the second quarter of 2027, we intend to begin the early prosecution of appropriate MS patient populations through non-registered corporate sponsorship studies. Subject to FDA approval, our development of LT-100 in the United States will in the near term, have two distinct focuses (i) the treatment of the certain symptoms of knee OA and (ii) the quality of life issues surrounding knee OA, such as pain and lack of mobility.

Living with a chronic disease is challenging, as it interferes with physical, mental, and social functions and thus greatly affects a person's quality of life. Indeed, chronically ill patients are facing major struggles such as higher expenditures, social isolation and loneliness, disabilities, fatigue, pain/discomfort, feelings of distress, anger, hopelessness, frustration, anxiety, and depression. There is the general assumption that symptom reduction increases a patient's quality of life. Our approach with LT-100 centers around this concept — effectively treating certain symptoms of the patient's disease, thus improving their overall quality of life. Bee venom has been shown to have anti-inflammatory effects. At low doses, bee venom can suppress inflammatory cytokines such as interleukin-6 (IL-6), IL-8, interferon-γ (IFN-γ), and tumor necrosis factor-α (TNF-α). A decrease in the signaling pathways responsible for the activation of inflammatory cytokines, such as nuclear factor-kappa B (NF-κB), extracellular signal-regulated kinases (ERK1/2) and protein kinase Akt, and porphyromonas gingivalis lipopolysaccharide (PgLPS)-treated human keratinocytes has been associated with treatments involving bee venom. We believe the driver of pain in the highest category of OA is correlated to the key inflammatory elements treated by bee venom, meaning the evaluation of our Phase III data may lead to a small indication for narcotic use reduction in the treatment of stage 4 OA.

Our Product Candidate

LT-100 is purified honeybee (Apis mellifera) venom manufactured as a lyophilized powder for reconstitution in 0.5% preservative-free lidocaine (lmg/mg) prior to intradermal dose injections that are administered up to 1,500 micrograms per weekly visit. The biologically active components include melittin (40-50%), apamin (2-3%), mast cell degranulating ("MCD") peptide (Peptide 401,2-3%), phospholipase A2 (10-15%), hyaluronidase (1.5-2%) and other components in small amounts, including dopamine and norepinephrine. According to a publication entitled "Pharmacological effects and mechanisms of bee venom and its main components: Recent progress and perspective" by Shi et al., certain components of honeybee venom have been found to have both anti-inflammatory and analgesic effects. The anti-inflammatory and analgesic effects are attributed to the presence of Peptide 401, adolapin and other components that inhibit prostaglandin synthesis. The hormone-stimulating effects are attributed to the presence of melittin, cardiopep and other components that stimulate the pituitary-adrenal axis to produce cortisol. Results from an animal study entitled "Effect of bee venom and melittin on plasma cortisol in the unanesthetized monkey" published by Vick et al., indicate that melittin appears to stimulate the production of cortisol from the adrenal gland. The immune-modulating effects, especially as it pertains to MS, are suggested to be mediated by CD4+CD2S+Foxp3+ regulatory T cells (Tregs) that are influenced by phospholipase A2. While the exact mechanism of action of LT-100 is not fully understood, research such as the publication entitled "Therapeutic Use of Bee Venom and Potential Applications in Veterinary Medicine" by Bava et al., suggests that certain components in LT-100 may ameliorate immune-inflammatory responses associated with MS. Such studies suggested that treatments with melittin prevent inflammatory cytokine expression and produces anti-inflammatory effects. The proposed indication for LT-100 is to provide add-on therapy for the signs and symptoms of MS in patients whose condition is relapsing-remitting (RRMS), primary-progressive (PPMS) or secondary progressive (SPMS).

Clinical Development History

Founded in 1989, Apimeds Korea pursued a traditional drug development process in South Korea for Apis mellifera, the bee venom API for Apitoxin. Apimeds Korea completed a formal preclinical study to validate dosing and safety for human administration with a focus on antigenicity and toxicology in 1993.

A Phase I trial was completed in 1994, studying the toxicity and safety of LT-100 in in 20 healthy subjects. The purpose of the Phase I trial was to determine if therapeutic doses of Apitoxin was safe and to identify possible side-effects, if any. Injections of Apitoxin were given two to three times a week, for a total of 12 sessions spanning over four to six weeks. Laboratory and physical examination of the subjects included (i) serum cortisol levels (to see if Apitoxin stimulated the release of cortisol), (ii) serum ionized calcium level (to determine if Apitoxin decreased the serum calcium level), (iii) urinalysis, (iv) hematology and blood chemistry, and (v) vital signs. The Phase I trial demonstrated that there were no significant changes pre- and post-testing of the serum cortisol levels, serum ionized calcium levels, hematology, blood chemistry, urinalysis, and vital signs after the subjects were injected with Apitoxin according to the protocol. There were no significant physiological changes in the clinical evaluations of the subjects and localized itching was the most frequent side effect and was managed with ice packs or external anti-itching gels. No severe side effects or aftereffects were observed. The Phase I trial indicated that LT-100 is safe for humans when applied in therapeutic doses.

The Phase I trial was followed by a Phase II trial in 101 subjects to determine the efficacy of Apitoxin at various dose levels. This was a randomized active-controlled clinical trial with three groups receiving the study drug at various dose levels and one group receiving the control drug (nabumetone) for a six-week period. Patients received twice weekly injections of Apitoxin intradermally at dosages titrated to a maximum of 0.7 mg (Group A), 1.5 mg (Group B), and 2.0 mg (Group C) for a period of six weeks. Control group patients (Group D) received 1,000 mg of nabumetone orally each day for the same six-week period. There were 25, 26, 25 and 25 patients assigned to Groups A, B, C and D, respectively. Efficacy of treatment was evaluated by the physician investigators using a 4-point Likert-like symptom severity rating scale developed by the authors to assess Pain, Disability and Physical Signs. A similar 5-point scale was used for patient self-evaluation. Safety of the Apitoxin injection was evaluated by patient reaction, hematologic examination, and laboratory chemistry analysis of blood and urine. Efficacy data was reported for the 81 patients who completed the study. While there were no significant differences in symptom severity scores among the four groups at baseline, symptom scores were significantly better in the bee venom injection groups than in the control group at six weeks and 10 weeks after the start of treatment ($p<0.01$). A treatment was considered effective if there was a 20% improvement from baseline in symptom scores after 6 weeks of treatment. Based on this definition, therapy demonstrated overall efficacy in 70.0% of patients in Group A, 85.7% in Group B, 90.0% in Group C, and 61.9% in Group D (drug control). Overall efficacy was significantly greater in treatment Groups B and C combined than in the nabumetone-treated control group D ($p<0.0177$). Importantly, efficacy of treatment among all patients treated with Apitoxin injection was greater than among nabumetone-treated patients for each category assessed: Pain: 85.2% versus 76.2%; Disability: 77.0% versus 71.4%; and Physical Signs: 62.3% vs. 23.8%. It is also noteworthy that, unlike the drug control group, the Apitoxin injection groups continued to demonstrate improved symptom scores at four weeks after the last treatment (10 weeks). There were no significant changes in vital signs or results of laboratory examinations of any patient in this clinical trial. Localized itching was experienced by all patients who received Apitoxin injections. Itching at the injection site generally lasted for two to three weeks; several patients had this reaction for a longer period. This Phase II study showed that Apitoxin was significantly more effective than the control drug, nabumetone, in the treatment of knee and spinal osteoarthritis patients. It clearly showed that improvement in pain, disability and physical signs was greater in the bee venom injection groups than in the nabumetone control group. No significant side effects developed at the therapeutic doses studied. However, research should be continued to minimize itching and pain at bee venom injection sites, and possible allergic reaction should always be considered with treatment at high doses.

In 2002, a formal Phase III double-blind, placebo-controlled trial was completed with 407 subjects (311 of which obeyed the trial protocol and completed the clinical study). The purpose of the Phase III trial was conducted to verify the efficacy and safety of the medicine resulting from the prior Phase I and Phase II trials. The therapeutic course treatment included a total of 12 injections over a period of 6 weeks. Final evaluations were completed in the 8th week, following two weeks of no injections. During the trial period, laboratory tests were carried out three times (before injection, in the second week, in the sixth week), and the efficacy evaluation was performed four times (before injection, in the second week, in the sixth week, and in the eighth week). Safety of the Apitoxin injection was evaluated by hematologic examination, measurement of cortisol and calcium levels, and laboratory chemistry analysis of blood and urine. The primary efficacy variable for the trial was the ratio of the subjects who showed more than 20% improvement in the total points of test items for efficacy evaluation 6 weeks after injection, compared with the total points before injection of the medicine (the “improvement rate”). Data obtained from subjects of the clinical test were analyzed by two methods, ITT (Intention to Treat) analysis and PP (Per Protocol) Among 310 subjects who participated in the efficacy evaluation, 153 and 157 patients belonged to the Apitoxin group and the nabumetone group, respectively. For the Apitoxin group, the ratio of the subjects who showed more than 20% improvement in the total points was 48.70% (75/154 subjects, 95% confidence interval (“CI”): 40.8~56.6%), while for the nabumetone group, it was 46.15% (72/156 subjects, 95% CI: 38.3~54.0%), indicating that the improvement rate in the Apitoxin group was greater than in the nabumetone group; however, there was no statistical significance. ($p=0.6533$). Among a total of 407 subjects (Apitoxin group: 204; Nabumetone group: 203), 38.24% (78/204) of the Apitoxin group showed more than 20% improvement during the 6th week of injection, while 38.42% of the Nabumetone group improved by more than 20%, indicating that the two groups showed similar improvement rate ($p=0.9688$). The second efficacy variable was the improvement rate during the 8th week (2 weeks after the completion of the final injection). According to results from comparing the total points of efficacy evaluation items during the second week after completion of injection (during the 8th week after injection) with the total points before injection, 58.44% (90/154) of the Apitoxin group showed a higher improvement rate than during the 6th week (48.70%), while 42.95% (67/156) of the Nabumetone group showed lower improvement rate than during the 6th week (46.15%). There was statistical difference in total point of efficacy evaluation items between the two groups ($p=0.0064$). These results suggest that even after treatment stops, the efficacy of Apitoxin continues. With respect to safety, among a total of 407 subjects who participated in the safety evaluation, 69 (33.82%) of the Apitoxin group showed

an adverse event, while 59 (29.06%) of the Nabumetone indicated adverse event. These results indicate that the Apitoxin group had an elevated adverse event rate than the Nabumetone group, but there was no statistically significant difference between the two groups (p=0.3526).

In May 2003, MFDA granted approval for the use of Apitoxin in the treatment of pain and mobility in patients with OA. A post-marketing/approval safety study in South Korea followed 3,194 patients from 2003 through 2009, with no serious adverse events or negative safety signals.

In 2013, preliminary Phase III clinical trials were authorized to enroll patients by the FDA to study the same indication approved in South Korea — treatment of pain and lack of mobility in patients with OA. The results of the preliminary Phase III clinical trial indicated statistical and clinically significant improvements in all outcome measures of pain, physical function, and disease assessment in the study group. The study group included 330 patients with diagnosed osteoarthritis of the knee. The subjects were evaluated for relief of pain using Western Ontario and McMaster Osteoarthritis Index (WOMAC) and physician and patient global assessments. The primary efficacy measure was relief of pain and inflammation over a 12-week treatment period after randomization into the trial. The secondary efficacy measure was improvement of mobility. Treatment effect will be compared in a 2-1 Apitox vs active control. Compared with the placebo group (histamine), subjects in the LT-100 group who received a maximum dose (1500 micrograms) at each weekly visit over 12 weeks showed a significantly more improvement in all outcome measures (WOMAC pain, WOMAC physical function, visual analog scale ("VAS") pain, patient and physician global assessments of OA). Further, post hoc analyses showed that a statistically significant greater percentage of LT-100-treated subjects had at least a 40% and 60% reduction in WOMAC pain as compared to placebo-treated subjects. Sensitivity analyses confirmed the validity of the statistical methods and population definitions. The improvements in pain endpoints were highly significant for both the modified intention to treat and per protocol populations and the improvement was sustained during the four weeks following LT-100 treatment.

Except for an expected higher incidence of injection site reactions (<5%) in the LT-100 group, the overall safety profiles were comparable between the treatment groups. A serious adverse event of the anaphylactic reaction occurred in an LT-100-treated subject because of a quick injection rate. However, the subject was treated, and the event was resolved within one day. The incidence of adverse events overall was similar between the LT-100 and Placebo groups (49.0% and 46.3%, respectively), and there were no clinically meaningful changes, within and between groups, in laboratory parameters, vital signs, physical examination, or electrocardiogram results.

During Apimeds Korea meetings with the FDA, the FDA highlighted concerns regarding the opioid crisis. As Apitoxin has been previously approved in South Korea, we believe LT-100 could be a viable treatment option within the United States after additional clinical investigation, including our anticipated Phase III trial. Initially, Apimeds Korea elected not to pursue the OA indication in the United States based on its evaluation of potential market adoption and the existing competitive environment for OA. Based on results from the Apimeds Korea Phase III OA Trial and correspondence with the FDA, we believe we are now in a position to continue to advance our Phase IIb trial for knee OA.

We intend to conduct a Phase IIb trial in knee OA. Based on our previous correspondence with the FDA, we have started to design and will implement our Phase IIb trial to best address our patient population of patients with grade 2, 3 and 4 knee OA, appropriate dosing, and the most effective way to evaluate LT-100 in meeting a patient's needs. This trial will be an update to the plan of execution based on review of data, discussions with former principal investigators from Apimeds Korea. Upon successful completion of the Phase IIb trial and FDA clearance of our Phase III trials in knee OA, we will be positioned to submit a BLA.

We intend that the purpose of this trial will be to evaluate the effectiveness of LT-100 in the treatment of grade 2, 3 and 4 OA of the knee. The trial will be designed with a specific focus on the identified subgroup from which we see the highest degree of benefit.

The following table summarizes the preliminary clinical trial activity by Apimeds Korea with respect to Apitoxin:

	Phase 1	Phase II	Phase III	Phase I	NDA (KFDA)	Phase IV*	MS Society Sponsored Study	Phase II	FDA/Phase III Osteoarthritis
Company/ Investigator	Brando Pharma/ Chris Kim, MD	Brando Pharma/Guju Pharma	Guju Pharma Apimeds Korea	Hauser et al 2001 Altern Compl Ther.	Guju Pharma Apimeds Korea	Guju Pharma Apimeds Korea	Wesselius et al 2005 Neurology	Apimeds Korea	Apimeds Korea
Indication	Osteoarthritis Mobility/Pain	Osteoarthritis Mobility/Pain	Osteoarthritis Mobility/Pain	Multiple Sclerosis	Osteoarthritis Mobility/Pain	Osteoarthritis Mobility/Pain	Multiple Sclerosis	Osteoarthritis Mobility/Pain	Osteoarthritis Mobility/Pain
Year	1994	1996	2002	2001	2003	2003-2009	2005	2011	2016
Subjects	20	161	407	51	N/A	3,194	26	40	330
Design	Toxicity and Safety	Efficacy and Safety	Efficacy and Safety	Safety and Efficacy	Regulatory Submission	Post Marketing Safety	Safety and Efficacy	Efficacy and Safety	Efficacy and Safety
Results	No Neg Safety Signals	Improvement in mobility and pain reduction	Improvement in OA mobility and reduction in pain	Improvement in MS fatigue, endurance, balance, bladder control, coordination No Serious Adverse Events	Approved	No Serious Adverse Events No negative safety signals	Mean Improvement in MS Functional Composite symptoms No Serious Adverse Events	No Serious Adverse Event Improvement of OA Symptoms	Improvement in OA mobility and reduction in pain
Statistical and Clinical Significance	No Negative Safety signals	Significant reduction in pain and disability (p = 0.0177)	Significant reduction in pain and disability (p = 0.0019	MS Outcome Improved: 35 patients No Improvement 16 Patients	N/A	No Serious Adverse Events	MS Functional Composite Baseline -0.85 ± 1.41 Venom -1.12 ± 1.95	Significant pain reduction (p = 0.0355) Apitox vs Control	Significant pain reduction (p = 0.0057) with Apitox dose vs Placebo

Preliminary Clinical Data in MS Patients

The United States data from the literature on bee venom studies in MS patients, Table A (Hauser et al. 2001) below, showed clinically significant improvements in disability symptoms following treatment.

In Table A, results were categorized into the following groups: dramatic disability improvement (>12 points on the Related Observable Symptom Scale ("ROSS"), good improvement (7-12 points on ROSS), minimal improvement (<7 points on ROSS), no improvement (<2 points on ROSS), and negative (any total negative response on ROSS). Descriptive analysis of the ROSS clinical outcomes showed that more than 68% of MS patients showed some kind of positive improvement in disability (dramatic, good or minimal) and 58% demonstrated a marked improvement (dramatic or good).

Table A. Summary of Patient Disability Improvement to Bee Venom Treatment Using ROSS

	N	% of Participants	Follow-up Survey (% improvement)	Related Observable Symptoms Scale (points improvement)
Dramatic	15	29.4%	>30%, or	>12 points
Good	15	29.4%	10 – 29%, or	7 – 12 points
Minimal	5	9.8%	<10%, or	<7 points
None	15	29.4%	<2%, or	<2 points
Negative	1	2.0%	Any total negative response	Any total negative response

After 1 year of bee-venom injections, 68.6 percent of participants showed improvement. N = number of participants.

Apimeds Korea used data from its first Phase III clinical trial for OA and peer reviewed publications, including those referenced in Table A above and formal Phase I (the "Castro Phase I Trial") and Phase II (the "Wesselius Phase II Trial") publications specific to MS, to support its submission in 2014 of its Investigational New Drug Application ("IND") 122804 (A Phase III, Multi-Center, Randomized, Double-Blind, Placebo-Controlled, Parallel Group Study to Evaluate the Safety and Efficacy of LT-100 Add-on Therapy for Improving Disability and Quality of Life in Patients with Multiple Sclerosis).

Castro Phase I Trial

The Castro Phase I Trial involved a total of nine bee venom nonallergic patients with progressive forms of MS, who were 21 – 55 years of age with no other illnesses. The subjects distributed across four groups (A, B, C, and D) and followed a structured 1-year immunization schedule. Hyperreactivity to bee venom was evaluated by questionnaire, physical examination, and a battery of hematologic, metabolic, and immunologic tests. Responses to therapy were evaluated by questionnaire, functional neurological tests, and changes in measurement of somatosensory-evoked potentials. While no serious adverse allergic reactions were observed in any of the subjects, four experienced worsening of neurological symptoms, requiring their discontinuation in the study. The observed negative effects could not be conclusively attributed to adverse reactions arising from the administered therapy. Of the remaining five subjects, three reported subjective amelioration of symptoms and two exhibited objective improvement. Despite suggesting safety in this preliminary study, the small sample size precluded definitive conclusions regarding the efficacy of the treatment for MS. Larger and more carefully conducted multicenter studies were required to establish efficacy.

Wesselius Phase II Trial

The Wesselius Phase II Trial involved a randomized crossover study of 26 patients diagnosed with relapsing-remitting or relapsing secondary progressive MS. Participants were assigned to 24 weeks of medically supervised bee sting therapy, or a control period of 24 weeks of no treatment. Live bees (up to a maximum of 20) were used to administer bee venom three times per week. The primary outcome was the cumulative number of new gadolinium-enhancing lesions on T1-weighted MRI of the brain. Secondary outcomes were lesion load on T2*-weighted MRI, relapse rate, disability (Expanded Disability Status Scale, Multiple Sclerosis Functional Composite, Guy's Neurologic Disability Scale), fatigue (Abbreviated Fatigue Questionnaire, Fatigue Impact Scale), and health-related quality of life (Medical Outcomes Study 36-Item Short Form General Health Survey). The results of the Wesselous Phase II Trial indicated that during bee sting therapy, there was no significant reduction in the cumulative number of new gadolinium-enhancing lesions. The T2*-weighted lesion load further progressed, and there was no significant reduction in relapse rate. There was no improvement of disability, fatigue, and quality of life. Bee sting therapy was well tolerated, and there were no serious adverse events. In this trial, treatment with bee venom in patients with relapsing multiple sclerosis did not reduce disease activity, disability, or fatigue and did not improve quality of life measured using gadolinium-enhancing MRI.

From June 2014 to June 2018, Apimeds Korea corresponded with the FDA and there were no clinical holds at that time. Sponsorship of IND 122804 was transferred from Apimeds Korea to us in October 2020. On September 21, 2021, we responded to customary non-clinical hold comments from the FDA. In November 2021, we received a customary clinical hold from the FDA due to the retirement of the former principal investigator. We have subsequently updated the FDA with a new principal investigator via our Chief Medical Officer, Dr. Christopher Kim. In February 2023, the FDA removed the clinical hold and concluded it may be initiated. We have subsequently made the strategic decision to focus our efforts and capital on our Phase III trial in knee OA, and instead focus our MS efforts on the early prosecution of appropriate MS patient populations through non-registered corporate sponsorship studies.

Our Commercialization Strategy

We are dedicated to the effective implementation of regulatory, clinical and legal strategies to create value in LT-100. The effective execution of this strategy will provide us the opportunity to evaluate and potentially acquire other assets that fit within our space for development.

Manufacturing

We intend to continue to engage a third-party manufacturer, Piramal Pharma Solutions, in Lexington, Kentucky to support our Phase III trial and, if LT-100 is approved by the FDA, commercial manufacturing. This manufacturer has dedicated experience in development and technology transfer of sterile dose formulations, including liquid and lyophilized formulations.

Research and Development

We are currently engaged exclusively in the clinical development of LT-100 for continued use in knee OA through a Phase III trial in knee OA and potential use for MS through the early prosecution of appropriate patient populations through non-registered corporate sponsorship studies.

Sales and Marketing

The healthcare providers associated with the treatment of inflammation and pain management symptoms associated with OA and MS are not limited to one specialist but involve a comprehensive team of providers focused on slowing the progression of the disease along with the physical, emotional and day-to-day management of the condition. Each of these providers represents a potential customer for LT-100.

Apitoxin, which will be known as LT-100 in the United States, has established technological credibility through its preclinical testing, Phase I, Phase II and preliminary Phase III clinical studies completed by Apimeds Korea. Apimeds Korea received regulatory approval for Apitoxin by the MFDA in South Korea, as well as long-term safety data from treatment of patients in Korea from 2003 to 2009. There were no serious adverse events from over 3,000 patients monitored, and Apitoxin has been approved and marketed in South Korea for OA since 2003. We update the FDA annually on safety data generated by Apimeds Korea from South Korea.

We aim to obtain FDA approval for LT-100 in the United States market for treatment of inflammation and pain management symptoms associated with knee OA, and eventually MS, and expand the indication portfolio in the autoimmune market with a strategic marketing partner. The marketing partner strategy is common in the pharmaceutical marketplace, as the infrastructure, overhead, and barriers to entry dilute the focus and can rapidly erode the financial well-being of small, product development-based companies such as us. By identifying the strategic marketing partner at an early stage, the companies can deliver a final product, or family of products, in a form factor or variety of form factors over time, that specifically suit the target market. We believe that LT-100 represents a significant opportunity as a platform technology, with numerous product-line extensions, and the potential for new, ancillary products such as delivery devices.

Reimbursement Strategy

Lokahi expects to apply to the Centers for Medicare and Medicaid Services (“CMS”) for temporary generic reimbursement codes 12 to 18 months prior to a BLA approval. Temporary codes are used until manufacturers apply for, and receive, permanent codes, which identify the drug and its therapeutic class. Permanent codes are issued by CMS on a rolling quarterly basis.

We will engage third party contractors to assist us with reimbursement, coding and policy development prior to, during and at the time of approval of LT-100. We will look for a contractor to provide the following services to us:

● Coding Assessment and Strategy/Execution — CPT Review of LT-100 Administration by Multiple Intradermal Injections. Assess the landscape to ensure a clear understanding of the key dynamics and analyze relevant proxies and precedent. Further assess relevant drug administration codes and whether appropriate codes exist.

● Medical Coverage Policy Analysis — Provide a framework and set expectations for Medicare’s anticipated coverage approach to LT-100, specifically in the context of intra articular hyaluronic acid use agent coverage policies and implications of their efficacy uncertainty.

● Medicare Local Coverage Analysis and Implications — Given the significance of Medicare policy standards, local and national Medicare policies often shape payer and provider perceptions and decisions. As complex statutory and regulatory guidance shape Medicare decision-making, ADVI analyzes, investigates, and synthesize Medicare policies that could affect access (coverage, coding and reimbursement) for LT-100.

● Medicaid and Commercial Coverage Analysis and Implications — Analyze available medical policies for five large state Medicaid agencies (based on population and geographic variation) and major commercial payers (where publicly available).

● Payer Policy Internal Expert Interviews — Conduct payer interviews with relevant Medicare, Medicaid and commercial policy advisors.

● HCPCS Coding and Payment Assessment — Assess the coding and reimbursement landscape to ensure Lokahi has a clear understanding of the key dynamics with the HCPCS application process and the Medicare Hospital Outpatient Prospective Payment System (OPPS) pass-through status application process. Through this assessment, identify the areas of concern, expectations, timing, timelines, and processes associated. This is especially relevant given the 2020 implementation of a new HCPCS review process.

● Address key Part B/medical benefit implications to LT-100 in the following fields:

● HCPCS and OPPS application timelines (and potential evolution leading to launch),

● coding/access implications prior to code assignment (e.g., NOC/miscellaneous codes), review the merits/risks of Q-code,

● further review the application processes, expectations, case examples, timelines, and hurdles that APUS may face across settings of care, payers, and with CMS,

● case examples, timelines, and hurdles across settings of care with payers and CMS,

● review of reimbursement implications, and

● methodologies (ASP, WAC, AWP), role of sequestration, 340B, patient financial burden.

● Develop Payer (with Emphasis on Medicare) Launch Recommendations — Based on the above primary and secondary research, synthesize the discussions and summarize the overall findings of the payer survey, highlighting themes, and provide recommendations and considerations for optimizing market access, given the current and evolving reimbursement landscape. This section will include payer (emphasis on Medicare) launch strategy recommendations (including timeline) and a local/national Medicare engagement strategy.

Competition

We compete in an industry characterized by rapidly advancing technologies, intense competition, a changing regulatory and legislative landscape and a strong emphasis on the benefits of intellectual property protection and regulatory exclusivities.

Like any biopharmaceutical company, we face competition from multiple sources, including large or established pharmaceutical, biotechnology, and wellness companies, academic research institutions, government agencies, and private institutions. We believe our drug candidate will prevail amid the competitive landscape through its efficacy, safety, administration methods, cost, public and institutional demand, intellectual property portfolio, and treatment of the root cause of many age-associated diseases.

Many of our competitors, either alone or with strategic partners, have substantially greater financial, technical, and human resources than we do. Accordingly, our competitors may be more successful in obtaining approval for treatments and achieving widespread market acceptance, rendering our treatments obsolete or non-competitive. Accelerated merger and acquisition activity in the biotechnology and biopharmaceutical industries may result in even more resources concentrated among a smaller number of our competitors. These companies also compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical study sites, patient registration for clinical studies, and acquiring technologies complementary to, or necessary for, our programs. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. Our commercial opportunity could be substantially limited in the event that our competitors develop and commercialize products that are more effective, safer, more tolerable, more convenient, or less expensive than our comparable products. In geographies that are critical to our commercial success, competitors may also obtain regulatory approvals before us, resulting in our competitors building a strong market position in advance of our products' entry. We believe the factors determining the success of our programs will be the efficacy, safety, and convenience of our drug candidates.

Additionally, consumer preference for branded, generic or private label products sold by competitors could adversely impact our financial performance. Our competitors, which differ within individual geographic markets, include large-scale retailers, smaller high-growth companies (which often operate on a regional basis and offer aggressive competition), multinational corporations moving into or expanding their presence in the consumer healthcare market, and "private-label" products sold by retailers.

Our aim is to reduce the use of NSAIDS and opioid use as it relates to the pain management associated with OA. We believe that if approved by the FDA, LT-100 may be a non-addictive option to patients experiencing debilitating pain.

Business Agreement

On August 2, 2021, we entered into an agreement with Apimeds Korea, a principal stockholder of the Company (the "Business Agreement"). Pursuant to the Business Agreement, Apimeds Korea granted to the Company a sublicensable, royalty-bearing license to utilize all prior clinical development data associated with Apitoxin, LT-100, and all related names, advance clinical research, develop, manufacture and commercialize and sell LT-100 in the United States. In exchange for this license, the Company will pay Apimeds Korea a perpetual royalty of 5% of the Company's earnings before interest and taxes (as determined consistent with GAAP, derived from the sale or license of LT-100, less any shipping, handling, and insurance charges, credits (arising from returns or other adjustments), discounts, rebates, or allowances of any kind (if any). The Business Agreement can be terminated by mutual written agreement by the parties and will automatically terminate upon the bankruptcy or dissolution of the Company.

Assignment Agreement

On October 12, 2021, we entered into an intellectual property assignment agreement (the "Assignment Agreement"), which was effective as of May 12, 2020, with Apimeds Korea and Dr. Christopher Kim, the Company's Chairman and Chief Medical Officer and the founder of Apimeds Korea. During Dr. Kim's engagement with Apimeds Korea, he contributed to the development of the intellectual property as it relates to Apitoxin, which will be marketed in the United States as LT-100 (the "Assigned IP").

Pursuant to the Assignment Agreement, Dr. Kim sold, transferred, and conveyed all his rights, title and interest in the Assigned IP to Apimeds Korea. Dr. Kim retained no right to use the Assigned IP. Additionally, the Assignment Agreement acknowledged that the Assigned IP was licensed to us to use via the Business Agreement.

Intellectual Property

LT-100's API is bee venom, a natural, non-synthetic compound that is not patentable, so we rely principally on trade secrets to protect our rights to LT-100, particularly the method and process of manufacturing LT-100.

Supplier

We purchase venom from our United States supplier, Apico, Inc. ("Apico"), via a letter agreement. Pursuant to the letter agreement, Apico agreed that for a period of ten years, or until November 3, 2031 it would not supply Apis Mellifea venom for pharmaceutical use for any buyer other than us; provided that Apico may also supply Apimeds Korea for its use outside of the United States. The letter agreement excludes customers using venom for immunology, cosmetic or any other "non-pharmaceutical" use. The letter agreement may be terminated upon mutual written consent of both Apico and the Company.

Apico has developed and practices a proprietary method of harvesting venom. It operates under and is certified in current good manufacturing practice regulations enforced by the FDA and has an active and current Drug Master File ("DMF") with the FDA. DMF's are submissions to the FDA used to provide confidential, detailed information about facilities, processes, or articles used in the manufacturing, processing, packaging, and storing of human drug products. We have an exclusive relationship with our supplier for pharmaceutical use in the United States and they are not permitted to sell to any other party for pharmaceutical use.

Apimeds Korea has a number of proprietary analytical methods for the classification and identification of specific pharmacologically active fractions of its venom, along with numerous manufacturing processes from filtration, vial filing and lyophilization required to produce Apitoxin. Apitoxin is the only approved and commercially available therapeutic product containing purified and sterile bee venom that is registered as an API in South Korea. The proprietary methods developed and practiced for the commercial manufacturing of Apitoxin include dilution, filtering, vial staging and lyophilization parameters and cycles.

We plan to file LT-100 as a BLA with the Centers for Biologics and Research of the FDA following the successful completion of our Phase III trial for knee OA. The FDA provides 12-year market exclusivity at the time of approval of a BLA, with the potential for a six-month extension upon approval for pediatric use. If the BLA is approved, the 12-year period would be retroactive to the date of the application.

We intend to file a U.S. trademark application for the brand name to be associated with "LT-100" at the appropriate time.

Regulatory Environment

Government Regulation and Product Approval

In the United States, biological products are subject to regulation under the Federal Food, Drug, and Cosmetic Act (the "FDCA"), and the Public Health Service Act (the "PHSA"), and other federal, state, and local statutes and regulations. Both the FDCA and PHSA and their corresponding regulations govern, among other things, the research, development, clinical trials, testing, manufacturing, quality control, safety, purity and potency (efficacy), labeling, packaging, storage, record keeping, distribution, reporting, marketing, promotion, advertising, post-approval monitoring, and post-approval reporting involving biological products. Along with third-party contractors, we will be required to navigate the various preclinical and clinical regulatory obligations and the commercial approval requirements of the governing regulatory agencies of the countries in which we wish to conduct studies or seek approval or licensure of our product candidate. The processes for obtaining regulatory approvals in the United States, along with subsequent compliance with applicable laws and regulations and other regulatory authorities, require the expenditure of substantial time and financial resources.

Government policies may change, and additional government regulations may be enacted that could prevent or delay further development or regulatory approval of any product candidates, product or manufacturing changes, additional disease indications or label changes. We cannot predict the likelihood, nature or extent of government regulation that might arise from future legislative or administrative action.

Review and Approval for Licensing Biologics in the United States

In the United States, FDA regulates our current product candidate as a biological product, or biologics, under the FDCA, the PHSA, and associated implementing regulations. Biologics, like other drugs, are used for the diagnosis, cure, mitigation, treatment, or prevention of disease in humans. In contrast to low molecular weight drugs, which have a well-defined structure and can be thoroughly characterized, biologics are generally derived from living material (human, animal, or microorganism), are complex in structure, and thus are usually not fully characterized.

Biologics are also subject to other federal, state, and local statutes and regulations. The failure to comply with applicable statutory and regulatory requirements at any time during the product development process, approval process, or after approval may subject a sponsor or applicant to administrative or judicial enforcement actions. These actions could include the suspension or termination of clinical trials by FDA, FDA's refusal to approve pending applications or supplemental applications, withdrawal of an approval, issuance of warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, import detention, injunctions, fines, refusals of government contracts, restitution, disgorgement of profits, or civil or criminal investigations and penalties brought by FDA, the Department of Justice ("DOJ"), and other governmental entities.

An applicant seeking approval to market and distribute a biologic in the United States must typically undertake the following:

● completion of non-clinical laboratory tests and studies performed in accordance with FDA's good laboratory practice ("GLP") regulations;

● manufacture, labeling and distribution of investigational drugs in compliance with FDA's current good manufacturing practice ("cGMP") requirements;

● submission to FDA of an investigational new drug application ("IND"), which must become effective before clinical trials may begin and must be updated annually and when significant changes are made;

● approval by an independent institutional review board ("IRB") for each clinical site before each clinical trial may be initiated;

● performance of adequate and well-controlled human clinical trials in accordance with FDA's Good Clinical Practices ("GCP") to establish the safety, purity, and potency of the proposed biological product candidate for its intended purpose;

● after completion of all pivotal clinical trials, preparation of and submission to FDA of a BLA requesting marketing approval, which includes providing sufficient evidence to establish the efficacy, safety, purity, and potency of the proposed biological product for its intended use, including from results of nonclinical testing and clinical trials;

● satisfactory completion of an FDA advisory committee review, when appropriate, as may be requested by FDA to assist with its review;

● satisfactory completion of one or more FDA inspections of the manufacturing facility or facilities at which the proposed product, or certain components thereof, are produced to assess compliance with cGMP and data integrity requirements to assure that the facilities, methods, and controls are adequate to preserve the biological product's identity, strength, quality, and purity and, if applicable, FDA's good tissue practice ("GTP") requirements for human cellular and tissue products;

● satisfactory completion of FDA inspections of selected clinical investigation sites to assure compliance with GCP requirements and the integrity of the clinical data;

● satisfactory completion of an FDA sponsor GCP inspection, often conducted at the applicant's headquarters facility;

● payment of user fees (unless there is a waiver, exemption, or reduction) under the Prescription Drug User Fee Act ("PDUFA") for the relevant year;

● FDA's review and approval of the BLA to permit commercial marketing of the licensed biologic for particular indications for use in the United States;

● compliance with post-approval requirements, including the potential requirements to implement a risk evaluation and mitigation strategy ("REMS"), to report adverse events and biological product deviations, and to complete any post-approval studies; and

● completion of any post-approval clinical studies required by FDA, such as confirmatory trials or pediatric studies.

From time to time, legislation is drafted, introduced, and passed in Congress that could significantly change the statutory provisions governing the testing, approval, manufacturing, and marketing of biological products regulated by FDA. In addition to new legislation, FDA regulations, guidance documents, and policies are often revised or interpreted by the agency in ways that may significantly affect the regulation of biological products in the United States. It is impossible to predict whether further legislative changes will be enacted or whether FDA regulations, guidance, policies, or interpretations will change, and the effects of any such changes.

Preclinical and Clinical Development

Before an applicant can begin testing the potential product candidate in human subjects, the applicant must first conduct preclinical studies. Preclinical studies may include laboratory evaluations of product chemistry, toxicity, and formulation, as well as in vitro and animal studies to assess the potential safety and activity of the drug for initial testing in humans and to establish a rationale for therapeutic use. Preclinical studies are subject to federal regulations and requirements, including GLP regulations, which govern the conduct of animal studies designed to test a product's safety. None of our preclinical studies to date have been animal studies. The results of an applicant's preclinical studies are submitted to FDA as part of an IND.

An IND is a request for authorization from FDA to administer an investigational new drug product to humans. An IND is an exemption from the FDCA that allows an unapproved drug to be shipped in interstate commerce for use in a clinical trial. Such authorization must be secured prior to interstate shipment and administration of a biological drug that is not subject of an approved BLA. In support of an IND, applicants must submit a protocol for each clinical trial, which details, among other things, the objectives of the trial, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. A separate submission to the existing IND must be made for each successive clinical trial conducted during product development and for any subsequent protocol amendments.

Human clinical trials may not begin until an IND is effective. The IND automatically becomes effective 30 days after receipt by FDA, unless FDA raises safety concerns or questions about the proposed clinical trial within the 30-day time period. In such a case, FDA may place the IND on clinical hold and the IND sponsor must resolve any of FDA's outstanding concerns or questions before the clinical trial can begin. Submission of an IND therefore may or may not result in regulatory authorization to begin a clinical trial.

FDA may also place a clinical hold or partial clinical hold on a clinical trial following commencement of the trial under an IND. A clinical hold is an order issued by FDA to the sponsor to delay a proposed clinical investigation or to suspend an ongoing investigation. A partial clinical hold is a delay or suspension of only part of the clinical work requested under the IND. For example, under a partial clinical hold, FDA may instruct a sponsor not to enroll any new patients into a study but permit the previously enrolled patients to continue in the study. No more than 30 days after imposition of a clinical hold or partial clinical hold, FDA will provide the sponsor a written explanation of the basis for the hold. Following issuance of a clinical hold or partial clinical hold, an investigation may only resume after the FDA has notified the sponsor that the investigation may proceed. FDA will base that determination on information provided by the sponsor addressing the deficiencies previously cited or otherwise satisfying FDA that the investigation can proceed.

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with GCP regulations, which include the requirement that all research subjects provide their informed consent for their participation in any clinical trial. If a sponsor chooses to conduct a foreign clinical study under an IND, all FDA IND requirements must be met unless waived. When the foreign clinical study is not conducted under an IND, the sponsor must ensure that the study complies with GCP regulations in order to use the study as support for an IND or application for marketing approval, including review and approval by an IRB and informed consent from subjects.

Furthermore, an independent IRB for all sites participating in a clinical trial must review and approve the plan for any clinical trial and its informed consent form before the clinical trial begins at each site and must monitor the trial until completed. Regulatory authorities, the IRB, or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk or that the trial is unlikely to meet its stated objectives.

Some trials also include oversight by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board ("DSMB"). DSMBs review unblinded study data at pre-specified times during the course of the study. If the DSMB determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy, the DSMB can make a recommendation to the sponsor to modify or stop the trial.

Other grounds for a sponsor's decision to suspend or terminate a study may be made based on evolving business objectives or the competitive climate.

For purposes of BLA approval, clinical trials are typically conducted in the following sequential phases:

● Phase 1: The investigational product is initially introduced into a small group of healthy human subjects or patients with the target disease or condition. These trials are designed to test the safety, dosage tolerance, absorption, metabolism and distribution of the investigational product in humans and the side effects associated with increasing doses. These trials may also yield early evidence of effectiveness.

● Phase 2: The investigational product is administered to a slightly larger patient population with a specified disease or condition to evaluate the preliminary efficacy, optimal dosages, and dosing schedule and to identify possible adverse side effects and safety risks. Multiple Phase 2 clinical trials may be conducted to obtain information prior to beginning larger and more expensive Phase III clinical trials.

● Phase 3: The investigational product is administered to an expanded patient population to further evaluate dosage, to provide statistically significant evidence of clinical efficacy and to further test for safety, generally at multiple geographically dispersed clinical trial sites. These clinical trials are intended to generate sufficient data to statistically demonstrate the efficacy and safety of the product, to establish the overall risk/benefit ratio of the investigational product, and to provide an adequate basis for product approval by FDA.

These phases may overlap or be combined. In some cases, FDA may require, or companies may voluntarily pursue, additional clinical trials after a product are approved to gain more information about the product, referred to as Phase 4 trials. Post-approval trials are conducted following initial approval, often to develop additional data and information relating to the use of the product in new indications.

Progress reports detailing the results of the clinical trials must be submitted at least annually to FDA. In addition, IND safety reports must be submitted to FDA for any of the following: serious and unexpected suspected adverse reactions in study subjects; findings from epidemiological studies, pooled analysis of multiple studies, animal or in vitro testing, or other clinical studies, whether or not conducted under an IND, and whether or not conducted by the sponsor, that suggest a significant risk in humans exposed to the drug; and any clinically important increase in the rate of a serious suspected adverse reaction over such rate listed in the protocol or investigator brochure.

A sponsor's planned clinical trials may not be completed successfully within any specified period, or at all. Furthermore, the FDA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution, or an institution it represents, if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients. FDA will typically inspect one or more clinical sites to assure compliance with GCP and the integrity of the clinical data submitted.

During clinical development, the sponsor often refines the indication and endpoints on which the BLA will be based. For endpoints based on patient-reported outcomes ("PROs"), the process typically is an iterative one. FDA has issued guidance on the framework it uses to evaluate PRO instruments. Although the agency may offer advice on optimizing PRO instruments during the clinical development process, FDA usually reserves final judgment until it reviews the BLA.

Concurrent with clinical trials, companies often complete additional animal studies, and develop additional information about the chemistry and physical characteristics of the drug and finalize a process for manufacturing the product in commercial quantities in accordance with cGMP. The manufacturing process must be capable of consistently producing quality batches of the drug candidate and, among other things, must develop methods for testing the identity, strength, quality, purity and potency of the final drug. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the drug candidate does not undergo unacceptable deterioration over its shelf life.

BLA Submission and Review

Assuming successful completion of all required clinical testing in accordance with all applicable regulatory requirements, an applicant may submit a BLA requesting licensing to market the biologic for one or more indications in the United States. The BLA must include the results of nonclinical studies and clinical trials; detailed information on the product's chemistry, manufacture, controls; and proposed labeling. Under the PDUFA, a BLA submission is subject to an application user fee, unless a waiver, reduction, or exemption applies.

FDA will initially review the BLA for completeness before accepting it for filing. Under FDA's procedures, the agency has 60 days from its receipt of a BLA to determine whether the application will be accepted for filing and substantive review. If the agency determines that the application does not meet this initial threshold standard, FDA may refuse to file the application and request additional information, in which case the application must be resubmitted with the requested information and review of the application delayed.

After the BLA is accepted for filing, FDA reviews the BLA to determine, among other things, whether a product is safe, pure, and potent and if the facility in which it is manufactured, processed, packed, or held meets standards designed to assure the product's continued identity, strength, quality, safety, purity, and potency. To ensure cGMP, GLP, GCP, GTP, and other regulatory compliance, an applicant must incur significant expenditure of time, money, and effort in the areas of training, record keeping, production and quality control. In addition, FDA expects that all data be reliable and accurate, and requires sponsors to implement meaningful and effective strategies to manage data integrity risks. Data integrity is an important component of the sponsor's responsibility to ensure the safety, efficacy and quality of its product or products.

For cellular products, FDA will not approve the product if the manufacturer is not in compliance with the GTPs, to the extent applicable. GTPs are FDA regulations and guidance documents that govern the methods used in, and the facilities and controls used for, the manufacture of human cells, tissue, and cellular and tissue-based products ("HCT/Ps"), which are human cells or tissue intended for implantation, transplant, infusion, or transfer into a human recipient. The primary intent of the GTP requirements is to ensure that cell and tissue-based products are manufactured in a manner designed to prevent the introduction, transmission and spread of communicable disease. FDA regulations also specify how HCT/P establishments must register and list their HCT/Ps with FDA and how they must evaluate donors through screening and testing, where applicable.

If the FDA determines that the application, manufacturing process or manufacturing facilities are not acceptable, it will outline the deficiencies in the submission and often will request additional testing or information. Notwithstanding the submission of any requested additional information, FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

The performance goals and policies implemented by FDA under the PDUFA generally provide for FDA action on an original BLA within 10 months of filing, which (as discussed above) typically occurs within 60 days of submission, but that deadline is extended in certain circumstances. Furthermore, the review process is often significantly extended by FDA's requests for additional information or clarification.

FDA may refer applications for novel products or products that present difficult questions of safety or efficacy to an advisory committee. Typically, an advisory committee consists of a panel that includes clinicians and other experts who will review, evaluate, and provide a recommendation as to whether the application should be approved and, if so, under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions and usually has followed such recommendations.

After FDA evaluates a BLA and conducts inspections of manufacturing facilities where the investigational product and/or its components will be produced, FDA may issue an approval letter or a Complete Response Letter ("CRL"). An approval letter authorizes commercial marketing of the biological with specific prescribing information for specific indications. A CRL will describe all of the deficiencies that FDA has identified in the BLA, except that where FDA determines that the data supporting the application are inadequate to support approval, FDA may issue the CRL without first conducting required inspections, testing submitted product lots and/or reviewing proposed labeling. If and when the deficiencies have been addressed to FDA's satisfaction in a resubmission of the BLA, FDA will issue an approval letter. In issuing the CRL, the FDA may recommend actions that the applicant might take to place the BLA in condition for approval, including requests for additional data, information, or clarification. FDA may delay or refuse approval of a BLA if applicable regulatory criteria are not satisfied and may require additional testing or information and/or require new clinical trials. Even with submission of this additional information, FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

During the approval process, FDA will determine whether a REMS is necessary to help ensure the benefits outweigh the risks of the biologic. A REMS is a safety strategy to manage a known or potential serious risk associated with a product and to enable patients to have continued access to such medicines by managing their safe use, and could include medication guides, physician communication plans or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. If FDA concludes that a REMS is needed, the BLA sponsor must submit a proposed REMS and FDA will not approve the BLA without a REMS that the agency has determined is acceptable.

If the FDA approves a product, it may limit the approved indications for use for the product, or require that contraindications, warnings, or precautions be included in the product labeling. FDA may also require that post-approval studies, including Phase 4 clinical trials, be conducted to further assess the drug's safety after approval. FDA may prevent or limit further marketing of a product based on the results of post-market studies or surveillance programs.

FDA may also require testing and surveillance programs to monitor the product after commercialization. For biologics, such testing may include official lot release, which requires the manufacturer to perform certain tests on each lot of the product before it is released for distribution. The manufacturer then typically must submit samples of each lot of products to the FDA, together with a release protocol showing a summary of the history of manufacture of the lot and the results of all of the manufacturer's tests performed on the lot. The FDA may also perform certain confirmatory tests on lots of some products itself, before releasing the lots for distribution by the manufacturer.

In general, an approved BLA only allows the sponsor to market the biologic as approved, without modification. If, for example, a sponsor modifies an approved T cell product to target different peptides or in our case to target another HLA type, the sponsor would be required to either file a supplemental BLA with FDA or receive FDA approval for a comparability protocol in order to implement this change into the final product.

The FDA may withdraw the product approval if compliance with pre- and post-marketing requirements is not maintained or if problems occur after the product reaches the marketplace.

Post-Approval Requirements

Any products manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by FDA, including, among other things, requirements relating to recordkeeping, periodic reporting, reporting of certain deviations and adverse experiences, product sampling and distribution, and advertising and promotion of the product. After approval, many types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are often subject to further testing requirements and FDA review and approval, depending on the nature of the post-approval change. There also are continuing user fee requirements, under which FDA assesses an annual program fee for each product identified in an approved BLA. Biologic manufacturers and their third-party contractors are required to register their facilities with the FDA and certain state agencies. These facilities are subject to routine and periodic unannounced inspections by FDA and certain state agencies for compliance with cGMP, post-marketing safety reporting and data integrity requirements, which impose certain procedural and documentation requirements to assure quality of manufacturing and product. FDA has increasingly observed cGMP violations involving data integrity during site inspections and is a significant focus of its oversight. Requirements with respect to data integrity include, among other things, controls ensuring complete and secure data; activities documented at the time of performance; audit trail functionality; authorized access and limitations; validated computer systems; and review of records for accuracy, completeness, and compliance with established standards.

Post-approval changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting requirements upon the sponsor and any third-party manufacturers that the sponsor may use. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain compliance with cGMP, data integrity, pharmacovigilance, and other aspects of regulatory compliance.

The FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-approval studies to assess new safety risks; or imposition of distribution or other restrictions under a REMS. Other potential consequences include, for example:

- restrictions on the marketing or manufacturing of a product, complete withdrawal of the product from the market, or product recalls;
- fines, warning or untitled letters, or holds on post-approval clinical studies;
- refusal of FDA to approve pending applications or supplements to approved applications, or suspension or revocation of existing product approvals;
- product seizure or detention, or refusal of FDA to permit the import or export of products; or
- permanent injunctions and consent decrees, including the imposition of civil or criminal penalties.

FDA strictly regulates the marketing, labeling, advertising, and promotion of prescription drug products placed on the market. A company can make only those claims relating to safety and efficacy, purity and potency that are approved by the FDA and in accordance with the provisions of the approved labeling. FDA's regulation includes, among other things, standards and regulations for direct-to-consumer advertising, communications regarding unapproved uses, industry-sponsored scientific and educational activities and promotional activities involving the Internet and social media. Promotional claims relating to a product's safety or effectiveness are prohibited before the drug is approved. After approval, a product generally may not be promoted for uses that are not approved by FDA, as reflected in the product's prescribing information. In the United States, healthcare professionals are generally permitted to prescribe drugs for such uses not described in the drug's labeling, known as off-label uses, because FDA does not regulate the practice of medicine. However, FDA regulations impose rigorous restrictions on manufacturers' communications and prohibit the promotion of off-label uses. It may be permissible, under very specific, narrow conditions, for a manufacturer to engage in non-promotional, non-misleading communication regarding off-label information, such as distributing scientific or medical journal information.

If a company is found to have promoted off-label uses, it may become subject to adverse public relations and administrative and judicial enforcement by FDA, the DOJ, or the Office of the Inspector General of the Department of Health and Human Services ("HHS"), as well as other federal and state authorities. This could subject a company to a range of penalties that could have a significant commercial impact, including civil, administrative, and criminal fines, penalties, and agreements that materially restrict the manner in which a company promotes or distributes products. The federal government has levied large civil, administrative, and criminal fines and penalties against companies for alleged improper promotion and has also requested that companies enter into Corporate Integrity Agreements and Consent Decrees of Permanent Injunction under which specified promotional conduct is changed or curtailed.

The distribution of prescription drugs and biologics are subject to the Drug Supply Chain Security Act ("DSCSA"), which requires manufacturers and other stakeholders to comply with product identification, tracing, verification, detection and response, notification, and licensing requirements. In addition, the Prescription Drug Marketing Act and its implementing regulations and state laws limit the distribution of prescription pharmaceutical product samples, and the DSCSA imposes requirements to ensure accountability in distribution and to identify and remove prescription drug and biological products that may be counterfeit, stolen, contaminated, or otherwise harmful from the market.

Expedited Development and Review Programs

FDA offers a number of expedited development and review programs for qualifying product candidates. The fast-track program is intended to expedite or facilitate the process of reviewing new products that meet certain criteria. Specifically, new products are eligible for fast-track designation if they are intended to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. A product intended to treat a serious or life-threatening disease or condition may also be eligible for breakthrough therapy designation to expedite its development and review. Any marketing application for a biologic submitted to FDA for approval, including a product with a fast-track designation and/or breakthrough therapy designation, may be eligible for other types of FDA programs intended to expedite FDA review and approval process, such as priority review and accelerated approval. FDA also may grant accelerated approval to certain products studied for their safety and effectiveness in treating serious or life-threatening diseases or conditions.

The RMAT designation, which we are currently planning to seek for some of our therapies, is intended to facilitate an efficient development program for, and expedite review of, any drug that meets the following criteria: (1) the drug is a cell therapy, therapeutic tissue engineering product, human cell and tissue product, or any combination product using such therapies or products, with limited exceptions; (2) the drug is intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition; and (3) preliminary clinical evidence indicates that the drug has the potential to address unmet medical needs for such a disease or condition. Like breakthrough therapy designation, RMAT designation provides potential benefits that include more frequent meetings with FDA to discuss the development plan for the product candidate and eligibility for rolling review and priority review. Products granted RMAT designation may also be eligible for accelerated approval on the basis of a surrogate or intermediate endpoint reasonably likely to predict long-term clinical benefit, or reliance upon data obtained from a meaningful number of sites (including through expansion to additional sites) so as to remove any likelihood of site-specific or investigator-specific bias on the evidence of effectiveness. Once approved, when appropriate, FDA can permit fulfillment of post-approval requirements for RMATs receiving accelerated approval through the submission of clinical evidence, clinical studies, patient registries, or other sources of real-world evidence such as electronic health records; through the collection of larger confirmatory datasets; or through post-approval monitoring of all patients treated with the therapy prior to approval.

Fast track designation, breakthrough therapy designation, priority review, accelerated approval, and RMAT designation do not change the standards for approval but may expedite the development or approval process.

Patent Term Restoration and Marketing Exclusivity

After approval, owners of relevant drug or biological product patents may apply for up to a five year term patent extension to restore a portion of patent term lost during product development and FDA review of a BLA if approval of the application is the first permitted commercial marketing or use of a drug or biologic containing the active ingredient under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Act. The allowable patent term extension is calculated as one-half of the product's testing phase, which is the time between the effective date of an IND and initial BLA submission, and all of the approval phase, which is the time between BLA submission and approval, up to a maximum of five years. The time can be shortened if the FDA determines that the applicant did not pursue approval with due diligence. The total patent term after the extension may not exceed 14 years from the date of FDA approval of the product. Only one patent claiming each approved product is eligible for restoration and the patent holder must apply for restoration within 60 days of approval, even if the product cannot be commercially marketed at that time. The USPTO, in consultation with FDA, reviews and approves the application for patent term restoration.

For patents that might expire during the BLA application phase, the patent owner may request an interim patent extension. An interim patent extension increases the patent term by one year and may be renewed up to four times. For each interim patent extension granted, the post-approval patent extension is reduced by one year. The director of the USPTO must determine that approval of the product candidate covered by the patent for which a patent extension is being sought is likely. Interim patent extensions are not available for a product candidate for which a BLA has not been submitted.

Biosimilars and Marketing Exclusivities

The Biologics Price Competition and Innovation Act ("BPCIA") created an abbreviated approval pathway for biological product candidates shown to be highly similar to or interchangeable with an FDA licensed biological product. A biological product on which another biological product candidate's BLA relies to establish bio similarity is known as a reference product. Bio similarity sufficient to reference a prior FDA-approved product requires that there be no differences in conditions of use, route of administration, dosage form and strength, and no clinically meaningful differences between the biological product candidate and the reference product in terms of safety, purity, and potency. Bio similarity must be shown through analytical trials, animal trials and at least one clinical trial, unless the Secretary of HHS waives a required element. A biosimilar product candidate may be deemed interchangeable with a prior approved product if it meets the higher hurdle of demonstrating that it can be expected to produce the same clinical results as the reference product and, for products administered multiple times, the biological product candidate and the reference biologic may be switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic. Complexities associated with the larger, and often more complex, structures of biologics, as well as the process by which such products are manufactured, pose significant hurdles to implementation of the abbreviated approval pathway that are still being resolved by FDA.

A reference biologic is granted 12 years of exclusivity from the time of first licensure of the reference product, and no application for a biosimilar can be submitted for four years from the date of licensure of the reference product. The first biological product candidate submitted under the abbreviated approval pathway that is determined to be interchangeable with the reference product has exclusivity against a finding of interchangeability for other biologics for the same condition of use for the lesser of (i) one year after first commercial marketing of the first interchangeable biosimilar, (ii) 18 months after the first interchangeable biosimilar is approved if there is no patent challenge, (iii) 18 months after resolution of a lawsuit over the patents of the reference biologic in favor of the first interchangeable biosimilar applicant, or (iv) 42 months after the first interchangeable biosimilar's application has been approved if a patent lawsuit is ongoing within the 42 month period. At this time, it is unclear whether products deemed "interchangeable" by FDA will, in fact, be readily substituted by pharmacies, which are governed by state pharmacy laws and regulations.

Healthcare Regulation

Coverage, Pricing, and Reimbursement

Our ability to successfully commercialize any products for which we receive regulatory approval for commercial sale will depend, in part, on the extent to which third-party payors provide coverage and establish adequate reimbursement levels for such products, and significant uncertainty exists as to the coverage and reimbursement status of any products for which may we obtain regulatory approval. In the United States, third-party payors include federal and state health care programs, private managed care providers, health insurers and other organizations. The process for determining whether a third-party payor will provide coverage for a product may be separate from the process for setting the price of a product or for establishing the reimbursement rate that such a payor will pay for the product. Third-party payors may limit coverage to specific products on an approved list, also known as a formulary, which might not include all of the FDA-approved products for a particular indication. Third-party payors are increasingly challenging the price, examining the medical necessity, and reviewing the cost-effectiveness of medical products, therapies, and services, in addition to questioning their safety and efficacy. We may need to conduct expensive pharmaco-economic studies in order to demonstrate the medical necessity and cost-effectiveness of our products, in addition to the costs required to obtain the FDA approvals. Our product candidates may not be considered medically necessary or cost-effective. A payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Further, one payor's determination to provide coverage for a product does not assure that other payors will also provide coverage for the product. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development.

The marketability of any product candidates for which we receive regulatory approval for commercial sale may suffer if the government and third-party payors fail to provide adequate coverage and reimbursement. In addition, emphasis on managed care in the United States has increased and we expect will continue to increase the pressure on healthcare pricing. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Other Healthcare Laws and Compliance Requirements

Although we currently do not have any commercialized products, our current and future business operations may be subject to additional healthcare regulation and enforcement by the federal government and by authorities in the states and foreign jurisdictions in which we conduct our business. Such laws include, without limitation, state and federal anti-kickback, fraud and abuse, false claims, privacy and security, price reporting and physician sunshine laws. Some of our pre-commercial activities are subject to some of these laws.

The federal Anti-Kickback Statute makes it illegal for any person or entity, including a prescription drug manufacturer or a party acting on its behalf to knowingly and willfully, directly or indirectly, solicit, receive, offer, or pay any remuneration in cash or in kind that is intended to induce or reward the referral of business, including the purchase, order, or lease of any item or service for which payment may be made under a federal healthcare program, such as Medicare or Medicaid. The term "remuneration" has been broadly interpreted to include anything of value. The Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand and prescribers, purchasers, formulary managers and beneficiaries on the other.

Although there are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, the exceptions and safe harbors are drawn narrowly. Practices that involve remuneration that may be alleged to be intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all its facts and circumstances. Several courts have found that the Anti-Kickback Statute may be violated if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare program business. In addition, liability may be established without actual knowledge of the statute or specific intent to violate it. Violations of this law are punishable by up to ten years in prison, and can also result in criminal fines, civil money penalties and exclusion from participation in federal healthcare programs.

Moreover, a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act.

The federal civil False Claims Act prohibits, among other things, individuals or entities from knowingly presenting, or causing to be presented, a false or fraudulent claim for payment of government funds or knowingly making, using, or causing to be made or used, a false record or statement material to an obligation to pay money to the government or knowingly concealing or knowingly and improperly avoiding, decreasing, or concealing an obligation to pay money to the federal government. Persons and entities can be held liable under these laws if they are deemed to "cause" the submission of false or fraudulent claims by, for example, providing inaccurate billing or coding information to customers or promoting a product off-label. Many pharmaceutical and other healthcare companies have been investigated and have reached substantial financial settlements with the federal government under the civil False Claims Act for a variety of alleged improper marketing activities, including: providing free product to customers with the expectation that the customers would bill federal programs for the product; providing sham consulting fees, grants, free travel and other benefits to physicians to induce them to prescribe the company's products; and inflating prices reported to private price publication services, which are used to set drug payment rates under government healthcare programs. Penalties for federal civil False Claims Act violations may include up to three times the actual damages sustained by the government, plus mandatory civil penalties of between $13,508 and $27,018 for each separate false claim, and the potential for exclusion from participation in federal healthcare programs. In addition, although the federal False Claims Act is a civil statute, False Claims Act violations may also implicate various federal criminal statutes.

The healthcare fraud provisions of the Health Insurance Portability and Accountability Act ("HIPAA") prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Like the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

Many states have analogous laws and regulations, such as: state anti-kickback and false claims laws that may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to certain healthcare providers; laws that require drug manufacturers to report information related to clinical trials or information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; laws that restrict the ability of manufacturers to offer co-pay support to patients for certain prescription drugs; and laws and local ordinances that require identification or licensing of sales representatives.

HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act ("HITECH"), and their implementing regulations, mandates, among other things, the adoption of uniform standards for the electronic exchange of information in common healthcare transactions, as well as standards relating to the privacy and security of individually identifiable health information, which require the adoption of administrative, physical and technical safeguards to protect such information. Among other things, HITECH makes HIPAA's security standards directly applicable to business associates, defined as independent contractors or agents of covered entities that create, receive, or obtain protected health information in connection with providing a service for or on behalf of a covered entity. HITECH also increased the civil and criminal penalties that may be imposed against covered entities and business associates and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorney's fees and costs associated with pursuing federal civil actions. In addition, certain state laws govern the privacy and security of health information in certain circumstances, some of which are more stringent than HIPAA and many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. Failure to comply with these laws, where applicable, can result in the imposition of significant civil and/or criminal penalties.

The U.S. federal Physician Payment Sunshine Act, implemented as the Open Payments Program, requires manufacturers of drugs, devices, biologics, and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to CMS information related to direct or indirect payments and other transfers of value to physicians and teaching hospitals (and certain other practitioners as of 2022), as well as ownership and investment interests held in the company by physicians and their immediate family members.

Because we intend to commercialize products that could be reimbursed under a federal health care program and other governmental healthcare programs, we intend to develop a comprehensive compliance program that establishes internal control to facilitate adherence to the rules and program requirements to which we will or may become subject. Although the development and implementation of compliance programs designed to establish internal control and facilitate compliance can mitigate the risk of investigation, prosecution, and penalties assessed for violations of these laws, the risks cannot be entirely eliminated.

If our operations are found to be in violation of any of such laws or any other governmental regulations that apply to us, we may be subject to penalties, including, without limitation, administrative, civil and criminal penalties, damages, fines, disgorgement, contractual damages, reputational harm, diminished profits and future earnings, the curtailment or restructuring of our operations, exclusion from participation in federal and state healthcare programs and individual imprisonment, any of which could adversely affect our ability to operate our business and our financial results.

Health Care Reforms

In the United States and some foreign jurisdictions, there have been, and continue to be, legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of product candidates, restrict or regulate post-approval activities, and affect the ability to profitably sell product candidates for which marketing approval is obtained. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives.

For example, the Affordable Care Act ("ACA") substantially changed the way healthcare is financed by both the government and private insurers, and significantly impacts the U.S. pharmaceutical industry. The ACA contains provisions that may reduce the profitability of drug products through increased rebates for drugs reimbursed by Medicaid programs, extension of Medicaid rebates to Medicaid managed care plans, mandatory discounts for certain Medicare Part D beneficiaries, and annual fees based on pharmaceutical companies' share of sales to federal health care programs. The ACA made several changes to the Medicaid Drug Rebate Program, including increasing pharmaceutical manufacturers' rebate liability by raising the minimum basic Medicaid rebate. The ACA also expanded the universe of Medicaid utilization subject to drug rebates by requiring pharmaceutical manufacturers to pay rebates on Medicaid managed care utilization and by enlarging the population potentially eligible for Medicaid drug benefits.

There have been judicial challenges to certain aspects of the ACA, as well as efforts by Congress to modify, and by agencies to alter the implementation of, certain aspects of the ACA. For example, Congress eliminated the tax penalty for failure to comply with the ACA's individual mandate to carry health insurance. Further, the Bipartisan Budget Act of 2018, among other things, amended the ACA to increase from 50 percent to 70 percent the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D to close the coverage gap in most Medicare drug plans, commonly referred to as the donut hole.

It is possible that the ACA, as currently enacted or as may be amended in the future, as well as other healthcare reform measures, including those that may be adopted in the future, may result in more rigorous coverage criteria, and less favorable payment methodologies, or other downward pressure on coverage and payment and the price that we receive for any approved product. Any reduction in reimbursement or restriction on coverage under Medicare or other federal health care programs may result in a similar reduction or restriction by private payors.

Other legislative changes have been proposed and adopted in the U.S. since the ACA was enacted. For example, the Inflation Reduction Act introduces several changes to the Medicare Part D benefit, including a limit on annual out-of-pocket costs and a change in manufacturer liability under the program which could negatively affect the profitability of our product candidates. The IRA sunsets the current Part D coverage gap discount program starting in 2025 and replaces it with a new manufacturer discount program. Failure to pay a discount under this new program will be subject to a civil monetary penalty. In addition, the IRA establishes a Medicare Part B inflation rebate scheme effective January 2023 and a Medicare Part D inflation rebate scheme effective October 2022, under which, generally speaking, manufacturers will owe rebates if the price of a Part B or Part D drug increases faster than the pace of inflation. Failure to timely pay a Part B or D inflation rebate is subject to a civil monetary penalty. The IRA also creates a drug price negotiation program under which the prices for Medicare units of certain high Medicare spend drugs and biologicals without generic or biosimilar competition will be capped by reference to, among other things, a specified non-federal average manufacturer price starting in 2026. Failure to comply with requirements under the drug price negotiation program is subject to an excise tax and/or a civil monetary penalty. Congress continues to examine various policy proposals that may result in pressure on the prices of prescription drugs with respect to the government health benefit programs and otherwise. The IRA or other legislative changes could impact the market conditions for our product candidates.

In general, there has been heightened governmental scrutiny over the manner in which drug manufacturers set prices for their commercial products, which has resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

Drug Pedigree Laws

State and federal governments have proposed or enacted various drug pedigree laws which can require the tracking of all transactions involving prescription drugs from the manufacturer to the pharmacy (or other dispensing) level. Companies are required to maintain records documenting the chain of custody of prescription drug products beginning with the purchase of such products from the manufacturer. Compliance with these pedigree laws requires implementation of extensive tracking systems as well as heightened documentation and coordination with customers and manufacturers. While we fully intend to comply with these laws, there is uncertainty about future changes in legislation and government enforcement of these laws. Failure to comply could result in fines or penalties, as well as loss of business that could have a material adverse effect on our financial results.

Federal Regulation of Patent Litigation Settlements and Authorized Generic Arrangements

As part of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, companies are required to file with the U.S. Federal Trade Commission ("FTC") and the U.S. Department of Justice certain types of agreements entered into between brand and generic pharmaceutical companies related to the settlement of patent litigation or manufacture, marketing and sale of generic versions of branded drugs. This requirement could affect the manner in which generic drug manufacturers resolve intellectual property litigation and other disputes with brand pharmaceutical companies and could result generally in an increase in private-party litigation against pharmaceutical companies or additional investigations or proceedings by the FTC or other governmental authorities.

Other

The U.S. federal government, various states and localities have laws regulating the manufacture and distribution of pharmaceuticals, as well as regulations dealing with the substitution of generic drugs for branded drugs. Our operations are also subject to regulation, licensing requirements and inspection by the states and localities in which our operations are located or in which we conduct business.

Certain of our activities are also subject to FTC enforcement actions. The FTC enforces a variety of antitrust and consumer protection laws designed to ensure that the nation's markets function competitively, are vigorous, efficient and free of undue restrictions. Federal, state, local and foreign laws of general applicability, such as laws regulating working conditions, also govern us.

In addition, we are subject to numerous and increasingly stringent federal, state and local environmental laws and regulations concerning, among other things, the generation, handling, storage, transportation, treatment and disposal of toxic and hazardous substances, the discharge of pollutants into the air and water and the cleanup of contamination. We are required to maintain and comply with environmental permits and controls for some of our operations, and these permits are subject to modification, renewal and revocation by the issuing authorities. Our environmental capital expenditures and costs for environmental compliance may increase in the future as a result of changes in environmental laws and regulations or increased manufacturing activities at any of our facilities. We could incur significant costs or liabilities as a result of any failure to comply with environmental laws, including fines, penalties, third-party claims and the costs of undertaking a clean-up at a current or former site or at a site to which our wastes were transported. In addition, we have grown in part by acquisition, and our diligence may not have identified environmental impacts from historical operations at sites we have acquired in the past or may acquire in the future.

Employees

As of the date of this prospectus supplement, we have nine (9) full time employees. We have no part-time employees. We believe that we maintain good relations with our employees.

USE OF PROCEEDS

We expect the net proceeds to us from this offering after deducting commissions and estimated offering expenses to be approximately $2.85 million. We intend to use the net proceeds from the sale of the Securities offered by this prospectus supplement to repay approximately $1,341,288 of outstanding indebtedness under the Bridge Notes, which bear interest at a rate of 8% per annum and mature on April 14, 2027, with the remainder to be used for general corporate and working capital purposes.

DESCRIPTION OF SECURITIES WE ARE OFFERING

In this offering, we are offering shares of our Common Stock and Pre-Funded Warrants to purchase shares of our Common Stock.

Authorized Capital Stock

Our authorized capital stock consists of 250,000,000 shares of Common Stock, par value $0.001 per share, and 10,000,000 shares of preferred stock, par value $0.001 per share, the rights and preferences of which may be established from time to time by our Board. As of the date of this prospectus supplement, we had 848,629 shares of Common Stock outstanding and 46,312 shares of preferred stock outstanding, consisting of 46,312 shares of Preferred Stock.

Common Stock

Voting

For all matters submitted to a vote of stockholders, each holder of Common Stock is entitled to one vote for each share registered in his or her name on our books. Our Common Stock does not have cumulative voting rights. As a result, holders of a majority of our outstanding Common Stock can elect all of the directors who are up for election in a particular year.

Dividends

If our board of directors declares a dividend, holders of Common Stock will receive payments from our funds that are legally available to pay dividends. However, this dividend right is subject to any preferential dividend rights we may grant to the persons who hold Preferred Stock, if any is outstanding.

Liquidation and Dissolution

If we are liquidated or dissolve, the holders of our Common Stock will be entitled to the right to receive ratably, all of the assets and funds that remain after we pay our liabilities and any amounts we may owe to the persons who hold Preferred Stock, if any is outstanding.

Other Rights and Restrictions

Holders of our Common Stock do not have preemptive or subscription rights, and they have no right to convert their Common Stock into any other securities. Our Common Stock is not subject to redemption by us. The rights, preferences and privileges of common stockholders are subject to the rights of the stockholders of any series of Preferred Stock which we may designate in the future. Our Certificate of Incorporation and our Bylaws do not restrict the ability of a holder of Common Stock to transfer his or her shares of Common Stock.

Market, Symbol and Transfer Agent

Our Common Stock is listed for trading on the Nasdaq Capital Market under the symbol “GCTK”. The transfer agent and registrar for our Common Stock is VStock Transfer, LLC, 18 Lafayette Pl, Woodmere, NY 11598, and its telephone number is (212) 828-8436.

Pre-Funded Warrants

The following summary of certain terms and provisions of the Pre-Funded Warrants that are being offered hereby is not complete and is subject to, and qualified in its entirety by, the provisions of the Pre-Funded Warrant, the form of which will be filed as an exhibit to a Current Report on Form 8-K filed with the SEC in connection with this offering. Prospective investors should carefully review the terms and provisions of the form of Pre-Funded Warrant for a complete description of the terms and conditions of the Pre-Funded Warrants.

General

The term "pre-funded" refers to the fact that the purchase price of the Pre-Funded Warrants in this offering includes almost the entire exercise price that will be paid under the Pre-Funded Warrants, except for a nominal remaining exercise price of $0.001. The purpose of the Pre-Funded Warrants is to enable investors that may have restrictions on their ability to beneficially own more than 4.99% (or, at the election of the holder, 9.99%) of our outstanding Common Stock following the consummation of this offering the opportunity to invest capital into the Company without triggering their ownership restrictions, by receiving Pre-Funded Warrants in lieu of shares of our Common Stock which would result in such ownership of more than 4.99% (or, at the election of the holder, 9.99%), and receiving the ability to exercise their option to purchase the shares underlying the Pre-Funded Warrants at a nominal price at a later date.

Form

The Pre-Funded Warrants will be issued as individual warrant agreements to the investors. You should review the form of Pre-Funded Warrant, filed as an exhibit to a Current Report on Form 8-K filed with the SEC in connection with this offering, for a complete description of the terms and conditions applicable to the Pre-Funded Warrants.

Exercisability

The Pre-Funded Warrants are exercisable at any time after their original issuance. The Pre-Funded Warrants will be exercisable, at the option of each holder, in whole or in part, by delivering to us a duly executed exercise notice accompanied by payment in full in immediately available funds for the number of shares of our Common Stock purchased upon such exercise (except in the case of a cashless exercise as described below). A holder (together with its affiliates) may not exercise any portion of the Pre-Funded Warrant to the extent that the holder would own more than 4.99% (or, at the election of the holder, 9.99%) of the outstanding Common Stock immediately after exercise, except that upon at least 61 days' prior notice from the holder to us, the holder may increase the amount of ownership of outstanding stock after exercising the holder's Pre-Funded Warrants up to 9.99% of the number of shares of our Common Stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the Pre-Funded Warrants. Purchasers of Pre-Funded Warrants in this offering may also elect prior to the issuance of the Pre-Funded Warrants to have the initial exercise limitation set at 9.99% of our outstanding Common Stock. No fractional shares of Common Stock will be issued in connection with the exercise of a Pre-Funded Warrant. In lieu of fractional shares, we will pay the holder an amount in cash equal to the fractional amount multiplied by the exercise price.

Duration and Exercise Price

The exercise price per whole share of our Common Stock purchasable upon the exercise of the Pre-Funded Warrants is $0.001 per share of Common Stock. The Pre-Funded Warrants will be immediately exercisable and may be exercised at any time until the Pre-Funded Warrants are exercised in full. The exercise price of the Pre-Funded Warrants is subject to appropriate adjustment in the event of certain stock dividends and distributions, stock splits, stock combinations, reclassifications or similar events affecting our Common Stock and also upon any distributions of assets, including cash, stock or other property to our stockholders.

Cashless Exercise

If, at any time after the issuance of the Pre-Funded Warrants, the holder exercises its Pre-Funded Warrants and a registration statement registering the issuance of the shares of Common Stock underlying the Pre-Funded Warrants under the Securities Act is not then effective or available (or a prospectus is not available for the resale of shares of Common Stock underlying the Pre-Funded Warrants), then in lieu of making the cash payment otherwise contemplated to be made to us upon such exercise in payment of the aggregate exercise price, the holder shall instead receive upon such exercise (either in whole or in part) only the net number of shares of Common Stock determined according to a formula set forth in the Pre-Funded Warrants. Notwithstanding anything to the contrary, in the event we do not have or maintain an effective registration statement, there are no circumstances that would require us to make any cash payments or net cash settle the Pre-Funded Warrants to the holders.

Transferability

Subject to applicable laws, the Pre-Funded Warrants may be offered for sale, sold, transferred or assigned at the option of the holder upon surrender of the Pre-Funded Warrant to us together with the appropriate instruments of transfer.

Exchange Listing

There is no established trading market for the Pre-Funded Warrants and we do not plan on applying to list the Pre-Funded Warrants on the Nasdaq Capital Market or any other national securities exchange or any other nationally recognized trading system.

Fundamental Transactions

In the event of a fundamental transaction, as described in the Pre-Funded Warrants and generally including any reorganization, recapitalization or reclassification of our Common Stock, the sale, transfer or other disposition of all or substantially all of our properties or assets, our consolidation or merger with or into another person, the acquisition of more than 50% of our outstanding Common Stock, or any person or group becoming the beneficial owner of 50% of the voting power represented by our outstanding Common Stock, the holders of the Pre-Funded Warrants will be entitled to receive upon exercise of the Pre-Funded Warrants the kind and amount of securities, cash or other property that the holders would have received had they exercised the Pre-Funded Warrants immediately prior to such fundamental transaction without regard to any limitations on exercise contained in the Pre-Funded Warrants.

Rights as a Stockholder

Except by virtue of such holder’s ownership of shares of our Common Stock, the holder of a Pre-Funded Warrant does not have the rights or privileges of a holder of our Common Stock, including any voting rights, until the holder exercises the Pre-Funded Warrant.

DILUTION

If you invest in our securities in this offering, your ownership interest may be diluted immediately depending on the difference between the effective public offering price per share of our Common Stock and the as adjusted net tangible book value per share of our Common Stock immediately after this offering (assuming no sale of any Pre-Funded Warrants in this offering). All references to shares of Common Stock and per share numbers give effect to the Reverse Stock Split.

Our historical net tangible book value as of June 30, 2026, was approximately $(1.7) million, or $(4.17) per share of Common Stock, based on 417,286 shares of Common Stock outstanding as of that date.

Our pro forma net tangible book value as of June 30, 2026, would have been approximately $(32.0) million, or $(64.71) per share of Common Stock. We present dilution on a pro forma basis to give effect to (i) the Merger, including the issuance of 77,323 shares of Common Stock, (ii) the Bridge Financing (assuming no conversion of the Bridge Notes and no exercise of the Bridge Warrants) for net proceeds of $7,440,641, and (iii) the Interim PIPE (assuming no exercise of the PIPE Warrants), for net proceeds of $2,000,000 and (iv) the September PIPE (assuming no conversion of the September Notes and no exercise of the September Warrants) for net proceeds of $4,500,000.

After giving effect to the sale of 1,519,608 shares of Common Stock offered hereby at the offering price of $2.04 per share (assuming only Shares are sold and no Pre-Funded Warrants are sold), and after deducting commissions and estimated offering expenses payable by us, our as adjusted net tangible book value as of June 30, 2026 would have been $(29.2) million, or $(14.48) per share of Common Stock. This represents an immediate increase in net tangible book value of $50.24 per share to our existing stockholders and an immediate dilution in net tangible book value of $16.52 per share to new investors in this offering.

Offering Price per Share			$	2.04
Net tangible book value per share of Common Stock at June 30, 2026	$	(4.17)		
Pro forma decrease in net tangible book value per share as of June 30, 2026	$	(60.54)		
Increase in net tangible book value per share attributable to new investors		50.24		
Pro forma as adjusted net tangible book value per share as of June 30, 2026, after giving effect to this offering[(1)]			$	(14.48)
Dilution per share to investors participating in this offering			$	16.52

The table and discussion above reflect 417,286 shares of our Common Stock outstanding as of June 30, 2026 and excludes:

- 1,100 shares of Common Stock issuable upon the exercise of options outstanding at a weighted average exercise price of $866.25 per share;
- 146,554 shares of Common Stock issuable upon exercise of warrants; and
- 6,503 shares of Common Stock issuable under the Glucotrack, Inc. 2024 Equity Incentive Plan (as amended, the “Plan”).
- 4,631,200 shares of Common Stock issuable upon conversion of 46,312 shares of Preferred Stock (such conversion subject to stockholder and Nasdaq approval);
- All shares of Common Stock issuable upon conversion of the Bridge Notes and exercise of the Bridge Warrants (such issuances subject to stockholder approval);
- All shares of Common Stock issuable upon exercise of the Commitment Warrant; and
- 355,556 shares of Common Stock issuable upon exercise of the PIPE Warrants.

BENEFICIAL OWNERSHIP OF SECURITIES

The following table provides information regarding the beneficial ownership of our Common Stock as of September 23, 2026 (the "Evaluation Date") by: (i) each of our current directors, (ii) each of our named executive officers, (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 848,629 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	28(1)	*
Peter C. Wulff	—	*
Luis Malavé	542(2)	*
Erin Carter	415(3)	*
Victoria Carr-Brendel	300(4)	*
Andrew K. Balo	584(5)	*
Erik Emerson	39,439(6)	4.6%
All of our executive officers and directors as a group (7 individuals)	41,304	4.8%
5% or Greater Stockholders		
White Lion Capital	77,492(7)	9.1%

* Indicates less than one percent of the outstanding shares of the Company's Common Stock.

(1) Includes (i) 2 shares of Common Stock subject to options currently exercisable or exercisable within 60 days of the Evaluation Date, (ii) 3 warrants currently exercisable and (iii) 23 shares of Common Stock held directly by Mr. Goode.

(2) Includes (i) 271 shares of Common Stock subject to options currently exercisable or exercisable within 60 days of the Evaluation Date, and (ii) 271 shares of Common Stock held directly by Mr. Malavé.

(3) Includes (i) 271 shares of Common Stock subject to options currently exercisable or exercisable within 60 days of the Evaluation Date, and (ii) 144 shares of Common Stock held directly by Ms. Carter.

(4) Includes (i) 271 shares of Common Stock subject to options currently exercisable or exercisable within 60 days of the Evaluation Date, and (ii) 29 shares of Common Stock held directly by Ms. Carr-Brendel.

(5) Includes (i) 271 shares of Common Stock subject to options currently exercisable or exercisable within 60 days of the Evaluation Date, and (ii) 313 shares of Common Stock held directly by Mr. Balo.

(6) Includes 39,439 shares of Common Stock, consisting of (i) 8 shares of Common Stock held directly by Mr. Emerson and (ii) 39,431 shares of Common Stock held by RXRR Capital Partners ("RXRR"), over which Mr. Emerson has voting and investment power. Beneficial ownership does not include an aggregate of 2,362,200 shares of Common Stock underlying 5 shares of Preferred Stock held by Mr. Emerson directly and 23,617 shares of Series A Preferred Stock held by RXRR which were issued in connection with the Business Combination Transactions, which may not be convertible within 60 days of the Evaluation Date.

(7) Includes 77,492 restricted commitment shares issued from the total commitment shares of 167,035, leaving 89,543 shares remaining in the obligation which are yet to be issued in connection with certain beneficial ownership caps within the agreement

CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

Other than as listed below, during 2025 and 2024, we were not a participant in any transaction or series of transactions in which the amount involved exceeded or may be expected to exceed the lesser of $120,000 or 1% of the average of our total assets at year-end for 2025 and 2024 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).

Glucotrack, Inc.

For information relating to certain relationships and related transactions relating to Glucotrack, Inc., please refer to the section entitled "Item 12. Certain Relationships and Related Transactions, and Director Independence" in Glucotrack, Inc.'s Annual Report, which is incorporated by reference into this prospectus supplement.

Lokahi Therapeutics Inc.

References in this sub-section to the "Company," "we," "us," or "our" refer to Lokahi Therapeutics, Inc., a Nevada corporation.

Promissory Note with APUS

On March 21, 2025, the biopharmaceutical business of Lokahi Therapeutics Inc. ("The Company"), formerly known as Apimeds Pharmaceuticals US, Inc. ("APUS") (the "Parent"), entered into an unsecured promissory note (the "Promissory Note") with Inscobee Inc. ("Inscobee"), a majority stockholder of APUS, pursuant to which the Company received loan proceeds of $250,000. The Promissory Note bears interest at a rate of 5% per annum and matures on December 31, 2026. The Promissory Note may be prepaid at any time, in whole or in part, without penalty or premium. Upon the occurrence of an event of default, amounts outstanding under the Promissory Note bear interest at a default rate equal to the stated interest rate plus 5%, or 10% per annum. The Promissory Note is unsecured and was assumed by APUS upon the effectiveness of the merger between APUS and MindWave Innovations Inc ("MindWave"), which was consummated on December 1, 2025. As of the balance sheet date, the full principal amount of $250,000 was assumed by APUS and is not presented within the Company's financial statements herein.

Promissory Notes with Inscobee

The Company is party to three unsecured promissory notes with Inscobee Inc. ("Inscobee"), a majority stockholder of APUS, a subsidiary of the Company. Inscobee is therefore considered a related party of the Company. The Company assumed these promissory notes in connection with the Confidential Settlement and Mutual Release Agreement (the "Settlement Agreement") described elsewhere in this prospectus supplement. The material terms of each promissory note are as follows:

On May 20, 2024, Inscobee made a loan to APUS in the principal amount of $100,000, evidenced by an unsecured promissory note with an original maturity date of May 20, 2025. On May 16, 2025, the maturity date was extended to December 31, 2026. The note bears interest at 5% per annum and may be prepaid at any time without penalty. Upon an event of default, amounts outstanding bear interest at a default rate of 10% per annum.

On August 19, 2024, Inscobee made a loan to APUS in the principal amount of $150,000, evidenced by an unsecured promissory note with an original maturity date of August 19, 2025. The maturity date was subsequently extended to December 31, 2026. The note bears interest at 5% per annum and may be prepaid at any time without penalty. Upon an event of default, amounts outstanding bear interest at a default rate of 10% per annum.

On March 21, 2025, Inscobee made a loan to APUS in the principal amount of $250,000, evidenced by an unsecured promissory note maturing on December 31, 2026. The note bears interest at 5% per annum and may be prepaid at any time without penalty. Upon an event of default, amounts outstanding bear interest at a default rate of 10% per annum.

The aggregate principal amount outstanding under the three promissory notes with Inscobee is $500,000.

Settlement Agreement

On April 24, 2026 (the "Effective Date"), the Company entered into a Confidential Settlement and Mutual Release Agreement ("The Settlement Agreement") by and among the Company, the Parent, MindWave, a wholly owned subsidiary of the Parent, Erik Emerson, individually and in his capacity as Bio Business Representative under the Merger Agreement ("Emerson"), Inscobee, and Apimeds Inc. ("Apimeds Korea"), a wholly owned subsidiary of Inscobee. The Settlement Agreement resolves, without litigation, disputes that arose among the parties following the Merger consummated on December 1, 2025, pursuant to the merger agreement, dated December 1, 2025, by and between APUS, Apimeds Merger Sub, Inc., Mindwave, the Company, and Emerson (the "Merger Agreement"), including disputes regarding the validity of certain stockholder consents and related support and voting agreements.

Under the Settlement Agreement, the Company irrevocably and unconditionally agreed to transfer to the Parent, or its designee, a working capital contribution of $4,000,000 (the "Working Capital Contribution"), later amended to $3,000,000 along with the forgiveness or assumption of the assets or liabilities defined herein. The Company also agreed to forgive, release and discharge all amounts previously advanced by the Company to the Parent or its subsidiaries, including (i) $750,000 advanced on or about February 2, 2026, together with any interest, penalties or equity that may be due to the Company (ii) the related party notes in aggregate principal balance of $500,000 (iii) balances due from APUS in the amount of approximately $360,000.

In connection with the Settlement Agreement, the Parent agreed to (i) assign to the Company the Prevail CRO credit facility, having an aggregate value of approximately $2,200,000, to support continued development of the Apitox program, and (ii) assign to the Company the rights under the related license agreement, with the Company retaining all rights relating to the Apitox program, including intellectual property, regulatory materials, development data, manufacturing information and other associated program assets. In addition, within five business days following fulfillment of the Working Capital Contribution, the Parent is required to distribute 51% of the common stock of the Company as directed by Emerson, with the remaining 49% retained by the Parent. The Company's board composition and management appointments are determined solely by the Company, and Emerson continues as the Company's Chief Executive Officer and President.

The Company further irrevocably waived certain covenants and rights under the Merger Agreement and under an amended and restated side letter agreement dated December 1, 2025, including rights to allocations of financing proceeds raised by the Parent and the right to be repaid a $50,000 diligence fee. The Settlement Agreement also provides for mutual releases among the parties of all claims arising from facts, acts, omissions, circumstances, events or transactions occurring before its execution, subject to customary carve-outs, which releases become effective only upon payment by the Company of the Working Capital Contribution. In connection with the Settlement Agreement, the Company assumed the Related Party Notes payable to Inscobee described above, together with accrued interest thereon.

PLAN OF DISTRIBUTION

We have entered into a securities purchase agreement with certain institutional and accredited investors pursuant to which we have agreed to issue and sell directly to such investors, and such investors have agreed to purchase directly from us, an aggregate of (i) 169,388 shares of Common Stock and (ii) Pre-Funded Warrants to purchase up to 1,350,220 shares of Common Stock.

Pursuant to a placement agency agreement dated September 24, 2026, we engaged Dawson James Securities, Inc. to act as our placement agent in connection with this offering of our Securities pursuant to this prospectus supplement and accompanying prospectus. Under the terms of the placement agency agreement, the placement agent is not purchasing or selling any Securities offered by us in this offering and is not required to arrange for the sale of any specific number or dollar amount of the Securities, other than to use its reasonable best efforts to arrange for the sale of such Securities by us.

We expect to deliver the Shares and Pre-Funded Warrants being offered pursuant to this prospectus supplement on or about September 25, 2026.

The securities purchase agreement, placement agency agreement and a form of the securities purchase agreement will be filed as exhibits to a Current Report on Form 8-K filed with the SEC in connection with this offering and incorporated by reference into the registration statement of which this prospectus supplement forms a part.

Fees and Expenses

We have agreed to pay the placement agent a cash fee equal to 8.0% of the gross proceeds of this offering. We have also agreed to reimburse the placement agent at closing for out-of-pocket expenses, including legal expenses, incurred by it in connection with the offering up to a maximum of $50,000.

We estimate the total expenses payable by us for this offering will be approximately $100,000, which amount excludes the placement agent’s fees and expenses.

Indemnification

We have agreed to indemnify the placement agent against certain liabilities, including liabilities under the Securities Act, and to reimburse the placement agent for certain expenses. We have also agreed to contribute to payments that the placement agent or such other indemnified parties may be required to make in respect of those liabilities.

Lock-Up Agreements

We have agreed not to (i) offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend, or otherwise transfer or dispose of, directly or indirectly, any shares of capital stock of the Company or any securities convertible into or exercisable or exchangeable for shares of capital stock of the Company; (ii) file or cause to be filed any registration statement with the Commission relating to the offering of any shares of capital stock of the Company or any securities convertible into or exercisable or exchangeable for shares of capital stock of the Company, other than pursuant to a registration statement on Form S-8 for employee benefit plans, whether any such transaction described in clause (i) or (ii) above is to be settled by delivery of shares of capital stock of the Company or such other securities, in cash or otherwise; or (iii) publicly announce an intention to effect any transaction specified in clause (i) or (ii), for a period of six months following entry into the placement agency agreement (the “Lock-Up Period”). These restrictions on future issuances are subject to exceptions for (i) the issuance of shares of our Common Stock sold in this offering and the issuance of the Pre-Funded Warrants and shares of Common Stock issuable upon exercise of those Pre-Funded Warrants, (ii) the issuance by the Company of Common Stock upon the exercise of stock options, warrants or the conversion of a security, in each case, that is outstanding on the date hereof, and (iii) the grant by the Company of stock options or other stock-based awards, or the issuance of shares of capital stock of the Company under any stock compensation plan of the Company in effect on the date hereof. The foregoing restrictions shall not apply to the Company’s issuance of Common Stock or Common Stock Equivalents pursuant to an at-the-market facility with the placement agent as sales agent.

In addition, each of our directors and executive officers has entered into a lock-up agreement with the placement agent. Under the lock-up agreements, the directors and executive officers may not, during the period commencing on the date of the final prospectus relating to the offering and ending six months thereafter, (1) offer, pledge, sell, contract to sell, grant, lend, or otherwise transfer or dispose of, directly or indirectly, any shares of capital stock or any securities convertible into or exercisable or exchangeable for shares of capital stock, whether currently owned or thereafter acquired or with respect to which the director or executive officer has or thereafter acquires the power of disposition (collectively, the "Lock-Up Securities"); (2) enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of the Lock-Up Securities; (3) establish or increase a put equivalent position or liquidate or decrease a call equivalent position within the meaning of Section 16 of the Exchange Act and the rules and regulations of the SEC promulgated thereunder with respect to any Common Stock owned directly by the director or executive officer (including holding as a custodian) or with respect to which the director or executive officer has beneficial ownership within the rules and regulations of the SEC, whether any such transaction described in clause (1), (2) or (3) above is to be settled by delivery of Lock-Up Securities, in cash or otherwise; (4) make any demand for or exercise any right with respect to the registration of any Lock-Up Securities; or (5) publicly disclose the intention to make any offer, sale, pledge or disposition, or to enter into any transaction, swap, hedge or other arrangement relating to any Lock-Up Securities.

Regulation M Restrictions

The placement agent may be deemed to be an underwriter within the meaning of Section 2(a)(11) of the Securities Act, and any commissions received by it and any profit realized on the resale of the securities sold by it while acting as our placement agent might be deemed to be underwriting discounts or commissions under the Securities Act. As an underwriter, the placement agent would be required to comply with the requirements of the Securities Act and the Exchange Act, including, without limitation, Rule 415(a)(4) under the Securities Act and Rule 10b-5 and Regulation M under the Exchange Act. These rules and regulations may limit the timing of purchases and sales of shares of securities by the placement agent acting as placement agent. Under these rules and regulations, the placement agent:

- may not engage in any stabilization activity in connection with our securities; and
- may not bid for or purchase any of our securities or attempt to induce any person to purchase any of our securities, other than as permitted under the Exchange Act, until it has completed its participation in the distribution.

Electronic Distribution

This prospectus supplement and accompanying prospectus may be made available in electronic format on websites or via email or through other online services maintained by the Company and/or the placement agent. Other than this prospectus supplement and the accompanying prospectus in electronic format, the information on the Company's and/or the placement agent's websites and any information contained in any other websites maintained by the Company and/or the placement agent is not part of this prospectus supplement, accompanying prospectus, or the registration statement of which this prospectus supplement and accompanying prospectus form a part, has not been approved or endorsed by us or the placement agent, and should not be relied upon by investors.

The foregoing does not purport to be a complete statement of the terms and conditions of the placement agency agreement or the securities purchase agreement. See "*Where You Can Find More Information*".

Price Stabilization, Short Positions

No person has been authorized by the Company to engage in any form of price stabilization in connection with this offering.

Other Relationships

The placement agent and its affiliates are full service financial institutions engaged in various activities, which may include sales and trading, commercial and investment banking, advisory, investment management, investment research, principal investment, hedging, market making, brokerage and other financial and non-financial activities and services. The placement agent and its affiliates have provided, and may in the future provide, a variety of these services to us and to persons and entities with relationships with us, for which they received or will receive customary fees and expenses.

In the ordinary course of their various business activities, the placement agent and its affiliates, officers, directors and employees may purchase, sell or hold a broad array of investments and actively trade securities, derivatives, loans, commodities, currencies, credit default swaps and other financial instruments for their own account and for the accounts of their customers, and such investment and trading activities may involve or relate to our assets, securities and/or instruments (directly, as collateral securing other obligations or otherwise) and/or persons and entities with relationships with us. The placement agent and its affiliates may also communicate independent investment recommendations, market color or trading ideas and/or publish or express independent research views in respect of such assets, securities or instruments and may at any time hold, or recommend to clients that they should acquire, long and/or short positions in such assets, securities and instruments.

On November 14, 2024, the Company closed a best efforts public offering for the offer and sale of an aggregate of (i) 121,867 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, (iii) 359,712 Series A Warrants, and (iv) 359,712 Series B Warrants. In connection with the offering, the Company paid the placement agent $799,618.94 in placement agent fees.

On September 10, 2026, the Company entered into a securities purchase agreement with certain investors, pursuant to which the Company issued senior secured convertible promissory notes in the aggregate principal amount of $11,596,172.68, in exchange for (i) aggregate cash consideration of $4,500,000 and (ii) the surrender and exchange of $4,545,014.69 in aggregate principal amount of certain outstanding senior secured convertible promissory notes held by certain investors. In connection with the offering, the Company also issued to the investors warrants to purchase 4,831,739 shares of Common Stock. In connection with the offering, the Company paid the placement agent (a) a cash placement fee equal to 7% of the gross cash proceeds received by the Company, (b) warrants to purchase 148,668 shares of Common Stock at an exercise price equal to 125% of the initial conversion price, and (c) reimbursement of the placement agent's actual accountable expenses, including legal and diligence expenses, not to exceed $50,000.

Common Stock Listing

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

LEGAL MATTERS

The validity of the Shares and Pre-Funded Warrant Shares offered hereby and certain legal matters relating to the Pre-Funded Warrants will be passed upon for us by Nelson Mullins Riley & Scarborough LLP, Raleigh, NC. Dawson James is being represented in connection with this offering by ArentFox Schiff LLP, Washington, DC.

EXPERTS

The audited financial statements for the year ended December 31, 2024 incorporated by reference in this prospectus supplement and elsewhere in the registration statement have been so incorporated by reference in reliance upon the report of Fahn Kanne & Co. Grant Thornton Israel, independent registered public accountants, upon the authority of said firm as experts in accounting and auditing. The audited financial statements for the year ended December 31, 2025 incorporated by reference in this prospectus supplement and elsewhere in the registration statement have been so incorporated by reference in reliance upon the report of CBIZ CPAs P.C., independent registered public accountants, upon the authority of said firm as experts in accounting and auditing.

The audited financial statements of Lokahi Therapeutics, Inc. for the year ended December 31, 2025 incorporated by reference in this prospectus supplement have been audited by Kreit & Chiu CPA LLP, independent registered public accounting firm, as set forth in their report thereon, and are included in reliance upon such report given on the authority of such firm as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

We have filed a registration statement on Form S-3 with the SEC under the Securities Act of 1933 with respect to the shares of Common Stock offered by this prospectus supplement. This prospectus supplement and the accompanying prospectus are part of the registration statement but the registration statement includes and incorporates by reference additional information and exhibits. This prospectus supplement does not contain all the information set forth in the registration statement and its exhibits and schedules, portions of which have been omitted as permitted by the rules and regulations of the SEC. For further information about us, we refer you to the registration statement and to its exhibits and schedules. Certain information in the registration statement has been omitted from this prospectus supplement and the accompanying prospectus in accordance with the rules of the SEC. We file annual, quarterly and current reports, proxy statements and other information with the SEC. The SEC maintains a website that contains reports, proxy and information statements and other information regarding companies, such as ours, that file documents electronically with the SEC. The address of that website is http://www.sec.gov. The information on the SEC's website is not part of this prospectus supplement or the accompanying prospectus, and any references to this website or any other website are inactive textual references only.

We also make available free of charge our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, proxy statements and amendments to those reports, on our website at www.glucotrack.com as soon as reasonably practicable after filing such documents with the SEC. The information contained on, or that may be accessed through, our website is not a part of, and is not incorporated into, this prospectus.

INCORPORATION BY REFERENCE

The SEC permits us to "incorporate by reference" the information contained in documents we file with the SEC, which means that we can disclose important information to you by referring you to those documents rather than by including them in this prospectus supplement and the accompanying prospectus. Information that is incorporated by reference is considered to be part of this prospectus supplement and the accompanying prospectus and you should read it with the same care that you read this prospectus supplement and the accompanying prospectus. Later information that we file with the SEC will automatically update and supersede the information that is either contained, or incorporated by reference, in this prospectus supplement and the accompanying prospectus, and will be considered to be a part of this prospectus supplement and the accompanying prospectus from the date those documents are filed. We have filed with the SEC, and incorporate by reference in this prospectus supplement and the accompanying prospectus:

- The Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2025 filed with the SEC on March 30, 2026;

- The Company's Quarterly Report on Form 10-Q for the quarters ended March 31, 2026 and June 30, 2026, filed with the SEC on May 14, 2026 and August 14, 2026, respectively;

- The Company's Current Reports on Form 8-K filed with the SEC on March 13, 2026, April 14, 2026, April 30, 2026, May 15, 2026, July 15, 2026 (as amended on August 28, 2026), July 27, 2026 (as amended on July 29, 2026), August 5, 2026, August 10, 2026, August 19, 2026, August 28, 2026, September 9, 2026, September 11, 2026, September 14, 2026, September 18, 2026 and September 24, 2026; and

- The description of the Company's Common Stock contained in its Registration Statement on Form 8-A, as filed with the SEC on December 8, 2021, including any amendments or reports filed with the SEC for the purpose of updating such description.

We also incorporate by reference all additional documents that we file with the Securities and Exchange Commission under the terms of Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act that are made after the date of the initial registration statement but prior to effectiveness of the registration statement and after the date of this prospectus supplement but prior to the termination of the offering of the securities covered by this prospectus supplement and the accompanying prospectus. We are not, however, incorporating, in each case, any documents or information that we are deemed to furnish and not file in accordance with Securities and Exchange Commission rules.

You may request, and we will provide you with, a copy of these filings, at no cost, by calling us or by writing to us at the following address and phone number. If you make a request for such information in writing or by telephone, we will provide you, without charge, a copy of any or all of the information incorporated by reference into this prospectus supplement and the accompanying prospectus (other than an exhibit to any filing unless we have specifically incorporated that exhibit by reference into the filing). Any such request should be directed to:

GLUCOTRACK, INC.
301 Route 17 North, Ste. 800
Rutherford, NJ 07070
(201) 842-7715

Our website address is https://glucotrack.com/. Except for any documents that are incorporated by reference into this prospectus supplement and the accompanying prospectus that may be accessed from our website, the information available on or through our website is not part of this prospectus supplement or the accompanying prospectus.

PROSPECTUS

$30,000,000

Common Stock
Preferred Stock
Debt Securities
Warrants
Units

From time to time, we may offer and sell our securities listed above in one or more offerings in amounts, at prices and on terms that we will determine at the time of the offering. The aggregate initial offering price of all securities sold by us under this prospectus will not exceed $30,000,000.

Each time we offer our securities, we will provide you with specific terms of the securities offered in supplements to this prospectus. This prospectus may not be used to offer and sell our securities unless accompanied by a prospectus supplement. Accompanying prospectus supplements may add, update or change information contained in this prospectus. You should read this prospectus, the accompanying prospectus supplements, the information incorporated by reference into this prospectus and the accompany prospectus supplements and the additional information described below under the heading "*Where You Can Find More Information*" carefully before you invest in our securities.

Our securities may be offered and sold to or through underwriters, brokers, dealers or agents as designated from time to time, or directly to one or more other purchasers or through a combination of such methods. For additional information, you should refer to the section captioned "*Plan of Distribution*" on page 25 of this prospectus. If any underwriters, dealers or agents are involved in the sale of any of our securities, their names, and any applicable purchase price, fee, commission or discount arrangements between or among them, will be set forth, or will be calculable from the information set forth, in the accompanying prospectus supplement. The price to the public of our securities and the net proceeds that we expect to receive from such sale will also be set forth in the accompanying prospectus supplement.

You should read this document and any prospectus supplement or amendment carefully before you invest in our securities.

Our securities are currently trading on The Nasdaq Capital Market under the stock symbol "GCTK." On September 20, 2024, the closing price for our common stock, as reported on The Nasdaq Capital Market, was $2.66 per share. Our principal executive office is located at 301 Rte. 17 North, Ste. 800, Rutherford, NJ 07070, and our telephone number is (201) 842-7715.

As of September 30, 2024, the aggregate market value of our outstanding common stock held by non-affiliates was approximately $11,297,859, which we calculated based on 5,478,436 shares of outstanding common stock, of which 3,842,809 shares were held by non-affiliates, and a price per share of $2.94 as of September 12, 2024, which is a date within 60 days prior to the date of this prospectus. Pursuant to General Instruction I.B.6 of Form S-3, in no event will we sell, pursuant to the registration statement of which this prospectus forms a part, securities in a public primary offering with a value exceeding one-third of the aggregate market value of our outstanding common stock held by non-affiliates in any 12-month period, so long as the aggregate market value of our outstanding common stock held by non-affiliates remains below $75 million. During the 12 calendar months prior to and including the date of this prospectus, we have not offered or sold any securities pursuant to General Instruction I.B.6 of Form S-3.

We may amend or supplement this prospectus from time to time by filing amendments or supplements as required. You should read the entire prospectus and any amendments or supplements carefully before you make your investment decision.

We are a "smaller reporting company" as defined under the federal securities laws and, as such, are eligible for reduced public company reporting requirements. See "*Prospectus Summary—Smaller Reporting Company*" on page 4 of this prospectus.

Investing in our securities involves a high degree of risk. See "*Risk Factors*" on page 5 of this prospectus, in any accompanying prospectus supplement and in the documents incorporated or deemed incorporated by reference into this prospectus and the accompanying prospectus supplement before you invest in our securities.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.

The date of this prospectus is October 3, 2024.

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ABOUT THIS PROSPECTUS

This prospectus is part of a registration statement that we filed with the United States Securities and Exchange Commission (the "SEC"), using a "shelf" registration process. Under this shelf registration process, we may from time to time sell any combination of the securities described in this prospectus in one or more offerings up to a total amount of $30,000,000.

This prospectus provides you with a general description of the securities we may offer. Each time we sell securities pursuant to this prospectus, we will provide one or more prospectus supplements that will contain specific information about the terms of the offering. The specific terms of the offered securities may vary from the general terms of the securities described in this prospectus, and accordingly the description of the securities contained in this prospectus is subject to, and qualified by reference to, the specific terms of the offered securities contained in the applicable prospectus supplement. We may also authorize one or more free writing prospectuses to be provided to you that may contain material information relating to these offerings. The prospectus supplement and any related free writing prospectus that we may authorize to be provided to you may also add, update or change any information contained in this prospectus or in the documents that we have incorporated by reference into this prospectus. You should carefully read this prospectus, any applicable prospectus supplement and any free writing prospectuses we have authorized for use in connection with a specific offering, together with the additional information described under the heading "*Where You Can Find More Information*" beginning on page 28 of this prospectus.

This prospectus may not be used to consummate a sale of securities unless it is accompanied by a prospectus supplement.

You should rely only on the information contained in or incorporated by reference in this prospectus, any applicable prospectus supplement or in any related free writing prospectus filed by us with the SEC. We have not authorized anyone to provide you with different information. We take no responsibility for, and can provide no assurance as to the reliability of, any information that others may provide. This prospectus, any applicable prospectus supplement to this prospectus or any related free writing prospectus do not constitute an offer to sell or the solicitation of an offer to buy any securities other than the registered securities to which they relate, nor do this prospectus, any applicable supplement to this prospectus or any related free writing prospectus constitute an offer to sell or the solicitation of an offer to buy such securities in any circumstances in which such offer or solicitation is unlawful. You should assume that the information in this prospectus, any applicable prospectus supplement, any free writing prospectus and any information in documents that we have incorporated by reference is accurate only as of their respective dates. Our business, financial condition, results of operations and prospects may have changed materially since those dates.

This prospectus and the information incorporated herein by reference contain summaries of certain provisions contained in some of the documents described herein, but reference is made to the actual documents for more complete information. All of the summaries are qualified in their entirety by the actual documents. Copies of some of the documents referred to herein have been filed, will be filed or will be incorporated by reference as exhibits to the registration statement of which this prospectus is a part, and you may obtain copies of those documents as described below under the section titled "Where You Can Find Additional Information."

Unless the context otherwise indicates, references in this prospectus to "the Company," "we," "our" and "us" refer, collectively, to Glucotrack, Inc., a Delaware corporation, and its consolidated subsidiaries.

PROSPECTUS SUMMARY

This summary highlights certain information about us, this offering and selected information contained elsewhere in this prospectus. This summary is not complete and does not contain all of the information that you should consider before deciding whether to invest in the securities covered by this prospectus. For a more complete understanding of the Company and this offering, we encourage you to read and consider carefully the more detailed information in this prospectus, any related prospectus supplement and any related free writing prospectus, including the information set forth in the section titled "Risk Factors" in this prospectus, any related prospectus supplement and any related free writing prospectus in their entirety before making an investment decision.

Overview

The Company (formerly known as Integrity Applications, Inc.) 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 Glucose Monitor (CGM) for persons with Type 1 diabetes and insulin-dependent Type 2 diabetes (the "Glucotrack CBGM Product").

The Company was founded with a mission to develop Glucotrack®, a noninvasive 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 Implantable continuous glucose monitor ("CGM"). 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 an Implantable 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 our animal study with an initial prototype system which demonstrated a simple implant procedure and good functionality. The results of both were recently presented in poster form at the American Diabetes Association annual conference. The Company has also initiated a longer-term animal trial (to support projected longevity studies) as well as development of its commercial device. A regulatory submission has been made for a first in human study, expected to initiate in Q3 2024. Further to the above progress on our CBGM product, we have also successfully demonstrated continuous glucose sensing in the epidural space. This latter approach is of importance for patients with painful diabetic neuropathy 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.

Our Senior Management team includes Chief Executive Officer and President, Paul V. Goode PhD, who has a decorated career developing innovative medical technologies, including at DexCom, Inc. ("DexCom") and MiniMed; CFO, James Cardwell, CPA who has over 16 years of experience as a Chief Financial Officer and Chief Operating Officer with a concentration in both SEC financial reporting and tax compliance; James P. Thrower PhD, Vice President of Engineering, a seasoned executive formerly of Sterling Medical Devices, Mindray DS USA and DexCom; Mark Tapsak PhD, Vice President of Sensor Technology, a medical research scientist who brings over 25 years of experience in the diabetes industry, including previous senior roles at DexCom and Medtronic plc ("Medtronic"); and 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. Luis J. Malavé, formerly of Insulet Corp, Medtronic and MiniMed is the Chairman of the Company's Board of Directors (the "Board" or "Board of Directors"). Several highly talented and accomplished executives joined the Company as senior advisors to the Board. These include Daniel McCaffrey MBA MA, a world-renowned behavioral scientist and digital health expert formerly at Samsung Health and Dexcom, Inc., and Dr. David C. Klonoff, world renowned endocrinologist and diabetes technology thought leader. We intend to continue to invest in our talent and to expand and strengthen all areas within the Company.

Recent Developments

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.

Reverse Stock Split

We filed with the Delaware Secretary of State a Certificate of Amendment to our Certificate of Incorporation (the "Certificate of Amendment") which became effective at 4:30 p.m. on May 17, 2024 (the "Effective Time") to effect a one-for-five (1:5) reverse stock split (the "Reverse Stock Split") of the shares of our common stock. The 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 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 Reverse Stock Split, and any person who would otherwise be entitled to a fractional share of common stock as a result of the 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 Effective Time.

Following the Reverse Stock Split, the number of shares of common stock outstanding was proportionally reduced from 27,392,996 shares to approximately 5,478,599 shares. The shares of common stock underlying the outstanding stock options and warrants were similarly adjusted along with corresponding adjustments to their exercise prices. The 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.

Nasdaq Listing Status

Nasdaq Stockholder Equity Requirement

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, Nasdaq notified us that our Quarterly Report on Form 10-Q for the period ended March 31, 2024, indicated that we no longer meet the Minimum Stockholders' Equity Requirement. Failure to meet the Minimum Stockholders' Equity Requirement is a basis for delisting our common stock.

Because we were under review for failure to meet the Minimum Bid Price Requirement (which requires listed securities to maintain a minimum bid price of $1.00 per share) 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 has 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 granting us an extension until November 18, 2024 to regain compliance with the Minimum Stockholders' Equity Requirement.

There can be no assurance regarding the outcome of the hearing or that we will be able to satisfy Nasdaq's continued listing requirements, regain compliance with the Minimum Stockholders' Equity Requirement, and maintain compliance with other Nasdaq listing requirements.

Implications of Being a Smaller Reporting Company

We are a "smaller reporting company," meaning that the market value of our shares held by non-affiliates is less than $700 million and our annual revenue was less than $100 million during the most recently completed fiscal year. We may continue to be a smaller reporting company if either (i) the market value of our shares held by non-affiliates is less than $250 million or (ii) our annual revenue was less than $100 million during the most recently completed fiscal year and the market value of our shares held by non-affiliates was less than $700 million. As a smaller reporting company, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not smaller reporting companies.

Corporate Information

Our principal offices are located at 301 Rte. 17 North, Suite 800, Rutherford NJ 07070, and our telephone number is 201-842-7715. Our website address is http://www.glucotrack.com. Our common stock is traded on the Nasdaq Capital Market under the symbol "GCTK."

We are subject to the informational requirements of the Exchange Act and file or furnish reports, proxy statements, and other information with the SEC. Such reports and other information filed by us with the SEC will be available free of charge on our website. The SEC maintains a website that contains proxy and other information that issuers file electronically with the SEC at www.sec.gov.

The references to such website addresses above do not constitute incorporation by reference of the information contained on the website and such information should not be considered part of this prospectus. Further, our references to the URLs for these websites are intended to be inactive textual references only.

All trademarks, service marks and trade names appearing in this prospectus are the property of their respective holders. Use or display by us of other parties' trademarks, trade dress, or products in this prospectus is not intended to, and does not, imply a relationship with, or endorsements or sponsorship of, us by the trademark or trade dress owners.

RISK FACTORS

Investing in our securities involves a high degree of risk. Prior to making a decision about investing in our securities, you should carefully consider the specific factors discussed under the heading "Risk Factors" in the applicable prospectus supplement and any related free writing prospectus, together with all of the other information contained or incorporated by reference in the prospectus supplement or appearing or incorporated by reference in this prospectus. You should also consider the risks, uncertainties and assumptions discussed under Item 1A, "Risk Factors," in our most recent Annual Report on Form 10-K and any updates described in our Quarterly Reports on Form 10-Q, all of which are incorporated herein by reference, and may be amended, supplemented or superseded from time to time by other reports we file with the SEC in the future and any prospectus supplement related to a particular offering. The risks and uncertainties we have described are not the only ones we face. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also affect our operations. Past performance may not be a reliable indicator of future performance, and historical trends should not be used to anticipate results or trends in future periods. The occurrence of any of these known or unknown risks could adversely affect our business, operating results and financial condition, as well as adversely affect the value of an investment in our securities, and the occurrence of any of these known or unknown risks might cause you to lose all or part of your investment in the offered securities. Please also read carefully the section below titled "*Special Note Regarding Forward-Looking Statements*."

The risk factors set forth below supplement the risk factors previously disclosed and should be read together with the risk factors incorporated by reference herein and any additional risk factors that we may include in subsequent periodic filings with the SEC.

We have debt which is secured by all our assets. If there is an occurrence of an uncured event of default, the lender can foreclose on all our assets, which would make any stock in the Company worthless.

On July 30, 2024, we entered into a secured convertible promissory note in the aggregate principal amount of 4,000,000 (the "Note") with a certain lender (the "lender"). The Note is secured by a first-priority security interest on all Company assets. The Note is due and payable in cash on the earlier of: (a) the twelve (12) month anniversary of Note, or (b) the date of closing of a Sale Transaction (as defined in the Note). The Note is secured by a first-priority security interest on all Company assets. In the event we are unable to make payments, when due, on our secured debt, the lender may foreclose on all our assets. In the event the lender forecloses on our assets, any stock in the Company would have no value. Our ability to make payments on secured debt, when due, will depend upon our ability to raise additional funds through equity or debt financings. At the moment, we have no funding commitments that have not been previously disclosed, and we may not obtain any in the future.

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 contract manufacturers could delay clinical development or regulatory clearance or approval of our product candidates or commercialization of our future product candidates, 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.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus, including the information incorporated by reference in this prospectus, contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Exchange Act. Forward-looking statements include statements that may relate to our plans, objectives, goals, strategies, future events, future revenues or performance, capital expenditures, financing needs and other information that is not historical information. Forward-looking statements can often be identified by the use of terminology such as "subject to," "believe," "anticipate," "plan," "expect," "intend," "estimate," "project," "may," "will," "should," "would," "could," "can," the negatives thereof, variations thereon and similar expressions, or by discussions of strategy.

All forward-looking statements, including, without limitation, our examination of historical operating trends, are based upon our current expectations and various assumptions. We believe there is a reasonable basis for our expectations and beliefs, but they are inherently uncertain. We may not realize our expectations, and our beliefs may not prove correct. Actual results could differ materially from those described or implied by such forward-looking statements. These forward-looking statements are subject to a number of risks, uncertainties, assumptions and other important factors, including those described in this prospectus and the documents incorporated herein by reference, particularly in the sections of such documents titled "*Risk Factors*" and "*Management's Discussion and Analysis of Financial Condition and Results of Operations*." The following uncertainties and factors, among others, could affect future performance and cause actual results to differ materially from those matters expressed in or implied by forward-looking statements:

- 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 if we fail to meet any of its applicable listing requirements; and
- the difficulty of predicting our quarterly 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.

All forward-looking statements in this prospectus, including the documents we incorporate by reference, apply only as of the date made and are expressly qualified in their entirety by the cautionary statements included in this prospectus. We undertake no obligation to publicly update or revise any forward-looking statements to reflect subsequent events or circumstances.

In addition, statements that “we believe” and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this prospectus, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain, and you are cautioned not to unduly rely upon these statements.

SELECTED FINANCIAL DATA

Reverse Stock Split

On May 17, 2024, we effected a 1-for-5 Reverse Stock Split of our common stock. In connection with the Reverse Stock Split, the par value per share of our common stock remained unchanged at $0.001 per share. Concurrently with the Reverse Stock Split, we reduced our authorized shares of common stock proportionately. Our audited consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2023 filed with the SEC on March 28, 2024 and our unaudited condensed consolidated financial statements included in our Quarterly Report on Form 10-Q for the period ended March 31, 2024 filed with the SEC on May 15, 2024 that are incorporated by reference into this prospectus are presented without giving effect to the Reverse Stock Split. The unaudited condensed consolidated financial statements included in our Quarterly Report on Form 10-Q for the period ended June 30, 2024 filed with the SEC on August 15, 2024 that is incorporated by reference into this prospectus are presented after giving effect to the Reverse Stock Split. Except where the context otherwise requires, share and per share numbers in this prospectus reflect the 1-for-5 Reverse Stock Split of our common stock.

The following selected financial data has been derived from our audited consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2023 and our unaudited condensed consolidated interim financial statements included in our Quarterly Report on Form 10-Q for the period ended March 31, 2024, as adjusted to reflect the Reverse Stock Split for all periods presented. Our historical results are not indicative of the results that may be expected in the future and results of interim periods are not indicative of the results for the entire year.

AS REPORTED (in thousands, except per share data)

	Year Ended	
	December 31, 2023	**December 31, 2022**
Net loss	$ (7,098)	$ (4,412)
Net loss per share of common stock, basic and diluted	$ (0.38)	$ (0.29)
Weighted average common stock outstanding, basic and diluted	20,760,266	15,474,600
Common stock outstanding at year end	20,892,193	15,500,730

	Three Months Ended	
	March 31, 2024	**March 31, 2023**
	(unaudited)	
Net loss	$ (2,921)	$ (1,281)
Net loss per share of common stock, basic and diluted	$ (0.12)	$ (0.08)
Weighted average common stock outstanding, basic and diluted	24,959,768	15,503,632
Common stock outstanding at period end	26,756,369	15,503,632

AS ADJUSTED FOR 1-FOR-5 REVERSE STOCK SPLIT (in thousands, except per share data)

	Year Ended	
	December 31, 2023	**December 31, 2022**
	(unaudited)	
Net loss	$ (7,098)	$ (4,412)
Net loss per share of common stock, basic and diluted	$ (1.92)	$ (1.43)
Weighted average common stock outstanding, basic and diluted	4,152,053	3,094,920
Common stock outstanding at year end	4,178,274	3,099,982

	Three Months Ended	
	March 31, 2024	**March 31,2023**
	(unaudited)	
Net loss	$ (2,921)	$ (1,281)
Net loss per share of common stock, basic and diluted	$ (0.59)	$ (0.41)
Weighted average common stock outstanding, basic and diluted	4,991,954	3,100,726
Common stock outstanding at period end	5,351,274	3,100,726

USE OF PROCEEDS

We intend to use the net proceeds from the sale of any securities offered under this prospectus for general corporate purposes unless otherwise indicated in the applicable prospectus supplement. General corporate purposes may include research and development and clinical development costs to support the advancement of our product; repayment and refinancing of debt; working capital; and capital expenditures. We may also use a portion of the net proceeds to acquire or invest in businesses, products and technologies that are complementary to our own, although we have no commitments or agreements with respect to any acquisitions as of the date of this prospectus. Pending these uses, we may invest the net proceeds in a variety of capital preservation instruments, including short-term, investment-grade, interest-bearing instruments and U.S. government securities, or may hold such proceeds as cash, until they are used for their stated purpose. We have not determined the amount of net proceeds to be used specifically for such purposes. As a result, management will retain broad discretion over the allocation of net proceeds. We will set forth in the applicable prospectus supplement or free writing prospectus our intended use for the net proceeds received from the sale of any securities sold pursuant to the prospectus supplement or free writing prospectus.

SECURITIES WE MAY OFFER

This prospectus contains summary descriptions of the securities we may offer from time to time. These summary descriptions are not meant to be complete descriptions of each security. The particular terms of any security will be described in the applicable prospectus supplement.

DESCRIPTION OF CAPITAL STOCK

We have authorized capital stock consisting of 100,000,000 shares of common stock and 10,000,000 shares of preferred stock, each of par value $0.001 per share. Except as otherwise provided in the certificate of designation of any series of preferred stock we may issue, the number of authorized shares of common stock or preferred stock may from time to time be increased or decreased (but not below the number of shares of such class outstanding) by the affirmative vote of the holders of a majority in voting power of the outstanding shares of our capital stock.

As of the date of this prospectus, we had 5,478,436 shares of common stock issued and outstanding, and no shares of preferred stock issued and outstanding. Unless stated otherwise, the following discussion summarizes the term and provisions of our certificate of incorporation, as amended (the "Charter") and our bylaws, as amended (the "Bylaws").

Common Stock

Registration

Our common stock is registered under Section 12 of the Securities Exchange Act of 1934, as amended.

Dividends

Holders of our common stock are entitled to receive dividends ratably, if any, as may be declared by our board of directors out of legally available funds, subject to any preferential dividend rights of any preferred stock then outstanding.

Voting

Holders of our common stock are entitled to one vote for each share of our common stock held of record for the election of directors and on all matters submitted to a vote of the stockholders. The holders of our common stock do not have any cumulative voting rights.

Distributions on Liquidation

In the event of our dissolution, liquidation or winding up, holders of our common stock are entitled to share ratably in our net assets legally available after the payment of all our debts and other liabilities, subject to the preferential rights of any preferred stock then outstanding. The rights, preferences and privileges of holders of our common stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of preferred stock that we may designate and issue in the future.

Other Rights

Holders of our common stock have no preemptive, subscription, redemption or conversion rights, and no sinking fund provisions are applicable to our common stock.

Relationship to Preferred Stock

Under our Charter, our board of directors is authorized, without further action by the stockholders, to designate and issue up to an aggregate of 10,000,000 shares of preferred stock in one or more series and to fix the rights, preferences, privileges and restrictions thereof. These rights, preferences and privileges could include dividend rights, conversion rights, voting rights, terms of redemption, liquidation preferences, sinking fund terms and the number of shares constituting, or the designation of, such series, any or all of which may be greater than the rights of our common stock. Our board of directors may authorize the issuance of preferred stock with voting or conversion rights that could adversely affect the voting power or other rights of the holders of our common stock and the likelihood that such holders will receive dividend payments and payments upon our liquidation.

The purpose of authorizing our board of directors to issue preferred stock in one or more series and determine the number of shares in the series and its rights, preferences, privileges and restrictions is to eliminate delays associated with a stockholder vote on specific issuances. The issuance of preferred stock, while providing flexibility in connection with possible future financings and acquisitions and other corporate purposes could, under certain circumstances, have the effect of delaying, deferring or preventing a change in control of our company. See the section entitled "*Anti-Takeover Effects of Provisions of our Charter, our Bylaws and Delaware Law—Undesignated Preferred Stock*" for more information.

Undesignated Preferred Stock

Our Charter provides for 10,000,000 authorized shares of preferred stock. The existence of authorized but unissued shares of preferred stock may enable our board of directors to render more difficult or to discourage an attempt to obtain control of us by means of a merger, tender offer, proxy contest or otherwise. For example, if in the due exercise of its fiduciary obligations, our board of directors were to determine that a takeover proposal is not in the best interests of our stockholders, our board of directors could cause shares of preferred stock to be issued without stockholder approval in one or more private offerings or other transactions that might dilute the voting or other rights of the proposed acquirer or insurgent stockholder or stockholder group. The issuance of shares of preferred stock could decrease the amount of earnings and assets available for distribution to holders of shares of our common stock. The issuance may also adversely affect the rights and powers, including voting rights, of these holders and may have the effect of delaying, deterring or preventing a change in control of us.

Other Convertible Securities

In July 2010, the Company adopted the 2010 Share Incentive Plan (the "2010 Plan"), pursuant to which the Company's Board was authorized to grant options exercisable into common stock of the Company. On April 26, 2024, the Company adopted the Glucotrack, Inc. 2024 Equity Incentive Plan (the "2024 Plan"). Following the adoption of the 2024 Plan, no additional stock awards will be granted under the 2010 Plan, provided that any awards outstanding will continue to be outstanding and in effect, until they are exercised, vest or are terminated under the provisions of the 2010 Plan. The purpose of the 2024 Plan is to provide employees, directors, and consultants with opportunities to acquire the Company's common stock, 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. The 2024 Plan provides for the grant of stock options, stock appreciation rights, restricted stock, restricted stock units, and other stock-based awards. Up to 535,127 shares of our common stock may be issued under the 2024 Plan.

Anti-Takeover Effects of our Charter, our Bylaws and Delaware Law

Certain provisions of the Delaware General Corporation Law ("DGCL") and of our Charter and Bylaws could have the effect of delaying, deferring or discouraging another party from acquiring control of us. These provisions, which are summarized below, are expected to discourage certain types of coercive takeover practices and inadequate takeover bids and, as a consequence, they might also inhibit temporary fluctuations in the market price of our common stock that often result from actual or rumored hostile takeover attempts. These provisions are also designed in part to encourage anyone seeking to acquire control of us to first negotiate with our board of directors. These provisions might also have the effect of preventing changes in our management. It is possible that these provisions could make it more difficult to accomplish transactions that stockholders might otherwise deem to be in their best interests. However, we believe that the advantages gained by protecting our ability to negotiate with any unsolicited and potentially unfriendly acquirer outweigh the disadvantages of discouraging such proposals, including those priced above the then-current market value of our common stock, because, among other reasons, the negotiation of such proposals could improve their terms.

Delaware Anti-Takeover Statute

We are subject to the provisions of Section 203 of the DGCL. In general, Section 203 prohibits a publicly held Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a three-year period following the time that this stockholder becomes an interested stockholder, unless the business combination is approved in a prescribed manner. Under Section 203, a business combination between a corporation and an interested stockholder is prohibited unless it satisfies one of the following conditions:

- before the stockholder became interested, the board of directors approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;

- upon consummation of the transaction which resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the voting stock outstanding, shares owned by persons who are directors and also officers, and employee stock plans, in some instances, but not the outstanding voting stock owned by the interested stockholder; or

- at or after the time the stockholder became interested, the business combination was approved by the board of directors and authorized at an annual or special meeting of the stockholders by the affirmative vote of at least two-thirds of the outstanding voting stock which is not owned by the interested stockholder.

Section 203 defines a business combination to include:

- any merger or consolidation involving the corporation and the interested stockholder;

- any sale, transfer, lease, pledge or other disposition involving the interested stockholder of 10% or more of the assets of the corporation;

- subject to exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;

- subject to exceptions, any transaction involving the corporation that has the effect of increasing the proportionate share of the stock of any class or series of the corporation beneficially owned by the interested stockholder; and

- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation.

In general, Section 203 defines an interested stockholder as any entity or person beneficially owning 15% or more of the outstanding voting stock of the corporation and any entity or person affiliated with or controlling or controlled by the entity or person.

Board Composition and Filling Vacancies

In accordance with our Charter, any vacancy on our board of directors, however occurring, including a vacancy resulting from an increase in the size of our board, may only be filled by the affirmative vote of a majority of our directors then in office, even if less than a quorum. These provisions may discourage a third-party from voting to remove incumbent directors and simultaneously gaining control of the board of directors by filling the vacancies created by that removal with its own nominees.

Meetings of Stockholders

Our Charter and our Bylaws provide that only a majority of the members of our board of directors then in office, the Chairman of the Board, or the President may call special meetings of stockholders, and only those matters set forth in the notice of the special meeting may be considered or acted upon at a special meeting of stockholders. Our Bylaws limit the business that may be conducted at an annual meeting of stockholders to those matters properly brought before the meeting. These provisions may discourage another person or entity from making a tender offer, even if it acquired a majority of our outstanding voting stock, because the person or entity could only take action at a duly called stockholders' meeting relating to the business specified in the notice of meeting and not by written consent.

Advance Notice Requirements

Our Bylaws establish advance notice procedures with regard to stockholder proposals relating to the nomination of candidates for election as directors or new business to be brought before meetings of our stockholders. These procedures provide that notice of stockholder proposals must be timely given in writing to our corporate secretary prior to the meeting at which the action is to be taken. Generally, to be timely, notice must be received at our principal executive offices not less than 90 days nor more than 120 days prior to the first anniversary date of the notice for the annual meeting for the preceding year. Our Bylaws specify the requirements as to form and content of all stockholders' notices. These provisions could delay stockholder actions that are favored by the holders of a majority of our outstanding stock until the next stockholders' meeting.

Amendment to our Charter and our Bylaws

As required by the DGCL, any amendment of our Charter must first be approved by a majority of our board of directors, and if required by law or our Charter, must thereafter be approved by a majority of the outstanding shares entitled to vote on the amendment and a majority of the outstanding shares of each class entitled to vote thereon as a class.

Our Bylaws may be amended by the affirmative vote of a majority of the directors then in office, subject to any limitations set forth in the Bylaws, provided that, any Bylaw adopted or amended by the directors of the Company, and any powers thereby conferred, may be amended, altered or repealed by the stockholders.

Limitations of Liability and Indemnification Matters

For a discussion of liability and indemnification, see "*Item 15. Indemnification of Directors and Officers*".

Transfer Agent

We have appointed VStock Transfer, LLC to serve as transfer agent and registrar for our common stock.

DESCRIPTION OF DEBT SECURITIES

We may issue debt securities from time to time, in one or more series, as either senior or subordinated debt or as senior or subordinated convertible debt. While the terms we have summarized below will apply generally to any debt securities that we may offer under this prospectus, we will describe the particular terms of any debt securities that we may offer in more detail in the applicable prospectus supplement. The terms of any debt securities offered under a prospectus supplement may differ from the terms described below. Unless the context requires otherwise, whenever we refer to the indenture, we also are referring to any supplemental indentures that specify the terms of a particular series of debt securities.

We will issue the debt securities under the indenture that we will enter into with the trustee named in the indenture. The indenture will be qualified under the Trust Indenture Act of 1939, as amended, or the Trust Indenture Act. We have filed the form of indenture as an exhibit to the registration statement of which this prospectus is a part, and supplemental indentures and forms of debt securities containing the terms of the debt securities being offered will be filed as exhibits to the registration statement of which this prospectus is a part, or will be incorporated by reference from, reports that we file with the SEC.

The following summary of material provisions of the debt securities and the indenture is subject to, and qualified in its entirety by reference to, all of the provisions of the indenture applicable to a particular series of debt securities. We urge you to read the applicable prospectus supplements and any related free writing prospectuses related to the debt securities that we may offer under this prospectus, as well as the complete indenture that contains the terms of the debt securities.

General

The indenture does not limit the amount of debt securities that we may issue. It provides that we may issue debt securities up to the principal amount that we may authorize and may be in any currency or currency unit that we may designate. Except for the limitations on consolidation, merger and sale of all or substantially all of our assets contained in the indenture, the terms of the indenture do not contain any covenants or other provisions designed to give holders of any debt securities protection against changes in our operations, financial condition or transactions involving us.

We may issue the debt securities issued under the indenture as “discount securities,” which means they may be sold at a discount below their stated principal amount. These debt securities, as well as other debt securities that are not issued at a discount, may be issued with “original issue discount,” or OID, for U.S. federal income tax purposes because of interest payment and other characteristics or terms of the debt securities. Material U.S. federal income tax considerations applicable to debt securities issued with OID will be described in more detail in any applicable prospectus supplement.

We will describe in the applicable prospectus supplement the terms of the series of debt securities being offered, including:

- the title of the series of debt securities;
- any limit upon the aggregate principal amount that may be issued;
- the maturity date or dates;
- the form of the debt securities of the series;
- the applicability of any guarantees;
- whether or not the debt securities will be secured or unsecured, and the terms of any secured debt;
- whether the debt securities rank as senior debt, senior subordinated debt, subordinated debt or any combination thereof, and the terms of any subordination;

- if the price (expressed as a percentage of the aggregate principal amount thereof) at which such debt securities will be issued is a price other than the principal amount thereof, the portion of the principal amount thereof payable upon declaration of acceleration of the maturity thereof, or if applicable, the portion of the principal amount of such debt securities that is convertible into another security or the method by which any such portion shall be determined;

- the interest rate or rates, which may be fixed or variable, or the method for determining the rate and the date interest will begin to accrue, the dates interest will be payable and the regular record dates for interest payment dates or the method for determining such dates;

- our right, if any, to defer payment of interest and the maximum length of any such deferral period;

- if applicable, the date or dates after which, or the period or periods during which, and the price or prices at which, we may, at our option, redeem the series of debt securities pursuant to any optional or provisional redemption provisions and the terms of those redemption provisions;

- the date or dates, if any, on which, and the price or prices at which we are obligated, pursuant to any mandatory sinking fund or analogous fund provisions or otherwise, to redeem, or at the holder's option to purchase, the series of debt securities and the currency or currency unit in which the debt securities are payable;

- the denominations in which we will issue the series of debt securities, if other than denominations of $1,000 and any integral multiple thereof;

- any and all terms, if applicable, relating to any auction or remarketing of the debt securities of that series and any security for our obligations with respect to such debt securities and any other terms which may be advisable in connection with the marketing of debt securities of that series;

- whether the debt securities of the series shall be issued in whole or in part in the form of a global security or securities; the terms and conditions, if any, upon which such global security or securities may be exchanged in whole or in part for other individual securities; and the depositary for such global security or securities;

- if applicable, the provisions relating to conversion or exchange of any debt securities of the series and the terms and conditions upon which such debt securities will be so convertible or exchangeable, including the conversion or exchange price, as applicable, or how it will be calculated and may be adjusted, any mandatory or optional (at our option or the holders' option) conversion or exchange features, the applicable conversion or exchange period and the manner of settlement for any conversion or exchange;

- if other than the full principal amount thereof, the portion of the principal amount of debt securities of the series which shall be payable upon declaration of acceleration of the maturity thereof;

- additions to or changes in the covenants applicable to the particular debt securities being issued, including, among others, the consolidation, merger or sale covenant;

- additions to or changes in the events of default with respect to the securities and any change in the right of the trustee or the holders to declare the principal, premium, if any, and interest, if any, with respect to such securities to be due and payable;

- additions to or changes in or deletions of the provisions relating to covenant defeasance and legal defeasance;

- additions to or changes in the provisions relating to satisfaction and discharge of the indenture;

- additions to or changes in the provisions relating to the modification of the indenture both with and without the consent of holders of debt securities issued under the indenture;

- the currency of payment of debt securities if other than U.S. dollars and the manner of determining the equivalent amount in U.S. dollars;

- whether interest will be payable in cash or additional debt securities at our or the holders' option and the terms and conditions upon which the election may be made;

- the terms and conditions, if any, upon which we will pay amounts in addition to the stated interest, premium, if any and principal amounts of the debt securities of the series to any holder that is not a "United States person" for federal tax purposes;

- any restrictions on transfer, sale or assignment of the debt securities of the series; and

- any other specific terms, preferences, rights or limitations of, or restrictions on, the debt securities, any other additions or changes in the provisions of the indenture, and any terms that may be required by us or advisable under applicable laws or regulations.

Conversion or Exchange Rights

We will set forth in the applicable prospectus supplement the terms on which a series of debt securities may be convertible into or exchangeable for our common stock or our other securities. We will include provisions as to settlement upon conversion or exchange and whether conversion or exchange is mandatory, at the option of the holder or at our option. We may include provisions pursuant to which the number of shares of our common stock or our other securities that the holders of the series of debt securities receive would be subject to adjustment.

Consolidation, Merger or Sale

Unless we provide otherwise in the prospectus supplement applicable to a particular series of debt securities, the indenture will not contain any covenant that restricts our ability to merge or consolidate, or sell, convey, transfer or otherwise dispose of our assets as an entirety or substantially as an entirety. However, any successor to or acquirer of such assets (other than any subsidiary of ours) must assume all of our obligations under the indenture or the debt securities, as appropriate.

Events of Default under the Indenture

Unless we provide otherwise in the prospectus supplement applicable to a particular series of debt securities, the following are events of default under the indenture with respect to any series of debt securities that we may issue:

- if we fail to pay any installment of interest on any series of debt securities, as and when the same shall become due and payable, and such default continues for a period of 90 days; provided, however, that a valid extension of an interest payment period by us in accordance with the terms of any indenture supplemental thereto shall not constitute a default in the payment of interest for this purpose;

- if we fail to pay the principal of, or premium, if any, on any series of debt securities as and when the same shall become due and payable whether at maturity, upon redemption, by declaration or otherwise, or in any payment required by any sinking or analogous fund established with respect to such series; provided, however, that a valid extension of the maturity of such debt securities in accordance with the terms of any indenture supplemental thereto shall not constitute a default in the payment of principal or premium, if any;

- if we fail to observe or perform any other covenant or agreement contained in the debt securities or the indenture, other than a covenant specifically relating to another series of debt securities, and our failure continues for 90 days after we receive written notice of such failure, requiring the same to be remedied and stating that such is a notice of default thereunder, from the trustee or holders of at least 25% in aggregate principal amount of the outstanding debt securities of the applicable series; and

- if specified events of bankruptcy, insolvency or reorganization occur.

If an event of default with respect to debt securities of any series occurs and is continuing, other than an event of default specified in the last bullet point above, the trustee or the holders of at least 25% in aggregate principal mount of the outstanding debt securities of that series, by notice to us in writing, and to the trustee if notice is given by such holders, may declare the unpaid principal of, premium, if any, and accrued interest, if any, due and payable immediately. If an event of default specified in the last bullet point above occurs with respect to us, the principal amount of and accrued interest, if any, of each issue of debt securities then outstanding shall be due and payable without any notice or other action on the part of the trustee or any holder.

The holders of a majority in principal amount of the outstanding debt securities of an affected series may waive any default or event of default with respect to the series and its consequences, except defaults or events of default regarding payment of principal, premium, if any, or interest, unless we have cured the default or event of default in accordance with the indenture. Any waiver shall cure the default or event of default.

Subject to the terms of the indenture, if an event of default under an indenture shall occur and be continuing, the trustee will be under no obligation to exercise any of its rights or powers under such indenture at the request or direction of any of the holders of the applicable series of debt securities, unless such holders have offered the trustee reasonable indemnity. The holders of a majority in principal amount of the outstanding debt securities of any series will have the right to direct the time, method and place of conducting any proceeding for any remedy available to the trustee, or exercising any trust or power conferred on the trustee, with respect to the debt securities of that series, provided that:

- the direction so given by the holder is not in conflict with any law or the applicable indenture; and
- subject to its duties under the Trust Indenture Act, the trustee need not take any action that might involve it in personal liability or might be unduly prejudicial to the holders not involved in the proceeding.

A holder of the debt securities of any series will have the right to institute a proceeding under the indenture or to appoint a receiver or trustee, or to seek other remedies only if:

- the holder has given written notice to the trustee of a continuing event of default with respect to that series;
- the holders of at least 25% in aggregate principal amount of the outstanding debt securities of that series have made written request,
- such holders have offered to the trustee indemnity satisfactory to it against the costs, expenses and liabilities to be incurred by the trustee in compliance with the request; and
- the trustee does not institute the proceeding, and does not receive from the holders of a majority in aggregate principal amount of the outstanding debt securities of that series other conflicting directions within 90 days after the notice, request and offer.

These limitations do not apply to a suit instituted by a holder of debt securities if we default in the payment of the principal, premium, if any, or interest on, the debt securities.

We will periodically file statements with the trustee regarding our compliance with specified covenants in the indenture.

Modification of Indenture; Waiver

We and the trustee may change an indenture without the consent of any holders with respect to specific matters:

- to cure any ambiguity, defect or inconsistency in the indenture or in the debt securities of any series;
- to comply with the provisions described above under "*Description of Debt Securities—Consolidation, Merger or Sale*";
- to provide for uncertificated debt securities in addition to or in place of certificated debt securities;
- to add to our covenants, restrictions, conditions or provisions such new covenants, restrictions, conditions or provisions for the benefit of the holders of all or any series of debt securities, to make the occurrence, or the occurrence and the continuance, of a default in any such additional covenants, restrictions, conditions or provisions an event of default or to surrender any right or power conferred upon us in the indenture;
- to add to, delete from or revise the conditions, limitations, and restrictions on the authorized amount, terms, or purposes of issue, authentication and delivery of debt securities, as set forth in the indenture;
- to make any change that does not adversely affect the interests of any holder of debt securities of any series in any material respect;
- to provide for the issuance of and establish the form and terms and conditions of the debt securities of any series as provided above under "*Description of Debt Securities—General*" to establish the form of any certifications required to be furnished pursuant to the terms of the indenture or any series of debt securities, or to add to the rights of the holders of any series of debt securities;
- to evidence and provide for the acceptance of appointment under any indenture by a successor trustee; or

- to comply with any requirements of the SEC in connection with the qualification of any indenture under the Trust Indenture Act.

In addition, under the indenture, the rights of holders of a series of debt securities may be changed by us and the trustee with the written consent of the holders of at least a majority in aggregate principal amount of the outstanding debt securities of each series that is affected. However, unless we provide otherwise in the prospectus supplement applicable to a particular series of debt securities, we and the trustee may make the following changes only with the consent of each holder of any outstanding debt securities affected:

- extending the fixed maturity of any debt securities of any series;
- reducing the principal amount, reducing the rate of or extending the time of payment of interest, or reducing any premium payable upon the redemption of any series of any debt securities; or
- reducing the percentage of debt securities, the holders of which are required to consent to any amendment, supplement, modification or waiver.

Discharge

Each indenture provides that we can elect to be discharged from our obligations with respect to one or more series of debt securities, except for specified obligations, including obligations to:

- provide for payment;
- register the transfer or exchange of debt securities of the series;
- replace stolen, lost or mutilated debt securities of the series;
- pay principal of and premium and interest on any debt securities of the series;
- maintain paying agencies;
- hold monies for payment in trust;
- recover excess money held by the trustee;
- compensate and indemnify the trustee; and
- appoint any successor trustee.

In order to exercise our rights to be discharged, we must deposit with the trustee money or government obligations sufficient to pay all the principal of, any premium, if any, and interest on, the debt securities of the series on the dates payments are due.

Form, Exchange and Transfer

We will issue the debt securities of each series only in fully registered form without coupons and, unless we provide otherwise in the applicable prospectus supplement, in denominations of $1,000 and any integral multiple thereof. The indenture provides that we may issue debt securities of a series in temporary or permanent global form and as book-entry securities that will be deposited with, or on behalf of, The Depository Trust Company, or DTC, or another depositary named by us and identified in the applicable prospectus supplement with respect to that series. To the extent the debt securities of a series are issued in global form and as book-entry, a description of terms relating to any book-entry securities will be set forth in the applicable prospectus supplement.

At the option of the holder, subject to the terms of the indenture and the limitations applicable to global securities described in the applicable prospectus supplement, the holder of the debt securities of any series can exchange the debt securities for other debt securities of the same series, in any authorized denomination and of like tenor and aggregate principal amount.

Subject to the terms of the indenture and the limitations applicable to global securities set forth in the applicable prospectus supplement, holders of the debt securities may present the debt securities for exchange or for registration of transfer, duly endorsed or with the form of transfer endorsed thereon duly executed if so required by us or the security registrar, at the office of the security registrar or at the office of any transfer agent designated by us for this purpose. Unless otherwise provided in the debt securities that the holder presents for transfer or exchange, we will impose no service charge for any registration of transfer or exchange, but we may require payment of any taxes or other governmental charges.

We will name in the applicable prospectus supplement the security registrar, and any transfer agent in addition to the security registrar, that we initially designate for any debt securities. We may at any time designate additional transfer agents or rescind the designation of any transfer agent or approve a change in the office through which any transfer agent acts, except that we will be required to maintain a transfer agent in each place of payment for the debt securities of each series.

If we elect to redeem the debt securities of any series, we will not be required to:

- issue, register the transfer of, or exchange any debt securities of that series during a period beginning at the opening of business 15 days before the day of mailing of a notice of redemption of any debt securities that may be selected for redemption and ending at the close of business on the day of the mailing; or

- register the transfer of or exchange any debt securities so selected for redemption, in whole or in part, except the unredeemed portion of any debt securities we are redeeming in part.

Information Concerning the Trustee

The trustee, other than during the occurrence and continuance of an event of default under an indenture, undertakes to perform only those duties as are specifically set forth in the applicable indenture. Upon an event of default under an indenture, the trustee must use the same degree of care as a prudent person would exercise or use in the conduct of his or her own affairs. Subject to this provision, the trustee is under no obligation to exercise any of the powers given it by the indenture at the request of any holder of debt securities unless it is offered reasonable security and indemnity against the costs, expenses and liabilities that it might incur.

Payment and Paying Agents

Unless we otherwise indicate in the applicable prospectus supplement, we will make payment of the interest on any debt securities on any interest payment date to the person in whose name the debt securities, or one or more predecessor securities, are registered at the close of business on the regular record date for the interest.

We will pay principal of and any premium and interest on the debt securities of a particular series at the office of the paying agents designated by us, except that unless we otherwise indicate in the applicable prospectus supplement, we will make interest payments by check that we will mail to the holder or by wire transfer to certain holders. Unless we otherwise indicate in the applicable prospectus supplement, we will designate the corporate trust office of the trustee as our sole paying agent for payments with respect to debt securities of each series. We will name in the applicable prospectus supplement any other paying agents that we initially designate for the debt securities of a particular series. We will maintain a paying agent in each place of payment for the debt securities of a particular series.

All money we pay to a paying agent or the trustee for the payment of the principal of or any premium or interest on any debt securities that remains unclaimed at the end of two years after such principal, premium or interest has become due and payable will be repaid to us, and the holder of the debt security thereafter may look only to us for payment thereof.

Governing Law

The indenture and the debt securities will be governed by and construed in accordance with the laws of the state of New York, except to the extent that the Trust Indenture Act of 1939 is applicable.

DESCRIPTION OF WARRANTS

The following description, together with the additional information we may include in any applicable prospectus supplements, summarizes the material terms and provisions of the warrants that we may offer under this prospectus and the related warrant agreements and warrant certificates. While the terms summarized below will apply generally to any warrants that we may offer, we will describe the particular terms of any series of warrants in more detail in the applicable prospectus supplement. If we indicate in the prospectus supplement, the terms of any warrants offered under that prospectus supplement may differ from the terms described below. Specific warrant agreements will contain additional important terms and provisions and will be incorporated by reference as an exhibit to the registration statement, which includes this prospectus.

General

We may issue warrants for the purchase of common stock, and, or preferred stock in one or more series. We may issue warrants independently or together with common stock, and, or preferred stock, and the warrants may be attached to or separate from these securities.

We will evidence each series of warrants by warrant certificates that we will issue under a separate warrant agreement. We will enter into the warrant agreement with a warrant agent. We will indicate the name and address of the warrant agent in the applicable prospectus supplement relating to a particular series of warrants.

We will describe in the applicable prospectus supplement the terms of the series of warrants, including:

- the offering price and aggregate number of warrants offered;
- the currency for which the warrants may be purchased;
- if applicable, the designation and terms of the securities with which the warrants are issued and the number of warrants issued with each such security or each principal amount of such security;
- if applicable, the date on and after which the warrants and the related securities will be separately transferable;
- in the case of warrants to purchase common stock or preferred stock, the number of shares of common stock or preferred stock, as the case may be, purchasable upon the exercise of one warrant and the price at which these shares may be purchased upon such exercise;
- the effect of any merger, consolidation, sale or other disposition of our business on the warrant agreement and the warrants;
- the terms of any rights to redeem or call the warrants;
- any provisions for changes to or adjustments in the exercise price or number of securities issuable upon exercise of the warrants;
- the periods during which, and places at which, the warrants are exercisable;
- the manner of exercise;
- the dates on which the right to exercise the warrants will commence and expire;
- the manner in which the warrant agreement and warrants may be modified;
- federal income tax consequences of holding or exercising the warrants;
- the terms of the securities issuable upon exercise of the warrants; and
- any other specific terms, preferences, rights or limitations of or restrictions on the warrants.

DESCRIPTION OF UNITS

We may issue units comprised of shares of common stock, shares of preferred stock and warrants in any combination. We may issue units in such amounts and in as many distinct series as we wish. This section outlines certain provisions of the units that we may issue. If we issue units, they will be issued under one or more unit agreements to be entered into between us and a bank or other financial institution, as unit agent. The information described in this section may not be complete in all respects and is qualified entirely by reference to the unit agreement with respect to the units of any particular series. The specific terms of any series of units offered will be described in the applicable prospectus supplement. If so described in a particular supplement, the specific terms of any series of units may differ from the general description of terms presented below. We urge you to read any prospectus supplement related to any series of units we may offer, as well as the complete unit agreement and unit certificate that contain the terms of the units. If we issue units, forms of unit agreements and unit certificates relating to such units will be incorporated by reference as exhibits to the registration statement, which includes this prospectus.

Each unit that we may issue will be issued so that the holder of the unit is also the holder of each security included in the unit. Thus, the holder of a unit will have the rights and obligations of a holder of each included security. The unit agreement under which a unit is issued may provide that the securities included in the unit may not be held or transferred separately, at any time or at any time before a specified date. The applicable prospectus supplement may describe:

- the designation and terms of the units and of the securities comprising the units, including whether and under what circumstances those securities may be held or transferred separately;
- any provisions of the governing unit agreement;
- the price or prices at which such units will be issued;
- the applicable United States federal income tax considerations relating to the units;
- any provisions for the issuance, payment, settlement, transfer or exchange of the units or of the securities comprising the units; and
- any other terms of the units and of the securities comprising the units.

The provisions described in this section, as well as those described under "*Description of Capital Stock*," and "*Description of Warrants*" will apply to the securities included in each unit, to the extent relevant and as may be updated in any prospectus supplements.

Issuance in Series

We may issue units in such amounts and in as many distinct series as we wish. This section summarizes terms of the units that apply generally to all series. Most of the financial and other specific terms of a particular series of units will be described in the applicable prospectus supplement.

Unit Agreements

We will issue the units under one or more unit agreements to be entered into between us and a bank or other financial institution, as unit agent. We may add, replace or terminate unit agents from time to time. We will identify the unit agreement under which each series of units will be issued and the unit agent under that agreement in the applicable prospectus supplement.

The following provisions will generally apply to all unit agreements unless otherwise stated in the applicable prospectus supplement:

Modification without Consent

We and the applicable unit agent may amend any unit or unit agreement without the consent of any holder:

- to cure any ambiguity; any provisions of the governing unit agreement that differ from those described below;
- to correct or supplement any defective or inconsistent provision; or
- to make any other change that we believe is necessary or desirable and will not adversely affect the interests of the affected holders in any material respect.

We do not need any approval to make changes that affect only units to be issued after the changes take effect. We may also make changes that do not adversely affect a particular unit in any material respect, even if they adversely affect other units in a material

respect. In those cases, we do not need to obtain the approval of the holder of the unaffected unit; we need only obtain any required approvals from the holders of the affected units.

Modification with Consent

We may not amend any particular unit or a unit agreement with respect to any particular unit unless we obtain the consent of the holder of that unit, if the amendment would:

- impair any right of the holder to exercise or enforce any right under a security included in the unit if the terms of that security require the consent of the holder to any changes that would impair the exercise or enforcement of that right; or

- reduce the percentage of outstanding units or any series or class the consent of whose holders is required to amend that series or class, or the applicable unit agreement with respect to that series or class, as described below.

Any other change to a particular unit agreement and the units issued under that agreement would require the following approval:

- If the change affects only the units of a particular series issued under that agreement, the change must be approved by the holders of a majority of the outstanding units of that series; or

- If the change affects the units of more than one series issued under that agreement, it must be approved by the holders of a majority of all outstanding units of all series affected by the change, with the units of all the affected series voting together as one class for this purpose.

These provisions regarding changes with majority approval also apply to changes affecting any securities issued under a unit agreement, as the governing document.

In each case, the required approval must be given by written consent.

Unit Agreements Will Not Be Qualified under Trust Indenture Act

No unit agreement will be qualified as an indenture, and no unit agent will be required to qualify as a trustee, under the Trust Indenture Act. Therefore, holders of units issued under unit agreements will not have the protections of the Trust Indenture Act with respect to their units.

Mergers and Similar Transactions Permitted; No Restrictive Covenants or Events of Default

The unit agreements will not restrict our ability to merge or consolidate with, or sell our assets to, another corporation or other entity or to engage in any other transactions. If at any time we merge or consolidate with, or sell our assets substantially as an entirety to, another corporation or other entity, the successor entity will succeed to and assume our obligations under the unit agreements. We will then be relieved of any further obligation under these agreements.

The unit agreements will not include any restrictions on our ability to put liens on our assets, nor will they restrict our ability to sell our assets. The unit agreements also will not provide for any events of default or remedies upon the occurrence of any events of default.

Governing Law

The unit agreements and the units will be governed by New York law.

Form, Exchange and Transfer

We will issue each unit in global—i.e., book-entry—form only. Units in book-entry form will be represented by a global security registered in the name of a depositary, which will be the holder of all the units represented by the global security. Those who own beneficial interests in a unit will do so through participants in the depositary's system, and the rights of these indirect owners will be governed solely by the applicable procedures of the depositary and its participants. We will describe book-entry securities, and other terms regarding the issuance and registration of the units in the applicable prospectus supplement.

Each unit and all securities comprising the unit will be issued in the same form.

If we issue any units in registered, non-global form, the following will apply to them.

The units will be issued in the denominations stated in the applicable prospectus supplement. Holders may exchange their units for units of smaller denominations or combined into fewer units of larger denominations, as long as the total amount is not changed.

- Holders may exchange or transfer their units at the office of the unit agent. Holders may also replace lost, stolen, destroyed or mutilated units at that office. We may appoint another entity to perform these functions or perform them ourselves.

- Holders will not be required to pay a service charge to transfer or exchange their units, but they may be required to pay for any tax or other governmental charge associated with the transfer or exchange. The transfer or exchange, and any replacement, will be made only if our transfer agent is satisfied with the holder's proof of legal ownership. The transfer agent may also require an indemnity before replacing any units.

- If we have the right to redeem, accelerate or settle any units before their maturity, and we exercise our right as to less than all those units or other securities, we may block the exchange or transfer of those units during the period beginning 15 days before the day we mail the notice of exercise and ending on the day of that mailing, in order to freeze the list of holders to prepare the mailing. We may also refuse to register transfers of or exchange any unit selected for early settlement, except that we will continue to permit transfers and exchanges of the unsettled portion of any unit being partially settled. We may also block the transfer or exchange of any unit in this manner if the unit includes securities that are or may be selected for early settlement.

Only the depositary will be entitled to transfer or exchange a unit in global form, since it will be the sole holder of the unit.

Payments and Notices

In making payments and giving notices with respect to our units, we will follow the procedures as described in the applicable prospectus supplement.

PLAN OF DISTRIBUTION

We may sell securities:

- through underwriters;
- through dealers;
- through agents;
- directly to purchasers;
- in an “at the market offering”, within the meaning of Rule 415(a)(4) of the Securities Act; or
- through a combination of any of these methods or any other method permitted by law.

In addition, we may issue the securities as a dividend or distribution or in a subscription rights offering to our existing security holders. This prospectus may be used in connection with any offering of our securities through any of these methods or other methods described in the applicable prospectus supplement.

We may directly solicit offers to purchase securities, or agents may be designated to solicit such offers. In the prospectus supplement relating to such offering, we will name any agent that could be viewed as an underwriter under the Securities Act and describe any commissions that we must pay to any such agent. Any such agent will be acting on a best efforts basis for the period of its appointment or, if indicated in the applicable prospectus supplement, on a firm commitment basis. This prospectus may be used in connection with any offering of our securities through any of these methods or other methods described in the applicable prospectus supplement.

The distribution of the securities may be effected from time to time in one or more transactions:

- at a fixed price, or prices, which may be changed from time to time;
- at market prices prevailing at the time of sale;
- at prices related to such prevailing market prices; or
- at negotiated prices.

Each prospectus supplement will describe the method of distribution of the securities and any applicable restrictions.

The prospectus supplement with respect to the securities of a particular series will describe the terms of the offering of the securities, including the following:

- the name of the agent or any underwriters;
- the public offering or purchase price;
- any discounts and commissions to be allowed or paid to the agent or underwriters;
- all other items constituting underwriting compensation;
- any discounts and commissions to be allowed or paid to dealers; and
- any exchanges on which the securities will be listed.

If any underwriters or agents are used in the sale of the securities in respect of which this prospectus is delivered, we will enter into an underwriting agreement, sales agreement or other agreement with them at the time of sale to them, and we will set forth in the prospectus supplement relating to such offering the names of the underwriters or agents and the terms of the related agreement with them.

In connection with the offering of securities, we may grant to the underwriters an option to purchase additional securities with an additional underwriting commission, as may be set forth in the accompanying prospectus supplement. If we grant any such option, the terms of such option will be set forth in the prospectus supplement for such securities.

If a dealer is used in the sale of the securities in respect of which the prospectus is delivered, we will sell such securities to the dealer, as principal. The dealer, who may be deemed to be an "underwriter" as that term is defined in the Securities Act, may then resell such securities to the public at varying prices to be determined by such dealer at the time of resale.

If we offer securities in a subscription rights offering to our existing security holders, we may enter into a standby underwriting agreement with dealers, acting as standby underwriters. We may pay the standby underwriters a commitment fee for the securities they commit to purchase on a standby basis. If we do not enter into a standby underwriting arrangement, we may retain a dealer-manager to manage a subscription rights offering for us.

Agents, underwriters, dealers and other persons may be entitled under agreements which they may enter into with us to indemnification by us against certain civil liabilities, including liabilities under the Securities Act, and may be customers of, engage in transactions with or perform services for us in the ordinary course of business.

If so indicated in the applicable prospectus supplement, we will authorize underwriters or other persons acting as our agents to solicit offers by certain institutions to purchase securities from us pursuant to delayed delivery contracts providing for payment and delivery on the date stated in the prospectus supplement. Each contract will be for an amount not less than, and the aggregate amount of securities sold pursuant to such contracts shall not be less nor more than, the respective amounts stated in the prospectus supplement. Institutions with whom the contracts, when authorized, may be made include commercial and savings banks, insurance companies, pension funds, investment companies, educational and charitable institutions and other institutions, but shall in all cases be subject to our approval. Delayed delivery contracts will not be subject to any conditions except that:

- the purchase by an institution of the securities covered under that contract shall not at the time of delivery be prohibited under the laws of the jurisdiction to which that institution is subject; and

- if the securities are also being sold to underwriters acting as principals for their own account, the underwriters shall have purchased such securities not sold for delayed delivery. The underwriters and other persons acting as our agents will not have any responsibility in respect of the validity or performance of delayed delivery contracts.

Offered securities may also be offered and sold, if so indicated in the prospectus supplement, in connection with a remarketing upon their purchase, in accordance with a redemption or repayment pursuant to their terms, or otherwise, by one or more remarketing firms, acting as principals for their own accounts or as agents for us. Any remarketing firm will be identified and the terms of its agreement, if any, with us and its compensation will be described in the applicable prospectus supplement. Remarketing firms may be deemed to be underwriters in connection with their remarketing of offered securities.

Certain agents, underwriters and dealers, and their associates and affiliates, may be customers of, have borrowing relationships with, engage in other transactions with, or perform services, including investment banking services, for us or one or more of our respective affiliates in the ordinary course of business.

In order to facilitate the offering of the securities, any underwriters may engage in transactions that stabilize, maintain or otherwise affect the price of the securities or any other securities the prices of which may be used to determine payments on such securities. Specifically, any underwriters may overallot in connection with the offering, creating a short position for their own accounts. In addition, to cover overallotments or to stabilize the price of the securities or of any such other securities, the underwriters may bid for, and purchase, the securities or any such other securities in the open market. Finally, in any offering of the securities through a syndicate of underwriters, the underwriting syndicate may reclaim selling concessions allowed to an underwriter or a dealer for distributing the securities in the offering if the syndicate repurchases previously distributed securities in transactions to cover syndicate short positions, in stabilization transactions or otherwise. Any of these activities may stabilize or maintain the market price of the securities above independent market levels. Any such underwriters are not required to engage in these activities and may end any of these activities at any time.

We may engage in at the market offerings into an existing trading market in accordance with Rule 415(a)(4) under the Securities Act. In addition, we may enter into derivative transactions with third parties, or sell securities not covered by this prospectus to third parties in privately negotiated transactions. If the applicable prospectus supplement so indicates, in connection with those derivatives, the third parties may sell securities covered by this prospectus and the applicable prospectus supplement, including in short sale transactions. If so, the third party may use securities pledged by us or borrowed from us or others to settle those sales or to close out any related open borrowings of stock, and may use securities received from us in settlement of those derivatives to close out any related open borrowings of stock. The third party in such sale transactions will be an underwriter and, if not identified in this prospectus, will be named in the applicable prospectus supplement (or a post-effective amendment). In addition, we may otherwise loan or pledge securities to a financial institution or other third party that in turn may sell the securities short using this prospectus and an applicable prospectus supplement. Such financial institution or other third party may transfer its economic short position to investors in our securities or in connection with a concurrent offering of other securities.

Under Rule 15c6-1 of the Exchange Act, trades in the secondary market generally are required to settle in one business day, unless the parties to any such trade expressly agree otherwise. The applicable prospectus supplement may provide that the original issue date for your securities may be more than one scheduled business day after the trade date for your securities. Accordingly, in such a case, if you wish to trade securities on any date prior to the first business day before the original issue date for your securities, you will be required, by virtue of the fact that your securities initially are expected to settle in more than one scheduled business day after the trade date for your securities, to make alternative settlement arrangements to prevent a failed settlement.

The securities may be new issues of securities and may have no established trading market. The securities may or may not be listed on a national securities exchange. We can make no assurance as to the liquidity of or the existence of trading markets for any of the securities.

The specific terms of any lock-up provisions in respect of any given offering will be described in the applicable prospectus supplement.

The underwriters, dealers and agents may engage in transactions with us, or perform services for us, in the ordinary course of business for which they receive compensation.

The anticipated date of delivery of offered securities will be set forth in the applicable prospectus supplement relating to each offer.

LEGAL MATTERS

Certain legal matters in connection with this offering will be passed upon for us by Nelson Mullins Riley & Scarborough LLP, Raleigh, North Carolina. Any underwriters will also be advised about the validity of the securities and other legal matters by their own counsel, which will be named in the prospectus supplement.

EXPERTS

The audited financial statement incorporated by reference in the prospectus and elsewhere in the registration statement have been so incorporated by reference in reliance upon the report of Fahn Kanne & Co. Grant Thornton Israel, independent registered public accountants, upon the authority of said firm as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a registration statement on Form S-3 under the Securities Act with respect to the securities offered by this prospectus. This prospectus, which is part of the registration statement, omits certain information, exhibits, schedules and undertakings set forth in the registration statement. For further information pertaining to us and the securities offered in this prospectus, reference is made to that registration statement and the exhibits and schedules to the registration statement. Statements contained in this prospectus as to the contents or provisions of any documents referred to in this prospectus are not necessarily complete, and in each instance where a copy of the document has been filed as an exhibit to the registration statement, reference is made to the exhibit for a more complete description of the matters involved.

We file annual, quarterly and current reports, proxy statements and other information with the SEC. Our SEC filings are available to the public over the Internet at the SEC's website at www.sec.gov and on our website at https://glucotrack.com. The information found on, or that can be accessed from or that is hyperlinked to, our website is not part of this prospectus. You may inspect a copy of the registration statement through the SEC's website, as provided herein. You may also request a copy of these filings, at no cost, by writing or telephoning us at: 301 Rte. 17 North, Ste. 800, Rutherford, NJ 07070, (201) 842-7715.

INCORPORATION BY REFERENCE

We have elected to incorporate the following documents into this prospectus, together with all exhibits filed therewith or incorporated therein by reference, to the extent not otherwise amended or superseded by the contents of this prospectus:

- our Annual Report on Form 10-K for the fiscal year ended December 31, 2023, as filed with the SEC on March 28, 2024;
- our Quarterly Reports on Form 10-Q for the quarter ended March 31, 2024, as filed with the SEC on May 15, 2024, and for the quarter ended June 30, 2024, as filed with the SEC on August 13, 2024;
- our definitive proxy statement on Schedule 14A, as filed with the SEC on April 1, 2024, to the extent incorporated by reference into Part III of the Annual Report on Form 10-K for the fiscal year ended December 31, 2023;
- our Current Reports on Form 8-K filed with the SEC on January 2, 2024, February 16, 2024, May 2, 2024, May 20, 2024, May 24, 2024, June 20, 2024, July 1, 2024, July 22, 2024, July 31, 2024, September 3, 2024, September 10, 2024, and September 26, 2024; (other than any reports or portions thereof that are furnished under Item 2.02 or Item 7.01 and any exhibits included with such Items); and
- the description of our common stock contained in our Registration Statement on Form 8-A filed with the SEC on December 8, 2021, including any amendments or reports filed with the SEC for the purposes of updating such description.

The information incorporated by reference is an important part of this prospectus. In addition, we incorporate by reference in this prospectus any future filings we make with the SEC under Sections 13(a), 13(c), 14, or 15(d) of the Exchange Act (excluding any information furnished and not filed with the SEC) after the date on which the registration statement that includes this prospectus was initially filed with the SEC (including all such documents we may file with the SEC after the date of the initial registration statement and prior to the effectiveness of the registration statement) and until all offerings under this prospectus are terminated.

Any statement contained in a document incorporated by reference herein shall be deemed to be modified or superseded for all purposes to the extent that a statement contained in this prospectus or in any other subsequently filed document which is also incorporated or deemed to be incorporated by reference, modifies or supersedes such statement. Any statement so modified or superseded shall not be deemed, except as so modified or superseded, to constitute a part of this prospectus.

We will provide, without charge, to each person, including any beneficial owner, to whom a copy of this prospectus is delivered, upon such person's written or oral request, a copy of any and all of the information incorporated by reference in this prospectus. You may request a free copy of any of the documents incorporated by reference in this prospectus by writing or telephoning us at the following address:

GLUCOTRACK, INC.
301 Route 17 North, Ste. 800
Rutherford, NJ 07070
(201) 842-7715

Exhibits to the filings will not be sent, however, unless those exhibits have specifically been incorporated by reference in this prospectus or any accompanying prospectus supplement.

You may also access these documents, free of charge on the SEC's website at *www.sec.gov* or on our website at http://www.glucotrack.com. Information contained on our website is not incorporated by reference into this prospectus, and you should not consider any information on, or that can be accessed from, our website as part of this prospectus or any accompanying prospectus supplement.

Glucotrack, Inc.

[__] shares of Common Stock
[__] Pre-Funded Warrants to Purchase up to [__] shares of Common Stock
[__] Shares of Common Stock Underlying Pre-Funded Warrants

PROSPECTUS SUPPLEMENT

Dawson James Securities, Inc.

September 24, 2026