Filed pursuant to Rule 424(b)(4)
Registration Statement No. 333-293322

PROSPECTUS

Up to 14,285,715 Units, each consisting of:
One Share of Common Stock or One Pre-Funded Warrant to Purchase One Share of Common Stock and One Common Stock Warrant to Purchase up to One Share of Common Stock

Up to 14,285,715 Shares of Common Stock or Shares of Common Stock Underlying Pre-Funded Warrants

Up 14,285,715 Shares of Common Stock Underlying Common Stock Warrants

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We are offering on a reasonable best efforts basis up to 14,285,715 units ("Units"), each consisting of one share of our common stock, par value $0.0001 per share (our "common stock"), and one warrant (each a "Common Stock Warrant" or "warrant"), each warrant to purchase one share of our common stock, at the public offering price of $0.35 per Unit, for gross proceeds of approximately $5 million. The public offering price per Unit has been determined between us and the placement agent based on market conditions at the time of pricing. The Units have no stand-alone rights and will not be certificated or issued as stand-alone securities. The common stock or Pre-Funded Warrants (as defined below) and Common Stock Warrants are immediately separable and will be issued separately in this offering. Each warrant will be immediately exercisable for one share of common stock at an exercise price of $0.35 per share (100% of the public offering price per Unit) and will expire on the fifth anniversary of the original issuance date.

Our common stock is listed on The Nasdaq Capital Market ("Nasdaq") under the symbol "BRTX". On February 11, 2026, the last reported sale price of our common stock was $0.41 per share.

We are also offering to investors in Units that would otherwise result in the investor's beneficial ownership exceeding 4.99% of our outstanding common stock immediately following the consummation of this offering the opportunity to invest in Units consisting of one pre-funded warrant to purchase one share of our common stock ("Pre-Funded Warrant") (in lieu of one share of our common stock), and one Common Stock Warrant. 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 to up to 9.99%) of our common stock outstanding immediately after giving effect to such exercise. Each Pre-Funded Warrant will be exercisable for one share of our common stock. The purchase price of each Unit including a Pre-Funded Warrant will be equal to the price per Unit including one share of our common stock, minus $0.0001, and the exercise price of each Pre-Funded Warrant will equal $0.0001 per share. The Pre-Funded Warrants will be immediately exercisable (subject to the beneficial ownership cap) and may be exercised at any time until all of the Pre-Funded Warrants are exercised in full. For each Unit including a Pre-Funded Warrant purchased (without regard to any limitation on exercise set forth therein), the number of Units including a share of our common stock we are offering will be decreased on a one-for-one basis.

The securities will be offered at a fixed price and are expected to be issued in a single closing. We expect this offering to be completed not later than one business day following the commencement of sales in this offering (after the effective date of the registration statement of which this prospectus forms a part) and we will deliver all securities to be issued in connection with this offering delivery versus payment or receipt versus payment, as the case may be, upon our receipt of investor funds. Accordingly, neither we nor the placement agent have made any arrangements to place investor funds in an escrow account or trust account since the placement agent will not receive investor funds in connection with the sale of the securities offered hereunder.

We have engaged Rodman & Renshaw LLC (the "placement agent" or "Rodman") to act as our exclusive placement agent in connection with this offering. The placement agent has agreed to use its reasonable best efforts to arrange for the sale of the securities offered by this prospectus. 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. We have agreed to pay to the placement agent the fees set forth in the table below, which assumes that we sell all of the securities offered by this prospectus. There is no arrangement for funds to be received in escrow, trust or similar arrangement. There is no minimum offering requirement as a condition of closing of this offering. We may sell fewer than all of the Units offered hereby, which may significantly reduce the amount of proceeds received by us. Because there is no escrow account and no minimum number of securities or amount of proceeds, investors could be in a position where they have invested in us, but we have not raised sufficient proceeds in this offering to adequately fund the intended uses of the proceeds as described in this prospectus. See "Risk Factors" for more information regarding risks related to this offering. We will bear all costs associated with the offering. See "Plan of Distribution" for more information regarding these arrangements.

	Per Unit Consisting of Common Stock and Warrant	Per Unit Consisting of Pre-Funded Warrant and Warrant	Total[2]
Public offering price	$ 0.35	$ 0.35	$ 5,000,000.25
Placement agent fees[1]	$ 0.0245	$ 0.0245	$ 350,000.02
Proceeds to us, before expenses	$ 0.3255	$ 0.3255	$ 4,650,000.23

(1) The placement agent fees shall equal 7.0% of the gross proceeds of the securities sold by us in this offering. The placement agent will receive compensation in addition to the placement agent fees described above. See "Plan of Distribution" for a description of the compensation payable to the placement agent.

(2) The foregoing assumes that no Pre-Funded Warrants are issued as part of the Units.

There is no established trading market for the Pre-Funded Warrants or the Common Stock Warrants and we do not expect an active trading market to develop. We do not intend to list the Pre-Funded Warrants or the Common Stock Warrants on any securities exchange or other trading market. Without an active trading market, the liquidity of these securities will be limited.

We are a smaller reporting company under the federal securities laws and, as such, have elected to comply with certain reduced public company reporting requirements.

Investing in our securities involves a high degree of risk. You should carefully read and consider the risks that are described in the "Risk Factors" section beginning on page 6 of this prospectus before making a decision to invest in our securities.

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.

We anticipate that delivery of the securities against payment will be made on or about February 13, 2026.

Rodman & Renshaw LLC

This prospectus is dated February 11, 2026.

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This prospectus includes references to our federally registered trademarks, *BioRestorative Therapies and Dragonfly design*, *BRTX-100, ThermoStem and BRTX*. The *Dragonfly logo* is also registered with the U.S. Copyright Office. This prospectus also includes references to trademarks, trade names and service marks that are the property of other organizations. Solely for convenience, trademarks and trade names referred to in this prospectus appear without the ®, ℠ or ™ symbols, and copyrighted content appears without the use of the symbol ©, but the absence of use of these symbols does not reflect upon the validity or enforceability of the intellectual property owned by us or third parties.

ABOUT THIS PROSPECTUS

You should rely only on the information contained in this prospectus. Neither we nor the placement agent has authorized any other person to provide you with any information that is different. If anyone provides you with different or inconsistent information, you should not rely on it. We are offering to sell, and seeking offers to buy, our securities only in jurisdictions where offers and sales are permitted. The distribution of this prospectus and the offering of our securities in certain jurisdictions may be restricted by law. Persons outside the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of our securities and the distribution of this prospectus outside the United States. This prospectus does 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 by any person in any jurisdiction in which it is unlawful for such person to make such an offer or solicitation.

The information contained in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or of any sale of our securities. Our business, financial condition, results of operations and prospects may have changed since that date. It is important for you to read and consider all information contained in this prospectus in making your investment decision. You should read this prospectus and the additional information described under "Where You Can Find More Information" in this prospectus before investing in our securities.

This prospectus includes trademarks, service marks and trade names owned by us or other companies. All trademarks, service marks and trade names included in this prospectus are the property of their respective owners. Solely for convenience, trademarks and trade names referred to in this prospectus, including logos, artwork and other visual displays, may appear without the ® or ^{TM} symbols, but such references are not intended to indicate, in any way, that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto. We do not intend our use or display of other companies' trade names or trademarks to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

This prospectus includes estimates regarding market and industry data that we prepared based on our management's knowledge and experience in the markets in which we operate, together with information obtained from various sources, including publicly available information, industry reports and publications, surveys, our customers and consultants, trade and business organizations and other contacts in the markets in which we operate. In some cases, we do not expressly refer to the sources from which this data is derived. Management estimates are derived from publicly available information released by independent industry analysts and third-party sources, as well as data from our internal research, and are based on assumptions made by us upon reviewing such data and our knowledge of such industry and markets which we believe to be reasonable.

Unless the context of this prospectus indicates otherwise, the terms "BioRestorative," the "Company," "we," "us" or "our" refer to BioRestorative Therapies, Inc. and its consolidated subsidiaries.

PROSPECTUS SUMMARY

This summary highlights information contained elsewhere in this prospectus. This summary is not complete and does not contain all of the information that you should consider in making your investment decision. Before investing in our securities, you should carefully read the entire prospectus carefully, including "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations," our financial statements and related notes included in this prospectus and the exhibits to the registration statement of which this prospectus is a part.

Company Overview

We develop therapeutic products using cell and tissue protocols, primarily involving adult stem cells. As described below, our two core programs relate to the treatment of disc/spine disease and metabolic disorders. We also operate a commercial biocosmeceutical platform.

● *Disc/Spine Program (brtxDisc)*. Our lead cell therapy candidate, *BRTX-100*, is a product formulated from autologous (or a person's own) cultured mesenchymal stem cells collected from the patient's bone marrow. We intend that the product will be used for the non-surgical treatment of painful lumbosacral disc disorders or as a complimentary therapeutic to a surgical procedure. The *BRTX-100* production process utilizes proprietary technology and involves collecting a patient's bone marrow, isolating and culturing stem cells from the bone marrow and cryopreserving the cells. In an outpatient procedure, *BRTX-100* is injected by a physician into the patient's damaged disc. The treatment is intended for patients whose pain has not been alleviated by non-surgical procedures and who potentially face the prospect of surgery. We are conducting a Phase 2 clinical trial using *BRTX-100* to treat chronic lower back pain arising from degenerative disc disease. We have also obtained U.S. Food and Drug Administration ("FDA") Investigational New Drug ("IND") clearance to evaluate *BRTX-100* in the treatment of chronic cervical discogenic pain.

● *Metabolic Program (ThermoStem)*. We are developing cell-based therapy candidates to target obesity and metabolic disorders using brown adipose (fat) derived stem cells ("BADSC") to generate brown adipose tissue ("BAT"), as well as exosomes secreted by BADSC. We refer to this as our *ThermoStem Program*. BAT is intended to mimic naturally occurring brown adipose depots that regulate metabolic homeostasis in humans. Initial preclinical research indicates that increased amounts of brown fat in animals may be responsible for additional caloric burning as well as reduced glucose and lipid levels. Researchers have found that people with higher levels of brown fat may have a reduced risk for obesity and diabetes. BADSC secreted exosomes may also impact weight loss. Patents related to the *ThermoStem Program* have been issued in the United States and other jurisdictions.

● *BioCosmeceuticals.* We operate a commercial biocosmeceutical platform. Our current commercial product, formulated and manufactured using our cGMP ISO-7 certified clean room, is a cell-based secretome containing exosomes, proteins and growth factors. This proprietary biologic serum has been specifically engineered by us to reduce the appearance of fine lines and wrinkles and bring forth other areas of cosmetic effectiveness. Moving forward, we also intend to explore the potential of expanding our commercial offering to include a broader family of cell-based biologic aesthetic products and therapeutics via IND-enabling studies, with the aim of pioneering FDA approvals in the emerging biocosmeceuticals space.

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 plus the proposed aggregate amount of gross proceeds to us as a result of this offering 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 after this offering 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 is less than $700 million. For as long as we remain a smaller reporting company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company, we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K. Also, smaller reporting companies have reduced disclosure obligations regarding executive compensation.

Corporate Information

We are a Nevada corporation. Our headquarters are located at 40 Marcus Drive, Suite One, Melville, New York 11747. Our telephone number is (631) 760-8100. We maintain certain information on our website at www.biorestorative.com. The information on our website is not (and should not be considered) part of this prospectus and is not incorporated in this prospectus by reference.

THE OFFERING

Securities offered by us	Up to 14,285,715 Units, each consisting of one share of our common stock and one Common Stock Warrant, each Common Stock Warrant to purchase one share of common stock. We are also offering to investors in Units that would otherwise result in the investor's beneficial ownership exceeding 4.99% of our outstanding common stock immediately following the consummation of this offering the opportunity to invest in Units consisting of one Pre-Funded Warrant to purchase one share of common stock in lieu of one share of common stock. For each Unit that includes a Pre-Funded Warrant purchased (without regard to any limitation on exercise set forth therein), the number of Units including a share of common stock we are offering will be decreased on a one-for-one basis. Subject to limited exceptions, a holder of Pre-Funded Warrants will not have the right to exercise any portion of its Pre-Funded Warrant 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 to up to 9.99%) of the 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 Unit including a Pre-Funded Warrant (and accompanying Common Stock Warrant) will be equal to the price per Unit including one share of common stock, minus $0.0001, and the exercise price of each Pre-Funded Warrant will equal $0.0001 per share. The Pre-Funded Warrants will be immediately exercisable (subject to the beneficial ownership cap) and may be exercised at any time in perpetuity or until all of the Pre-Funded Warrants are exercised in full. This offering also relates to the shares of common stock issuable upon the exercise of the Pre-Funded Warrants. The Units will not be certificated or issued in stand-alone form. The shares of our common stock (or Pre-Funded Warrants) and the Common Stock Warrant comprising the Units are immediately separable upon issuance and will be issued separately in this offering.

	The Common Stock Warrants will have an exercise price per share of 100% of the public offering price per Unit, will be exercisable immediately and will expire on the fifth anniversary of the original issuance date. Each Common Stock Warrant is exercisable for one share of common stock, subject to adjustment in the event of stock dividends, stock splits, stock combinations, reclassifications, reorganizations or similar events affecting our common stock as described herein. Each holder of Common Stock Warrants will be prohibited from exercising its warrant for shares of our common stock if, as a result of such exercise, the holder, together with its affiliates, would own more than 4.99% of the total number of shares of our common stock then issued and outstanding. However, any holder may increase such percentage to any other percentage not in excess of 9.99%. This offering also relates to the offering of the shares of common stock issuable upon the exercise of the Common Stock Warrants. For more information regarding the warrants, you should carefully read the section entitled "Description of Our Securities — Warrants" in this prospectus.
Shares of common stock outstanding as of the date of this prospectus	9,046,242 shares
Shares of common stock to be outstanding immediately after this offering	Up to 23,331,957 shares (assuming the maximum number of Units covered by this prospectus, no issuance of Pre-Funded Warrants, and no exercise of Common Stock Warrants issued in this offering).
Use of proceeds	We estimate that the net proceeds to us from the sale of 14,285,715 Units in this offering will be approximately $4.4 million (assuming all the securities covered by this prospectus are sold), based on the public offering price of $0.35 per Unit, and after deducting placement agent fees and estimated offering expenses payable by us. We currently intend to use the net proceeds from this offering in connection with our clinical trials with respect to *BRTX-100*, pre-clinical research and development with respect to our *ThermoStem Program,* the development of our commercial biocosmeceuticals platform and for general corporate purposes and working capital. We may also use a portion of the net proceeds from this offering to acquire or invest in complementary businesses, technologies, product candidates or other intellectual property, although we have no present commitments or agreements to do so. See "Use of Proceeds."
Risk factors	Investing in our securities involves a high degree of risk. See the "Risk Factors" section of this prospectus beginning on page 6.
Reasonable best efforts:	We have agreed to offer and sell the securities offered hereby directly to the purchasers. We have retained the placement agent to act as our exclusive placement agent to use its reasonable best efforts to solicit offers to purchase the securities offered by this prospectus. The placement agent is not required to buy or sell any specific number or dollar amount of the securities offered hereby. See "Plan of Distribution."

Lock-up agreements	Our officers and directors have agreed with the placement agent, subject to certain exceptions, for a period of 90 days following the closing of this offering, not to sell, transfer or otherwise dispose of, directly or indirectly, any shares of our capital stock or any securities convertible into or exercisable or exchangeable for shares of capital stock for such applicable period. See "Plan of Distribution."
Market for common stock	Our common stock is listed on Nasdaq under the symbol "BRTX".

The number of shares of common stock to be outstanding after this offering is based on 9,046,242 shares of our common stock outstanding as of February 11, 2026 and excludes, as of that date, the following:

- 1,398,158 shares of our common stock issuable upon the conversion of 1,398,158 shares of Series B preferred stock;
- 748,055 shares of our common stock held in abeyance in connection with a warrant exercise (due to a beneficial ownership limitation) and issuable at the request of the securityholder;
- 4,495,038 shares of our common stock issuable upon the exercise of outstanding warrants with a weighted average exercise price of $4.91 per share;
- 5,252,319 shares of our common stock issuable upon the exercise of outstanding stock options, with a weighted average exercise price of $2.58 per share; and
- 4,248,635 shares of our common stock reserved for future issuance pursuant to future awards granted under our 2021 Stock Incentive Plan (the "2021 Plan").

Except as otherwise indicated, all information in this prospectus assumes:

- all of the securities covered by this prospectus are sold, there is no issuance of Pre-Funded Warrants and there is no exercise of the Common Stock Warrants;
- no conversion of the outstanding Series B preferred stock;
- no issuance of the shares of common stock held in abeyance;
- no exercise of the outstanding warrants;
- no exercise of the outstanding stock options; and
- no grants of awards under the 2021 Plan.

RISK FACTORS

You should consider carefully the risks described below, together with other information in this prospectus, before you make a decision to invest in our common stock. If any of the events described below actually occur, our business, operating results, prospects or financial condition could be materially and adversely affected. This could cause the trading price of our common stock to decline and you may lose all or part of your investment. The risks described below are not the only ones that we face. Additional risks not presently known to us or that we currently deem immaterial may also affect our business operations.

Preceding the full risk factors is a list of certain of the risk factors that follow. Reference is made to the complete risk factors for a full description of the risks involved.

Risks Related to Our Business Generally

- We have a limited operating history; we have incurred substantial losses since inception; we expect to continue to incur losses for the near term.
- We depend on our executive officers and on our ability to attract and retain additional qualified personnel.
- In the event that we are unable to utilize our current premises and need to relocate, we will be required to comply with regulatory requirements as to the operation of our laboratory, which could have had a material adverse effect on the conduct of our clinical trials and on our business.

Risks Related to Our Cell Therapy Product Development Efforts

- Our future success is significantly dependent on the timely and successful development and commercialization of *BRTX-100*, our lead product candidate for the treatment of chronic lumbar disc disease; if we encounter delays or difficulties in the development of this product candidate, as well as any other product candidates, our business prospects would be significantly harmed.
- Any disruption to our access to the media (including cell culture media) and reagents we are using in the clinical development of our cell therapy product candidates could adversely affect our ability to perform clinical trials and seek future regulatory submissions.
- Our clinical trials may fail to demonstrate adequately the safety and efficacy of our product candidates, which would prevent or delay regulatory approval and commercialization.
- Even if we complete the necessary clinical trials, we cannot predict when, or if, we will obtain regulatory approval to commercialize a product candidate, and the approval may be for a narrower indication than we seek.
- We presently lack manufacturing capabilities to produce our product candidates at commercial scale quantities and do not have an alternate manufacturing supply at this time, which could negatively impact our ability to meet any future demand for the products.
- We may have difficulties in sourcing brown adipose (fat) tissue.
- If safety problems are encountered by us or others developing new stem cell-based therapies, our stem cell initiatives could be materially and adversely affected.
- We are vulnerable to competition and technological change, and also to physicians' inertia.
- We have limited experience in the development and marketing of cell therapies and may be unsuccessful in our efforts to establish a profitable business.

- Our cell therapy business is based on novel technologies that are inherently expensive, risky and may not be understood by or accepted in the marketplace, which could adversely affect our future value.
- We may be subject to significant product liability claims and litigation, including potential exposure from the use of our product candidates in human subjects, and our insurance may be inadequate to cover claims that may arise.
- Our inability to obtain reimbursement for our products and services from private and governmental insurers could negatively impact demand for our products and services.

Risks Related to Our Intellectual Property

- We may not be able to protect our proprietary rights.
- Changes to United States patent law may have a material adverse effect on our intellectual property rights.
- In certain countries, patent holders may be required to grant compulsory licenses, which would likely have a significant and detrimental effect on any future revenues in such country.

Risks Related to Government Regulation

- Even if we obtain regulatory approval for a product candidate, our products will remain subject to regulatory oversight.
- The failure to receive regulatory approvals for our cell therapy product candidates would likely have a material and adverse effect on our business and prospects.
- If we are unable to conduct clinical studies in accordance with regulations and accepted standards, we may be delayed in receiving, or may never receive, regulatory approvals of our product candidates from the FDA and other regulatory authorities.
- It is uncertain to what extent the government, private health insurers and third-party payors will approve coverage or provide reimbursement for the therapies and products to which our services relate. Availability for such reimbursement may be further limited by reductions in Medicare, Medicaid and other federal healthcare program funding in the United States.
- Competitor companies or hospitals in the European Union ("EU") may be able to take advantage of EU rules permitting sales of unlicensed medicines for individual patients to sell competing products without a marketing authorization.

Risks Related to Our Common Stock

- Our common stock is classified as a "penny stock;" the restrictions of the penny stock regulations of the SEC may result in less liquidity for our common stock.
- Anti-takeover provisions and the regulations to which we may be subject may make it more difficult for a third party to acquire control of us, even if the change in control would be beneficial to our securityholders.

Risks Associated with Our Nasdaq Listing

- We cannot assure you that we will be able to continue to comply with the minimum bid price requirement of Nasdaq.

Risks Related to this Offering

- This is a reasonable best efforts offering, with no minimum amount of Units required to be sold, and we may sell fewer than all of the Units offered hereby.
- Following this offering, we will still need to raise substantial additional funding, which may not be available on acceptable terms, if at all, to be able to continue as a going concern and advance our business plan.
- We have broad discretion as to the use of proceeds from this offering and may not use the proceeds effectively.
- You will experience immediate and substantial dilution in net tangible book value.
- There may be significant future issuances or resales of our common stock which may materially and adversely dilute your ownership interest and affect the market price of our shares.

Risks Related to Our Business Generally

We have a limited operating history; we have incurred substantial losses since inception; we expect to continue to incur losses for the near term.

We have a limited operating history. Since our inception, we have incurred net losses. As of September 30, 2025, our accumulated deficit was $166,713,054. For the nine months ended September 30, 2025, we had a net loss of $11.0 million and negative cash flows from operations of $8.4 million and, as of September 30, 2025, we had working capital of $1.3 million. We anticipate that we will continue to incur net losses and negative cash flows from operations as we execute our development plans for 2026 and beyond, as well as other potential strategic and business development initiatives. These conditions raise substantial doubt about our ability to continue as a going concern for at least twelve months after the issuance date of the financial statements included herein. Our current funds will not be sufficient to enable us to fully complete our development activities or attain profitable operations. If we are unable to obtain such needed additional financing on a timely basis, we may have to curtail our development, marketing and promotional activities, which would have a material adverse effect on our business, financial condition and results of operations, and ultimately we could be forced to discontinue our operations and liquidate.

Our business strategy is high risk.

We are focusing our resources and efforts primarily on the development of cellular-based products and services which will require extensive cash for research, development and commercialization activities. This is a high-risk strategy because there is no assurance that our products and services, including our *Disc/Spine Program* and our *ThermoStem* metabolic brown fat research initiative, will ever become commercially viable (commercial risk), that we will prevent other companies from depriving us of market share and profit margins by offering services and products based on our inventions and developments (legal risk), that we will successfully manage a company in a new area of business, regenerative medicine, and on a different scale than we have operated in the past (operational risk), that we will be able to achieve the desired therapeutic results using stem and regenerative cells (scientific risk), or that our cash resources will be adequate to develop our products and services until we become profitable, if ever (financial risk). We are using our cash in one of the riskiest industries in the economy (strategic risk). This may make our securities an unsuitable investment for many investors.

We will need to enter into agreements in order to implement our business strategy.

Except for a certain license agreement with Regenerative Sciences, LLC and agreements relating to the conduct of our Phase 2 clinical trial, we do not have any material agreements or understandings in place with respect to the implementation of our business strategy. No assurances can be given that we will be able to enter into any necessary agreements with respect to the development of our business. Our inability to enter into any such agreements would have a material adverse effect on our results of operations and financial condition.

We depend on our executive officers and on our ability to attract and retain additional qualified personnel.

Our performance is substantially dependent on the performance of Lance Alstodt, our Chief Executive Officer. We rely upon him for strategic business decisions and guidance. We are also dependent on the performance of Francisco Silva, our Vice President of Research and Development. Each of Messrs. Alstodt and Silva is subject to an employment agreement with us that is scheduled to expire on March 18, 2026. We do not have any key-man insurance policies on the lives of either of our executive officers. We believe that our future success in developing marketable products and services and achieving a competitive position will depend in large part upon whether we can attract and retain additional qualified management and scientific personnel. Competition for such personnel is intense, and there can be no assurance that we will be able to attract and retain such personnel. The loss of the services of Mr. Alstodt and/or Mr. Silva or the inability to attract and retain additional personnel and develop expertise as needed would have a substantial negative effect on our results of operations and financial condition.

In the event that we are unable to utilize our current premises and need to relocate, we will be required to comply with regulatory requirements as to the operation of our laboratory, which could have had a material adverse effect on the conduct of our clinical trials and on our business.

We are utilizing our laboratory, which includes a cGMP ISO-7 certified clean room, to provide the cell processing services necessary for the clinical production of *BRTX-100* for our Phase 2 disc clinical trial and to manufacture our commercial product. In the event that we are required to relocate our premises, whether due to a casualty event or otherwise, we will be required to comply with regulatory requirements as to the operation of our laboratory which could have a material adverse effect on the conduct of our clinical trials and on our business.

Risks Related to Our Cell Therapy Product Development Efforts

Our future success is significantly dependent on the timely and successful development and commercialization of BRTX-100, our lead product candidate for the treatment of chronic lumbar disc disease; if we encounter delays or difficulties in the development of this product candidate, as well as any other product candidates, our business prospects would be significantly harmed.

We are dependent upon the successful development, approval and commercialization of our product candidates. Before we are able to seek regulatory approval of our product candidates, we must conduct and complete extensive clinical trials to demonstrate their safety and efficacy in humans. We are currently conducting a Phase 2 clinical trial using *BRTX-100* to treat chronic lower back pain due to degenerative disc disease related to protruding/bulging discs.

Clinical testing is expensive, difficult to design and implement, and can take many years to complete. Importantly, a failure of one or more of these or any other clinical trials can occur at any stage of testing. We may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to complete our clinical studies, receive regulatory approval or commercialize our cell therapy product candidates, including the following:

- suspensions, delays or changes in the design, initiation, enrollment, implementation or completion of required clinical trials; adverse changes in our financial position or significant and unexpected increases in the cost of our clinical development program; changes or uncertainties in, or additions to, the regulatory approval process that require us to alter our current development strategy; clinical trial results that are negative, inconclusive or less than desired as to safety and/or efficacy, which could result in the need for additional clinical studies or the termination of the product's development; delays in our ability to manufacture the product in quantities or in a form that is suitable for any required clinical trials;
- intellectual property constraints that prevent us from making, using, or commercializing any of our cell therapy product candidates;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of these product candidates may be insufficient or inadequate; the inability to generate sufficient pre-clinical, toxicology, or other in vivo or in vitro data, to support the initiation of clinical studies;
- delays in reaching agreement on acceptable terms with prospective clinical study sites, the terms of which can be subject to extensive negotiation and may vary significantly among different clinical study sites;
- delays in obtaining required Institutional Review Board ("IRB") approval at each clinical study site;
- imposition of a temporary or permanent clinical hold by regulatory agencies for a number of reasons, including after review of an IND application or amendment, or equivalent application or amendment; as a result of a new safety finding that presents unreasonable risk to clinical trial participants; a negative finding from an inspection of our clinical study operations or study sites; developments on trials conducted by competitors or approved products post-market for related technology that raise FDA concerns about risk to patients of the technology broadly; or if the FDA finds that the investigational protocol or plan is clearly deficient to meet its stated objectives;
- difficulty collaborating with patient groups and investigators;
- failure by our contract research organization ("CRO"), other third parties, or us to adhere to clinical study requirements;
- failure to perform in accordance with the FDA's current Good Clinical Practices or ("GCP") requirements, or applicable regulatory guidelines in other countries;
- delays in having patients qualify for or complete participation in a study or return for post-treatment follow-up;
- patients dropping out of a study;
- occurrence of adverse events associated with the product candidate that are viewed to outweigh its potential benefits;
- changes in the standard of care on which a clinical development plan was based, which may require new or additional trials;

- transfer of manufacturing processes from any academic collaborators to larger-scale facilities operated by either a contract manufacturing organization ("CMO"), or by us, and delays or failure by our CMOs or us to make any necessary changes to such manufacturing process;
- delays in our clinical trials caused by health emergencies;
- delays in manufacturing, testing, releasing, validating, or importing/exporting sufficient stable quantities of our product candidates for use in clinical studies or the inability to do any of the foregoing;
- the FDA not accepting clinical data from trials that are conducted at clinical sites in countries where the standard of care is potentially different from the United States; and
- failure to raise sufficient funds to complete our clinical trials.

Any inability to successfully complete pre-clinical and clinical development could result in additional costs to us or impair our ability to generate revenue. In addition, if we make manufacturing or formulation changes to our product candidates, we may be required, or we may elect, to conduct additional studies to bridge our modified product candidates to earlier versions. Clinical study delays could also shorten any periods during which our products have patent protection and may allow our competitors to bring products to market before we do, which could impair our ability to successfully commercialize our product candidates and may harm our business and results of operations.

Even if we are able to successfully complete our clinical development program for our product candidates, and ultimately receive regulatory approval to market one or more of the products, we may, among other things:

- obtain approval for indications that are not as broad as the indications we sought;
- have the product removed from the market after obtaining marketing approval;
- encounter issues with respect to the manufacturing of commercial supplies;
- be subject to additional post-marketing testing requirements; and/or
- be subject to restrictions on how the product is distributed or used.

We anticipate that we will not be able to commercialize our *BRTX-100* product candidate for at least five years; however, due to the unknowns relating to the FDA regulatory process, such time period may be longer or shorter.

We may experience delays and other difficulties in enrolling a sufficient number of patients in our clinical trials which could delay or prevent the receipt of necessary regulatory approvals.

We may not be able to initiate or complete as planned any clinical trials if we are unable to identify and enroll a sufficient number of eligible patients to participate in the clinical trials required by the FDA or other regulatory authorities. We also may be unable to engage a sufficient number of clinical trial sites to conduct our trials.

We may face challenges in enrolling patients to participate in our clinical trials due to the novelty of our cell-based therapies, the size of the patient populations and the eligibility criteria for enrollment in the trial. In addition, some patients may have concerns regarding cell therapy that may negatively affect their perception of therapies under development and their decision to enroll in the trials. Furthermore, patients suffering from diseases within target indications may enroll in competing clinical trials, which could negatively affect our ability to complete enrollment of our trials. Enrollment challenges in clinical trials often result in increased development costs for a product candidate, significant delays and potentially the abandonment of the clinical trial.

We may have other delays in completing our clinical trials and we may not complete them at all.

Since we lack significant experience in completing clinical trials and bringing a drug through commercialization, we have hired outside consultants with such experience. Clinical trials for *BRTX-100* and other product candidates in development may be delayed or terminated as a result of many factors, including the following:

- patients failing to complete clinical trials due to dissatisfaction with the treatment, side effects, or other reasons;
- failure by regulators to authorize us to commence a clinical trial;
- suspension or termination by regulators of clinical research for many reasons, including concerns about patient safety, the failure of study sites and/or investigators in our clinical research program to comply with GCP requirements, or our failure, or the failure of our contract manufacturers, to comply with current Good Manufacturing Practice ("cGMP") requirements;
- delays or failure to obtain clinical supply for our products necessary to conduct clinical trials from contract manufacturers;
- treatment candidates demonstrating a lack of efficacy during clinical trials;
- treatment candidates demonstrating significant safety signals; and/or
- inability to continue to fund clinical trials or to find a partner to fund the clinical trials.

Any delay or failure to complete clinical trials and obtain FDA approval for our product candidates could have a material adverse effect on our cost to develop and commercialize, and our ability to generate revenue from, a particular product candidate.

The development of our cell therapy product candidates is subject to uncertainty because autologous cell therapy is inherently variable.

When manufacturing an autologous cell therapy, the number and composition of the cell population varies from patient to patient. Such variability in the number and composition of these cells could adversely affect our ability to manufacture autologous cell therapies in a cost-effective or profitable manner and meet acceptable product release specifications for use in a clinical trial or, if approved, for commercial sale. As a consequence, the development and regulatory approval process for autologous cell therapy products could be delayed or may never be completed.

Any disruption to our access to the media (including cell culture media) and reagents we are using in the clinical development of our cell therapy product candidates could adversely affect our ability to perform clinical trials and seek future regulatory submissions.

Certain media (including cell culture media) and reagents, as well as devices, materials and systems, that we intend to use in our clinical trials, and that we may need or use in commercial production, are provided by unaffiliated third parties. Any lack of continued availability of these media, reagents, devices, materials and systems for any reason would have a material adverse effect on our ability to complete these studies and could adversely impact our ability to achieve commercial manufacture of our planned therapeutic products. Although other available sources for these media, reagents, devices, materials and systems may exist in the marketplace, we have not evaluated their cost, effectiveness, or intellectual property foundation and therefore cannot guarantee the suitability or availability of such other potential sources.

Products that appear promising in research and development may be delayed or may fail to reach later stages of clinical development.

The successful development of cellular based products is highly uncertain. Product candidates that appear promising in preclinical and early research and development may be delayed or fail to reach later stages of development. Decisions regarding the further development of product candidates must be made with limited and incomplete data, which makes it difficult to ensure or even accurately predict whether the allocation of limited resources and the expenditure of additional capital on specific product candidates will result in desired outcomes. Pre-clinical and clinical data can be interpreted in different ways, and negative or inconclusive results or adverse events during a clinical trial could delay, limit or prevent the development of a product candidate. Positive preclinical data may not continue or occur for future subjects in our clinical studies and may not be repeated or observed in ongoing or future studies involving our product candidates. Furthermore, our product candidates may also fail to show the desired safety and efficacy in later stages of clinical development despite having successfully advanced through initial clinical studies. In addition, regulatory delays or rejections may be encountered as a result of many factors, including changes in regulatory policy during the period of product development.

Our clinical trials may fail to demonstrate adequately the safety and efficacy of our product candidates, which would prevent or delay regulatory approval and commercialization.

The clinical trials of our product candidates are, and the manufacturing and marketing of our products will be, subject to extensive and rigorous review and regulation by numerous government authorities in the United States and in other countries where we intend to test and market our product candidates. Before obtaining regulatory approvals for the commercial sale of any of our product candidates, we must demonstrate through lengthy, complex and expensive preclinical testing and clinical trials that our product candidates are both safe and effective for use in each target indication. In particular, because some of our product candidates are subject to regulation as biological drug products, we will need to demonstrate that those products are safe, pure, and potent for use in their target indications. Each product candidate must demonstrate an adequate risk versus benefit profile in its intended patient population and for its intended use. The risk/benefit profile required for product licensure will vary depending on these factors and may include decrease or elimination of pain, adequate duration of response, a delay in the progression of the disease, an improvement in function and/or decrease in disability.

In addition, even if such trials are successfully completed, we cannot guarantee that the FDA will interpret the results as we do or that the FDA will apply the policies and standards that we expect due to rapid and unpredictable regulatory policy changes associated with the Trump Administration, and more trials could be required before we submit our product candidates for approval. To the extent that the results of the trials are not satisfactory to the FDA for support of a marketing application, we may be required to expend significant resources, which may not be available to us, to conduct additional trials in support of potential approval of our product candidates.

Even if we complete the necessary clinical trials, we cannot predict when, or if, we will obtain regulatory approval to commercialize a product candidate, and the approval may be for a narrower indication than we seek.

We cannot commercialize a product candidate until the appropriate regulatory authorities have reviewed and approved the product candidate. Even if our product candidates meet their safety and efficacy endpoints in clinical trials, the regulatory authorities may not complete their review processes in a timely manner, or we may not be able to obtain regulatory approval. Additional delays may result if an FDA Advisory Committee or other regulatory authority recommends non-approval or restrictions or conditions on approval. In addition, we may experience delays or rejections based upon additional government regulation from future legislation or administrative action, or changes in regulatory authority policy during the period of product development, clinical trials and the review process. For example, executive orders and other government cost-saving measures may result in reductions in the number of FDA personnel available to review our applications or conduct necessary pre-approval inspections of our manufacturing sites resulting in delays in the approvals of our product candidates. Regulatory authorities also may approve a product candidate for more limited indications than requested or they may impose significant limitations in the form of narrow indications, contraindications or a Risk Evaluation and Mitigation Strategy ("REMS"). These regulatory authorities may require warnings or precautions with respect to conditions of use or they may grant approval subject to the performance of costly post-marketing clinical trials. In addition, regulatory authorities may not approve the labeling claims or allow the promotional claims that are necessary or desirable for the successful commercialization of our product candidates. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates and materially and adversely affect our business, financial condition, results of operations and prospects.

We may never obtain FDA approval for any of our product candidates in the United States and, even if we do, we may never obtain approval for or commercialize any of our product candidates in any foreign jurisdiction, which would limit our ability to realize our full market potential.

In order to eventually market any of our product candidates in any particular foreign jurisdiction, we must establish and comply with numerous and varying regulatory requirements regarding safety and efficacy on a jurisdiction-by-jurisdiction basis. Approval by the FDA in the United States, if obtained, does not ensure approval by regulatory authorities in other countries or jurisdictions. In addition, preclinical studies and clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not guarantee regulatory approval in any other country.

Approval processes vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking foreign regulatory approval could result in difficulties and costs for us and require additional preclinical studies or clinical trials which could be costly and time consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our product candidates in those countries. The foreign regulatory approval process involves similar risks to those associated with FDA approval. We do not have any product candidates approved for sale in any jurisdiction, including international markets, nor have we attempted to obtain such approval. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, or if regulatory approvals in international markets are delayed, our target market will be reduced and our ability to realize the full market potential of our products may be unrealized.

We presently lack manufacturing capabilities to produce our product candidates at commercial scale quantities and do not have an alternate manufacturing supply at this time, which could negatively impact our ability to meet any future demand for the products.

We have utilized our laboratory to provide the cell processing services necessary for clinical production of *BRTX-100* for our Phase 2 disc clinical trial. We believe that we have sufficient laboratory capacity to provide such services with regard to the balance of the Phase 2 trial; however, we would need to significantly expand our manufacturing capabilities to provide such cell processing services to meet potential commercial demand for *BRTX-100* and any other of our product candidates, if approved, as well as any of our other product candidates that might attain regulatory approval. Such expansion would require additional regulatory approvals. Even if we increase our manufacturing capabilities, it is possible that we may still lack sufficient capacity to meet demand. Ultimately, if we are unable to supply our products to meet commercial demand, whether because of processing constraints or other disruptions, delays or difficulties that we experience, sales of the products and their long-term commercial prospects could be significantly damaged.

We may seek to utilize a third-party manufacturer for *BRTX-100* or any of our other product candidates; however, we do not have any arrangements in place with a third-party manufacturer. If our facilities at which these product candidates would be manufactured or our equipment were significantly damaged or destroyed, or if there were other disruptions, delays or difficulties affecting manufacturing capacity, our planned and future clinical studies and commercial production for these product candidates would likely be significantly disrupted and delayed. It would be both time consuming and expensive to replace this capacity with third parties, particularly since any new facility would need to comply with the regulatory requirements.

Ultimately, if we are unable to supply our cell therapy product candidates to meet commercial demand (assuming commercial approval is obtained), whether because of processing constraints or other disruptions, delays or difficulties that we experience, our production costs could dramatically increase and sales of the product and its long-term commercial prospects could be significantly damaged.

The commercial potential and profitability of our products are unknown and subject to significant risk and uncertainty.

Even if we successfully develop and obtain regulatory approval for our cell therapy product candidates, the market may not understand or accept the products, which could adversely affect both the timing and level of future sales. Ultimately, the degree of market acceptance of our product candidates (or any of our future product candidates) will depend on a number of factors, including:

- the clinical effectiveness, safety and convenience of the product particularly in relation to alternative treatments;
- our ability to distinguish our products (which involve adult cells) from any ethical and political controversies associated with stem cell products derived from human embryonic or fetal tissue; and
- the cost of the product, the reimbursement policies of government and third-party payors and our ability to obtain sufficient third-party coverage or reimbursement.

Even if we are successful in achieving sales of our product candidates, it is not clear to what extent, if any, the products will be profitable. The costs of goods associated with production of cell therapy products are significant. In addition, some changes in manufacturing processes or procedures generally require FDA or foreign regulatory authority review and approval prior to implementation. We may need to conduct additional pre-clinical studies and clinical trials to support approval of any such changes. Furthermore, this review process could be costly and time-consuming and could delay or prevent the commercialization of product candidates.

We may have difficulties in sourcing brown adipose (fat) tissue.

We use brown adipose (fat) tissue to identify and characterize brown adipose derived stem cells for use in our pre-clinical *ThermoStem Program.* There is no certainty that we will be able to continue to collect brown adipose samples through any relationships that we have, have had or may establish with potential sources of brown adipose tissue. The inability to procure brown fat tissue would have a material adverse effect upon our ability to advance our *ThermoStem Program.*

If safety problems are encountered by us or others developing new stem cell-based therapies, our stem cell initiatives could be materially and adversely affected.

The use of stem cells for therapeutic indications is still in the very early stages of development. If an adverse event occurs during clinical trials related to one of our proposed products and/or services or those of others, the FDA and other regulatory authorities may halt clinical trials or require additional studies. The occurrence of any of these events would delay, and increase the cost of, our development efforts and may render the commercialization of our proposed products and/or services impractical or impossible.

We are vulnerable to competition and technological change, and also to physicians' inertia.

We will compete with many domestic and foreign companies in developing our technology and products, including biotechnology, medical device and pharmaceutical companies. Many current and potential competitors have substantially greater financial, technological, research and development, marketing, and personnel resources. There is no assurance that our competitors will not succeed in developing alternative products and/or services that are more effective, easier to use, or more economical than those which we may develop, or that would render our products and/or services obsolete and non-competitive. In general, we may not be able to prevent others from developing and marketing competitive products and/or services similar to ours or which perform similar functions or which are marketed before ours.

Competitors may have greater experience in developing products, therapies or devices, conducting clinical trials, obtaining regulatory clearances or approvals, manufacturing and commercialization. It is possible that competitors may obtain patent protection, approval or clearance from the FDA or achieve commercialization earlier than we can, any of which could have a substantial negative effect on our business.

We will compete against cell-based therapies derived from alternate sources, such as bone marrow, adipose tissue, umbilical cord blood and potentially embryos. Doctors historically are slow to adopt new technologies like ours, whatever the merits, when older technologies continue to be supported by established providers. Overcoming such inertia often requires very significant marketing expenditures or definitive product performance and/or pricing superiority.

We expect that physicians' inertia and skepticism will also be a significant barrier as we attempt to gain market penetration with our future products and services. We may need to finance lengthy time-consuming clinical studies (so as to provide convincing evidence of the medical benefit) in order to overcome this inertia and skepticism.

The recent extensive use of both FDA-approved and compounded versions of glucagon-like peptide-1 (GLP-1) receptor agonist drug products, such as Wegovy and Ozempic (semaglutide), including the launch of FDA-approved oral Wegovy in January 2026, for the treatment of obesity has significantly increased the competition in the obesity market.

We may form or seek collaborations or strategic alliances or enter into additional licensing arrangements in the future, and we may not realize the benefits of such alliances or licensing arrangements.

We may form or seek strategic alliances, create joint ventures or collaborations, or enter into additional licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to our product candidates and any future product candidates that we may develop. Any of these relationships may require us to incur non-recurring and other charges, increase our near and long-term expenditures, issue securities that dilute the shares of our existing stockholders, or disrupt our management and business. In addition, we face significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex. Moreover, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for our product candidates because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view our product candidates as having the requisite potential to demonstrate safety and efficacy. To date, such efforts have not been successful.

Further, collaborations involving our product candidates, such as our collaborations with third-party research institutions, are subject to numerous risks, which may include the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to a collaboration;
- collaborators may not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in their strategic focus due to the acquisition of competitive products, availability of funding, or other external factors, such as a business combination that diverts resources or creates competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial, stop a clinical trial, abandon a product candidate, repeat or conduct new clinical trials, or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates;
- a collaborator with marketing and distribution rights to one or more products may not commit sufficient resources to their marketing and distribution;

- collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- disputes may arise between us and a collaborator that cause the delay or termination of the research, development or commercialization of our product candidates, or that result in costly litigation or arbitration that diverts management attention and resources;
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates; and
- collaborators may own or co-own intellectual property covering our products that results from our collaborating with them, and in such cases, we would not have the exclusive right to commercialize such intellectual property.

As a result, if we enter into collaboration agreements and strategic partnerships or license our products or businesses, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture, which could delay our timelines or otherwise adversely affect our business. We also cannot be certain that, following a strategic transaction or license, we will achieve the revenue or specific net income that justifies such transaction. Any delays in entering into new collaborations or strategic partnership agreements related to our product candidates could delay the development and commercialization of our product candidates in certain geographies for certain indications, which would harm our business prospects, financial condition, and results of operations.

We have limited experience in the development and marketing of cell therapies and may be unsuccessful in our efforts to establish a profitable business.

Our business plan has been focused historically on capturing a piece of the burgeoning field of cell therapy. We have limited experience in the areas of cell therapy product development and marketing, and in the related regulatory issues and processes. Although we have recruited a team that has experience with designing and conducting clinical trials and have hired FDA consultants, as a company, we have limited experience in conducting clinical trials and no experience in conducting clinical trials through to regulatory approval of any product candidate. In part because of this lack of experience, we cannot be certain that planned clinical trials will begin or be completed on time, if at all. We cannot assure that we will successfully achieve our clinical development goals or fulfill our plans to capture a piece of the cell therapy market.

Our cell therapy business is based on novel technologies that are inherently expensive, risky and may not be understood by or accepted in the marketplace, which could adversely affect our future value.

The clinical development, commercialization and marketing of cell and tissue-based therapies are at an early-stage, substantially research-oriented, and financially speculative. To date, very few companies have been successful in their efforts to develop and commercialize a cell therapy product. In general, cell-based or tissue-based products may be susceptible to various risks, including undesirable and unintended side effects, unintended immune system responses, inadequate therapeutic efficacy, or other characteristics that may prevent or limit their approval or commercial use. In addition, *BRTX-100* is a cell-based candidate that is produced by using a patient's own stem cells derived from bone marrow. Regulatory approval of novel product candidates such as *BRTX-100*, which is manufactured using novel manufacturing processes, can be more complex and expensive and take longer than other, more well-known or extensively studied pharmaceutical or biopharmaceutical products, due to the FDA's lack of experience with them. To our knowledge, the FDA has not yet approved a disc related stem cell therapy product. This lack of experience may lengthen the regulatory review process, require us to conduct additional studies or clinical trials, which would increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of these product candidates or lead to significant post-approval limitations or restrictions. Furthermore, the number of people who may use cell or tissue-based therapies is difficult to forecast with accuracy. Our future success is dependent on the establishment of a large global market for cell- and tissue-based therapies and our ability to capture a share of this market with our product candidates.

Our cell therapy product candidates for which we intend to seek approval as biologic products may face competition sooner than anticipated.

The enactment of the Biologics Price Competition and Innovation Act of 2009 (the "BPCIA") created an abbreviated regulatory pathway for the approval of products demonstrated to be biosimilar, or "highly similar," to or "interchangeable" with an FDA-approved innovator (original) biologic product. The abbreviated regulatory pathway establishes legal authority for the FDA to review and approve biosimilar biologics, including the possible designation of a biosimilar as "interchangeable" based on its similarity to an existing reference product. Under the BPCIA, an application for a biosimilar product cannot be approved by the FDA until 12 years after the original branded product is approved under a BLA. The FDA has developed considerable experience with the biosimilar and interchangeable biosimilar processes since the enactment of the BPCIA in 2009. Should any of our product candidates be approved via the BLA pathway, we expect that biosimilar applicants will seek approval of biosimilar, and/or interchangeable, versions of our product that could result in lower prices for our products.

We believe that, if any of our product candidates are approved as a biological product under a BLA, it should qualify for the 12-year period of exclusivity. However, there is a risk that the FDA could approve biosimilar applicants for other reference products that no longer have such exclusivity, thus potentially creating the opportunity for greater competition sooner than anticipated.

We may also face competition from unapproved stem cell therapies performed by treatment centers that do not comply with FDA requirements. Despite the FDA's successful enforcement against unapproved stem cell treatments in the federal courts (*United States v. Regenerative Sciences, LLC* (2014 D.C. Cir.), *United States v. U.S. Stem Cell Clinic LLC* (2021 11th Cir.) and *United States v. California Stem Cell Treatment Center, Inc.* (2024 9th Cir. *cert. denied*), thousands of clinics continue to offer unapproved stem cell therapies due to high demand, FDA enforcement limitations, and tactical rebranding to avoid FDA enforcement action. The FDA lacks the resources to bring enforcement actions against thousands of individual small-office clinics simultaneously. Therefore, we could face competition from stem cell clinics that would not be required to undergo the costly and time-consuming FDA approval and compliance process.

The FDA's regulation of regenerative medicine products remains unpredictable and we are not certain what impact this will have on the potential approval of our products.

The FDA's regulation of therapies derived from stem cell products and technologies is evolving and may continue to evolve. In December 2016, the 21st Century Cures Act (the "Cures Act") was signed into law in the United States to advance access to medical innovations. Among other things, the Cures Act established a new FDA regenerative medicine advanced therapy ("RMAT") designation. This designation offers a variety of benefits to product candidates, including enhanced FDA support during clinical development, priority review on application filing, accelerated approval based on potential surrogate endpoints, and the potential use of patient registry data and other forms of real world evidence for post-approval confirmatory studies. There is no certainty that any of our product candidates will receive RMAT designation or any other type of expedited review program designation from the FDA. In any event, the receipt of an FDA RMAT designation or other expedited review program designation may not result in a faster development process, review or approval compared to products considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA.

We may be subject to significant product liability claims and litigation, including potential exposure from the use of our product candidates in human subjects, and our insurance may be inadequate to cover claims that may arise.

Our business exposes us to potential product liability risks inherent in the testing, processing and marketing of cell therapy products. Such liability claims may be expensive to defend and result in large judgments against us. We face an inherent risk of product liability exposure related to the testing of our current and any future product candidates in human clinical trials and will face an even greater risk with respect to any commercial sales of our products should they be approved. No product candidate has been widely used over an extended period of time, and therefore safety data is limited. Cell therapy companies derive the raw materials for manufacturing of product candidates from human cell sources, and therefore the manufacturing process and handling requirements are extensive, which increases the risk of quality failures and subsequent product liability claims.

We will need to maintain insurance coverage adequate to cover our clinical trials and increase that coverage before commercializing product candidates, if ever. At any time during our clinical trials or after commercialization, if that occurs, we may not be able to obtain or maintain product liability insurance on acceptable terms with adequate coverage or at all, or if claims against us substantially exceed our coverage, then our financial position could be significantly impaired.

Whether or not we are ultimately successful in any product liability litigation that may arise, such litigation could consume substantial amounts of our financial and managerial resources, result in decreased demand for our products and injure our reputation.

We seek to maintain errors and omissions, directors and officers, workers' compensation and other insurance at levels we believe to be appropriate to our business activities. If, however, we were subject to a claim in excess of this coverage or to a claim not covered by our insurance and the claim succeeded, we would be required to pay the claim from our own limited resources, which could have a material adverse effect on our financial condition, results of operations and business. Additionally, liability or alleged liability could harm our business by diverting the attention and resources of our management and damaging our reputation.

Our internal computer systems, or those that are expected to be used by our clinical investigators, clinical research organizations or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of development programs for our product candidates.

We rely on information technology systems to keep financial records, maintain laboratory and corporate records, communicate with staff and external parties and operate other critical functions. Any significant degradation or failure of these computer systems could cause us to inaccurately calculate or lose data. Despite the implementation of security measures, these internal computer systems and those used by our clinical investigators, clinical research organizations, and other contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war, and telecommunication and electrical failures. The techniques that could be used by criminal elements or foreign governments to attack these computer systems are sophisticated, change frequently and may originate from less regulated and remote areas of the world. While we have not experienced any such system failure, theft of information, accident or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our clinical development activities. For example, the loss of clinical trial data from historical or future clinical trials could result in delays in regulatory approval efforts and significantly increase costs to recover or reproduce the data. To the extent that any disruption, theft of information, or security breach were to result in a loss of or damage to data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the clinical development and future development of our product candidates could be delayed.

To operate and sell in international markets carries great risk.

We intend to market our products and services both domestically and in foreign markets. A number of risks are inherent in international transactions. In order for us to market our products and services in non-U.S. jurisdictions, we need to obtain and maintain required regulatory approvals or clearances in these countries and must comply with the country specific regulations regarding safety, manufacturing processes and quality. These regulations, including the requirements for approvals or clearances to market, may differ from the FDA regulatory scheme. International operations and sales also may be limited or disrupted by political instability, price controls, trade restrictions and changes in tariffs. Additionally, fluctuations in currency exchange rates may adversely affect demand for our services and products by increasing the price of our products and services in the currency of the countries in which the products and services are offered.

There can be no assurance that we will obtain regulatory approvals or clearances in all of the countries where we intend to market our products and services, that we will not incur significant costs in obtaining or maintaining foreign regulatory approvals or clearances, or that we will be able to successfully commercialize our products and services in various foreign markets. Delays in receipt of approvals or clearances to market our products and services in foreign countries, failure to receive such approvals or clearances or the future loss of previously received approvals or clearances could have a substantial negative effect on our results of operations and financial condition.

Our inability to obtain reimbursement for our products and services from private and governmental insurers could negatively impact demand for our products and services.

Market acceptance and sales of our product candidates may depend on coverage and reimbursement policies and health care reform measures. Decisions about formulary coverage as well as levels at which government authorities and third-party payors, such as private health insurers and health maintenance organizations, reimburse patients for the price they pay for our product candidates, as well as levels at which these payors pay directly for our product candidates, where applicable, could affect whether we are able to successfully commercialize these products. We cannot guarantee that reimbursement will be available for any of our product candidates. We also cannot guarantee that coverage or reimbursement amounts will not reduce the demand for, or the price of, our product candidates.

If coverage and reimbursement are not available or are available only at limited levels, we may not be able to successfully commercialize our products. The Patient Protection and Affordable Care Act (the "PPACA"), as well as the Inflation Reduction Act, passed in August 2022, and other health reforms include measures that would limit or prohibit payments for certain medical treatments or subject the pricing of drugs and biologics to government control. In addition, in many foreign countries, particularly the countries of the EU, the pricing of drugs and biologics is subject to government control. If our products are or become subject to government regulation that limits or prohibits payment for our products, or that subjects the price of our products to government control, we may not be able to generate revenue, attain profitability or commercialize our products.

In addition, third-party payors are increasingly limiting both coverage and the level of reimbursement of new drugs and biologics. They may also impose strict prior authorization requirements and/or refuse to provide any coverage of uses of approved products for medical indications other than those for which the FDA has granted market approvals. As a result, significant uncertainty exists as to whether and how much third-party payors will reimburse patients for their use of newly-approved drugs and biologics. If we are unable to obtain adequate levels of reimbursement for our product candidates, our ability to successfully market and sell our product candidates will be harmed.

Our activity as a contract manufacturer of biologic-based cosmetics could result in FDA enforcement for reasons outside of our control, which could disrupt the development of our own product candidates or harm our reputation.

We manufactured a commercial product as a contract manufacturer for a third-party company. While we believe the product we manufactured for the third party was intended for cosmetic uses, we (as the contract manufacturer) did not ultimately have control over how the product was marketed. It is possible that the FDA could determine, based on how the product was marketed (among other considerations), that it was intended for unapproved therapeutic use(s), which could result in the temporary or permanent suspension of manufacturing and/or commercialization of the product and/or a wide range of enforcement actions, such as warning letters, recall, 'dear doctor' letters, and others. If the FDA takes enforcement action against the third party or us in connection with this product, or against others for whom we may serve in the future as a contract manufacturer, it could have an adverse impact on our operations and/or harm our reputation as a biologics company.

Risks Related to Our Intellectual Property

We may not be able to protect our proprietary rights.

Our commercial success will depend in large part upon our ability to protect our proprietary rights. There is no assurance, for example, that any additional patents will be issued based on our or our licensor's pending applications or, if issued, that such patents will not become the subject of a re-examination, will provide us with competitive advantages, will not be challenged by any third parties, or that the patents of others will not prevent the commercialization of products and services incorporating our technology. Furthermore, there can be no guarantee that others will not independently develop similar products and services, duplicate any of our products and services, or design around any patents we obtain.

Our commercial success will also depend upon our ability to avoid infringing patents issued to others. If we were judicially determined to be infringing on any third-party patent, we could be required to pay damages, alter our products, services or processes, obtain licenses, or cease certain activities. If we are required in the future to obtain any licenses from third parties for some of our products and/or services, there can be no guarantee that we would be able to do so on commercially favorable terms, if at all. United States and foreign patent applications are not immediately made public, so we might be surprised by the grant to someone else of a patent on a technology we are actively using. Although we conducted a freedom to operate ("FTO") search years ago on the licensed technology associated with our *Disc/Spine Program*, modifications made, and/or further developments that may be made, to that technology may not be covered by the initial FTO. No FTO has been undertaken with respect to our *ThermoStem* brown fat initiative.

Litigation, which would result in substantial costs to us and the diversion of effort on our part, may be necessary to enforce or confirm the ownership of any patents issued or licensed to us, or to determine the scope and validity of third-party proprietary rights. If our competitors claim technology also claimed by us and prepare and file patent applications in the United States, we may have to participate in interference proceedings declared by the U.S. Patent and Trademark Office (the "Patent Office") or a foreign patent office to determine priority of invention, which could result in substantial costs and diversion of effort, even if the eventual outcome is favorable to us. Any such litigation or interference proceeding, regardless of outcome, could be expensive and time-consuming.

Successful challenges to our patents through oppositions, re-examination proceedings or interference proceedings could result in a loss of patent rights in the relevant jurisdiction. If we are unsuccessful in actions we bring against the patents of other parties, and it is determined that we infringe upon the patents of third parties, we may be subject to litigation, or otherwise prevented from commercializing potential products and/or services in the relevant jurisdiction, or may be required to obtain licenses to those patents or develop or obtain alternative technologies, any of which could harm our business. Furthermore, if such challenges to our patent rights are not resolved in our favor, we could be delayed or prevented from entering into new collaborations or from commercializing certain products and/or services, which could adversely affect our business and results of operations.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential or sensitive information could be compromised by disclosure in the event of litigation. In addition, during the course of litigation there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock.

In addition to patents, we rely on unpatented trade secrets and proprietary technological expertise. Some of our intended future cell-related therapeutic products and/or services may fit into this category. We also rely, in part, on confidentiality agreements with our partners, employees, advisors, vendors, and consultants to protect our trade secrets and proprietary technological expertise. There can be no guarantee that these agreements will not be breached, or that we will have adequate remedies for any breach, or that our unpatented trade secrets and proprietary technological expertise will not otherwise become known or be independently discovered by competitors.

Failure to obtain or maintain patent protection, failure to protect trade secrets, third-party claims against our patents, trade secrets, or proprietary rights or our involvement in disputes over our patents, trade secrets, or proprietary rights, including involvement in litigation, could divert our efforts and attention from other aspects of our business and have a substantial negative effect on our results of operations and financial condition.

We may not be able to protect our intellectual property in countries outside of the United States.

Intellectual property law outside the United States is uncertain and, in many countries, is currently undergoing review and revisions. The laws of some countries do not protect our patent and other intellectual property rights to the same extent as United States laws. Third parties may attempt to oppose the issuance of patents to us in foreign countries by initiating opposition proceedings. Opposition proceedings against any of our patent filings in a foreign country could have an adverse effect on our corresponding patents that are issued or pending in the United States. It may be necessary or useful for us to participate in proceedings to determine the validity of our patents or our competitors' patents that have been issued in countries other than the United States. This could result in substantial costs, divert our efforts and attention from other aspects of our business, and could have a material adverse effect on our results of operations and financial condition.

Changes to United States patent law may have a material adverse effect on our intellectual property rights.

The Leahy-Smith America Invents Act (the "AIA"), which was signed into law in 2011, significantly changes United States patent law. It may take some time to establish what the law means, since it is just being interpreted by the lower courts, Federal Circuit Courts of Appeal, and the Supreme Court. The effects of these decisions are still not known. The first major change is that AIA switches the United States patent system from a "first to invent" system to a "first to file" system. Now that the first to file system is in effect, there is a risk that another company may independently develop identical or similar patents at approximately the same time, and be awarded the patents instead of us. Further, for the second major change, AIA abolished interference proceedings, and establishes derivation proceedings to replace interference proceedings in all cases in which the time period for instituting an interference proceeding has not lapsed where an inventor named in an earlier application derived the claimed invention from a named inventor. Now that the derivation proceedings are in effect, there is a risk that the inventorship of any pending patent application can be challenged for reasons of derivation. The third major change is that AIA established post-grant opposition proceedings that will apply only to patent applications filed after "first to file" became effective. Post-grant opposition will enable a person who is not the patent owner to initiate proceedings in the Patent Office within nine months after the grant of a patent that can result in cancellation of a patent as invalid. In addition to AIA, recent court decisions have created uncertainty with regard to our ability to obtain and maintain patents. Therefore, there is a risk that any of our patents once granted may be subject to post-grant opposition, which will increase uncertainty on the validity of any newly granted patent or may ultimately result in cancellation of the patent.

In addition, the Supreme Court has recently taken more limiting positions as to what constitutes patentable subject matter. As a result, many patents covering what were previously patentable inventions are now determined to cover inventions which are deemed non-statutory subject matter and are now invalid. As a result of this and subsequent opinions by the Court of Appeals for the Federal Circuit, the Patent Office is now applying more stringent limitations to claims in patent applications and is refusing to grant patents in areas of technology where patents were previously deemed available. Therefore, there is a risk that we will be unable to acquire patents to cover our products and, if such patents are granted, they may subsequently be found to be invalid.

In certain countries, patent holders may be required to grant compulsory licenses, which would likely have a significant and detrimental effect on any future revenues in such country.

Many countries, including some countries in Europe, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, most countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may be limited to monetary relief and may be unable to enjoin infringement, which could materially diminish the value of the patent. Compulsory licensing of life-saving products is also becoming increasingly common in developing countries, either through direct legislation or international initiatives. Such compulsory licenses could be extended to our product candidates, which may limit our potential revenue opportunities, including with respect to any future revenues that may result from our product candidates.

Risks Related to Government Regulation

Even if we obtain regulatory approval for a product candidate, our products will remain subject to regulatory oversight.

Our product candidates for which we obtain regulatory approval will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, record-keeping and submission of safety and other post-market information. Any regulatory approvals that we receive for our product candidates also may be subject to a REMS or the specific obligations imposed as a condition for marketing authorization by equivalent authorities in a foreign jurisdiction, limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials, and surveillance to monitor the quality, safety and efficacy of the product. For example, in the United States, the holder of an approved new drug application ("NDA") or BLA is obligated to monitor and report adverse events and any failure of a product to meet the specifications in the NDA or BLA. The holder of an approved NDA or BLA also must submit new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling or manufacturing process. Advertising and promotional materials must comply with the Federal Food, Drug and Cosmetic Act (the "FDCA") and implementing regulations and are subject to FDA oversight and post-marketing reporting obligations, in addition to other potentially applicable federal and state laws.

In addition, product manufacturers and their facilities may be subject to payment of application and program fees and are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP requirements and adherence to commitments made in the NDA, BLA or foreign marketing application. If we or a regulatory authority discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, or if a regulatory authority disagrees with the promotion, marketing or labeling of our product, a regulatory authority may impose restrictions relative to that product, the manufacturing facility or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing.

If we fail to comply with applicable regulatory requirements for any product candidate following approval, a regulatory authority may:

- issue a warning or untitled letter asserting that we are in violation of the law;
- seek an injunction or impose administrative, civil or criminal penalties or monetary fines;
- suspend or withdraw regulatory approval;
- suspend any ongoing clinical trials;
- refuse to approve a pending BLA or comparable foreign marketing application (or any supplements thereto) submitted by us or our strategic partners;
- restrict the marketing or manufacturing of the product;
- seize or detain the product or otherwise demand or require the withdrawal or recall of the product from the market;
- refuse to permit the import or export of products;
- request and publicize a voluntary recall of the product; or
- refuse to allow us to enter into supply contracts, including government contracts.

Any government enforcement action or investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. The occurrence of any event or penalty described above may inhibit our ability to commercialize our product candidates and adversely affect our business, financial condition, results of operations and prospects.

We may be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws and health information privacy and security laws. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.

In the United States, the research, manufacturing, distribution, sale, and promotion of drugs and biologic products are subject to regulation by various federal, state, and local authorities, including the FDA, the Centers for Medicare and Medicaid Services ("CMS"), other divisions the Department of Health and Human Services ("HHS") (e.g., the Office of Inspector General), the United States Department of Justice offices of the United States Attorney, the Federal Trade Commission and state and local governments. Our operations are directly, or indirectly through our prescribers, customers and purchasers, subject to various federal and state fraud and abuse laws and regulations, including the federal Anti-Kickback Statute ("AKS"), the federal civil and criminal False Claims Act ("FCA") the Physician Payments Sunshine Act and regulations and equivalent provisions in other countries. In addition, we may be subject to patient privacy laws by both the federal government and the states in which we conduct our business.

State and federal regulatory and enforcement agencies continue actively to investigate violations of health care laws and regulations, and the United States Congress continues to strengthen the arsenal of enforcement tools. For example, the Bipartisan Budget Act of 2018 increased the criminal and civil penalties that can be imposed for violating certain federal health care laws, including the AKS. Enforcement agencies also continue to pursue novel theories of liability under these laws. Government agencies have recently increased regulatory scrutiny and enforcement activity with respect to programs supported or sponsored by pharmaceutical companies, including reimbursement and co-pay support, funding of independent charitable foundations and other programs that offer benefits for patients. Several investigations into these programs have resulted in significant civil and criminal settlements.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. If our operations are found to be in violation of any of the laws described above or any other government regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from participation in government health care programs, such as Medicare and Medicaid, imprisonment and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which could harm our financial condition and divert the attention of our management from operating our business.

Further, in the event we determine to operate in foreign jurisdictions, including conducting clinical trials, we will need to comply with the United States Foreign Corrupt Practices Act of 1977, (the "FCPA"). The FCPA prohibits a corporation, including its subsidiaries, third-party contractors, distributors, consultants and employees, from corruptly making or offering to make payments to foreign officials for the purpose of obtaining or enhancing business. Under the law, "foreign officials" include employees of health systems operated by government entities. The FCPA also establishes specific record-keeping and internal accounting controls. Violations of the FCPA can result in the imposition of civil penalties or criminal prosecution. Failure to comply with the FCPA will adversely affect our business.

In addition to the FCPA, we will also need to comply with the foreign government laws and regulations of each individual country in which any therapy centers that we may establish are located and products are to be distributed and sold. These regulations vary in complexity and can be as stringent, and on occasion even more stringent, than FDA regulations in the United States. Due to the fact that there are new and emerging stem cell and cell therapy regulations that have recently been drafted and/or implemented in various countries around the world, the application and subsequent implementation of these new and emerging regulations have little to no precedence. Therefore, the level of complexity and stringency is not always precisely understood today for each country, creating greater uncertainty for the international regulatory process. Furthermore, there can be no guarantee that laws and regulations will not be implemented, amended and/or reinterpreted in a way that will negatively affect our business. Likewise, there can be no assurance that we will be able, or will have the resources, to maintain compliance with all such healthcare laws and regulations. Failure to comply with such healthcare laws and regulations, as well as the costs associated with such compliance or with enforcement of such healthcare laws and regulations, may have a material adverse effect on our operations or may require restructuring of our operations or impair our ability to operate profitably.

Our current and future employees, consultants and advisors and our future principal investigators, medical institutions and commercial partners may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements.

We are exposed to the risk of fraud or other misconduct by our current and future employees, consultants, advisors, principal investigators, medical institutions and commercial partners, including contract laboratories, and CROs. Misconduct by these parties could include intentional failures to comply with FDA regulations or the regulations applicable in other jurisdictions, provide accurate information to the FDA and other regulatory authorities, comply with healthcare fraud and abuse laws and regulations in the United States and abroad, report financial information or data accurately or disclose unauthorized activities to us.

We currently do not and in the future may not independently conduct all aspects of our product candidate research and preclinical and clinical testing and product candidate manufacturing. If we rely on third parties, including CROs, medical institutions, and contract laboratories to monitor and manage data for our ongoing preclinical and clinical programs, we will still maintain responsibility for ensuring their activities are conducted in accordance with the applicable study protocol, legal, regulatory and scientific standards. We and our third-party vendors will be required to comply with current cGMP, GCP, and Good Laboratory Practice ("GLP") requirements, which are a collection of laws and regulations enforced by the FDA, the EU and comparable foreign authorities for all of our product candidates in clinical development.

In addition, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Such misconduct also could involve the improper use of information obtained in the course of clinical trials or interactions with the FDA or other regulatory authorities, which could result in regulatory sanctions and cause serious harm to our reputation.

The precautions we take to detect and prevent employee and third-party misconduct may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from government investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, financial condition, results of operations and prospects, including the imposition of significant fines or other sanctions.

The failure to receive regulatory approvals for our cell therapy product candidates would likely have a material and adverse effect on our business and prospects.

To date, we have not received regulatory approval to market any of our product candidates in any jurisdiction. If we seek approval of any of our cell therapy product candidates, we will be required to submit to the FDA and potentially other regulatory authorities extensive pre-clinical and clinical data supporting its safety and efficacy, as well as information about the manufacturing process and to undergo inspection of our manufacturing facility or other contract manufacturing facilities, if utilized, among other things. The process of obtaining FDA and other regulatory approvals is expensive, generally takes many years and is subject to numerous risks and uncertainties, particularly with complex and/or novel product candidates such as our cell-based product candidates. Changes in regulatory approval requirements, policies, or court decisions may cause delays in the approval or rejection of an application, make it easier for our competitors to gain regulatory approval to enter the marketplace, or allow competitors to enter the market without having to obtain FDA approval. Executive orders and other government cost-saving measures may result in reductions in the number of FDA personnel available to review our applications or conduct necessary pre-approval inspections of our manufacturing sites resulting in delays in the approvals of our product candidates. Ultimately, the FDA and other regulatory agencies have substantial discretion in the approval process and may refuse to accept any application or may decide that our product candidate data are insufficient for approval without the submission of additional preclinical, clinical or other studies. In addition, varying agency interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent regulatory approval of a product candidate. Any difficulties or failures that we encounter in securing regulatory approval for our product candidates would likely have a substantial adverse impact on our ability to generate product sales, and could make any search for a collaborative partner more difficult. Similarly, any regulatory approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.

If we are unable to conduct clinical studies in accordance with regulations and accepted standards, we may be delayed in receiving, or may never receive, regulatory approvals of our product candidates from the FDA and other regulatory authorities.

To obtain marketing approvals for our product candidates in the United States and abroad, we must, among other requirements, complete adequate and well-controlled clinical trials sufficient to demonstrate to the FDA and other regulatory bodies that the product candidate is safe and effective for each indication for which approval is sought. If the FDA finds that patients enrolled in the trial are or would be exposed to an unreasonable and significant risk of illness or injury, due to, among other things, occurrence of a serious adverse event in an ongoing clinical trial, the FDA can place one or more of our clinical trials on hold. If safety concerns develop, we may, or the FDA or an institutional review board may require us to, stop the affected trials before completion.

The completion of our clinical trials also may be delayed or terminated for a number of other reasons, including if:

- third-party clinical investigators do not perform the clinical trials on the anticipated schedule or consistent with the clinical trial protocol, good clinical practices required by the FDA and other regulatory requirements, or other third parties do not perform data collection and analysis in a timely or accurate manner;

- inspections of clinical trial sites by the FDA or other regulatory authorities reveal violations that require us to undertake corrective action, suspend or terminate one or more sites, or prohibit use of some or all of the data in support of marketing applications; or

- the FDA or one or more institutional review boards suspends or terminates the trial at an investigational site, or precludes enrollment of additional subjects.

Our development costs will increase if there are material delays in our clinical trials, or if we are required to modify, suspend, terminate or repeat a clinical trial. If we are unable to conduct our clinical trials properly, we may never receive regulatory approval to market our product candidates.

Health care companies have been the subjects of federal and state investigations, and we could become subject to investigations in the future.

Both federal and state government agencies have heightened civil and criminal enforcement efforts. There are numerous ongoing investigations of health care companies, as well as their executives and managers. In addition, amendments to the federal FCA, including under healthcare reform legislation, have made it easier for private parties to bring "*qui tam*" (or whistleblower) lawsuits against companies under which the whistleblower may be entitled to receive a percentage of any money paid to the government. The FCA provides, in part, that an action can be brought against any person or entity that has knowingly presented, or caused to be presented, a false or fraudulent request for payment from the federal government, or who has made a false statement or used a false record to get a claim approved. The government has taken the position that claims presented in violation of the federal AKS, Stark Law or other healthcare-related laws, including laws enforced by the FDA, may be considered a violation of the FCA. Penalties include substantial fines for each false claim, plus three times the amount of damages that the federal government sustained because of the act of that person or entity and/or exclusion from the Medicare and Medicaid programs. In addition, a majority of states have adopted similar state whistleblower and false claims provisions.

We are not aware of any government investigations involving any of our facilities or management. While we believe that we are in compliance with applicable governmental healthcare laws and regulations, any future investigations of our business or executives could cause us to incur substantial costs, and result in significant liabilities or penalties, as well as damage to our reputation.

It is uncertain to what extent the government, private health insurers and third-party payors will approve coverage or provide reimbursement for the therapies and products to which our services relate. Availability for such reimbursement may be further limited by reductions in Medicare, Medicaid and other federal healthcare program funding in the United States.

To the extent that health care providers cannot obtain coverage or reimbursement for our products and therapies, they may elect not to provide such products and therapies to their patients and, thus, may not need our services. Further, as cost containment pressures are increasing in the health care industry, government and private payors may adopt strategies designed to limit the amount of reimbursement paid to health care providers.

Similarly, the trend toward managed health care and bundled pricing for health care services in the United States, could significantly influence the purchase of healthcare products and services, resulting in lower prices and reduced demand for our therapeutic products under development.

We may directly or indirectly receive revenues from federal health care programs, such as Medicare. Federal health care programs are subject to changes in coverage and reimbursement rules and procedures, including retroactive rate adjustments. These contingencies could materially decrease the range of services covered by such programs or the reimbursement rates paid directly or indirectly for our products and services. To the extent that any health care reform favors the reimbursement of other therapies over our therapeutic products under development, such reform could affect our ability to sell our services, which may have a material adverse effect on our revenues.

The limitation on reimbursement available from private and government payors may reduce the demand for, or the price of, our products and services, which could have a material adverse effect on our revenues. Additional legislation or regulation relating to the health care industry or third-party coverage and reimbursement may be enacted in the future which could adversely affect the revenues generated from the sale of our products and services.

Furthermore, there has been a trend in recent years towards reductions in overall funding for Medicare, Medicaid and other federal health care programs. The reduced funding of governmental programs could have a negative impact on the demand for our services to the extent it relates to products and services which are reimbursed by government and private payors.

Unintended consequences of healthcare reform in the United States may adversely affect our business.

The healthcare industry is undergoing fundamental changes resulting from political, economic and regulatory influences. In the United States, the PPACA was signed into law in 2010 under the Obama administration. By implementing comprehensive reforms, the law seeks to, among other things, increase access to healthcare for the uninsured and control the escalation of healthcare expenditures within the economy.

In addition, other legislative changes have been adopted since the PPACA was enacted. These changes include aggregate reductions in Medicare payments to providers of 2% per fiscal year, which went into effect in April 2013 and, following passage of the Bipartisan Budget Act of 2018, will remain in effect through 2030 unless additional Congressional action is taken. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, further reduced Medicare payments to several types of providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Congress has since considered additional reductions in Medicare reimbursement for drugs and devices as part of legislation to reduce the budget deficit. Similar legislation could be enacted in the future. The Medicare regulations and interpretive determinations that determine how drugs, devices and services are covered and reimbursed also are subject to change. These laws, regulations, and interpretive determinations may result in additional reductions in Medicare and other health care funding, which could impact our business.

In August 2022, President Biden signed the Inflation Reduction Act (the “IRA”), which provides for (i) the government to set or negotiate prices for select high-cost Medicare Part D (beginning in 2026) and Medicare Part B drugs (beginning in 2028) that are more than nine years (for small-molecule drugs) or 13 years (for biological products) from their FDA approval, (ii) manufacturers to pay a rebate for Medicare Part B and Part D drugs when prices increase faster than inflation beginning in 2022 for Medicare Part D and 2023 for Medicare Part B drugs, and (iii) Medicare Part D redesign which replaces the current coverage gap provisions and establishes a $2,000 cap for out-of-pocket limits costs for Medicare beneficiaries beginning in 2025, with manufacturers being responsible for 10% of costs up to the $2,000 cap and 20% after that cap is reached. Implementation of the IRA is expected to be carried out through upcoming actions by regulatory authorities, the outcome of which is uncertain.

Healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and decreased reimbursement. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our product candidates. It is difficult to predict how enforcement initiatives under the PPACA, the IRA, and/or additional legislation or regulation enacted in the future may impact our business. If the PPACA, the IRA, and/or additional legislation or regulation enacted in the future cause such unintended consequences or indirect impact, they could have a material adverse effect on our business, financial condition and results of operations.

Competitor companies or hospitals in the EU may be able to take advantage of EU rules permitting sales of unlicensed medicines for individual patients to sell competing products without a marketing authorization.

The EU medicines rules allow individual member states to permit the supply of a medicinal product without a marketing authorization to fulfill special needs, where the product is supplied in response to a bona fide unsolicited order, formulated in accordance with the specifications of a healthcare professional and for use by an individual patient under his direct personal responsibility. This may, in certain countries, also apply to products manufactured in a country outside the EU and imported to treat specific patients or small groups of patients. In addition, advanced therapy medicinal products do not need a marketing authorization if they are prepared on a non-routine basis and are used within the same EU member state in a hospital in accordance with a medical prescription for an individual patient.

These exemptions could allow our competitors to make sales in the EU without having obtained a marketing authorization and without undergoing the expense of clinical trials, especially if those competitors have cell processing facilities in the relevant EU member state. Similarly, certain hospitals may be able to compete with us on the basis of these rules.

Risks Related to Our Common Stock

We pay no dividends.

We have never paid cash dividends in the past, and currently do not intend to pay any cash dividends in the foreseeable future. We intend to retain earnings, if any, to finance the development and expansion of our business. Our future dividend policy will be subject to the discretion of our Board of Directors and will be contingent upon future earnings, if any, our financial condition, capital requirements, general business conditions, and other factors. Therefore, we can give no assurance that any dividends of any kind will ever be paid to holders of our common stock.

There is no assurance that an active trading market for our common stock will be sustained.

Our common stock is listed on Nasdaq. However, no assurance can be given that an active market for our common stock will be sustained. In addition, although there have been market makers in our common stock, we cannot assure that these market makers will continue to make a market in our securities or that other factors outside of our control will not cause them to stop market making in our securities. Making a market in securities involves maintaining bid and ask quotations and being able to effect transactions in reasonable quantities at those quoted prices, subject to various securities laws and other regulatory requirements. Furthermore, the development and maintenance of a public trading market depends upon the existence of willing buyers and sellers, the presence of which is not within our control or that of any market maker. Market makers are not required to maintain a continuous two-sided market, are required to honor firm quotations for only a limited number of securities, and are free to withdraw firm quotations at any time. Even with a market maker, factors such as our past losses from operations and the small size of our company mean that there can be no assurance of an active and liquid market for our securities developing in the foreseeable future. Even if there is a market for our securities, we cannot assure that securityholders will be able to resell their securities at any price.

Stockholders who hold unregistered shares of our common stock are subject to resale restrictions pursuant to Rule 144 due to our former status as a "shell company."

We previously were a "shell company" pursuant to Rule 144, promulgated under the Securities Act, or Rule 144, and, as such, sales of our securities pursuant to Rule 144 cannot be made unless, among other things, we continue to remain subject to Section 13 or 15(d) of the Exchange Act, and we file all of our required periodic reports with the SEC under the Exchange Act. Because our unregistered securities cannot be sold pursuant to Rule 144 unless we continue to meet such requirements, any unregistered securities we sell in the future or issue to consultants or employees, in consideration for services rendered or for any other purpose, will have no liquidity unless we continue to comply with such requirements. As a result, it may be more difficult for us to obtain financing to fund our operations and pay our consultants and employees with our securities instead of cash.

We have incurred, and will continue to incur, increased costs as a result of being an SEC reporting company.

The Sarbanes-Oxley Act of 2002 (the "Sarbanes-Oxley Act"), as well as a variety of related rules implemented by the SEC, have required changes in corporate governance practices and generally increased the disclosure requirements of public companies. As a reporting company, we incur significant legal, accounting and other expenses in connection with our public disclosure and other obligations. Based upon SEC regulations currently in effect, we are required to establish, evaluate and report on our internal control over financial reporting. We believe that compliance with the myriad of rules and regulations applicable to reporting companies and related compliance issues will continue to require a significant amount of time and attention from our management.

Material weaknesses in our internal control over financial reporting have caused and may cause us to fail to timely and accurately report our financial results or result in a material misstatement of our consolidated financial statements.

We identified control deficiencies in the design and operation of our internal control over financial reporting that constituted material weaknesses. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our consolidated financial statements will not be prevented or detected on a timely basis. Our material weaknesses related to the following control deficiencies:

- Lack of adherence to formal policies and procedures;

- Lack of risk assessment procedures on internal controls to detect financial reporting risks on a timely manner;

- Lack of design and implementation of effective controls to achieve complete and accurate financial reporting and disclosures, including documented controls over the preparation and review of journal entries, account reconciliations and income taxes.

- Lack of design and implementation of effective controls over the accounting for warrants issued in connection with equity financings.

The deficiencies described above resulted in a past misstatement and, if not remedied, could result in a misstatement of one or more account balances or disclosures in our annual or interim consolidated financial statements that would not be prevented or detected, and, accordingly, we determined that these control deficiencies constituted material weaknesses.

To address our material weaknesses, we have engaged an external financial consulting firm to assist us with implementing enhancements and controls within our accounting systems, and further evolving our accounting and quarterly and annual close processes. We will not be able to remediate these control deficiencies until these steps have been completed and have been operating effectively for a sufficient period of time and management has concluded, through testing, that the controls are operating effectively. The redesign and implementation of improvements to our accounting and proprietary systems and controls may be costly and time consuming and the cost to remediate may impair our results of operations in the future.

If we fail to remediate our material weakness, identify future material weaknesses in our internal control over financial reporting or fail to meet the demands that have been placed upon us as a public company, including the requirements of the Sarbanes-Oxley Act, we may be unable to accurately report our financial results or report them within the timeframes required by law or stock exchange regulations. Failure to comply with Section 404 of the Sarbanes-Oxley Act could also potentially subject us to sanctions or investigations by the SEC or other regulatory authorities. If additional material weaknesses exist or are discovered in the future, and we are unable to remediate any such material weakness, our reputation, results of operations and financial condition could suffer.

Our stock price may fluctuate significantly and be highly volatile and this may make it difficult for a securityholder to resell our securities at the volume, prices and times the securityholder finds attractive.

The market price of our common stock may be subject to significant fluctuations and be highly volatile, which may make it difficult for a securityholder to resell our securities at the volume, prices and times the securityholder finds attractive. There are many factors that will impact our stock price and trading volume, including, but not limited to, the factors listed above under “Risks Related to Our Business Generally,” “Risks Related to Our Cell Therapy Product Development Efforts,” “Risks Related to Our Intellectual Property,” “Risks Related to Government Regulation,” “Risks Related to Our Common Stock” and “Risks Associated with Our Nasdaq Listing.”

Stock markets, in general, experience significant price and volume volatility, and the market price of our securities may continue to be subject to such market fluctuations that may be unrelated to our operating performance and prospects. Increased market volatility and fluctuations could result in a substantial decline in the market price of our securities.

Our common stock is classified as a "penny stock;" the restrictions of the penny stock regulations of the SEC may result in less liquidity for our common stock.

The SEC has adopted regulations which define a "penny stock" to be any equity security that has a market price (as therein defined) of less than $5.00 per share or an exercise price of less than $5.00 per share, subject to certain exceptions. Unless exempt, the rules require the delivery, prior to any transaction involving a penny stock by a retail customer, of a disclosure schedule prepared by the SEC relating to the penny stock market. Disclosure is also required to be made about commissions payable to both the broker/dealer and the registered representative and current quotations for the securities. Finally, monthly statements are required to be sent disclosing recent price information for the penny stock held in the account and information on the limited market in penny stocks. The market price for shares of our common stock is currently below $5.00 and we do not satisfy any of the exceptions to the SEC's definition of penny stock. Accordingly, our common stock is currently classified as a penny stock. As a result of the penny stock restrictions, brokers or potential investors may be reluctant to trade in our securities, which may result in less liquidity for our shares.

Anti-takeover provisions and the regulations to which we may be subject may make it more difficult for a third party to acquire control of us, even if the change in control would be beneficial to our securityholders.

We are incorporated in Nevada. Anti-takeover provisions in Nevada law and our articles of incorporation and bylaws could make it more difficult for a third party to acquire control of us and may prevent stockholders from receiving a premium for their securities. Our certificate of incorporation provides that our Board of Directors may issue up to 20,000,000 shares of preferred stock, in one or more series, without stockholder approval and with such terms, preferences, rights and privileges as the Board of Directors may deem appropriate. Of such 20,000,000 authorized shares, 1,398,158 shares of Series B preferred stock are issued and outstanding. These provisions and other factors may hinder or prevent a change in control, even if the change in control would be perceived as beneficial to, or sought by, our other stockholders.

Risks Associated with Our Nasdaq Listing

We cannot assure you that we will be able to continue to comply with the minimum bid price requirement of Nasdaq.

Although the market price of our common stock satisfied the initial listing minimum bid price requirement for Nasdaq, there can be no assurance that the market price of our common stock will increase to, or remain at, the $1.00 per share level required for continuing compliance with that requirement. There are many factors, such as negative financial or operational results, that could adversely affect the market price of our common stock and jeopardize our ability to maintain Nasdaq's minimum bid price requirement. On February 11, 2026, the last reported sale price of our common stock was $0.41 per share.

The 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 our Nasdaq listing has helped generate greater and broader investor interest, including institutional investors, there can be no assurances in that regard. 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.

Risks Relating To This Offering

This is a reasonable best efforts offering, with no minimum amount of Units required to be sold, and we may sell fewer than all of the Units offered hereby.

The placement agent has agreed to use its reasonable best efforts to solicit offers to purchase the Units in this offering. The placement agent has no obligation to buy any of the Units from us or to arrange for the purchase or sale of any specific number or dollar amount of the Units. There is no required minimum number of Units that must be sold as a condition to complete this offering. As there is no minimum offering amount required as a condition to the closing of this offering, the actual offering amount, placement agent fees and proceeds to us are not presently determinable and may be substantially less than the maximum amounts set forth in this prospectus. We may sell fewer than all of the Units offered hereby, which would significantly reduce the amount of proceeds received by us, and investors in this offering will not receive a refund in the event that we do not sell all of the Units offered in this offering. The success of this offering will impact our ability to use the proceeds to execute our business plans. We may have insufficient capital to implement our business plans, potentially resulting in greater operating losses or dilution unless we are able to raise capital from alternative sources.

There is substantial doubt regarding our ability to continue as a going concern. Following this offering, we will still need to raise substantial additional funding, which may not be available on acceptable terms, if at all, to be able to continue as a going concern and advance our business plan. The report of our independent registered public accounting firm contains an explanatory paragraph that expresses substantial doubt about our ability to continue as a going concern.

There is substantial doubt regarding our ability to continue as a going concern. Our existence in our current form is dependent upon our ability to obtain additional capital. Our cash and cash equivalents and investments held in marketable securities following this offering will not be sufficient to fund our long-term operations. Raising funds in the current economic environment is challenging and financing may not be available in sufficient amounts or on acceptable terms, if at all. The issuance of additional securities, whether equity or debt, or the possibility of such issuance, may cause the market price of our common stock to decline. The sale of additional equity or convertible debt securities may dilute the ownership of existing stockholders.

If we are unable to raise adequate funds, we may have to delay, reduce the scope of or eliminate some or all of our business plan expenditures, and the failure to procure such required financing could have a material and adverse effect on our business, liquidity, financial condition and results of operations as well as our ability to continue as a going concern. If we are unable to continue as a going concern, we might have to liquidate our assets and the values we receive for our assets in liquidation or dissolution could be significantly lower than the values reflected in our financial statements. The inclusion of the going concern explanatory paragraph by our auditors, our lack of cash resources and our potential inability to continue as a going concern may materially adversely affect our business, share price, and our ability to raise new capital or to enter into critical contractual relations with third parties due to concerns about our ability to meet our contractual obligations.

The report of our independent registered public accounting firms with respect to our financial statements as of December 31, 2024 and 2023 and for the years then ended indicates that our financial statements have been prepared assuming that we will continue as a going concern. The report states that, as of December 31, 2024 there is substantial doubt about our ability to continue as a going concern within one year after the issuance date of such financial statements. Our plans in regard to these matters are described in footnote 1 to such financial statements. Our financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Following this offering, we will need to obtain additional financing to continue our ongoing development and proposed operations.

Following this offering, even if we sell all of the securities covered by this prospectus, we will still require significant additional funds in the future through equity or debt financings, government funding or grants, private capital, royalty agreements, customer payments, or other strategic alliances with third parties, either alone or in combination, to fund our business plan and to complete our initiatives. Our business plan, which includes the conduct of a Phase 3 clinical trial for *BRTX-100* and the development of our *ThermoStem Program* and biocosmeceuticals platform, has required and will continue to require substantial capital expenditures. We will require financing to fund our research and development, and initial commercial production activities, including the legal, operational set-up, general and administrative, marketing, employee salaries and other related expenses.

Obtaining additional funding will be subject to various additional factors, including investor acceptance of our business plan, the status of our development program and ongoing results from our biocosmeceuticals efforts. If we are not able to secure adequate additional funding when needed, we will need to re-evaluate our operating plan and may be forced to make significant reductions in spending, extend payment terms with suppliers, liquidate assets where possible, limit, suspend or curtail planned development programs and cease operations entirely. Having insufficient funds may also require us to relinquish rights to assets and technology that we would otherwise prefer to develop ourselves, or on less favorable terms than we would otherwise choose. The foregoing actions and circumstances could materially adversely impact our business, liquidity, results of operations and future prospects.

Any such required financing may not be available in amounts or on terms acceptable to us or at all, and the failure to procure such required financing could have a material and adverse effect on our business, financial condition and results of operations.

Depending on the type and the terms of any financing we pursue, stockholders' rights and the value of their investment in our common stock could be reduced. Any additional equity financing will dilute stockholdings, and debt financing, if available, may involve restrictions on financing and operating activities. In addition, if we issue secured debt securities, the holders of the debt would have a claim to our assets that would be prior to the rights of stockholders until the debt is paid. Interest on such debt securities would increase costs and negatively impact operating results. If the issuance of new securities results in diminished rights to holders of our common stock, the market price of our common stock could be negatively impacted. Any sale of securities will also need to comply with the applicable rules of the stock exchanges on which our securities are listed or quoted for trading. Further, strategic collaboration or royalty agreements may provide us with non-dilutive or minimally dilutive financing but adversely impact our future results of operations or capital resources. Following this offering, there is no guarantee that we will be able to secure any additional funding or be able to secure funding which will provide us with sufficient funds to meet our objectives, which may adversely affect our business and financial position.

We have broad discretion as to the use of proceeds from this offering and may not use the proceeds effectively.

We intend to use the net proceeds of this offering in connection with our clinical trials with respect to *BRTX-100*, pre-clinical research and development with respect to our *ThermoStem Program*, the development of our commercial biocosmeceuticals platform and for general corporate purposes and working capital. We may also use a portion of the net proceeds from this offering to acquire or invest in complementary businesses, technologies, product candidates or other intellectual property, although we have no present commitments or agreements to do so. We have not allocated any specific portion of the net proceeds to any particular purpose, and our management will have the discretion to allocate the proceeds as it determines. We will have significant flexibility and broad discretion in applying the net proceeds of this offering, and we may not apply these proceeds effectively. Our management might not be able to yield a significant return, if any, on any investment of these net proceeds, and you will not have the opportunity to influence our decisions on how to use our net proceeds from this offering.

You will experience immediate and substantial dilution in net tangible book value.

The public offering price will be substantially higher than the as adjusted net tangible book value per share of our outstanding shares of common stock as of September 30, 2025. As a result, investors in this offering will incur immediate dilution of $0.08 per share, based upon the public offering price of $0.35 per Unit, and assuming that all of the securities covered by this prospectus are sold. Investors in this offering will pay a price per share that substantially exceeds the book value of our tangible assets after subtracting our liabilities. See "Dilution" for a more complete description of how the value of your investment will be diluted upon the completion of this offering.

You may experience future dilution as a result of future equity offerings.

In order to raise additional capital, we may in the future offer additional shares of our common stock or other securities convertible into, or exercisable 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 of our common stock 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 of common stock or other securities in the future could have rights superior to existing stockholders.

There may be significant future issuances or resales of our common stock which may materially and adversely dilute your ownership interest and affect the market price of our shares.

We currently have authorization to issue up to 75,000,000 shares of common stock of which, as of February 11, 2026, 9,046,242 shares were issued and outstanding. We are not restricted from issuing additional shares of our common stock in the future, including securities convertible into, or exchangeable or exercisable for, shares of our common stock. In addition, there are 1,398,158 shares of Series B preferred stock issued and outstanding. Such shares are convertible under certain circumstances into an equal number of shares of common stock. Pursuant to our November 2021 public offering of securities, we issued warrants for the purchase of an aggregate of 2,645,000 shares of common stock (of which warrants for the purchase of 970,000 shares of common stock remain outstanding) as well as underwriter warrants for the purchase of 235,970 shares of common stock. We have an effective registration statement on Form S-3 under the Securities Act registering the issuance of such shares. The shares issuable pursuant to the registration statement on Form S-3 will be freely tradable in the public market, except for shares held by affiliates. In addition, pursuant to agreements entered into with the holders of certain warrants, we have issued an aggregate of 2,603,525 shares of common stock and warrants for the purchase of an aggregate of 2,513,686 shares of common stock and are obligated to issue an additional 748,055 shares of common stock that are being held in abeyance due to the holder's maximum beneficial ownership limitation. We have registered the resale of the shares of common stock issuable upon the exercise of such warrants. The issuance of shares of common stock upon exercise of the above warrants would dilute the ownership of our stockholders. We also have effective registration statements on Form S-8 under the Securities Act registering an aggregate of 9,850,000 shares of our common stock issuable under our 2021 Stock Incentive Plan. As of February 11, 2026, options to purchase 5,252,319 shares of our common stock were outstanding under the 2021 Plan. The shares issuable pursuant to the registration statements on Form S-8 will be freely tradable in the public market, except for shares held by affiliates. We may include a resale prospectus in our registration statement on Form S-8 with regard to the 2021 Plan covering the resale of the shares issuable to Lance Alstodt and Francisco Silva, our Chief Executive Officer and Vice President, Research and Development, respectively (and other affiliates), upon their exercise of options held by them and with regard to shares of our common stock issued to them upon the vesting of restricted stock units. The resale of such shares will be currently subject to the volume limitations imposed by Rule 144. The issuance of shares of our common stock pursuant to the 2021 Plan would dilute the ownership of our stockholders. We also have an effective registration statement on Form S-1 with regard to the resale of up to 508,592 shares of our common stock issuable upon the exercise of warrants. Further, we have an effective shelf registration statement on Form S-3 under the Securities Act registering $75,000,000 of our equity and debt securities. Pursuant to the requirements of Form S-3, we currently may sell pursuant to such Form S-3, during any 12 month period, securities having an aggregate market value of not more than one-third of the aggregate market value of the shares of our common stock held by non-affiliates. As of January 31, 2026, the aggregate market value of shares of our common stock held by non-affiliates pursuant to General Instruction I.B.6 of Form S-3 was $9,239,458. In addition, our Board of Directors (our "Board") is authorized to designate and issue 18,456,842 shares of preferred stock without further stockholder approval, containing such rights and preferences as our Board shall determine.

The sale of a substantial number of shares of our common stock or securities convertible into, or exchangeable or exercisable for, shares of our common stock, whether directly by us in future offerings or by our existing securityholders in the secondary market, the perception that such issuances or resales could occur or the availability for future issuances or resale of shares of our common stock or securities convertible into, or exchangeable or exercisable for, shares of our common stock could materially and adversely affect the market price of our securities and our ability to raise capital through future offerings of equity or equity-related securities on attractive terms or at all.

The Common Stock Warrants and the Pre-Funded Warrants are speculative in nature and there is not expected to be an active trading market for the warrants.

The Common Stock Warrants and the Pre-Funded Warrants offered in this offering do not confer any rights of common stock ownership on their holders, such as voting rights or the right to receive dividends, but rather merely represent the right to acquire shares of our common stock at a fixed price for a limited period of time. Specifically, commencing on the date of issuance, holders of the Common Stock Warrants may exercise their right to acquire the common stock and pay an exercise price of $0.35 per share (100% of the public offering price of a Unit), prior to five years from the date of issuance, after which date any unexercised warrants will expire and have no further value. In the case of Pre-Funded Warrants, holders may exercise their right to acquire the common stock and pay an exercise price of $0.0001 per share. The Pre-Funded Warrants do not expire. In addition, there is no established trading market for the Common Stock Warrants or Pre-Funded Warrants and we do not expect an active trading market to develop. Without an active trading market, the liquidity of the Common Stock Warrants and Pre-Funded Warrants will be limited.

Holders of the Common Stock Warrants or Pre-Funded Warrants will have no rights as a holder of Common Stock until they acquire our Common Stock.

Until holders of the Common Stock Warrants or Pre-Funded Warrants acquire shares of our common stock upon exercise of the Common Stock Warrants or Pre-Funded Warrants, the holders will have no rights with respect to shares of our common stock issuable upon exercise of the Common Stock Warrants or Pre-Funded Warrants. Upon exercise of the Common Stock Warrants or Pre-Funded Warrants, the holder will be entitled to exercise the rights of a holder of common stock as to the security exercised only as to matters for which the record date occurs after the exercise.

Provisions of the Common Stock Warrants could discourage an acquisition of us by a third party.

Certain provisions of the Common Stock Warrants could make it more difficult or expensive for a third party to acquire us. The Common Stock Warrants prohibit us from engaging in certain transactions constituting “fundamental transactions” unless, among other things, the surviving entity assumes our obligations under the Common Stock Warrants. These and other provisions of the warrants offered by this prospectus could prevent or deter a third party from acquiring us even where the acquisition could be beneficial to you.

CAPITALIZATION

The following table sets forth our cash and cash equivalents, investments held in marketable securities and capitalization as of September 30, 2025:

- on an actual basis; and
- on an as adjusted basis to give effect to our issuance and sale of up to 14,285,715 Units in this offering at the public offering price of $0.35 per Unit, after deducting the estimated placement agent fees and estimated offering expenses payable by us

The as adjusted information below is illustrative only, and our cash and cash equivalents, investments held in marketable securities and capitalization following the closing of this offering will be adjusted based on the actual public offering price and other terms of this offering determined at pricing. You should read this information in conjunction with our financial statements and related notes and the section entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations" included in this prospectus and other financial information contained in this prospectus.

	As of September 30, 2025 (unaudited)	
	Actual	**As Adjusted**
Cash and cash equivalents	$ 602,444	$ 4,984,444
Investments held in marketable securities	$ 3,887,383	$ 3,887,383
Stockholders' equity:		
Preferred stock, $0.01 par value; 20,000,000 shares authorized; Series B Convertible Preferred	$ 13,982	$ 13,982
Common stock, $0.0001 par value; 75,000,000 shares authorized, 7,978,117 shares issued and outstanding, actual; 22,263,832 shares issued and outstanding, as adjusted	$ 797	$ 2,226
11Additional paid-in capital	$ 168,905,254	$ 173,216,759
Accumulated deficit	$ (166,713,054)	$ (166,713,054)
Total stockholders' equity	$ 2,206,979	$ 6,519,913
Total capitalization	$ 2,206,979	$ 6,519,913

The number of shares of our common stock outstanding after this offering is based on 7,978,117 shares of our common stock outstanding as of September 30, 2025, and excludes as of that date the following:

- 1,398,158 shares of our common stock issuable upon the conversion of 1,398,158 shares of Series B preferred stock;
- 1,138,055 shares of our common stock held in abeyance in connection with a warrant exercise (due to a beneficial ownership limitation) and issuable at the request of the securityholder;
- 3,951,384 shares of our common stock issuable upon the exercise of outstanding warrants with a weighted average exercise price of $5.21 per share;
- 5,262,973 shares of our common stock issuable upon the exercise of outstanding stock options, with a weighted average exercise price of $2.58 per share; and
- 4,237,981 shares of our common stock reserved for future issuance pursuant to future awards granted under the 2021 Plan.

DILUTION

If you invest in this offering, your ownership interest will be diluted to the extent of the difference between the public offering price per Unit and the as adjusted net tangible book value per share after giving effect to this offering. We calculate net tangible book value per share by dividing the net tangible book value, which is tangible assets less total liabilities, by the number of outstanding shares of our common stock. Dilution represents the difference between the amount per share paid by purchasers of the securities in this offering and the as adjusted net tangible book value per share of our common stock immediately after giving effect to this offering. Our net tangible book value as of September 30, 2025 was approximately $1.65 million, or approximately $0.21 per share of common stock.

After giving effect to the sale of our securities pursuant to this prospectus in the aggregate amount of approximately $5 million at the public offering price of $0.35 per Unit (assuming that all of the securities covered by this prospectus are sold and there are no issuances of Pre-Funded Warrants), and after deducting the estimated placement agent fees and estimated aggregate offering expenses payable by us, our net tangible book value as of September 30, 2025 would have been approximately $6.0 million, or $0.27 per share of common stock. This represents an increase in the net tangible book value per share to our existing stockholders of approximately $0.06 per share and an immediate dilution in the net tangible book value of approximately $0.08 per share to new investors.

The following table illustrates this per share dilution for new investors based on the amount of funds we expect to receive:

Public offering price per Unit	$	0.35
Net tangible book value per share as of September 30, 2025	$	0.21
Increase per share attributable to this offering	$	0.06
As adjusted net tangible book value per share as of September 30, 2025, after giving effect to this offering	$	0.27
Dilution per share to new investors purchasing Units in this offering	$	0.08

The foregoing table and discussion are based on 7,978,117 shares of our common stock outstanding as of September 30, 2025 and excludes, as of September 30, 2025, (i) outstanding warrants to purchase up to 3,951,384 shares of our common stock at a weighted average exercise price of $5.21 per share; (ii) outstanding options to purchase up to 5,262,973 shares of our common stock at a weighted average exercise price of $2.58 per share; (iii) 1,398,158 shares of Series B preferred stock convertible into an equal number of shares of our common stock at a conversion price of $10.00 per share; and (iv) 1,138,055 shares of our common stock held in abeyance in connection with a warrant exercise (due to a beneficial ownership limitation) and issuable at the request of the securityholder. To the extent that warrants and options are exercised, Series B preferred stock is converted and shares held in abeyance are issued, there may be further dilution to new investors.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements regarding future events and our future results that are based on our current expectations, estimates, forecasts and projections as well as the current beliefs and assumptions of our management, including about our business, our financial condition, our results of operations, our operating requirements and utilization of our capital resources, and the industry and environment in which we operate. Statements that include words such as "believe," "may," "will," "estimate," "continue," "anticipate," "would," "could," "should," "intend" and "expect," variations of these words, and similar expressions, are intended to identify forward-looking statements.

These forward-looking statements may include, among other things:

- statements relating to projected growth and management's long-term performance goals;
- statements relating to the anticipated effects on results of operations or our financial condition from expected developments or events;
- statements relating to our business and growth strategies; and
- any other statements which are not historical facts.

These forward-looking statements speak only as of the date of this prospectus and are subject to risks, uncertainties and assumptions that are difficult to predict. Therefore, actual results may differ materially and adversely from those expressed in any forward-looking statements. Factors that might cause or contribute to such differences, and other factors that we believe affect our performance, include those discussed in the sections entitled "Risk Factors" and "Management's Discussion and Analysis of Financial Conditions and Results of Operations" in this prospectus, and in other reports we file with the SEC.

These factors include without limitation:

- our current and anticipated cash needs and our need for additional financing;
- federal, state and foreign regulatory requirements;
- our ability to conduct clinical trials with respect to our products and services;
- our ability to develop and commercialize our products and services;
- our ability to enter into agreements to implement our business strategy;
- the acceptance of our products and services by patients and the medical community;
- our ability to secure necessary media and reagents, as well as devices, materials and systems, for our clinical trials and commercial production;
- our manufacturing capabilities to produce our products;
- our ability to obtain brown adipose (fat) tissue in connection with our *ThermoStem Program*;
- our ability to protect our intellectual property;
- our ability to obtain and maintain an adequate level of product liability insurance;
- our ability to obtain third party reimbursement for our products and services from private and governmental insurers;
- the effects of competition in our market areas;
- our reliance on certain key personnel; and
- further sales or other dilution of our equity, which may adversely affect the market price of our common stock.

While forward-looking statements are based on the reasonable expectations of our management at the time that they are made, you should not rely on them. We undertake no obligation to revise or update publicly any forward-looking statements for any reason, whether as a result of new information, future events or otherwise, except as may be required by law.

USE OF PROCEEDS

We estimate that the net proceeds from this offering, after deducting the estimated placement agent fees and offering expenses, payable by us, will be approximately $4.4 million (assuming that all of the securities covered by this prospectus are sold and there are no issuances of Pre-Funded Warrants) based on the public offering price of $0.35 per Unit.

We currently intend to use the net proceeds from this offering, together with our existing cash and cash equivalents and investments held in marketable securities, in connection with our clinical trials with respect to *BRTX-100*, pre-clinical research and development with respect to our *ThermoStem Program*, the development of our commercial biocosmeceuticals platform and for general corporate purposes and working capital. We may also use a portion of the net proceeds from this offering to acquire or invest in complementary businesses, technologies, product candidates or other intellectual property, although we have no present commitments or agreements to do so.

The amounts and timing of our actual expenditures will depend on numerous factors, including the factors described under "Risk Factors" in this prospectus, as well as the amount of cash used in our operations. We may find it necessary or advisable to use the net proceeds for other purposes, and our management will have broad discretion in the application of the net proceeds to us from this offering, including for any of the purposes described above. Pending the use of the net proceeds from this offering, we intend to invest the net proceeds in interest-bearing, investment-grade securities, certificates of deposit or government securities.

BUSINESS

General

We develop therapeutic products, using cell and tissue protocols, primarily involving adult stem cells. As described below, our two core programs relate to the treatment of disc/spine disease and metabolic disorders. We also operate a commercial biocosmeceutical platform:

- ***Disc/Spine Program (brtxDisc).*** Our lead cell therapy candidate, *BRTX-100*, is a product formulated from autologous (or a person's own) cultured mesenchymal stem cells ("MSCs") collected from the patient's bone marrow. We intend that the product will be used for the non-surgical treatment of painful lumbosacral disc disorders or as a complimentary therapeutic to a surgical procedure. The *BRTX-100* production process utilizes proprietary technology and involves collecting a patient's bone marrow, isolating and culturing stem cells from the bone marrow and cryopreserving the cells. In an outpatient procedure, *BRTX-100* is injected by a physician into the patient's damaged disc. The treatment is intended for patients whose pain has not been alleviated by non-surgical procedures and who potentially face the prospect of surgery. We are conducting a Phase 2 clinical trial using *BRTX-100* to treat chronic lower back pain arising from degenerative disc disease. We have also obtained FDA IND clearance to evaluate *BRTX*-100 in the treatment of chronic cervical discogenic pain. See "Disc/Spine Program" below.

- ***Metabolic Program (ThermoStem)***. We are developing cell-based therapy candidates to target obesity and metabolic disorders using brown adipose (fat) derived stem cells ("BADSC") to generate brown adipose tissue ("BAT") as well as exosomes secreted by BADSC. We refer to this as our *ThermoStem Program*. BAT is intended to mimic naturally occurring brown adipose depots that regulate metabolic homeostasis in humans. Initial preclinical research indicates that increased amounts of brown fat in animals may be responsible for additional caloric burning as well as reduced glucose and lipid levels. Researchers have found that people with higher levels of brown fat may have a reduced risk for obesity and diabetes. BADSC secreted exosomes may also impact weight loss. Patents related to the *ThermoStem Program* have been issued in the United States and other jurisdictions. See "Metabolic Brown Adipose (Fat) Program" below.

- ***BioCosmeceuticals***: We operate a commercial biocosmeceutical platform. Our current commercial product, formulated and manufactured using our cGMP ISO-7 certified clean room, is a cell-based secretome containing exosomes, proteins and growth factors. This proprietary biologic serum has been specifically engineered by us to reduce the appearance of fine lines and wrinkles and bring forth other areas of cosmetic effectiveness. Moving forward, we also intend to explore the potential of expanding our commercial offering to include a broader family of cell-based biologic aesthetic products and therapeutics via IND-enabling studies, with the aim of pioneering FDA approvals in the emerging biocosmeceuticals space.

We have also licensed an investigational curved needle device designed to deliver cells and/or other therapeutic products or material to the spine and discs (and other parts of the body). We anticipate that FDA approval or clearance will be necessary for this device prior to commercialization. We do not intend to utilize this device in connection with our Phase 2 clinical trial with regard to *BRTX-100*. See "Curved Needle Device" below.

The patents and patent applications for the *Disc/Spine Program*, the *ThermoStem Program* and the curved needle device are described below under "Technology; Research and Development."

Overview

Every human being has stem cells in his or her body. These cells exist from the early stages of human development until the end of a person's life. Throughout our lives, our body continues to produce stem cells that regenerate to produce differentiated cells that make up various aspects of the body such as skin, blood, muscle and nerves. These are generally referred to as adult (non-embryonic) stem cells. These cells are important for the purpose of medical therapies aiming to replace lost or damaged cells or tissues or to otherwise treat disorders.

Regenerative cell therapy relies on replacing diseased, damaged or dysfunctional cells with healthy, functioning ones or repairing damaged or diseased tissue. A great range of cells can serve in cell therapy, including cells found in peripheral and umbilical cord blood, bone marrow and adipose (fat) tissue. Physicians have been using adult stem cells from bone marrow to treat various blood cancers for 70 years (the first successful bone marrow transplant was performed in 1956). Recently, physicians have begun to use stem cells to treat various other diseases. We intend to develop cell and tissue products and regenerative therapy protocols, primarily involving adult stem cells, to allow patients to undergo cellular-based treatments.

We are concentrating initially on therapeutic areas in which risk to the patient is low, recovery is relatively easy, results can be demonstrated through sufficient clinical data, and patients and physicians will be comfortable with the procedure. We believe that there will be readily identifiable groups of patients who will benefit from these procedures. We also believe that these procedures will be significantly less expensive than the most common surgical procedure alternatives and will compare favorably, over the long-term, to conservative treatment costs which may persist for years.

Accordingly, we have focused our initial developmental efforts on cellular-based therapeutic products and clinical development programs in selective areas of medicine for which the treatment protocol is minimally invasive. Such areas include the treatment of the disc and spine and metabolic-related disorders. Upon regulatory approval, we will seek to obtain third party reimbursement for our products and procedures; however; if we are not successful, patients may be required to pay for our products and procedures out of pocket in full and without the ability to be reimbursed by any governmental and other third party payers, which would adversely impact our prospects.

We have undertaken research and development efforts in connection with the development of investigational therapeutic products and medical therapies using cell and tissue protocols, primarily involving adult stem cells. See "Disc/Spine Program," "Metabolic Brown Adipose (Fat) Program" and "Curved Needle Device" below. As a result of these programs, we have seven United States patents, eighteen foreign patents and one United States patent application related to research regarding our *ThermoStem Program.* We have also obtained licenses for two United States patent applications related to our *Disc/Spine Program,* one United States patent related to our *Disc/Spine Program,* and a license for one United States patent related to a curved needle device.

We have established a research laboratory facility with cGMP capabilities to produce clinical grade products and we will seek to further develop cellular-based treatments, products and protocols, stem cell-related intellectual property ("IP") and translational research applications. See "Laboratory" below.

We have not generated any significant revenues to date. In November 2021, we completed a $23,000,000 public offering of our securities. In 2023, we raised approximately $2,680,000 in additional gross proceeds through public offerings of our securities. In February 2024, we received approximately $8,100,000 in gross proceeds pursuant to the exercise of warrants. During 2025, we received approximately $2,000,000 of gross proceeds pursuant to what is commonly is referred to as an "at-the-market" program with Rodman & Renshaw, LLC (the "2024 ATM"). As of January 31, 2026, we had the ability to raise an additional approximately $1,017,040 under the 2024 ATM. In October 2025, we received approximately $1,100,000 in gross proceeds pursuant to a registered direct public offering of our common stock.

Our BRTX-100 program has been granted a fast track designation by the FDA which may result in a reduction in the length of time required to complete our Phase 2 clinical trial and consequently a reduction in the costs involved. However, notwithstanding the above, we believe that our current funds may not be sufficient for us to complete our Phase 2 clinical trial investigating the use of *BRTX-100* in the treatment of chronic lower back pain arising from degenerative disc disease, as further described in this section, continue our pre-clinical research and development efforts with respect to our *ThermoStem Program* and satisfy our current working capital needs through the end of the 12 month period following the date of the financial statements included in this prospectus. In addition, the implementation of our business plan, as discussed below, will require the receipt of significant additional financing to fund our research and development efforts, including our contemplated Phase 3 clinical trial with regard to *BRTX-100* and our contemplated clinical trials relating to our *ThermoStem Program*, and otherwise fund our operations. We intend to seek to raise capital through our 2024 ATM and warrant exercises as well as through investment bankers and from biotech funds, strategic partners and other financial institutions. No assurance can be given that the amount of funding that we anticipate may be required for the above purposes is correct or that we will be able to accomplish our goals within the timeframes projected. In addition, no assurance can be given that we will be able to obtain any required financing on commercially reasonable terms or otherwise. If we are unable to obtain adequate funding, we may be required to significantly curtail or discontinue our proposed operations.

Disc/Spine Program

General

Among the initiatives that we are currently pursuing is our *Disc/Spine Program*, with our initial product candidate being called *BRTX-100*. We have obtained an exclusive license (see "*Exclusive License*" below) that permits us to use technology for adult stem cell treatment of disc and spine conditions. The technology is an advanced stem cell culture and injection procedure into the intervertebral disc ("IVD") that may offer relief from lower back pain, buttock and leg pain, and numbness and tingling in the leg and foot.

Lower back pain is the most common, most disabling, and most costly musculoskeletal ailment faced worldwide. According to a 2016 market report from Trinity Partners, a global life sciences consulting firm, of the 250 million American adults, nearly 25 million have chronic lower back pain of which approximately 12 million have been diagnosed with and treated for disc degeneration and approximately 5.6 million have pain caused by a protruding or injured disc. We believe that between 500,000 and one million invasive surgical procedures are performed each year to try to alleviate the pain associated with these lower back conditions and that such procedures cost approximately $40 billion. Clinical studies have documented that the source of the pain is most frequently damage to the IVD. This can occur when forces, whether a single load or repetitive microtrauma, exceed the IVD's inherent capacity to resist those loads. Aging, obesity, smoking, lifestyle, and certain genetic factors may predispose one to an IVD injury. Current surgical approaches to back pain are extremely invasive (often altering the spine's biomechanics unfavorably and predisposing it to further disc degeneration) and are associated with unacceptably low success rates (with a second operation occurring 10% to 20% of the time). In addition, current surgical approaches are costly with spinal fusion surgery costing approximately $110,000, discectomy costing approximately $20,000 to $50,000 and disc replacement surgery costing approximately $80,000 to $150,000. Even conservative treatments can be costly, with oral medications costing between $1,000 and $2,000 per year, injection treatments costing approximately $8,000 per year and physical therapy costing approximately $20,000 annually. We anticipate that the cost of a single treatment using *BRTX-100* will compare favorably to conservative treatments which may continue for years and will be less expensive than the most common surgical procedures.

While once thought to be benign, the natural history of lower back pain is often one of chronic recurrent episodes of pain leading to progressive disability. This is believed to be a direct result of the IVD's poor healing capacity after injury. The IVD is the largest avascular (having few or no blood vessels) structure in the body and is low in cellularity. Therefore, its inherent capacity to heal after injury is poor. The clinical rationale of *BRTX-100* is to deliver a high concentration of the patient's own cultured MSCs into the site of pathology to promote healing and relieve pain.

We have developed a mesenchymal stem cell product candidate, *BRTX-100,* derived from autologous (or a person's own) human bone marrow, cultured and formulated, in a proprietary method, specifically for introduction into a painful lumbar disc. The product candidate was developed utilizing in part the exclusive license described below under "*Exclusive License*." As described below under "*BRTX-100*" and "*Production and Delivery*," *BRTX-100* is a hypoxic (low oxygen) stem cell product developed through a culturing process. In order to enhance the survivability of our bone marrow-derived MSCs in the avascular environment of the damaged disc, *BRTX-100* is designed to expand under hypoxic conditions. This process is intended to result in a large cell count population with enhanced viability and therapeutic potential following injection into the injured disc.

In February 2017, pursuant to an IND application, we received authorization from the FDA to commence a Phase 2 clinical trial investigating the use of *BRTX-100*, our lead cell therapy candidate, in the treatment of chronic lower back pain arising from degenerative disc disease. We are conducting our Phase 2 clinical trial as described below under "*Clinical Trial*." We believe that, based upon our periodic reports to the FDA as to our clinical trial, the existing IND remains effective.

In addition to developing *BRTX-100*, we may also seek to sublicense the technology to a strategic third party, who may assist in gaining FDA approval for a lumbar disc indication, or third parties for use in connection with cellular-based developmental programs with regard to disc and spine related conditions.

We have established a laboratory, which includes a clean room facility, to perform the production of cell products (including *BRTX-100*) for use in our clinical trials, for third party cell products or for general research purposes. We may also use this laboratory to develop our pipeline of future products and expand our stem cell-related IP. See "Laboratory" and "Technology; Research and Development" below.

In March 2022, a United States patent related to *BRTX-100* was issued. We have been granted exclusive license rights with respect to the patent. See "*Exclusive License*" below.

BRTX-100

Our lead product candidate*, BRTX-100,* is an autologous hypoxic (low oxygen) cultured mesenchymal stem cell product derived from a patient's own bone marrow and formulated with a proprietary biomaterial carrier (platelet lysate) to increase potency, viability and survivability. We have designed the cryopreserved sterile cellular product candidate to be provided in vials for injection into painful lumbar discs. We anticipate the product candidate will be delivered using a standard 20 gauge 3.5 inch introducer needle and a 25 gauge 6 inch needle that will extend into the disc center upon delivery. Upon regulatory approval, we plan to provide training to medical practitioners with regard to the approved injection procedure. It is anticipated that the delivery of the product candidate will be a 30 minute procedure.

Mesenchymal stem cells used in *BRTX-100* are similar to other MSCs under development by others; however, in order to enhance the survivability of our bone marrow-derived MSCs in the avascular environment of the damaged disc, *BRTX-100* is designed to expand under hypoxic conditions for a period of approximately three weeks. This process is intended to result in an approximate 40 million cell count population with enhanced viability and therapeutic potential following injection locally into injured spinal discs. Publications and scientific literature have indicated that MSCs preconditioned in a hypoxic environment show enhanced skeletal muscle regeneration properties and improved impacts upon circulation and vascular formation compared to MSCs cultured under normoxic (normal oxygen) conditions.

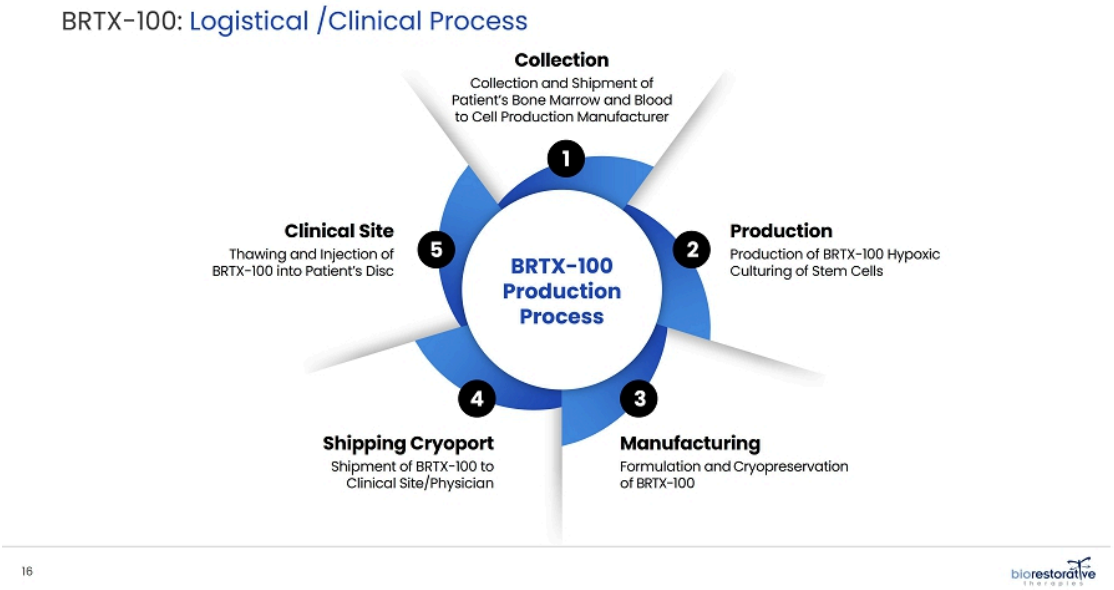
In August 2018, the *Journal of Translational Medicine* published the results of our study evaluating the benefits of long-term hypoxic culturing of human bone marrow-derived MSCs.

In September 2021, we were awarded a National Institutes of Health Small Business Technology Transfer (STTR) Phase 1 grant for $256,000 to evaluate the therapeutic effects on our hypoxic cultured bone marrow derived mesenchymal stem cells (*BRTX-100*) after encapsulation with a PEG-peptide hydrogel. The work was done in collaboration with Washington University of St. Louis.

Since June 2022, we have entered into clinical trial agreements with 16 sites to conduct our Phase 2 clinical trial targeting chronic lumbar disc disease. See "*Clinical Trial*" below.

Production and Delivery

The production of our product candidate, *BRTX-100,* begins with the physician collecting bone marrow from the patient under local anesthesia. Peripheral blood is also collected from the patient. The physician will then send the patient's bone marrow and blood samples to our laboratory (or a contract laboratory) for culturing and formulation. The hypoxic culturing process is intended to result in the selection of a cell population that is suitable for an improved possibility of survival in the internal disc environment. We anticipate that the cell culturing process and product formulation will take approximately three weeks, with an additional two weeks required for quality control testing required to meet product release criteria. We will then send the therapeutic cryopreserved stem cells (*BRTX-100*) in a sterile vial back to the physician's offices where it will undergo a controlled thaw prior to the procedure. The price structure for the procedure and our services has not been determined and no assurances can be given as to the effect that such price structure will have on the marketability of such procedure and services. The following illustrates the process:



Exclusive License

Pursuant to our license agreement with Regenerative Sciences, LLC ("Regenerative") that became effective in April 2012 (the "Regenerative License Agreement"), we have obtained, among other things, a worldwide (excluding Asia and Argentina), exclusive, royalty-bearing license from Regenerative to utilize or sublicense a certain method for culturing cells for use in our developmental program involving disc and spine conditions, including protruding or painful discs and the treatment of avascular zones. The investigational technology that has been licensed is an advanced stem cell culture and injection procedure that may offer relief from lower back pain, buttock and leg pain, and numbness and tingling in the leg and foot. Pursuant to the Regenerative License Agreement, we have also obtained a worldwide, exclusive, royalty-bearing license from Regenerative to utilize or sublicense a certain investigational curved needle device for the administration of specific cells and/or cell products to the disc and/or spine (and other parts of the body). It will be necessary to advance the design of this investigational device to facilitate the delivery of substances, including living cells, to specific locations within the body and minimize the potential for damage to nearby structures.

The patents that are the subject of the Regenerative License Agreement have been assigned to Regenexx, LLC which we have been advised by Regenerative is an affiliate of Regenerative.

Animal Study

The efficacy and safety of our product candidate, *BRTX-100,* has been tested in a degenerative intervertebral rabbit disc model. In this study, 80 rabbits underwent surgery to create a puncture in the discs. Four weeks post-surgery, each rabbit had either contrast, a biomaterial carrier or *BRTX-100* injected into the discs. In order to study the biodistribution and efficacy of *BRTX-100*, the rabbits were evaluated at day 56 and day 120.

The key safety findings of the animal study are as follows:

- There was no evidence or observation of gross toxicity related to the administration of *BRTX-100* at either time point. The clinical pathology across both groups and time points were within expected normal historical ranges and under the conditions of the test. No abnormalities (including fractures or overt signs of lumbar disc disease) were identified after review of the radiographic images taken at both endpoints for both groups. No toxicity or adverse finding was evident in the systemic tissues or the discs of animals receiving *BRTX-100*.

- There was no detectable presence of human cells (*BRTX-100*) observed at the day 56 interim time point. This is consistent with the proposed mechanism of action that *BRTX-100* acts through a paracrine effect of secreted growth and immunomodulation factors.

The key efficacy findings of the animal study are as follows:

- *BRTX-100* showed a statistically significant DHI (disc height increase) over the control group at day 120.

- *BRTX-100* showed a statistically significant improvement in disc histology over the control group at day 120 as graded by a validated histology scale. *BRTX-100* showed a significant improvement in the cellularity and matrix of the disc when compared to the control group at day 120.

Clinical Trial

Pursuant to an IND application we submitted to the FDA, we have obtained authorization to conduct a Phase 2 clinical trial investigating the use of *BRTX-100*, our lead cell therapy candidate, in the treatment of chronic lower back pain arising from degenerative disc disease. We are conducting our Phase 2 clinical trial as discussed below.

The following describes the Phase 2 clinical trial authorized by the FDA:

A Phase 2 Prospective, Double-Blinded, Placebo Controlled, Randomized Study

- General
    - 99 patients; randomized 2:1, *BRTX-100* to control, 40 million cells/dose
    - 10-20 clinical trial sites (we intend to utilize up to 16 clinical trial sites)
    - Primary efficacy endpoint at 12 months
    - Patient safety and efficacy follow up at 24 months
    - Included subjects must have only one symptomatic diseased disc
    - Included subjects must have current diagnosis of chronic lumbar disc disease typical pain with degeneration of a single disc confirmed by history, exam, radiography, or other acceptable means
    - Included subjects must have exhausted previous conservative non-operative therapies

- Primary Efficacy Endpoint
    - Responder endpoint - percentage of patients that meet the improvement in function and reduction in pain threshold
    - Improvement in function defined as at least a 30% increase in function based on the Oswestry questionnaires (ODI)
    - Reduction of pain defined as at least a 30% decrease in pain as measured using the Visual Analogue Scale (VAS)

- Additional or Secondary Endpoints
    - Clinical response at 12 months
    - Changes from baseline in pain as assessed with the VAS score and ODI at weeks 2, 12, 26, 52 and 104
    - Changes from baseline in function as assessed with the ODI at weeks 2, 12, 26, 52 and 104
    - Changes from baseline in function as assessed by Roland Morris Disability Questionnaire (RMDQ) at weeks 26, 52 and 104
    - Changes from baseline function as assessed by Functional Rating Index (FRI) at weeks 12, 52 and 104
    - Changes from baseline Quality of Life assessment (SF-12 questionnaire) scores at weeks 2, 12, 26, 52 and 104

In December 2021, we entered into a Master Service Agreement with Professional Research Consulting Inc. d/b/a PRC Clinical, a CRO specializing in clinical trial management, to conduct our Phase 2 clinical trial.

In April 2023, we announced that we had completed enrollment for the safety run-in component of our Phase 2 clinical study of *BRTX-100*.

In May 2023, we announced that we had signed a clinical trial agreement with Northwell Health, New York State's largest health care provider and private employer, pursuant to which Northwell Health is participating in our Phase 2 clinical study of *BRTX-100*.

In June 2023, we announced that the final subject in our *BRTX-100* Phase 2 clinical trial safety cohort had been dosed.

In June 2023, we announced that the independent Data Safety Monitoring Board, which is overseeing our Phase 2 clinical trial, unanimously recommended the continuation of our study in accordance with the version of the protocol with no changes.

In April 2024, we announced that the FDA cleared an important amendment to the protocol of our ongoing Phase 2 study investigating the use of *BRTX-100*. The protocol amendment removed saline injection in the control arm of the study and replaced it with a sham injection.

In November 2024, we announced new preliminary 26–52 week blinded data from the first 10 patients with cLDD enrolled in our ongoing Phase 2 clinical trial of *BRTX-100*. No serious adverse events were reported in any of the 10 safety run-in subjects. In addition, there was no dose limiting toxicity at 26-52 weeks.

In February 2025, we announced new preliminary 26–52 week blinded data from the first 15 patients with cLDD enrolled in our ongoing Phase 2 clinical trial of *BRTX-100*. No serious adverse events were reported in any of the 15 subjects. In addition, there was no dose limiting toxicity at 26-52 weeks. Further, we announced certain positive preliminary data analyses.

In May 2025, we announced that preliminary 26-, 52- and 104- week blinded data from the first 15 patients with cLDD enrolled in our ongoing Phase 2 clinical trial of *BRTX-100* was presented by our Vice President of Research and Development at the International Society for Cell and Gene Therapy 2025 Annual meeting. No serious adverse events were reported and there was no dose limiting toxicity at 26-104 weeks.

In June 2025, we announced that new preliminary blinded clinical data from 36 patients enrolled in our ongoing Phase 2 trial of *BRTX-100* for the treatment of cLDD was presented by our Vice President of Research and Development at the International Society for Stem Cell Research 2025 Annual Meeting. Over 74% of the subjects showed greater than 50% improvement in function by 52 weeks and over 72% of the subjects reported greater than 50% in reduction in pain by 52 weeks. No serious adverse events or dose limiting toxicities were reported between 26 and 104 weeks at the target dose.

In November 2025, we announced that we were granted a Type B meeting with the FDA to discuss a potential accelerated biologics license application ("BLA") approval pathway for the Fast-Track-Designated *BRTX-100* program for the treatment of cLDD. The meeting took place in December 2025.

In February 2026, we announced that we had completed the enrollment of 99 patients in our Phase 2 clinical trial of *BRTX-100.*

The FDA approval process can be lengthy, expensive and uncertain and there is no guarantee that the clinical trial(s) will be completed or that the product will ultimately receive approval or clearance.

As an alternative to undertaking any necessary clinical trials ourselves, we may explore the licensing of our rights with respect to our product candidate, *BRTX-100,* to a strategic partner. Such an arrangement could possibly eliminate or significantly reduce the need to raise the substantial capital needed to commence and complete the clinical trials and undertake the commercialization of *BRTX-100* and would provide licensing-related revenue to us in lieu of product sales revenue. No assurance can be given that any licensing agreement will be entered into, whether upon commercially reasonable terms or otherwise.

Defined Health Report

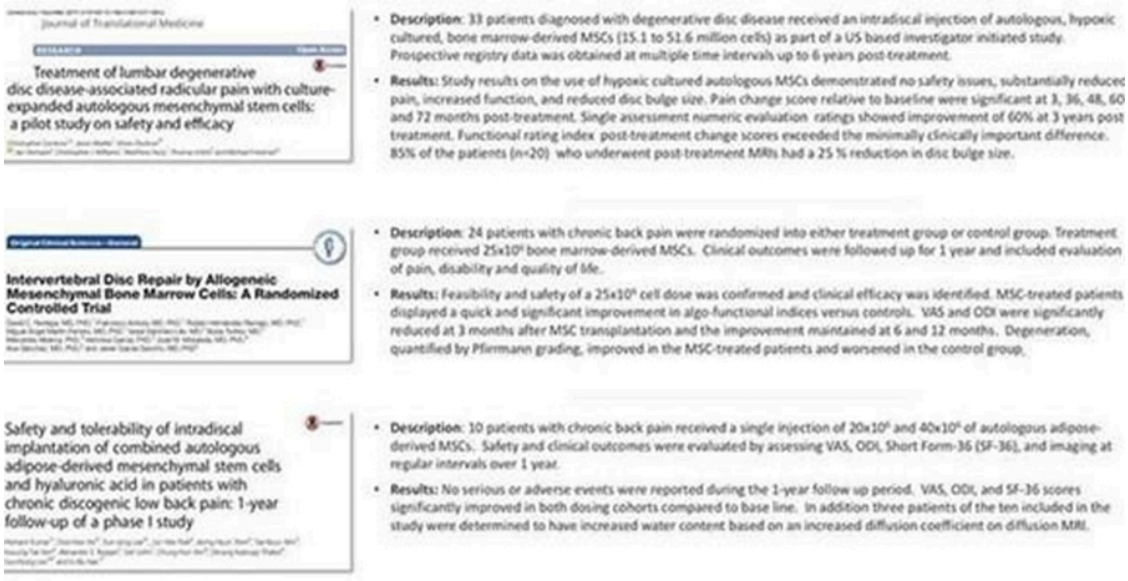
In March 2018, we engaged Defined Health, a business development and strategy consulting firm, to conduct an independent review of *BRTX-100*. Defined Health has worked with many of the leading companies in the pharmaceutical, biotech and healthcare industries for over 25 years.

The review was intended to collect informed, independent opinions regarding *BRTX-100* among key opinion leaders ("KOLs") (i.e., orthopedic surgeons specializing in back and spine surgery with experience in stem cell therapy), who, upon studying applicable clinical material, could offer opinions regarding the future therapeutic potential of *BRTX-100*.

As noted in the Defined Health report, the KOLs indicated that stem cell therapies have great potential to treat chronic lumbar disc disease and other therapeutic areas. The KOLs reacted positively to the value proposition of our product candidate, *BRTX-100,* and were optimistic that the clinical data presented to date is likely to be mirrored in future clinical investigations. Given the opportunity, the KOLs indicated that they would likely participate in a clinical trial should it be offered at their center and that they would recommend the study to appropriately eligible patients. The report indicated that, if *BRTX-100* were to be granted FDA approval, the KOLs anticipate that it would be integrated into the standard of care for eligible chronic lumbar disc disease patients.

Similar Therapies

Human data from studies of therapies comparative to *BRTX-100* have shown reduced pain, increased function, and an absence of significant safety issues with a durable response, as shown below:



Impact on Public Health

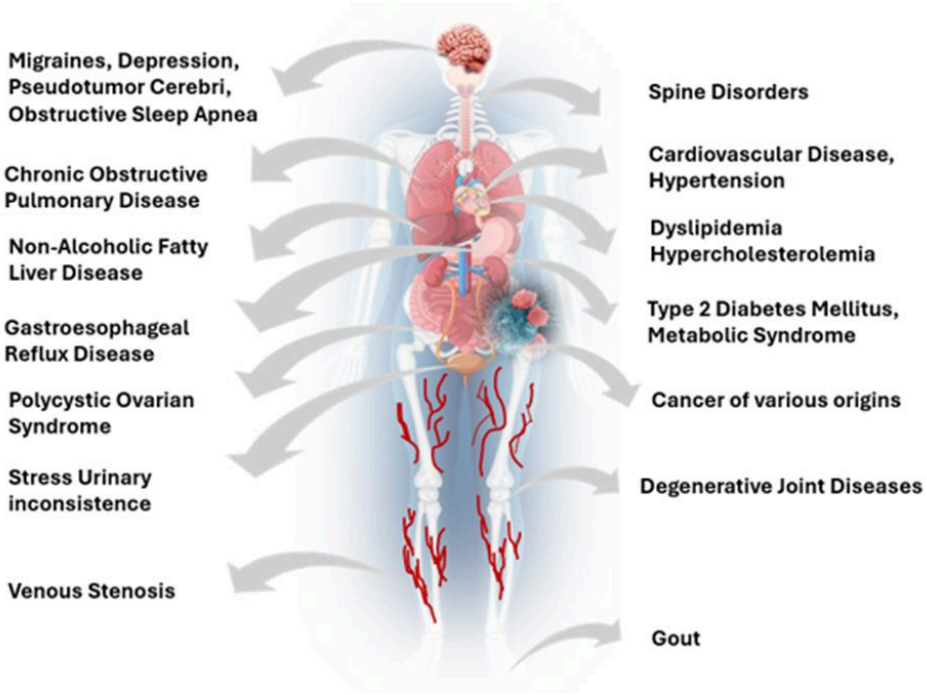
The United States is the world's leading consumer of hydrocodone (99%) and oxycodone (83%) and leads the world in per capital consumption of such drugs (twice as much as second ranked Canada). In 2020, 91,000 persons in the United States died from overdoses.

Total annual healthcare and lost productivity costs in the United States related to pain, including headache, back pain and neck pain, are estimated to be $600 billion, which is twice the annual costs related to heart disease and greater than the combined annual costs related to cancer and diabetes.

Metabolic Brown Adipose (Fat) Program

Since June 2011, we have been engaging in pre-clinical research efforts with respect to an investigational platform technology utilizing brown adipose (fat) derived stem cells ("BADSCs") for therapeutic purposes. We have labeled this initiative our *ThermoStem Program*.

Brown fat is a specialized adipose (fat) tissue found in the human body that plays a key role in the evolutionarily conserved mechanisms underlying thermogenesis (generation of non-shivering body heat) and energy homeostasis in mammals - long known to be present at high levels in hibernating mammals and human newborns. Recent studies have demonstrated that brown fat is present in the adult human body and may be correlated with the maintenance and regulation of healthy metabolism, thus potentially being involved in caloric regulation. The pre-clinical *ThermoStem Program* involves the use of a cell-based (brown adipose tissue construct) treatment for metabolic disease, such as type 2 diabetes, obesity, hypertension and other metabolic disorders, as well as cardiac deficiencies. The diseases, disorders and syndromes that may be targeted by our *ThermoStem Program* are as follows:



We have had initial success in transplanting the brown adipose tissue construct in animals, and we are currently exploring ways to deliver into humans. Even though present, BAT mass is very low in healthy adults and even lower in obese populations. Therefore, it may not be sufficient to either naturally impact whole body metabolism, or to be targeted by drugs intended to increase its activity in the majority of the population. Increasing BAT mass is crucial in order to benefit from its metabolic activity and this is what our *ThermoStem Program* seeks to accomplish. We may also identify other naturally occurring biologics and chemically engineered molecules that may enhance brown adipose tissue performance and activity.

Obesity, the abnormal accumulation of white fat tissue, leads to a number of metabolic disorders and is the driving force behind the rise of type 2 diabetes and cardiovascular diseases worldwide. Pharmacological efforts to alter metabolic homeostasis through modulating central control of appetite and satiety have had limited market penetration due to significant psychological and physiological safety concerns directly attributed to modulating these brain centers. Adipose tissue is one of the largest organs in the human body and plays a key role in central energy balance and lipid homeostasis. White and brown adipose tissues are found in mammals. White adipose tissue's function is to store energy, whereas BAT specializes in energy expenditure. As discussed in a 2020 article published in the *International Journal of Molecular Sciences*, recent advancements in unraveling the mechanisms that control the induction, differentiation, proliferation, and thermogenic activity of BAT, along with the application of imaging technologies for human BAT visualization, have generated optimism that these advances may provide novel strategies for targeting BAT activation/thermogenesis, leading to efficacious and safe obesity targeted therapies.

We are developing cell-based product candidates to target obesity and metabolic disorders using BADSCs. Our goal is to develop a bioengineered implantable brown adipose tissue construct intended to mimic ones naturally occurring in the human body. We have isolated and characterized a human multipotent stem cell population that resides within BAT depots. We have expanded these stem cells to clinically relevant numbers and successfully differentiated them into functional brown adipocytes. We intend to use adult stem cells that may be differentiated into progenitor or fully differentiated brown adipocytes, or a related cell type, which can be used therapeutically in patients. We are focusing on the development of treatment protocols that utilize allogeneic cells (i.e., stem cells from a genetically similar but not identical donor).

In order to deliver these differentiated cells into target locations *in vivo*, we seeded BADSCs onto 3-dimensional biological scaffolds. Pre-clinical animal models of diet-induced obesity, that were transplanted with differentiated BADSCs supported by a biological scaffold, presented significant reductions in weight and blood glucose levels compared to scaffold only controls. We are identifying technology for *in vivo* delivery in small animal models. Having completed our proof of concept using our BAT in small animals, we are currently developing our next generation BAT. It is anticipated that this next version will contain a higher purity of BADSC and a greater percent of functional brown adipocytes, which is expected to increase the therapeutic effect compared to our first-generation product. In addition, we are exploring the delivery of the therapeutic using encapsulation technology, which will only allow for reciprocal exchange of small molecules between the host circulation and the BAT implant. We expect that encapsulation may present several advantages over our current biological scaffolds, including prevention of any immune response or implant rejection that might occur in an immunocompetent host and an increase in safety by preventing the implanted cells from invading the host tissues. We have developed promising data on the loading of human stem cell-derived tissue engineered brown fat into an encapsulation device to be used as a cell delivery system for our metabolic platform program for the treatment of type 2 diabetes, obesity, hyperlipidemia and hypertension. This advancement may lead to successful transplantation of brown fat in humans. We are evaluating the next generation of BAT constructs that will first be tested in small animal models. No assurance can be given that this delivery system will be effective *in vivo* in animals or humans. Our allogeneic brown adipose derived stem cell platform potentially provides a therapeutic and commercial model for the cell-based treatment of obesity and related metabolic disorders.

In February 2014, our research with regard to the identification of a population of brown adipose derived stem cells was published in *Stem Cells*, a respected stem cell journal.

In March 2014, we entered into a Research Agreement with Pfizer Inc., a global pharmaceutical company. Pursuant to the Research Agreement with Pfizer, we were engaged to provide research and development services with regard to a joint study of the development and validation of a human brown adipose cell model. The Research Agreement with Pfizer provided for an initial payment to us of $250,000 and the payment of up to an additional $525,000 during the two-year term of the Agreement, all of which has been received. The Research Agreement expired upon completion of the services provided for therein.

In August 2015, we entered into a one year research collaboration agreement with the University of Pennsylvania with regard to the understanding of brown adipose biology and its role in metabolic disorders. In September 2018, we entered into a one year research collaboration agreement with the University of Pennsylvania pursuant to which the university was provided access to our proprietary brown adipose tissue cells for research purposes. No amounts were payable by or to us pursuant to either agreement.

In September 2015, a United States patent related to the *ThermoStem Program* was issued to us.

In April 2017, an Australian patent related to the *ThermoStem Program* was issued to us.

In December 2017, a Japanese patent related to the *ThermoStem Program* was issued to us.

In January 2019, a United States patent related to the *ThermoStem Program* was issued to us.

In October 2019, an Australian patent related to the *ThermoStem Program* was issued to us.

In October 2019, an Israeli patent related to the *ThermoStem Program* was issued to us.

In March 2020, a United States patent related to our *ThermoStem Program* was issued to us.

In March 2020, our collaboration with the University of Pennsylvania resulted in a publication in *Cell Reports*, a respected peer reviewed journal, with regard to our *ThermoStem Program*.

In April 2020, a European patent related to our *ThermoStem Program* was issued to us. This European patent was validated in Belgium, France, Germany, Italy, Poland, Spain, Sweden, Switzerland, and the United Kingdom.

In May 2020, an Israeli patent related to our *ThermoStem Program* was issued to us.

In January 2021, a European patent related to our *ThermoStem Program* was issued to us. This European patent was validated in France, Germany, Italy, Spain, and the United Kingdom.

In March 2021, a United States patent related to our *ThermoStem Program* was issued to us.

In June 2021, a Japanese patent related to our *ThermoStem Program* was issued to us.

In July 2021, a United States patent related to our *ThermoStem Program* was issued to us.

In August 2021, an Australian patent related to our *ThermoStem Program* was issued to us.

In February 2022, a Japanese patent related to our *ThermoStem Program* was issued to us.

In March 2022, an Israeli patent related to our *ThermoStem Program* was issued to us.

In December 2022, we announced that we were awarded a Small Business Innovation Research (SBIR) Phase 1 grant from Eunice Kennedy Shriver National Institute of Child Health & Human Development of the National Institutes of Health to enable the development and the evaluation of our *ThermoStem Program* for the treatment of polycystic ovary syndrome (PCOS). The work is to be done in collaboration with Dr. Sheng Wu, Associate Professor, Center for Metabolic Disease Research at Temple University.

In June 2023, a Japanese patent related to our *ThermoStem Program* was issued to us.

In June 2023, a United States patent related to our *ThermoStem Program* was issued to us.

In July 2023, a European patent related to our *ThermoStem Program* was issued to us. This European patent was validated in France, Germany, Italy, Spain, and the United Kingdom.

In December 2023, a United States patent related to our *ThermoStem Program* was issued to us.

In July 2024, a Japanese patent related to our *ThermoStem* program was issued to us.

In March 2025, a European patent related to our *ThermoStem Program* was issued to us. This European patent was validated in France, Germany, Italy, Spain and the United Kingdom.

In March 2025, an Israeli patent related to our *ThermoStem Program* was issued to us.

In September 2025, a Japanese patent related to our *ThermoStem Program* was issued to us.

In November 2025, a notice of allowance was issued for an Australian patent application related to our *ThermoStem Program*. This application is expected to issue as an Australian patent in the near future.

We have completed proof of concept preclinical animal studies using our first generation brown adipose derived stem cells. We intend to undertake additional preclinical animal studies in order to optimize delivery and explore the feasibility of targeting additional indications.

We anticipate that much of our development work in this area will take place at our laboratory facility, outside core facilities at academic, research or medical institutions, or contractors. See “Laboratory” below.

BioCosmeceuticals

We operate a commercial biocosmeceutical platform. Our current commercial product, formulated and manufactured using our cGMP ISO-7 certified clean room, is a cell-based secretome containing exosomes, proteins and growth factors. This proprietary biologic serum has been specifically engineered by us to reduce the appearance of fine lines and wrinkles and bring forth other areas of cosmetic effectiveness. Moving forward, we also intend to explore the potential of expanding our commercial offering to include a broader family of cell-based biologic aesthetic products and therapeutics via IND-enabling studies, with the aim of pioneering FDA approvals in the emerging biocosmeceuticals space.

We market our biocosmeceutical products to distributors, medical spas and direct to consumers.

In June 2025, we announced the hiring of Sandy Lipkins whose responsibilities focus on technology commercialization and business development.

In October 2025, we announced that we hired Crystal Romano as our Head of Global Commercial Operations.

Curved Needle Device

Pursuant to the Regenerative License Agreement discussed under "Disc/Spine Program-*Exclusive License*" above, we have licensed and further developed an investigational curved needle device ("CND") that is a needle system with a curved inner cannula to allow access to difficult-to-locate regions for the delivery or removal of fluids and other substances. The investigational CND is intended to deliver stem cells and/or other therapeutic products or material to the interior of a human intervertebral disc, the spine region, or potentially other areas of the body. The device is designed to rely on the use of pre-curved nested cannulae that allow the cells or material to be deposited in the posterior and lateral aspects of the disc to which direct access is not possible due to outlying structures such as vertebra, spinal cord and spinal nerves. We anticipate that the use of the investigational CND will facilitate the delivery of substances, including living cells, to specific locations within the body and minimize the potential for damage to nearby structures. The investigational device may also have more general use applications. In August 2015, a United States patent for the CND was issued to the licensor, Regenerative. We anticipate that FDA approval or clearance will be necessary for the investigational CND prior to commercialization. We do not intend to utilize the CND in connection with our Phase 2 clinical trial with regard to *BRTX-100*. The FDA review and approval process can be lengthy, expensive and uncertain and there is no guarantee of ultimate approval or clearance.

Laboratory

We have established a laboratory in Melville, New York for research purposes and have built a cleanroom within the laboratory for the production of cell-based product candidates, such as *BRTX-100*, for use in a clinical trial, for third party cell products or for general research purposes.

We have expanded our laboratory to include capabilities for the clinical production of our pipeline of clinical and investigational cell therapy candidates. Our expanded cGMP facility includes process development space, ISO 7 cleanrooms and state-of-the-art equipment. We have expanded our research and development operations to include clinical manufacturing, a necessary step for our Phase 2 clinical trial for *BRTX-100*. The new facility has been designed to provide cGMP manufacturing according to FDA and European Medicines Agency regulations and guidelines to support clinical grade cell production. In May 2023, we announced that we had received a license from the New York State Department of Health (the "NYSDOH") to act as a tissue bank for the processing of mesenchymal stem cells from autologous donors. In November 2024, we announced that we received a provisional license from the NYSDOH for the processing of allogeneic (non-autologous) donor tissue material for the isolation, expansion and cryopreservation of various cell types, including stem cells, for medical research.

As we develop our business and our stem cell product candidates, and we obtain regulatory approval, we will seek to establish ourselves as a key provider of adult stem cells for therapies and expand to provide cells in other market areas for stem cell therapy. We may also use outside laboratories specializing in cell therapy services and manufacturing of cell products.

Technology; Research and Development

We intend to utilize our laboratory or a third party laboratory in connection with cellular research activities. We also intend to obtain cellular-based therapeutic technology licenses and increase our IP portfolio. We intend to seek to develop potential stem cell delivery systems or devices. The goal of these specialized delivery systems or devices is to deliver cells into specific areas of the body, control the rate, amount and types of cells used in a treatment, and populate these areas of the body with sufficient stem cells so that there is a successful therapeutic result.

We also intend to perform research to develop certain stem cell optimization compounds, media designed to enhance cellular growth and regeneration for the purpose of improving pre-treatment and post-treatment outcomes.

In our *Disc/Spine Program*, fourteen patent applications have been filed with regard to technology that is the subject of the Regenerative License Agreement (see "Disc/Spine Program-*Exclusive License*" above). Regenerative has been issued a patent from one of these applications with regard to its curved needle therapeutic delivery device. This patent expires in March 2031. In addition, in March 2022, a United States patent related to *BRTX*-100 was issued. This patent expires in December 2029. Of the other twelve applications that were filed, one application remains pending. The patents that are the subject of the Regenerative License Agreement have been assigned to Regenexx, LLC which we have been advised is an affiliate of Regenerative.

In our *ThermoStem Program*, we have one pending United States patent application and seven United States patents within three patent families. Four of the patents expire in June 2032 and three of the patents expire in April 2034. With regard to the first patent family in the *ThermoStem Program,* patent applications have been filed in five foreign jurisdictions (of which four applications have been granted as foreign patents and one application has lapsed). The patents expire in June 2032. With regard to the second patent family in the *ThermoStem Program,* patent applications have been filed in four foreign jurisdictions (of which four applications have been granted as foreign patents). The patents expire in April 2034. With regard to the third patent family in the *ThermoStem Program*, patent applications have been filed in four foreign jurisdictions (of which four applications have been granted as foreign patents). The patents expire in April 2040.

In March 2014, we entered into a Research and Development Agreement with Rohto Pharmaceutical Co., Ltd., a Japanese pharmaceutical company ("Rohto"). Pursuant to the Research and Development Agreement with Rohto, we were engaged to provide research and development services with regard to stem cells. The agreement with Rohto expired upon the completion of the services provided for therein.

We have secured registrations in the U.S. Patent and Trademark Office for the following trademarks:

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- BRTX-100
- THERMOSTEM
- BRTX

The *Dragonfly Logo* is also registered with the U.S. Copyright Office.

We also have federal common law rights in the trademark *BioRestorative Therapies* and other trademarks and trade names used in the conduct of our business that are not registered.

Our success will depend in large part on our ability to develop and protect our proprietary technology. We intend to rely on a combination of patent, trade secret and know-how, copyright and trademark laws, as well as confidentiality agreements, licensing agreements, non-compete agreements and other agreements, to establish and protect our proprietary rights. Our success will also depend upon our ability to avoid infringing upon the proprietary rights of others, for if we are judicially determined to have infringed such rights, we may be required to pay damages, alter our services, products or processes, obtain licenses or cease certain activities.

During the years ended December 31, 2024 and 2023, we incurred $5,348,709 and $4,034,591, respectively, in research and development expenses.

Scientific Advisors

We have established a Scientific Advisory Board whose purpose is to provide advice and guidance in connection with scientific matters relating to our business. The Scientific Advisory Board has established a Disc Advisory Committee which focuses on matters relating to our *Disc/Spine Program*. Our Scientific Advisory Board members are Dr. Wayne Marasco (Chairman), Dr. Jason Lipetz, Dr. Wayne Olan, Dr. Joy Cavagnaro, Dr. Harvinder Sandhu and Dr. Christopher Plastaras. The Disc Advisory Committee members are Dr. Lipetz (Chairman), Dr. Olan, Dr. Sandhu and Dr. Plastaras. See "Management" for a listing of the principal positions for Drs. Marasco, Lipetz, Olan, Cavagnaro, Sandhu and Plastaras.

Competition

We will compete with many pharmaceutical, biotechnology and medical device companies, as well as other private and public stem cell companies involved in the development and commercialization of cell-based medical technologies and therapies.

Regenerative medicine is rapidly progressing, in large part through the development of cell-based therapies or devices designed to isolate cells from human tissues. Most efforts involve cell sources, such as bone marrow, adipose tissue, embryonic and fetal tissue, umbilical cord and peripheral blood and skeletal muscle.

Companies working in the area of regenerative medicine with regard to the disc and spine include, among others, Mesoblast, Fibrogenesis, DiscGenics and Isto Biologics. Companies that are developing products and therapies to combat obesity and diabetes include Novo Nordisk, Sanofi, Merck, Eli Lilly, Roche, Pfizer, Regeneron and Altimmune. The recent extensive use of both FDA-approved and compounded versions of glucagon-like peptide-1 (GLP-1) receptor agonist drug products, such as Wegovy and Ozempic (semaglutide), including the launch of FDA-approved oral Wegovy in January 2026, for the treatment of obesity has significantly increased the competition in the obesity market.

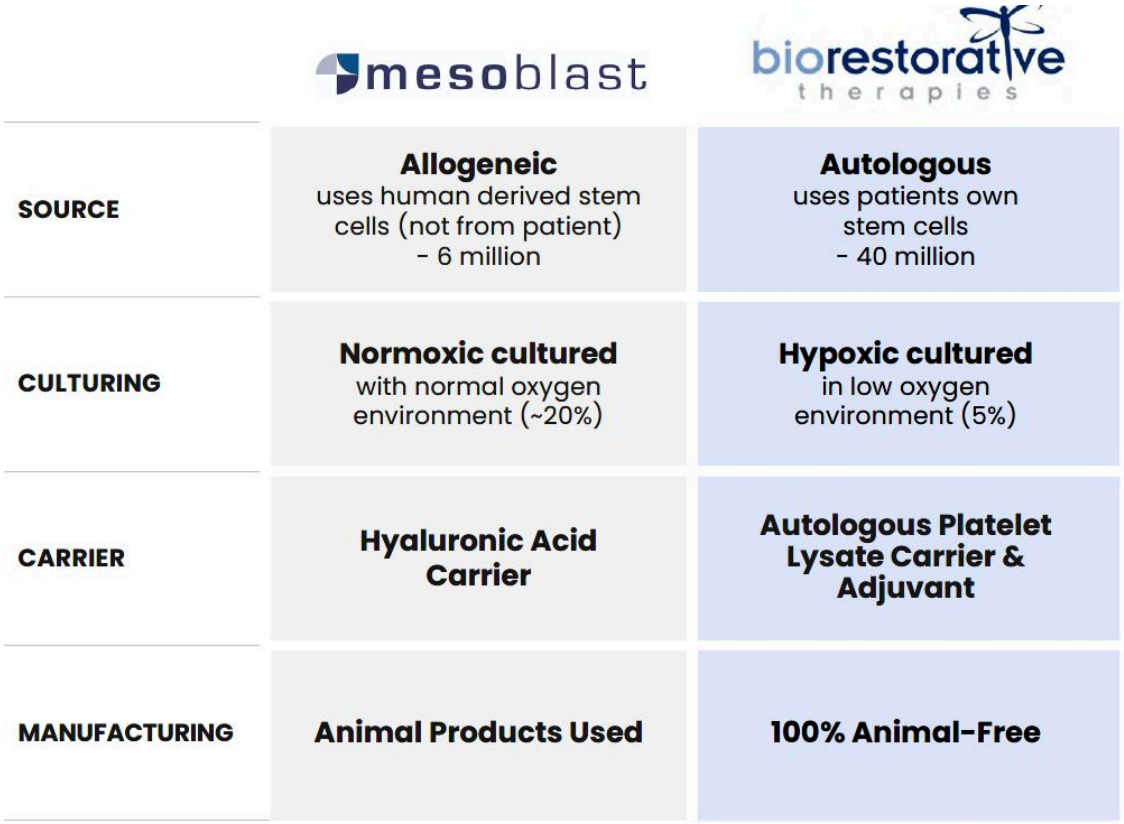
Many of our competitors and potential competitors have substantially greater financial, technological, research and development, marketing and personnel resources than we do. We cannot, with any accuracy, forecast when or if these companies are likely to bring their products and therapies to market in competition with those that we are pursuing.

The Biologics Price Competition and Innovation Act (the "BPCIA") sets forth an abbreviated pathway for the approval of biosimilar and interchangeable biological products that could be used by future competitors, if any, of our product candidates that are approved by the FDA as a biologic. For the FDA to approve a biosimilar product, it must find that there are no clinically meaningful differences between the reference product and the proposed biosimilar product. Interchangeability requires that a product is biosimilar to the reference product, and the product must be expected to produce the same clinical results as the reference product and, for products administered multiple times, the biologic 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. Under the BPCIA, an application for a biosimilar product cannot be submitted to the FDA until four years following approval of the reference product, and it may not be approved by the FDA until 12 years after the original branded product is approved under a BLA.

We believe that, if any of our product candidates are approved as a biological product under a BLA, it should qualify for the 12-year period of exclusivity. However, there is a risk that the FDA could permit biosimilar applicants to reference approved biologics other than our therapeutic candidates, thus circumventing our exclusivity and potentially creating the opportunity for competition sooner than anticipated. Additionally, this period of regulatory exclusivity does not apply to companies pursuing regulatory approval via their own traditional BLA, rather than via the abbreviated pathway. Moreover, it is possible that a biosimilar product could be approved as "interchangeable" with our product and therefore substitutable for our product by a healthcare professional under applicable state laws.

We may also face competition from unapproved stem cell therapies performed by treatment centers that do not comply with FDA requirements. Despite the FDA's successful enforcement against unapproved stem cell treatments in the federal courts (*United States v. Regenerative Sciences, LLC* (2014 D.C. Cir.), *United States v. U.S. Stem Cell Clinic LLC* (2021 11th Cir.) and *United States v. California Stem Cell Treatment Center, Inc.* (2024 9th Cir. *cert. denied*), thousands of clinics continue to offer unapproved stem cell therapies due to high demand, FDA enforcement limitations, and tactical rebranding to avoid FDA enforcement action. The FDA lacks the resources to bring enforcement actions against thousands of individual small-office clinics simultaneously. Therefore, we could face competition from stem cell clinics that would not be required to undergo the costly and time-consuming FDA approval and compliance process.

Set forth below is a comparison of *BRTX-100* to Mesoblast's adult stem cell biologic:



We believe that *BRTX-100* has competitive advantages to Mesoblast's product for the following reasons:

- The use of autologous cells results in low to no risk of rejection, greater safety profile (introduction of viral/genetic) and potentially a streamlined regulatory path
- Hypoxic culturing creates increased cell proliferation, greater plasticity, increased paracrine effect and increased cell survival after application
- Autologous platelet lysate provides growth factors that interact with the cells, allowing for better cell survival
- Low to no risk of safety concerns related to immunological and zoonotic (animal to human) transmission

Customers

Upon regulatory approval, our cell product candidates are intended to be marketed to physicians, other health care professionals, hospitals, research institutions, pharmaceutical companies and the military. It is anticipated that physicians who are trained and skilled in performing spinal injections will be the physicians most likely to treat discs with injections of *BRTX-100* upon regulatory approval. These physicians would include interventional physiatrists (physical medicine physicians), pain management anesthesiologists, interventional radiologists and neurosurgeons.

Governmental Regulation

U.S. Government Regulation

The health care industry is highly regulated in the United States. The federal government, through various departments and agencies, state and local governments, and private third-party accreditation organizations, regulate and monitor the health care industry, associated products, and operations. The FDA and comparable regulatory agencies in state and local jurisdictions and in foreign countries impose substantial requirements upon the clinical development, approval, manufacture, distribution and marketing of medical products, including drugs, biologics, and medical devices. These agencies and other federal, state and local entities regulate research and development activities and the testing, manufacture, quality control, safety, effectiveness, labeling, packaging, storage, distribution, record keeping, approval, post-approval monitoring, advertising, promotion, sampling and import and export of medical products. The following is a general overview of the laws and regulations pertaining to our business.

FDA Regulation of Stem Cell Treatment and Products

The FDA regulates the manufacture of human stem cell treatments and associated products under the authority of the Public Health Service Act ("PHSA") and the Federal Food, Drug, and Cosmetic Act (the "FDCA"). Stem cells can be regulated under the FDA's Human Cells, Tissues, and Cellular and Tissue-Based Products Regulations ("HCT/Ps") or may also be subject to the FDA's drug, biologic, or medical device regulations, each as discussed below.

Human Cells, Tissues, and Cellular and Tissue-Based Products Regulation

Under Section 361 of the PHSA, the FDA issued specific regulations governing the use of HCT/Ps in humans. Pursuant to Part 1271 of Title 21 of the Code of Federal Regulations ("CFR") (the "HCT/P Regulations"), the FDA established a unified registration and listing system for establishments that manufacture and process HCT/Ps. The regulations also include provisions pertaining to donor eligibility determinations; current good tissue practices covering all stages of production, including harvesting, processing, manufacture, storage, labeling, packaging, and distribution; and other procedures to prevent the introduction, transmission, and spread of communicable diseases.

The HCT/P Regulations define HCT/Ps as articles "containing or consisting of human cells or tissues that are intended for implantation, transplantation, infusion or transfer into a human recipient." The HCT/P Regulations strictly constrain the types of products that may be regulated solely as HCT/P. Factors considered include the degree of manipulation, whether the product is intended for a homologous function, whether the product has been combined with noncellular or non-tissue components, and the product's effect or dependence on the body's metabolic function. In those instances where cells, tissues, and cellular and tissue-based products have been only minimally manipulated, are intended strictly for homologous use, have not been combined with noncellular or nontissue substances, and do not depend on or have any effect on the body's metabolism, the manufacturer is only required to register with the FDA, submit a list of manufactured products, and adopt and implement procedures for the control of communicable diseases. If one or more of the above factors has been exceeded, the product would be regulated as a drug, biological product, or medical device rather than an HCT/P.

Because we are an enterprise in the early stages of operations and have not generated significant revenues from operations, it is difficult to anticipate the likely regulatory status of the array of products and services that we may offer. We believe that some of the adult autologous (self-derived) stem cells that will be used in our cellular therapy products and services, including the brown adipose (fat) tissue that we intend to use in our *ThermoStem Program*, may be regulated by the FDA as HCT/Ps under the HCT/P Regulations. However, the FDA may disagree with this position or conclude that some or all of our stem cell therapy products or services do not meet the applicable definitions and exemptions to the regulation. If we are not regulated solely under the HCT/P Regulations, we would need to expend significant resources to comply with the FDA's broad regulatory authority under the FDCA. Historically, the U.S. federal courts have upheld the FDA's authority to regulate stem cell products under the FDCA that do not comply with the FDA's interpretations of the HCT/P Regulations. In October 2025, the United States Supreme Court refused to hear an appeal of the FDA's enforcement victory in *United States v. California Stem Cell Treatment Center, Inc.*, leaving in place the federal appellate court decision upholding the FDA's regulation of stem cell treatments as biological products.

If regulated solely under the FDA's HCT/P statutory and regulatory provisions, once our laboratory in the United States becomes operational, it will need to satisfy the following requirements, among others, to process and store stem cells:

- registration and listing of HCT/Ps with the FDA;
- donor eligibility determinations, including donor screening and donor testing requirements;
- current good tissue practices, specifically including requirements for the facilities, environmental controls, equipment, supplies and reagents, recovery of HCT/Ps from the patient, processing, storage, labeling and document controls, and distribution and shipment of the HCT/Ps to the laboratory, storage, or other facility;
- tracking and traceability of HCT/Ps and equipment, supplies, and reagents used in the manufacture of HCT/Ps;
- adverse event reporting;
- FDA inspection; and
- abiding by any FDA order of retention, recall, destruction, and cessation of manufacturing of HCT/Ps.

Non-reproductive HCT/Ps and non-peripheral blood stem/progenitor cells that are offered for import into the United States and regulated solely under Section 361 of the PHSA must also satisfy the requirements under 21 C.F.R. § 1271.420. Section 1271.420 requires that the importer of record of HCT/Ps notify the FDA prior to, or at the time of, importation and provide sufficient information for the FDA to make an admissibility decision. In addition, the importer must hold the HCT/P intact and under conditions necessary to prevent transmission of communicable disease until an admissibility decision is made by the FDA.

If the FDA determines that we have failed to comply with applicable regulatory requirements, it can impose a variety of enforcement actions including public warning letters, fines, consent decrees, orders of retention, recall or destruction of product, orders to cease manufacturing, and criminal prosecution. If any of these events were to occur, it could materially adversely affect us.

To the extent that our cellular therapy activities are limited to developing products and services outside the United States, as described in detail below, the products and services would not be subject to FDA regulation, but will be subject to the applicable requirements of the foreign jurisdiction. We intend to comply with all applicable foreign governmental requirements.

Drug and Biological Product Regulation

An HCT/P product that does not meet the criteria for being solely regulated under Section 361 of the PHSA will be regulated as a drug, device or biological product under the FDCA and/or Section 351 of the PHSA, and applicable FDA regulations. The FDA has broad regulatory authority over drugs and biologics marketed for sale in the United States. The FDA regulates the research, clinical testing, manufacturing, safety, effectiveness, labeling, storage, recordkeeping, promotion, distribution, and production of drugs and biological products. The FDA also regulates the export of drugs and biological products manufactured in the United States to international markets in certain situations.

The process required by the FDA before a drug or biologic may be marketed in the United States generally involves the following:

- completion of non-clinical laboratory tests, animal studies and formulation studies conducted according to GLP or other applicable regulations;
- submission of an IND, which allows clinical trials to begin unless the FDA objects within 30 days;
- performance of adequate and well-controlled human clinical trials to establish the safety and efficacy of the proposed drug or biologic for its intended use or uses conducted in accordance with FDA regulations and GCP, which are international ethical and scientific quality standards meant to ensure that the rights, safety and well-being of trial participants are protected and that the integrity of the data is maintained;
- registration of clinical trials of FDA-regulated products and certain clinical trial information;
- preparation and submission to the FDA of an NDA, in the case of a drug or BLA in the case of a biologic;
- review of the product by an FDA advisory committee, where appropriate or if applicable;
- satisfactory completion of pre-approval inspection of manufacturing facilities and clinical trial sites at which the product, or components thereof, are produced to assess compliance with cGMP requirements and of selected clinical trial sites to assess compliance with GCP requirements; and
- FDA approval of an NDA or BLA which must occur before a drug or biologic can be marketed or sold.

Approval of an NDA requires a showing that the drug is safe and effective for its intended use and that the methods, facilities, and controls used for the manufacturing, processing, and packaging of the drug are adequate to preserve its identity, strength, quality, and purity. To obtain a BLA, a manufacturer must show that the proposed product is safe, pure, and potent and that the facility in which the product is manufactured, processed, packed, or held meets established quality control standards.

For purposes of an NDA or BLA approval by the FDA, human clinical trials are typically conducted in the following phases (which may overlap):

- Phase 1: The investigational product is initially given to healthy human subjects or patients and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion. These trials may also provide early evidence on effectiveness. During Phase 1 clinical trials, sufficient information about the investigational product's pharmacokinetics and pharmacologic effects may be obtained to permit the design of well-controlled and scientifically valid Phase 2 clinical trials.

- Phase 2: These clinical trials are conducted in a limited number of human subjects in the target population to identify possible adverse effects and safety risks, to determine the efficacy of the investigational product for specific targeted diseases and to determine dosage tolerance and dosage levels. Multiple Phase 2 clinical trials may be conducted by the sponsor to obtain information prior to beginning larger and more costly Phase 3 clinical trials.

- Phase 3: Phase 3 clinical trials are undertaken after Phase 2 clinical trials demonstrate that a dosage range of the investigational product appears effective and has a tolerable safety profile. The Phase 2 clinical trials must also provide sufficient information for the design of Phase 3 clinical trials. Phase 3 clinical trials are conducted to provide statistically significant evidence of clinical efficacy and to further test for safety risks in an expanded human subject population at multiple clinical trial sites. These clinical trials are intended to further evaluate dosage, effectiveness and safety, to establish the overall benefit-risk profile of the investigational product and to provide an adequate basis for product labeling and approval by the FDA. In most cases, the FDA requires two adequate and well-controlled Phase 3 clinical trials to demonstrate the efficacy of an investigational drug or biologic.

All clinical trials must be conducted in accordance with FDA regulations, GCP requirements and their protocols in order for the data to be considered reliable for regulatory purposes. Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and more frequently if serious adverse events occur. Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, or at all. These government regulations may delay or prevent approval of product candidates for a considerable period of time and impose costly procedures upon our business operations.

The FDA may require, or companies may pursue, additional clinical trials, referred to as Phase 4 clinical trials, after a product is approved. Such trials may be made a condition to be satisfied for continuing drug approval. The results of Phase 4 clinical trials can confirm the effectiveness of a product candidate and can provide important safety information. In addition, the FDA has authority to require sponsors to conduct post-marketing trials to specifically address safety issues identified by the agency.

Under the Pediatric Research Equity Act ("PREA"), certain NDAs and BLAs and certain supplements to an NDA or BLA must contain data to assess the safety and efficacy of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may grant deferrals for submission of pediatric data or full or partial waivers. A sponsor who is planning to submit a marketing application for a drug that includes a new active ingredient, new indication, new dosage form, new dosing regimen, or new route of administration submit an initial Pediatric Study Plan ("PSP") to the FDA within 60 days of an end-of-Phase 2 meeting or, if there is no such meeting, as early as practicable before the initiation of the Phase 3 or Phase 2/3 study. The initial PSP must include an outline of the pediatric study or studies that the sponsor plans to conduct, including study objectives and design, age groups, relevant endpoints and statistical approach, or a justification for not including such detailed information, and any request for a deferral of pediatric assessments or a full or partial waiver of the requirement to provide data from pediatric studies along with supporting information. The FDA and the sponsor must reach an agreement on the PSP. A sponsor can submit amendments to an agreed-upon initial PSP at any time if changes to the pediatric plan need to be considered based on data collected from preclinical studies, early phase clinical trials, and/or other clinical development programs.

Changes to some of the conditions established in an approved application, including changes in indications, labeling, manufacturing processes or facilities, require submission and FDA approval of a new NDA or BLA, or an NDA or BLA supplement, before the change can be implemented. An NDA or BLA supplement for a new indication typically requires clinical data similar to that in the original application, and the FDA uses the same procedures and actions in reviewing NDA and BLA supplements as it does in reviewing NDAs and BLAs.

Drug and biological products must also comply with applicable requirements, including monitoring and recordkeeping activities, manufacturing requirements, reporting to the applicable regulatory authorities of adverse experiences with the product, providing the regulatory authorities with updated safety and efficacy information, product sampling and distribution requirements, and complying with promotion and advertising requirements, which include, among others, standards for direct-to-consumer advertising, restrictions on promoting drugs for uses or in patient populations that are not described in the drug's approved labeling, or off-label use, limitations on industry-sponsored scientific and educational activities and requirements for promotional activities involving the internet. Although physicians may, in their independent professional medical judgment, prescribe legally available drugs for off-label uses, manufacturers typically may not market or promote such off-label uses.

We have determined that, under the FDA's current interpretation of the applicable law, our *BRTX-100* product candidate will be regulated as a biological product under the PHSA. Therefore, we will need to expend significant resources to ensure regulatory compliance. There is no assurance as to whether or when we will receive FDA approval of the *BRTX-100* product candidate. The process of designing, conducting, compiling and submitting the non-clinical and clinical studies required for BLA approval is time-consuming, expensive and unpredictable. The process can take many years, depending on the product and the FDA's requirements.

In addition, even if a product candidate receives regulatory approval, the approval may be limited to specific disease states, patient populations and dosages, or might contain significant limitations on use in the form of warnings, precautions or contraindications, or in the form of onerous risk management plans, restrictions on distribution or use, or post-marketing trial requirements. Further, even after regulatory approval is obtained, later discovery of previously unknown problems with a product may result in restrictions on the product, including safety labeling or imposition of a Risk Evaluation and Mitigation Strategy, the requirement to conduct post-market studies or clinical trials or even complete withdrawal of the product from the market. Delay in obtaining, or failure to obtain, regulatory approval for our products, or obtaining approval but for significantly limited use, would harm our business. Further, we cannot predict what adverse governmental regulations may arise from future United States or foreign governmental action.

If the FDA determines that we have failed to comply with applicable regulatory requirements, it can impose a variety of enforcement actions from public warning letters, fines, injunctions, consent decrees and civil penalties to suspension or delayed issuance of approvals, seizure of our products, total or partial shutdown of our production, withdrawal of approvals, and criminal prosecutions. If any of these events were to occur, it could materially adversely affect us.

FDA Expedited Review Programs

The FDA is authorized to expedite the review of NDAs and BLAs in several ways. Under the Fast Track program, the sponsor of a drug or biologic product candidate may request the FDA to designate the product for a specific indication as a Fast Track product concurrent with or after the filing of the IND. Drug and biologic products are eligible for Fast Track designation if they are intended to treat a serious or life-threatening condition and demonstrate the potential to address unmet medical needs for the condition. Fast Track designation applies to the combination of the product candidate and the specific indication for which it is being studied.

In addition to other benefits, such as the ability to have greater interactions with the FDA, the FDA may initiate review of sections of a Fast Track NDA or BLA before the application is complete, a process known as rolling review.

Any product submitted to the FDA for marketing, including under a Fast Track program, may also be eligible for the following other types of FDA programs intended to expedite development and review:

- Breakthrough therapy designation. To qualify for the breakthrough therapy program, product candidates must be intended to treat a serious or life-threatening disease or condition, and preliminary clinical evidence must indicate that such product candidates may demonstrate substantial improvement on one or more clinically significant endpoints over existing therapies. The FDA will seek to ensure the sponsor of a breakthrough therapy product candidate receives intensive guidance on an efficient drug development program, intensive involvement of senior managers and experienced staff on a proactive, collaborative and cross-disciplinary review, and rolling review.

- Priority review. A product candidate is eligible for priority review if it treats a serious condition and, if approved, it would be a significant improvement in the safety or effectiveness of the treatment, diagnosis or prevention of a serious condition compared to marketed products. The FDA aims to complete its review of priority review applications within six months as opposed to ten months for standard review.

- Accelerated approval. Drug or biologic products studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may receive accelerated approval. Accelerated approval means that a product candidate may be approved on the basis of adequate and well-controlled clinical trials establishing that the product candidate has an effect on a surrogate endpoint that is reasonably likely to predict a clinical benefit, or on the basis of an effect on a clinical endpoint other than survival or irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity and prevalence of the condition and the availability or lack of alternative treatments. As a condition of approval, the FDA may require that a sponsor of a drug or biologic product candidate receiving accelerated approval perform adequate and well-controlled post-marketing clinical trials. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials. As a result of the FDA's controversial use of the accelerated approval pathway for an Alzheimer's drug (aducanumab), Congress revised the accelerated approval process as a part of the Food and Drug Omnibus Reform Act of 2022 to provide the FDA with additional authorities to enforce the post-approval study requirements and to withdraw approvals when those requirements are not met.

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

Further, the FDA is authorized to accelerate review and approval of products designated as regenerative advanced therapies. A product is eligible for this designation if it is a regenerative medicine advanced therapy ("RMAT") (which may include a cell therapy) that is intended to treat, modify, reverse or cure a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug has the potential to address unmet medical needs for such disease or condition. The benefits of a RMAT designation include early interactions with the FDA to expedite development and review, benefits available to breakthrough therapies, potential eligibility for priority review and accelerated approval based on surrogate or intermediate endpoints.

Medical Device Regulation

The FDA also has broad authority over the regulation of medical devices marketed for sale in the United States. The FDA regulates the research, clinical testing, manufacturing, safety, labeling, storage, recordkeeping, premarket clearance or approval, promotion, distribution, and production of medical devices. The FDA also regulates the export of medical devices manufactured in the United States to international markets.

Under the FDCA, medical devices are classified into one of three classes, Class I, Class II, or Class III, depending upon the degree of risk associated with the medical device and the extent of control needed to ensure safety and effectiveness. Class I devices are subject to the lowest degree of regulatory scrutiny because they are considered low risk devices and need only comply with the FDA's General Controls. The General Controls include compliance with the registration, listing, adverse event reporting requirements, and applicable portions of the Quality System Regulation as well as the general misbranding and adulteration prohibitions.

Class II devices are subject to the General Controls as well as certain Special Controls such as 510(k) premarket notification. Class III devices are subject to the highest degree of regulatory scrutiny and typically include life supporting and life sustaining devices and implants. They are subject to the General Controls and Special Controls that include a premarket approval application ("PMA"). "New" devices are automatically regulated as Class III devices unless they are shown to be low risk, in which case they may be subject to de novo review to be moved to Class I or Class II. Clinical research of an investigational device is subject to the FDA's Investigational Device Exemption ("IDE") regulations. Nonsignificant risk devices are subject to abbreviated requirements that do not require a submission to the FDA but must have Institutional Review Board (IRB) approval and comply with other requirements pertaining to informed consent, labeling, recordkeeping, reporting, and monitoring. Significant risk devices require the submission of an IDE application to the FDA and the FDA's approval of the IDE application.

The FDA premarket clearance and approval process can be lengthy, expensive and uncertain. It generally takes three to twelve months from submission to obtain 510(k) premarket clearance, although it may take longer. Approval of a PMA could take one to four years, or more, from the time the application is submitted and there is no guarantee of ultimate clearance or approval. Securing FDA clearances and approvals may require the submission of extensive clinical data and supporting information to the FDA. Additionally, the FDA actively enforces regulations prohibiting marketing and promotion of devices for indications or uses that have not been cleared or approved by the FDA. In addition, modifications or enhancements of products that could affect the safety or effectiveness or effect a major change in the intended use of a device that was either cleared through the 510(k) process or approved through the PMA process may require further FDA review through new 510(k) or PMA submissions.

In the event we develop processes, products or services which qualify as medical devices subject to FDA regulation, we intend to comply with such regulations. If the FDA determines that our products are regulated as medical devices and we have failed to comply with applicable regulatory requirements, it can impose a variety of enforcement actions from public warning letters, application integrity proceedings, fines, injunctions, consent decrees and civil penalties to suspension or delayed issuance of approvals, seizure of our products, total or partial shutdown of our production, withdrawal of approvals, and criminal prosecutions. If any of these events were to occur, it could materially adversely affect us.

Current Good Manufacturing Practices and other FDA Regulations of Cellular Therapy Products

Products that fall outside of the HCT/P regulations and are regulated as drugs, biological products, or devices must comply with applicable cGMP regulations. These cGMPs and related quality standards are designed to ensure the products that are processed at a facility meet the FDA's applicable requirements for identity, strength, quality, sterility, purity, and safety. In the event that our domestic United States operations are subject to the FDA's drug, biological product, or device regulations, we intend to comply with the applicable cGMPs and quality regulations.

If the FDA determines that we have failed to comply with applicable regulatory requirements, it can impose a variety of enforcement actions from public warning letters, fines, injunctions, consent decrees and civil penalties to suspension or delayed issuance of approvals, seizure of our products, total or partial shutdown of our production, withdrawal of approvals, and criminal prosecutions. If any of these events were to occur, it could materially adversely affect us.

Promotion of Foreign-Based Cellular Therapy Treatment— "Medical Tourism"

We may establish, or license technology to third parties in connection with their establishment of, adult stem cell therapy facilities outside the United States. We also intend to work with hospitals and physicians to make the stem cell-based therapies available for patients who travel outside the United States for treatment. "Medical tourism" is defined as the practice of traveling across international borders to obtain health care.

The Federal Trade Commission (the "FTC") has the authority to regulate and police advertising of medical treatments, procedures, and regimens in the United States under the Federal Trade Commission Act (the "FTCA"). The FTC has regulatory authority to prevent unfair and deceptive practices and false advertising. Specifically, the FTC requires advertisers and promoters to have a reasonable basis to substantiate and support claims. The FTC has many enforcement powers, one of which is the power to order disgorgement by promoters deemed in violation of the FTCA of any profits made from the promoted business and can order injunctions from further violative promotion. Advertising that we may utilize in connection with our medical tourism operations will be subject to FTC regulatory authority, and we intend to comply with such regulatory régime. Similar laws and requirements are likely to exist in other countries and we intend to comply with such requirements.

Federal Regulation of Clinical Laboratories

The federal Clinical Laboratory Improvement Amendments ("CLIA") provides the Centers for Medicare and Medicaid Services ("CMS") authority over all laboratory testing, except research, that is performed on humans in the United States. The Division of Laboratory Services, within the Survey and Certification Group, under the Center for Medicaid and State Operations ("CMSO"), has the responsibility for implementing the CLIA program.

The CLIA program is designed to establish quality laboratory testing by ensuring the accuracy, reliability, and timeliness of patient test results. Under CLIA, a laboratory is a facility that does laboratory testing on specimens derived from humans and used to provide information for the diagnosis, prevention, treatment of disease, or impairment of, or assessment of health. Laboratories that handle stem cells and other biologic matter are, therefore, included under the CLIA program. Under the CLIA program, laboratories must be certified by the government, satisfy governmental quality and personnel standards, undergo proficiency testing, be subject to inspections, and pay fees. To the extent that our business activities require CLIA certification, we intend to obtain and maintain such certification. If we are subject to CLIA, the failure to comply with CLIA standards could result in suspension, revocation, or limitation of a laboratory's CLIA certificate. In addition, fines or criminal penalties could also be levied. If any of these events were to occur, it could impact our business operations.

Health Insurance Portability and Accountability Act—Protection of Patient Health Information

We may be subject to data privacy and security regulation by both the federal government and the states in which we conduct our business. The Health Insurance Portability Act of 1996 ("HIPAA") as amended by the Health Information Technology for Economic and Clinical Health Act ("HITECH"), and their respective implementing regulations imposes specified requirements relating to the privacy, security and transmission of individually identifiable health information on certain types of individuals and organizations. In addition, certain state laws govern the privacy and security of health information in certain circumstances, many of which differ from each other and from HIPAA in significant ways and may not have the same effect, thus complicating compliance efforts. Further, we may need to also comply with additional federal or state privacy laws and regulations that may apply to certain diagnoses, such as HIV/AIDS, to the extent that they apply to us.

The Department of Health and Human Services ("HHS"), through its Office for Civil Rights, investigates breach reports and determines whether administrative or technical modifications are required and whether civil or criminal sanctions should be imposed. Companies failing to comply with HIPAA and the implementing regulations may also be subject to civil money penalties or in the case of knowing violations, potential criminal penalties, including monetary fines, imprisonment, or both. In some cases, the State Attorneys General may seek enforcement and appropriate sanctions in federal court.

Other Applicable U.S. Laws

In addition to the above-described regulation by United States federal and state government, the following are other federal and state laws and regulations that could directly or indirectly affect our ability to operate the business:

- state and local licensure, registration, and regulation of the development of pharmaceuticals and biologics;
- state and local licensure of medical professionals;
- state statutes and regulations related to the corporate practice of medicine;
- laws and regulations administered by U.S. Customs and Border Protection related to the importation of biological material into the United States;
- other laws and regulations administered by the FDA;
- other laws and regulations administered by HHS;
- state and local laws and regulations governing human subject research and clinical trials;
- the federal physician self-referral prohibition, also known as Stark Law, and any state equivalents to Stark Law;
- the federal False Claims Act ("FCA");
- the federal Anti-Kickback Statute ("AKS") and any state equivalent statutes and regulations;
- federal and state coverage and reimbursement laws and regulations;
- state and local laws and regulations for the disposal and handling of medical waste and biohazardous material;
- Occupational Safety and Health Administration ("OSHA") regulations and requirements;
- the Intermediate Sanctions rules of the IRS providing for potential financial sanctions with respect to "excess benefit transactions" with tax-exempt organizations;

- the Physician Payments Sunshine Act (in the event that our products are classified as drugs, biologics, devices or medical supplies and are reimbursed by Medicare, Medicaid or the Children's Health Insurance Program);

- state and other federal laws addressing the privacy of health information; and

- state and foreign law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payer, including commercial insurers, state 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 healthcare professionals and other potential referral sources, state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare professionals or marketing expenditures, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

Violation of any of the laws described above or any other governmental laws and regulations may result in penalties, including civil and criminal penalties, damages, fines, the curtailment or restructuring of operations, the exclusion from participation in federal and state healthcare programs and imprisonment. Furthermore, efforts to ensure that business activities and business arrangements comply with applicable healthcare laws and regulations can be costly for manufacturers of branded prescription products.

Foreign Government Regulation

In general, we will need to comply with the government regulations of each individual country in which our therapy centers are located and products are to be distributed and sold. These regulations vary in complexity and can be as stringent, and on occasion even more stringent, than FDA regulations in the United States. Due to the fact that there are new and emerging cell therapy regulations that have recently been drafted and/or implemented in various countries around the world, the application and subsequent implementation of these new and emerging regulations have little to no precedence. Therefore, the level of complexity and stringency is not always precisely understood for each country, creating greater uncertainty for the international regulatory process. Furthermore, government regulations can change with little to no notice and may result in up-regulation of our product(s), thereby creating a greater regulatory burden for our cell processing technology products. We have not yet thoroughly explored the applicable laws and regulations that we will need to comply with in foreign jurisdictions. It is possible that we may not be permitted to expand our business into one or more foreign jurisdictions.

We do not have any definitive plans or arrangements with respect to the establishment by us of stem cell therapy clinics in any country. We intend to explore any such opportunities as they arise.

Offices

Our principal executive offices and laboratory are located at 40 Marcus Drive, Suite One, Melville, New York, and our telephone number is (631) 760-8100. We occupy 6,800 square feet of space at the premises pursuant to a lease that expired in December 2024. The lease provided for a current annual base rental of $173,060. We currently occupy the premises on a month-to-month basis at a monthly rental of $14,422 and are negotiating an extension of the term of the lease. Our premises are suitable and adequate for our current operations. Our website is www.biorestorative.com. Our internet website and the information contained therein or connected thereto are not intended to be incorporated by reference into this prospectus.

Employees

We currently have 14 employees, 13 of whom are full-time employees. We believe that our employee relations are good.

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis of the consolidated results of operations and financial condition of BioRestorative Therapies, Inc. as of December 31, 2024 and 2023 and for the years ended December 31, 2024 and 2023 and as of September 30, 2025 and for the nine months ended September 30, 2025 and 2024 should be read in conjunction with our financial statements and the notes to those financial statements that are included elsewhere in this prospectus. References in this "Management's Discussion and Analysis of Financial Condition and Results of Operations" to "us," "we," "our," and similar terms refer to BioRestorative Therapies, Inc. This prospectus contains forward-looking statements as that term is defined in the federal securities laws. The events described in forward-looking statements contained in this prospectus may not occur. Generally, these statements relate to business plans or strategies, projected or anticipated benefits or other consequences of our plans or strategies, projected or anticipated benefits from acquisitions that may be made by us, or projections involving anticipated revenues, earnings or other aspects of our operating results. The words "may," "will," "expect," "believe," "anticipate," "project," "plan," "intend," "estimate," and "continue," and their opposites and similar expressions, are intended to identify forward-looking statements. We caution you that these statements are not guarantees of future performance or events and are subject to a number of uncertainties, risks and other influences, many of which are beyond our control, which may influence the accuracy of the statements and the projections upon which the statements are based. Reference is made to "Risk Factors" for a discussion of some of the uncertainties, risks and assumptions associated with these statements.

These risks and factors include, by way of example and without limitation:

- our ability to obtain financing needed to complete our clinical trials and implement our business plan;
- our ability to successfully develop and commercialize BRTX-100, our lead product candidate for the treatment of chronic lumbar disc disease, as well as our metabolic ThermoStem Program and commercial biocosmeceuticals platform;
- our ability to protect our proprietary rights;
- our ability to achieve and sustain profitability of the existing lines of business;
- our ability to attract and retain world-class research and development talent;
- our ability to attract and retain key science, technology and management personnel and to expand our management team;
- the accuracy of estimates regarding expenses, future revenue, capital requirements, profitability, and needs for additional financing;
- business interruptions resulting from geo-political actions, including war and terrorism or disease outbreaks;
- our ability to attract and retain customers;

- our ability to navigate through the increasingly complex therapeutic regulatory environment;
- our ability to successfully engage in any new business lines that we pursue; and
- risks related to the restatement of our previously issued financial statements.

Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity or performance. Except as required by applicable law, including the securities laws of the United States, we do not intend to update any of the forward-looking statements to conform these statements to actual results.

Readers are urged to carefully review and consider the various disclosures made by us in this prospectus and in our other reports filed with the SEC. We undertake no obligation to update or revise forward-looking statements to reflect changed assumptions, the occurrence of unanticipated events or changes in the future operating results over time, except as required by law. We believe that our assumptions are based upon reasonable data derived from and known about our business and operations. No assurances are made that actual results of operations or the results of our future activities will not differ materially from our assumptions.

Overview

We develop therapeutic products and medical therapies using cell and tissue protocols, primarily involving adult stem cells.

We are currently pursuing our *Disc/Spine Program* with our initial investigational therapeutic product being called *BRTX-100*. In March 2022, a United States patent issued in our *Disc/Spine Program* Phase 2 clinical trial investigating the use of *BRTX-100* in the treatment of chronic lower back pain arising from degenerative disc disease. We have obtained an exclusive license to use technology for investigational adult stem cell treatment of disc and spine conditions, including protruding and bulging lumbar discs. The technology is an advanced stem cell injection procedure that may offer relief from lower back pain, buttock and leg pain, and numbness and tingling in the leg and foot. We are investigating the expansion of the clinic application of *BRTX-100* to other indications within the body.

We are also developing our *ThermoStem Program*. This pre-clinical program involves the use of brown adipose (fat) in connection with the cell-based treatment of type 2 diabetes and obesity as well as hypertension, other metabolic disorders and cardiac deficiencies. United States patents related to the *ThermoStem Program* were issued in September 2015, January 2019, March 2020, March 2021, July 2021, June 2023 and December 2023; Australian patents related to the *ThermoStem Program* were issued in April 2017, October 2019 and August 2021; Japanese patents related to the *ThermoStem Program* were issued in December 2017, June 2021, February 2022 June 2023, July 2024 and September 2025; Israeli patents related to our *ThermoStem Program* were issued in October 2019, May 2020, March 2022 and March 2025; and European patents related to the *ThermoStem Program* were issued in April 2020, January 2021, July 2023 and March 2025.

We operate a commercial biocosmeceutical platform. Our current commercial product, formulated and manufactured using our cGMP ISO-7 certified clean room, is a cell-based secretome containing exosomes, proteins and growth factors. This proprietary biologic serum has been specifically engineered by us to reduce the appearance of fine lines and wrinkles and bring forth other areas of cosmetic effectiveness. Moving forward, we also intend to explore the potential of expanding our commercial offering to include a broader family of cell-based biologic aesthetic products and therapeutics via IND-enabling studies, with the aim of pioneering FDA approvals in the emerging biocosmeceuticals space.

We have also licensed a patented curved needle device that is a needle system designed to deliver cells and/or other therapeutic products or materials to the spine and discs or other potential sites. We anticipate that FDA approval or clearance will be necessary for this device prior to commercialization. We do not intend to utilize this device in connection with our Phase 2 clinical trial with regard to *BRTX-100*.

Our offices are located in Melville, New York where we have established a laboratory facility in order to increase our capabilities for the further development of possible cellular-based treatments, products and protocols, stem cell-related intellectual property and translational research applications.

As of September 30, 2025, our accumulated deficit was $166,713,054. We have historically only generated a modest amount of revenue, and our losses have principally been operating expenses incurred in research and development, marketing and promotional activities in order to commercialize our products and services, plus costs associated with meeting the requirements of being a public company. We expect to continue to incur substantial costs for these activities over at least the next year.

In November 2024, we entered into an At The Market Offering Agreement with Rodman under which we currently have the ability to issue and sell shares of our common stock, from time to time, through Rodman, up to an aggregate offering price of approximately $3,614,000 in an at-the-market ("ATM") program. During the nine months ended September 30, 2025, we sold 965,424 shares of our common stock under the ATM program with Rodman at a weighted-average gross price of approximately $2.08 per share and raised approximately $2,011,000 of gross proceeds. The total commissions and related legal and accounting fees were approximately $222,000 and we received net proceeds of approximately $1,789,000. We did not sell any shares of our common stock under the ATM program during the year ended December 31, 2024. As of January 31, 2026, we had remaining capacity to sell up to an additional $1,017,040 of common stock under the ATM program with Rodman.

In October 2025, we sold 678,125 shares of our common stock in a registered direct offering. We received net proceeds of approximately $900,000 from the offering.

For the year ended December 31, 2024 and nine months ended September 30, 2025, we had a net loss of $9.0 million and $11.0 million, respectively, and negative cash flows from operations of $8.2 million and $8.4 million, respectively, and, as of September 30, 2025, we had working capital of $1.3 million. We anticipate that we will continue to incur net losses and negative cash flows from operations as we execute our development plans for 2026 and beyond, as well as other potential strategic and business development initiatives. These conditions raise substantial doubt about our ability to continue as a going concern for at least twelve months after the issuance date of the financial statements included in this prospectus. We will require significant additional funding to complete our clinical trials using *BRTX-100.* We will require a substantial amount of additional funding to implement our other programs as discussed in this prospectus under "Business", including our metabolic *ThermoStem Program*, and fund general operations. No assurance can be given that the amount of funding that we anticipate may be required for such purposes is correct or that we will be able to accomplish our goals within the timeframes projected. In addition, no assurance can be given that we will be able to obtain any required financing on commercially reasonable terms or otherwise.

We derive revenue pursuant to a license agreement with a stem cell treatment company (the "SCTC") entered into in January 2012, as amended in November 2015 and November 2022. Pursuant to the license agreement, the SCTC has granted to us an exclusive license to use certain intellectual property related to, among other things, stem cell disc procedures and we have granted to the SCTC a sublicense to use, and the right to sublicense to third parties the right to use, in certain locations in the United States and the Cayman Islands, certain of the licensed intellectual property. In consideration of the sublicense, the SCTC has agreed to pay us royalties on a per disc procedure basis.

We also derive product revenue from our biocosmeceuticals commercial product.

On June 16, 2025, our Board of Directors authorized a common stock repurchase program under which we may repurchase up to $2,000,000 of our outstanding common stock through June 16, 2026. No repurchases have been made to date.

Consolidated Results of Operations

Nine Months Ended September 30, 2025 Compared With Nine Months Ended September 30, 2024

The following table presents selected items in our consolidated statements of operations for the nine months ended September 30, 2025 and 2024, respectively:

	For the Nine Months Ended September 30,	
	2025	**2024**
Revenues	$ 340,100	$ 357,700
Cost of goods sold	22,208	24,733
Gross profit	317,892	332,967
Operating Expenses:		
Research and development	7,467,532	5,004,794
General and administrative	4,672,192	4,193,225
Total Operating Expenses	12,139,724	9,198,019
Loss From Operations	(11,821,832)	(8,865,052)
Other (Expense) Income:		
Interest income	231,621	497,089
Other income	3,336	150,498
Gain on exchange of warrants	-	1,711,698
Change in fair value of warrant liabilities	552,536	(837,466)
Total Other Income	787,493	1,521,819
Net Loss	$ (11,034,339)	$ (7,343,233)

Revenues

For the nine months ended September 30, 2025 and 2024, we generated $40,100 and $57,700, respectively, of royalty revenue in connection with our sublicense agreement with the SCTC. The decrease was primarily due to a decrease in disc procedures.

For the nine months ended September 30, 2025 and 2024, we generated $300,000 in each period of cosmetic product sales revenue in connection with our exclusive supply agreement with Cartessa.

Research and Development

Research and development expenses include cash and non-cash compensation of (a) our Vice President of Research and Development; (b) our Scientific Advisory Board members; and (c) laboratory staff and costs related to our brown fat and disc/spine initiatives and biocosmeceuticals program. Research and development expenses are expensed as they are incurred. For the nine months ended September 30, 2025, research and development expenses increased by $2,462,738, or 49.2%, as compared to the nine months ended September 30, 2024. The increase was primarily the result of an increase in recruitment and other costs for our Phase 2 clinical trial of $2,010,122, an increase in lab supply expense of $438,183, and an increase in headcount costs of $19,290, partially offset by a decrease in bonus expense of $86,372 and a decrease in stock-based compensation expense of $5,976. We expect that our research and development expenses will continue to increase in subsequent fiscal periods.

General and Administrative

General and administrative expenses consist primarily of salaries, bonuses, payroll taxes and stock-based compensation to employees, as well as corporate expenses such as legal and professional fees, investor relations and occupancy-related expenses. For the nine months ended September 30, 2025, general and administrative expenses increased by $478,967, or 11.4%, as compared to the nine months ended September 30, 2024, primarily driven by an increase in stock-based compensation expense of $246,803 related to the vesting of awards, an increase in consulting expense of $127,621, and an increase in payroll of $91,274, partially offset by a decrease in professional fees of $20,748.

Interest Income

For the nine months ended September 30, 2025, interest income was $231,621, as compared to interest income of $497,089 for the nine months ended September 30, 2024. The change was primarily due to a decrease in interest income from the investments held in marketable securities due to a lower average balance of the marketable securities during the 2025 period as compared to the 2024 period.

Other Income

For the nine months ended September 30, 2025, other income was $3,336, as compared to other income of $150,498 for the nine months ended September 30, 2024. The change was primarily due to a one-time payment received in the 2024 period in connection with the development of our biocosmeceuticals product line.

Gain on Exchange of Warrants

For the nine months ended September 30, 2024, we recognized a gain on exchange of $1,711,698 related to the issuance of warrants and common stock in exchange for the cancellation of existing warrants. There was no gain on exchange of warrants for the nine months ended September 30, 2025.

Change in Fair Value of Warrant Liabilities

For the nine months ended September 30, 2025, we recognized a gain on the change in fair value of warrant liabilities of $552,536 related to the decrease in fair value of warrants that are accounted for as warrant liabilities. For the nine months ended September 30, 2024, we recognized a loss on the change in fair value of warrant liabilities of $837,466 related to the increase in fair value of warrants that are accounted for as warrant liabilities.

Year Ended December 31, 2024 Compared with Year Ended December 31, 2023

The following table presents selected items in our consolidated statements of operations for the years ended December 31, 2024 and 2023, respectively:

	For the Years Ended December 31,	
	2024	**2023**
Revenues	$ 401,000	$ 145,800
Cost of goods sold	28,072	-
Gross profit	372,928	145,800
Operating Expenses:		
Research and development	5,348,709	4,034,591
General and administrative	6,579,413	11,331,983
Total Operating Expenses	11,928,122	15,366,574
Loss From Operations	(11,555,194)	(15,220,774)
Other Income:		
Interest income	616,077	552,293
Grant income	-	83,333
Other income	150,850	169,664
Gain on exchange of warrants	1,711,698	-
Change in fair value of warrant liabilities	97,188	3,997,780
Total Other Income	2,575,813	4,803,070
Net Loss	$ (8,979,381)	$ (10,417,404)

Revenues

For the years ended December 31, 2024 and 2023, we generated $401,000 and $145,800, respectively, of royalty revenue in connection with our sublicense agreement and sales revenue in connection with our cosmeceuticals business.

Research and development

Research and development expenses include cash and non-cash compensation of (a) our Vice President of Research and Development; (b) our Scientific Advisory Board members; and (c) laboratory staff and costs related to our brown fat and disc/spine initiatives. Research and development expenses are expensed as they are incurred. For the year ended December 31, 2024, research and development expenses increased by $1,314,118, or 33%, to $5,348,709 compared to $4,034,591 for the year ended December 31, 2023. The increase was primarily driven by headcount costs of $323,025 and general lab supplies expense of $1,041,952, partially offset by the reversal of a 2023 bonus accrual of $257,873.

We expect that our research and development expenses will continue to increase with the continuation of the aforementioned initiatives.

General and administrative

General and administrative expenses consist primarily of salaries, bonuses, payroll taxes and stock-based compensation to employees (excluding any cash or non-cash compensation of our Vice President of Research and Development and our laboratory staff), as well as corporate expenses such as legal and professional fees, investor relations and occupancy related expenses. For the year ended December 31, 2024, general and administrative expenses decreased by $4,752,570, or 42% to $6,579,413 from $11,331,983 for the year ended December 31, 2023. The decrease was primarily driven by a decrease in stock-based compensation expense of $4,970,401 and a decrease in headcount costs of $111,363, offset by an increase in professional fees of $229,273.

We expect that our general and administrative expenses related to operations will increase as we expand our staff, develop our infrastructure and incur additional costs to support the growth of our business.

Interest income

For the year ended December 31, 2024, interest income increased $63,784, or 12%, to $616,077 from $552,293 for the year ended December 31, 2023. The increase was due to the interest and dividend income of the investments held in marketable securities.

Grant income

There was no grant income for the year ended December 31, 2024. Grant income of $83,333 during the year ended December 31, 2023 consisted of funding received under a National Institutes of Health Small Business Technology Transfer (STTR) Phase 1 grant, offset by related expenses.

Other income

For the year ended December 31, 2024, other income of $150,850 primarily related to investment dividend income and other miscellaneous income. For the year ended December 31, 2023, other income of $169,664 primarily related to an Employee Retention Tax Credit, gains from settlements of certain accrued expenses and realized and unrealized gain on investments.

Gain on Exchange of Warrants

For the year ended December 31, 2024, we recognized a gain on exchange of $1,711,698 related to the issuance of warrants and common stock in exchange for the cancellation of existing warrants.

Change in fair value of derivative liabilities

For the year ended December 31, 2024, we recognized a gain on the change in fair value of warrant liabilities of $97,188 related to the reduction in the fair value of the warrants that are accounted for as warrant liabilities. For the year ended December 31, 2023, we recognized a gain on the change in fair value of warrant liabilities of $3,997,780 related to the reduction in the fair value of the warrants that are accounted for as warrant liabilities.

Liquidity and Capital Resources

Liquidity

We measure our liquidity in a number of ways, including the following:

	September 30, 2025	December 31, 2024	December 31, 2023
Cash and cash equivalents	$ 602,444	$ 547,890	$ 884,377
Investments held in marketable securities	$ 3,887,383	$ 10,184,701	$ 10,181,618
Working capital	$ 1,271,781	$ 7,395,815	$ 8,783,181

Availability of Additional Funds

For the nine months ended September 30, 2025, we had a net loss of $11.0 million and negative cash flows from operations of $8.4 million, and, as of September 30, 2025, we had working capital of $1.3 million. For the year ended December 31, 2024, we had a net loss of $9.0 million and negative cash flows from operations of $8.2 million and, as of December 31, 2024, we had working capital of $7.4 million. We anticipate that we will continue to incur net losses and negative cash flows from operations as we execute our development plans for 2026 and beyond, as well as other potential strategic and business development initiatives. Based on these conditions, we believe we may not have sufficient cash for at least twelve months after the issuance date of the financial statements included in this prospectus which raises substantial doubt about our ability to continue as a going concern.

Our operating needs include the planned costs to operate our business, including amounts required to fund our clinical trials, working capital and capital expenditures. Our future capital requirements and the adequacy of our available funds will depend on many factors, including our ability to successfully commercialize our products and services, competing technological and market developments, and the need to enter into collaborations with other companies or acquire other companies or technologies to enhance or complement our product and service offerings.

We may be unable to raise sufficient additional capital when we need it or raise capital on favorable terms. Future financing may require us to pledge certain assets and enter into covenants that could restrict certain business activities or our ability to incur further indebtedness and may contain other terms that are not favorable to our stockholders or us. If we are unable to obtain adequate funds on reasonable terms, we may be required to significantly curtail or discontinue operations or obtain funds by entering into financing agreements on unattractive terms.

"At-the-Market" Offering

In November 2024, we entered into an At The Market Offering Agreement with Rodman, under which we currently have the ability to issue and sell shares of our common stock, from time to time, through Rodman, up to an aggregate offering price of approximately $3,614,000 in an ATM, program. During the nine months ended September 30, 2025, we sold 965,424 shares of our common stock under the ATM program with Rodman at a weighted-average gross price of approximately $2.08 per share and raised approximately $2,011,000 of gross proceeds. The total commissions and related legal and accounting fees were approximately $222,000 and we received net proceeds of approximately $1,789,000. As of January 31, 2026, we had remaining capacity to sell up to an additional $1,017,040 of common stock under the ATM program with Rodman.

Warrant Exercises

In February 2024, we received gross proceeds of approximately $8,100,000 pursuant to the exercise of outstanding warrants.

Cash Flows

Nine Months Ended September 30, 2025 Compared With Nine Months Ended September 30, 2024

During the nine months ended September 30, 2025 and 2024, our sources and uses of cash were as follows:

	Nine Months Ended September 30,	
	2025	**2024**
Net Cash Used In Operating Activities	$ (8.373.790)	$ (5,882,501)
Net Cash Provided By (Used In) Investing Activities	$ 6,496,796	$ (1,018,078)
Net Cash Provided By Financing Activities	$ 1,931,548	$ 7,505,646
Net Increase in Cash	$ 54,554	$ 605,067

Net Cash Used in Operating Activities

Net cash used in operating activities was $8,373,790 for the nine months ended September 30, 2025, primarily due to cash used to fund the net loss of $11,034,339, adjusted for net non-cash expenses of $2,246,501, and $414,048 of cash provided by changes in operating assets and liabilities. Net cash used in operating activities was $5,882,501 for the nine months ended September 30, 2024, primarily due to cash used to fund the net loss of $7,343,233, adjusted for net non-cash expenses of $1,520,670, and $59,938 of cash used in changes in operating assets and liabilities.

Net Cash Provided by (Used in) Investing Activities

Net cash provided by investing activities was $6,496,796 for the nine months ended September 30, 2025 primarily due to a sale of marketable securities which provided $9,212,343 of cash, offset by a purchase of marketable securities which used $2,679,147 of cash and a purchase of equipment which used $36,400 of cash. Net cash used in investing activities was $1,018,078 for the nine months ended September 30, 2024 primarily due to a purchase of marketable securities which used $18,294,566 of cash and a purchase of equipment which used $93,755 of cash, offset by a sale of marketable securities which provided $17,370,243 of cash.

Net Cash Provided by Financing Activities

Net cash provided by financing activities was $1,931,548 for the nine months ended September 30, 2025 due to net proceeds of $1,938,445 received in connection with the issuance of common stock for the 2024 ATM offering and $42,411 due to the exercise of stock options, partially offset by deferred offering costs of $49,308, compared to $7,505,646 net cash provided by financing activities for the nine months ended September 30, 2024 due to net proceeds of $7,528,027 received in connection with the exercise and issuance of warrants, partially offset by deferred offering costs of $22,381.

Year Ended December 31, 2024 Compared with Year Ended December 31, 2023

During the years ended December 31, 2024 and 2023, our sources and uses of cash were as follows:

	Year Ended December 31,	
	2024	**2023**
Net Cash Used In Operating Activities	$ (8,230,346)	$ (6,430,211)
Net Cash Provided By Investing Activities	$ 514,529	$ 3,252,043
Net Cash Provided By Financing Activities	$ 7,379,330	$ 2,348,773
Net Decrease in Cash	$ (336,487)	$ (829,395)

Net Cash Used in Operating Activities

Net cash used in operating activities was $8,230,346 for the year ended December 31, 2024, primarily due to cash used to fund the net loss of $8,979,381 which gives effect to net non-cash expenses of $720,382, partially offset by $28,653 of cash provided by changes in operating assets and liabilities. Net cash used in operating activities was $6,430,211 for the year ended December 31, 2023, primarily due to cash used to fund the net loss of $10,417,704 which gives effect to net non-cash expenses of $3,472,167, partially offset by $515,326 of cash provided by changes in our operating assets and liabilities.

Net Cash Provided by Investing Activities

Net cash provided by investing activities decreased by $2,737,514 for the year ended December 31, 2024 compared to the year ended December 31, 2023, primarily due to the purchase of marketable securities.

Net Cash Provided by Financing Activities

Net cash provided by financing activities increased by $5,030,557 for the year ended December 31, 2024 compared to the year ended December 31, 2023 due to the gross proceeds from the exchange and issuance of warrants of $8,123,391, less issuance costs of $595,364, all partially offset by $2,348,773 of gross proceeds from the sale of common stock pursuant to an ATM and direct offering undertaken during the year ended December 31, 2023.

Effects of Inflation

We do not believe that inflation had a material impact on our business, revenues or operating results during the periods presented.

Critical Accounting Estimates

We prepare our consolidated financial statements in accordance with U.S. generally accepted accounting principles, or GAAP, which require our management to make estimates that affect the reported amounts of assets, liabilities and disclosures of contingent assets and liabilities at the balance sheet dates, as well as the reported amounts of revenues and expenses during the reporting periods. To the extent that there are material differences between these estimates and actual results, our financial condition or results of operations would be affected. We base our estimates on our own historical experience and other assumptions that we believe are reasonable after taking account of our circumstances and expectations for the future based on available information. We evaluate these estimates on an ongoing basis.

We consider an accounting estimate to be critical if: (i) the accounting estimate requires us to make assumptions about matters that were highly uncertain at the time the accounting estimate was made, and (ii) changes in the estimate that are reasonably likely to occur from period to period or the use of different estimates that we reasonably could have used in the current period would have a material impact on our financial condition or results of operations. There are items within our financial statements that require estimation but are not deemed critical, as defined above.

For a detailed discussion of our significant accounting policies and related judgments, see Note 2 of the Notes to Consolidated Financial Statements and Note 2 of the Notes to Unaudited Condensed Consolidated Financial Statements included in this prospectus.

Recently Issued Accounting Pronouncements

See Note 2 to our consolidated financial statements for the years ended December 31, 2024 and 2023 and Note 2 to our unaudited condensed consolidated financial statements for the three and nine months ended September 30, 2025 and 2024 included elsewhere in this prospectus.

Off-Balance Sheet Arrangements

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

MANAGEMENT

Directors and Executive Officers

Information regarding our directors and executive officers is set forth below. Each of our officers devotes his full business time in providing services on our behalf.

Name	Age	Positions Held
Lance Alstodt	55	Chief Executive Officer, President and Chairman of the Board
Francisco Silva	51	Vice President of Research and Development, Secretary and Director
Robert E. Kristal	59	Chief Financial Officer
Nickolay Kukekov, Ph.D.	52	Director, Compensation Committee Chair
Patrick F. Williams	53	Director, Audit Committee Chair
David Rosa	62	Director, Nominating Committee Chair

Lance Alstodt

Lance Alstodt has served as our Chief Executive Officer, President and Chairman of the Board since November 2020. He served as our Executive Vice President and Chief Strategy Officer from October 2018 to February 2020. Since 2013, Mr. Alstodt has served as Chief Executive Officer of MedVest Consulting Corporation, an advisory and capital firm that focuses exclusively on the healthcare industry. Prior to MedVest, he was an investment banker with over 23 years of experience with respect to healthcare investment banking, including mergers and acquisitions. From 2011 to 2013, Mr. Alstodt was a Managing Director at Leerink Partners where he helped lead its medical technology sector. From 2009 to 2011, he was a Managing Director and Head of Medical Technology at Oppenheimer & Co. From 2000 to 2009, Mr. Alstodt was a Managing Director in the Healthcare Group and Global Mergers and Acquisitions Group at Bank of America Merrill Lynch. He previously spent seven years as a Vice President in the Global Mergers and Acquisitions Group at J.P. Morgan Chase, where he worked extensively on acquisitions, leveraged buyouts, private and public financings, exclusive sales and general advisory assignments. Mr. Alstodt received a degree in Economics from the State University of New York at Albany, with a secondary concentration in Finance and Marketing. We believe that Mr. Alstodt's executive-level management experience with us and other healthcare businesses and his extensive experience in the investment banking field relating to the healthcare sector give him the qualifications to serve as one of our directors.

Francisco Silva

Francisco Silva has served as our Vice President of Research and Development since March 2013, having also previously served in such position from April 2011 until March 2012. Mr. Silva was elected our Secretary and a director in November 2020. He served as our Research Scientist from March 2012 to June 2012 and as our Chief Scientist from June 2012 to March 2013. From 2007 to 2011, Mr. Silva served as Chief Executive Officer of DV Biologics LLC, and as President of DaVinci Biosciences, LLC, companies engaged in the commercialization of human based biologics for both research and therapeutic applications. From 2003 to 2007, Mr. Silva served as Vice President of Research and Development for PrimeGen Biotech LLC, a company engaged in the development of cell based platforms. From 2002 to 2003, he was a Research Scientist with PrimeGen Biotech and was responsible for the development of experimental designs that focused on germ line reprogramming stem cell platforms. Mr. Silva has taught courses in biology, anatomy and advanced tissue culture at California State Polytechnic University. He has obtained a number of patents relating to stem cells and has had numerous articles published with regard to stem cell research. Mr. Silva graduated from California State Polytechnic University with a degree in Biology. He also obtained a Graduate Presidential Fellowship and MBRS Fellowship from California State Polytechnic University. We believe that Mr. Silva's executive-level management experience with us since April 2011 and his extensive knowledge of the science related to our business give him the qualifications to serve as one of our directors.

Robert E. Kristal

Robert E. Kristal has served as our Chief Financial Officer since November 2021. Mr. Kristal is an experienced Wall Street and Bay Street professional who has served in various management roles within multiple business lines of investment banks. From 2016 to 2020, he was Head of Equity Research at H.C. Wainwright. Mr. Kristal provided investment banking and merchant banking services from 2013 to 2016 at H.C. Wainwright and T.R. Winston. He is a Charted Financial Analyst. Mr. Kristal received a Bachelor of Arts degree in Economics from Wilfrid Laurier University and a Bachelor of Commerce (Honors) degree in Finance from the University of Windsor.

Nickolay Kukekov, Ph.D.

Nickolay Kukekov, Ph.D. has served as one of our directors since March 2021 and Chair of our Board's Compensation Committee since November 2021. For more than the past fifteen years, Dr. Kukekov has held a number of healthcare investment banking positions. He has served as Senior Managing Director of Paulson Investment Company, LLC since 2020. From 2012 to 2020, Dr. Kukekov was a founding partner of Highline Research Advisors LLC. He served as a Managing Director of Summer Street Research Partners from 2010 to 2012. From 2007 to 2009, Dr. Kukekov was a Managing Director of Paramount Capital. He served as a Vice President of Rodman & Renshaw from 2006 to 2007. He serves as a director of Brain Scientific, Inc. and Omnia Wellness Inc. whose shares are publicly traded. Dr. Kukekov received a Bachelor of Arts degree in molecular, cellular and developmental biology from the University of Colorado at Boulder and a Ph.D. in neuroscience from Columbia University College of Physicians and Surgeons. We believe that Dr. Kukekov's extensive experience in the investment banking field relating to the healthcare sector and his strong background in regenerative medicine give him the qualifications to serve as one of our directors.

Patrick F. Williams

Patrick F. Williams has served as one of our directors and Chair of our Board's Audit Committee since November 2021. Mr. Williams has more than 25 years of experience across medical device, consumer product goods and technology sectors. Appointed as Chief Financial Officer of NeuroPace Inc., or NeuroPace, in June 2025, Mr. Williams is responsible for optimizing the financial performance of NeuroPace and ensuring the scalability of various functions to support high growth expansion. Mr. Williams served as Chief Financial Officer of STAAR Surgical Company from July 2020 to March 2025. From 2016 to 2019, he served as the Chief Financial Officer of Sientra, Inc. before transitioning to General Manager for its miraDry® business unit. From 2012 to 2016, Mr. Williams served as Chief Financial Officer of ZELTIQ Aesthetics, Inc., a publicly-traded medical device company that was acquired by Allergan. Previously, he served as Vice President in finance, strategy and investor relations roles from 2007 to 2012 at NuVasive, Inc., a San-Diego based medical device company servicing the spine sector. He has also held finance roles with Callaway Golf and Kyocera Wireless. Mr. Williams received an MBA in Finance and Management from San Diego State University and a Bachelor of Arts in Economics from the University of California, San Diego. We believe that Mr. Williams' executive-level management experience with healthcare-related businesses, including his financial management expertise, give him the qualifications to serve as one of our directors.

David Rosa

David Rosa has served as one of our directors and Chair of our Board's Nominating Committee since November 2021. Mr. Rosa has served as the Chief Executive Officer, President and a director of NeuroOne Medical Technologies Corporation, or NeuroOne (Nasdaq: NMTC), since July 2017 and served as Chief Executive Officer and a director of NeuroOne, Inc., formerly its wholly-owned subsidiary, from October 2016 until December 2019, when NeuroOne, Inc. merged with and into NeuroOne. NeuroOne is committed to providing minimally invasive and hi-definition solutions for EEG recording, brain stimulation and ablation solutions for patients suffering from epilepsy, Parkinson's disease, dystonia, essential tremors, chronic pain due to failed back surgeries and other related neurological disorders that may improve patient outcomes and reduce procedural costs. From November 2009 to November 2015, Mr. Rosa served as the Chief Executive Officer and President of Sunshine Heart, Inc., n/k/a CHF Solutions, Inc. (Nasdaq: CHFS), a publicly-held early-stage medical device company. From 2008 to November 2009, he served as Chief Executive Officer of Milksmart, Inc., a company that specializes in medical devices for animals. From 2004 to 2008, Mr. Rosa served as the Vice President of Global Marketing for Cardiac Surgery and Cardiology at St. Jude Medical, Inc. He serves as a director on the board of directors of Biotricity Inc. (Nasdaq:BTCY) and Healthcare Triangle, Inc. (Nasdaq:HCTI). Mr. Rosa previously served as Chairman of Neuro Event Labs, a privately-held company in Finland, and is an Advisory Board member of SYNAPS Dx, a privately-held company in Bethesda, Maryland. We believe that Mr. Rosa's senior leadership experience in the medical device industry and his strong technical, strategic, and operational expertise give him the qualifications to serve as one of our directors.

Scientific Advisory Board

The following persons are the members of our Scientific Advisory Board:

Name	Principal Positions
Wayne Marasco, M.D., Ph.D. Chairman	Professor, Department of Cancer Immunology & AIDS, Dana-Farber Cancer Institute; Professor of Medicine, Harvard Medical School; Principal Faculty Member, Harvard Stem Cell Institute
Jason Lipetz, M.D. Chairman, Disc Advisory Committee	Founder, Long Island Spine Rehabilitation Medicine; Chief of Spine Medicine, Northwell Health Spine Center; Clinical Assistant Professor, Department of Physical Medicine and Rehabilitation, Zucker School of Medicine at Hofstra/Northwell

Wayne J. Olan, M.D.	Director, Interventional and Endovascular Neurosurgery; Associate Professor, Neurosurgery and Radiology, George Washington University Medical Center; Consulting Physician, Department of Radiology, National Institutes of Health
Joy Cavagnaro, Ph.D., DABT, RAC	President and Founder, Access BIO, L.C.; Fellow, Academy of Toxicological Sciences and the Regulatory Professional Society; Formerly Senior Pharmacologist and Director of Quality Assurance, Food and Drug Administration's Center for Biologics Evaluation and Research
Harvinder Sandhu, M.D.	Orthopedic Spine Surgeon, Hospital for Special Surgery; Formerly Chief of Spinal Surgery Service, UCLA Medical Center
Christopher Plastaras, M.D.	Clinical Director of Musculoskeletal Spine and Sports Rehabilitation Medicine and Physiatrist, MossRehab; Formerly Director of The Penn Spine and Rehabilitation Center; Formerly Director of Spine, Sports and Musculoskeletal Medicine Fellowship, University of Pennsylvania

Family Relationships

There are no family relationships among any of our executive officers, directors and Scientific Advisory Board members.

Term of Office

We have a classified Board of Directors. The directors will hold office until the respective annual meetings of stockholders indicated below and until their respective successors are elected and qualified or until their earlier resignation or removal.

Name	Class	Term Expires
Lance Alstodt	III	2026
Francisco Silva	II	2028
Nickolay Kukekov	I	2027
Patrick F. Williams	III	2026
David Rosa	II	2028

Each executive officer will hold office until the initial meeting of the Board of Directors following the next annual meeting of stockholders and until his successor is elected and qualified or until his or her earlier resignation or removal.

EXECUTIVE COMPENSATION

Summary Compensation Table

The following Summary Compensation Table sets forth all compensation earned in all capacities during the fiscal years ended December 31, 2025 and 2024 by (i) our principal executive officer, and (ii) our two most highly compensated executive officers, other than our principal executive officer, who were serving as an executive officer as of December 31, 2025 and whose total compensation for the 2025 fiscal year, as determined by Regulation S-K, Item 402, exceeded $100,000 (the individuals falling within categories (i) and (ii) are collectively referred to as the Named Executive Officers):

Name and Principal Position	Year	Salary	Bonus	Stock Awards[1]	Option Awards[1]	All Other Compensation	Total
Lance Alstodt	2025	$ 596,666	$ -[2]	$ -	$ 1,512,500	$ -	$ 2,109,167
Chief Executive Officer	2024	$ 539,583	$ 275,000[3]	$ -	$ 500,000	$ -	$ 1,314,583
Francisco Silva	2025	$ 566,666	$ -[2]	$ -	$ 1,468,750	$ -	$ 2,035,416
VP, Research and Development	2024	$ 514,583	$ 262,500[3]	$ -	$ 450,000	$ -	$ 1,227,083
Robert Kristal	2025	$ 343,750	$ -[2]	$ -	$ 318,000	$ -	$ 661,750
Chief Financial Officer	2024	$ 293,752	$ 90,000[5]	$ -	$ 300,000	$ -	$ 683,752

(1) Amounts reflect the aggregate grant date fair value of grants made in the fiscal year computed in accordance with stock-based accounting rules (FASB ASC Topic 718-Stock Compensation). Assumptions used in the calculations of these amounts are included in Note 8 to our consolidated financial statements included in this Annual Report.

(2) No determination has yet been made as to the amount of the discretionary bonus in consideration of 2025 services.

(3) The 2024 Bonus amount represents a discretionary bonus in consideration of 2024 services which was paid in 2025.

Outstanding Equity Awards at Fiscal Year-End

The following table provides information on outstanding equity awards as of December 31, 2025 to the Named Executive Officers:

	Option Awards					Stock Awards			
Name	Number of securities underlying unexercised options exercisable	Number of securities underlying unexercised options unexercisable	Equity incentive plan awards: Number of securities underlying unexercised unearned options	Option exercise price	Option expiration date	Number of shares or units of stock that have not vested	Market value of shares of units that have not vested	Equity incentive plan awards: Number of unearned shares, units or other rights that have not vested	Equity incentive plan awards: Market or payout value of unearned shares, units or other rights that have not vested
Lance Alstodt	293,479	-	-	$ 5.08	3/18/31	-	$ -	-	$ -
Lance Alstodt	42,059	-	-	$ 5.08	11/4/31	-	$ -	-	$ -
Lance Alstodt	106,762	-	-	$ 2.91	2/17/33	-	$ -	-	$ -
Lance Alstodt	328,947	109,649(1)	-	$ 1.45	2/13/34	-	$ -	-	$ -
Lance Alstodt	395,943	395,942(2)	-	$ 2.46	2/14/35	-	$ -	-	$ -
Francisco Silva	15	-		$ 3,000	6/10/26	-	$ -	-	$ -
Francisco Silva	20	-		$ 3,000	7/12/27	-	$ -	-	$ -
Francisco Silva	25	-		$ 3,000	10/29/28	-	$ -	-	$ -
Francisco Silva	293,479	-	-	$ 5.08	3/18/31	-	$ -	-	$ -
Francisco Silva	42,059	-	-	$ 5.08	11/4/31	-	$ -	-	$ -
Francisco Silva	106,762	-	-	$ 2.91	2/17/33	-	$ -	-	$ -
Francisco Silva	296,053	98,684(1)	-	$ 1.45	2/13/34	-	$ -	-	$ -
Francisco Silva	384,490	384,489(2)	-	$ 2.46	2/14/35	-	$ -	-	$ -
Robert Kristal	10,490	-	-	$ 5.08	11/4/31	-	$ -	-	$ -
Robert Kristal	88,968	-	-	$ 2.91	2/17/33	-	$ -	-	$ -
Robert Kristal	197,369	65,789(1)	-	$ 1.45	2/13/34	-	$ -	-	$ -
Robert Kristal	83,246	83,246(2)	-	$ 2.46	2/14/35	-	$ -	-	$ -

(1) Option becomes exercisable in four nearly equal quarterly installments beginning on February 13, 2026.

(2) Option becomes exercisable in eight nearly equal quarterly installments beginning on February 14, 2026.

Employment Agreements

Lance Alstodt

Effective November 16, 2020, Mr. Alstodt was elected our Chief Executive Officer, President and Chairman of the Board. On March 18, 2021, we entered into an employment agreement with Mr. Alstodt which provides for a term ending on March 18, 2026. Pursuant to the employment agreement, Mr. Alstodt currently is entitled to receive an annual salary of $600,000 (giving effect to a $150,000 performance salary increase received in November 2021 and $50,000 annual increases in salary pursuant to his employment agreement). Concurrently with the execution of the employment agreement, we granted to Mr. Alstodt pursuant to the 2021 Plan (i) a ten year option for the purchase of 293,479 shares of our common stock at an exercise price of $47.60 per share (which exercise price was subsequently reduced to $13.50 per share and further reduced to $5.08 per share) and (ii) 146,740 RSUs. The option vested to the extent of 50% thereof on the date of grant, 12.5% on November 4, 2021 and the balance in six equal quarterly installments commencing on December 18, 2021. The RSUs vested in three equal annual installments on the first, second and third anniversaries of the date of grant. In the event that Mr. Alstodt's employment is terminated by us without "cause", or Mr. Alstodt terminates his employment for "good reason" (each as defined in the employment agreement), Mr. Alstodt will be entitled to receive severance in an amount up to one time his then annual base salary. If Mr. Alstodt's employment with us is terminated without cause, the option granted to Mr. Alstodt will remain exercisable until its expiration date notwithstanding such termination of employment with us. In March 2022, we and Mr. Alstodt agreed that, in lieu of a $50,000 increase in his annual salary (as provided for in his employment agreement), we issued to Mr. Alstodt 12,438 RSUs (having a value of $50,000), which RSUs vested in twelve equal monthly installments. Such grant was in consideration of Mr. Alstodt deferring his right to receive the $50,000 increase in his salary for one year.

Francisco Silva

On March 18, 2021, we and Mr. Silva entered into an employment agreement which provides for a term ending on March 18, 2026. Pursuant to the employment agreement, Mr. Silva is currently entitled to receive an annual salary of $575,000 (giving effect to a $150,000 performance salary increase received in November 2021 and $50,000 annual increases in salary pursuant to his employment agreement). Concurrently with the execution of the employment agreement, we granted to Mr. Silva pursuant to the 2021 Plan (i) a ten year option for the purchase of 293,479 shares of our common stock at an exercise price of $47.60 per share (which exercise price was subsequently reduced to $13.50 per share and further reduced to $5.08 per share) and (ii) 146,740 RSUs. The option vested to the extent of 50% thereof on the date of grant, 12.5% on November 4, 2021 and the balance in six equal quarterly installments commencing on December 18, 2021. The RSUs vested in three equal annual installments on the first, second and third anniversaries of the date of grant. In the event that Mr. Silva's employment is terminated by us without "cause", or Mr. Silva terminates his employment for "good reason" (each as defined in the employment agreement), Mr. Silva will be entitled to receive severance in an amount up to one time his then annual base salary. If Mr. Silva's employment with us is terminated without cause, the option granted to Mr. Silva will remain exercisable until its expiration date notwithstanding such termination of employment with us. In March 2022, we and Mr. Silva agreed that, in lieu of a $50,000 increase in his annual salary (as provided for in his employment agreement), we issued to Mr. Silva 12,438 RSUs (having a value of $50,000), which RSUs vested in twelve equal monthly installments. Such grant was in consideration of Mr. Silva deferring his right to receive the $50,000 increase in his salary for one year.

Director Compensation

The following table sets forth certain information concerning the compensation of our non-employee directors for the fiscal year ended December 31, 2025:

Name	Fees Earned or Paid in Cash	Stock Awards	Option Awards	Non-Equity Incentive Plan Compensation	Nonqualified Deferred Compensation Earnings	All Other Compensation	Total
Nickolay Kukekov	$ 35,000	$ -	$ 100,001(1)	$ -	$ -	$ -	$ 135,001
Patrick F. Williams	$ 35,000	$ -	$ 100,001(2)	$ -	$ -	$ -	$ 135,001
David Rosa	$ 35,000	$ -	$ 100,001(3)	$ -	$ -	$ -	$ 135,001

(1) As of December 31, 2025, Dr. Kukekov held options for the purchase of 189,542 shares of common stock.

(2) As of December 31, 2025, Mr. Williams held options for the purchase of 174,796 shares of common stock.

(3) As of December 31, 2025, Mr. Rosa held options for the purchase of 174,796 shares of common stock.

Dr. Kukekov and Messrs. Williams and Rosa, our non-employee directors, as compensation for their services as a director, are entitled to receive per annum $35,000 in cash and $100,000 in option grants.

Equity Award Grant Practices

Equity awards are discretionary and are generally granted to our named executive officers in the second or third week of February each year. In certain circumstances, including the hiring or promotion of an officer, the Compensation Committee may approve grants to be effective at other times. The Compensation Committee did not take material nonpublic information into account when determining the timing and terms of equity awards in 2025, and we do not time the disclosure of material nonpublic information for the purpose of affecting the value of executive compensation.

CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS; DIRECTOR INDEPENDENCE

Director Independence

Board of Directors

Our Board of Directors is comprised of Lance Alstodt (Chair), Francisco Silva, Nickolay Kukekov, Patrick F. Williams and David Rosa. Each of Dr. Kukekov, Mr. Williams and Mr. Rosa is an "independent director" based on the definition of independence in Listing Rule 5605(a)(2) of The Nasdaq Stock Market.

Audit Committee

Mr. Williams (Chair), Dr. Kukekov and Mr. Rosa are the members of our Board's Audit Committee. Each of Mr. Williams, Dr. Kukekov and Mr. Rosa is an "independent director" based on the definition of independence in Listing Rule 5605(a)(2) of The Nasdaq Stock Market and Rule 10A-3(b)(1) under the Exchange Act. Our Board of Directors has determined that Mr. Williams qualifies as an "audit committee financial expert," as that term is defined in Item 407(d)(5) of Regulation S-K.

Nominating Committee

Mr. Rosa (Chair), Dr. Kukekov and Mr. Williams are the members of our Board's Nominating Committee. Each of Mr. Rosa, Dr. Kukekov and Mr. Williams is an "independent director" based on the definition of independence in Listing Rule 5605(a)(2) of The Nasdaq Stock Market.

Compensation Committee

Dr. Kukekov (Chair), Mr. Williams and Mr. Rosa are the members of our Board's Compensation Committee. Each of Dr. Kukekov, Mr. Williams and Mr. Rosa is an "independent director" based on the definition of independence in Listing Rule 5605(a)(2) of The Nasdaq Stock Market.

BENEFICIAL OWNERSHIP OF SECURITIES

The following table sets forth certain information regarding the beneficial ownership of our common stock, as of February 11, 2026, known by us, through transfer agent records and reports filed with the SEC, to be held by: (i) each person who beneficially owns 5% or more of the shares of common stock then outstanding; (ii) each of our directors; (iii) each of our Named Executive Officers (as defined above); and (iv) all of our directors and executive officers as a group. The following table also sets forth certain information regarding the beneficial ownership of our Series B preferred stock as of February 11, 2026.

The information in this table reflects "beneficial ownership" as defined in Rule 13d-3 of the Exchange Act. To our knowledge, and unless otherwise indicated, each stockholder has sole voting power and investment power over the shares listed as beneficially owned by such stockholder, subject to community property laws where applicable. Percentage ownership prior to this offering is based on 9,046,242 shares of common stock (exclusive of the shares of common stock issuable to Auctus Fund, LLC, or Auctus, as discussed in footnote (11) to the following table) and 1,398,158 shares of Series B preferred stock outstanding as of February 11, 2026.

Name and Address of Beneficial Owner	Number of Shares of Common Stock Beneficially Owned	Approximate Percent of Class Prior to this Offering	Approximate Percent of Class After this Offering[12]	Number of Shares of Series B Preferred Stock Beneficially Owned	Approximate Percent of Class
Directors and Executive Officers					
Lance Alstodt[1]	1,431,592[2]	13.9%	5.8%	-	-
Francisco Silva[1]	1,379,155[3]	13.5%	5.6%	-	-
Robert Kristal[1]	414,920[4]	4.4%	1.7%	-	-
Nickolay Kukekov	189,542[5]	2.1%	*	-	-
Patrick F. Williams	174,796[5]	1.9%	*	-	-
David Rosa	174,796[5]	1.9%	*	-	-
All directors and executive officers as a group (6 persons)	3,764,801[6]	30.3%	14.1%	-	-
Certain Beneficial Owners					
Dale Broadrick[7]	923,905[8]	10.2%	4.0%	-	-
Todd Hale Morrison	685,000[9]	7.6%	2.9%	-	-
Auctus Fund, LLC[10]					
Auctus Fund Management LLC[10]					
Alfred Sollami[10]					
Louis Posner[10]	908,898[11]	9.99%	9.99%[13]	1,398,158[14]	100%

* Less than 1%

(1) Address is c/o BioRestorative Therapies, Inc., 40 Marcus Drive, Suite One, Melville, New York 11747.

(2) Includes 1,244,095 shares of common stock issuable upon the exercise of options that are exercisable currently or within 60 days.

(3) Includes 1,195,635 shares of common stock issuable upon the exercise of options that are exercisable currently or within 60 days and 12,136 shares of common stock held by Mr. Silva in a retirement account.

(4) Includes 406,926 shares of common stock issuable upon the exercise of options that are exercisable currently or within 60 days.

(5) Represents shares of common stock issuable upon the exercise of options that are exercisable currently or within 60 days.

(6) Includes 3,385,790 shares of common stock issuable upon the exercise of options that are exercisable currently or within 60 days.

(7) Address is 3003 Brick Church Pike, Nashville, Tennessee

(8) Based upon Amendment No. 9 to Schedule 13D and Forms 4 filed with the SEC. Includes 477,972 shares of common stock held by Fleetco Inc. of which Mr. Broadrick is a 93% stockholder.

(9) Based upon Schedule 13G, as amended, filed with the SEC, Mr. Morrison has shared voting and dispositive power with respect to the 685,000 shares of common stock.

(10) Address is 545 Boylston Street, 2nd Floor, Boston, Massachusetts 02116.

(11) Based upon Amendment No. 5 to Schedule 13G filed with the SEC on August 14, 2025, other filings made by Auctus with the SEC and other information of which we are aware. Auctus holds warrants for the purchase of up to 1,613,685 shares of our common stock. In addition, Auctus' shares of Series B preferred stock are convertible into an aggregate of 1,398,158 shares of our common stock. In connection with the transaction in which certain of the above warrants were issued, we issued to Auctus certain shares of our common stock and have agreed to issue to Auctus, upon receipt of notice from Auctus, subject to the limitation discussed below, 748,055 shares of our common stock (the "Additional Shares"). However, such warrants are not exercisable for the purchase of our common stock, such Series B preferred stock is not convertible into shares of our common stock and the Additional Shares are not issuable to the extent Auctus would beneficially own, after such exercise, conversion or issuance, more than 9.99% of our outstanding shares of common stock. Auctus has advised that, as of February 11, 2026, it owned 857,054 shares of common stock, which represented approximately 9.5% of the then 9,046,242 outstanding shares of common stock, and that the Additional Shares are issuable to it, upon notice from it, to the extent that such issuances would not result in Auctus beneficially owning after such issuances more than 9.99% of our outstanding shares of common stock. Based upon the foregoing, as of such date, 51,844 Additional Shares were issuable to Auctus (to comply with the 9.99% beneficial ownership limitation), the remaining Additional Shares were not issuable, Auctus' warrants were not then currently exercisable for the purchase of shares of common stock and its Series B preferred stock was not currently convertible into shares of common stock. The number of shares of common stock beneficially owned by Auctus includes the 51,844 Additional Shares currently issuable to it. Without the 9.99% limitation discussed above, as of February 11, 2026, Auctus would have beneficial ownership of 4,616,952 shares of common stock.

(12) Assumes that (a) all of the securities offered by this prospectus are sold, (b) there are no issuances of Pre-Funded Warrants and (c) none of the Common Stock Warrants or Placement Agent Warrants are exercised.

(13) Subject to upward adjustment to the extent that, due to the offering and the reduction in Auctus' percentage ownership of our common stock, a portion of Auctus' warrants would become exercisable, its Series B preferred stock would be convertible and/or the Additional Shares would be issuable. Does not give effect to any purchases by Auctus of the securities offered by this prospectus.

(14) Pursuant to the Certificate of Designations of Preferred Stock with regard to the Series B preferred stock, Auctus, as the sole holder of the 1,398,158 outstanding shares of Series B preferred stock, is entitled to vote such shares based on the number of shares of common stock into which such shares are convertible (currently 1,398,158); however, pursuant to such Certificate of Designations of Preferred Stock, as indicated in footnote (11), such Series B preferred stock is not convertible into shares of common stock to the extent Auctus would beneficially own, after such conversion, more than 9.99% of our then outstanding shares of common stock. Since Auctus has advised that, as of February 11, 2026, it owned 857,054 shares of common stock, which represented approximately 9.5% of the outstanding shares of common stock, and, as indicated in footnote (11) above, 51,844 Additional Shares were issuable to it, Auctus' Series B preferred stock was not currently convertible into shares of common stock. Accordingly, as of February 11, 2026, Auctus, as the sole holder of the Series B preferred stock, was not entitled to any votes for such shares.

Securities Authorized for Issuance Under Equity Compensation Plans

The following table sets forth information as of December 31, 2025 with respect to compensation plans (including individual compensation arrangements) under which our common stock are authorized for issuance, aggregated as follows:

- All compensation plans previously approved by security holders; and
- All compensation plans not previously approved by security holders.

EQUITY COMPENSATION PLAN INFORMATION

	Number of securities to be issued upon exercise of outstanding options (a)	Weighted-average exercise price of outstanding options (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))
Equity compensation plans approved by security holders	5,266,600	$ 2.57	4,234,354
Total	5,266,600	$ 2.57	4,234,354

MARKET FOR OUR COMMON STOCK AND RELATED STOCKHOLDER MATTERS

Market Information

Transactions in our common stock are currently reported under the symbol “BRTX” on the Nasdaq Capital Market.

Holders

As of February 4, 2026, there were 343 record holders of our shares of common stock.

Dividends

Holders of our shares of common stock are entitled to dividends when, as and if declared by our Board of Directors out of funds legally available.

We have not declared or paid any dividends in the past to the holders of our common stock and do not currently anticipate declaring or paying any dividends in the foreseeable future. We intend to retain earnings, if any, to finance the development and expansion of our business. Future dividend policy will be subject to the discretion of our Board of Directors and will be contingent upon future earnings, if any, our financial condition, capital requirements, general business conditions, and other factors. Therefore, we can give no assurance that any dividends of any kind will ever be paid to holders of our common stock.

CHANGE IN CERTIFYING ACCOUNTANTS

Resignation of Independent Registered Public Accounting Firm

On November 1, 2024, CBIZ CPAs P.C. acquired the attest business of Marcum LLP ("Marcum"). On April 16, 2025, Marcum informed us that Marcum resigned as our independent registered public accounting firm.

Neither of Marcum's reports on our financial statements for either of the two fiscal years ended December 31, 2024 and December 31, 2023, respectively, contained an adverse opinion or a disclaimer of opinion, or was qualified or modified as to uncertainty, audit scope, or accounting principles, except for including in its report on our financial statements for the fiscal year ended December 31, 2024 an explanatory paragraph as to substantial doubt about our ability to continue as a going concern.

During our fiscal years ended December 31, 2024 and December 31, 2023, respectively, and the subsequent interim period through April 16, 2025, there were no disagreements with Marcum on any matter of accounting principles or practices, financial statement disclosure, or auditing scope or procedure, which disagreement(s), if not resolved to the satisfaction of Marcum, would have caused it to make reference to the subject matter of the disagreement(s) in connection with its report.

During our fiscal years ended December 31, 2024 and December 31, 2023, respectively, and the subsequent interim period through April 16, 2025, we had the following "reportable events" (as such term is defined in Item 304(a)(1)(v) of Regulation S-K): As disclosed in Part II, Item 9A of our Form 10-Ks for the fiscal years ended December 31, 2024 and 2023, there were material weaknesses identified in internal control over financial reporting related to lack of adherence to formal policies and procedures, lack of risk assessment procedures on internal controls to detect financial reporting risks in a timely manner, lack of design and implementation of effective controls to achieve complete and accurate financial reporting and disclosures, including documented controls over the preparation and review of journal entries, account reconciliations and income taxes, and lack of design and implementation of effective controls over the accounting for warrants issued in connection with equity financings.

We provided Marcum with a copy of the above disclosures prior to our filing of the above with the SEC. A letter to the SEC, dated April 21, 2025, from Marcum regarding its concurrence with the statements made by us concerning the resignation of Marcum as our independent registered public accounting firm was filed with the SEC.

Appointment of New Independent Registered Public Accounting Firm

On April 16, 2025, the Audit Committee of our Board of Directors engaged CBIZ CPAs P.C. as our independent registered public accounting firm.

During our fiscal years ended December 31, 2024 and December 31, 2023, respectively, and the subsequent interim period through April 16, 2025, neither we nor anyone on our behalf consulted with CBIZ CPAs P.C. with respect to either (i) the application of accounting principles to a specified transaction, either completed or proposed, or the type of audit opinion that might be rendered on our consolidated financial statements, and neither a written report nor oral advice was provided to us that CBIZ CPAs P.C. concluded was an important factor considered by us in reaching a decision as to any accounting, auditing or financial reporting issue; or (ii) any matter that was either the subject of a disagreement (as defined in Item 304(a)(1)(iv) of Regulation S-K and the related instructions to Item 304 of Regulation S-K) or a reportable event (as defined in Item 304(a)(1)(v) of Regulation S-K).

PLAN OF DISTRIBUTION

We are offering on a reasonable best efforts basis up to 14,285,715 Units, based on the public offering price of $0.35 per Unit for gross proceeds of up to approximately $5 million, before deduction of placement agent fees and offering expenses. There is no minimum amount of proceeds that is a condition to closing of this offering. The actual amount of gross proceeds, if any, in this offering could vary substantially from the gross proceeds from the sale of the maximum amount of securities being offered in this prospectus.

Pursuant to a placement agency agreement, dated as of February 11, 2026, we have engaged Rodman to act as our exclusive placement agent to solicit offers to purchase the securities offered by this prospectus. The placement agent is not purchasing or selling any securities, nor is it required to arrange for the purchase and sale of any specific number or dollar amount of securities, other than to use its "reasonable best efforts" to arrange for the sale of the securities by us. Therefore, we may not sell the entire amount of securities being offered. Investors purchasing securities offered hereby will have the option to execute a securities purchase agreement with us. In addition to the rights and remedies available to all investors in this offering under federal and state securities laws, the investors who enter into a securities purchase agreement will also be able to bring claims of breach of contract against us. Investors who do not enter into a securities purchase agreement shall rely solely on this prospectus in connection with the purchase of our securities in this offering. The placement agency agreement provides that the placement agent's obligations are subject to conditions contained in the placement agency agreement.

The Units will be offered at a fixed price and are expected to be issued in a single closing. There is no minimum number of Units to be sold or minimum aggregate offering proceeds for this offering to close. We expect this offering to be completed not later than one trading day following the commencement of this offering and we will deliver all securities issued in connection with this offering delivery versus payment ("DVP")/receipt versus payment ("RVP") upon our receipt of investor funds. Accordingly, neither we nor the placement agent has made any arrangements to place investor funds in an escrow account or trust account since the placement agent will not receive investor funds in connection with the sale of securities offered hereunder.

We will deliver the securities being issued to the investors upon receipt of investor funds for the purchase of the securities offered pursuant to this prospectus. We expect to deliver the securities being offered pursuant to this prospectus on or about February 13, 2026.

Rodman & Renshaw LLC has agreed to purchase in this offering, on the same terms and conditions, an aggregate of 860,000 Units for a total purchase price of $301,000.

Placement Agent Fees and Expenses

Upon the closing of this offering, we will pay the placement agent a cash transaction fee equal to 7.0% of the aggregate gross cash proceeds to us from the sale of the securities in the offering. In addition, we will reimburse the placement agent for certain of its out-of-pocket expenses incurred in connection with this offering, including the placement agent's legal fees, and actual travel and reasonable out-of-pocket expenses if this offering is completed, in an amount not to exceed $100,000, subject to reduction under certain circumstances, and up to $15,950 for the placement agent's closing costs.

The following table shows the public offering price, placement agent fees and proceeds, before expenses, to us, assuming the sale of all Units in this offering and no sale of any Pre-Funded Warrants in this offering.

	Per Unit Consisting of Common Stock and Warrant	Per Unit Consisting of Pre-Funded Warrant and Warrant	Total[2]
Public offering price	$ 0.35	$ 0.35	$ 5,000,000.25
Placement agent fees[1]	$ 0.0245	$ 0.0245	$ 350,000.02
Proceeds to us, before expenses	$ 0.3255	$ 0.3255	$ 4,650,000.23

(1) The placement agent fees shall equal 7.0% of the gross proceeds of the securities sold by us in this offering.
(2) The foregoing assumes that no Pre-Funded Warrants are issued as part of the Units.

We estimate that the total expenses of the offering, including registration and filing fees, printing fees and legal and accounting expenses, but excluding the placement agent fees, will be approximately $268,000, all of which are payable by us. This figure includes, among other things, the placement agent's expenses (including the legal fees, costs and expenses for the placement agent's legal counsel) that we have agreed to reimburse.

Placement Agent Warrants

We have agreed to issue to Rodman (or its permitted assignees) warrants (the "Placement Agent Warrants") to purchase a number of shares of common stock equal to 7.0% of the total number of shares of common stock and/or Pre-Funded Warrants being sold in this offering, which Placement Agent Warrants are exercisable at an exercise price equal to 125% of the public offering price and will terminate five (5) years from the date of the commencement of sales in this offering. The Placement Agent Warrants will be substantially similar to the Common Stock Warrants issued hereunder. See the form of Placement Agent Warrant filed as an exhibit to the registration statement of which this prospectus forms a part for a complete description of the terms. The Placement Agent Warrants and the shares of common stock underlying the warrants are being registered on the registration statement of which this prospectus is a part.

Listing

Our shares of common stock are listed on Nasdaq under the symbol "BRTX."

The last reported sale price of our common stock on Nasdaq on February 11, 2026, was $0.41 per share. The public offering price was determined between us and the placement agent.

Lock-Up Agreements

Our directors and officers will enter into lock-up agreements in connection with this offering. Under these agreements, these individuals will agree, subject to specified exceptions, not to sell or transfer any shares of common stock or securities convertible into, or exchangeable or exercisable for, our common stock during a period ending 90 days following the closing of this offering. Specifically, these individuals have agreed, in part, not to sell, hypothecate, pledge or otherwise dispose of (or enter into any transaction which is designed to, or might reasonably be expected to, result in the disposition (whether by actual disposition or effective economic disposition due to cash settlement or otherwise), or 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, with respect to, any shares of our common stock or securities convertible, exchangeable or exercisable into shares of our common stock beneficially owned by them. Notwithstanding these limitations, these shares of common stock may be transferred under limited circumstances, including, without limitation, by gift, will or intestate succession.

In addition, we have agreed that, subject to certain exceptions, we will not issue, enter into any agreement to issue or announce the issuance or proposed issuance of any shares of common stock or common stock equivalents for a period of 90 days following the closing of this offering or effect or enter into an agreement to effect any issuance by us or our subsidiaries of any securities that involve a variable rate transaction (as defined in the securities purchase agreement) for a period of nine months following the closing date of this offering.

Right of First Refusal

Upon the closing of this offering, for a period of twelve months following such time, if we, or any of our subsidiaries, decide to raise funds by means of a public offering (including an at-the-market facility), private placement or any other capital-raising financing of equity, equity-linked or debt securities, the placement agent has the right to act as book-running manager, underwriter or placement agent for such financing, subject to certain exceptions.

Tail

Upon the closing of this offering, if, within twelve months following such time, we, or any of our affiliates, complete any public or private offering of equity, or other financing or capital-raising, then, to the extent we receive any capital or funds from any of the investors who were contacted by the placement agent in connection with this offering or introduced to us by the placement agent during the term of our engagement agreement with the placement agent, then we will pay the placement agent, upon the closing of such financing, compensation equal to 7.0% of the gross proceeds of such financing received from such investors.

Transfer Agent

The transfer agent for our common stock is Transhare Corporation.

Determination of Offering Price

The public offering price of the securities offered by this prospectus, and the exercise price of the Common Stock Warrants included in the Units we are offering, were determined by negotiation among us, the placement agent and the investors in this offering. Among the factors that were considered in determining the public offering price were the following:

- our history and our prospects;
- the industry in which we operate;
- our past and present operating results;
- the previous experience of our executive officers; and
- the general condition of the securities markets at the time of this offering.

The public offering price stated on the cover page of this prospectus should not be considered an indication of the actual value of the shares of common stock sold in this offering. That price is subject to change as a result of market conditions and other factors and we cannot assure you that the shares of common stock sold in this offering can be resold at or above the public offering price.

Electronic Distribution

A prospectus in electronic format may be made available on a website maintained by the placement agent or an affiliate. Other than this prospectus, the information on the placement agent's website and any information contained in any other website maintained by the placement agent is not part of this prospectus or the registration statement of which this prospectus forms a part, has not been approved and/or endorsed by us or the placement agent, and should not be relied upon by investors. In connection with the offering, the placement agent or selected dealers may distribute prospectuses electronically. No forms of electronic prospectus other than prospectuses that are printable as Adobe® PDF will be used in connection with this offering.

Other Relationships

In the ordinary course of their business activities, the placement agent and its affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial instruments (including bank loans) for their own account and for the accounts of their customers. Such investments and securities activities may involve securities and/or instruments of ours or our affiliates. The placement agent and its affiliates may also make investment recommendations and/or publish or express independent research views in respect of such securities or financial instruments and may hold, or recommend to clients that they acquire, long and/or short positions in such securities and instruments.

Indemnification

We have agreed to indemnify the placement agent against certain liabilities, including certain liabilities arising under the Securities Act, or to contribute to payments that the placement agent may be required to make for these liabilities.

Regulation M

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 principal 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 10b-5 and Regulation M under the Exchange Act. These rules and regulations may limit the timing of purchases and sales of our securities by the placement agent acting as principal. Under these rules and regulations, the placement agent (i) may not engage in any stabilization activity in connection with our securities and (ii) 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.

DESCRIPTION OF OUR SECURITIES

This prospectus contains a summary description of our capital stock and the warrants we are offering pursuant to this prospectus. This summary description does not purport to be complete and is subject to, and qualified in its entirety by reference to, the more complete descriptions thereof set forth in our amended and restated articles of incorporation ("our charter") and our bylaws, each as amended to date, and the forms of the warrants, which are included as exhibits to the registration statement of which this prospectus forms a part and are incorporated by reference herein.

Authorization

Our authorized capital stock consists of 95,000,000 shares of capital stock. We are authorized to issue 75,000,000 shares of common stock, par value $0.0001 per share, and 20,000,000 shares of preferred stock, par value $0.01 per share.

Common Stock

Dividend Rights. Subject to preferences that may be applicable to any shares of our preferred stock that may be outstanding, the holders of our common stock are entitled to share ratably in such dividends as may be declared by our Board out of funds legally available therefor.

Voting Rights. Each share of our common stock entitles its holder to one vote in the election of directors as well as all other matters to be voted on by stockholders.

No Preemptive Rights. Holders of our common stock do not have any preemptive rights to subscribe for additional shares on a pro rata basis or otherwise when additional shares are offered for sale by us.

Liquidation Rights. Subject to preferences that may be applicable to any shares of our preferred stock that may be outstanding, in the event of our liquidation, dissolution or winding up, the holders of our common stock would be entitled to receive, pro rata, after payment of all of our debts and liabilities, all of our remaining assets available for distribution.

Other Rights. Holders of our common stock have no preferences or conversion or exchange rights. Shares of our common stock will not be liable for further calls or assessments by us and are not subject to redemption.

Preferred Stock

Our Board is authorized to provide, out of the unissued shares of preferred stock, for one or more series of preferred stock and, with respect to each such series, to fix the number of shares constituting such series and the designation of such series, the voting powers, if any, of the shares of such series, and the preferences and relative, participating, optional or other special rights, if any, and any qualifications, limitations or restrictions thereof, of the shares of such series, as are stated in the resolution or resolutions providing for the issuance of such series adopted by our Board. The authority of our Board with respect to each series of preferred stock includes determination of the following:

- the designation of the series;

- the number of shares of the series;
- the dividend rate or rates on the shares of that series, whether dividends will be cumulative and, if so, from which date or dates, and the relative rights of priority, if any, of payment of dividends on shares of that series;
- whether the series will have voting rights in addition to the voting rights provided by law and, if so, the terms of such voting rights;
- whether the series will have conversion privileges and, if so, the terms and conditions of such conversion, including provision for adjustment of the conversion rate in such events as our Board determines;
- whether or not the shares of that series will be redeemable, in whole or in part, at our option or at the option of the holder thereof and, if made subject to such redemption, the terms and conditions of such redemption, including the date or dates upon or after which they will be redeemable, and the amount per share payable in case of redemptions, which amount may vary under different conditions and at different redemption rates;
- the terms and amount of any sinking fund provided for the purchase or redemption of the shares of such series;
- the rights of the shares of that series in the event of voluntary or involuntary liquidation, dissolution or winding up of our company, and the relative rights of priority, if any, of payment of shares of that series;
- the restrictions, if any, on the issue or reissue of any additional preferred stock; and
- any other relative rights, preferences and limitations of that series.

Warrants

Common Stock Warrants

Overview. The following summary of certain terms and provisions of the Common Stock Warrants offered hereby is not complete and is subject to, and qualified in its entirety by, the provisions of the form of Common Stock Warrant which is filed as an exhibit to the registration statement of which this prospectus is a part. Prospective investors should carefully review the terms and provisions set forth in the warrant agency agreement, including the annexes thereto and the form of Common Stock Warrant. Each Common Stock Warrant issued in this offering entitles the registered holder to purchase one share of our common stock at a price equal to $0.35 per share, subject to adjustment as discussed below, immediately following the issuance of such warrant and terminating at 5:00 p.m., New York City time, on the fifth anniversary of the original issuance date.

Exercisability. The Common Stock Warrants are exercisable at any time after their original issuance date until the fifth anniversary of the original issuance date. The Common Stock Warrants may be exercised upon surrender of the warrant on or prior to the expiration date at the offices of the Company, with the exercise form included with the Common Stock Warrant completed and executed as indicated. If we fail to maintain the effectiveness of the registration statement and current prospectus relating to the common stock issuable upon exercise of the Common Stock Warrants, the holders of the warrants shall have the right to exercise the warrants via a cashless exercise feature provided for in the Common Stock Warrants, until such time as there is an effective registration statement and current prospectus. See "— Cashless Exercise" below.

Exercise Limitation. A holder (together with its affiliates) may not exercise any portion of the Common Stock Warrants 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 Common Stock 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 Common Stock Warrants.

Exercise Price. The exercise price per whole share of our common stock purchasable upon the exercise of the Common Stock Warrants is $0.35 per share of common stock. The warrants will be immediately exercisable and may be exercised at any time up to the date that is the fifth anniversary of the original issuance date. The exercise price and number of shares of common stock issuable upon exercise of the warrants may be adjusted in certain circumstances, including in the event of a stock dividend or recapitalization, reorganization, merger or consolidation. However, the Common Stock Warrants will not be adjusted for issuances of common stock at prices below their exercise price.

Cashless Exercise. If, at any time after the issuance of the Common Stock Warrants, a holder of the warrants exercises the warrants and a registration statement registering the issuance of the shares of common stock underlying the warrants under the Securities Act is not then effective or available (or a prospectus is not available for the resale of the shares of common stock underlying the 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 Common Stock Warrants.

Fractional Shares. No fractional shares of Common Stock will be issued upon exercise of the warrants. If, upon exercise of a Common Stock Warrant, the holder would be entitled to receive a fractional interest in a share, we will, in our discretion and upon exercise, either pay a cash adjustment in respect of such final fraction in an amount equal to such fraction multiplied by the exercise price or round up to the next whole share.

Transferability. Subject to applicable laws, the Common Stock Warrants may be offered for sale, sold, transferred or assigned at the option of the holder without our consent.

Certificated Form. The Common Stock Warrants shall be issued solely in certificated (physical) form, with each Common Stock Warrant represented by a duly executed warrant certificate delivered to the Holder, and shall not be issued in book-entry or uncertificated form without the prior written consent of the Holder.

Fundamental Transactions. In the event of a "fundamental transaction," as described in the Common Stock 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, or any person or group becoming the beneficial owner of greater than 50% of the voting power represented by our outstanding equity, the holders of the Common Stock Warrants will be entitled to receive upon exercise of the warrants the kind and amount of securities, cash or other property that the holders would have received had they exercised the warrants immediately prior to such fundamental transaction. Notwithstanding the foregoing, in the event of a fundamental transaction, under certain circumstances, the holders of the Common Stock Warrants have the right to require us or a successor entity to redeem the Common Stock Warrants for cash in the amount of the Black-Scholes Value (as defined in the Common Stock Warrants) of the unexercised portion of the Common Stock Warrants concurrently with or within 30 days following the consummation of a fundamental transaction.

Rights as a Stockholder. Except by virtue of such holder's ownership of shares of our common stock, the holder of a Common Stock Warrant does not have the rights or privileges of a holder of our common stock, including any voting rights, until the holder exercises the warrant.

Pre-Funded Warrants

Overview. The following summary of certain terms and provisions of the Pre-Funded Warrants offered hereby is not complete and is subject to the form of Pre-Funded Warrant, which is filed as an exhibit to the registration statement of which this prospectus is a part. Prospective investors should carefully review the terms and provisions set forth in the form of Pre-Funded Warrant. Each Pre-Funded Warrant issued in this offering entitles the registered holder to purchase one share of our common stock at a purchase price of $0.0001, subject to adjustment as discussed below, immediately following the issuance of such warrant and terminating at the time no Pre-Funded Warrants are outstanding. The Pre-Funded Warrants will be issued in certificated form.

Exercisability. The Pre-Funded Warrants are exercisable at any time after their original issuance date until the Pre-Funded Warrants are exercised in full. 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 for the number of shares of common stock purchased upon such exercise (except in the case of a cashless exercise as discussed below).

Exercise Limitation. A holder (together with its affiliates) may not exercise any portion of the Pre-Funded Warrants 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.

Exercise Price. The exercise price per whole share of our common stock purchasable upon the exercise of the Pre-Funded Warrants is $0.0001 per share of common stock. The warrants will be immediately exercisable and may be exercised at any time until the Pre-Funded Warrants are exercised in full. The exercise price and number of shares of common stock issuable upon exercise of the warrants may be adjusted in certain circumstances, including in the event of a stock dividend or recapitalization, reorganization, merger or consolidation.

Cashless Exercise. If, at any time after the issuance of the Pre-Funded Warrants, a holder of the warrants exercises the warrants and a registration statement registering the issuance of the shares of common stock underlying the 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 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.

Fractional Shares. No fractional shares of common stock will be issued upon exercise of the warrants. If, upon exercise of a Pre-Funded Warrant, the holder would be entitled to receive a fractional interest in a share, we will, in our discretion and upon exercise, either pay a cash adjustment in respect of such final fraction in an amount equal to such fraction multiplied by the exercise price or round up to the next whole share.

Transferability. Subject to applicable laws, the Pre-Funded Warrants may be offered for sale, sold, transferred or assigned at the option of the holder without our consent.

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, or any person or group becoming the beneficial owner of greater than 50% of the voting power represented by our outstanding equity, the holders of the Pre-Funded Warrants will be entitled to receive upon exercise of the warrants the kind and amount of securities, cash or other property that the holders would have received had they exercised the warrants immediately prior to such fundamental transaction.

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 warrant.

Certain Provisions Having Potential Anti-Takeover Effects

General. The following is a summary of the material provisions of the Nevada Revised Statues (the "NRS") and our charter and bylaws that address matters of corporate governance and the rights of stockholders. Certain of these provisions may delay or prevent takeover attempts not first approved by our Board (including takeovers which certain stockholders may deem to be in their best interests). These provisions also could delay or frustrate the removal of incumbent directors or the assumption of control by stockholders. The primary purpose of these provisions is to encourage negotiations with our management by persons interested in acquiring control of our company. All references to the charter and bylaws are to our charter and bylaws in effect on the date of this prospectus.

Combinations with Interested Stockholder. Sections 78.411-78.444, inclusive, of the NRS contain provisions governing combinations with an interested stockholder. For purposes of the NRS, "combinations" include: (i) any merger or consolidation with any interested stockholder, (ii) any sale, lease, exchange, mortgage, pledge, transfer or other disposition to any interested stockholder of corporate assets with an aggregate market value equal to more than 5% of the aggregate market value of the corporation's consolidated assets, more than 5% of the aggregate market value of outstanding shares of the corporation or more than 10% of the earning power or net income of the corporation, (iii) the issuance to any interested stockholder of voting shares (except pursuant to a share dividend or similar proportionate distribution) with an aggregate market value equal to 5% or more of the aggregate market value of all the outstanding shares of the corporation, (iv) the adoption of the dissolution of the corporation if proposed by or on behalf of any interested stockholder, (v) any reclassification of securities, recapitalization or corporate reorganization that will have the effect of increasing the proportionate share of the corporation's outstanding voting shares held by any interested stockholder and (vi) any receipt by the interested stockholder of the benefit (except proportionately as a stockholder) of any loan, advance, guarantee, pledge or other financial assistance. For purposes of the NRS, an "interested stockholder" is defined to include any beneficial owner of more than 10% of any class of the voting securities of a Nevada corporation and any person who is an affiliate or associate of the corporation and was at any time during the preceding two years the beneficial owner of more than 10% of any class of the voting securities of the Nevada corporation.

Subject to certain exceptions, the provisions of the NRS statute governing combinations with interested stockholders provide that a Nevada corporation may not engage in a combination with an interested stockholder for two years after the date that the person first became an interested stockholder unless the combination or the transaction by which the person first became an interested stockholder is approved by the Board of Directors before the person first became an interested stockholder, or unless the combination is approved by the Board of Directors and 60% of the corporation's voting power not beneficially owned by the interested stockholder, its affiliates and associates.

Control Share Acquisitions. The NRS also contains a "control share acquisitions statute." If applicable to a Nevada corporation, this statute restricts the voting rights of certain stockholders referred to as "acquiring persons," that acquire or offer to acquire ownership of a "controlling interest" in the outstanding voting stock of an "issuing corporation." For purposes of these provisions, a "controlling interest" means with certain exceptions the ownership of outstanding voting stock sufficient to enable the acquiring person to exercise one-fifth or more but less than one-third, one-third or more but less than a majority, or a majority or more of all voting power in the election of directors; "issuing corporation" means a Nevada corporation that has 200 or more stockholders of record, at least 100 of whom have addresses in Nevada appearing on the stock ledger of the corporation at all times during the 90 days immediately preceding such date, and which does business in Nevada directly or through an affiliated corporation. The voting rights of an acquiring person in the affected shares will be restored only if such restoration is approved by the holders of a majority of the voting power of the corporation. The NRS allows a corporation to "opt-out" of the control share acquisitions statute by providing in such corporation's articles of incorporation or bylaws that the control share acquisitions statute does not apply to the corporation or to an acquisition of a controlling interest specifically by types of existing or future stockholders, whether or not identified. The Company has not opted out of this statute.

Authorized But Unissued Shares. Nevada law does not require stockholder approval for any issuance of authorized shares. Authorized but unissued shares may be used for a variety of corporate purposes, including future public or private offerings to raise additional capital or to facilitate corporate acquisitions. One of the effects of the existence of authorized but unissued shares may be to enable our Board to issue shares to persons friendly to current management, which issuance could render more difficult or discourage an attempt to obtain control of our company by means of a merger, tender offer, proxy contest or otherwise, and thereby protect the continuity of our management and possibly deprive the stockholders of opportunities to sell their shares of common stock at prices higher than prevailing market prices.

Preferred Stock. Under the terms of our charter, our Board is authorized to issue shares of preferred stock in one or more series without stockholder approval. Our Board has the discretion to determine the rights, preferences, privileges and restrictions, including voting rights, dividend rights, conversion rights, redemption privileges and liquidation preferences, of each series of preferred stock. The purpose of authorizing our Board to issue preferred stock and determine its rights and preferences is to provide flexibility and eliminate delays associated with a stockholder vote on specific issues. However, the ability of our Board to issue preferred stock and determine its rights and preferences may have the effect of delaying or preventing a change in control.

Classified Board. We have a classified Board of Directors consisting of three classes of directors. A classified board is one in which a certain number, but not all, of the directors are elected on a rotating basis each year. This method of electing directors makes changes in the composition of our Board more difficult, and thus a potential change in control may be a lengthier process. The existence of our classified Board reduces the possibility that a third party could effect an unsolicited change in control of our Board. Since our classified Board will increase the amount of time required for a takeover bidder to obtain control of us without the cooperation of our Board, even if the takeover bidder were to acquire a majority of our outstanding common stock, the existence of our classified Board could tend to discourage certain tender offers which stockholders might feel would be in their best interests. Our classified Board will likely allow management, if confronted by a proposal from a third party who has acquired a block of our common stock, sufficient time to review the proposal and appropriate alternatives to the proposal and to attempt to negotiate a better transaction, if possible, for our stockholders.

Special Meetings of Stockholders. Our bylaws provide that special meetings of stockholders may be called only by our Board or the Chairman of the Board.

Filling Vacancies. Vacancies occurring in our Board and newly created directorships resulting from an increase in the authorized number of directors may be filled by a majority of the remaining directors, even if less than a quorum.

Removal of Directors by Stockholders. Under the terms of our charter, stockholders may remove directors with or without cause with the affirmative vote of holders of 75% of the voting power of all of the then-outstanding shares of our capital stock then entitled to vote at an election of directors, voting together as a single class.

Amendment of Bylaws. Our bylaws may be amended by our Board or by the holders of at least 75% of the voting power of our company.

Amendment of Certain Charter Provisions. Under the terms of our charter, amending certain charter provisions requires the affirmative vote of the holders of at least 75% of the voting power of all of the then-outstanding shares of our capital stock entitled to vote thereon, voting together as a single class. The provisions subject to such heightened requirement include those relating to stockholder action by written consent, the calling of special meetings, board classification, the filling of board vacancies, the removal of directors and the ability to amend our bylaws, among others.

Advance Notification of Stockholder Nominations and Proposals. Our bylaws establish advance notice procedures with respect to the nomination of persons for election as directors, other than nominations made by or at the direction of our Board, and stockholder proposals for business.

Stockholder Nominees; Stockholder Proposals.

In order for a stockholder to nominate a candidate for director at, or bring any business before, an annual meeting of stockholders, under our bylaws, timely notice of the nomination or business must be received by us in advance of the meeting. To be timely, a stockholder's notice must be delivered to or mailed and received by our Secretary at our principal executive offices not less than 90 days nor more than 120 days prior to the one-year anniversary of the date on which we first mailed the proxy materials for the preceding year's annual meeting of stockholders; provided, however, that if the meeting is convened more than 30 days prior to or delayed more than 60 days after the anniversary of the preceding year's annual meeting, to be timely a stockholder's notice must be received not earlier than the close of business on the 120th day prior to the date of such annual meeting and not later than the close of business on the later of the 90th day prior to the date of such annual meeting or, if the first public announcement of the date of such annual meeting is less than 100 days prior to the date of such annual meeting, the 10th day following the day on which public announcement of the date of such meeting is first made by us.

The stockholder sending the notice of nomination or proposed business must describe various matters, including the following:

- as to each person whom the stockholder proposes to nominate for election as a director, all information relating to such person as would be required to be disclosed in solicitations of proxies for election of such nominee as a director pursuant to Regulation 14A under the Exchange Act;

- (i) the name and address of such stockholder, as they appear on our books and of such beneficial owner or Control Person (as defined in our bylaws), if any, (ii) the number of our shares which are, directly or indirectly, owned beneficially and of record by such stockholder and such beneficial owner or Control Person, if any (iii) a representation that the stockholder intends to appear at the meeting in person or by proxy to submit the business specified in such notice, (iv) if the notice relates to any business other than a nomination of director(s), a brief description of the business desired to be brought before the meeting, including the complete text of any resolutions proposed for consideration, and the reasons for conducting such business at the meeting, (v) any direct or indirect personal or other interest of the stockholder in the business to be submitted, (vi) a description of any agreement, arrangement or understanding (including any derivative or short positions, profit interests, options, hedging transactions, and borrowed or loaned shares) that has been entered into as of the date of the stockholder's notice by, or on behalf of, such stockholder or beneficial owner and by any Control Person or any other person acting in concert with any of the foregoing, the effect or intent of which is to mitigate loss, manage risk or benefit from changes in the share price of any class of our stock, or maintain, increase or decrease the voting power of the stockholder or beneficial owner with respect to shares of our stock, and a representation that the stockholder will notify us in writing within five business days after the record date for such meeting of any such agreement, arrangement or understanding in effect as of the record date for the meeting, (vii) a representation whether the stockholder or the beneficial owner, if any, and any Control Person will engage in a solicitation with respect to the nomination or business and, if so, the name of each participant (as defined in Item 4 of Schedule 14A under the Exchange Act) in such solicitation and whether such person intends or is part of a group which intends to deliver a proxy statement and/or form of proxy to holders of at least the percentage of our outstanding stock required to approve or adopt the business to be proposed (in person or by proxy) by the stockholder and (viii) any other information relating to such stockholder, beneficial owner or Control Person, if any, that would be required to be disclosed in a proxy statement and form of proxy or other filings required to be made in connection with solicitations of proxies for, as applicable, the proposal and/or for the election of directors in a contested election pursuant to Section 14 of the Exchange Act and the rules and regulations promulgated thereunder.

These provisions are intended to enhance the likelihood of continuity and stability in the composition of our Board and in policies formulated by our Board and to discourage certain types of transactions that may involve an actual or threatened change of control of our company. These provisions are designed to reduce our vulnerability to an unsolicited proposal for a takeover that does not contemplate the acquisition of all of our outstanding shares or an unsolicited proposal for the restructuring or sale of all or part of our company.

Limitations on Director Liability

Our charter provides that our directors shall generally not be liable to us or any of our stockholders for damages for breach of duty as a director. This provision will eliminate such liability except for (i) any breach of the director's duty of loyalty to us or to our stockholders, (ii) acts and omissions not in good faith or which involve intentional misconduct or a knowing violation of law, (iii) liability for unlawful payment of dividends or unlawful stock purchases or redemptions in violation of the NRS, and (iv) any transaction from which the director derived an improper personal benefit.

Indemnification of Directors and Officers

Section 78.7502(1) of the NRS provides that a corporation may, and our charter and bylaws provide that we shall, indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative (an "Action"), by reason of the fact that he is or was our director, officer, employee or agent or is or was serving at our request in such capacity in another corporation, partnership, joint venture, trust or other enterprise (the "Indemnified Party"), against expenses (including attorney's fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by him in connection with such Action if he acted in good faith and in a manner he reasonably believed to be in or not opposed to our best interests, and, with respect to any criminal Action, had no reasonable cause to believe his conduct was unlawful; provided, however, no indemnification shall be made in respect of any Action by or in our right if the Indemnified Party shall have been adjudged by a court of competent jurisdiction, after exhaustion of any appeals, to be liable to us, unless and only to the extent that the court shall determine that, despite the adjudication of liability but in view of all circumstances, such person is fairly and reasonably entitled to indemnity.

Under the NRS, the directors have a fiduciary duty to us that is not eliminated by this provision of our charter and, in appropriate circumstances, equitable remedies such as injunctive or other forms of non-monetary relief will remain available. In addition, each director will continue to be subject to liability under the NRS for breach of the director's duty of loyalty to us for acts or omissions which are found by a court of competent jurisdiction to not be in good faith or involve intentional misconduct, for knowing violations of law, for actions leading to improper personal benefit to the director, and for payment of dividends or approval of stock repurchases or redemptions that are prohibited by the NRS. This provision also does not affect the directors' responsibilities under any other laws, such as the federal securities laws or state or federal environmental laws.

Furthermore, Section 78.7502(3) of the NRS provides that determination of an Indemnified Party's eligibility for indemnification by us shall be made on a case-by-case basis by: (i) the stockholders; (ii) the Board of Directors by a majority vote of a quorum consisting of directors who were not parties to the Action; or (iii) independent legal counsel's written opinion if: (1) a majority vote of a quorum consisting of directors who were not parties to the Action so orders; or (2) a quorum consisting of directors who were not parties to the Action cannot be obtained.

Lastly, Section 78.752(1) of the NRS empowers a corporation to purchase and maintain insurance or make other financial arrangements with respect to liability arising out of the actions or omissions of directors, officers, employees or agents in their capacity or status as such, whether or not the corporation has the authority to indemnify him against such liability.

Our charter provides that, to the fullest extent permitted by the NRS, no director or officer shall be personally liable to us or to our stockholders for monetary damages for breach of fiduciary duty as a director or an officer, except to the extent that such exemption from liability or limitation thereof is not permitted under the NRS currently in effect or as the same may be amended. If the NRS is amended to further eliminate or limit or authorize corporate action to further eliminate or limit the liability of directors or officers, the liability of our directors and officers shall be eliminated or limited to the fullest extent permitted by the NRS, as so amended from time to time. No repeal or modification of this provision of our charter will apply to or have any effect on the liability or alleged liability of any of our directors or officers for or with respect to any acts or omissions of such directors or officers occurring prior to such repeal or modification.

Our bylaws provide that we will indemnify and hold harmless any person who was or is a party or is threatened to be made a party to any threatened, pending or completed Action in such manner, under such circumstances and to the fullest extent permitted by our charter and the NRS.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to our directors, officers and controlling persons under the provisions discussed above or otherwise, we have been advised that, in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable.

LEGAL MATTERS

The validity of the issuance of the securities offered hereby will be passed upon by our counsel, Certilman Balin Adler & Hyman, LLP. The placement agent is being represented in connection with this offering by Ellenoff Grossman & Schole LLP.

EXPERTS

Our consolidated financial statements as of December 31, 2023 and 2024 and for the years then ended have been included in this prospectus in reliance upon the report of Marcum LLP, an independent registered public accounting firm, which report includes an explanatory paragraph regarding our ability to continue as a going concern, included herein, and upon the authority of said firm as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

We file reports, proxy statements and other information with the SEC. The SEC maintains a website that contains reports, proxy and information statements and other information about issuers, such as us, who file electronically with the SEC. The address of that website is http://www.sec.gov.

Our website address is www.biorestorative.com. This website address, and the website addresses included in any documents incorporated by reference herein, are not intended to function as hyperlinks, and the information contained on such websites and on the SEC's website is not incorporated by reference in this prospectus and you should not consider it a part of this prospectus.

BIORESTORATIVE THERAPIES, INC. AND SUBSIDIARY
INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

BIORESTORATIVE THERAPIES, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS

	September 30, 2025 (unaudited)	December 31, 2024
Assets		
Current Assets:		
Cash and cash equivalents	$ 602,444	$ 547,890
Investments held in marketable securities	3,887,383	10,184,701
Accounts receivable	13,400	188,400
Prepaid expenses and other current assets	204,237	223,230
Total Current Assets	4,707,464	11,144,221
Deferred offering costs	69,066	148,697
Property and equipment, net	309,498	362,936
Intangible assets, net	556,634	623,945
Total Assets	$ 5,642,662	$ 12,279,799
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable	$ 859,898	$ 483,070
Accrued expenses and other current liabilities	607,470	744,485
Warrant liabilities	1,968,315	2,520,851
Total Current Liabilities	3,435,683	3,748,406
Commitments and contingencies		
Stockholders' Equity:		
Preferred stock, $0.01 par value; 20,000,000 shares authorized; Series B Convertible Preferred Stock; 1,543,158 shares designated, 1,398,158 shares issued and outstanding at September 30, 2025 and December 31, 2024	13,982	13,982
Common stock, $0.0001 par value; 75,000,000 shares authorized; 7,978,117 and 6,919,919 shares issued and outstanding at September 30, 2025 and December 31, 2024, respectively	797	692
Additional paid-in capital	168,905,254	164,195,434
Accumulated deficit	(166,713,054)	(155,678,715)
Total Stockholders' Equity	2,206,979	8,531,393
Total Liabilities and Stockholders' Equity	$ 5,642,662	$ 12,279,799

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

BIORESTORATIVE THERAPIES, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(unaudited)

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2025	**2024**	**2025**	**2024**
Revenues	$ 11,800	$ 233,600	$ 340,100	$ 357,700
Cost of goods sold	10,570	18,243	22,208	24,733
Gross profit	1,230	215,357	317,892	332,967
Operating Expenses:				
Research and development	2,594,750	1,453,363	7,467,532	5,004,794
General and administrative	1,115,491	1,048,987	4,672,192	4,193,225
Total Operating Expenses	3,710,241	2,502,350	12,139,724	9,198,019
Loss From Operations	(3,709,011)	(2,286,993)	(11,821,832)	(8,865,052)
Other (Expense) Income:				
Interest income	57,740	158,547	231,621	497,089
Other income	930	566	3,336	150,498
Gain on exchange of warrants	-	-	-	1,711,698
Change in fair value of warrant liabilities	612,064	1,036,464	552,536	(837,466)
Total Other Income	670,734	1,195,577	787,493	1,521,819
Net Loss	$ (3,038,277)	$ (1,091,416)	$ (11,034,339)	$ (7,343,233)
Net Loss Per Share - Basic and Diluted	$ (0.33)	$ (0.13)	$ (1.26)	$ (0.96)
Weighted Average Common Shares Outstanding - Basic and Diluted	9,116,172	8,121,499	8,742,085	7,643,437

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

BIORESTORATIVE THERAPIES, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY
(unaudited)

	For the Nine Months Ended September 30, 2025						
	Series B Convertible Preferred Stock		Common Stock		Additional Paid-In	Accumulated	
	Shares	Amount	Shares	Amount	Capital	Deficit	Total
Balance - January 1, 2025	1,398,158	$ 13,982	6,919,919	$ 692	$ 164,195,434	$ (155,678,715)	$ 8,531,393
Exercise of stock options	-	-	29,249	3	42,408	-	42,411
Issuance and sale of common stock, net of issuance costs [1]	-	-	492,087	49	901,561	-	901,610
Common stock issued in connection with abeyance shares	-	-	63,525	6	(6)	-	-
Stock-based compensation:							
Options	-	-	-	-	2,009,126	-	2,009,126
Net loss	-	-	-	-	-	(5,339,799)	(5,339,799)
Balance - March 31, 2025	1,398,158	$ 13,982	7,504,780	$ 750	$ 167,148,523	$ (161,018,514)	$ 6,144,741
Issuance and sale of common stock, net of issuance costs [2]	-	-	473,337	47	888,091	-	888,138
Stock-based compensation:							
Options	-	-	-	-	468,708	-	468,708
Net loss	-	-	-	-	-	(2,656,263)	(2,656,263)
Balance - June 30, 2025	1,398,158	$ 13,982	7,978,117	$ 797	$ 168,505,322	$ (163,674,777)	$ 4,845,324
Stock-based compensation:							
Options	-	-	-	-	399,932	-	399,932
Net loss	-	-	-	-	-	(3,038,277)	(3,038,277)
Balance - September 30, 2025	1,398,158	$ 13,982	7,978,117	$ 797	$ 168,905,254	$ (166,713,054)	$ 2,206,979

	For the Nine Months Ended September 30, 2024						
	Series B Convertible Preferred Stock		Common Stock		Additional Paid-In	Accumulated	
	Shares	Amount	Shares	Amount	Capital	Deficit	Total
Balance - January 1, 2024	1,398,158	$ 13,982	4,706,917	$ 471	$ 156,689,256	$ (146,699,334)	$ 10,004,375
Common stock issued in connection with warrant exchange [3]	-	-	2,000,000	200	4,742,043		4,742,243
Return and cancellation of shares in lieu of payroll tax withholding	-	-	(34,825)	(4)	(48,406)	-	(48,410)
Stock-based compensation:							
Restricted share units	-	-	97,827	10	985,028	-	985,038
Options	-	-	-	-	1,043,336	-	1,043,336
Net loss	-	-	-	-	-	(2,223,255)	(2,223,255)
Balance - March 31, 2024	1,398,158	$ 13,982	6,769,919	$ 677	$ 163,411,257	$ (148,922,589)	$ 14,503,327
Common stock issued in connection with abeyance shares	-	-	150,000	15	(15)		-
Stock-based compensation:							
Options	-	-	-	-	324,322	-	324,322
Net loss	-	-	-	-	-	(4,028,562)	(4,028,562)
Balance - June 30, 2024	1,398,158	$ 13,982	6,919,919	$ 692	$ 163,735,564	$ (152,951,151)	$ 10,799,087
Stock-based compensation:							
Options	-	-	-	-	284,245	-	284,245
Net loss	-	-	-	-	-	(1,091,416)	(1,091,416)
Balance -September 30, 2024	1,398,158	$ 13,982	6,919,919	$ 692	$ 164,019,809	$ (154,042,567)	$ 9,991,916

[1]Represents the gross proceeds of $1,083,915, less issuance costs of $182,305, resulting in net proceeds of $901,610. See Note 4 - Stockholders' Equity - ATM Sales for additional details.

[2]Represents the gross proceeds of $927,335, less issuance costs of $39,197, resulting in net proceeds of $888,138. See Note 4 - Stockholders' Equity - ATM Sales for additional details.

[3]Represents the aggregate fair value of 3,351,580 shares of common stock, which includes 2,000,000 shares that were issued at the time of the warrant exchange and 1,351,580 shares that were held in abeyance at the time of the warrant exchange. See Note 4 - Stockholders' Equity - Warrant Exercise and Issuance and Note 5 - Fair Value Measurement for additional details.

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

BIORESTORATIVE THERAPIES, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(unaudited)

	For the Nine Months Ended September 30,	
	2025	**2024**
Cash Flows From Operating Activities:		
Net loss	$ (11,034,339)	$ (7,343,233)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	157,149	138,687
Dividend and interest income	(235,878)	(492,476)
Stock-based compensation	2,877,766	2,636,941
Non-cash lease expense	-	111,750
Gain on exchange of warrants	-	(1,711,698)
Change in fair value of warrant liabilities	(552,536)	837,466
Changes in operating assets and liabilities:		
Accounts receivable	175,000	(145,700)
Prepaid expenses and other current assets	18,993	23,124
Accounts payable	357,070	211,990
Accrued expenses and other current liabilities	(137,015)	(29,449)
Lease liability	-	(119,903)
Net Cash Used In Operating Activities	(8,373,790)	(5,882,501)
Cash Flows From Investing Activities:		
Sale of marketable securities	9,212,343	17,370,243
Purchase of marketable securities	(2,679,147)	(18,294,566)
Purchases of equipment	(36,400)	(93,755)
Net Cash Provided By (Used In) Investing Activities	6,496,796	(1,018,078)
Cash Flows From Financing Activities:		
Proceeds from issuance of common stock in at-the-market offering	2,011,250	-
Payment of issuance costs	(72,805)	-
Exercise of stock options	42,411	-
Proceeds from exchange and issuance of warrants, net	-	7,528,027
Deferred offering costs	(49,308)	(22,381)
Net Cash Provided By Financing Activities	1,931,548	7,505,646
Net Increase In Cash and Cash Equivalents	54,554	605,067
Cash and Cash Equivalents - Beginning of the Period	547,890	884,377
Cash and Cash Equivalents - End of the Period	$ 602,444	$ 1,489,444
Supplemental Disclosures of Cash Flow Information:		
Cash paid during the period for:		
Interest	$ -	$ -
Income taxes	$ -	$ -
Non-cash investing and financing activities:		
Return and cancellation of shares in lieu of payroll tax withholding	$ -	$ 48,410
Issuance of common stock held in abeyance	$ 6	$ 15
Reclassification of deferred offering costs	$ 148,697	$ -
Deferred offering costs included in accounts payable	$ 19,758	$ -

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

BIORESTORATIVE THERAPIES, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)

NOTE 1 – BUSINESS ORGANIZATION, NATURE OF OPERATIONS, BASIS OF PRESENTATION AND LIQUIDITY

Corporate History

BioRestorative Therapies, Inc. has one wholly-owned subsidiary, Stem Pearls, LLC ("Stem Pearls"). BioRestorative Therapies, Inc. and its subsidiary are referred to collectively as "BRT" or the "Company".

On December 23, 2022, the Company reincorporated from Delaware to Nevada by filing Articles of Incorporation with the state of Nevada. The reincorporation was structured as a statutory merger.

Business Operations

BRT develops therapeutic products and medical therapies using cell and tissue protocols, primarily involving adult stem cells. BRT's website is at www.biorestorative.com. The information contained in the website or connected thereto is not intended to be incorporated by reference into this Quarterly Report. BRT is currently developing a Disc/Spine Program referred to as "brtxDISC". Its lead cell therapy candidate, *BRTX-100*, is a product formulated from autologous (or a person's own) cultured mesenchymal stem cells collected from the patient's bone marrow. The product is intended to be used for the non-surgical treatment of painful lumbosacral disc disorders or as a complimentary therapeutic to a surgical procedure. BRT is also engaging in research efforts with respect to a platform technology utilizing brown adipose (fat) for therapeutic purposes to treat type 2 diabetes, obesity and other metabolic disorders and has labeled this initiative its ThermoStem Program. In addition, in continuation of BRT's mission of developing and commercializing cell-based biologics, it is seeking to develop a biologics-based cosmetic products business. Pursuant to such business, BRT would formulate, manufacture and sell products designed for cosmetic and aesthetic uses. Further, BRT has licensed a patented curved needle device that is a needle system designed to deliver cells and/or other therapeutic products or material to the spine and discs or other potential sites.

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP") for interim financial information and with the instructions to Form 10-Q and Article 8 of Regulation S-X. Accordingly, they do not include all of the information and disclosures required by U.S. GAAP for complete financial statements. In the opinion of management, such statements include all adjustments (consisting only of normal recurring items) that are considered necessary for a fair presentation of the unaudited condensed consolidated financial statements of the Company as of September 30, 2025 and for the three and nine months then ended. The results of operations for the three and nine months ended September 30, 2025 are not necessarily indicative of the operating results for the full year ending December 31, 2025 or any other period. The December 31, 2024 consolidated balance sheet data were derived from audited financial statements but do not include all disclosures required by U.S. GAAP. These unaudited condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and related disclosures of the Company as of December 31, 2024 and for the year then ended, which were filed with the Securities and Exchange Commission ("SEC") on March 28, 2025 (the "Form 10-K").

Liquidity

The accompanying unaudited condensed consolidated financial statements have been prepared on the basis that the Company will continue as a going concern, which contemplates realization of assets and satisfying liabilities in the normal course of business. For the nine months ended September 30, 2025, the Company had a net loss of $11.0 million, and negative cash flows from operations of $8.4 million, and as of September 30, 2025, the Company had working capital of $1.3 million. The Company anticipates that it will continue to incur net losses and negative cash flows from operations as it executes its development plans during 2025 and beyond, as well as other potential strategic and business development initiatives. These conditions raise substantial doubt about the Company's ability to continue as a going concern for at least twelve months after the issuance date of these financial statements.

The Company has previously funded, and plans to continue funding, these losses primarily through current cash on hand, investments in marketable securities and additional infusions of cash from equity and debt financing. During the nine months ended September 30, 2025, the Company sold 965,424 shares of its common stock under its at-the-market offering agreement (the "2024 ATM") with Rodman & Renshaw LLC ("Rodman") and raised approximately $2.0 million of gross proceeds. On October 8, 2025, the Company closed on the sale of an aggregate of 678,125 shares of its common stock for aggregate gross proceeds of approximately $1.1 million. Concurrently, the Company issued to the investors warrants to purchase an aggregate of 508,592 shares of its common stock at an exercise price of $2.75 per share. See Note 6 – Subsequent Events for additional details.

The Company's current funds will not be sufficient to enable the Company to fully complete its development activities or attain profitable operations. If the Company is unable to obtain such needed additional financing on a timely basis, the Company may have to curtail its development, marketing and promotional activities, which would have a material adverse effect on the Company's business, financial condition and results of operations, and ultimately the Company could be forced to discontinue its operations and liquidate.

The accompanying unaudited condensed consolidated financial statements have been prepared in conformity with U.S. GAAP, which contemplate continuation of the Company as a going concern and the realization of assets and satisfaction of liabilities in the normal course of business. The carrying amounts of assets and liabilities presented in the unaudited condensed consolidated financial statements do not necessarily purport to represent realizable or settlement values. The accompanying unaudited condensed consolidated financial statements do not include any adjustments that might be necessary should the Company be unable to continue as a going concern.

NOTE 2 – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Reclassifications

Certain prior period statements of operations amounts have been reclassified to conform to the Company's fiscal 2025 presentation. These reclassifications have no impact on the Company's previously reported net loss.

Cash and Cash Equivalents

Financial instruments that potentially subject the Company to concentrations of credit risk consist of a cash account in a financial institution. The Company maintains deposits in its accounts that hold cash and cash equivalents in excess of the Federal Depository Insurance Corporation ("FDIC") coverage of $250,000 per banking institution. The Company had deposits in excess of FDIC coverage of $290,180 and $252,801 as of September 30, 2025 and December 31, 2024, respectively. As of September 30, 2025, the Company has not experienced losses on this account.

Investments Held in Marketable Securities

As of September 30, 2025 and December 31, 2024, investments held in marketable securities consists of U.S. Treasury securities held in a trust account. The Company's investments held in the trust account are presented on the unaudited condensed consolidated balance sheets at fair value at the end of each reporting period. Gains and losses resulting from the change in fair value of these securities are included in interest income in the accompanying unaudited condensed consolidated statements of operations.

Customer and Revenue Concentrations

All of the Company's contract service revenue is derived from one customer. Additionally, all of the Company's product sales revenue is derived from one customer.

Accounts Receivable

Accounts receivable are carried at their contractual amounts, less an estimate for credit losses. As of September 30, 2025 and December 31, 2024, no allowances for credit losses were determined to be necessary. Management estimates the allowance for credit losses based on existing economic conditions, the financial conditions of the customers, and the amount and age of past due accounts. Receivables are considered past due if full payment is not received by the contractual due date. Past due accounts are generally written off against the allowance for credit losses only after all collection attempts have been exhausted.

Deferred Contract Costs

The Company defers costs associated with fulfilling its contracts if those costs meet all of the following criteria: (i) the costs relate directly to a contract, (ii) the costs generate or enhance resources of the Company that will be used in satisfying performance obligations in the future, and (iii) the costs are expected to be recovered. Deferred contract costs are recognized as cost of revenues in the period when the related revenue is recognized. Deferred contract costs consist of consumables and labor costs and are included in prepaid and other current assets in the unaudited condensed consolidated balance sheets. The Company had $7,491 and $10,250 deferred contract costs as of September 30, 2025 and December 31, 2024, respectively.

Deferred Offering Costs

Deferred offering costs, which primarily consist of direct, incremental professional fees incurred in connection with a financing, are capitalized as non-current assets on the balance sheet. Upon consummation of a financing, the deferred offering costs would be offset against the offering proceeds. If the completion of a contemplated financing was no longer probable, the related deferred offering costs would be charged to general and administrative expense in the unaudited condensed consolidated financial statements. The Company had $69,066 and $148,697 of deferred offering costs as of September 30, 2025 and December 31, 2024, respectively.

Derivative Financial Instruments

The Company evaluates all of its agreements to determine if such instruments have derivatives or contain features that qualify as embedded derivatives. For derivative financial instruments that are accounted for as liabilities, the derivative instrument is initially recorded at its fair value and is then re-valued at each reporting date, with changes in the fair value reported in the unaudited condensed consolidated statements of operations. For stock-based derivative financial instruments, the Company uses a weighted-average Black-Scholes option pricing model to value the derivative instruments at inception and on subsequent valuation dates. The classification of derivative instruments, including whether such instruments should be recorded as liabilities or as equity, is evaluated at the end of each reporting period.

Fair Value of Financial Instruments

Fair value is defined as the amount that would be received for selling an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date and is measured using inputs in one of the following three categories:

Level 1 measurements are based on unadjusted quoted prices in active markets for identical assets or liabilities that we have the ability to access. Valuation of these items does not entail a significant amount of judgment.

Level 2 measurements are based on quoted prices for similar assets or liabilities in active markets, quoted prices for identical or similar assets or liabilities in markets that are not active or market data other than quoted prices that are observable for the assets or liabilities.

Level 3 measurements are based on unobservable data that are supported by little or no market activity and are significant to the fair value of the assets or liabilities.

The Company considers cash and cash equivalents, investments held in marketable securities, accounts receivable, accounts payable and warrant liabilities to meet the definition of financial instruments. As of September 30, 2025 and December 31, 2024, the carrying amount of cash and cash equivalents, investments held in marketable securities, accounts receivable, and accounts payable approximate their fair value due to the relatively short period of time between their origination and their expected realization or payment. The warrant liabilities are measured at fair value (see Note 5 – Fair Value Measurement for additional details).

Revenue Recognition

The Company recognizes revenue in accordance with Accounting Standards Codification (“ASC”) Topic 606, “Revenue from Contracts with Customers” (“ASC 606”). The core principle of ASC 606 requires that an entity recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. ASC 606 defines a five-step process to achieve this core principle and, in doing so, it is possible more judgment and estimates may be required within the revenue recognition process, including identifying performance obligations in the contract, estimating the amount of variable consideration to include in the transaction price and allocating the transaction price to each separate performance obligation. The Company recognizes revenue primarily from the following different types of contracts:

- **Product sales** - Revenue is recognized at the point in time the customer obtains control of the goods and the Company satisfies its performance obligation.

- **Royalty revenue** - Revenue is recognized as a usage-based royalty from customers’ usage of intellectual property pursuant to a license agreement at the point in time in which the underlying sale occurs.

The Company recognizes bill-and-hold revenue from its sale of cosmetic vials warehoused at a Company location for a specified period of time in accordance with directions received from the Company's customer. Even though the vials are held at a Company location, a sale is recognized at the point in time when the customer obtains control of the product. Control is transferred to the customer in a bill-and-hold arrangement when: (i) customer acceptance specifications have been met, (ii) legal title has transferred, (iii) the customer has a present obligation to pay for the product and (iv) the risks and rewards of ownership have transferred to the customer. Additionally, all the following bill-and-hold criteria have to be met in order for control to be transferred to the customer:

- the reason for the bill-and-hold arrangement is substantive
- the customer has requested the product be warehoused
- the product has been identified as separately belonging to the customer
- the product is currently ready for physical transfer to the customer
- the Company does not have the ability to use the product or direct it to another customer.

The following table summarizes the Company's revenue recognized in its unaudited condensed consolidated statements of operations:

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2025	2024	2025	2024
Product revenue	$ -	$ 230,700	$ 300,000	$ 300,000
Royalty revenue	11,800	2,900	40,100	57,700
	$ 11,800	$ 233,600	$ 340,100	$ 357,700

Net Loss Per Common Share

Net loss per share is computed by dividing net loss by the weighted average number of shares of common stock outstanding during the year. All outstanding options and warrants are considered potential common stock. For the three and nine months ended September 30, 2025, the Company had 1,138,055 shares held in abeyance included in basic loss per share given that they are issuable for no additional consideration. For the three and nine months ended September 30, 2024, the Company had 1,201,580 shares held in abeyance included in basic loss per share given that they are issuable for no additional consideration (see Note 4 – Stockholders' Equity for additional details). The dilutive effect, if any, of stock options and warrants are calculated using the treasury stock method. All outstanding convertible preferred stock is considered common stock at the beginning of the period or at the time of issuance, if later, pursuant to the if-converted method. Since the effect of common stock equivalents is anti-dilutive with respect to losses, options, warrants, restricted stock units ("RSUs") and convertible preferred stock have been excluded from the Company's computation of diluted net loss per common share for the three and nine months ended September 30, 2025 and 2024.

The following table summarizes the securities that were excluded from the diluted per share calculation because the effect of including these potential shares was antidilutive due to the Company's net loss position even though the exercise or conversion price could be less than the average market price of the common shares:

	For the Three and Nine Months Ended September 30,	
	2025	**2024**
Stock options	5,262,973	3,401,608
Warrants	3,951,384	3,952,504
Convertible Preferred Stock	1,398,158	1,398,158
	10,612,515	8,752,270

Segment Reporting

Operating segments are defined as components of an enterprise about which separate discrete information is available for evaluation by the chief operating decision-maker ("CODM"), or decision-making group, in deciding how to allocate resources and in assessing performance. The Company has one operating and reporting segment (BioRestorative Therapies, Inc.) which develops therapeutic products and medical therapies using cell and tissue protocols, primarily involving adult stem cells. The Company's Chief Executive Officer serves as the CODM and reviews financial information presented on a consolidated basis to make operational decisions and evaluate financial performance. The CODM reviews profit and loss information on a consolidated basis, as presented in the statement of operations. Disaggregated expense data beyond what is included in the unaudited condensed consolidated statements of operations is not provided to the CODM. Since the Company's operations consist of a single reporting segment, the segment assets are presented on the accompanying unaudited condensed consolidated balance sheets as total assets.

Recently Issued Accounting Pronouncements

In December 2023, the FASB issued ASU No. 2023-09, "Income Taxes (Topic 740): Improvements to Income Tax Disclosures," ("ASU 2023-09"). The amendments in ASU 2023-09 are designed to enhance the transparency of income tax disclosures by requiring consistent categories and greater disaggregation of information in the rate reconciliation, and income taxes paid disaggregated by jurisdiction. ASU 2023-09 is effective for fiscal years beginning after December 15, 2024, with early adoption permitted. The amendments in ASU 2023-09 should be applied on a prospective basis. Retrospective application is permitted. The Company is currently evaluating the impact of this update on its consolidated financial statements and related disclosures.

In November 2024, the FASB issued ASU No. 2024-03, "Income Statement - Reporting Comprehensive Income - Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses," ("ASU 2024-03"), which is intended to require more detailed disclosures about specified categories of expenses (including employee compensation, depreciation, and amortization) included in certain expense captions presented on the face of the income statement. ASU 2024-03 is effective for fiscal years beginning after December 15, 2026, and for interim periods within fiscal years beginning after December 15, 2027, with early adoption permitted. The amendments may be applied either (1) prospectively to financial statements issued for reporting periods after the effective date of ASU 2024-03 or (2) retrospectively to all prior periods presented in the financial statements. The Company is currently evaluating the potential impact of this update on its consolidated financial statements and related disclosures.

Tax Law Change

On July 4th, 2025, the President signed into law significant federal tax legislation, H.R.1 (the "Tax Reform Act of 2025"). The legislation includes numerous changes to U.S. corporate income tax law, including but not limited to: permanent 100% bonus depreciation for qualified property, immediate expensing of domestic research and experimental expenditures, modifications to the limitation on business interest expense, increased Section 179 expensing limits, changes to the international tax regime, and expanded limitations on the deductibility of executive compensation under IRC Section 162(m). Most provisions are effective for tax years beginning after December 31, 2024, with certain transition rules and exceptions. The Company does not expect the enactment of the Tax Reform Act of 2025 to have a material impact on its consolidated financial statements.

NOTE 3 - ACCRUED EXPENSES AND OTHER CURRENT LIABILITIES

Accrued expenses and other current liabilities consist of:

	September 30 , 2025	December 31, 2024
Accrued bonuses	$ 538,875	$ 704,000
Accrued general and administrative expenses	68,595	40,485
Total accrued expenses and other current liabilities	$ 607,470	$ 744,485

NOTE 4 - STOCKHOLDERS' EQUITY

Warrant Exercise and Issuance

On February 6, 2024, the Company entered into agreements with certain holders of its existing warrants exercisable for an aggregate of 3,351,580 shares of its Common Stock (collectively, the "Existing Warrants"), to exercise their warrants at a reduced exercise price of $2.33 per share, in exchange for the issuance of new warrants (the "New Warrants") as described below (the "Warrant Exercise and Issuance"). The aggregate gross proceeds from the exercise of the Existing Warrants and the payment of the New Warrants, as described below, was approximately $8.1 million, before deducting cash issuance costs in the amount of $595,364. The reduction of the exercise price of the Existing Warrants and the issuance of the New Warrants was structured as an at-market transaction under Nasdaq rules. Of the 3,351,580 shares of Common Stock underlying the Existing Warrants, 1,201,580 shares issuable to Auctus Fund, LLC ("Auctus") were held in abeyance as of December 31, 2024, due to Auctus' maximum beneficial ownership limitation (the "Abeyance Shares"). On March 20, 2025, the Company issued 63,525 of these shares, reducing the remaining Abeyance Shares to 1,138,055. As of September 30, 2025, the Company had issued an aggregate of 2,213,525 shares of Common Stock. Such Abeyance Shares have been fully paid for and are issuable upon notice from Auctus to the Company. See Note 6 – Subsequent Events – for additional details regarding shares issued to Auctus subsequent to September 30, 2025.

In consideration for the immediate exercise of the Existing Warrants for cash and the payment of $0.125 per share underlying the New Warrants, the exercising holders received the New Warrants to purchase shares of Common Stock in a private placement pursuant to Section 4(a)(2) of the Securities Act of 1933, as amended (the "Securities Act"). The New Warrants will be exercisable for a period of five years into an aggregate of 2,513,686 shares of Common Stock at an exercise price of $2.43 per share. The securities offered in the private placement have not been registered under the Securities Act or applicable state securities laws. Accordingly, the securities may not be offered or sold in the United States except pursuant to an effective registration statement or an applicable exemption from the registration requirements of the Securities Act and such applicable state securities laws. As part of the transaction, the Company agreed to file a resale registration statement with the SEC to register the resale of the shares of Common Stock underlying the New Warrants issued in the private placement. Such resale registration statement was filed and was declared effective by the SEC on April 18, 2024. In connection with the transaction described above, the Company entered into a financial advisory services agreement, dated February 5, 2024, with Roth Capital Partners, LLC ("Roth"), pursuant to which the Company has paid Roth a cash fee of approximately $528,000 for its services, in addition to reimbursement for certain expense. During the nine months ended September 30, 2024, the Company incurred an aggregate of $595,364 of cash issuance costs related to the Warrant Exercise and Issuance.

Prior to the Warrant Exercise and Issuance, the Existing Warrants were classified as derivative liabilities. Additionally, the Company analyzed the form of the New Warrants and determined that they should be classified as derivative liabilities in accordance with ASC 815-40, Derivatives and Hedging — Contracts in Entity's Own Equity. Under the New Warrants, the Company does not control the occurrence of events, such as a tender offer or exchange, that may trigger cash settlement of the New Warrants and not result in a change of control of the Company. As a result, such New Warrants do not meet the criteria for equity treatment. Additionally, certain New Warrants contain adjustments to the settlement amount based on a variable that is not an input to the fair value of a "fixed-for-fixed" option as defined under ASC 815-40 and, accordingly, such New Warrants are not considered indexed to the Company's own stock and are not eligible for an exception from derivative accounting. See Note 5 – Fair Value Measurement for details regarding the valuation of warrants accounted for as derivative liabilities.

Warrants

See Note 5 – Fair Value of Financial Instruments for details regarding the valuation of warrants accounted for as derivative liabilities.

A summary of the Company's warrant activity and related information follows:

	Number of Warrants	Weighted Average Exercise Price	Weighted Average Remaining Life In Years
Outstanding, January 1, 2025	3,951,634	$ 5.22	
Expired	(250)	60.00	
Outstanding, September 30, 2025	3,951,384	$ 5.21	2.55
Exercisable, September 30, 2025	3,951,384	$ 5.21	2.55

Stock Options

On February 14, 2025, the Company granted options to purchase an aggregate of 2,152,908 shares of the Company's common stock at an exercise price of $2.46 per share to employees, the Company's board of directors and a member of the Company's Scientific Advisory Board. The options had an aggregate grant date fair value of $4,044,250 and vest as follows: (i) options to purchase an aggregate 323,459 shares of common stock vest monthly over one year, and (ii) options to purchase an aggregate of 1,829,449 shares of common stock vest to the extent of 50% immediately with the remainder vesting quarterly over two years commencing one year from the date of grant. The Company is recognizing the grant date fair value of the options on a straight-line basis over the vesting period.

On June 5, 2025, the Company granted an option to purchase 25,000 shares of the Company's common stock at an exercise price of $1.78 per share to an employee. The option had a grant date fair value of $34,250 and vests to the extent of 50% immediately with the remainder vesting quarterly over two years commencing one year from the date of grant. The Company is recognizing the grant date fair value of the option on a straight-line basis over the vesting period.

On October 13, 2025, the Company granted an option to purchase 25,000 shares of the Company's common stock at an exercise price of $1.62 per share to an employee. See Note 6 – Subsequent Events for additional details.

In applying the Black-Scholes option pricing model to stock options granted, the Company used the following assumptions:

	For the Nine Months Ended September 30,	
	2025	**2024**
Risk free interest rate	4.03 - 4.40%	4.14 - 4.30%
Expected term (years)	2.77 - 5.38	2.77 - 5.38
Expected volatility	98.14 - 99.22%	101 - 102%
Expected dividends	0.00%	0.00%

There were no stock options granted during the three months ended September 30, 2025 or 2024. Options granted during the nine months ended September 30, 2025 and 2024 had a weighted average grant date fair value per share of $1.87 and $1.11 per share, respectively.

A summary of the stock option activity during the nine months ended September 30, 2025 is presented below:

	Number of Options	**Weighted Average Exercise Price**	**Weighted Average Remaining Life In Years**	**Intrinsic Value**
Outstanding, January 1, 2025	3,263,467	$ 2.63		
Granted	2,177,908	2.45		
Exercised	(29,249)	1.45		
Forfeited	(149,153)	2.23		
Outstanding, September 30, 2025	5,262,973	$ 2.58	7.8	$ -
Exercisable, September 30, 2025	3,805,964	$ 2.72	7.3	$ -

Stock-Based Compensation Expense

The following table presents information related to stock-based compensation expense:

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,		Unrecognized at September 30, 2025	Weighted Average Remaining Amortization Period (Years)
	2025	2024	2025	2024		
Research and development	$ 175,398	$ 133,333	$ 1,308,322	$ 1,314,298		
General and administrative	$ 224,535	$ 150,912	$ 1,569,444	$ 1,322,643		
Total	$ 399,932	$ 284,245	$ 2,877,766	$ 2,636,941	$ 1,878,612	1.76

The following table presents stock-based compensation by award type:

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2025	2024	2025	2024
Options	$ 399,932	$ 284,245	$ 2,877,766	$ 1,651,903
RSUs	-	-	-	985,038
Total	$ 399,932	$ 284,245	$ 2,877,766	$ 2,636,941

ATM Sales

During the three months ended September 30, 2025, there were no sales of common stock under the 2024 ATM. During the nine months ended September 30, 2025, the Company sold 965,424 shares of its common stock under the 2024 ATM, generating gross proceeds of $2,011,250. For the nine months ended September 30, 2025, the total commissions and related legal and accounting fees incurred were $72,805, resulting in net proceeds of $1,938,445. During the nine months ended September 30, 2025, the Company reclassified previously capitalized deferred offering costs of $148,697 to additional paid-in capital.

Common Stock Repurchase Program

On June 16, 2025, the Company's Board of Directors authorized a common stock repurchase program under which the Company may repurchase up to $2,000,000 of its outstanding common stock through June 16, 2026. No repurchases have been made as of September 30, 2025.

Common Stock Issuances

During the three months ended September 30, 2025, there were no issuances of common stock by the Company.

During the nine months ended September 30, 2025, the Company issued 63,525 shares of common stock to Auctus Fund, LLC in partial satisfaction of shares held in abeyance.

During the nine months ended September 30, 2025, the Company issued 29,249 shares of common stock related to the exercise of an option at an exercise price of $1.45 per share, which resulted in gross cash proceeds to the Company of $42,411.

NOTE 5 – FAIR VALUE MEASUREMENT

On September 30, 2025 and December 31, 2024, the Company estimated the aggregate fair value of warrants that are accounted for as warrant liabilities to be $1,968,315 and $2,520,851, respectively, using the Black-Scholes option price model (Level 3 inputs). The Company recognized a gain on the change in fair value of these warrant liabilities of $612,064 and $552,536 for the three and nine months ended September 30, 2025, respectively. The Company recognized a gain (loss) on the change in fair value of these warrant liabilities of $1,036,464 and ($837,466) for the three and nine months ended September 30, 2024, respectively. The following table shows the detail of the valuation assumptions used as of September 30, 2025:

	September 30, 2025
Risk free interest rate	3.63%-3.68%
Expected term (years)	1.11 - 3.36
Expected volatility	71% - 95%
Expected dividends	0.00%

The following table sets forth a summary of the changes in the fair value of Level 3 liabilities that are measured at fair value on a recurring basis during the three months ended September 30, 2025 and three months ended September 30, 2024:

	For the Three Months Ended September 30,	
	2025	2024
Balance, July 1,	$ 2,580,379	$ 4,491,969
Change in fair value of warrant liability	(612,064)	(1,036,464)
Balance, September 30,	$ 1,968,315	$ 3,455,505

The following table sets forth a summary of the changes in the fair value of Level 3 liabilities that are measured at fair value on a recurring basis during the nine months ended September 30, 2025 and nine months ended September 30, 2024:

	For the Nine Months ended September 30,	
	2025	2024
Balance, January 1,	$ 2,520,851	$ 2,618,039
Change in fair value of warrant liability	(552,536)	837,466
Balance, September 30,	$ 1,968,315	$ 3,455,505

Assets and liabilities measured at fair value on a recurring basis are as follows:

	Fair value measurements at reporting date using:			
	Quoted prices in active markets for identical liabilities (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)	Total Fair Value
Assets:				
Marketable securities as of September 30, 2025	$ 3,887,383	$ -	$ -	$ 3,887,383
Marketable securities as of December 31, 2024	$ 10,184,701	$ -	$ -	$ 10,184,701
Liabilities:				
Warrant liabilities as of September 30, 2025	$ -	$ -	$ 1,968,315	$ 1,968,315
Warrant liabilities as of December 31, 2024	$ -	$ -	$ 2,520,851	$ 2,520,851

NOTE 6 – SUBSEQUENT EVENTS

Registered Offering and Private Placement

On October 6, 2025, the Company entered into subscription agreements (the "Subscription Agreements") with several investors (the "Purchasers") pursuant to which the Company agreed to sell and issue to the Purchasers an aggregate of 678,125 shares of the Company's common stock in a registered direct offering at an offering price of $1.60 per share (the "Registered Offering") for aggregate gross proceeds of approximately $1.1 million. Pursuant to the Subscription Agreements, in a concurrent private placement offering (the "Private Placement"), the Company agreed to issue to the Purchasers unregistered warrants to purchase up to an aggregate of 508,592 shares of the Company's common stock at an exercise price of $2.75 per share. The Registered Offering and the Private Placement closed on October 8, 2025.

In connection with the offering, the Company entered into an engagement letter, dated August 11, 2025, with Alere Financial Partners (a division of Cova Capital Partners, LLC) (the "Placement Agent"), pursuant to which the Company agreed to pay the Placement Agent a cash fee equal to 6% of the gross proceeds of the offering from investors introduced to the Company by the Placement Agent (the "Placement Agent Investors") (4% for other investors). The Company has also agreed to reimburse the Placement Agent approximately $8,300 for out-of-pocket expenses for legal fees and other expenses. In addition, the Company agreed to issue to the Placement Agent, at the closing of the offering, a warrant exercisable commencing six months from the date of issuance until the five year anniversary of the date of issuance to purchase up to 6% of the number of Shares sold in the Registered Offering to Placement Agent Investors (4% for other investors), at a per share exercise price of $2.75.

Option Grants

On October 13, 2025, the Company granted an option to purchase 25,000 shares of the Company's common stock at an exercise price of $1.62 per share to an employee. The option vests as follows: (i) 50% immediately, and (ii) the remainder quarterly over two years commencing one year from the date of grant. The Company will recognize the grant date fair value of the option on a straight-line basis over vesting period.

Common Stock Issuance

On October 27, 2025, the Company issued 220,000 shares of common stock to Auctus Fund, LLC in partial satisfaction of shares held by abeyance.

Report of Independent Registered Public Accounting Firm

To the Stockholders and Board of Directors of
BioRestorative Therapies, Inc.

Opinion on the Financial Statements

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

Explanatory Paragraph – Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As more fully described in Note 1, the Company has incurred significant losses and negative cash flows from operations, and needs to raise additional funds to meet its obligations and sustain its operations. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

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

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

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

Critical Audit Matters

Critical audit matters are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. We determined that there are no critical audit matters.

/s/ Marcum LLP

Marcum LLP

We have served as the Company's auditor since 2020**.**

Marlton, New Jersey
March 27, 2025

BIORESTORATIVE THERAPIES, INC.
CONSOLIDATED BALANCE SHEETS

	December 31, 2024	December 31, 2023
Assets		
Current Assets:		
Cash and cash equivalents	$ 547,890	$ 884,377
Investments held in marketable securities	10,184,701	10,181,618
Accounts receivable	188,400	19,300
Prepaid expenses and other current assets	223,230	305,231
Total Current Assets	11,144,221	11,390,526
Deferred offering costs	148,697	-
Property and equipment, net	362,936	356,055
Right-of-use assets	-	151,447
Intangible assets, net	623,945	713,692
Total Assets	$ 12,279,799	$ 12,611,720
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable	$ 483,070	$ 189,389
Accrued expenses and other current liabilities	744,485	711,686
Lease liability	-	162,317
Warrant liabilities	2,520,851	1,543,953
Total Current Liabilities	3,748,406	2,607,345
Total Liabilities	3,748,406	2,607,345
Commitments and contingencies		
Stockholders' Equity:		
Preferred stock, $0.01 par value; 20,000,000 shares authorized;		
Series B Convertible Preferred Stock; 1,543,158 shares designated, 1,398,158 shares issued and outstanding at December 31, 2024 and 2023.	13,982	13,982
Common stock, $0.0001 par value; 75,000,000 shares authorized; 6,919,919 and 4,706,917 shares issued and outstanding at December 31, 2024 and 2023, respectively	692	471
Additional paid-in capital	164,195,434	156,689,256
Accumulated deficit	(155,678,715)	(146,699,334)
Total Stockholders' Equity	8,531,393	10,004,375
Total Liabilities and Stockholders' Equity	$ 12,279,799	$ 12,611,720

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

BIORESTORATIVE THERAPIES, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS

	For the Years Ended December 31,	
	2024	**2023**
Revenues, net	$ 401,000	$ 145,800
Cost of revenues	28,072	-
Gross profit	372,928	145,800
Operating Expenses:		
Research and development	5,348,709	4,034,591
General and administrative	6,579,413	11,331,983
Total Operating Expenses	11,928,122	15,366,574
Loss From Operations	(11,555,194)	(15,220,774)
Other Income:		
Interest income	616,077	552,293
Grant income	-	83,333
Other income	150,850	169,664
Gain on exchange of warrants	1,711,698	-
Change in fair value of warrant liabilities	97,188	3,997,780
Total Other Income	2,575,813	4,803,070
Net Loss	$ (8,979,381)	$ (10,417,704)
Net Loss Per Share - Basic and Diluted	$ (1.16)	$ (2.47)
Weighted Average Common Shares Outstanding - Basic and Diluted	7,763,932	4,218,347

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

BIORESTORATIVE THERAPIES, INC.
CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY
FOR THE YEARS ENDED DECEMBER 31, 2024 AND 2023

	Series B Convertible Preferred Stock		Common Stock		Additional Paid-In	Accumulated	
	Shares	Amount	Shares	Amount	Capital	Deficit	Total
Balance - January 1, 2023	1,518,158	$ 15,182	3,677,775	$ 369	$ 146,556,418	$ (136,281,630)	$ 10,290,339
Stock-based compensation:							
Restricted share units	-	-	89,840	9	4,633,655	-	4,633,664
Options	-	-	-	-	3,141,803	-	3,141,803
Common stock	-	-	1,442	-	7,500	-	7,500
Conversion of Series B Convertible Preferred Stock into common stock	(120,000)	(1,200)	120,000	12	1,188	-	-
Issuance and sale of common stock, net of issuance costs	-	-	817,860	81	2,348,692	-	2,348,773
Net loss	-	-	-	-	-	(10,417,704)	(10,417,704)
Balance - December 31, 2023	1,398,158	$ 13,982	4,706,917	$ 471	$ 156,689,256	$ (146,699,334)	$ 10,004,375
Common stock issued in connection with warrant exchange [1]	-	-	2,000,000	200	4,742,043	-	4,742,243
Return and cancellation of shares in lieu of payroll tax withholding	-	-	(34,825)	(4)	(48,406)	-	(48,410)
Common stock issued in connection with abeyance shares	-	-	150,000	15	(15)	-	-
Stock-based compensation:							
Restricted share units	-	-	97,827	10	985,028	-	985,038
Options	-	-	-	-	1,827,528	-	1,827,528
Net loss	-	-	-	-	-	(8,979,381)	(8,979,381)
Balance - December 31, 2024	1,398,158	$ 13,982	6,919,919	$ 692	$ 164,195,434	$ (155,678,715)	$ 8,531,393

[1]Represents the aggregate fair value of 3,351,580 shares of common stock, which includes 2,150,000 shares that have been issued and 1,201,580 shares held in abeyance. See Note 6 - Stockholders' Equity - Warrant Exercise and Issuance and Note 9 - Fair Value Measurement for additional details.

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

BIORESTORATIVE THERAPIES, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS

	For the Years Ended December 31,	
	2024	**2023**
Cash Flows From Operating Activities:		
Net loss	$ (8,979,381)	$ (10,417,704)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	189,056	165,735
Dividend and interest income	(623,801)	(569,068)
Stock-based compensation	2,812,566	7,782,967
Non-cash lease expense	151,447	90,313
Gain on exchange of warrants	(1,711,698)	-
Change in fair value of warrant liabilities	(97,188)	(3,997,780)
Changes in operating assets and liabilities:		
Accounts receivable	(169,100)	(3,300)
Prepaid expenses and other current assets	33,591	57,851
Accounts payable	293,680	18,487
Accrued expenses and other current liabilities	32,799	581,616
Lease liability	(162,317)	(139,328)
Net Cash Used In Operating Activities	(8,230,346)	(6,430,211)
Cash Flows From Investing Activities:		
Sale of marketable securities	21,508,641	20,964,373
Purchase of marketable securities	(20,887,923)	(17,541,287)
Purchases of equipment	(106,189)	(171,043)
Net Cash Provided By Investing Activities	514,529	3,252,043
Cash Flows From Financing Activities:		
Net proceeds from issuance of common stock in at-the-market offering	-	494,783
Net proceeds from issuance of common stock in direct-offering	-	1,853,990
Proceeds from exchange and issuance of warrants, net [1]	7,528,027	-
Deferred offering costs	(148,697)	-
Net Cash Provided By Financing Activities	7,379,330	2,348,773
Net Decrease In Cash and Cash Equivalents	(336,487)	(829,395)
Cash and Cash Equivalents - Beginning of the Year	884,377	1,713,772
Cash and Cash Equivalents - End of the Year	$ 547,890	$ 884,377
Supplemental Disclosures of Cash Flow Information:		
Cash paid during the year for:		
Interest	$ -	$ -
Income taxes	$ -	$ -
Non-cash investing and financing activities:		
Issuance of common stock held in abeyance	$ 15	$ -
Return and cancellation of shares in lieu of payroll tax withholding	$ 48,410	$ 39,308

[1]Includes gross proceeds of $8,123,391, less issuance costs of $595,364.

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

NOTE 1 - ORGANIZATION, LIQUIDITY, GOING CONCERN AND BUSINESS OPERATIONS

Corporate History

BioRestorative Therapies, Inc. has one wholly-owned subsidiary, Stem Pearls, LLC ("Stem Pearls"). BioRestorative Therapies, Inc. and its subsidiary are referred to collectively as "BRT" or the "Company".

On December 23, 2022, the Company reincorporated from Delaware to Nevada by filing Articles of Incorporation with the state of Nevada. The reincorporation was structured as a statutory merger.

Liquidity and Going Concern

The accompanying consolidated financial statements have been prepared on the basis that the Company will continue as a going concern, which contemplates realization of assets and satisfying liabilities in the normal course of business. For the year ended December 31, 2024, the Company had a net loss of $9.0 million, negative cash flows from operations of $8.2 million and working capital of $7.4 million. The Company anticipates that it will continue to incur net losses and negative cash flows from operations as it executes its development plans for 2025 and beyond, as well as other potential strategic and business development initiatives. These conditions raise substantial doubt about the Company's ability to continue as a going concern for at least twelve months after the issuance date of these financial statements.

The Company has previously funded, and plans to continue funding, these losses primarily through current cash on hand, investments in marketable securities and additional infusions of cash from equity and debt financing. During the year ended December 31, 2024, the Company raised net proceeds of approximately $7.5 million in connection with a warrant exercise program which is further discussed in Note 6 – Stockholders' Equity. On November 6, 2024, the Company entered into an at-the-market offering agreement (the "2024 ATM") pursuant to which the Company has an ability to issue and sell shares of its common stock up to an aggregate offering price of $3,614,170. Subsequent to December 31, 2024, the Company sold 492,000 shares of its common stock under the 2024 ATM and raised approximately $1,084,000 of gross proceeds See Note 10 – Subsequent Events for additional details regarding sales of the Company's common under the 2024 ATM subsequent to December 31, 2024.

The Company's current funds will not be sufficient to enable the Company to fully complete its development activities or attain profitable operations. If the Company is unable to obtain such needed additional financing on a timely basis, the Company may have to curtail its development, marketing and promotional activities, which would have a material adverse effect on the Company's business, financial condition and results of operations, and ultimately the Company could be forced to discontinue its operations and liquidate.

The accompanying consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("U.S. GAAP"), which contemplate continuation of the Company as a going concern and the realization of assets and satisfaction of liabilities in the normal course of business. The carrying amounts of assets and liabilities presented in the consolidated financial statements do not necessarily purport to represent realizable or settlement values. The accompanying consolidated financial statements do not include any adjustments that might be necessary should the Company be unable to continue as a going concern.

Business Operations

BRT develops therapeutic products and medical therapies using cell and tissue protocols, primarily involving adult stem cells. BRT's website is at www.biorestorative.com. The information contained in the website or connected thereto is not intended to be incorporated by reference into this Annual Report. BRT is currently developing a Disc/Spine Program referred to as "brtxDISC". Its lead cell therapy candidate, BRTX-100, is a product formulated from autologous (or a person's own) cultured mesenchymal stem cells collected from the patient's bone marrow. The product is intended to be used for the non-surgical treatment of painful lumbosacral disc disorders or as a complimentary therapeutic to a surgical procedure. BRT is also engaging in research efforts with respect to a platform technology utilizing brown adipose (fat) for therapeutic purposes to treat type 2 diabetes, obesity and other metabolic disorders and has labeled this initiative its ThermoStem Program. In addition, in continuation of BRT's mission of developing and commercializing cell-based biologics, it is seeking to develop a biologics-based cosmetic products business. Pursuant to such business, BRT would formulate, manufacture and sell products designed for cosmetic and aesthetic uses. Further, BRT has licensed a patented curved needle device that is a needle system designed to deliver cells and/or other therapeutic products or material to the spine and discs or other potential sites.

NOTE 2 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The accompanying consolidated financial statements have been prepared in accordance with U.S. GAAP. The summary of significant accounting policies presented below is designed to assist in understanding the Company's consolidated financial statements. Such consolidated financial statements and accompanying notes are the representations of Company's management, who is responsible for their integrity and objectivity.

Principles of Consolidation

The consolidated financial statements include the accounts of the Company and its wholly-owned subsidiary, Stem Pearls. All intercompany accounts and transactions have been eliminated in consolidation.

Use of Estimates

The preparation of the consolidated financial statements in conformity with U.S. GAAP requires management to make estimates, judgments and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses, together with amounts disclosed in the related notes to the financial statements. The Company bases its estimates and assumptions on historical experience, known or expected trends and various other assumptions that it believes to be reasonable. As future events and their effects cannot be determined with precision, actual results could differ from these estimates which may cause the Company's future results to be affected.

Segment Reporting

Operating segments are defined as components of an enterprise about which separate discrete information is available for evaluation by the chief operating decision-maker ("CODM"), or decision-making group, in deciding how to allocate resources and in assessing performance. The Company has one operating and reporting segment (BioRestorative Therapies, Inc.) which develops therapeutic products and medical therapies using cell and tissue protocols, primarily involving adult stem cells. The Company's Chief Executive Officer, serves as the CODM and reviews financial information presented on a consolidated basis to make operational decisions and evaluate financial performance. The CODM reviews profit and loss information on a consolidated basis, as presented in the statement of operations. Disaggregated expense data beyond what is included in the consolidated statements of operations is not provided to the CODM. Since the Company's operations consist of a single reporting segment, the segment assets are presented on the accompanying consolidated balance sheet as total assets.

Revenue Recognition

The Company recognizes revenue in accordance with ASC Topic 606, "Revenue from Contracts with Customers" ("ASC 606"). The core principle of ASC 606 requires that an entity recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. ASC 606 defines a five-step process to achieve this core principle and, in doing so, it is possible more judgment and estimates may be required within the revenue recognition process, including identifying performance obligations in the contract, estimating the amount of variable consideration to include in the transaction price and allocating the transaction price to each separate performance obligation. The Company recognizes revenue primarily from the following different types of contracts:

- **Product sales** - Revenue is recognized at the point in time the customer obtains control of the goods and the Company satisfies its performance obligation.
- **Royalty revenue** - Revenue is recognized as a usage-based royalty from customers' usage of intellectual property pursuant to a license agreement at the point in time in which the underlying sale occurs.

The Company recognizes bill-and-hold revenue from its sale of cosmetic vials warehoused at a Company location for a specified period of time in accordance with directions received from the Company's customer. Even though the vials are held at a Company location, a sale is recognized at the point in time when the customer obtains control of the product. Control is transferred to the customer in a bill-and-hold arrangement when: (i) customer acceptance specifications have been met, (ii) legal title has transferred, (iii) the customer has a present obligation to pay for the product and (iv) the risks and rewards of ownership have transferred to the customer. Additionally, all the following bill-and-hold criteria have to be met in order for control to be transferred to the customer:

- the reason for the bill-and-hold arrangement is substantive
- the customer has requested the product be warehoused
- the product has been identified as separately belonging to the customer
- the product is currently ready for physical transfer to the customer
- the Company does not have the ability to use the product or direct it to another customer.

The following table summarizes the Company's revenue recognized in its consolidated statements of operations:

	For the Years Ended December 31,	
	2024	**2023**
Product revenue	$ 300,000	$ -
Royalty revenue	101,000	145,800
	$ 401,000	$ 145,800

Cash and Cash Equivalents

Financial instruments that potentially subject the Company to concentrations of credit risk consist of a cash account in a financial institution. The Company maintains deposits in its accounts that hold cash and cash equivalents in excess of the Federal Depository Insurance Corporation ("FDIC") coverage of $250,000 per banking institution. The Company had deposits in excess of FDIC coverage of $252,801 and $604,226 as of December 31, 2024 and 2023, respectively. As of December 31, 2024, the Company has not experienced losses on this account.

Customer and Revenue Concentrations

All of the Company's royalty revenue is derived from one customer. Additionally, all of the Company's product sales revenue is derived from one customer.

Accounts Receivable

Accounts receivable are carried at their contractual amounts, less an estimate for credit losses. As of December 31, 2024 and 2023, no allowances for credit losses were determined to be necessary. Management estimates the allowance for credit losses based on existing economic conditions, the financial conditions of the customers, and the amount and age of past due accounts. Receivables are considered past due if full payment is not received by the contractual due date. Past due accounts are generally written off against the allowance for credit losses only after all collection attempts have been exhausted.

Deferred Contract Costs

The Company defers costs associated with fulfilling its contracts if those costs meet all of the following criteria: (i) the costs relate directly to a contract, (ii) the costs generate or enhance resources of the Company that will be used in satisfying performance obligations in the future, and (iii) the costs are expected to be recovered. Deferred contract costs are recognized as cost of revenues in the period when the related revenue is recognized. Deferred contract costs consist of consumables and labor costs and are included within prepaid & other current assets in the consolidated balance sheets. The Company had $10,250 and $0 deferred contract costs as of December 31, 2024 and 2023, respectively.

Deferred Offering Costs

Deferred offering costs, which primarily consist of direct, incremental professional fees incurred in connection with a financing, are capitalized as non-current assets on the balance sheet. Upon consummation of a financing, the deferred offering costs would be offset against the offering proceeds. If the completion of a contemplated financing was no longer probable, the related deferred offering costs would be charged to general and administrative expense in the consolidated financial statements. The Company had $148,697 and $0 deferred offering costs as of December 31, 2024 and 2023, respectively.

Property and Equipment

Property and equipment are recorded at cost. Depreciation is computed using straight-line method over the estimated useful lives of the related assets, generally three to fifteen years. Expenditures that enhance the useful lives of the assets are capitalized and depreciated. Computer equipment costs are capitalized, as incurred, and depreciated on a straight-line basis over a range of 3 years. Medical equipment costs are capitalized and depreciated over 5 years, while furniture and fixtures are depreciated over 4 years. Office equipment is depreciated over a period of 3 to 5 years, and manufacturing equipment over 4 to 5 years.

Leasehold improvements are amortized over the lesser of (i) the useful life of the asset, or (ii) the remaining lease term. Maintenance and repairs are charged to expense as incurred. The Company capitalizes cost attributable to the betterment of property and equipment when such betterment extends the useful life of the assets. At the time of retirement or other disposition of property and equipment, the cost and accumulated depreciation will be removed from the accounts and the resulting gain or loss, if any, will be reflected in operations.

Intangible Assets

The Company records its intangible assets at cost in accordance with ASC 350, *Intangibles - Goodwill and Other*. Definite lived intangible assets are amortized over their estimated useful life using the straight-line method, which is determined by identifying the period over which the cash flows from the asset are expected to be generated.

Impairment of Long-Lived Assets

The Company reviews long-lived assets, including definite-lived intangible assets and right-of-use assets from operating leases, for impairment whenever events or changes in circumstances indicate that the carrying amount of such assets may not be recoverable. Recoverability of these assets is determined by comparing the forecasted undiscounted net cash flows of the operation to which the assets relate to the carrying amount. If the operation is determined to be unable to recover the carrying amount of its assets, then these assets are written down first, followed by other long-lived assets of the operation to fair value. Fair value is determined based on discounted cash flows or appraised values, depending on the nature of the assets. For the years ended December 31, 2024 and 2023, the Company determined that there was no impairment charge for its long-lived assets.

Warrant and Option Valuation

The Company has computed the fair value of warrants and options granted using the Black-Scholes option pricing model. The expected term used for warrants and options issued to non-employees is the contractual life and the expected term used for options issued to employees and directors is the estimated period of time that options granted are expected to be outstanding. The Company utilizes the “simplified” method to develop an estimate of the expected term of “plain vanilla” employee option grants. The Company is utilizing an expected volatility figure based on a review of the historical volatilities, over a period of time, equivalent to the expected life of the instrument being valued, of similarly positioned public companies within its industry blended with the Company’s historical volatility. The risk-free interest rate was determined from the implied yields from U.S. Treasury zero-coupon bonds with a remaining term consistent with the expected term of the instrument being valued.

Derivative Financial Instruments

The Company evaluates all of its agreements to determine if such instruments have derivatives or contain features that qualify as embedded derivatives. For derivative financial instruments that are accounted for as liabilities, the derivative instrument is initially recorded at its fair value and is then re-valued at each reporting date, with changes in the fair value reported in the statements of operations. For stock-based derivative financial instruments, the Company uses a weighted-average Black-Scholes option pricing model to value the derivative instruments at inception and on subsequent valuation dates. The classification of derivative instruments, including whether such instruments should be recorded as liabilities or as equity, is evaluated at the end of each reporting period.

Fair Value of Financial Instruments

Fair value is defined as the amount that would be received for selling an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date and is measured using inputs in one of the following three categories:

Level 1 measurements are based on unadjusted quoted prices in active markets for identical assets or liabilities that we have the ability to access. Valuation of these items does not entail a significant amount of judgment.

Level 2 measurements are based on quoted prices for similar assets or liabilities in active markets, quoted prices for identical or similar assets or liabilities in markets that are not active or market data other than quoted prices that are observable for the assets or liabilities.

Level 3 measurements are based on unobservable data that are supported by little or no market activity and are significant to the fair value of the assets or liabilities.

The Company considers cash and cash equivalents, investments held in marketable securities, accounts receivable, accounts payable and warrant liabilities to meet the definition of financial instruments. As of December 31, 2024 and 2023, the carrying amount of cash and cash equivalents, investments held in marketable securities, accounts receivable, and accounts payable approximate their fair value due to the relatively short period of time between their origination and their expected realization or payment. The warrant liabilities are measured at fair value (see Note 9 – Fair Value Measurement for additional details).

During the years ended December 31, 2024 and 2023, the Company recognized aggregate dividend and interest income of $623,801 and $569,068 respectively, on its marketable securities, which was included within other income on its consolidated statements of operations.

Net Loss per Common Share

Net loss per share is computed by dividing net loss by the weighted average number of shares of common stock outstanding during the year. All outstanding options and warrants are considered potential common stock. The Company has 1,201,580 shares held in abeyance included in basic loss per share given that they are issuable for no additional consideration (see Note 6 – Stockholders' Equity for additional details). The dilutive effect, if any, of stock options and warrants are calculated using the treasury stock method. All outstanding convertible preferred stock is considered common stock at the beginning of the period or at the time of issuance, if later, pursuant to the if-converted method. Since the effect of common stock equivalents is anti-dilutive with respect to losses, options, warrants, restricted stock units ("RSUs") and convertible preferred stock have been excluded from the Company's computation of diluted net loss per common share for the years ended December 31, 2024 and 2023.

The following table summarizes the securities that were excluded from the diluted per share calculation because the effect of including these potential shares was antidilutive due to the Company's net loss position even though the exercise or conversion price could be less than the average market price of the common shares:

	For the Years Ended December 31,	
	2024	**2023**
Stock options	3,263,467	1,466,892
Warrants	3,951,634	4,791,019
Unvested RSUs	-	97,827
Convertible Preferred Stock	1,398,158	1,398,158
	8,613,259	7,753,896

Stock-Based Compensation

The Company measures the cost of services received in exchange for an award of equity instruments based on the fair value of the award. The fair value of the award is measured on the grant date and then is recognized over the period during which services are required to be provided in exchange for the award, usually the vesting period, on a straight-line basis. The Company computes the fair value of equity-classified warrants and options granted using the Black-Scholes option pricing model. Option forfeitures are recorded as incurred as a reduction of amounts previously expensed.

Income Taxes

Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the consolidated financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax assets, including tax loss and credit carry forwards, and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date.

The Company utilizes ASC 740, "Income Taxes," which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the consolidated financial statements or tax returns. The Company accounts for income taxes using the asset and liability method to compute the differences between the tax basis of assets and liabilities and the related financial amounts, using currently enacted tax rates. A valuation allowance is recorded when it is "more likely-than-not" that a deferred tax asset will not be realized.

For uncertain tax positions that meet a "more likely than not" threshold, the Company recognizes the benefit of uncertain tax positions in the consolidated financial statements. The Company's practice is to recognize interest and penalties, if any, related to uncertain tax positions in income tax expense in the consolidated statements of operations.

Leases

The Company determines whether an arrangement is a lease at inception. Operating leases are included in operating lease right-of-use ("ROU") assets and operating lease liabilities in our consolidated balance sheets.

ROU assets represent the Company's right to use an underlying asset for the lease term and lease liabilities represent its obligation to make lease payments arising from the lease. ROU assets and liabilities are recognized at commencement date based on the present value of lease payments over the lease term. As most of the Company's leases do not provide an implicit rate, the Company uses its incremental borrowing rate based on the estimated rate of interest for collateralized borrowing over a similar term of the lease payments at commencement date. The operating lease ROU asset also includes any lease payments made and excludes lease incentives. The Company's lease terms may include options to extend or terminate the lease when it is reasonably certain that it will exercise the option. Lease expense for lease payments is recognized on a straight-line basis over the lease term.

Recently Adopted Accounting Pronouncements

In November 2023, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2023-07, "Improvements to Reportable Segments Disclosures (Topic 280)" ("ASU 2023-07"), which updates reportable segment disclosure requirements, primarily through enhanced disclosures about significant segment expenses on both an annual and interim basis. The guidance becomes effective for fiscal years beginning after December 15, 2023 and interim periods within fiscal years beginning after December 15, 2024, with early adoption permitted. The adoption of this accounting standard on a retrospective basis did not have a material impact on the Company's consolidated financial statements.

Recently Issued Accounting Pronouncements

In December 2023, the FASB issued ASU No. 2023-09, "Income Taxes (Topic 740): Improvements to Income Tax Disclosures," ("ASU 2023-09"). The amendments in ASU 2023-09 are designed to enhance the transparency of income tax disclosures by requiring consistent categories and greater disaggregation of information in the rate reconciliation, and income taxes paid disaggregated by jurisdiction. ASU 2023-09 is effective for fiscal years beginning after December 15, 2024, with early adoption permitted. The Company is currently evaluating the impact of this update on its consolidated financial statements and related disclosures.

In November 2024, the FASB issued ASU No. 2024-03, "Income Statement - Reporting Comprehensive Income - Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses," ("ASU 2024-03"), which is intended to require more detailed disclosures about specified categories of expenses (including employee compensation, depreciation, and amortization) included in certain expense captions presented on the face of the income statement. ASU 2024-03 is effective for fiscal years beginning after December 15, 2026, and for interim periods within fiscal years beginning after December 15, 2027, with early adoption permitted. The amendments may be applied either (1) prospectively to financial statements issued for reporting periods after the effective date of ASU 2024-03 or (2) retrospectively to all prior periods presented in the financial statements. The Company is currently evaluating the potential impact of this update on its consolidated financial statements and related disclosures.

NOTE 3 - PROPERTY AND EQUIPMENT

Property and equipment consists of the following:

	December 31,	
	2024	**2023**
Medical equipment	$ 352,133	$ 352,133
Furniture and fixtures	123,486	123,486
Computer software and equipment	136,205	136,205
Office equipment	18,779	18,779
Manufacturing equipment	501,421	395,232
Leasehold improvements	342,048	342,048
	1,474,072	1,367,883
Less: accumulated depreciation	(1,111,136)	(1,011,828)
Property and equipment, net	$ 362,936	$ 356,055

Total depreciation expense for the years ended December 31, 2024 and 2023 was $99,309 and $75,989, respectively. Depreciation expense is reflected in general and administrative expenses and research and development expenses in the consolidated statements of operations.

NOTE 4 - INTANGIBLE ASSETS

The Company is a party to a license agreement with the SCTC (as amended) (the "SCTC Agreement"). Pursuant to the SCTC Agreement, the Company obtained, among other things, a worldwide (excluding Asia and Argentina), exclusive, royalty-bearing license from the SCTC to utilize or sublicense a certain method for culturing cells and a worldwide, exclusive, royalty-bearing license from the SCTC to utilize or sublicense a certain medical device patent for the administration of specific cells and/or cell products to the disc and/or spine (and other parts of the body).

In February 2017, the Company received authorization from the Food and Drug Administration (the "FDA") to proceed with a Phase 2 clinical trial. In February 2022, the Company announced that the United States Patent and Trademark Office issued a notice of allowance for a patent application relating to the Company's BRTX-100 clinical program. This patent was issued in March 2022.

Intangible assets consist of the following:

	Patents and Trademarks	Licenses	Accumulated Amortization	Total
Balance as of January 1, 2023	$ 3,676	$ 1,593,530	$ (793,768)	$ 803,438
Amortization expense	-	-	(89,746)	(89,746)
Balance as of December 31, 2023	3,676	1,593,530	(883,514)	713,692
Amortization expense	-	-	(89,747)	(89,747)
Balance as of December 31, 2024	$ 3,676	$ 1,593,530	$ (973,261)	$ 623,945
Weighted average remaining amortization period at December 31, 2024 (in years)	-	10.3		

Amortization of intangible assets consists of the following:

	Patents and Trademarks	Licenses	Accumulated Amortization
Balance as of January 1, 2023	$ 3,676	$ 790,092	$ 793,768
Amortization expense	-	89,746	89,746
Balance as of December 31, 2023	3,676	879,838	883,514
Amortization expense	-	89,747	89,747
Balance as of December 31, 2024	$ 3,676	$ 969,585	$ 973,261

Amortization expense for the next five years is as follows:

For the Years Ending December 31,	Total
2025	$ 89,746
2026	89,746
2027	89,746
2028	89,746
2029	89,746
	$ 448,730

NOTE 5 - ACCRUED EXPENSES AND OTHER CURRENT LIABILITIES

Accrued expenses and other current liabilities consist of:

	December 31,	
	2024	2023
Accrued bonuses	$ 704,000	$ 638,000
Accrued general and administrative expenses	40,485	73,686
Total accrued expenses and other current liabilities	$ 744,485	$ 711,686

NOTE 6 - STOCKHOLDERS' EQUITY

Series A Preferred Stock

On November 8, 2021, in connection with the Company's public offering, the Company's Board of Directors adopted a resolution allowing for the designation and issuance of 1,543,158 shares of the Company's Preferred Stock, $.01 par value per share, designated as Series A Preferred Stock ("Series A"). The Series A had a liquidation preference of $0.001 per share. On September 8, 2022, the Company issued 1,543,158 shares of Series B Preferred Stock ("Series B") to Auctus Fund, LLC ("Auctus") in exchange for an equal number of shares of the Company's outstanding Series A. Simultaneously, the stock certificate representing the Series A shares was being returned to the Company for cancellation. On such date and upon such exchange, the Company's Board of Directors cancelled the Series A.

Series B Preferred Stock

Effective September 8, 2022, the Company issued 1,543,158 shares of Series B to Auctus in exchange for an equal number of shares of the Company's outstanding Series A. The terms of the Series B are substantially identical to those of the Series A, except that, among other things, the limitation on beneficial ownership of common stock of the Company upon a conversion of the Series B into Common Stock, and the limitation on the number of votes attributable to the Series B, is 9.99% of the then outstanding Common Stock of the Company instead of 4.99% as provided for the Series A. The Company is required, at all times, to reserve from its authorized and unissued Common Stock a sufficient number of shares to provide for the issuance of Common Stock upon the full conversion of the Series B. The Series B is not subject to redemption by the Company or any Series B holder.

Dividends

Series B holders shall be entitled to receive, when and as declared by the Board of Directors, dividends on a pari passu basis with the holders of the shares of Common Stock based upon the number of shares of Common Stock into which the Series B is then convertible.

Voting Rights

Series B holders shall be entitled to vote on all matters presented to the stockholders of the Company for a vote at a meeting of stockholders of the Company or a written consent in lieu of a meeting of stockholders of the Company, and shall be entitled to such number of votes for each share of Series B entitled to vote at such meetings or pursuant to such consent, voting together with the holders of shares of Common Stock and other shares of preferred stock who are entitled to vote, and not as a separate class, except as required by law. The number of votes to which the Series B holders shall be entitled to vote for each share of Series B shall equal the number of shares of Common Stock into which such Series B is then convertible; provided, however, that in no event shall a Series B holder be entitled to vote more than 9.99% of the then outstanding shares of Common Stock.

Conversion

Optional Conversion - Each share of Series B shall be convertible, at any time and from time to time, at the option of the Series B holder, into one share of Common Stock; provided, however, that in no event shall a Series B holder be entitled to convert any shares of Series B to the extent that such conversion would result in beneficial ownership by such Series B holder of more than 9.99% of the outstanding shares of common stock.

Automatic Conversion - From time to time, in the event that an event occurs which has the effect of reducing a Series B holder's beneficial ownership of shares of Common Stock to less than 9.5% of the then publicly disclosed outstanding shares of Common Stock, then, within five business days, the Series B holder is required to provide notice to the Company to such effect, which notice shall state the number of shares of Common Stock beneficially owned by the Series B holder and shall provide reasonable detail with regard thereto, including the number of derivative securities compromising a portion of such beneficial share amount. Such notice shall have the effect of a notice of conversion with respect to the conversion of such number of shares of Series B as would increase the Series B holder's beneficial ownership of Common Stock to 9.99% of the then publicly disclosed outstanding shares of Common Stock.

On October 25, 2022, Auctus converted 25,000 shares of Series B into 25,000 shares of Common Stock. The number of shares of Series B remaining outstanding after this conversion was 1,518,158.

On April 4, 2023, Auctus converted 120,000 shares of Series B into 120,000 shares of Common Stock. As of December 31, 2024, the number of shares of Series B remaining outstanding after giving effect to such conversion was 1,398,158.

2021 Stock Incentive Plan

On March 18, 2021, the Company's Board of Directors adopted the BioRestorative Therapies, Inc. 2021 Stock Incentive Plan (the "2021 Plan"). The 2021 Plan was approved by the Company's stockholders on August 17, 2021. Pursuant to the 2021 Plan, a total of 1,175,000 shares of common stock were initially authorized to be issued pursuant to the grant of stock options, restricted stock units, restricted stock, stock appreciation rights and other incentive awards. On December 10, 2021, the Company's Board of Directors approved an amendment to increase the number of shares of Common Stock authorized to be issued from 1,175,000 to 2,500,000. Such amendment was approved by the Company's stockholders on November 3, 2022. On July 13, 2023, the Company's Board of Directors approved an amendment to the 2021 Plan to increase the number of shares of Common Stock authorized to be issued from 2,500,000 to 3,850,000. Such amendment was approved by the Company's stockholders on September 13, 2023.

On July 23, 2024, the Company's Board of Directors approved an amendment to the Company's 2021 Plan to increase the number of shares of common stock authorized to be issued under the 2021 Plan from 3,850,000 to 6,850,000. Such amendment was approved by the Company's stockholders on September 19, 2024.

Compensatory Common Stock Issuance

During the year ended December 31, 2023, the Company issued 1,442 shares of immediately vested common stock with a value of $7,500 to a consultant for services rendered.

Sales of Common Stock

In April 2023, the Company entered into a Capital on Demand Sales Agreement with JonesTrading Institutional Services LLC ("JonesTrading") under which the Company had the ability to issue and sell shares of its Common Stock, from time to time, through JonesTrading, up to an aggregate offering price of approximately $6,109,000 in what is commonly referred to as an "at-the-market" ("ATM") program. During the year ended December 31, 2023, the Company sold 132,827 shares of its Common Stock at a weighted average price of $4.68 per share and raised $494,782 in net proceeds under the JonesTrading ATM program. In November 2024, in connection with the ATM program with Rodman & Renshaw LLC ("Rodman") discussed below, the Company terminated the Capital on Demand Sales Agreement with JonesTrading.

On July 13, 2023, the Company sold an aggregate of 685,033 shares of Common Stock to several institutional buyers and accredited investors in a registered direct offering at an offering price of $3.03 per share. The offering closed on July 13, 2023 with net proceeds of $1,853,990. The Company intends to use the net proceeds from the offering in connection with its clinical trials with respect to its lead cell therapy candidate, BRTX-100, pre-clinical research and development with respect to its metabolic ThermoStem Program and for general corporate purposes and working capital.

In November 2024, the Company entered into an At The Market Offering Agreement with Rodman, under which the Company currently has the ability to issue and sell shares of its Common Stock, from time to time, through Rodman, up to an aggregate offering price of approximately $3,614,000 in an ATM program. See Note 10 - Subsequent Events – Common Stock Sales.

Warrant Exercise and Issuance

On February 6, 2024, the Company entered into agreements with certain holders of its existing warrants exercisable for an aggregate of 3,351,580 shares of its Common Stock (collectively, the "Existing Warrants"), to exercise their warrants at a reduced exercise price of $2.33 per share, in exchange for the issuance of new warrants (the "New Warrants") as described below (the "Warrant Exercise and Issuance"). The aggregate gross proceeds from the exercise of the Existing Warrants and the payment of the New Warrants, as described below, was approximately $8.1 million, before deducting cash issuance costs in the amount of $595,364. The reduction of the exercise price of the Existing Warrants and the issuance of the New Warrants was structured as an at-market transaction under Nasdaq rules. Of the 3,351,580 shares of Common Stock issuable upon the exercise of the Existing Warrants, through December 31, 2024, the Company had issued an aggregate of 2,150,000 shares of Common Stock. The remaining 1,201,580 shares of Common Stock, which are issuable to Auctus Fund, LLC ("Auctus"), are being held in abeyance due to Auctus' maximum beneficial ownership limitation (the "Abeyance Shares"). Such Abeyance Shares have been fully paid for and are issuable upon notice from Auctus to the Company.

In consideration for the immediate exercise of the Existing Warrants for cash and the payment of $0.125 per share underlying the New Warrants, the exercising holders received the New Warrants to purchase shares of Common Stock in a private placement pursuant to Section 4(a)(2) of the Securities Act of 1933, as amended (the "Securities Act"). The New Warrants will be exercisable for a period of five years into an aggregate of 2,513,686 shares of Common Stock at an exercise price of $2.43 per share. The securities offered in the private placement have not been registered under the Securities Act or applicable state securities laws. Accordingly, the securities may not be offered or sold in the United States except pursuant to an effective registration statement or an applicable exemption from the registration requirements of the Securities Act and such applicable state securities laws. As part of the transaction, the Company agreed to file a resale registration statement with the SEC to register the resale of the shares of Common Stock underlying the New Warrants issued in the private placement. Such resale registration statement was filed and was declared effective by the SEC on April 18, 2024.

In connection with the transaction described above, the Company entered into a financial advisory services agreement, dated February 5, 2024, with Roth Capital Partners, LLC ("Roth"), pursuant to which the Company has paid Roth a cash fee of approximately $528,000 for its services, in addition to reimbursement for certain expense. During the year ended December 31, 2024, the Company incurred an aggregate of $595,364 of cash issuance costs related to the Warrant Exercise and Issuance.

Prior to the Warrant Exercise and Issuance, the Existing Warrants were classified as derivative liabilities. Additionally, the Company analyzed the form of the New Warrants and determined that they should be classified as derivative liabilities in accordance with ASC 815-40, Derivatives and Hedging — Contracts in Entity's Own Equity. Under the New Warrants, the Company does not control the occurrence of events, such as a tender offer or exchange, that may trigger cash settlement of the New Warrants and not result in a change of control of the Company. As a result, such New Warrants do not meet the criteria for equity treatment. Additionally, certain New Warrants contain adjustments to the settlement amount based on a variable that is not an input to the fair value of a "fixed-for-fixed" option as defined under ASC 815-40 and, accordingly, such New Warrants are not considered indexed to the Company's own stock and are not eligible for an exception from derivative accounting. See Note 9– Fair Value Measurement for details regarding the valuation of the Existing Warrants and New Warrants.

The Company determined the Warrant Exercise and Issuance to be an exchange by investors of Existing Warrants with an aggregate fair value of $1,115,334 along with aggregate cash consideration of $8,123,392 (consisting of $7,809,181 paid to exercise the Existing Warrants and $314,211 paid for the New Warrants) for an aggregate of 3,351,580 shares of common stock with an aggregate fair value of $4,742,244, New Warrants with an aggregate fair value of $2,189,420 and aggregate cash issuance costs of $595,364 and, accordingly, the Company recorded a gain on exchange of warrants of $1,711,698 during the year ended December 31, 2024.

Warrant Activity Summary

A summary of the warrant activity during the year ended December 31, 2024 is presented below:

	Number of Warrants	Weighted Average Exercise Price	Weighted Average Remaining Life In Years
Outstanding, January 1, 2024	4,791,019	$ 10.57	
Granted	2,513,686	2.43	
Exercised	(3,351,580)	2.33	
Expired	(1,491)	1,770	
Outstanding, December 31, 2024	3,951,634	$ 5.22	3.30
Exercisable, December 31, 2024	3,951,634	$ 5.22	3.30

The weighted average estimated fair value of the warrants granted during the year ended December 31, 2024 was $0.87 per warrant. See Note 9 – Fair Value Measurement – for details regarding the fair value estimates of the Warrants that are classified as derivative liabilities. The Company did not issue any warrants during the year ended December 31, 2023.

The following table presents information related to stock warrants at December 31, 2024:

Warrants Outstanding		Warrants Exercisable	
Exercise Price	Outstanding Number of Warrants	Weighted Average Remaining Life In Years	Exercisable Number of Warrants
$ 2.43	2,513,686	4.1	2,513,686
$ 2.92	51,370	2.9	51,370
$ 10.00	1,150,358	1.9	1,150,358
$ 12.00	235,970	1.9	235,970
$ 60.00	250	0.0	250
	3,951,634		3,951,634

Stock Options

A summary of the option activity during the year ended December 31, 2024 is presented below:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Life In Years	Intrinsic Value
Outstanding, January 1, 2024	1,466,892	$ 4.11		
Granted	1,934,716	1.45		
Exercised	-	-		
Forfeited	(138,141)	1.76		
Outstanding, December 31, 2024	3,263,467	$ 2.63	7.5	$ -
Exercisable, December 31, 2024	2,499,132	$ 2.95	7.1	$ -

The weighted average grant date fair value of the stock options granted during the years ended December 31, 2024 and 2023 was $1.45 and $3.00, respectively.

The following table presents information related to stock options at December 31, 2024:

Options Outstanding		Options Exercisable	
Exercise Price	Outstanding Number of Options	Weighted Average Remaining Life In Years	Exercisable Number of Options
$ 1.45	1,825,067	8.1	1,138,579
$ 2.91	626,215	6.7	548,368
$ 5.08	812,185	5.9	812,185
	3,263,467		2,499,132

In applying the Black-Scholes option pricing model to stock options granted, the Company used the following assumptions:

	For the Years Ended December 31,	
	2024	2023
Risk free interest rate	4.14 - 4.30%	4.22%
Expected term (years)	2.77 - 5.38	3.5
Expected volatility	101 - 102%	175.00%
Expected dividends	0.00%	0.00%

Restricted Stock Units

Pursuant to the 2021 Plan, the Company may grant restricted stock units ("RSUs") to employees, consultants or non-employee directors ("Eligible Recipients"). The number, terms and conditions of the RSUs that are granted to Eligible Recipients are determined on an individual basis by the 2021 Plan administrator. On the distribution date, the Company shall issue to the Eligible Recipient one unrestricted, fully transferable share of the Company's common stock (or the fair market value of one such share in cash) for each vested and nonforfeitable RSU.

A summary of the unvested RSUs as of December 31, 2024 is as follows:

	Number of Shares
Non-vested at January 1, 2024	97,827
Granted	-
Vested	(97,827)
Forfeited	-
Non-vested at December 31, 2024	-

Stock-Based Compensation Expense

The following table presents information related to stock-based compensation expense:

	For the Years Ended December 31,		Unrecognized at December 31,	Weighted Average Remaining Amortization Period
	2024	2023	2024	(Years)
General and administrative	$ 2,812,566	$ 7,782,967	$ 774,470	0.95
Total	$ 2,812,566	$ 7,782,967	$ 774,470	0.95

NOTE 7 - INCOME TAXES

The Company identified its federal and New York tax returns as its "major" tax jurisdictions. The Company is no longer subject to income tax income examinations by these tax authorities for taxable years ended December 31, 2020, and prior. The Company reviewed the prior New York state income tax filings and concluded that the prior year return will be amended to change the apportionment from zero to 100%. The Company believes its income tax filing positions and deductions will be sustained on audit, and it does not anticipate any adjustments that would result in a material change to its financial position. Therefore, no liabilities for uncertain tax positions have been recorded.

At December 31, 2024, the Company had approximately $68,200,000 and $51,800,000, respectively, of federal and state net operating losses that may be available to offset future taxable income. As a result of the Tax Cuts and Jobs Act of 2017 (the "Tax Act"), certain future carryforwards do not expire. At December 31, 2024, approximately $7,800,000 of federal net operating losses will expire from 2030 to 2038 and approximately $60,400,000 have no expiration but are subject to a utilization limit equal to 80% of current taxable income. The state net operating losses have a 20 year carryforward period and will begin to expire beginning 2035.

In accordance with Section 382 of the Internal Revenue Code, the usage of the Company's net operating loss carryforwards are subject to annual limitations due to several greater than 50% ownership changes.

The Company has not performed a formal analysis for the year ended December 31, 2024, but it believes its ability to use such net operating losses and tax credit carryforwards in the future is subject to annual limitations due to change of control provisions under Sections 382 and 383 of the Internal Revenue Code, which will significantly impact its ability to realize these deferred tax assets.

Management assesses the available positive and negative evidence to estimate whether sufficient future taxable income will be generated to permit use of the existing deferred tax assets. A significant piece of objective negative evidence evaluated was the cumulative loss incurred over the three-year period ended December 31, 2024. For the period ended December 31, 2024, the Company has recorded a full valuation allowance against the gross deferred tax asset balance as management believes that it is more likely than not that the results of operations will not generate sufficient taxable income to realize any of the deferred tax assets.

As of the date of this filing, the Company has not filed its 2024 federal and state corporate income tax returns. The Company expects to file these documents as soon as practicable.

The Company's net deferred tax assets, liabilities and valuation allowance as of December 31, 2024 and 2023 are summarized as follows:

	December 31,	
	2024	**2023**
Deferred Tax Assets:		
Net operating loss carryforwards	$ 18,004,100	$ 14,311,000
Stock-based compensation	8,695,100	15,788,000
Research and development costs	2,694,200	1,676,000
Research and development credits	330,000	330,000
Right-of-use assets	-	25,000
Other	600	4,000
Total Deferred Tax Assets	29,724,000	32,134,000
Deferred Tax Liabilities:		
Depreciation	(153,200)	(122,000)
Intangible assets	(41,700)	(47,000)
Lease liability	-	(39,000)
Other	(95,000)	(86,000)
Total Deferred Tax Liabilities	(289,900)	(294,000)
Net Deferred Tax Asset	29,434,100	31,840,000
Less: valuation allowance	$ (29,434,100)	$ (31,840,000)
Deferred Tax Asset, Net of Valuation Allowance	$ -	$ -
Change in valuation allowance	$ 2,405,900	$ (4,064,000)

The income tax provision (benefit) as of December 31, 2024 and 2023 consists of the following:

	December 31,	
	2024	2023
Federal:		
Current	$ -	$ -
Deferred	3,567,000	(3,090,000)
State & Local:		
Current	-	-
Deferred	(1,161,100)	(974,000)
	2,405,900	(4,064,000)
Change in valuation allowance	(2,405,900)	4,064,000
Income tax provision (benefit)	$ -	$ -

A reconciliation of the statutory federal income tax benefit to actual tax benefit for the years ended December 31, 2024 and 2023 is as follows:

	December 31,	
	2024	2023
Federal statutory rate	21.0%	21.0%
State tax, net of valuation allowance	0.0%	1.7%
Permanent differences	1.0%	7.2%
Tax return to provision adjustment	0.4%	-0.2%
Change in federal valuation allowance	39.7%	-29.7%
Adjustment for stock-based compensation	-62.1%	-%
	0.0%	0.0%

NOTE 8 – LEASES

The Company is a party to a lease for 6,800 square feet of space located in Melville, New York (the "Melville Lease") with respect to its corporate and laboratory operations. The Melville Lease was scheduled to expire in March 2020 (subject to extension at the option of the Company for a period of five years) and provided for an annual base rental during the initial term ranging between $132,600 and $149,260. In June 2019, the Company exercised its option to extend the Melville Lease and entered into a lease amendment with the lessor whereby the five-year extension term commenced on January 1, 2020 with annual base rent ranging between $153,748 and $173,060. The lease expired on December 31, 2024 and the Company is currently leasing the premises on a month-to-month basis.

When measuring lease liabilities for leases that were classified as operating leases, the Company discounted lease payments using its estimated incremental borrowing rate at August 1, 2019. The weighted average incremental borrowing rate applied was 12%.

The following table presents net lease cost and other supplemental lease information:

	For the Years Ended December 31,	
	2024	2023
Lease Costs		
Operating lease cost (cost resulting from lease payments)	$ 173,060	$ 168,028
Net lease costs	$ 173,060	$ 168,028
Operating lease - operating cash flows (fixed payments)	$ 173,060	$ 168,028
Operating lease - operating cash flows (liability reduction)	$ 162,317	$ 139,328
Non-current leases - right of use assets	$ -	$ 151,447
Current liabilities - operating lease liabilities	$ -	$ 162,317
Non-current liabilities - operating lease liabilities	$ -	$ -

There are no future minimum payments under non-cancelable leases following the year ended December 31, 2024.

NOTE 9 – FAIR VALUE MEASUREMENT

The Company accounts for the Warrants as liabilities in accordance with the guidance contained in ASC 815-40, Derivatives and Hedging — Contracts in Entity's Own Equity. For certain Warrants, the Company does not control the occurrence of events, such as a tender offer or exchange, that may trigger cash settlement of the Warrants and not result in a change of control of the Company. As a result, such Warrants do not meet the criteria for equity treatment and the Warrants must be recorded as a derivative liability. Additionally, certain other Warrants contain adjustments to the settlement amount based on a variable that is not an input to the fair value of a "fixed-for-fixed" option as defined under ASC 815-40 and, accordingly, such Warrants are not considered indexed to the Company's own stock and are not eligible for an exception from derivative accounting.

On February 8, 2024, in connection with the Warrant Exercise and Issuance, the Company estimated the aggregate fair value of the Existing Warrants (see Note 6- Stockholders' Equity for details) to be $1,115,334 using the Black-Scholes option pricing model (Level 3 inputs). The following table shows the detail of the valuation assumptions used:

	February 8, 2024
Risk free interest rate	4.20 - 4.28%
Expected term (years)	2.75 - 2.76
Expected volatility	102%
Expected dividends	0.00%

On February 8, 2024, the Company estimated the aggregate issuance date fair value of the warrant liability related to the New Warrants (see Note 4 - Stockholders' Equity for details) as $2,189,420 using the Black-Scholes option pricing model (Level 3 inputs). The following table shows the detail of the valuation assumptions used:

	February 8, 2024
Risk free interest rate	4.12%
Expected term (years)	5.00
Expected volatility	101%
Expected dividends	0.00%

On December 31, 2024 and 2023, the Company estimated the aggregate fair value of the warrants classified as derivative liabilities to purchase an aggregate of 3,900,014 and 4,737,908 shares of common stock, respectively, to be $2,520,851 and $1,543,953, respectively, using the Black-Scholes option pricing model (Level 3 inputs) using the following assumptions:

	December 31,	
	2024	2023
Risk free interest rate	4.12% - 4.34%	4.04%
Expected term (years)	1.86 - 4.11	2.86
Expected volatility	97% - 110%	87.00%
Expected dividends	0.00%	0.00%

The following table sets forth a summary of the changes in the fair value of Level 3 liabilities that are measured at fair value on a recurring basis during the years ended December 31, 2024 and 2023:

Balance, January 1, 2023	$ 5,541,733
Change in fair value of derivative liability	(3,997,780)
Balance, January 1, 2024	1,543,953
Issuance of warrants	2,189,420
Exercise of warrants	(1,115,334)
Change in fair value of warrant liability	(97,188)
Balance, December 31, 2024	$ 2,520,851

Assets and liabilities measured at fair value on a recurring basis are as follows:

	Fair value measurements at reporting date using:			
	Quoted prices in active markets for identical liabilities (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)	Total Fair Value
Assets:				
Marketable securities as of December 31, 2024	$ 10,184,701	$ -	$ -	$ 10,184,701
Marketable securities as of December 31, 2023	$ 10,181,618	$ -	$ -	$ 10,181,618
Liabilities:				
Warrant liabilities as of December 31, 2024	$ -	$ -	$ 2,520,851	$ 2,520,851
Warrant liabilities as of December 31, 2023	$ -	$ -	$ 1,543,953	$ 1,543,953

NOTE 10 - SUBSEQUENT EVENTS

Common Stock Sales

Subsequent to the year ended December 31, 2024, the Company sold 492,000 shares of its common stock under the Rodman ATM program with a weighted-average gross price of approximately $2.20 per share and raised approximately $1,084,000 of gross proceeds. The total commissions and related legal and accounting fees were approximately $178,000 and the Company received net proceeds of approximately $906,000.

Option Grants

Subsequent to December 31, 2024, the Company granted options to purchase an aggregate 2,152,908 shares of the Company's common stock at an exercise price of $2.46 per share to employees, the Company's board of directors and a member of the Company's scientific advisory board. The options had an aggregate grant date fair value of $4,044,250 and vest as follows: (i) options to purchase an aggregate 323,459 shares of common stock vest monthly over one year, and (ii) options to purchase an aggregate of 1,829,449 shares of common stock vest 50% immediately with the remainder vesting quarterly over two years commencing one year from the date of grant. The Company will recognize the grant date fair value of the options proportionate to the vesting period.

Common Stock Issuance

Subsequent to the year ended December 31, 2024, the Company issued 63,525 shares of common stock to Auctus Fund, LLC in partial satisfaction of shares held by abeyance.

Up to 14,285,715 Units, each consisting of:
One Share of Common Stock or One Pre-Funded Warrant to Purchase One Share of Common Stock and One Common Stock Warrant to Purchase up to One Share of Common Stock

Up to 14,285,715 Shares of Common Stock or Shares of Common Stock Underlying Pre-Funded Warrants

Up 14,285,715 Shares of Common Stock Underlying Common Stock Warrants

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Prospectus

Rodman & Renshaw LLC

February 11, 2026
