2025 Annual Report

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

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2025

OR

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

For the transition period from to

Commission File Number 001-38244

Genprex, Inc.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	**90-0772347**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification Number)**
3300 Bee Cave Road #650-227 **Austin, Texas**	
(Address of principal executive offices)	**78746** **(Zip Code)**

Registrant's telephone number, including area code: (877) 774-4679

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

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

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

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

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

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

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

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

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

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

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

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

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

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant, computed by reference to the closing price of the registrant's common stock on June 30, 2025 (the last business day of the registrant's most recently completed second fiscal quarter), as reported by The Nasdaq Capital Market on such date, was approximately $7.5 million. This calculation does not reflect a determination that certain persons are affiliates of the registrant for any other purpose.

As of March 27, 2026, there were 9,044,856 shares of the registrant's common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE:

Portions of Genprex, Inc.'s Definitive Proxy Statement for its 2026 Annual Meeting of Stockholders are incorporated by reference into Part III of this Annual Report on Form 10-K, which Definitive Proxy Statement shall be filed with the Securities and Exchange Commission within 120 days after the end of the fiscal year to which this Annual Report on Form 10-K relates.

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS AND INDUSTRY DATA

This Annual Report on Form 10-K (this "Annual Report on Form 10-K" or this "Annual Report") contains forward-looking statements that involve substantial risks and uncertainties which are made pursuant to the safe harbor provisions of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Unless the context requires otherwise, references to "Genprex," the "Company," "we," "us" or "our" in this Annual Report refer to Genprex, Inc. Any statements in this Annual Report about our expectations, beliefs, plans, objectives, assumptions or future events or performance are not historical facts and are forward-looking statements. These statements are often, but not always, made through the use of words or phrases such as "believe," "will," "expect," "anticipate," "estimate," "intend," "plan," "would," and similar expressions. For example, statements concerning financial condition, possible or assumed future results of operations, growth opportunities, industry ranking, plans and objectives of management, markets for our product candidates and their respective targeted indications, including estimated or projected size or other expected trends in such markets, and any other statements involving anticipated or expected market or industry projections, statements regarding markets for our common stock and future management and organizational structure and statements about our current or future product candidates and their development, our beliefs regarding their preclinical or clinical profile or efficacy, and the regulatory approval process and pathway and the timing thereof, are all forward-looking statements. Forward-looking statements are not guarantees of performance. They involve known and unknown risks, uncertainties and assumptions that may cause actual results, levels of activity, performance or achievements to differ materially from any results, levels of activity, performance or achievements expressed or implied by any forward-looking statement.

Any forward-looking statements are qualified in their entirety by reference to the risk factors discussed throughout this Annual Report, including the risk factors described in Item 1A of this Annual Report. Some of the risks, uncertainties and assumptions that could cause actual results to differ materially from estimates or projections contained in the forward-looking statements include but are not limited to:

- Market conditions;
- Our capital position;
- Our ability to raise additional future financing and possible lack of financial and other resources, and our ability to continue to support and fund our preclinical and clinical development programs and growth of our business;
- Our ability to continue as a going concern;
- Our ability to maintain compliance with the continued listing requirements of The Nasdaq Capital Market and maintain the listing of our common stock;
- Our ability to compete effectively and with larger and/or better-financed biotechnology and pharmaceutical companies;
- Our uncertainty of developing marketable products;
- Our ability to develop and commercialize our products;
- Our ability to obtain regulatory approvals;
- Our ability and third-parties' ability to maintain and protect intellectual property rights;
- The effects and impacts of public health crises such as epidemics or outbreaks, which could significantly disrupt and have a material adverse effect upon our business, our clinical trials and our research programs; as well as on healthcare systems or the global economy as a whole;
- The success of our clinical trials through all phases of clinical development, including the ability of our third-party suppliers or manufacturers to supply or manufacture our products on a timely, consistent basis in a manner sufficient and appropriate as is commensurate to meet our clinical trial timing, courses of treatment, and other requisite fulfillment considerations necessary to adequately advance our development programs;
- Our ability to conduct and complete our clinical trials in accordance with projected timelines;
- Any delays in regulatory review and approval of our current and future product candidates;
- The effects of any strategic research and development prioritization initiatives, and any other strategic alternatives or other efforts that we take or may take in the future that are aimed at optimizing and re-focusing our diabetes, oncology and/or other clinical development programs including prioritization of resources, and the extent to which we are able to implement such efforts and initiatives successfully to achieve the desired and intended results thereof, including successful implementation of the separation of our diabetes clinical development program, including the anticipated benefits of the internal reorganization, the expected timing of the reorganization and/or if it is completed as contemplated or at all;

- Our dependence on third-party suppliers or manufacturers to supply or manufacture our key ingredients and/or raw materials, products and/or product components and successfully carry out a sustainable, reproducible and scalable manufacturing process in accordance with specifications or applicable regulations;
- Our ability to control product development costs;
- Our ability to attract and retain key employees;
- Our ability to enter into new strategic collaborations, licensing or other arrangements;
- Changes in government regulation affecting product candidates that could increase our development costs;
- Our involvement in patent, trademark and other intellectual property litigation that could be expensive and divert management's attention;
- The possibility that there may be no market acceptance for our products; and
- Changes in third-party reimbursement policies which could adversely affect potential future sales of any of our products that are approved for marketing.

The foregoing list sets forth some, but not all, of the factors that could affect our ability to achieve results described in any forward-looking statements, which speak only as of the date of this Annual Report or the date of the document incorporated by reference into this Annual Report. Except as required by law, we assume no obligation and expressly disclaim any duty to update any forward-looking statement to reflect events or circumstances after the date of this Annual Report or to reflect the occurrence of unanticipated events. In addition, we cannot assess the impact of each factor on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements contained in this Annual Report. All forward-looking statements are expressly qualified in their entirety by the cautionary statements contained in this section.

PART I

Item 1. Business.

Overview

We are a clinical stage gene therapy company pioneering the development of gene-based therapies for large patient populations with unmet medical needs. Our oncology platform utilizes our systemic, non-viral ONCOPREX® Delivery System which uses lipid-based nanoparticles in a lipoplex form to deliver tumor suppressor gene-expressing plasmids to cancer cells. The product is administered intravenously, where it is taken up by tumor cells that then express tumor suppressor proteins that were deficient in the tumor. Our diabetes technology is designed to work in Type 1 diabetes by transforming alpha cells in the pancreas into functional beta-like cells, which can produce insulin but may be distinct enough from beta cells to evade the body's immune system. In Type 2 diabetes, our technology is believed to work by replenishing and rejuvenating exhausted beta cells that make insulin.

Oncology Platform

Our lead oncology drug candidate, REQORSA® Gene Therapy (generic name: *quaratusugene ozeplasmid*), previously referred to as GPX-001, is initially being developed in combination with prominent, approved cancer drugs to treat Non-Small Cell Lung Cancer ("NSCLC") and Small Cell Lung Cancer ("SCLC"). REQORSA has multimodal effects on cancer cells. It harms the metabolism of cancer cells, which leads to reduced cancer cell growth. It has a mechanism of action whereby it decreases tumor glucose metabolism, interrupts cell signaling pathways that cause replication and proliferation of cancer cells, re-establishes pathways for apoptosis, or programmed cell death, in cancer cells, and increases the immune response against cancer cells. In preclinical studies, REQORSA has been shown to be complementary with targeted drugs and immunotherapies. Our strategy is to develop REQORSA in combination with currently approved therapies, and we believe REQORSA's unique attributes position it to provide treatments that improve on these current therapies for patients with NSCLC, SCLC, and possibly other cancers.

The TUSC2 gene, which is the key component of REQORSA and plays a vital role in cancer suppression and normal cell metabolism, is one of a series of genes on the short arm of Chromosome 3 whose therapeutic use is covered by our exclusive worldwide licenses from The University of Texas MD Anderson Cancer Center ("MD Anderson"). We believe that our ONCOPREX Delivery System allows for the delivery of a number of cancer-fighting tumor suppressor genes, alone or in combination with other cancer therapies, to combat multiple types of cancer and we are in early stages of discovery programs to identify other cancer candidates. In August 2022, we entered into a sponsored research agreement with MD Anderson to support further preclinical studies of TUSC2 and other tumor suppressor genes. As further described in the "Discovery Programs" section below, since not all patients respond to REQORSA, we have been collaborating with researchers at MD Anderson to identify biomarkers that might predict a strong positive or negative response to REQORSA in patients with lung cancer. This preclinical effort has led to the identification of two proteins whose expression appears to predict response to REQORSA. Validation in specimens from clinical trials will be needed to determine whether these potential biomarkers predict clinical response. We plan to test patient samples from our clinical trials for selected biomarkers to determine if sensitivities exist among our existing patient population in an effort to guide patient selection and improve clinical outcomes.

Acclaim – 1: We currently are enrolling and treating patients in the Phase 2a expansion portion of our Phase 1/2 Acclaim-1 clinical trial. The Acclaim-1 trial uses a combination of REQORSA and AstraZeneca's Tagrisso® (*osimertinib*) in patients with late-stage NSCLC that has activating epidermal growth factor receptor ("EGFR") mutations and progression on treatment with Tagrisso or Tagrisso-containing regimens. Following the May 2023 completion of the Phase 1 dose escalation portion of the study, the Acclaim-1 Safety Review Committee ("Acclaim-1 SRC") approved advancement from the Phase 1 dose escalation portion to the Phase 2a expansion portion of the study. Based on a review of safety data which showed no dose limiting toxicities ("DLTs"), the Acclaim-1 SRC determined the recommended Phase 2 dose ("RP2D") of REQORSA to be 0.12 mg/kg administered every 21 days. This was the highest dose level delivered in the Phase 1 portion of the study and is twice the highest dose level delivered in our prior clinical trial combining REQORSA with Tarceva® (*erlotinib*) for the treatment of late-stage lung cancer. There were three patients out of the twelve originally enrolled in the Phase 1 dose escalation portion of the study who had prolonged progression-free survival ("PFS"). One patient attained a partial remission after the second course of REQORSA and Tagrisso and has maintained this response through 60 courses of treatment (approximately 42 months) and this patient continues to receive REQORSA and Tagrisso treatment to date. A second patient had stable disease without disease progression through 32 courses of treatment (approximately 24 months), but then had disease progression and REQORSA treatment was stopped. A third patient had stable disease without disease progression through 14 courses of treatment (approximately 10 months) before disease progression and is no longer receiving treatment. The results of the Phase 1 dose escalation portion of the study were published in *Clinical Lung*

Cancer, a peer-reviewed journal covering various aspects of clinical and translational research of lung cancer, in January 2026. We opened the Phase 2a expansion portion of the study and enrolled and dosed the first patient in January 2024. The Phase 2a expansion portion of the trial is expected to enroll approximately 33 patients; all of whom have progressed on Tagrisso or Tagrisso-containing regimens. There will be an interim analysis following the treatment of 19 patients in the Phase 2a portion of the Acclaim-1 study. The Phase 2b randomized portion of the study, in which patients progressing on prior Tagrisso treatment will be randomized 1:1 to either REQORSA and Tagrisso combination therapy or to platinum-based chemotherapy, remains unchanged. We expect to complete the enrollment of the first 19 patients for interim analysis in the Phase 2a expansion portion of the study in the first half of 2026 and expect the interim analysis in the second half of 2026.

The Food and Drug Administration ("FDA") has granted Fast Track Designation for the Acclaim-1 treatment combination of REQORSA and Tagrisso in NSCLC patients who have progressed on Tagrisso treatment.

The Phase 2a expansion portion of the Acclaim-1 study provides us the advantage of early insight into drug effectiveness in defined and distinct patient populations at the maximum tolerated dose (the "MTD") or RP2D in order to better evaluate efficacy and increase the likelihood of a successful randomized Phase 2 trial which will follow the expansion portion of the study.

Acclaim – 2: The Acclaim-2 trial involved a combination of REQORSA and Merck & Co.'s Keytruda® (*pembrolizumab*) in patients with late-stage NSCLC whose disease has progressed after treatment with Keytruda. As previously announced in August 2024, based on a number of factors, including enrollment challenges and delays due to competition for investigators and eligible patients with numerous other trials involving the same patient population, we decided to cease enrollment of new patients in the Acclaim-2 trial to prioritize our resources and focus on the other two Acclaim trials in SCLC and NSCLC, respectively. There are no longer any patients receiving study treatment in the Acclaim-2 trial. Although the Acclaim-2 study in patients progressing on Keytruda containing regimens has been closed due to, among other factors, slow enrollment, we continue to believe that this combination could be beneficial.

Acclaim – 3: We are currently enrolling and treating patients in the Phase 2 expansion portion of our Phase 1/2 Acclaim-3 clinical trial. The Acclaim-3 clinical trial uses a combination of REQORSA and Genentech, Inc.'s Tecentriq® (*atezolizumab*) as maintenance therapy for patients with extensive stage small cell lung cancer ("ES-SCLC") who did not develop tumor progression after receiving Tecentriq and chemotherapy as initial standard treatment. Patients are treated with REQORSA and Tecentriq until disease progression or unacceptable toxicity is experienced. In December 2024, we announced that we had completed the Phase 1 dose escalation portion of the Acclaim-3 clinical trial. Based on full safety data, which showed no DLTs, the Acclaim-3 Safety Review Committee ("Acclaim-3 SRC") determined that the RP2D of REQORSA will be 0.12 mg/kg administered every 21 days, which was the highest dose level delivered in the Phase 1 portion of the trial, and approved the opening of the Phase 2 expansion portion of the trial. Although decreases in tumor size are not expected during maintenance therapy with atezolizumab alone, there were two patients out of the six enrolled in the Phase 1 dose escalation portion of the study who had marked decreases in measurable disease. We previously reported that the first patient treated in the Phase 1 dose escalation portion of the Acclaim-3 trial had a partial remission, which is defined as at least a thirty percent (30%) decrease in tumor size, from prior to the start of maintenance therapy to the time of the CT scan performed after two cycles of maintenance therapy. A CT scan performed after four cycles of maintenance therapy (three months), confirmed that the patient still had a 30% decrease in tumor size in measurable lesions; however, one lesion not previously measurable had grown in size, thus leading to a conclusion of disease progression at that time. Another patient in the Phase 1 dose escalation portion of the Acclaim-3 trial had a twenty-three percent (23%) decrease in tumor size from prior to the start of maintenance therapy to the time of the CT scan performed after two cycles of maintenance therapy. This patient received seven cycles of study therapy before progressing after 4.2 months. In addition, one patient in the Phase 1 dose escalation portion of the study achieved an unconfirmed partial remission after 24 cycles of therapy and continues to receive study treatment in the trial after more than 18 months. We anticipate that the Phase 2 expansion portion will enroll approximately 50 patients at approximately 10 to 15 U.S. sites. Patients will be treated with REQORSA and Tecentriq until disease progression or unacceptable toxicity is experienced. The primary endpoint of the Phase 2 portion is to determine the 18-week progression-free survival rate from the time of the start of maintenance therapy with REQORSA and Tecentriq in patients with ES-SCLC. Patients will also be followed for survival. A Phase 2 futility analysis will be performed after the 25th patient enrolled and treated reaches 18 weeks of follow up. We expect to complete enrollment of the first 25 patients for interim analysis in the Phase 2 expansion portion of the study in the first half of 2026 and expect the interim analysis in the second half of 2026.

The Acclaim-3 clinical trial has received FDA Fast Track Designation for this patient population and Acclaim-3 has also received an FDA Orphan Drug Designation.

Diabetes Gene Therapy

In diabetes, we have exclusively licensed from the University of Pittsburgh of the Commonwealth System of Higher Education ("University of Pittsburgh" or "UP") multiple technologies relating to the development of a gene therapy product for each of Type 1 and Type 2 diabetes. The same novel approach is used in each of Type 1 and Type 2 diabetes whereby an adeno-associated virus ("AAV") vector containing the Pdx1 and MafA genes is administered directly into the pancreatic duct. In humans, this can be done with a routine endoscopy procedure. Our diabetes product candidates are currently being evaluated and optimized in preclinical studies at the University of Pittsburgh. GPX-002 is being developed for the treatment of both Type 1 diabetes and Type 2 diabetes. GPX-002 for Type 1 diabetes is designed to work by transforming alpha cells in the pancreas into functional beta-like cells, which can produce insulin but may be distinct enough from beta cells to evade the body's immune system. In a similar approach, GPX-002 for Type 2 diabetes, where autoimmunity is not at play, is believed to work by replenishing and rejuvenating exhausted beta cells that make insulin. We are currently working with the University of Pittsburgh on species analyses for the animal models as well as other regulatory and clinical strategic planning, including the initiation of research in Type 2 diabetes animal models. In December 2025, we also executed on our strategic goal to submit a meeting request to the FDA by the end of the year to discuss the necessary Investigational New Drug ("IND")-enabling preclinical studies, an important step before potentially initiating clinical trials in humans. See the "Recent Developments" section below for more information on our meeting with the FDA which occurred in February 2026. In May 2025, following the completion of our August 2022 sponsored research agreement with UP, we entered into a new sponsored research agreement with UP to study Type 1 diabetes and Type 2 diabetes in animal models. The new sponsored research agreement also includes a revised research plan to encompass our most recent technologies to which we originally acquired exclusive rights from UP in July 2023 as amended and restated in the comprehensive New UP License Agreement in February 2025 (as defined and described below). These include a MafB promoter to drive expression of the Pdx1 and MafA transcription factors that can potentially be used for both Type 1 and Type 2 diabetes. See also "Note 7 – Commitments and Contingencies" to our consolidated financial statements included in this Annual Report on Form 10-K.

On February 17, 2025, we and the University of Pittsburgh entered into an amended and restated Exclusive License Agreement (the "New UP License Agreement"), which updated and consolidated into a single agreement our prior license agreements with UP. Pursuant to the New UP License Agreement, UP granted to us a worldwide, exclusive license for certain patents and related technology, collectively referred to as the "Licensed Technology," and a worldwide, non-exclusive license to use certain related know-how. The Licensed Technology covered by the New UP License Agreement is based on the same general gene therapy approach as covered under our prior license agreements with UP (less the previously-licensed macrophage technology), whereby an adeno-associated virus vector containing the Pdx1 and MafA genes is administered directly into the pancreatic duct. More specifically, the Licensed Technology covered by the New UP License Agreement is related to a gene therapy for both Type 1 diabetes and Type 2 diabetes using the genes of the Pdx1 and MafA transcription factors controlled by insulin, glucagon and MafB promoters.

In February 2023, our research collaborators at UP presented preclinical data in a non-human primate ("NHP") model of Type 1 diabetes highlighting the therapeutic potential of GPX-002 at the 16th International Conference on Advanced Technologies & Treatments for Diabetes (ATTD 2023) in Berlin, Germany. The statistically significant study results showed the treated animals had decreased insulin requirements, increased c-peptide levels, and improved glucose tolerance compared to baseline. In April 2023, we hosted a Key Opinion Leader virtual event entitled "Novel Gene Therapy to Treat Type 1 Diabetes," which discussed preclinical data reported at ATTD 2023 supporting gene therapy to treat Type 1 diabetes. In June 2025, our collaboration partners had two presentations at the 2025 American Diabetes Association ("ADA") 85th Scientific Sessions. Our research collaborators from UP were invited to give an oral presentation highlighting their work in NHP models of Type 1 diabetes. In addition, our contract development and manufacturing organization collaborators presented a poster on a non-viral lipid nanoparticle delivery system that would allow a patient to receive multiple treatments.

Convergen Biotech, Inc.

Additionally, in September 2024, we announced that we were considering various strategic alternatives and opportunities to enhance stockholder value, including evaluating ways to optimize our clinical and research programs and operational strategies, such as our intention to potentially transfer our diabetes clinical development program and our diabetes gene therapy assets into a new, initially wholly-owned subsidiary. In connection with this intended separation of the diabetes clinical development program, in February 2025, we announced that we had formed a wholly-owned subsidiary, Convergen Biotech, Inc. ("Convergen"), to implement this initial step of the reorganization and facilitate the separation of the diabetes program. If, and when, a potential separation is completed, Convergen will focus on developing and commercializing GPX-002. We plan to retain our oncology clinical development programs and other oncology pipeline assets.

Reverse Stock Splits

Effective as of February 2, 2024 and October 21, 2025, we effected reverse stock splits of our issued and outstanding shares of common stock, at respective ratios of one-for-forty (1:40) and one-for-fifty (1:50) (respectively referred to as the "2024 Reverse Stock Split" and "2025 Reverse Stock Split", and collectively, the "Reverse Stock Splits"). Our common stock continues to trade on The Nasdaq Capital Market under the same GNPX ticker following the Reverse Stock Splits, but following the 2025 Reverse Stock Split was assigned a new CUSIP number, 372446302. All share and per share amounts in this Annual Report on Form 10-K have been adjusted as appropriate to reflect the Reverse Stock Splits (see "Note 2 – Summary of Significant Accounting Policies" to our consolidated financial statements included in this Annual Report on Form 10-K).

Recent Developments

Diabetes Gene Therapy Updates

As previously disclosed, in December 2025 we submitted a request to meet with the FDA to discuss the necessary IND-enabling preclinical studies for our Type 1 diabetes gene therapy program, an important step before potentially initiating clinical trials in humans. On February 19, 2026, we met with the FDA and received feedback which aligned with our expectations and plans. Following the FDA meeting and receipt of the official meeting minutes, we now plan to continue with preclinical animal studies, as expected, which will allow us to finalize the design and initiate future toxicology studies. Subsequent data from toxicology studies are expected to enable IND filing. Toxicology studies are a required step of drug development, ensuring that new treatments are evaluated in animal models before human use in order to identify potential risks, determine safe dosages and monitor for side effects. Additionally, we plan to begin clinical scale production in a current Good Manufacturing Practices ("cGMP") compliant facility, allowing us to accelerate our manufacturing processes necessary for IND-enabling preclinical studies and clinical trials. We are also continuing work with third-party contract development and manufacturing organizations ("CDMOs") and research partners to optimize constructs and evaluate alternative second-generation approaches including different AAV and non-viral constructs.

At-the-Market Offering Program

On December 13, 2023, we entered into an At The Market ("ATM") Offering Agreement (the "ATM Agreement") with H.C. Wainwright & Co., LLC, serving as agent (the "Agent") with respect to an ATM offering program under which we may offer and sell through the Agent, from time to time at our sole discretion, up to such number or dollar amount of shares (the "Shares") of our common stock, as registered on the prospectus supplement covering the ATM offering, as may be amended or supplemented from time to time. We have agreed to pay the Agent a commission equal to three percent (3%) of the gross sales proceeds of any Shares sold through the Agent under the ATM Agreement, and also have provided the Agent with customary indemnification and contribution rights. During the year ended December 31, 2025, we sold 1,602,490 Shares through the Agent under the ATM Agreement for net proceeds of approximately $10.8 million. From January 1, 2026 through the date of filing of this Annual Report on Form 10-K, we have sold 5,714,798 Shares of our common stock for net proceeds to us totaling approximately $13.3 million through the Agent under the ATM Agreement.

NASDAQ Compliance

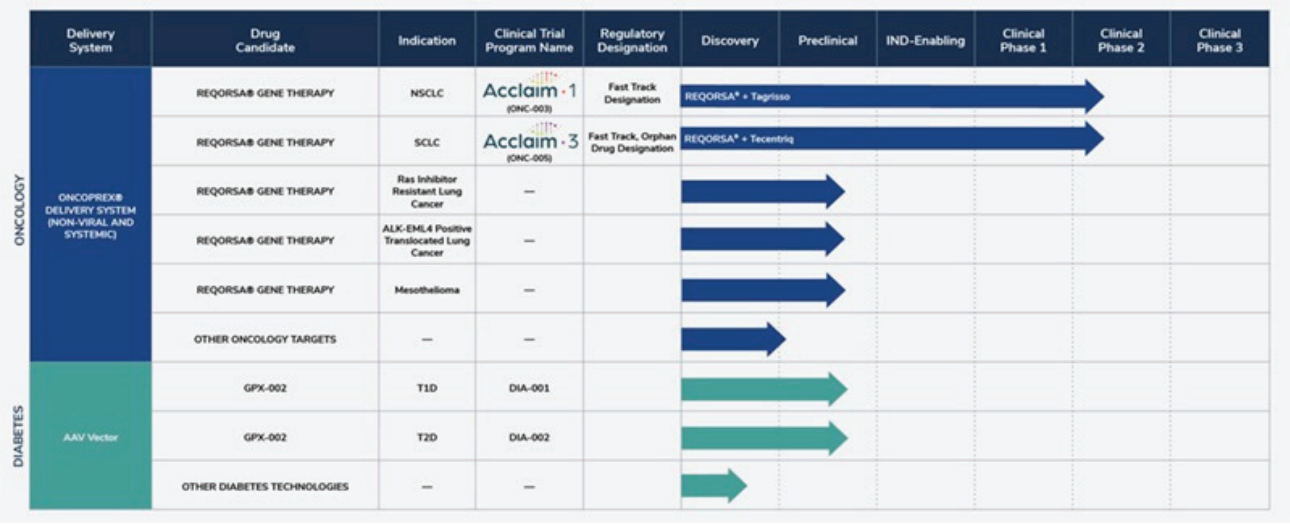
The Nasdaq Hearings Panel (the "Panel") of the Nasdaq Stock Market, LLC ("Nasdaq") notified us on October 13, 2025 that the Panel had granted our request for an exception to demonstrate compliance with the $1.00 Minimum Bid Price requirement set forth in Nasdaq Listing Rule 5550(a)(2) (the "Bid Price Requirement") and the minimum stockholders' equity requirement for continued listing on the Nasdaq Capital Market, under Nasdaq Listing Rule 5550(b)(1) (the "Stockholders' Equity Requirement") for continued listing through October 31, 2025. On November 25, 2025, we were formally notified that (i) the Panel determined that we regained compliance with the Bid Price Requirement; and (ii) the Panel also approved our request for an exception until December 31, 2025 to demonstrate long-term compliance with the Stockholders' Equity Requirement.

On January 7, 2026, we were formally notified that the Panel determined that we regained compliance with the Minimum Stockholders' Equity Rule. Pursuant to Nasdaq Listing Rule 5815(d)(4)(B), we will be subject to a mandatory panel monitor through January 7, 2027. If, within that one-year monitoring period, the Listing Qualifications Staff (the "Staff") of Nasdaq finds us again out of compliance with the Minimum Stockholders' Equity Rule that was the subject of the exception as previously granted by the Panel, notwithstanding Nasdaq Listing Rule 5810(c)(2), we will not be permitted to provide the Staff with a plan of compliance with respect to that deficiency and the Staff will not be permitted to grant additional time for us to regain compliance with respect to that deficiency, nor will we be afforded an applicable cure or compliance period pursuant to Nasdaq Listing Rule 5810(c)(3). Instead, the Staff will issue a Delist Determination Letter,

and we will have an opportunity to request a new hearing with the initial Panel or a newly convened Hearings Panel if the initial Panel is unavailable. We will have the opportunity to present to the Hearings Panel as provided by Nasdaq Listing Rule 5815(d)(4)(C), and our securities may be at that time delisted from Nasdaq.

Our Pipeline

Our technologies are designed to administer disease-fighting genes to provide new therapies for large patient populations with cancer and diabetes who currently have limited treatment options. We are developing our lead oncology product candidate REQORSA to be administered with targeted therapies and with immunotherapies for NSCLC and SCLC. We continue to conduct preclinical research to explore how REQORSA may be administered with targeted therapies and immunotherapies in other solid tumors, such as ALK-positive NSCLC, NSCLC progressing after rat sarcoma virus ("RAS") inhibitors, mesotheliomas, and gliomas, and we are researching how other cancer fighting genes, such as NPRL2, can enhance our portfolio using our systemic, non-viral gene therapy platform, the ONCOPREX Delivery System. Using a different gene therapy delivery system, we are also developing our preclinical diabetes candidate GPX-002 for both Type 1 diabetes and Type 2 diabetes. The following table summarizes our product development pipeline.



Introduction – Cancer

Cancer and Genetic Mutations. Cancer results from genetic mutations. Mutations that lead to cancer are usually present in two major classes of genes: oncogenes, which are involved in functions such as signal transduction and transcription; and tumor suppressor genes, which play multiple roles in governing cell growth and proliferation. Transduction is the process by which chemical and physical signals are transmitted into cells. In cancer cells, the oncogene mutations may overwhelm the natural tumor suppression processes, or those tumor suppression processes may be impaired or absent. Functional alterations due to mutations in oncogenes or tumor suppressor genes may result in the abnormal and uncontrolled growth patterns characteristic of cancer. These genetic alterations facilitate malignant growth by affecting signal transduction pathways and transcription, such as inhibiting normal growth signaling in the cell, circumventing the natural process of apoptosis, evading the immune system's response to cancer, and inducing angiogenesis, which is the formation of new blood vessels that supply cancer cells.

Common genetic alterations present in lung cancer are in tumor suppressor genes. Although some tumor suppressor genes develop mutations in cancer, the TUSC2 tumor suppressor gene is often deleted in cancers. To our knowledge, no targeted small molecule drugs have successfully been developed to compensate for TUSC2 tumor suppressor gene changes in NSCLC or SCLC.

Another genetic condition often associated with lung cancer is the presence of mutations of tyrosine kinases. Tyrosine kinases are enzymes that play an important role in signal transduction through the modification of proteins by adding phosphate groups (phosphorylation) onto the amino acid tyrosine, to change the proteins' function. When an EGFR ligand binds to the EGFR, two EGFR transmembrane proteins are brought close together on the cell membrane surface, and the intracellular tyrosine kinase domains can autophosphorylate, and activate downstream processes, including cell signaling pathways that can lead to cell growth and proliferation. EGFRs can act similarly to a switch that turns "on" and "off" when phosphate groups are either added or taken away. Mutated kinases can have a malfunctioning on/off switch, causing the switch to be stuck in the "on" position leading to the loss of control of cell growth.

Cancer and the Immune System. Cancer can also spread when the body's natural immune functions are impaired, including by the cancer cells themselves. PD-1, or Programmed Death-1, is a receptor expressed on the surface of activated T cells, which are part of the body's immune system. PD-L1 is a ligand for PD-1 which is expressed on the surface of cancer and other cells. The binding of PD-1 to PD-L1 has been shown to contribute to cancer cells' ability to evade the body's immune response. Antibodies to PD-1 and similar molecules are called immune checkpoint inhibitors because PD-1 and similar molecules can impede the normal immune response, for example by blocking the T cells from attacking the cancer cells. In many cancers, PD-L1 is up-regulated. Substantial research has been performed in the emerging field of immuno-oncology to discover drugs or antibodies that could block PD-1 and similar receptors. It is believed that blocking the PD-1/PD-L1 interaction pathway and other similar checkpoints, such as cytotoxic T-lymphocyte-associated protein 4, or CTLA-4, with drugs called checkpoint inhibitors, such as Keytruda or Tecentriq, can prevent cancer cells from inactivating T cells, leading to an attack of the immune system on the cancer.

Current Treatment of NSCLC. Chemotherapy is the standard treatment for the majority of NSCLC patients, as it is for many other cancer patients. Because it is a non-selective systemic treatment, rather than a targeted approach to treating cancer, chemotherapy also kills healthy cells and has a number of other undesirable side effects.

A subset of NSCLC patients carry a mutation in EGFR, which makes their tumors sensitive to EGFR tyrosine kinase inhibitors ("EGFR TKIs"). The two most common mutations are referred to as exon 19 deletion and exon 21 substitution. Several pharmacological and biological approaches, including EGFR TKIs, have been developed specifically to block activated EGFR for cancer therapy. EGFR TKI drugs are the most common targeted therapies used in lung cancer. Several EGFR TKI therapies are marketed commercially including, but not limited to, Tagrisso, Tarceva, Iressa, Gilotrif, Rybrevant and Lazcluze.

Approximately 10% to 20% of NSCLC patients of North American and European descent and approximately 40% to 50% of NSCLC patients of Asian descent have activating EGFR mutations. This means that the majority of NSCLC patients do not have activating EGFR mutations and are therefore "EGFR negative" and not optimal candidates for EGFR TKIs.

In addition, even among those patients who are EGFR positive and benefit from EGFR TKI therapy, nearly all eventually become resistant to and ultimately no longer respond to EGFR TKI therapy, resulting in eventual disease progression. For example, according to the FLAURA study, sponsored by AstraZeneca, the median time to tumor progression for lung cancer patients on Tagrisso monotherapy is approximately 18 months. Furthermore, recent clinical trials have shown that combining EGFR TKIs with conventional chemotherapy increases progression free survival, as well as overall survival, for lung cancer patients with EGFR mutations compared to Tagrisso monotherapy.

Current Treatment of SCLC. SCLC is staged as limited stage, in which the cancer is only on one side of the chest and can be treated with a single radiation therapy field, or as extensive stage ("ES"), which includes all other patients. Since SCLC is an aggressive disease, the vast majority of patients have extensive stage SCLC at the time of initial diagnosis. The standard treatment for ES-SCLC for many years was a combination chemotherapy with carboplatin and etoposide for 4 cycles of treatment, as treatment with chemotherapy for longer duration or treatment including other agents was not shown to be beneficial. In the last several years the addition of immune checkpoint inhibitors has been shown to have improved efficacy when added to 4 cycles of chemotherapy. Thus, standard treatment now consists of either Tecentriq or Imfinzi added to 4 cycles of carboplatin and etoposide, and then Tecentriq or Imfinzi are continued as maintenance therapy until disease progression.

However, treatment of ES-SCLC is not curative, and patients progress quickly. In patients receiving Tecentriq and chemotherapy, the PFS after starting maintenance Tecentriq is only 2.6 months. Further improvements in the treatment of ES-SCLC are needed.

Epidemiology of Lung Cancer. According to the World Health Organization's 2025 cancer facts, lung cancer was the leading cause of cancer deaths worldwide. According to the American Cancer Society in 2026, lung cancer accounts for about one in five of all cancer deaths in the United States, and causes more deaths in the U.S. than colon, breast and prostate cancers combined. In 2020, there were more than 2 million new lung cancer cases and approximately 1.8 million deaths from lung cancer worldwide. In the U.S., according to the American Cancer Society, it is estimated that in 2026 there will be more than 229,000 new cases of lung cancer and more than 124,000 deaths from this disease. NSCLC represents about 77% of all lung cancers and the five-year survival rate for patients with NSCLC with distant spread is 12%. SCLC represents about 13% of lung cancer patients and the five-year survival rate for patients with SCLC with distant spread is 4%. With limited benefit from current therapies, we believe there is a significant unmet medical need for new treatments for NSCLC and SCLC in the U.S. and globally, and we believe REQORSA may be suitable for the majority of lung cancer patients.

REQORSA®

REQORSA® Gene Therapy (generic name: *quaratusugene ozeplasmid*) decreases tumor glucose metabolism, interrupts cell signaling pathways that cause replication and proliferation of cancer cells, targets and kills cancer cells, and stimulates the natural immune responses against cancer. It re-expresses TUSC2 protein in the cell and also increases the anti-tumor immune cell population and down-regulates PD-L1, thereby potentially boosting the immune response to cancer.

REQORSA consists of a TUSC2 gene expressing plasmid encapsulated in non-viral lipid-based nanoparticles in a lipoplex form (our ONCOPREX Delivery System), which has a positive charge. REQORSA is designed to deliver the functioning TUSC2 gene to cancer cells while minimizing uptake by normal tissue. REQORSA is injected intravenously and specifically targets cancer cells. Cancer cells have elevated metabolism compared to healthy cells and as a result, are negatively charged compared to healthy cells, which are generally charge neutral. Thus, there is an electrostatic attraction of REQORSA to cancer cells. Cancers also have a leaky vasculature, so REQORSA leaks out of the blood vessels and can be taken up by cancer cells, which have a greater rate of pinocytosis (uptake of extracellular material) than normal cells. Laboratory studies conducted at MD Anderson show that the uptake of TUSC2 in tumor cells in vitro after REQORSA treatment was 10 to 33 times the uptake in normal cells. Biopsies in three patients with NSCLC treated with REQORSA show major increases in TUSC2 protein expression in the tumor cells one day after REQORSA administration. We believe that REQORSA is the first systemic gene therapy to be used for cancer in humans. Many other gene therapies require complex procedures, such as removal of cells from a patient and modification of those cells which are then reinfused into the patient, and many, unlike REQORSA, lead to permanent changes in a patient's DNA.

Many approved cancer therapeutics target only single molecules or a single specific genetic abnormality related to driving the proliferation and survival of cancer cells. In contrast, REQORSA has been shown to have a multimodal mechanism of action whereby it decreases tumor glucose metabolism, interrupts cell signaling pathways that cause replication and proliferation of cancer cells, re-establishes pathways for programmed cell death (apoptosis) in cancer cells, and modulates the immune response against cancer cells. REQORSA also has been shown to be complementary with a number of targeted drugs and immunotherapies.

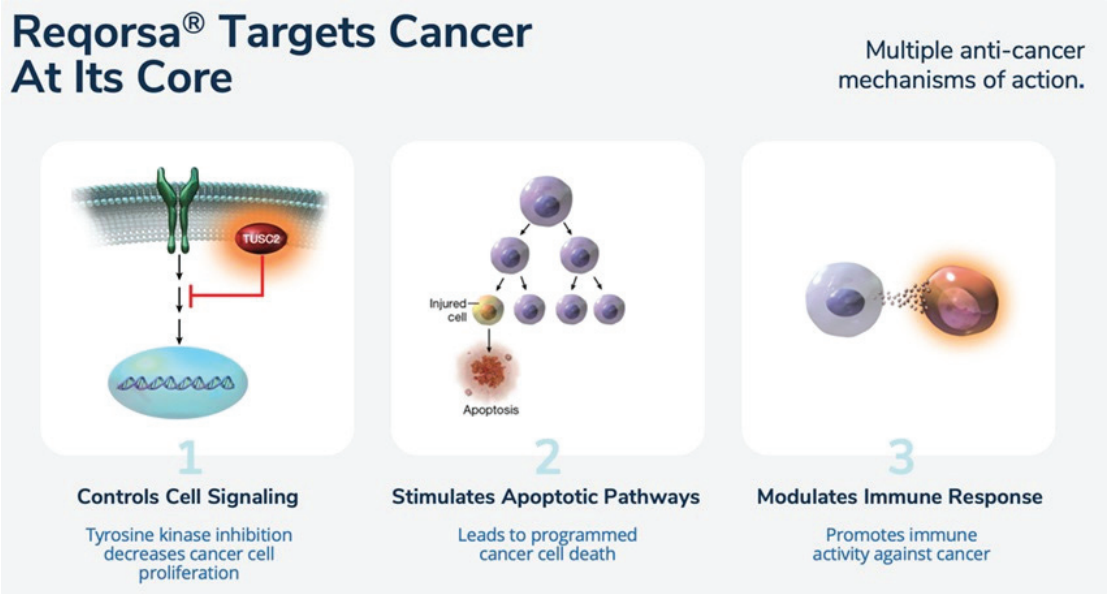
Resistance to targeted drugs and checkpoint inhibitors often develops through activation of alternate bypass pathways. For example, when PD-1 is blocked, the TIM-3 checkpoint is up-regulated. We believe that REQORSA's multimodal activity will block emerging bypass pathways, thereby potentially reducing the probability that drug resistance develops.

Our preclinical and clinical data indicate that REQORSA is well tolerated and may be effective alone or in combination with targeted small molecule therapies. Preclinical data indicate that REQORSA may also be effective with immunotherapies, and in a three-drug combination with immunotherapy and chemotherapy. These data suggest that REQORSA, when combined with other therapies, may be effective in a large proportion of lung cancer patients.

Additionally, we are collaborating with MD Anderson to discover, develop and utilize biomarkers to select the patient population most likely to respond to REQORSA and enable decisions on progression of our drug candidates to the next phase of development. MD Anderson researchers currently are analyzing biomarkers that may indicate a strong positive or negative response to REQORSA in lung cancer that could be used to enrich our population of responding patients in our clinical trials. We expect to expand our existing research with MD Anderson to investigate resistance mechanisms and identify biomarkers predictive of therapeutic response. As further described in the "Discovery Programs" section below, this preclinical effort has led to the identification of two proteins whose expression appears to predict response to REQORSA. Validation in specimens from clinical trials will be needed to determine whether these potential biomarkers predict clinical response. We plan to test patient samples from our clinical trials for selected biomarkers to determine if sensitivities exist among our existing patient population in an effort to guide patient selection and improve clinical outcomes.

TUSC2, the Tumor Suppressor Gene in REQORSA®

TUSC2 is a multifunctional gene that plays a vital role in cancer suppression and normal cell regulation, which is sometimes referred to as Fus1. Key TUSC2 anti-cancer mechanisms of action include decreasing tumor glucose metabolism, inactivation of multiple oncogenic kinases, the induction of apoptosis, the control of cell signaling and inflammation, and modulation of the immune system to fight cancer. REQORSA has been shown to be complementary with targeted drugs and immunotherapies. Our preclinical data indicate that REQORSA in combination with both EGFR TKIs and with immunotherapies can achieve results more favorable than results achieved with either REQORSA or such other therapies alone, and may make those drugs effective for patients with drug resistance who would not otherwise benefit from them.



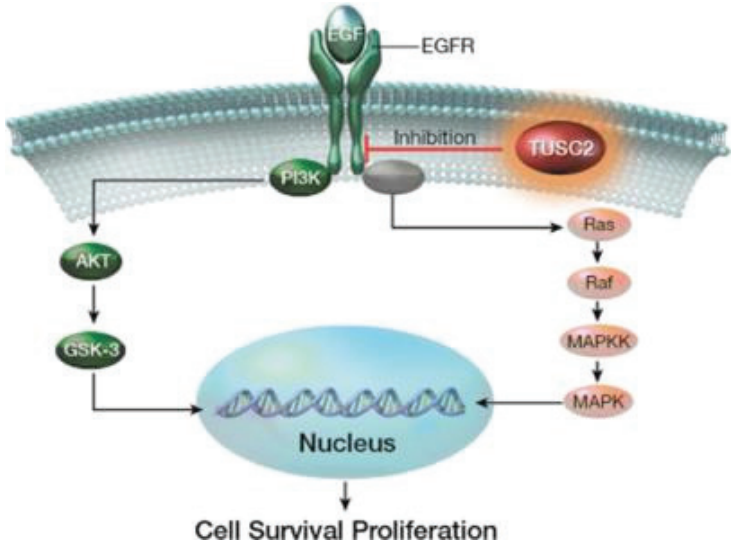
Normal TUSC2 function is often inactivated early in cancer development, making TUSC2 a potential target for all stages of cancer, including metastatic disease. The TUSC2 protein is reduced or absent in approximately 82% of NSCLCs and in 100% of SCLCs. In patients with NSCLC, the loss of TUSC2 expression has been associated with significantly worse overall survival than when TUSC2 expression is not decreased.

Studies show TUSC2 protein functions as a key mediator in the Apaf1-mediated mitochondrial apoptosis pathway by recruiting and directing cytoplasmic Apaf1 protein to a critical cellular location and activating it *in situ,* thereby up-regulating activity of other proapoptotic effectors. TUSC2 functions to mediate apoptosis in cancer cells through interaction with Apaf1 and also down-regulates multiple tyrosine kinases that control cell growth, including EGFR, AKT, platelet-derived growth factor receptor ("PDGFR"), c-Kit, and c-Abl.

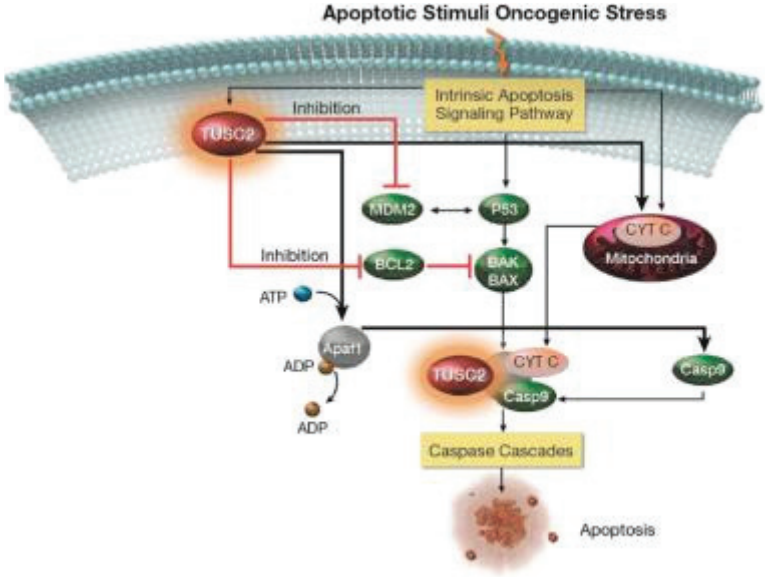
In normal cells, the proteins involved in the PI3K/AKT/mTOR pathway play an important role in cellular function and cellular trafficking. In this pathway, PI3K, a kinase, generates messenger molecules required to translocate AKT, another protein kinase, to the cell's plasma membrane where it is phosphorylated and activated. These proteins are often found to be aberrantly active in cancers, causing cells to lose their ability to control cell growth, proliferation, and differentiation. Thus, mutations in PI3K and its upstream activators, such as EGFR, have been associated with many forms of cancer.

Similarly, proteins in the Ras/MAPK pathway, which is a signal transduction pathway that transduces signals to the cell nucleus where specific genes are activated for cell growth, division and differentiation, play a critical role in cellular responses to various stress stimuli, including osmotic stress, DNA damage, and inflammation. As shown in the figures below, the TUSC2 protein, a potent pan-kinase inhibitor, blocks multiple cell-signaling pathways downstream of the EGFR receptor and leads to cell cycle interruption, thereby preventing cancer cell proliferation and survival.

Under stress conditions, such as oncogenic stress, cells go through a regulated process of programmed cell death, also known as apoptosis. As illustrated in the schematic below, the TUSC2 protein interacts via various apoptotic signaling pathways such as Apa1 to stimulate programmed cell death via the release of caspases, enzymes that play a significant role in apoptosis.



Pan-Kinase Inhibition by TUSC2



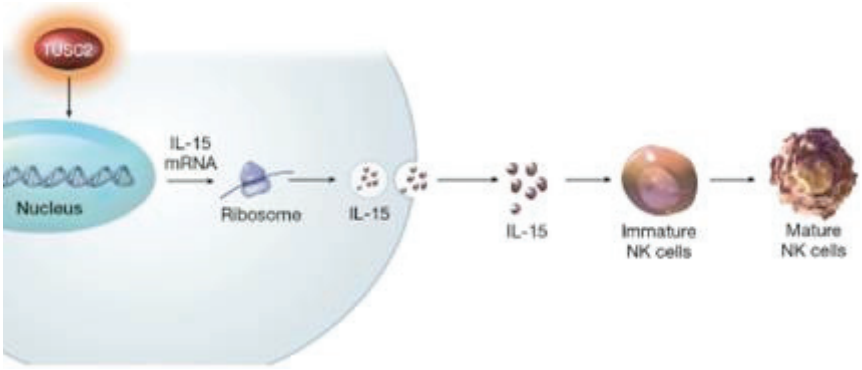
Stimulation of Apoptotic Signaling by TUSC2

Our clinical and preclinical data indicate that the combination of REQORSA with EGFR TKIs, may increase anti-tumor activity in cancers with or without EGFR mutations and in cancers that have become resistant to EGFR TKI therapy, thus potentially expanding the number of patients who could benefit from those drugs.

TUSC2 and the Immune Response. In addition to its pro-apoptotic cytotoxicity and tyrosine kinase inhibitory activity, TUSC2 enhances the immune response to cancer. Data from preclinical studies at MD Anderson has shown a benefit from the combination of TUSC2 and anti-PD-1 antibody and a key role for TUSC2 in regulating immune cell subpopulations including cytokines, natural killer ("NK") cells, and T lymphocytes. In addition, TUSC2 has been found to down-regulate PD-L1 on the surface of cancer cells. As a result, lymphocytes expressing the PD-1 receptor are more likely to recognize the cancer cell as an altered cell that should be destroyed. In addition, by inducing tumor cell apoptosis TUSC2 increases antigen release and presentation, thus promoting an enhanced antitumor response in the presence of other immune regulators.

NK cells, an important part of the innate immune system, have developed several mechanisms to distinguish healthy cells from target cells. These mechanisms allow NK cells to kill cells that are deemed dangerous to the host, including cancer cells. However, one of the consequences of malignant transformation is the ability of the cancer cell to evade the immune system. Cancer cells do so via the up-regulation and interplay of receptors, including checkpoint inhibitors such as PD-1 and PD-L1.

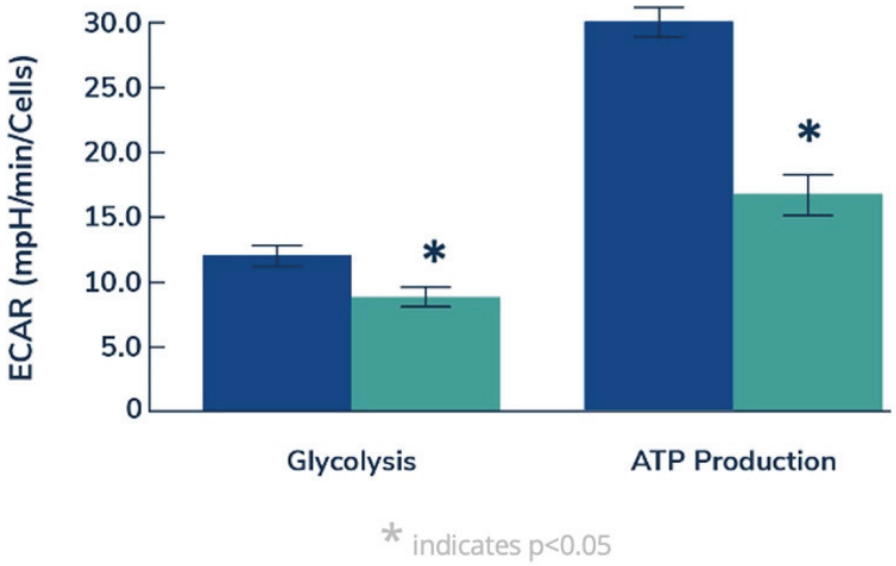
As shown in the illustration below, TUSC2 has been found to stimulate the release of interleukin-15, or IL-15, resulting in up-regulation of mature NK cells that circulate and target cancer cells.



Modulation by TUSC2 of the Immune Response to Cancer

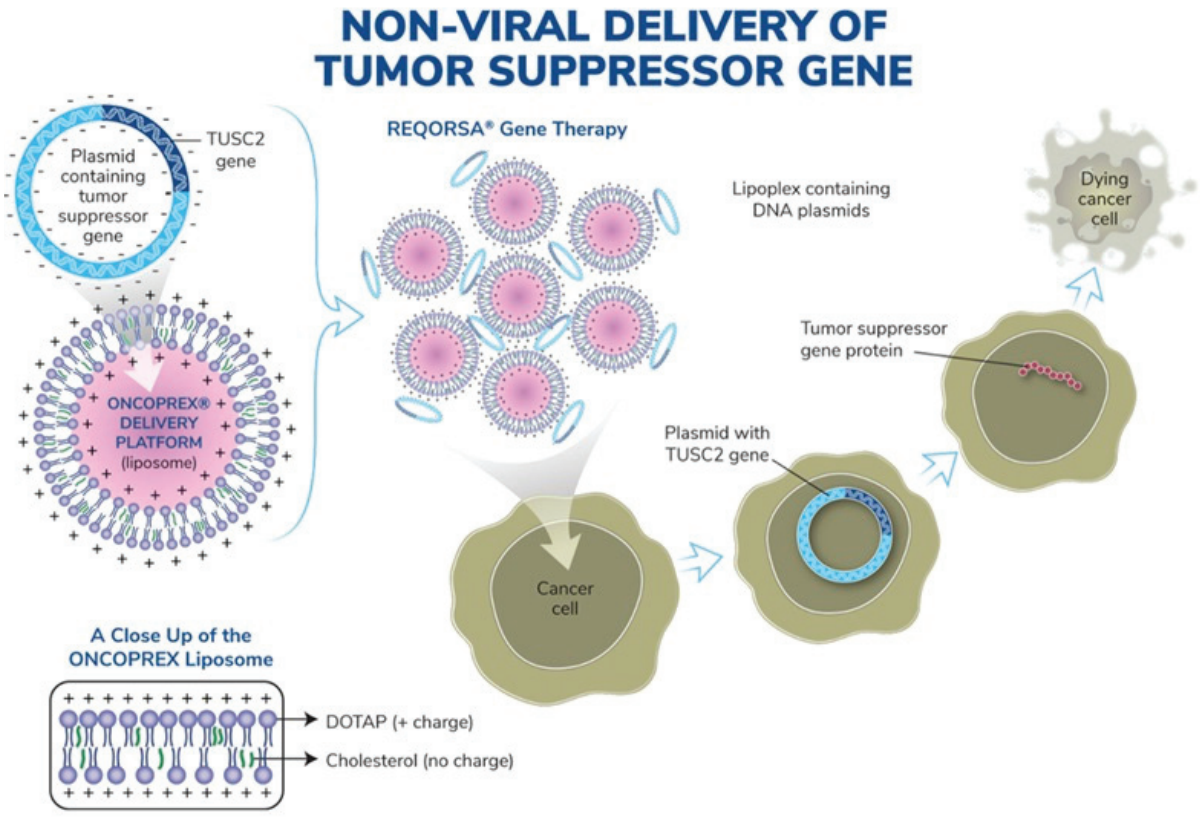
In work presented in an abstract for the 2024 American Association of Cancer Research ("AACR") meeting, our clinical collaborators have shown that TUSC2 has metabolic effects both in lung cancers and in normal cells. TUSC2 is encoded by the nuclear DNA, but the TUSC2 protein resides in the inner membrane of the mitochondria. TUSC2 has been shown to play a critical role in mitochondrial respiration/energy metabolism, reactive oxygen species production, and in Ca2+ flux to and from mitochondria. This recent work demonstrated that TUSC2 re-introduction to TUSC2-deficient cancer cells consistently suppressed both glycolysis and mitochondrial ATP production, thus leaving cells without sufficient energy to support their vital functions. This suggests that TUSC2 protein introduced to cancer cells lacking TUSC2 can decrease the high metabolic rate that is characteristic of cancer cells, leading to marked decreases in cell growth. The data also showed that both glycolytic and mitochondrial metabolism of a normal epithelial cell line were strengthened after the introduction of TUSC2, suggesting a beneficial role of TUSC2 for the metabolic health of normal cells. This suggests that TUSC2 effects on metabolism in normal lymphocytes could lead to the increased immune response to lung cancers seen in animal models receiving REQORSA. The study further suggested that REQORSA may play an important role as a cancer treatment to target and disrupt the metabolism of cancer cells, leading to a decrease in the rate of glycolysis and decreased production of energy in the form of ATP.

REQORSA Decreases Glycolysis and ATP Production in A549 Lung Cancer Cells



ONCOPREX® Delivery System

Our oncology platform consists of DNA plasmids expressing tumor suppressor genes contained in non-viral lipid-based nanoparticles in a lipoplex form ("lipoplexes") delivered intravenously. Lipoplexes (see figure below) have lipid-based nanoparticles that clump together, thus protecting the DNA between them from being destroyed in the bloodstream. REQORSA utilizes the ONCOPREX® Delivery System to encapsulate the TUSC2 gene in positively charged lipoplexes that are attracted to negatively charged cancer cells, and then enter the cancer cell through selective endocytosis, a process by which cells take in substances from outside the cell by engulfing them in a vesicle.



Operation of the ONCOPREX Delivery System

The cationic (positive) charge of the lipoplexes helps to target cancer cells, which have a slight negative charge due to their high glycolytic rate. A Phase 1 monotherapy clinical trial showed that intravenous REQORSA therapy selectively and preferentially targeted tumor cells, resulting in anticancer activity. The lipoplexes are non-immunogenic, allowing repetitive therapeutic dosing and providing extended half-life in the circulation.

The ONCOPREX Delivery System is a non-viral delivery system. Many gene therapies rely on viral based delivery systems. The benefit of the viral system is that viruses are skilled at penetrating cells. However, viruses can also affect more than one type of cell and it is possible that the virus may infect cells other than the targeted cells containing mutated genes. If this happens, healthy cells may be damaged causing other illness or diseases, and rarely can cause cancer if the virus integrates into the genes of the cell. Once REQORSA is taken up into a cancer cell, the TUSC2 gene is expressed and TUSC2 protein is capable of restoring certain defective functions in the cancer cell. REQORSA has been designed using the ONCOPREX Delivery System to deliver the functioning TUSC2 gene to cancer cells while minimizing their uptake by normal tissue. Laboratory studies showed that the uptake of TUSC2 in tumor cells after REQORSA treatment was 10 to 33 times the uptake in normal cells, and studies in three NSCLC patients showed a major increase in TUSC2 expression in tumor tissue one day after REQORSA administration. REQORSA is also delivered systemically as opposed to many other gene therapies which are locally delivered.

REQORSA Origins, Development Rationale, and Strategy

TUSC2 was discovered through a lung cancer research consortium from MD Anderson and The University of Texas Southwestern Medical Center along with the National Cancer Institute. The TUSC2 discovery teams included Jack A. Roth, MD, FACS, chairman of our Scientific Advisory Board.

Our goal is to utilize our novel gene therapy platform to provide more effective treatments to large patient populations suffering from devastating illness.

REQORSA, our lead oncology product candidate, initially is being developed as a potential treatment for NSCLC and SCLC. Clinical and preclinical data indicate that REQORSA, when combined with EGFR TKIs such as Tagrisso, Tarceva and Iressa, provides a synergistic effect. Further, our data shows that REQORSA may re-sensitize EGFR positive patients who become resistant to, and therefore no longer benefit from, EGFR TKIs alone. Preclinical and clinical data support our belief that REQORSA may provide medical benefit in several subpopulations of NSCLC patients for which there is an unmet medical need such as NSCLC patients with EGFR mutations, ALK positive NSCLC patients, and NSCLC patients progressing on RAS inhibitors. Data on REQORSA's effects in EGFR resistant cancer cells also served as the basis for the receipt from the FDA in January 2020 of our first Fast Track Designation. This FDA Fast Track Designation is for use of the combination of REQORSA with Tagrisso for the treatment of NSCLC patients with EGFR mutations whose tumors progressed on treatment with Tagrisso.

Preclinical data also have shown that REQORSA enhances the immune response to cancer. Data from preclinical studies at MD Anderson have shown a therapeutic benefit from the combination of TUSC2 and anti-PD-1 antibody or anti-PD-L1 antibody and a key role for TUSC2 in regulating immune cell subpopulations including cytokines, NK cells, and T lymphocytes. In addition, TUSC2 has been found to down-regulate PD-L1 on the surface of cancer cells. These data, along with our previous preclinical and clinical data, provided the basis for the receipt from the FDA in December 2021 of our second Fast Track Designation. In granting this Fast Track Designation, the FDA found that REQORSA has the potential to provide a benefit over existing therapies for patients whose tumors progress on Keytruda. This FDA Fast Track Designation is for use of the combination of REQORSA with Keytruda for the treatment of NSCLC patients whose tumors progressed after treatment with Keytruda. Although the Acclaim-2 study in patients progressing on Keytruda containing regimens has been closed due to, among other factors, slow enrollment, we continue to believe that this combination could be beneficial.

Our study in SCLC builds on the preclinical data showing that REQORSA enhances the immune response to cancer, and that the combination of REQORSA and immune checkpoint inhibitors demonstrates a significant benefit over immune checkpoint inhibitors alone. Immune checkpoint inhibitors, such as Tecentriq, have recently been approved for use in ES-SCLC. Tecentriq, for instance, is used in combination with the chemotherapy drugs carboplatin and etoposide for 4 cycles of therapy, and then Tecentriq is administered alone as maintenance therapy until disease progression. Unfortunately, this is a relatively short time since the median PFS after starting maintenance therapy is 2.6 months. Our goal with combining REQORSA and Tecentriq as maintenance therapy is to prolong PFS and survival of ES-SCLC patients. In June 2023, the FDA granted our third Fast Track Designation. In granting this Fast Track Designation, the FDA found that REQORSA has the potential to provide a benefit over existing therapies for patients with ES-SCLC. This FDA Fast Track Designation is for the use of the combination of REQORSA with Tecentriq as maintenance therapy in patients with ES-SCLC who did not develop tumor progression after receiving Tecentriq and chemotherapy as initial standard treatment. In August 2023, the FDA also granted Orphan Drug Designation to REQORSA for the treatment of SCLC.

Preclinical studies by our research collaborators have included combining REQORSA with:

- the EGFR TKI gefitinib (marketed as Iressa® by AstraZeneca Pharmaceuticals) in animals and in human NSCLC cells;
- third generation EGFR TKIs such as osimertinib (marketed as Tagrisso® by AstraZeneca Pharmaceuticals);
- MK2206 in animals (MK2206 is an inhibitor of AKT kinases, which affect cell signaling pathways downstream from tyrosine kinases);
- the anti-PD-1 antibody pembrolizumab (the checkpoint inhibitor marketed as Keytruda® by Merck & Co.) in animals;
- the anti-PD-1 antibody nivolumab (the checkpoint inhibitor marketed as Opdivo® by Bristol-Myers Squibb Company) in animals;
- the anti-CTLA4 antibody ipilimumab (marketed as Yervoy® by Bristol-Myers Squibb Company) in animals;
- the anti-PD-L1 antibody atezolizumab (marketed as Tecentriq® by Genentech/Roche) in animals;
- the RAS inhibitor sotorasib (marketed as Lumakras® by Amgen Inc.) in animals; and
- the ALK inhibitor alectinib (marketed as Alecensa® by Genentech/Roche) in animals.

The manufacturers of the marketed drugs were not involved in any of our clinical or preclinical studies. In clinical studies involving marketed drugs, the drugs were administered concurrently with REQORSA without being modified in any way, and the antibodies used in our preclinical studies that did not use the marketed drugs were the non-humanized equivalent to marketed drugs.

Data from these clinical and preclinical studies indicates that combining REQORSA with these other therapies in many cases yields results more favorable than either these therapies or REQORSA alone, with minimal side effects relative to other lung cancer drugs, thereby potentially making REQORSA a therapy complementary to these cancer treatments.

Acclaim-1

As described above, in January 2020, we received Fast Track Designation from the FDA for use of REQORSA in combination with TKI Tagrisso for the treatment of NSCLC patients with EGFR mutations whose tumors progressed on treatment with Tagrisso.

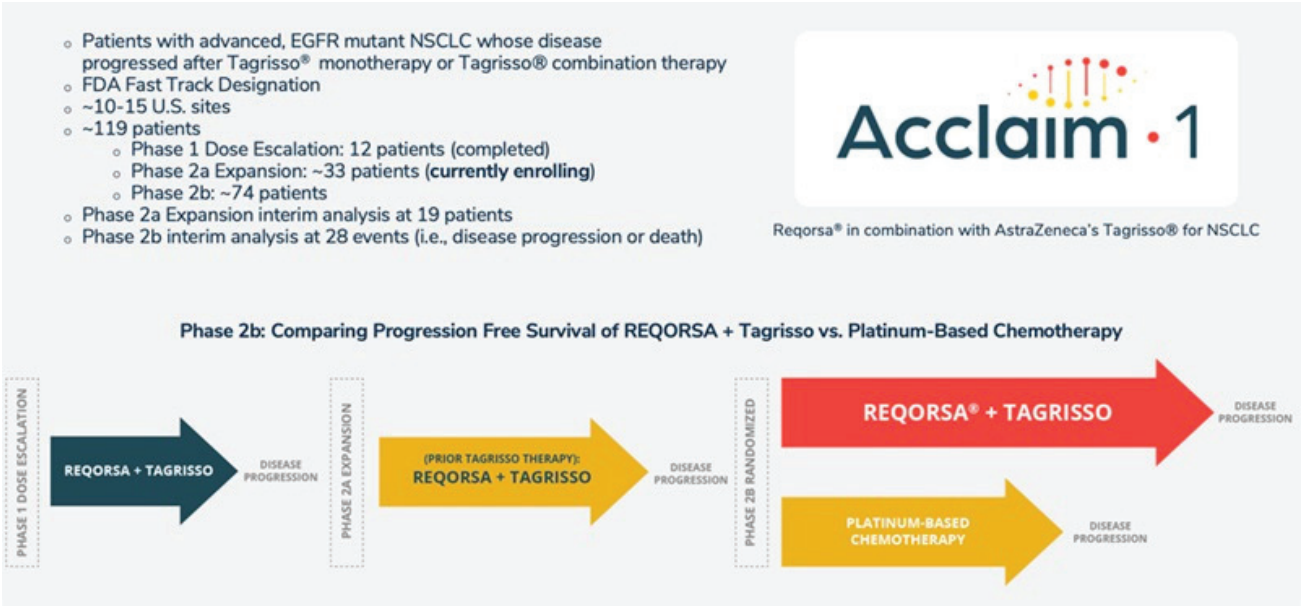
We currently are enrolling and treating patients in the Phase 2a expansion portion of our Phase 1/2 Acclaim-1 clinical trial, an open-label, dose-escalation and clinical response study of REQORSA in combination with Tagrisso in patients with advanced, EGFR-mutant, metastatic non-small-cell lung cancer progressing on treatment with Tagrisso or Tagrisso-containing regimens. Patients must have histologically confirmed unresectable stage III or IV EGFR-positive NSCLC (any histology) with:

- radiological progression on Tagrisso (third generation EGFR-TKI) or Tagrisso-containing regimens; and
- ECOG performance status of 0 to 1.

We enrolled 12 patients in the completed Phase 1 dose escalation portion of the Acclaim-1 study and estimate that the Phase 2a expansion portion will enroll approximately 33 patients (all of whom have progressed on Tagrisso or Tagrisso-containing regimens), and the randomized Phase 2b portion will enroll approximately 74 patients. Starting with the Phase 2a expansion portion of the study, all patients receiving REQORSA in this study are required to submit an archival biopsy specimen that can be evaluated for TUSC2 expression. The initial trial design of the Phase 2a expansion portion of the study included two cohorts with half being patients who received only prior Tagrisso treatment and the other half being patients who received prior Tagrisso treatment and chemotherapy. However, as previously announced in August 2024, based on resource prioritization and to focus on the patients for whom REQORSA is most likely to show a benefit, we decided to limit our enrollment efforts moving forward to patients who received only prior Tagrisso treatment and cease enrollment of the second cohort (patients who received prior Tagrisso treatment and chemotherapy). However, noting that two of the patients with markedly prolonged PFS in the Phase 1 portion of the study had previously received both chemotherapy and Tagrisso, in February 2025, we amended the protocol to allow entry of patients progressing on Tagrisso or Tagrisso-containing regimens in the Phase 2a expansion portion of the study. There will be an interim analysis following the treatment of 19 patients in the Phase 2a portion of the Acclaim-1 study. We expect to enroll patients at approximately 10-15 U.S. clinical sites for the Acclaim-1 study. We opened the Phase 2a expansion portion of the Acclaim-1 study and enrolled and dosed the first patient in January 2024. We expect to complete the enrollment of the first 19 patients for interim analysis in the Phase 2a expansion portion of the study in the first half of 2026 and expect the interim analysis in the second half of 2026. Patients enrolled in the Phase 2b portion of the study will be randomized 1:1 to either REQORSA and Tagrisso combination therapy or to platinum-based chemotherapy. Patients will be treated until disease progression or unacceptable toxicity is experienced.

The primary endpoint of the Phase 1 portion of the Acclaim-1 study was to determine a dose with DLT or, if DLT was not experienced, to determine the RP2D. Since no DLTs were experienced in Phase 1, the 0.12 mg/kg dose of REQORSA administered every 21 days was determined to be the RP2D. The primary endpoint of the Phase 2a expansion portion is overall response rate (ORR). The primary endpoint of the Phase 2b randomized portion of the trial is PFS which is defined as time from randomization to disease progression) or death. Patients will also be followed for survival.

In October 2023, one of our clinical collaborators presented a poster presentation at the 2023 AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics detailing the Phase 1 results of the Acclaim-1 study. While the Phase 1 portion of the Acclaim-1 study was designed primarily to assess safety, we believe promising efficacy results were also observed. The reported results showed no DLTs, established a RP2D of 0.12 mg/kg administered every 21 days (the highest dose level administered in the trial) and provided data showing early efficacy of REQORSA in combination with Tagrisso. Of the 12 patients treated with escalating doses of REQORSA and standard doses of Tagrisso, all of whom had progressed on Tagrisso containing regimens, three patients had experienced prolonged time to progression, including one with continuing partial response. Specifically, one patient at the 0.06 mg/kg dose level, previously treated with carboplatin, pemetrexed, and Tagrisso, had a partial remission by investigator evaluation and treatment is ongoing in the trial after 60 cycles, which is approximately 42 months. A second patient at the 0.12 mg/kg dose level who was previously treated with cisplatin, pemetrexed, carboplatin, and Tagrisso had stable disease and received 32 cycles, or approximately 24 months before disease progression occurred and REQORSA treatment was stopped. And a third patient who was at the 0.09 mg/kg dose level, previously treated with Tagrisso, had stable disease and received 14 cycles, over approximately 10 months before disease progression occurred and is no longer receiving treatment. The extended PFS of each of these patients is consistent with long-term PFS seen in several patients in prior early stage clinical trials of REQORSA and is not expected with treatment with Tagrisso alone after progression on Tagrisso containing regimens. REQORSA administration was generally well tolerated and there were no DLTs. The administration was associated with a delayed infusion-related reaction with symptoms such as muscle aches, fever and chills in some patients, which we believe is similar to reactions seen with the administration of antibodies routinely used in oncology treatment. This was managed with prophylactic steroids, acetaminophen and diphenhydramine, and symptoms were not increased, and in most cases decreased, with repeat cycles. The results of the Phase 1 dose escalation portion of the study were published in *Clinical Lung Cancer*, a peer-reviewed journal covering various aspects of clinical and translational research of lung cancer in January 2026. We believe this new mechanism and novel approach targeting lung cancer, which comes with a strong safety profile and early signs of efficacy, is paving new ground in the fight against lung cancer.



Acclaim-2

In December 2021, we received Fast Track Designation from the FDA for use of REQORSA in combination with the checkpoint inhibitor Keytruda for the treatment of advanced NSCLC patients whose tumors progressed after treatment with Keytruda.

In 2019, preclinical data were presented by MD Anderson collaborators relating to the combination of REQORSA, with Keytruda showing that TUSC2 combined with the checkpoint blockade mechanism of action of Keytruda was more effective than Keytruda alone in increasing the survival of mice with a human immune system (humanized mice) that had metastatic lung cancer with a human lung cancer. MD Anderson also presented preclinical data in 2019 for the combination of TUSC2, Keytruda and chemotherapy for the treatment of some of the most resistant metastatic lung cancers. This study found that the addition of TUSC2 demonstrates synergy with Keytruda and also with Keytruda combined with chemotherapy, and thus, may improve on the first-line standard of care for lung cancer which includes chemotherapy.

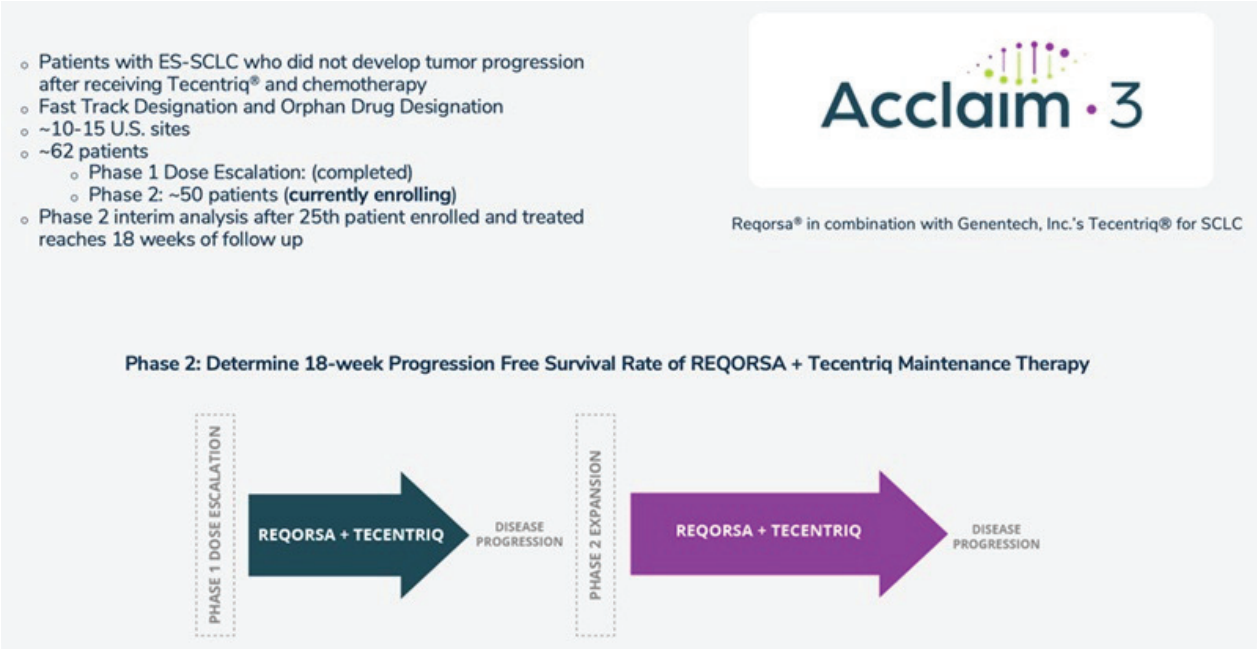
Based on these results, we started our Phase 1/2 Acclaim-2 clinical trial, an open-label, dose-escalation and clinical response study of REQORSA in combination with Keytruda in patients with advanced, metastatic non-small-cell lung cancer who have progressed after treatment with Keytruda. However, as previously announced in August 2024, Genprex has ceased enrollment in the Acclaim-2 trial. Enrollment was slow, due to competition with many other clinical trials for the same patient population, which led to the decision to end enrollment in the trial. All study closure procedures were completed as of December 2025. Although the Acclaim-2 study in patients progressing on Keytruda containing regimens has been closed due to, among other factors, slow enrollment, we continue to believe that this combination could be beneficial.

Acclaim-3

In June 2023, the FDA granted Fast Track Designation for the Acclaim-3 treatment combination of REQORSA and Tecentriq as maintenance therapy for patients with ES-SCLC who did not develop tumor progression after receiving Tecentriq and chemotherapy as initial standard treatment. In August 2023, the FDA granted Orphan Drug Designation to REQORSA for the treatment of SCLC. We have completed enrollment in the Phase 1 portion of the Acclaim-3 study and are currently enrolling patients in the Phase 2 portion of the study. Patients in the study will be enrolled after receiving initial treatment with 3-4 cycles of carboplatin, etoposide, and Tecentriq, and achieving complete response, partial response or stable disease. They will then receive treatment with REQORSA and Tecentriq as maintenance therapy every 21 days until disease progression. Patients will be treated with REQORSA and Tecentriq until disease progression or unacceptable toxicity is experienced.

In January 2024, we opened the Phase 1 portion of the Acclaim-3 study for enrollment and added multiple clinical sites through our collaboration with a large network of integrated, community-based oncology practices. The Phase 1 dose escalation portion of the trial was completed by the end of 2024. The primary endpoint of the Phase 1 escalation portion was to determine the MTD or RP2D. The Phase 1 portion of the trial had no DLTs, and therefore in December 2024, we announced that the Acclaim-3 SRC recommended that the RP2D be 0.12 mg/kg administered every 21 days, which was the highest dose level delivered in the Phase 1 portion of the trial. Although decreases in tumor size are not expected during maintenance therapy with atezolizumab alone, there were two patients out of the six enrolled in the Phase 1 dose escalation portion of the study who had marked decreases in measurable disease. We previously reported the first patient treated in the Phase 1 dose escalation portion of the Acclaim-3 trial had a partial remission, which is defined as at least a thirty percent (30%) decrease in tumor size, from prior to the start of maintenance therapy to the time of the CT scan performed after two cycles of maintenance therapy. A CT scan performed after four cycles of maintenance therapy (three months), confirmed that the patient still had a 30% decrease in tumor size in measurable lesions; however, one lesion not previously measurable had grown in size, thus leading to a conclusion of disease progression at that time. Another patient in the Phase 1 dose escalation portion of the Acclaim-3 trial had a twenty-three percent (23%) decrease in tumor size from prior to the start of maintenance therapy to the time of the CT scan performed after two cycles of maintenance therapy. This patient received seven cycles of study therapy before disease progression occurred after 4.2 months. In addition, one patient in the Phase 1 dose escalation portion of the study achieved an unconfirmed partial remission after 24 cycles of therapy and continues to receive study treatment in the trial after more than 18 months. As the maintenance therapy consists of REQORSA and Tecentriq, and the patients have already received four cycles of Tecentriq during induction therapy and thus responses to Tecentriq would likely have occurred earlier, we believe these data suggest that REQORSA may be providing clinical benefit.

We are currently enrolling and treating patients in the Phase 2 expansion portion of our Phase 1/2 Acclaim-3 clinical trial. We now anticipate enrolling approximately 50 patients at approximately 10 to 15 U.S. clinical sites. Patients will be treated with REQORSA and Tecentriq until disease progression or unacceptable toxicity is experienced. The primary endpoint of the Phase 2 portion is to determine the 18-week progression-free survival rate from the time of the start of maintenance therapy with REQORSA and Tecentriq in patients with ES-SCLC. Patients will also be followed for survival. A Phase 2 futility analysis will be performed after the 25th patient enrolled and treated reaches 18 weeks of follow up. We expect to complete enrollment of the first 25 patients for interim analysis in the Phase 2 expansion portion of the study in the first half of 2026 and expect the interim analysis in the second half of 2026.



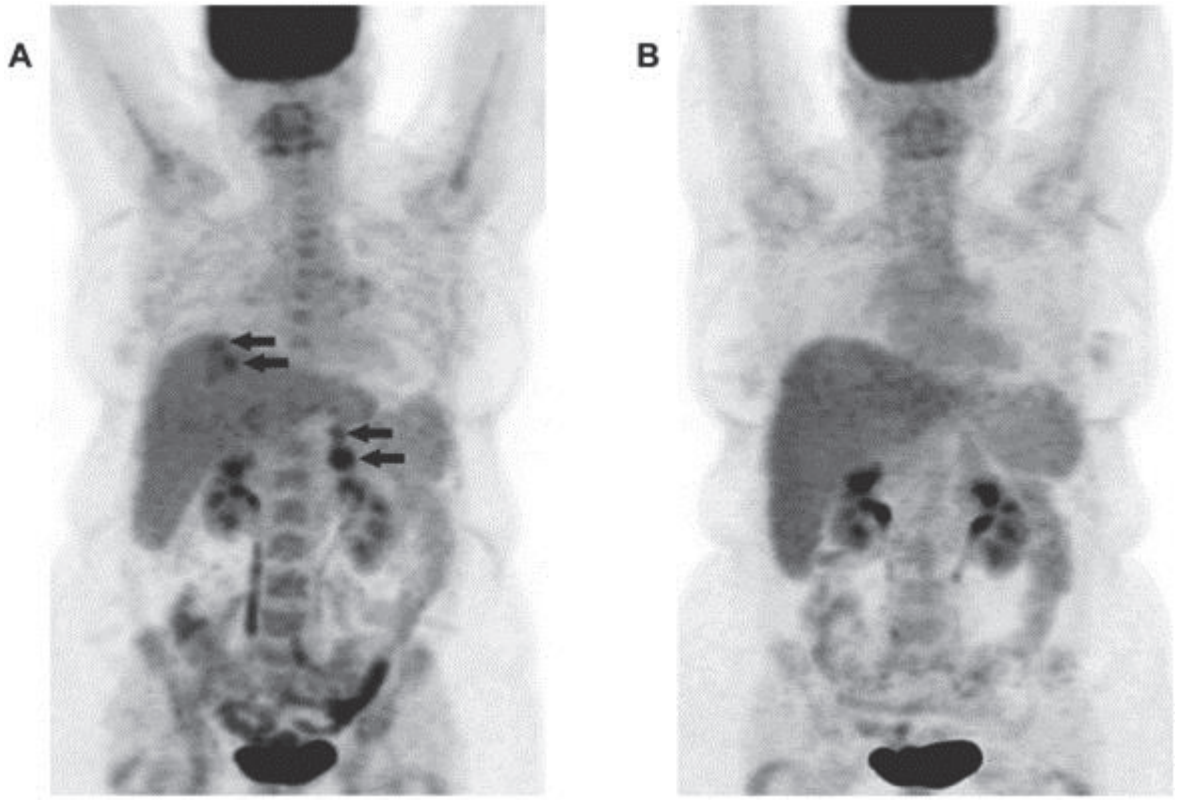
We have initiated the addition of new clinical trial sites for both Acclaim-1 and Acclaim-3, and we expect to open additional sites in 2026. We believe the addition of new sites will expedite patient enrollment in both Acclaim-1 and Acclaim-3. Furthermore, our academic research collaboration partners at MD Anderson are continuing to research biomarkers to identify patient populations that may indicate a likely response to REQORSA, which we believe could expedite patient enrollment. See the "Discovery Programs" section below for further information on the biomarker work with MD Anderson.

ONC-001: REQORSA® Phase 1 Monotherapy Trial (completed)

In 2012, MD Anderson researchers completed a Phase 1 clinical trial of REQORSA as a monotherapy (the "Phase 1 Monotherapy Trial") in patients with advanced NSCLC with disease progression at study entry. The primary objective of the REQORSA Monotherapy Trial was to assess the toxicity of REQORSA administered intravenously and to determine the MTD and RP2D of REQORSA alone. Secondary objectives were to assess the expression of TUSC2 following intravenous delivery of REQORSA in tumor biopsies and also to assess the anticancer activity of REQORSA. This trial showed that REQORSA was well tolerated and established the single-agent MTD and the therapeutic dosage for REQORSA at 0.06 mg/kg administered every 21 days. This MTD was established based on the occurrence of an asymptomatic, Grade 3 laboratory abnormality (hypophosphatemia) in 2 patients. Based on the present adverse event scales used in 2025, that laboratory abnormality would be classified as Grade 2. The definition of MTD used in the monotherapy trial was met based on this earlier version of the adverse event scale; however, with this new grading it is not clear that the MTD determined in this study is an accurate MTD for quaratusugene ozeplasmid, and in the ONC-003 and ONC-005 studies the RP2D was determined to be twice this dose. Although this trial was not designed to show changes in outcomes, a halt in cancer growth was observed in a number of patients, and tumor regressions occurred in primary lung tumors and metastatic cancers in the liver, pancreas, and lymph nodes. In addition, pre- and post-treatment patient biopsies demonstrated that intravenous REQORSA selectively and preferentially targeted patient's cancer cells and suggested that clinical anti-cancer activity was mediated by increased expression of TUSC2 in the cancer cells.

In the Phase 1 Monotherapy Trial, REQORSA was administered intravenously to stage IV (metastatic) lung cancer patients who had received traditional platinum combination chemotherapy but had tumor progression at the time of entry into the study. Thirty-one subjects were treated at six dose levels. Seventy percent of subjects had received two or more prior chemotherapy regimens. The only serious adverse events were grade 3 fever (experienced by three patients) and grade 3 hypotension (experienced by 1 patient). The only dose-limiting toxicities were two episodes of transient grade 3 hypophosphatemia (abnormally low levels of phosphate in the blood) resulting in an MTD of 0.06 mg/kg. Five patients, or 22% of the 23 evaluable patients, achieved disease control for periods ranging from 2.6 months to 10.8 months. The median disease control period for these patients was 5.0 months (95% CI: 2.0-7.6). Median survival for all subjects in the Phase 1 Monotherapy Trial was 8.3 months (95% CI 6.0-10.5 months) and mean survival time was 13.2 months (95%CI 8.9-7.5 months) with a range of two to 23+ months.

Two subjects had reductions in primary tumor size of 14% and 26%. One subject with stable disease, a 54-year-old female with a large cell neuroendocrine carcinoma who received 12 cycles of REQORSA therapy before having disease progression, had evidence of a durable metabolic response, which is a lasting reduction of metabolic activity in the tumor, as shown by positron emission tomography ("PET") imaging. The response was documented with PET scans performed after the second, fourth and sixth doses, all showing markedly decreased metabolic activity in the tumor with no changes in size or number of metastases by computed tomography ("CT") imaging. The illustration below is of the PET scan of this subject performed at baseline (Illustration A) and after the fourth dose (Illustration B). This subject had received six prior chemotherapy regimens. Prior to entry in the Phase 1 Monotherapy Trial, two hepatic metastases were progressing on gemcitabine. The subject also had a metastasis in the head of the pancreas and a peripancreatic lymph node, shown by the arrows in the illustration below. Illustration A shows the pretreatment PET scan. Illustration B shows the post treatment PET scan performed 20 days following the fourth dose of REQORSA. All scans were performed within a 60 to 90 minute window after injection.



Metabolic Tumor Response in a Metastatic Lung Cancer Subject

This subject survived after subsequent therapy more than seven years after the final treatment with REQORSA, to our knowledge, without evidence of cancer progression in the responding sites.

ONC-002: Phase 1/2 - Trial Combining REQORSA with Tarceva® (Phase 1 portion completed; Phase 2 portion closed in favor of conducting Acclaim-1 instead)

Phase 1 Portion: The Phase 1 Monotherapy Trial showed that REQORSA is well tolerated, that high levels of TUSC2 expression are detected in the tumor post-treatment, and that there was evidence of tumor growth suppression. Based on the results from the Phase 1 Monotherapy Trial and substantial preclinical evidence that REQORSA is complementary with EGFR TKIs, we began a Phase 1/2 trial (the "Phase 1/2 Combination Tarceva Trial") at MD Anderson combining REQORSA with Tarceva in patients with Stage IV (metastatic) or recurrent NSCLC that is not potentially curable by radiotherapy or surgery. Patients were enrolled whether or not they had an activating EGFR mutation. Enrollment in the Phase 1 portion of the Phase 1/2 Combination Tarceva Trial commenced in 2014 at MD Anderson with Dr. Charles Lu as the Principal Investigator.

In the Phase 1 portion of the Phase 1/2 Combination Tarceva Trial, 18 subjects were treated with the following dose levels:

Dose Level	Drug Doses
1	Tarceva (100 mg/day) + REQORSA (0.045 mg/kg)
2	Tarceva (100 mg/day) + REQORSA (0.060 mg/kg)
3	Tarceva (150 mg/day) + REQORSA (0.045 mg/kg)
4	Tarceva (150 mg/day) + REQORSA (0.060 mg/kg)

As in the Phase 1 Monotherapy Trial, subjects received a pre-treatment regimen of oral and intravenous dexamethasone and diphenhydramine to prevent infusion reaction symptoms such as fever, along with an infusion of REQORSA every three weeks. Subjects received oral Tarceva daily during each three-week cycle during the treatment period.

The Phase 1 portion of the Phase 1/2 Combination Tarceva Trial was also a dose escalation study with the primary purpose of determining the MTD. DLT were defined as grade 3, 4, or 5 events during the first cycle of treatment that were considered to be treatment related. At dose level 1, one subject had grade 3 adverse events of fatigue, muscle weakness, and hyponatremia (low sodium level) considered to be related to the study treatment (Tarceva). Therefore, three additional subjects were treated at this dose level (six subjects total), none of whom had a DLT. At dose level 2, there were no DLTs. At dose level 3, one subject had a grade 3 rash considered to be related to the study treatment (Tarceva); therefore, an additional three subjects were treated at this dose level (six subjects total). No additional subjects had a DLT. At dose level 4, there were no DLTs; thus, dose level 4, as the highest dose evaluated, was determined to be the dose to be used in the Phase 2 portion of the study.

Since the eligibility criteria, drug administration details (other than dose) and evaluation details were identical for the Phase 1 portion and the Phase 2 portion, the three subjects in the Phase 1 portion of the Phase 1/2 Combination Tarceva Trial who were treated at the Phase 2 dose (0.06 mg/kg) were included in the analysis of the Phase 2 portion of the study.

Phase 2 Portion: The Phase 2 portion of the Phase 1/2 Combination Tarceva Trial was a Simon two-stage trial designed to include subjects treated with the combination of REQORSA and Tarceva at the Phase 2 dose with the primary goal of measuring the response rate, and secondary endpoints of stable disease, time to progression and overall survival. The response rate for cancer therapies was defined as Complete Response (CR) + Partial Response (PR); disease control rate was defined as Complete Response (CR) + Partial Response (PR) + Stable Disease (SD) > 8 weeks. Although this Simon two-stage trial was closed early to start the Acclaim-1 study instead, the trial had already met the required response rate to advance to the second stage and to complete the full enrollment.

Enrollment criteria for the Phase 2 portion were identical to those in the Phase 1 portion. Subjects received three-week cycles of REQORSA in combination with Tarceva until the occurrence of progressive disease (PD), unacceptable toxicity, withdrawal of consent, or study treatment discontinuation for other reasons, whichever occurred first.

Of the 39 patients planned for the Phase 2 portion of the trial, 10 were enrolled (three of whom were also subjects of the Phase 1 portion of the Phase 1/2 Combination Tarceva Trial). None of the 10 subjects treated in the Phase 2 portion of the Phase 1/2 Combination Tarceva Trial had a DLT. Results from the Phase 2 portion for the 10 patients show that:

- One patient had a response of CR for a study CR rate of 10% and the overall response rate (CR + PR) was also 10%;
- Three patients had tumor regression; and
- Disease control rate was 70%.

The patient with the CR, a 58-year-old female, upon enrollment in the study had metastatic NSCLC following 6 cycles of pemetrexed and carboplatin and after two cycles of maintenance pemetrexed had cancer progression. The patient's tumor had EGFR exon 18 and 20 missense mutations, which are not sensitive to Tarceva alone. This patient had disappearance of lung lymph node metastases.

The response rate and disease control rate observed in the Phase 2 portion of the Phase 1/2 Combination Tarceva Trial substantially exceeds the response rate of 7% (with no CRs) and disease control rate of 58% reported for a clinical trial of the EGFR TKI afatinib (marketed as Gilotrif® by Boehringer Ingelheim Pharmaceuticals, Inc.) in a study referred to as the LUX-Lung 1 clinical trial. The LUX-Lung 1 clinical trial was a randomized, double blinded Phase 2b/3 clinical trial treating subjects with Stage IIIB or IV adenocarcinoma, a type of NSCLC. Patients in that trial had received one or two previous chemotherapy regimens and had disease progression after at least 12 weeks of treatment with EGFR inhibitors erlotinib or gefitinib. A total of 585 patients were enrolled in that Phase 2b/3 clinical trial, whose primary endpoint was overall survival and whose secondary endpoints included progression-free survival and RECIST response. The Phase 2 portion of our Phase 1/2 trial was not blinded and was designed to treat NSCLC subjects regardless of EGFR status.

The following table provides data from the Phase 2 portion of the Phase 1/2 Combination Tarceva Trial for subjects with and without EGFR mutations. Note that two patients with disease progression on Tarceva received 10 and 12 cycles of Tarceva, respectively, before disease progression and entry into the trial. With the combination of REQORSA and Tarceva, both of these patients had stable disease, suggesting that the combination therapy may be an effective treatment for patients whose disease is progressing after extensive Tarceva treatment. We are no longer enrolling the Phase 2 portion of the Phase 1/2 Combination Tarceva Trial in favor of conducting the Acclaim-1 trial, which combines REQORSA with Tagrisso, since Tagrisso has been shown to be more effective than Tarceva as initial therapy for patients with NSCLC with EGFR mutations.

REQORSA + TARCEVA COMBINATION

PHASE 2 PRELIMINARY DATA IN SUBJECTS WITH OR WITHOUT EGFR MUTATIONS

RESPONSE	NUMBER OF CYCLES	EGFR MUTATION STATUS	PRIOR THERAPY	PRIOR LINES OF THERAPY
Complete Response	11 cycles	Positive (exon 18+20)	Chemo	3
Stable Disease 24% Regression Target Lesion	6 cycles	Unknown	Chemo / anti-PD1	2
Stable Disease 30% regression one Target Lesion 17% regression all Target Lesion	8 cycles	Negative	Chemo / anti-PD1	6
Stable Disease	4 cycles	Positive (exon 21)	Erlotinib *(10 cycles) / Chemo*	3
Stable Disease	4 cycles	Positive (exon 21)	Erlotinib *(12 cycles)*	2
Stable Disease	4 cycles	Negative	Chemo	2
Stable Disease	4 cycles	Unknown	Chemo	4

Preclinical Studies of REQORSA Supporting Our Conduct of Acclaim-1

REQORSA and Tyrosine Kinases. Investigators at MD Anderson conducted preclinical research showing that REQORSA alone blocked the activation of the c-Abl tyrosine kinase. A number of other studies at MD Anderson have shown the complementary effects of REQORSA combined with a variety of targeted kinase inhibitory agents, both marketed and in various stages of clinical development, including Tarceva, Iressa, and Tagrisso.

REQORSA and TUSC2 deficient and Tarceva or Iressa resistant cell lines. MD Anderson researchers also tested REQORSA in TUSC2-deficient and Tarceva- or Iressa-resistant NSCLC cell lines. Treatment of the NSCLC EGFR mutation negative cell lines H1299, H322, H358 and H460 cancer cell line showed that the REQORSA combination significantly sensitized ($p<0.001$) response of the cancer cell lines to both Tarceva or Iressa treatment and synergistically induced apoptosis *in vitro*. The findings were confirmed *in vivo* in an H322 orthotopic lung cancer mouse model. These studies included the Kras mutant cell line H460, which is significant because patients with Kras mutant tumors are generally unresponsive to Tarceva or Iressa. Synergistic induction of apoptosis was observed with the combination of REQORSA and concentrations of Tarceva or Iressa similar to steady-state serum concentrations achievable with oral dosing. The combination of REQORSA and either Tarceva or Iressa induced similar levels of tumor cell growth inhibition, apoptosis induction, and inactivation of oncogenic protein kinases.

Data from these and other studies suggest a combination of REQORSA with Iressa or Tarceva can promote synergistic tumor cell killing and overcome drug-induced resistance by simultaneously inactivating the EGFR and the AKT signaling pathways and by inducing apoptosis in resistant cells with nonmutated EGFR. These data suggest that NSCLC patients with an activating EGFR mutation, whose cancer progresses on Tarceva, may potentially benefit from REQORSA with Tarceva combination therapy. These data also suggest that NSCLC patients without an activating EGFR mutation (generally unresponsive to Tarceva) may potentially benefit from REQORSA with Tarceva combination therapy. These data provided strong support for the ONC-002 trial, which combined REQORSA with Tarceva.

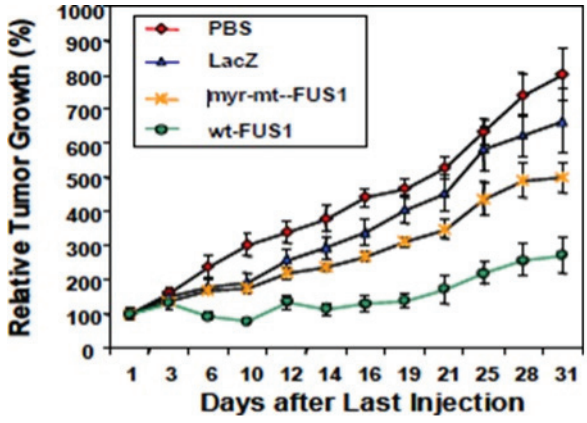
REQORSA in Tagrisso resistant cell lines. Tagrisso (osimertinib), a third-generation EGFR inhibitor, shows robust clinical activity, yet patients inevitably develop secondary resistance. An osimertinib resistant H1975-OsiR isogenic cell line was developed through continuous exposure to osimertinib, and an osimertinib resistant clone was selected which showed 100-fold higher resistance to osimertinib compared with its parental counterpart (H1975-parental). Xenograft tumors from both H1975-parental and H1975-OsiR cells were developed in NSG mice and were treated with osimertinib. H1975-OsiR tumors were significantly less sensitive than its parental counterpart. Synergistic antitumor activity of TUSC2+osimertinib was found in H1975-OsiR tumors where both TUSC2+osimertinib (5mg/kg) and TUSC2+osimertinib (10mg/kg) combinations showed a robust antitumor effect compared with single agent treatment groups. No synergistic effect was observed for H1975-parental tumors. In conclusion, TUSC2 therapy in combination with osimertinib showed synergistic antitumor efficacy in EGFR mutant osimertinib resistant NSCLC tumors. These data provide a strong biologic rationale for the Acclaim-1 clinical trial.

Preclinical Studies of TUSC2 in the Immune Response to Cancer Supporting Our Conduct of Acclaim-2

Preclinical studies indicate that REQORSA is selectively taken up by tumor cells with a 10 to 33 fold differential favoring uptake by tumor cells, thus imparting a passive targeting property without the need to attach targeting ligands. REQORSA targeting is partly due to the attraction of opposite charges (REQORSA has a positive charge, normal cells no charge, and most cancer cells have a negative charge), and partly due to increased endocytosis by tumor cells, and is enhanced by the leakiness that is characteristic of tumor vasculature compared to normal vasculature.

In experimental mouse xenograft models, the ONCOPREX delivery system was shown to efficiently deliver several therapeutic tumor suppressor genes (*TP53*, *FHIT*, *TUSC2*) to disseminated human cancer cells. Metastatic tumor growth was suppressed, and survival prolonged, after systemic administration of the genes via a nanovesicle vector. Human NSCLC A549 cells have virtually no *TUSC2* protein. As shown in Figure 1, intratumoral administration of REQORSA (referred to as FUS1 in Figure 1) to subcutaneous NSCLC H1299 tumor xenografts resulted in inhibition of tumor growth.

Figure 1. Effect of REQORSA on the Growth of H1299 Subcutaneous Tumor Xenografts in Nude Mice



Moreover, intravenous injections of REQORSA into mice bearing experimental A549 lung metastases resulted in a decrease in the number of metastatic tumor nodules. Lung tumor-bearing animals treated with REQORSA also had a significant increase (P=0.01) in survival time (median survival time: 80 days) compared with 48 to 51 days for control animals.

Analysis of *TUSC2* expression by IHC following REQORSA treatment showed distribution of *TUSC2* throughout the tumor in a high percentage of the tumor cells. These results demonstrate the potent tumor suppressing activity of the *TUSC2* gene, supporting the feasibility of using nanovesicles for systemic plasmid delivery to metastases as well as to primary tumors, and implicating REQORSA as a promising therapeutic agent for primary and disseminated human lung cancer.

REQORSA Synergizes with Keytruda® (pembrolizumab)

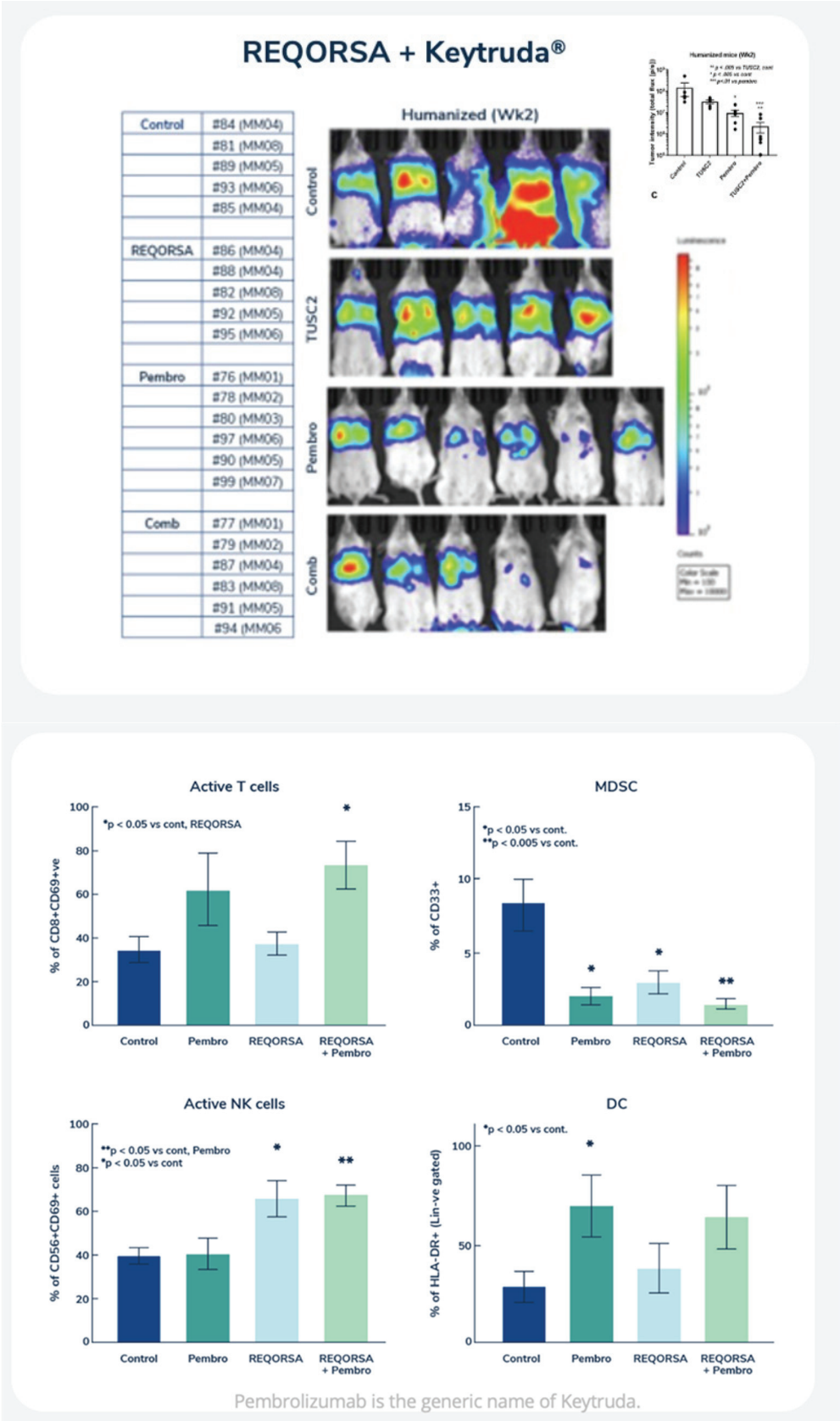
It was previously shown that the combination of REQORSA and an anti-PD1 antibody inhibited tumor growth synergistically in subcutaneous and metastatic NSCLC *KRAS* mutant syngeneic mouse models. To determine whether this synergy also applies to the *KRAS*/*LKB1* mutant subtype of human A549 NSCLC cells, humanized mice harboring *KRAS/LKB1* mutant A549 lung metastases were treated with REQORSA, pembrolizumab or the combination. These studies were performed with an improved humanized mouse model using fresh human umbilical cord blood derived CD34+ stem cells in irradiated NSG mice, in which mouse immune system cells have been largely destroyed. The reconstituted humanized mice have a fully competent human immune system with major functional immune populations and were used here to evaluate synergy between REQORSA and pembrolizumab.

The treatment strategy is shown in Figure 2. REQORSA (referred to as TUSC2 in Figure 2) was administered intravenously every 48 hours for a total of three injections, and pembrolizumab was administered every 3-4 days a total of three times. Bioluminescence imaging was performed to visualize the intensity of tumor burden for mice in different treatment groups both in humanized and non-humanized mice. Both REQORSA and pembrolizumab monotherapies reduced the tumor burden significantly, although pembrolizumab was moderately more effective. Importantly, REQORSA plus pembrolizumab inhibited tumor growth synergistically (*P< 0.05, **P< 0.005, ***, P< 0.0005). There was no antitumor effect of pembrolizumab and reduced change with REQORSA in non-humanized mice, which was expected since these mice have no immune cells.

To identify the immunological features associated with efficacy of this combination, in depth immune profiling of the tumor microenvironment was performed. An increased number of reconstituted human CD3+ T cells was found in all groups, compared with the untreated control. CD8+ T cells were significantly upregulated by pembrolizumab and its combination with REQORSA. Levels of activated CD8+ T cells (CD8+CD69+) were also significantly increased in the combination group and were slightly higher than the pembrolizumab group. There was no effect of pembrolizumab on NK/activated NK cells, whereas REQORSA alone enhanced their levels significantly, indicating REQORSA regulation of NK activation, which is consistent with the previous findings reported in syngeneic mice. The combination had a similar effect as REQORSA monotherapy. REQORSA, pembrolizumab, and the combination, were all associated with significant decrease of reconstituted human myeloid derived suppressor cells (“MDSCs”) (CD33+ve). Pembrolizumab and the combination had a profound stimulatory effect on HLA-DR+ dendritic cells (DCs). REQORSA alone enhanced HLA-DR+DC levels moderately. Taken together, these results show that the combination of REQORSA and pembrolizumab enhanced the immune response and inhibited tumor growth synergistically (*P< 0.05, **P< 0.005, ***, P< 0.0005).

REQORSA also showed synergistic antitumor activity with nivolumab in the same mouse model, highlighting the role of REQORSA rendering *KRAS/LKB1* mutant tumors more sensitive to immune checkpoint blockade. Thus, these data suggest that the synergy of REQORSA with immune checkpoint inhibitors is not limited to pembrolizumab.

Figure 2. Synergistic Antitumor Effect of REQORSA Gene Therapy with Keytruda® (pembrolizumab) on *KRAS/LKB1* Mutant Lung Metastases in the Humanized Mouse Model



Preclinical Studies of TUSC2 Supporting Our Conduct of Acclaim-3

Transfection of SCLC cells in vitro with TUSC2 showed growth inhibition and a marked suppression of colony formation compared to cells transfected with a control vector. These results demonstrate the potential tumor suppression function of TUSC2 in SCLC cells and suggest that TUSC2-mediated gene therapy could be a useful therapeutic strategy for the treatment of SCLC.

Data presented at the October 2023 AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics from studies in humanized mouse models of SCLC that use human H841 cells have shown that the combination of REQORSA (quaratusugene ozeplasmid) and Tecentriq® (atezolizumab) provides significantly better control of tumor burden than either agent alone (Figure 3, Figure 4, and Figure 5). H841 is a human SCLC cell line that does not express TUSC2 protein, and which was labeled with luciferase for these experiments. When injected intravenously, H841 cells metastasize to both lung and liver. The reconstituted humanized mice have a fully competent human immune system with major functional immune populations, which showed antigen specific T cell responses as well as antitumor activity with immune checkpoint blockade therapy and was used here to evaluate synergy between quaratusugene ozeplasmid and atezolizumab.

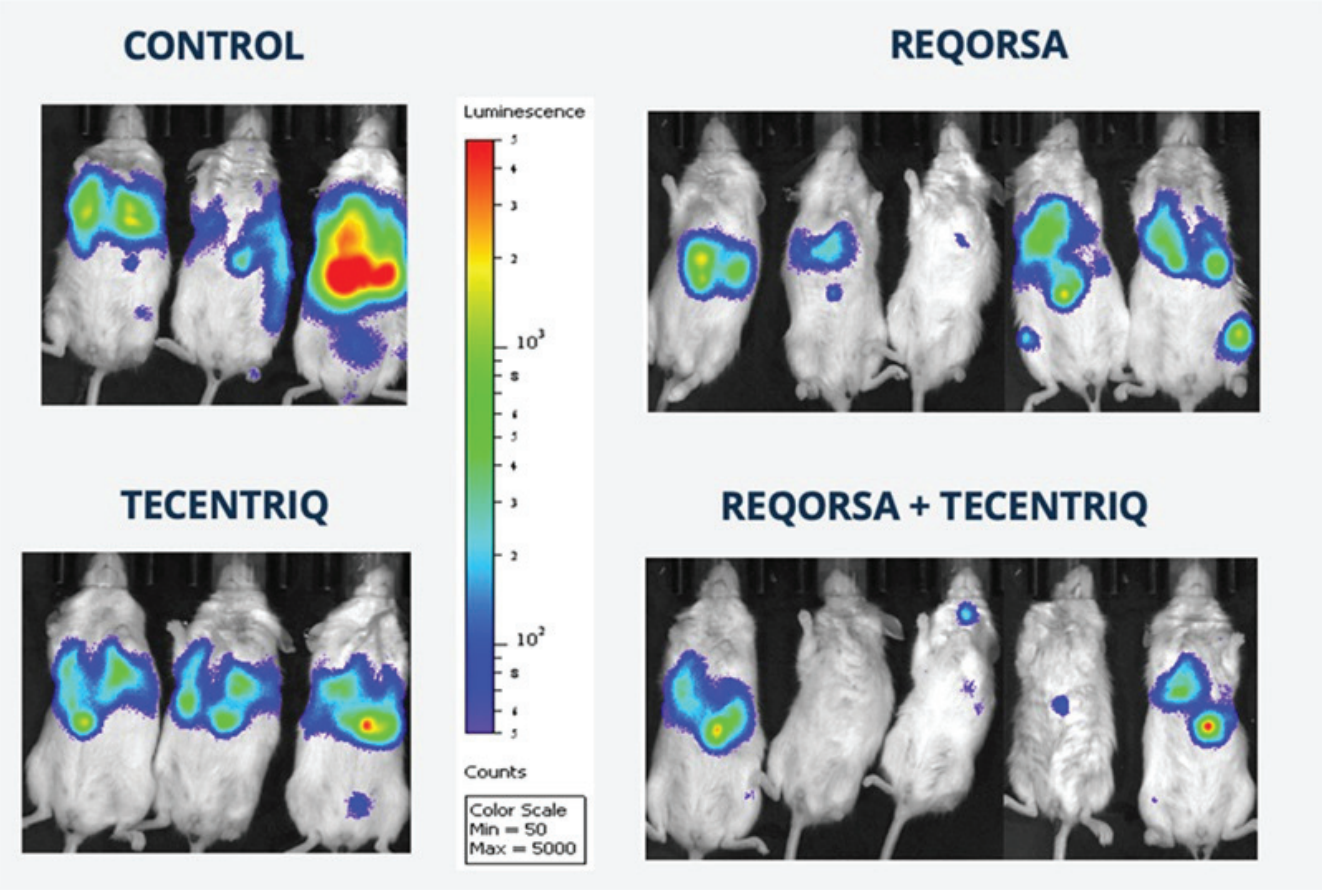
In these studies, one million H841 cells/mouse were injected intravenously, and treatment began 12 days later, after the metastases were well established. Quaratusugene ozeplasmid was administered intravenously every other weekday at a dose of 25 μg/mouse of plasmid DNA: 10 nmol liposome solution in 100 μL of D5W for 5 doses. Atezolizumab was administered at a dose of 300 μg/mouse intraperitoneal injection twice a week for 4 doses. Three weeks later, bioluminescence imaging was performed to visualize the intensity of tumor burden for mice in different treatment groups.

Humanized mice with H841 xenografts were treated with quaratusugene ozeplasmid, atezolizumab or the combination. With the combination of quaratusugene ozeplasmid and atezolizumab there was a highly significant reduction in tumor burden compared to the results with atezolizumab alone ($p=0.002$). There was approximately a 10-fold reduction in tumor burden in the quaratusugene ozeplasmid plus atezolizumab group compared to untreated control mice. Note that 3 out of 5 mice in the quaratusugene ozeplasmid plus atezolizumab group had complete or near-complete responses (Figure 3). Figure 4 provides a graph of the bioluminescence flux in the treatment groups.

Analysis of the tumor immune microenvironment in the H841 xenografts (Figure 5) shows that, compared to treatment with atezolizumab alone, the combination of quaratusugene ozeplasmid and atezolizumab leads to increased numbers of huCD8 T-cells, NK cells, and DC, and lower numbers of MDSCs. These changes indicate an increased immune response to the xenograft and identify at least one mechanism responsible for the increased tumor response seen with quaratusugene ozeplasmid and atezolizumab in combination.

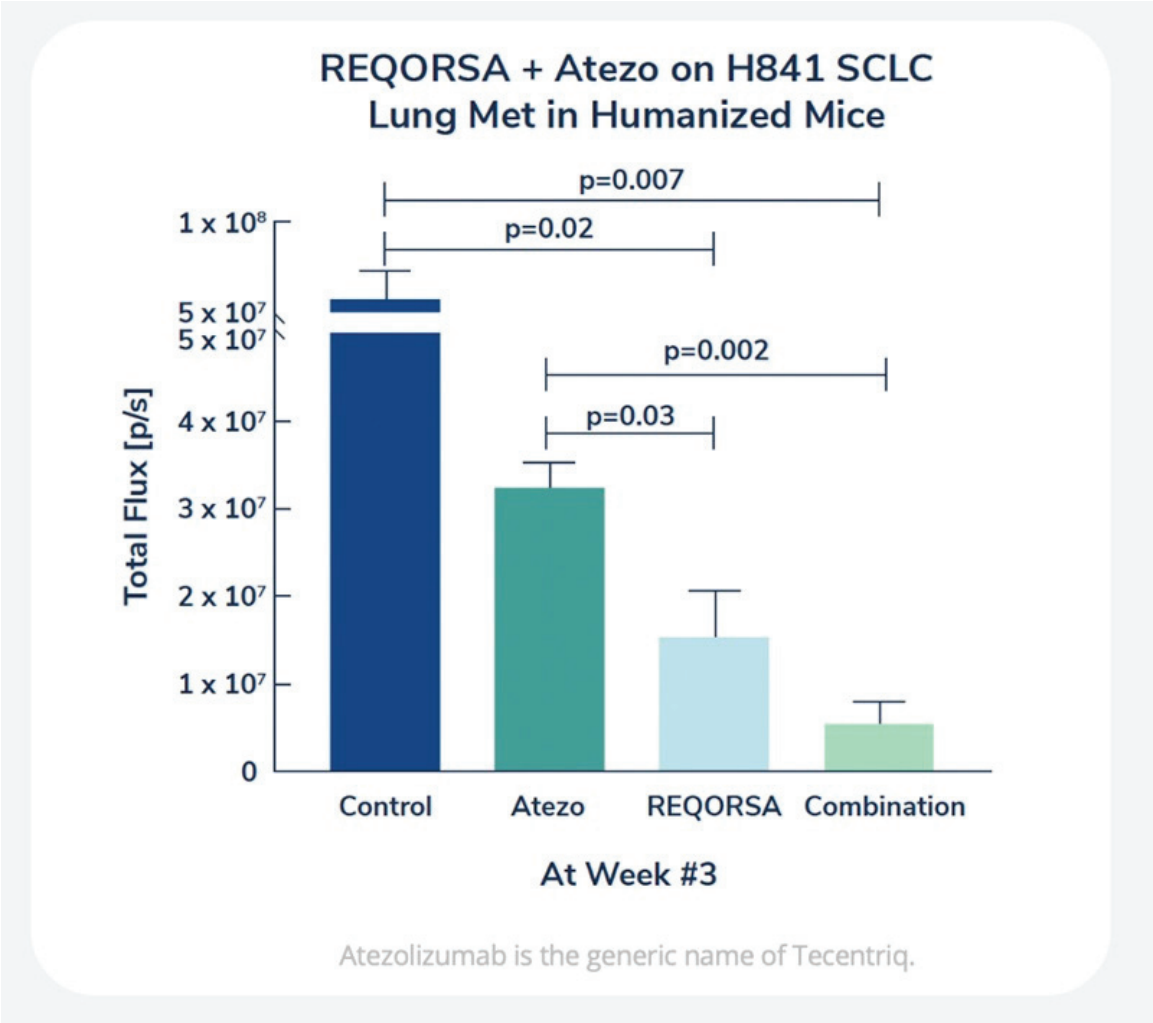
In summary, the data from these studies suggest that a combination treatment of quaratusugene ozeplasmid and atezolizumab can promote a significantly increased tumor cell killing effect in SCLC xenografts compared to that of atezolizumab alone.

Figure 3. Bioluminescence Flux after REQORSA (quaratusugene ozeplasmid) and Tecentriq (atezolizumab) as Single Agents and in Combination in H841 SCLC Model in Humanized Mice



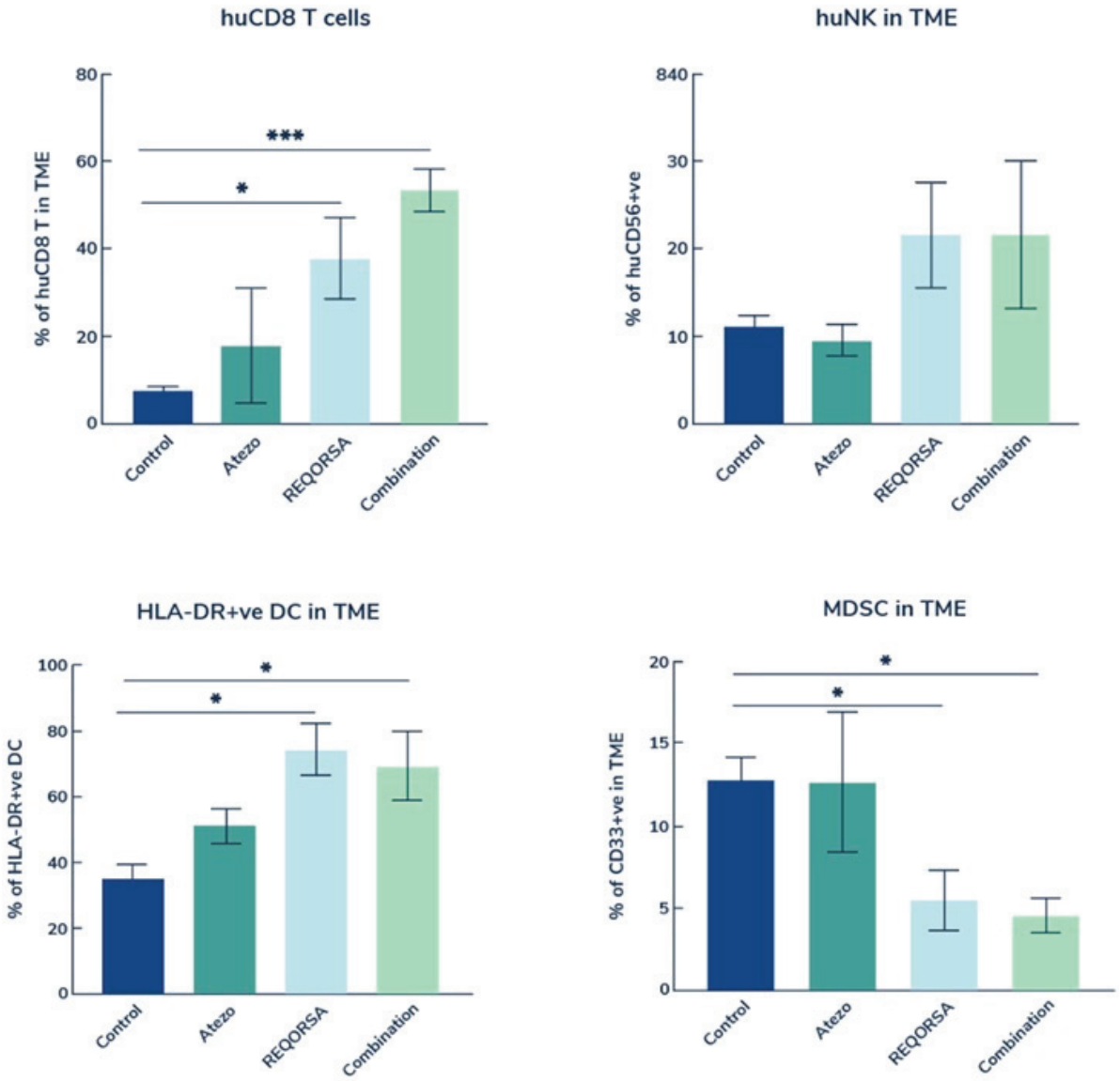
Abbreviations: Atezo = atezolizumab; max = maximum; min = minimum; Quar Oze = quaratusugene ozeplasmid; SCLC = small cell lung cancer

Figure 4. Graph of Bioluminescence Flux after Quaratusugene Ozeplasmid and Atezolizumab as Single Agents and in Combination in H841 SCLC Model in Humanized Mice



Abbreviations: Atezo = atezolizumab; Quar Oze = quaratusugene ozeplasmid; SCLC = small cell lung cancer

Figure 5. Analysis of the Tumor Immune Microenvironment After Quaratusugene Ozeplasmid and Atezolizumab as Single Agents and in Combination Using an H841 SCLC Model in Humanized Mice



Abbreviations: Atezo = atezolizumab; DC = dendritic cells; HLA-DR = human leukocyte antigen – DR isotype; huCD8 T cells = human CD8 T cells; huNK = human natural killer cells; MDSC = myeloid derived suppressor cells; Quar Oze = quaratusugene ozeplasmid; TME = tumor microenvironment

Introduction – Diabetes

Diabetes Mellitus. Diabetes mellitus refers to a group of metabolic diseases that affect how the body produces and uses blood sugar (glucose). Glucose is vital to health because it is an important source of energy for the cells that make up the body's muscles and tissues. It is also the brain's main source of fuel. Chronic diabetes conditions include Type 1 diabetes and Type 2 diabetes, both of which lead to excess glucose in the blood and can cause serious health problems. Left untreated, high blood glucose levels can damage the eyes, kidneys, nerves, and the heart, and can also lead to coma and death.

Epidemiology of Diabetes. According to the U.S. Center for Disease Control as of 2026, approximately 40.1 million Americans, or approximately 12% of the U.S. population, have diabetes. It is also believed that more than 115.2 million Americans aged 18 years or older have prediabetes. In 2024, approximately 589 million adults (20-79 years) worldwide were living with diabetes, and the total number of people living with diabetes is projected to rise to approximately 853 million by 2050. Also in 2024, diabetes caused more than 3.4 million deaths globally and diabetes resulted in approximately one trillion dollars in health expenditures, representing 12% of global health expenditures.

The Role of Alpha Cells and Beta Cells. The two most abundant endocrine cell types in the pancreas, the beta and the alpha cells, are essential for the maintenance of blood glucose homeostasis whereby levels of glucose are maintained by the body within a narrow range. While the beta cell produces insulin, the only blood glucose-lowering hormone of the body, the alpha cell releases glucagon, which elevates blood glucose.

In people with Type 1 diabetes, however, beta cells are destroyed by the immune system and no longer secrete insulin, leading to an absolute deficit of insulin. Type 2 diabetes is due to "insulin resistance," an initial resistance of the body's cells to obey the direction from insulin. To overcome this resistance, the beta cells secrete more insulin, and glucose is eventually forced into the cells. Glucose is maintained within normal limits, but at the expense of increased insulin secretion by the beta cells. After many years of such increased secretion, the beta cells become "tired" from working overtime, and the fatigue process begins. This fatigue tends to be progressive, and in time the compensation for insulin resistance disappears. At that point, blood glucose levels start going up.

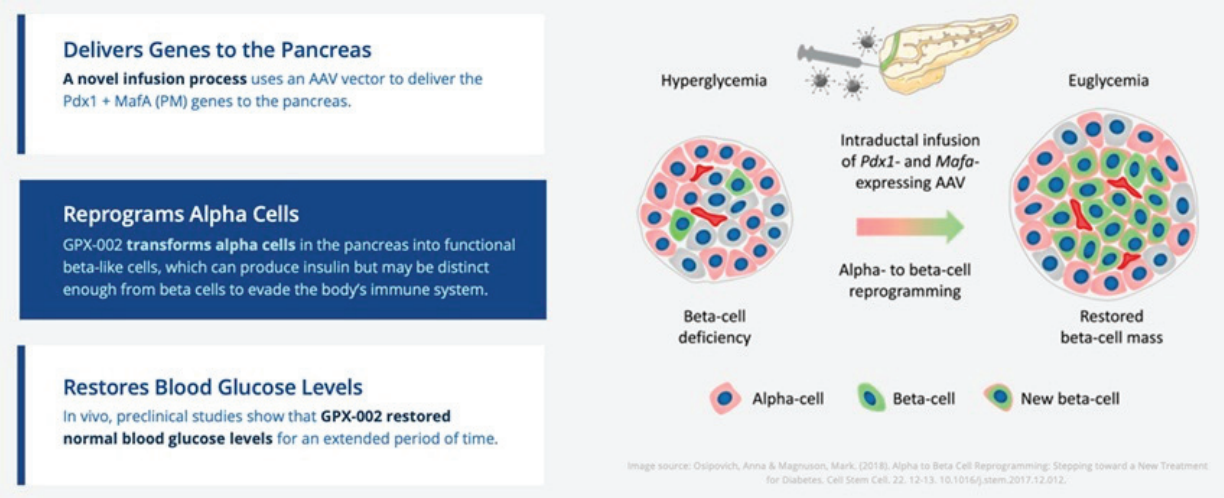
Current Treatments for Diabetes. Advances in new treatments have helped many people better manage the disease. However, despite patients' best attempts, managing diabetes remains a challenging, daily balancing act because exogenous insulin therapy simply cannot ideally mimic the body's biological function.

Type 1 diabetes patients are treated with insulin, with most of the progress in therapy relating to enhanced delivery of the drug and improved methods for measuring blood glucose levels. A variety of drug release technologies have allowed for rapid-acting, intermediate-acting and long-acting insulin injections that provide drug anywhere from one to 24 hours. In addition, improvements in needles, continuous delivery ports, and inhalation technologies all have helped patients better manage their disease and may impact quality of life, but none of these advances are disease modifying.

Type 2 diabetes patients are advised to use diet and exercise to manage their condition. When these lifestyle changes alone do not control the disease, Type 2 diabetes patients may be prescribed a variety of medications that help alter how the body manages blood sugar levels. For example, biguanides such as metformin, reduce the amount of glucose produced in the liver. DPP-4 inhibitors, such as Januvia®, Onglyza®, and Tradjenta®, improve blood sugar levels and prevent them from dropping too low. Glucagon-like peptides, such as Ozempic®, Mounjaro®, Wegovy®, Trulicity®, Byetta® and Victoza®, change the way the body produces insulin. Drugs in the SGLT2 inhibitor class, such as Farxiga® and Invokana®, release more glucose into the urine. Finally, insulin injections may be needed if these oral medications, along with diet and exercise, do not lower blood sugar levels enough. These medications, including insulin replacement therapy, while offering improvements for Type 2 diabetes patients, do not affect the underlying cause of the disease.

GPX-002

As further described in the "Licenses and Research Collaborations" section below, we have exclusively licensed from the University of Pittsburgh multiple technologies relating to the development of a gene therapy product for each of Type 1 and Type 2 diabetes. The same novel approach is used in each of Type 1 and Type 2 diabetes whereby an AAV vector containing the Pdx1 and MafA genes is administered directly into the pancreatic duct. In humans, we believe this can be done with a routine endoscopy procedure, called endoscopic retrograde cholangiopancreatography (ERCP). Our diabetes product candidates are currently being evaluated and optimized in preclinical studies at the University of Pittsburgh. GPX-002 is being developed for the treatment of both Type 1 diabetes and Type 2 diabetes. GPX-002 for Type 1 diabetes is designed to work by transforming alpha cells in the pancreas into functional beta-like cells, which can produce insulin but may be distinct enough from beta cells to evade the body's immune system. In a similar approach, GPX-002 for Type 2 diabetes, where autoimmunity is not at play, is believed to work by replenishing and rejuvenating exhausted beta cells that make insulin. We finalized the components of the original diabetes construct to take forward for preclinical studies and in December 2023, we submitted a request to meet with the FDA to obtain their guidance on the preclinical studies needed to file an IND application and initiate first-in-human studies. As a result of the FDA's response, we decided to continue with our planned additional preclinical studies before requesting regulatory guidance for the IND-enabling studies. We are currently working with the University of Pittsburgh on species analyses for the animal models as well as other regulatory and clinical strategic planning, including the planned initiation of research in Type 2 diabetes animal models. In December 2025, we also executed on our strategic goal to submit a meeting request to the FDA by the end of the year to discuss the necessary IND-enabling preclinical studies, an important step before potentially initiating clinical trials in humans. See the "Recent Developments" section above for more information on our meeting with the FDA which occurred in February 2026.



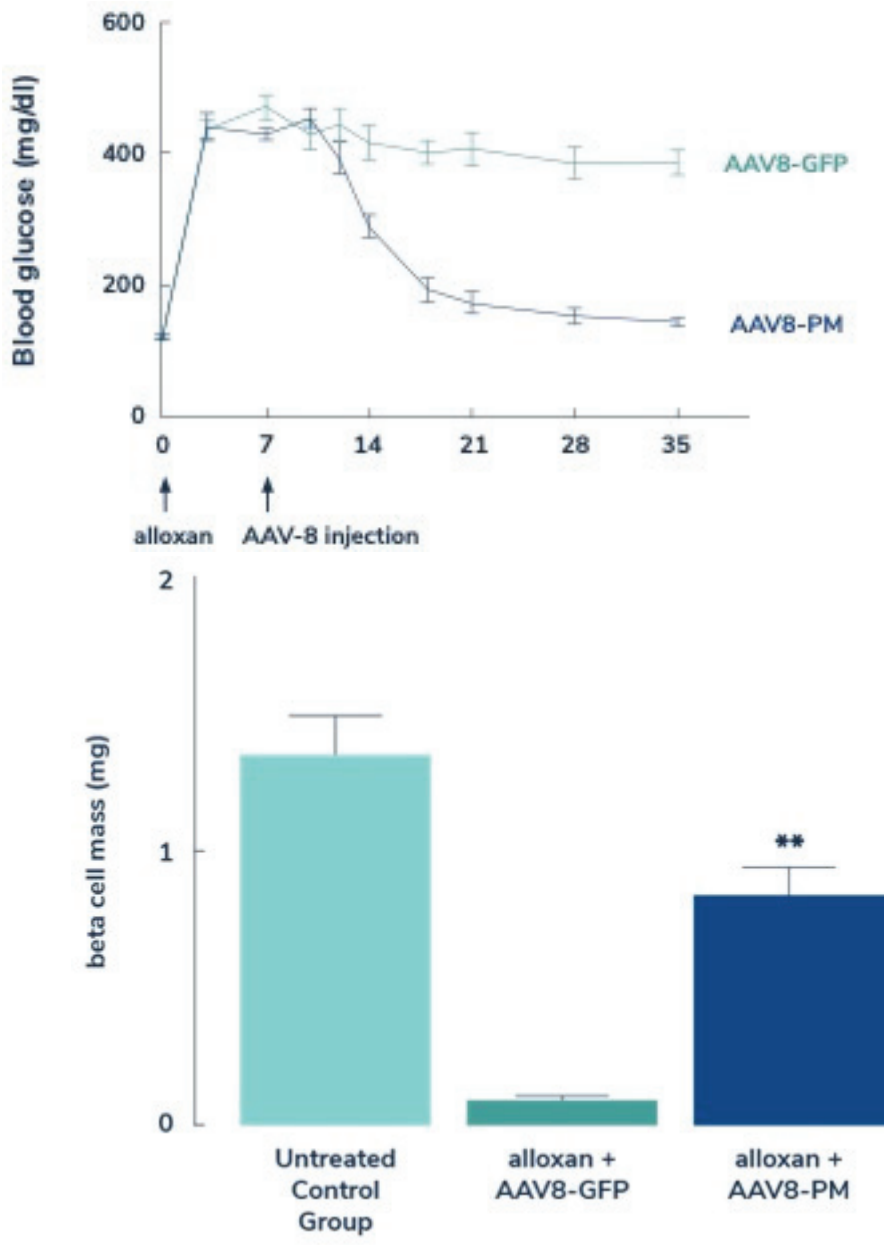
In May 2025, following the completion of our August 2022 sponsored research agreement with UP, we entered into a new sponsored research agreement with UP to study Type 1 diabetes and Type 2 diabetes in animal models. The new sponsored research agreement also includes a revised research plan to encompass our most recent technologies to which we originally acquired exclusive rights from UP in July 2023 as amended and restated in the comprehensive New UP License Agreement in February 2025. These include a MafB promoter to drive expression of the Pdx1 and MafA transcription factors that can potentially be used for both Type 1 and Type 2 diabetes.

This gene therapy approach has been tested *in vivo* in mice and NHPs using an earlier construct as described below.

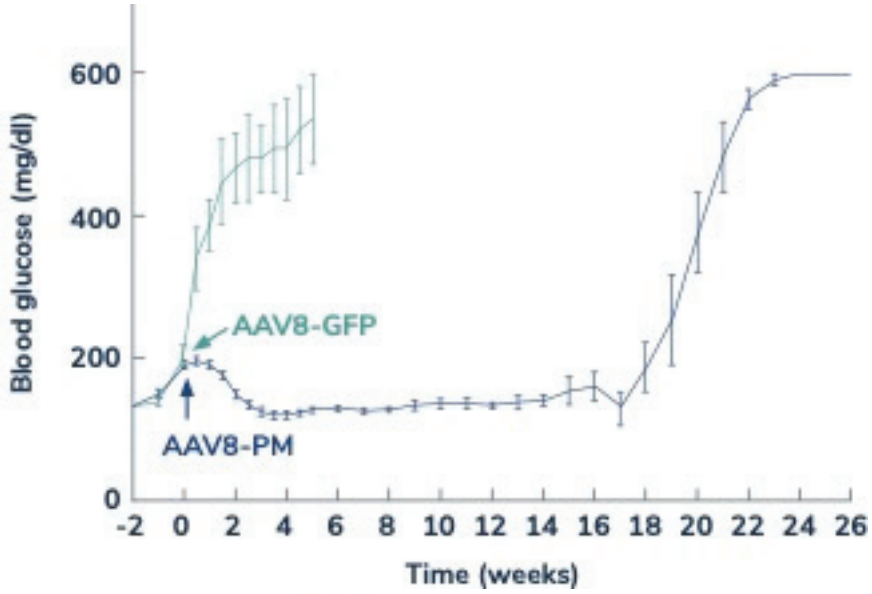
Preclinical Mouse Studies

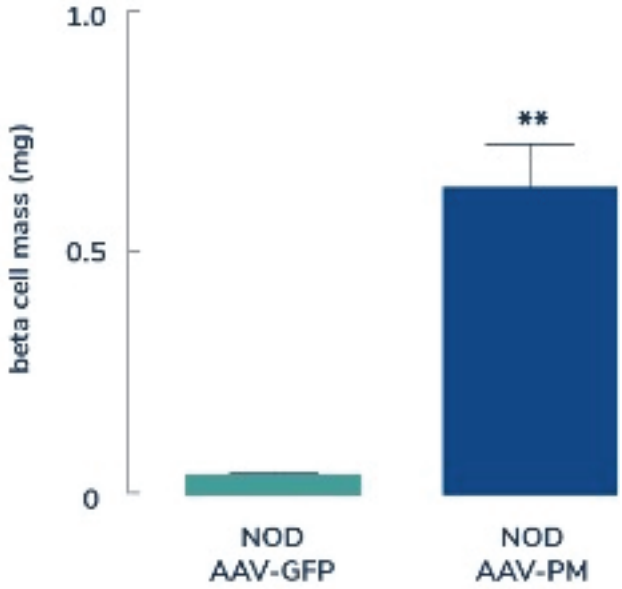
In studies in mice treated to destroy insulin producing beta cells and in non-obese diabetic ("NOD") mice, both of which are models of Type 1 diabetes, our gene therapy approach restored normal blood glucose levels for an extended period of time, and markedly increased the mass of insulin producing beta cells.

The figures below show that starting approximately one week after injection of the engineered AAV construct (labeled AAV8-PM) into the pancreatic duct, the blood glucose level markedly improved in mice in which insulin producing cells had been destroyed by the drug alloxan (ALX). In addition, the mass of beta cells and beta-like cells producing insulin was significantly increased.

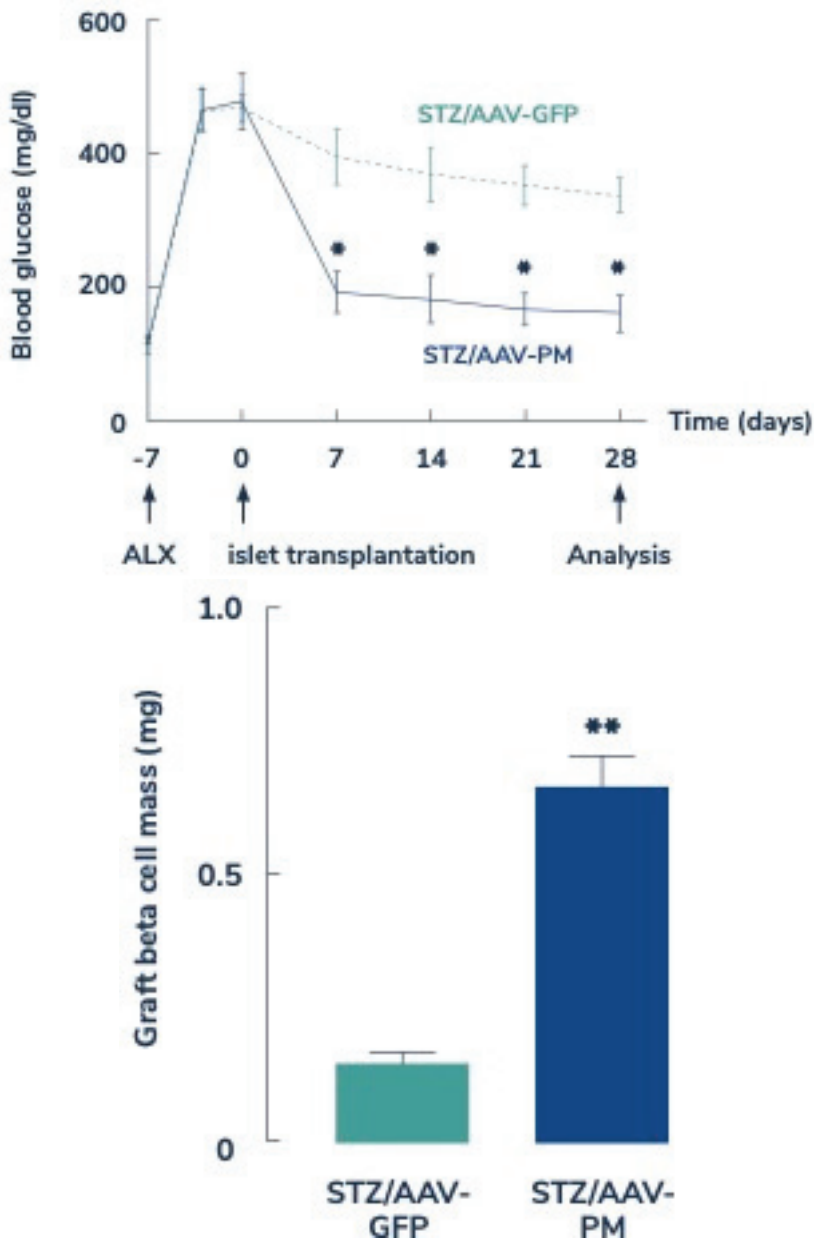


NOD mice develop diabetes due to an immune attack that destroys the insulin producing beta cells in the pancreas. The figures below show that starting approximately one week after injection of the engineered AAV construct (labeled AAV8-PM) into the pancreatic duct the blood glucose level markedly improved in NOD mice. In addition, there is a significant increase in the mass of beta cells and beta-like cells that produce insulin. The improvement in glucose level normalization lasted approximately 4 months, which, according to the researchers could potentially translate to decades in humans. Importantly, comparison to the effect of syngeneic islet transplants suggests that the beta-like cells generated in these experiments are recognized poorly by the immune system, as NOD mice given syngeneic islet transplants became hyperglycemic a median of 17 days after treatment compared to the 4 months of glucose control generated in these experiments.





The researchers also carried out an experiment to determine if the same AAV engineered construct could be used to convert human alpha cells to beta-like cells that would produce insulin as shown in the figures below. Human pancreatic islets were treated with streptozotocin (STZ) to destroy beta cells and then were treated with the AAV engineered construct. They were then transplanted into NOD mice that had been treated with alloxan (ALX) and were also modified so they would not reject human cells. The NOD mice that received the AAV engineered construct had significantly lower blood glucose levels and higher mass of beta and beta-like cells that secrete insulin than did control mice. These data suggest that the same AAV engineered construct can convert human alpha cells into insulin secreting beta-like cells.

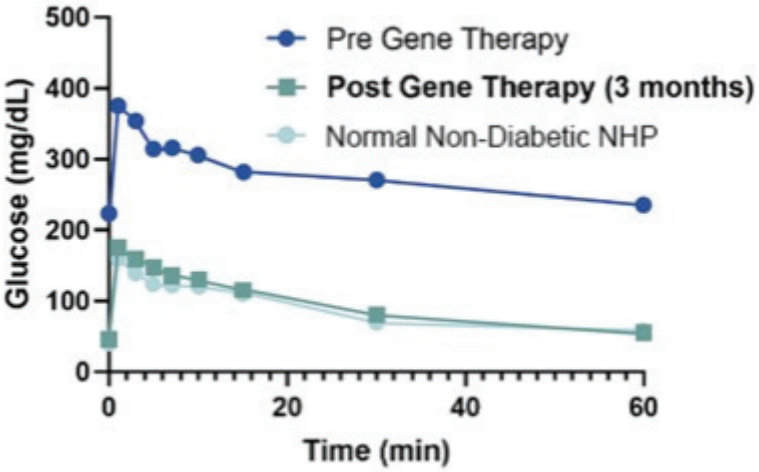


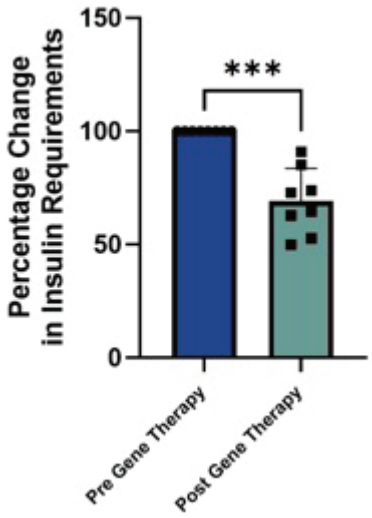
Preclinical Non-Human Primate Studies

In February 2023, our research collaborators at the University of Pittsburgh presented preclinical data in a NHP model of Type 1 diabetes highlighting the therapeutic potential of GPX-002 at the 16th International Conference on Advanced Technologies & Treatments for Diabetes (ATTD 2023) in Berlin, Germany. The statistically significant study results showed that after infusion of the AAV engineered construct all eight of the NHPs had:

- Decreased insulin requirements ($p<0.001$);
- Increased c-peptide levels ($p<0.05$);
- Improved glucose tolerance compared to baseline ($p<0.05$) with one demonstrating reestablished normoglycemia; and
- Insulin and glucagon staining in the same cells, suggesting the formation of insulin-producing cells.

We believe these data in NHPs demonstrate the potential for this gene therapy treatment to eliminate the need for insulin replacement therapy for Type 1 and Type 2 diabetic patients.

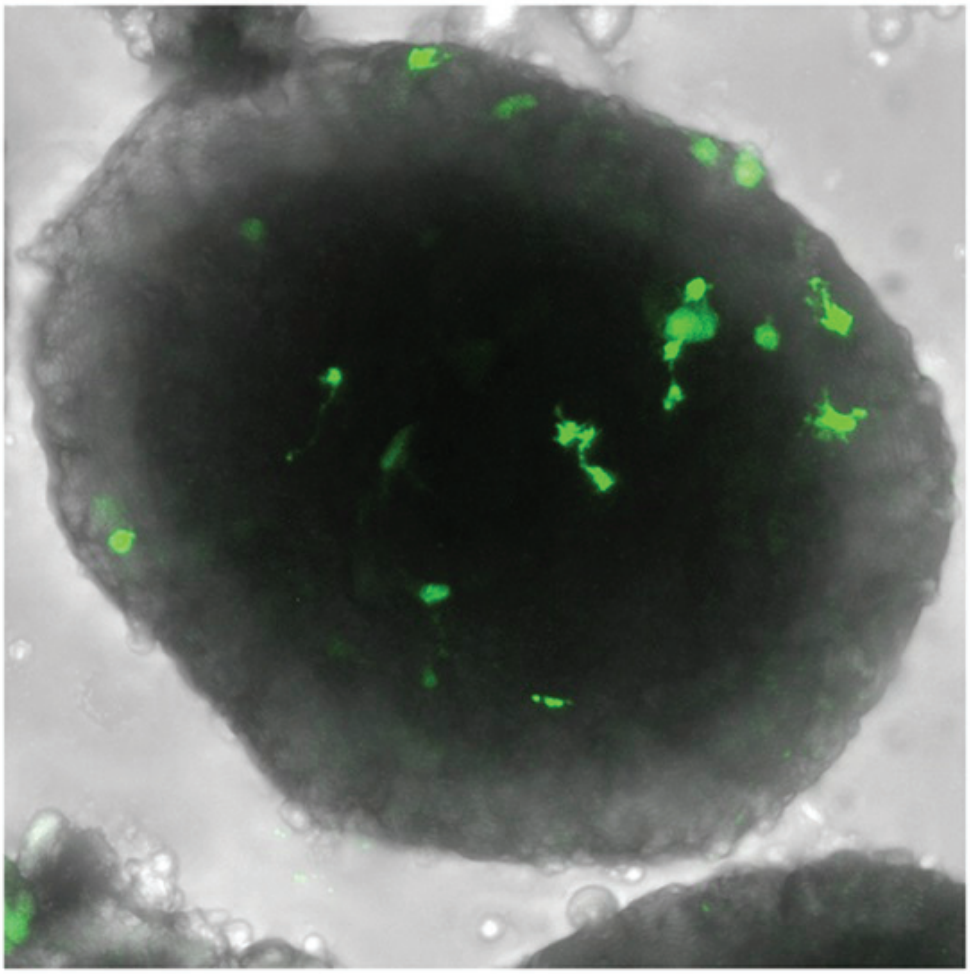




In June 2025, our collaboration partners had two presentations at the 2025 ADA 85th Scientific Sessions. Our research collaborators from UP were invited to give an oral presentation highlighting their work in NHP models of Type 1 diabetes. In addition, our contract development and manufacturing organization collaborators presented a poster on a non-viral lipid nanoparticle delivery system that would allow a patient to receive multiple treatments.

Lipid Nanoparticles ("LNPs") for Pancreatic Islet Cell Gene Therapy.

AAV vectors can only be administered once, as the immune system develops a response against the AAV virus. However, lipid nanoparticles are not associated with an immune response, which would thus allow repeat dosing of gene therapy to patients with diabetes. At the 2025 ADA 85th Scientific Sessions, our collaborators presented data on their initial work in isolated islets and in mice showing that lipid nanoparticles can be used to deliver plasmid DNA to islets in vitro and to islet cells in vivo. Several LNPs were identified that were highly efficient in transfecting α- and β-cells in isolated mouse Islets of Langerhans. Following injection of one of these LNPs containing a green fluorescent protein ("GFP") payload into the mouse common bile duct, isolated islets of Langerhans were evaluated for GFP expression. GFP was successfully detected in both the inner and outer cells of the islets (See Figure below).



Convergen Biotech, Inc.

In September 2024, we announced that we were considering various strategic alternatives and opportunities to enhance stockholder value, including evaluating ways to optimize our clinical and research programs and operational strategies, such as our intention to potentially transfer our diabetes clinical development program and our diabetes gene therapy assets into a new, initially wholly-owned subsidiary. In connection with this intended separation of the diabetes clinical development program, in February 2025, we announced that we had formed a wholly-owned subsidiary, Convergen Biotech, Inc. ("Convergen"), to implement this initial step of the reorganization and facilitate the separation of the diabetes program. We believe this intended separation once complete will allow for the enhancement of each program by focusing on the needs of their respective markets and patients. If, and when, a potential separation is completed, Convergen will focus on developing and commercializing GPX-002. We plan to retain our oncology clinical development programs and other oncology pipeline assets. We believe this separation could expedite clinical development and enable greater opportunity for direct investment and strategic collaboration into the diabetes program.

Discovery Programs

ONCOPREX® Delivery System as a platform. We believe that the ONCOPREX Delivery System may be applicable to delivery of a range of therapeutic and prophylactic plasmid DNA and RNA interference constructs and has the potential to demonstrate efficacy in cancers beyond lung cancer. We also believe that the manufacturing methods we have developed for REQORSA may be useful for a wide array of disease treatments. Clinical data from the use of REQORSA has shown that the ONCOPREX Delivery System is well tolerated in humans and can be delivered at high therapeutic doses.

REQORSA Biomarker Studies. Our collaborators at MD Anderson have performed extensive preclinical studies to identify biomarkers that may predict response to REQORSA. Their work, titled "*TROP2 and PTEN are biomarkers of primary resistance to TUSC2 gene therapy in non-small cell lung cancer*" has been accepted for a poster presentation at this year's meeting of the American Association of Cancer Research in April ("2026 AACR meeting"). In this study, researchers established models primarily resistant to TUSC2 gene therapy (REQORSA or also labeled as "Quar Oze") to find biomarkers indicative of TUSC2 gene therapy resistance in NSCLC cell lines, PDX-derived organoids and patient-derived xenografts. Protein expression profiling using reverse-phase protein array analysis across the three models showed low expression of TROP2 and high expression of PTEN as potential biomarkers of primary resistance. These findings suggest that TROP2 and PTEN may serve as biomarkers to predict TUSC2 response and guide therapeutic strategies in NSCLC.

REQORSA biology. Additional studies of REQORSA biology are ongoing. A poster titled "*Restoring TUSC2 function boosts NK cell cytotoxicity and antitumor immunity in vivo and in vitro*" has been accepted for presentation at the 2026 AACR meeting. In this study, Tusc2 knockout and wild-type mice were challenged with syngeneic tumor cells (344SQ) and treated with Quar Oze. The findings from this study suggest TUSC2 acts as a critical enhancer of innate antitumor immunity by boosting NK cell cytotoxic function. Therapeutic delivery of TUSC2 via Quar Oze suppresses tumor progression and, in many cases, drives complete tumor elimination in mouse models. These results highlight TUSC2 as a potent immunomodulatory tumor suppressor and support its development as a potential dual-function therapeutic that directly targets tumor cells while also activating NK cell–mediated immunity.

Rights to other Tumor Suppressor Genes. We have licensed rights to the tumor suppressor gene, TUSC2, which is located in a sub-region of human Chromosome 3 known as 3p21.3, on which multiple tumor suppressor genes are located, including for example, 101F6, NPRL2, CACNA2D2, PL6, BLU, RASSF1, HYAL 1 and HYAL2. Using a number of techniques, MD Anderson researchers and their collaborators have identified these genes as potentially having cancer-fighting characteristics. MD Anderson researchers have subsequently conducted a number of preclinical studies on certain of these genes, particularly NPRL2, as well as TUSC2, both alone and in combination with other compounds, in order to assess their actual effects on lung cancer. Under past and current sponsored research agreements with MD Anderson, we support continuing research into the cancer-fighting properties of these and other genes in the 3p21.3 sub-region.

Researchers at MD Anderson have collaborated with other researchers to identify other genes, such as those in the 3p21.3 chromosomal region, which may act as tumor suppressors or have other cancer fighting functions. We hold rights to certain of these genes under license agreements with MD Anderson. Data from preclinical studies performed by MD Anderson researchers and others suggest that TUSC2, the active agent in REQORSA, could be effective against other types of cancer, including glioblastoma, mesothelioma, head and neck, breast (including triple-negative breast cancer), renal cell (kidney), thyroid, and soft tissue sarcoma, as well as NSCLC and SCLC. Therefore, the ONCOPREX Delivery System may allow delivery of a number of cancer fighting genes, alone or in combination with other cancer therapies, to combat multiple types of cancer.

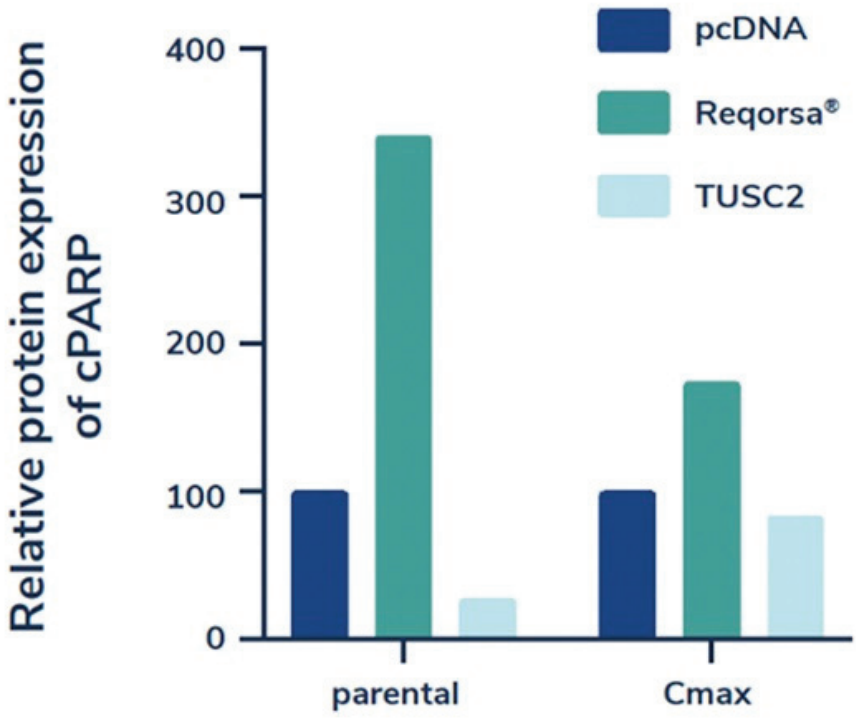
Preclinical Studies with Other Tumor Suppressor Genes

In addition, we have identified internally other tumor suppressor genes on which we have filed for intellectual property protection. NPRL2, a tumor suppressor gene, is often reduced in NSCLC. The restoration of NPRL2 activates cell cycle arrest and apoptosis. Genprex research collaborators presented additional research findings on NPRL2, the second tumor suppressor gene enabled by the ONCOPREX Delivery System, at the 2024 AACR meeting.

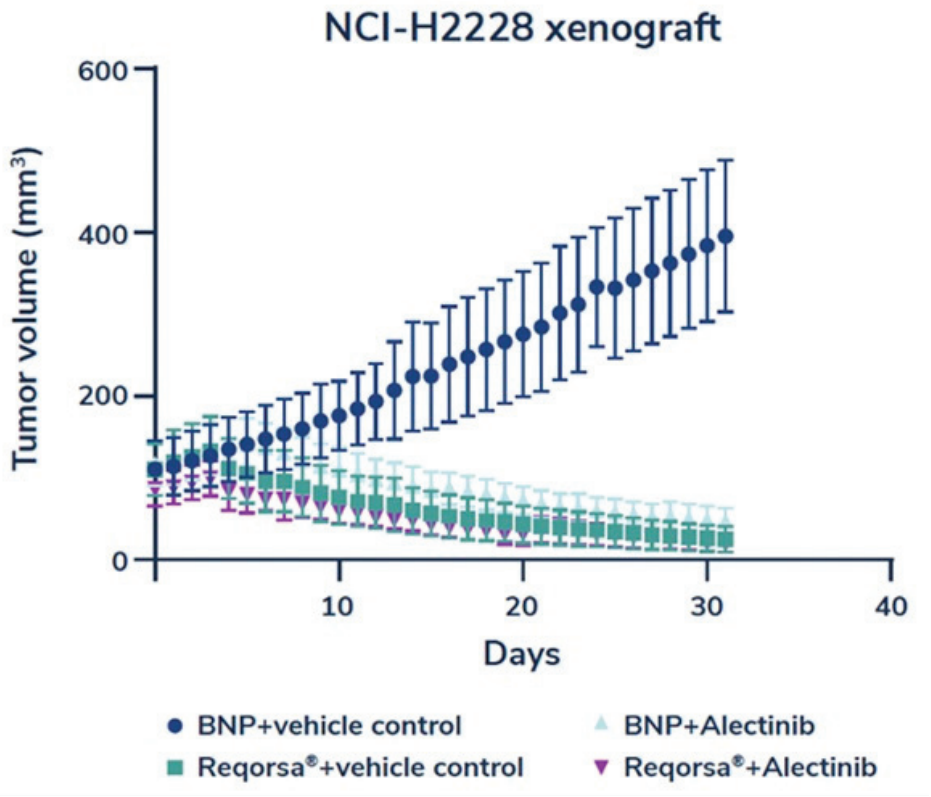
Our researchers investigated the anti-tumor immune responses to NPRL2 gene therapy in NSCLC cells with KRAS/STK11 co-mutations. The KRAS/STK11 co-mutation is associated with resistance to PD-1/PD-L1 inhibitors, such as Keytruda, and with poor overall survival in NSCLC patients. In the study, induced lung metastases in humanized mice were treated through intravenous injection of nanoparticles containing a plasmid with the NPRL2 gene, made with the ONCOPREX Delivery System, with or without Keytruda. The study found that the NPRL2 treatment decreased lung metastases, but Keytruda alone had no effect. Additionally, a greater anti-tumor effect was seen in humanized compared to non-humanized mice, demonstrating that immune cells play a role in the effects of the NPRL2 nanoparticle therapy. Study findings suggest that NPRL2 gene therapy induces anti-tumor activity against KRAS/STK11 mutant tumors, which are resistant to many treatments, including Keytruda, through dendritic cell-mediated antigen presentation and cytotoxic immune cell activation.

Preclinical Studies with REQORSA in ALK+ NSCLC

Another abstract presented by our clinical collaborators at the 2024 AACR meeting supports further clinical study of REQORSA in Anaplastic Lymphoma Kinase ("ALK")+ NSCLC, which are found in approximately 5% of patients with NSCLC. In this nonclinical study, TUSC2 expression in three ALK+ cell lines was evaluated before and after exposure to REQORSA, referred to as TUSC2 gene therapy in the abstract. Researchers in the University of Michigan Rogel Cancer Center Judith Tam ALK NSCLC research initiative found that overexpressing TUSC2 via REQORSA treatment in ALK+ lung cancer cell lines had the ability to inhibit colony formation by 50%, which indicates that REQORSA inhibits the growth of ALK+ cells. Researchers documented a strong pro-apoptotic response to TUSC2 expression (labeled REQORSA in the figure where TUSC2 indicates transfection of TUSC2 expressing plasmid) in ALK+ NSCLC. The study found that the use of REQORSA to overexpress TUSC2 in ALK+ NSCLC cell lines was effective in decreasing cell growth and proliferation through the activation of apoptotic pathways. The findings suggest REQORSA therapy may be a potential therapy for ALK+ NSCLC and the researchers believe the results support further clinical study of REQORSA as an anti-ALK NSCLC treatment strategy. In October 2024, we entered into a sponsored research agreement with the University of Michigan Rogel Cancer Center to study TUSC2 in combination with ALK-inhibitors in ALK-EML4 positive translocated lung cancer mouse models. We also announced at that time our collaboration with ALK Positive, a non-profit patient-driven research organization dedicated to improving the life expectancy and quality of life for ALK+ lung cancer patients. As a part of this collaboration, both Genprex and ALK Positive will share the cost of the sponsored research agreement with the University of Michigan Rogel Cancer Center. In November 2024, we entered into an exclusive license agreement with the University of Michigan, which granted us a worldwide, exclusive license to the University of Michigan's patent rights in a pending patent application relating to REQORSA in combination with ALK-inhibitors for the treatment of ALK-EML4 positive translocated lung cancer.



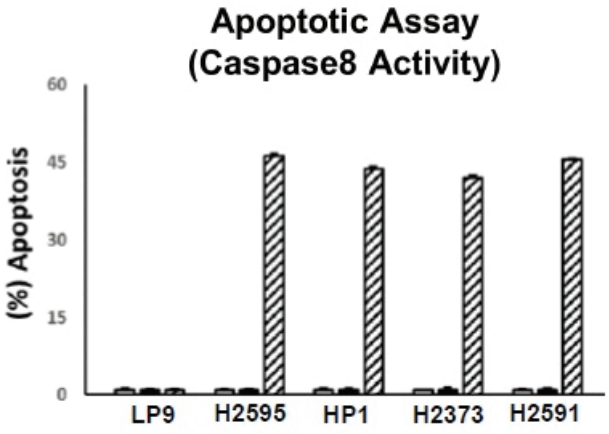
This work was extended in a presentation at the 2025 AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics in October. The data presented showed that the upregulation of TUSC2 by REQORSA induces apoptosis in ALK+ NSCLC cells, including those resistant to alectinib. Using an alectinib-sensitive model (a NCI-H2228-derived xenograft), single-agent REQORSA treatment resulted in a significant decrease in tumor growth that was little different from the combination of REQORSA and alectinib (see figure below). The experiments to date suggest that REQORSA mediated overexpression of TUSC2 in ALK+ NSCLC is effective in decreasing growth and proliferation through the activation of apoptotic pathways.



Additional work titled "*Quaratusugene ozeplasmid mediated TUSC2 upregulation in EML4-ALK bearing non-small cell lung carcinoma induces apoptosis and is highly effective in preclinical studies*" has been accepted for a poster presentation at the 2026 AACR meeting. In this study, researchers evaluated TUSC2 expression in a range of ALK+ cell lines and patient-derived organoids, both prior to and following exposure to Quar Oze. The findings show that Quar Oze-driven TUSC2 overexpression initiates a robust pro-apoptotic response in ALK+ models, not only in cells that are sensitive but also with acquired resistance (generated in the lab) to the ALK inhibitor, alectinib. The researchers believe that the in vitro and in vivo studies indicate that Quar Oze-mediated TUSC2 overexpression in ALK+ NSCLC effectively curtails tumor growth and proliferation via activation of apoptotic pathways, providing a compelling rationale for progressing toward a clinical trial.

Preclinical Studies with REQORSA in Mesothelioma

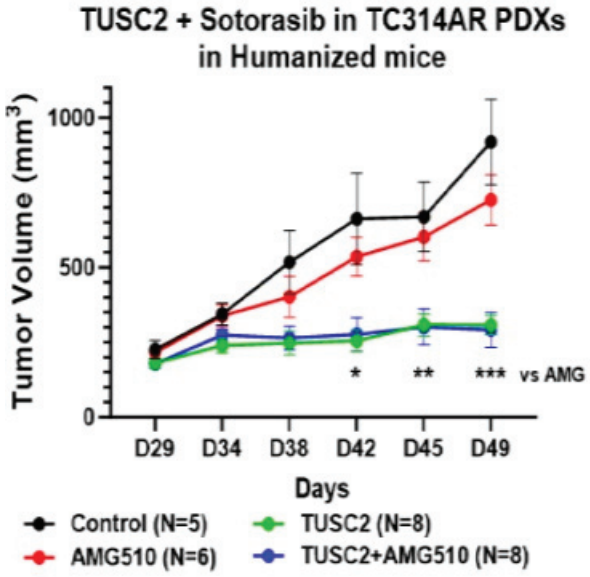
Malignant Pleural Mesothelioma ("MPM") is a rare, highly aggressive, asbestos-associated cancer with a median survival of 10-12 months. At least one of the normal two copies of the TUSC2 gene is absent in 36% of MPM. We and our research collaborators at New York University Langone Health are investigating whether TUSC2 transfection could modulate MPM aggressive properties, and Genprex has supported these studies with a sponsored research agreement. At the EORTC-NCI-AACR symposium in October 2024, our research collaborators delivered a poster presentation that demonstrated that REQORSA treatment resulted in significant decrease in cell proliferation, cell invasion, and a significant increase in cell apoptosis in four MPM cell lines. The four MPM cell lines and the non-malignant tert-transformed mesothelial LP9 cell line were treated with REQORSA and control liposomes for 48 hours. Treated cells were then evaluated for TUSC2 expression by semi quantitative RTPCR, Western blot analysis, and functional assays including cell proliferation, invasion, and apoptosis. RTPCR and Western blot analysis documented the successful expression of TUSC2 in all five cell lines. With REQORSA treatment, there was a marked decrease in cell proliferation and cell invasion in the 4 MPM cell lines, but not in the non-malignant LP9 cells. With REQORSA treatment (Quar Oze in the figure), there was also a marked increase in apoptosis in the 4 MPM cell lines, but not in the non-malignant LP9 cells (See figure below). Our collaborators concluded that the potent tumor-suppressive activity of the TUSC2 gene delivered by REQORSA could serve as a potential therapeutic strategy for the treatment of MPM. In April 2025, we entered into a license agreement with New York University, which granted us exclusive patent and commercial rights worldwide relating to our lead drug candidate REQORSA for the potential treatment of mesothelioma.



Preclinical Studies with REQORSA in Ras Inhibitor Resistant NSCLC

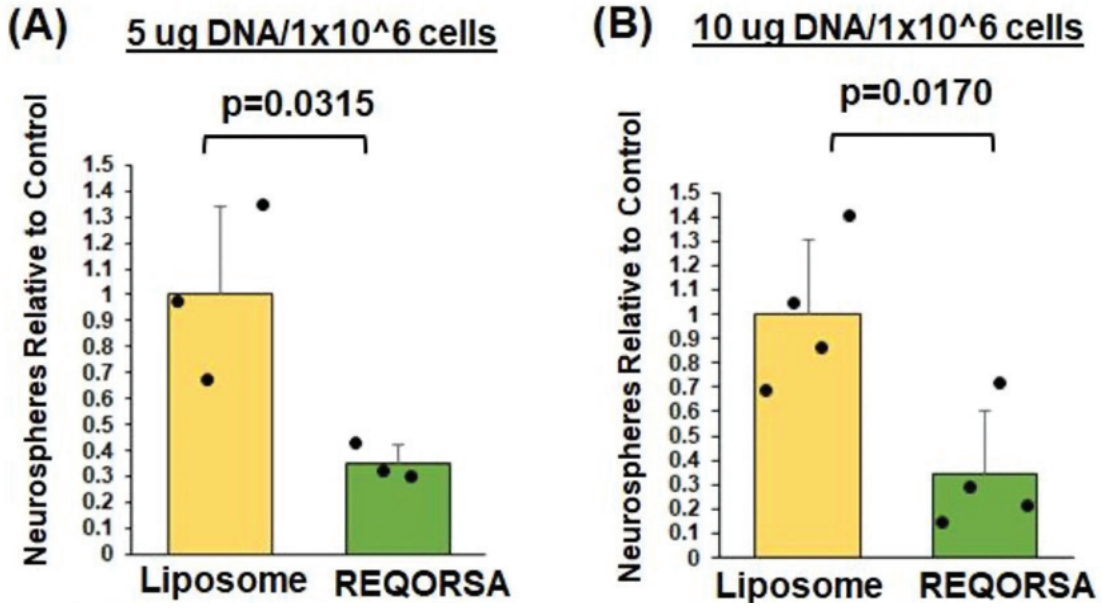
Acquired resistance ("AR") to sotorasib, the first FDA-approved KRASi, poses a significant challenge in the treatment of KRASG12C mutant NSCLC. Despite an initial response rate of up to 40%, research indicates that patients invariably develop resistance, necessitating alternative therapeutic strategies. In data presented at the October 2024 EORTC-NCI-AACR symposium, Genprex collaborators at MD Anderson demonstrated research that TUSC2 transfection and REQORSA treatment effectively overcomes sotorasib AR in KRAS-G12C mutant NSCLC in vitro and in vivo models.

Sotorasib-resistant cell lines and sotorasib-resistant patient derived xenografts ("PDX") in mice were generated. TUSC2 transfection significantly reduced colony formation in two AR cell lines. Transfection of cell lines with TUSC2 also markedly increased apoptosis in AR cells. REQORSA alone exhibited significantly strong antitumor effect on PDXs where sotorasib showed no significant antitumor activity. To further evaluate the antitumor immune responses, immune-competent humanized-NSG mice were generated to produce mice with human immune cells. REQORSA (labeled TUSC2 in the figure below) was found to overcome AR resistance by inducing antitumor immunity to PDXs in a humanized mouse model. The collaborators concluded that REQORSA therapy, alone or in combination with sotorasib, induced apoptosis, inhibited colony formation, and showed significant antitumor efficacy in KRAS-G12C mutant acquired resistant cell lines and PDX tumors. Thus, REQORSA could potentially be a treatment for sotorasib resistant KRAS-G12C NSCLC.



Preclinical Studies with REQORSA in Glioblastoma

Glioblastoma ("GBM") is the most common and deadliest primary brain tumor in adults and is associated with a poor prognosis. Genprex collaborators used patient-derived GBM cell lines and patient-derived glioma stem cell ("PD-GSC") lines to evaluate the effects of REQORSA on GBM in data presented at the 2024 EORTC-NCI-AACR symposium. Research indicates that REQORSA treatment significantly reduced GBM cell viability. REQORSA also strongly suppressed the glioma stem cell population that is highly resistant to therapy (see figure below) and REQORSA induced significant apoptosis in GBM and PD-GSC cells. Since GBM cells are highly infiltrative, GBM cell migration was evaluated. The migration assay results demonstrated that REQORSA suppressed GBM cell migration independent of its ability to suppress cell viability. The collaborators concluded that REQORSA demonstrated promising in vitro efficacy in GBM and PD-GSCs, and that these studies merited additional work on REQORSA's effects on GBM. In May 2025, we entered into a patent and technology license agreement with the Board of Regents of The University of Texas System on behalf of The University of Texas Health Sciences Center at Houston, which granted us exclusive patent and commercial rights worldwide relating to our lead drug candidate REQORSA for the potential treatment of glioblastoma.



Process Development and Manufacturing

We have made substantial investment in manufacturing for our product candidates with the goal of mitigating the risks associated with the complex manufacturing required to deliver gene therapies. While we continue to use third-party contract development and manufacturing organizations ("CDMOs") in the manufacture of our product candidates, we believe we have a competitive advantage in our field based on core competencies we have developed that we are leveraging in the manufacture of our product candidates. These core competencies include:

- Extensive and diverse internal and external consulting expertise;
- Customized chemistry, manufacturing and controls ("CMC") strategy for accelerated development;
- Risk assessment and remediation for FDA submissions;
- Novel and proprietary manufacturing processes;
- Integrated global Good Manufacturing Practices ("cGMP" or "GMP") manufacturing network; and
- Management of supply chain for business continuity.

In our oncology program, we are now focused on preparing for commercial readiness for REQORSA. To date we have developed a robust manufacturing process for REQORSA through years of process development activities that we continue to improve with the dramatic development and expansion of advanced technologies in the nascent gene therapy sector. REQORSA is a gene therapy with two main components. The active agent in REQORSA is a DNA plasmid encoding the TUSC2 protein. The plasmid is encapsulated by non-viral DOTAP cholesterol lipoplexes. This system of using lipoplexes to deliver the tumor suppressor gene-expressing plasmids to cancer cells is referred to by us as our systemic, non-viral ONCOPREX Delivery System. REQORSA has been shown to be scalable at cGMP and can be stored for approximately 18 to 20 months for later use. Successful technology transfer of REQORSA from MD Anderson, where it was developed and previously manufactured, to CDMOs has been achieved as well as scale-up of our clinical grade manufacturing production in accordance with cGMP. As noted above, the clinical grade material is being used to supply our Acclaim-1 and Acclaim-3 clinical trials.

For our diabetes program, which is an earlier stage program than our oncology program, the technology transfer associated with the manufacture of our GPX-002 construct to an appropriate integrated network of CDMOs and other vendors from our academic collaborators at University of Pittsburgh has been successfully completed. GPX-002 involves the delivery of the Pdx1 and MafA genes into the pancreas via the pancreatic duct utilizing an AAV vector. Novel advanced technologies were incorporated in these processes to optimize the plasmid construct to increase stability of expression and modify the backbone to align with other plasmids used for AAV products. The new plasmid was cloned, purified, and manufactured and is currently being used in the manufacture of AAV. We plan to begin clinical scale production in a cGMP compliant facility, allowing us to accelerate our manufacturing processes necessary for IND-enabling preclinical studies and clinical trials. We are also continuing work with CDMOs and research partners to optimize constructs and evaluate alternative second-generation approaches including different AAV and non-viral constructs. Our strategic collaboration with a CDMO to research a non-viral lipid nanoparticle delivery of our diabetes gene therapy drug candidate could allow for potential re-dosing of patients to optimize treatment.

We manage our manufacturing arrangements with our CDMOs and other vendors through various agreements.

Intellectual Property

Patents and other proprietary rights such as trademarks and trade secrets are critical to our business and to our ability to successfully develop and commercialize our product candidates. Our goal is to obtain, maintain, enhance and enforce patent protection for our products, formulations, processes, methods and other proprietary technologies, preserve our trade secrets, and operate without infringing on the proprietary rights of other parties, both in the U.S. and in other countries. Our policy is to actively seek the broadest intellectual property protection possible for our product candidates, proprietary information, and proprietary technology through a combination of contractual arrangements, patents, trade secrets, trademarks, copyrights and regulatory exclusivity both in the U.S. and elsewhere in the world. Patents provide a period of exclusivity intended to make it more difficult for competitors to make, use or sell competing technologies. We additionally rely on regulatory protection afforded through data exclusivity, market exclusivity, orphan drug designation and/or patent term extensions, where available. We have developed and/or in-licensed numerous patents and pending patent applications that relate to compositions-of-matter, methods-of-use and other technologies and possess substantial know-how and trade secrets relating to the development of gene therapy technologies.

As further described in the "Licenses and Research Collaborations" section below, we hold a worldwide, exclusive license from MD Anderson to patents covering the therapeutic use of TUSC2 and other genes that have been shown to have cancer fighting properties, including 16 issued patents and 11 pending patent applications for technologies developed at MD Anderson and The University of Texas Southwestern Medical Center. These patents comprise various therapeutic, diagnostic, technical and processing claims relating to REQORSA and our ONCOPREX Delivery System. We expect these patents and patent applications, if issued, to expire from 2032 to 2038. The rights we have obtained pursuant to our license agreement with MD Anderson are made subject to the rights of the U.S. government to the extent that the technology covered by the licensed intellectual property was developed under a funding agreement between MD Anderson and the U.S. government. As further described in the "Licenses and Research Collaborations" section below, we also hold worldwide, exclusive licenses to an issued patent and 6 pending patent applications for diabetes technologies developed at the University of Pittsburgh. We expect these patents and patent applications, if issued, to expire from 2035 to 2044. As further described in the "Licenses and Research Collaborations" section below, we also hold worldwide, exclusive licenses from the University of Michigan, New York University and the University of Texas Health Sciences Center at Houston for patent applications relating to the use of REQORSA in certain cancers. We are prosecuting 8 patent applications relating to various oncology targets in our discovery program. In addition, for certain of our product candidates we also expect to have further exclusivity in the form of data and marketing exclusivity under pharmaceutical regulatory laws, including for example, potentially up to 12 years of exclusivity from the date of first BLA approval of our product candidates. For a further description and discussion of these laws, exclusivities and their regulatory background, please see the "Business – Government Regulation" section below in this Part I, Item 1 of this Annual Report.

We also have received trademark registrations for the trademarks GENPREX, REQORSA, and ONCOPREX and we have a pending application for the trademark CONVERGEN. For a discussion of the challenges we face in obtaining or maintaining patent, trademark and/or trade secret protection, please see the risk factors under the heading "Risks Related to Our Intellectual Property" in Part I, Item 1A of this Annual Report.

Licenses and Research Collaborations

Agreements with MD Anderson

Our ONCOPREX and REQORSA technologies are exclusively licensed pursuant to a Patent and Technology License Agreement dated July 20, 1994, with MD Anderson, as amended on September 1, 1996, August 11, 1997, July 31, 1994 and October 4, 2001 (collectively, the "1994 MD Anderson License Agreement"), between MD Anderson and Introgen Therapeutics, Inc. (f/k/a Intron Therapeutics, Inc.) ("Introgen").

Pursuant to the 1994 MD Anderson License Agreement, we have rights to patents covering use of various genes, including the TUSC2 gene, for treatment of cancer, as well as know-how and related intellectual property.

The exclusive licenses under the 1994 MD Anderson License Agreement will continue until the expiration of all patents covered by such agreement. Upon the expiration of the exclusive licenses, we will have a non-exclusive, fully paid-up right and license to use and otherwise exploit the technology rights licensed under the agreement. MD Anderson may terminate the agreement for, among other things, a breach of the agreement by us which remains uncured.

Pursuant to a Technology Sublicense Agreement dated March 7, 2007 ("Sublicense Agreement"), Introgen sublicensed its rights under the 1994 MD Anderson License Agreement to Introgen Research Institute, Inc. ("IRI"). IRI is a Texas-based technology company formed by Rodney Varner, who prior to his passing in May 2024, was our President, Chief Executive Officer and Chairman of the Board and IRI's sole officer. IRI is owned by trusts of which Mr. Varner's descendants are the sole beneficiaries.

Pursuant to an Assignment and Collaboration Agreement dated April 13, 2009 ("IRI Collaboration Agreement"), IRI assigned its rights under the Sublicense Agreement to us, and we granted to IRI a non-exclusive, royalty-free license to use and practice the licensed technology for non-commercial research purposes. As consideration for this assignment, we agreed to assume all of IRI's obligations to MD Anderson under the 1994 MD Anderson License Agreement, including ongoing patent-related expenses and royalty obligations.

The IRI Collaboration Agreement was amended by an Amended Collaboration and Assignment Agreement dated July 1, 2011 ("2011 IRI Collaboration Agreement"). The 2011 Collaboration Agreement provided that IRI would provide additional licensing opportunities and services to us, in return for monthly payments and our obligation to pay to IRI a royalty of 1% on sales of products licensed to us under the 1994 MD Anderson License Agreement. In 2012, IRI's obligation to provide those opportunities and services, and our obligation to make monthly payments to IRI, were terminated; however, we are required to pay a 1% royalty to IRI upon sales of products licensed to us under the 1994 MD Anderson License Agreement which royalty obligation continues for 21 years after the later of the termination of the 1994 MD Anderson License Agreement and the termination of the sublicense assigned by IRI to us.

Pursuant to a Technology Sublicense Agreement dated June 1, 2011, we granted to IRI a non-exclusive sublicense, for non-commercial purposes, to the rights under the Sublicense Agreement.

At the time that we entered into the 2011 IRI Collaboration Agreement, Mr. Varner was not an officer or director of Genprex, but he was deemed to be an "affiliate" of the Company due to his beneficial ownership at that time of approximately 39% of our issued and outstanding shares. At the time we acquired the ONCOPREX and REQORSA technologies under the 2009 IRI Collaboration Agreement, they were the subject of the Phase 1 Monotherapy Trial. We completed the Phase 1 Monotherapy Trial and did substantial process development, manufacturing and regulatory work necessary to bring the technologies into a Phase 1/2 combination trial.

Pursuant to the 1994 MD Anderson License Agreement, the Sublicense Agreement and the 2009 IRI Collaboration Agreement, we are obligated to pay all fees, patent-related expenses, royalties, and other amounts that become due with respect to the licensed patents, patent application and other technologies. We are also obligated to pay to MD Anderson royalties of 1.5% of net sales of the licensed products, as well as 1.5% of advance payments received by us (excluding amounts paid to us in reimbursement of development or other costs) from third parties pursuant to sublicense, marketing, distribution or franchise arrangements. Under the 2011 IRI Collaboration Agreement, we are obligated to pay to IRI a royalty of 1.0% of net sales of licensed products and 1.0% of certain other payments received by us. This royalty obligation continues for 21 years after the later of the termination of the 1994 MD Anderson License Agreement and the termination of the Sublicense Agreement. We have no other payment obligations to IRI under the 2009 IRI Collaboration Agreement or the 2011 IRI Collaboration Agreement. We were not required to make any up-front payments to MD Anderson or IRI when we entered into the 1994 MD Anderson License Agreement, the Sublicense Agreement or the 2009 IRI Collaboration Agreement.

On May 4, 2020 (the "MD Effective Date"), we entered into a Patent and Technology License Agreement with MD Anderson, as amended on March 3, 2021 (collectively, the "2020 License Agreement" and together with the 1994 MD Anderson License Agreement, collectively, the "MD Anderson License Agreements"). Pursuant to the 2020 License Agreement, MD Anderson granted us a worldwide, exclusive, sublicensable, royalty-bearing license to certain licensed intellectual property and technology, including, without limitation, use of chemotherapy in combination with TUSC2 therapy and methods for treating cancer by administration of a TUSC2 in conjunction with EGFR inhibitors or other anti-cancer therapies in patients that are expected to be responsive to TUSC2 therapy (collectively, the "Licensed IP"), to manufacture, use, commercialize, seller, offer for sale and import licensed products related to the treatment of cancer using TUSC2 therapy in combination with certain immunotherapies (the "Licensed Products"). In consideration for our use of the Licensed IP, we are required to make certain payments to MD Anderson, including, without limitation, an upfront license fee as well as a fee paid to amend the agreement, annual maintenance fees ranging from the low five figures to low six figures, milestone payments aggregating up to a maximum of $6,150,000, low single digit royalty payments to low double digits royalty payments with lower net sales being subject to lower royalty payments, and minimum annual royalties after the first sale in a low six figure amount. In addition, we shall be required to reimburse MD Anderson for certain patent expenses. The 2020 License Agreement will expire on the later to occur of (a) the expiration of all patents issued under the Licensed IP and the cancellation, withdrawal, or express abandonment of all patent applications under the Licensed IP, or (b) 30 years after the MD Effective Date, unless earlier terminated pursuant to the terms thereof.

See also "Note 7 – Commitments and Contingencies" to our consolidated financial statements included in this Annual Report on Form 10-K.

License Agreement with the Regents of the University of Michigan

On November 11, 2024, the Company and the Regents of the University of Michigan ("UM") entered into a Patent License Agreement ("UM License Agreement"), which granted Genprex a worldwide, exclusive license to the University of Michigan's patent rights in a co-owned patent application relating to the use of REQORSA in combination with ALK-inhibitors for the treatment of ALK-EML4 positive translocated lung cancer (collectively, the "UM Licensed Products"). We currently expect this patent application, if issued, to expire in 2045. As consideration for the UM License Agreement, Genprex agreed to pay UM an initial license issue fee, running low single digit percentage royalties, minimum annual royalties in a fixed cash amount, a tiered double digit percentage share of non-royalty sublicense income, and certain potential clinical milestone payments through FDA regulatory approval up to an aggregate of approximately $350,000 in addition to certain potential commercial sales milestones. Genprex will use commercially reasonable efforts to bring the UM Licensed Products to market as soon as practicable, and continue active marketing efforts for the Licensed Products throughout the term of the UM License Agreement, and to achieve certain milestones within specified time periods. Genprex has agreed to submit semi-annual progress reports to UM including reports of manufacturing, sales and sublicense activities to UM.

License Agreement with New York University

On April 25, 2025, the Company and New York University ("NYU") entered into a License Agreement ("NYU License Agreement"), which granted Genprex exclusive patent and commercial rights worldwide relating to Genprex's lead drug candidate REQORSA for the potential treatment of mesothelioma. Pursuant to the NYU License Agreement, Genprex agreed to pay: (i) an initial license fee, (ii) annual license fees, (iii) running low single digit percentage royalties of net sales, (iv) certain potential technical milestone payments through regulatory approval up to an aggregate of approximately $400,000, and (v) certain patent-related expenses.

License Agreement with UTHealth Houston

On May 2, 2025, the Company and the Board of Regents of The University of Texas System on behalf of The University of Texas Health Sciences Center at Houston ("UTHealth Houston" or "UTH") entered into a Patent and Technology License Agreement (the "UTH License Agreement"), which granted Genprex exclusive patent and commercial rights worldwide relating to Genprex's lead drug candidate REQORSA for the potential treatment of glioblastoma. Pursuant to the UTH License Agreement, Genprex agreed to pay: (i) an initial license issue fee along with additional, staggered upfront license fees and an annual license management fee, (ii) running low single digit percentage royalties of net product sales, (iii) minimum annual royalties beginning after the first year in which royalties obligations commence pursuant to the UTH License Agreement, (iv) certain potential clinical and regulatory milestone payments through FDA and international regulatory approvals up to an aggregate of approximately $360,000, and (v) certain patent-related expenses.

License Agreement with University of Pittsburgh - Of the Commonwealth System of Higher Education

As noted above, on February 17, 2025, we and UP entered into an amended and restated Exclusive License Agreement (the "New UP License Agreement"), which updates and consolidates into a single agreement our prior license agreements with UP (the "Prior License Agreements"). The New UP License Agreement effectuates the termination of, and amends, restates, replaces and supersedes the Prior License Agreements between us and UP, except that our prior license from UP dated November 22, 2022, which had covered the macrophage technology was terminated in its entirety and is not incorporated into or covered by the New UP License Agreement. The New UP License Agreement authorizes us (including any affiliate of Genprex) to make, have made, use and sell the "Licensed Technology," which is related to a gene therapy for both Type 1 diabetes and Type 2 diabetes using the genes of the Pdx1 and MafA transcription factors controlled by insulin, glucagon and MafB promoters, and to practice under the patent rights in the field of diabetes therapy. Pursuant to the New UP License Agreement, we agree to use our best efforts to bring the Licensed Technology to market as soon as practicable, and continue active marketing efforts for the Licensed Technology throughout the term of the New UP License Agreement, and to achieve certain milestones within specified time periods. We have agreed to submit annual progress reports to UP and, quarterly reports of manufacturing, sales and sublicense activities to UP.

UP has reserved the royalty-free, nonexclusive right to practice the patent rights and know-how and to use the Licensed Technology for non-commercial education and research purposes, and we have agreed to sell products and/or services resulting from Licensed Technology to UP and its affiliates upon request at the price and terms as are made available to our most favored customer. The licenses granted to us under the New UP License Agreement are subject to the rights of the U.S. government, which may have acquired a nonexclusive, nontransferable, paid up license to practice or have practiced for or on behalf of the United States the inventions described in the patent rights throughout the world. As consideration for the New UP License Agreement, we agreed to pay UP an initial license fee, annual maintenance fees, running low single digit percentage royalties, minimum annual royalties in a fixed cash amount, a low double digit percentage share of non-royalty sublicense income, and certain milestone payments up to an aggregate of approximately $4,825,000, as well as patent prosecution expenses incurred prior to and after the effective date of the New UP License Agreement.

The New UP License Agreement remains in effect until the later of 20 years after the first commercial sale of the Licensed Technology or the expiration of the last valid claim of the patents licensed under the New UP License Agreement. UP may terminate the agreement in the event of our uncured default for thirty (30) days following notice thereof from UP, failure to achieve the specified milestones within the specified time period, or practice of the licensed patent rights or know-how outside the field of diabetes therapy, or if we cease to carry out our business, become bankrupt or insolvent, apply for or consent to the appointment of a trustee, receiver or liquidator of our assets or seek relief under any law for the relief of debtors. We may terminate the New UP License Agreement upon six months prior written notice to UP and payment of all amounts accrued or due to UP through the effective date of termination.

See also "Note 7 – Commitments and Contingencies" and "Note 10 – Subsequent Events" to our consolidated financial statements included in this Annual Report on Form 10-K.

Grants

Our technology discoveries and research and development programs have been the subject of numerous peer-reviewed publications and have been supported by Small Business Innovation Research ("SBIR") grants and grants from the National Institutes of Health ("NIH"), the United States Department of Treasury, and the State of Texas through its Texas Emerging Technology Fund. The rights we have obtained pursuant to our MD Anderson License Agreements are made subject to the rights of the U.S. government to the extent that the technology covered by the licensed intellectual property was developed under a funding agreement between MD Anderson and the U.S. government. Our collaborators at University of Pittsburgh have also received grants from the NIH in connection with preclinical work on GPX-002 and so, the rights we have obtained pursuant to our New UP License Agreement are made subject to the rights of the U.S. government to the extent that the technology covered by the licensed intellectual property was developed under a funding agreement between the University of Pittsburgh and the U.S. government. The Trump Administration previously announced a 15% cap on the indirect cost portion of existing and future NIH grants. Generally, indirect costs average above 30% for NIH grant recipients and many are substantially higher. The 15% cap is being challenged in lawsuits and has been temporarily suspended. As of February 2026, it remains uncertain how indirect costs will be handled in NIH grants. Changes in government funding for our collaborators may significantly impact their ability to conduct research. We are monitoring and evaluating the situation.

Competition

The biotechnology and pharmaceutical industries are intensely competitive and subject to rapid and significant technological change. There is also a strong emphasis on intellectual property and proprietary products. We have domestic and international competitors including major multinational pharmaceutical companies, established biotechnology companies, specialty pharmaceutical and generic drug companies and universities and other research institutions. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

Currently, there are a number of drugs approved and under development for treatment of lung cancer. Treatments competitive with our primary product candidates generally fall into the following categories: chemotherapies such as cisplatin, carboplatin, docetaxel and pemetrexed; targeted therapies such as Tarceva, Iressa, Gilotrif, Rybrevant, Lazcluze and Tagrisso, and immunotherapies such as checkpoint inhibitors and CAR and CAR T cells, and oncolytic virus-based technology. Any such competing therapy may be more effective and/or cost-effective than ours.

Type 1 diabetes is an autoimmune disease that permanently destroys beta cells of the pancreatic islet leading to the body no longer having the ability to produce insulin. Type 2 diabetes, also known as adult onset diabetes, is a condition associated with developed resistance to insulin. There are a number of approved treatments and therapies to manage diabetes including insulin, insulin analogs, continuous glucose monitoring, novel approaches to administration such as insulin pens and insulin pumps, and preventative therapeutics. There are also cellular therapies that have the potential to provide allogeneic beta cells that secrete insulin. Any of these therapies may be more effective, cost-effective, or considered less invasive than ours.

Many of our competitors have greater financial and other resources, such as larger research and development staff and more experienced marketing and manufacturing organizations than we do. Large pharmaceutical companies, in particular, have extensive experience in clinical testing, obtaining regulatory approvals, recruiting patients and manufacturing pharmaceutical products. These companies also have significantly greater research, sales and marketing capabilities and collaborative arrangements in our target markets with leading companies and research institutions. Established pharmaceutical companies may also invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make the product candidates that we develop obsolete. As a result of these factors, our competitors may succeed in obtaining patent protection and/or FDA approval or discovering, developing and commercializing drugs for the cancer indications that we are targeting before we do or may develop drugs that are deemed to be more effective or gain greater market acceptance than ours. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. In addition, many universities and private and public research institutes may become active in our target disease areas. Our competitors may succeed in developing, acquiring or licensing on an exclusive basis, technologies and drug products that are more effective or less costly than any product candidates that we are currently developing or that we may develop, which could render our products obsolete or noncompetitive. Any product candidates that we successfully develop and commercialize may compete with existing and new therapies that may become available in the future. The availability of reimbursement from government and other third-party payers will also significantly affect the pricing and competitiveness of our products. For a further discussion of the challenges we face from competition, please see the "Risk Factors" section in Part I, Item 1A of this Annual Report.

Government Regulation

Government authorities in the U.S., at the federal, state and local level, and other countries extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, recordkeeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing and export and import of products such as those we are developing. The pharmaceutical drug product candidates that we develop must be approved by the FDA before they may be legally marketed.

In the United States, the FDA regulates pharmaceutical products under the Federal Food, Drug, and Cosmetic Act ("FDCA") and implementing regulations and other federal, state and local statutes and regulations. In the case of biologics, the section of the FDCA that governs the approval of drugs via New Drug Applications ("NDAs") does not apply to the approval of biologics. Rather, biologics, such as gene therapy products, are approved for marketing under provisions of the Public Health Service Act ("PHSA") via a Biologics License Application ("BLA"). However, the application process and requirements for approval of BLAs are very similar to those for NDAs. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, the approval process or after approval, may subject an applicant to administrative or judicial sanctions. FDA sanctions could include refusal to approve pending applications, withdrawal of an approval, a clinical hold, warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution injunctions, fines, refusals of government contracts, restitution, disgorgement and civil and criminal penalties.

U.S. Biological Products Development Process

The process required by the FDA before a biological product, including our REQORSA, GPX-002, and potential future product candidates, may be marketed in the United States generally involves the following:

- completion of nonclinical laboratory tests and animal studies according to Good Laboratory Practices ("GLPs"), and applicable requirements for the humane use of laboratory animals or other applicable regulations;
- submission to the FDA of an application for an IND, which must become effective before human clinical trials may begin;
- performance of adequate and well-controlled human clinical trials according to the FDA's regulations, commonly referred to as Good Clinical Practices ("GCPs") and any additional requirements for the protection of human research patients and their health information, to establish the safety, purity, and potency of the proposed biological product for its intended use;
- compiling of information demonstrating that the product can be properly formulated, manufactured and stored;
- submission to the FDA of a BLA for marketing approval that includes substantive evidence of safety, purity, and potency from results of nonclinical testing and clinical trials;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities where the product is produced and tested to assess compliance with GMP requirements to assure that the facilities, methods and controls are adequate to preserve the product's identity, strength, quality and purity;
- potential FDA audit of the nonclinical and clinical trial sites that generated the data in support of the BLA; and
- FDA review and approval, or licensure, of the BLA.

Within the FDA, the Center for Biologics Evaluation and Research ("CBER") regulates gene therapy products. The FDA has published guidance documents related to, among other things, gene therapy products in general, their preclinical assessment, observing patients involved in gene therapy studies for delayed adverse events, potency testing, and chemistry, manufacturing and control information in gene therapy INDs.

Before testing any product candidate, including a gene therapy product, in humans, the product candidate enters the preclinical testing stage. Preclinical tests, which are a subset of nonclinical studies, include laboratory evaluations of product chemistry, toxicity and formulation, as well as animal studies to assess the potential safety and activity of the product candidate. The conduct of certain preclinical tests must comply with federal regulations and requirements, including GLPs.

The clinical trial sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, to the FDA as part of the IND. Some nonclinical testing usually continues after the IND is submitted. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA places the clinical trial on a clinical hold within that 30-day time period. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. The FDA may also impose clinical holds on a product candidate at any time before or during clinical trials due to safety concerns or non-compliance. If the FDA imposes a clinical hold, trials may not recommence without FDA authorization and then only under terms authorized by the FDA.

Clinical trials involve the administration of the product candidate to volunteers or patients under the supervision of qualified investigators, generally physicians not employed by or under the clinical trial sponsor's control. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, patient selection and exclusion criteria, effectiveness criteria to be evaluated, and the parameters to be used to monitor patient safety, including stopping rules that assure a clinical trial will be stopped if certain adverse events occur. Each protocol and any amendments to the protocol must be submitted to the FDA as part of the IND. Clinical trials must be conducted and monitored in accordance with the FDA's regulations comprising the GCP requirements, including the requirement that all patients provide informed consent. The FDA may order the temporary or permanent discontinuation of a clinical trial at any time, or impose other sanctions, if it believes that the clinical trial either is not being conducted in accordance with FDA regulations or presents an unacceptable risk to the clinical trial patients.

Further, each clinical trial must be reviewed and approved by an independent institutional review board ("IRB") at or servicing each institution or site at which the clinical trial will be conducted. An IRB is charged with protecting the welfare and rights of clinical trial participants and considers such items as whether the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the form and content of the informed consent, which must be signed by each clinical trial patient or his or her legal representative, and must monitor the clinical trial until completed. Clinical trials involving biological product candidates also must be reviewed by an institutional biosafety committee ("IBC"), a local institutional committee that reviews and oversees basic and clinical research conducted at that institution. The IBC assesses the safety of the research and identifies any potential risk to public health or the environment.

Clinical trials to support BLAs for marketing approval are typically conducted in three sequential phases that may overlap or be combined:

- Phase 1. The investigational product candidate is initially introduced into human patients and tested to assess metabolism, pharmacokinetics, pharmacological actions, side effects associated with drug exposure, and to obtain early evidence of a treatment effect if possible. In the case of some products for severe or life-threatening diseases, especially when the product candidate may be inherently too toxic to be ethically administered to healthy volunteers, the initial human testing is often conducted in patients; gene therapy is usually administered to patients in Phase 1 trials. This is also true in situations where toxicity can only be judged in patients with disease. An evaluation for preliminary evidence of efficacy can be performed at this time.
- Phase 2. The investigational product candidate is evaluated in a limited patient population to identify possible common adverse effects and safety risks, to evaluate preliminarily the efficacy of the product candidate for specific targeted diseases, and to generate hypotheses for the dosage tolerance, optimal dosage, and dosing schedule.
- Phase 3. Clinical trials are undertaken to evaluate further dosage, clinical efficacy, potency, and safety in an expanded patient population at geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the product candidate and provide an adequate basis for product labeling.

In most cases, the FDA requires two adequate and well-controlled Phase 3 clinical trials to demonstrate the efficacy of the drug. A single trial may be sufficient in some instances, including (1) where the study is a large multicenter trial demonstrating internal consistency and a statistically very persuasive finding of a clinically meaningful effect on mortality, irreversible morbidity or prevention of a disease with a potentially serious outcome and confirmation of the result in a second trial would be practically or ethically impossible or (2) when there is one adequate and well-controlled clinical investigation plus other confirmatory evidence. Typically, during the development of certain therapies, such as oncology therapies and AAV trials, the subjects enrolled in Phase 1 clinical trials are disease-affected patients and, as a result, considerably more information on clinical activity may be collected during such trials than during Phase 1 clinical trials for other therapies. A single pivotal trial may be sufficient in rare instances to provide substantial evidence of effectiveness (generally subject to the requirement of additional post-approval studies).

In addition, the manufacturer of an investigational biologic in a Phase 2 or Phase 3 clinical trial for a serious or life-threatening disease is required to make available, such as by posting on its website, its policy on evaluating and responding to requests for expanded access to such investigational biologic.

Post-approval clinical trials, sometimes referred to as Phase 4 clinical trials, may be conducted after initial marketing approval. These clinical trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication, particularly for long-term safety follow-up. The FDA recommends that sponsors observe patients for potential gene therapy-related delayed adverse events with agents such as those we are developing for a period of up to 15 years, including a minimum of five years of annual examinations followed by ten years of annual queries, either in person or by questionnaire, of clinical trial patients.

During all phases of clinical development, regulatory agencies require extensive monitoring and auditing of all clinical activities, clinical data, and clinical trial investigators. Development safety update reports (DSURs) assessing the safety of the clinical trials and/or annual progress reports detailing the results of the clinical trials are submitted to the FDA. Written IND safety reports must be promptly submitted to the FDA, and the investigators for serious and unexpected adverse events, any findings from other trials, tests in laboratory animals or *in vitro* testing that suggest a significant risk for human patients, or any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. The sponsor must submit an IND safety report within 15 calendar days after the sponsor determines that the information qualifies for expedited reporting. The sponsor must also notify the FDA of any unexpected fatal or life-threatening suspected adverse reaction within seven calendar days after the sponsor's initial receipt of the information. Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, if at all. The FDA, the sponsor, or its data safety monitoring board may suspend a clinical trial at any time on various grounds, including a finding that the patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the investigational product candidate has been associated with unexpected serious harm to patients.

Concurrently with clinical trials, companies usually complete additional animal studies and also develop additional information about the physical characteristics of the components of a product as well as finalize processes for manufacturing the components in commercial quantities in accordance with GMP requirements. To help reduce the risk of the introduction of adventitious agents with use of biological products, the PHSA, emphasizes the importance of manufacturing control for products whose attributes cannot be precisely defined. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, the sponsor must develop methods for testing the identity, strength, quality, potency and purity of the final product. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the components of a product candidate do not undergo unacceptable deterioration over their shelf life.

U.S. Review and Approval Processes

After the completion of clinical trials of an investigational biologic product, a BLA is prepared and submitted to the FDA. FDA approval of a BLA must be obtained before commercial marketing and distribution of the product may begin in the United States. The BLA must include results of product development, laboratory, and animal studies, human trials, information on the manufacture and composition of the product, proposed labeling and other relevant information. The testing and approval processes require substantial time and effort and there can be no assurance that the FDA will file the BLA and, even if filed, that any approval will be granted on a timely basis, if at all.

Under the Prescription Drug User Fee Act, as amended ("PDUFA"), each BLA must be accompanied by a significant user fee. The FDA adjusts the PDUFA user fees on an annual basis. PDUFA also imposes annual program fees on prescription drugs, including biologics. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business. No user fees are assessed on BLAs for products designated as orphan drugs, unless the application also includes a non-orphan indication.

Within 60 days following submission, the FDA reviews the BLA to determine if it is substantially complete before the agency files it. The FDA may request additional information or may refuse to file any BLA that it deems incomplete or not properly reviewable at the time of submission.

In this event, the BLA must be resubmitted with the additional information. The resubmitted application also is subject to an initial filing review before the FDA files it. Once the submission is filed, the FDA begins an in-depth substantive review of the BLA. Under PDUFA, FDA has agreed to performance goals to review 90% of original standard BLAs within 10 months of the 60-day filing date and 90% of original priority BLAs within six months of the 60-day filing date, whereupon a review decision is to be made. The FDA does not always meet its PDUFA goal dates for standard and priority BLAs. The review process and the PDUFA goal date may be extended by three months if the FDA requests or the BLA sponsor otherwise provides additional information or clarification regarding information already provided in the BLA submission. The FDA reviews the BLA to determine, among other things, whether the proposed product is safe and potent, or effective, for its intended use, and has an acceptable purity profile, and whether the product is being manufactured in accordance with GMP to assure and preserve the product's identity, safety, strength, quality, potency and purity.

The FDA may refer applications for novel products or products that present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations when making decisions. During the product approval process, the FDA also will determine whether a Risk Evaluation and Mitigation Strategy ("REMS") is necessary to assure that the benefits of the biologic outweigh the potential risks of the product to patients. A REMS can include medication guides, communication plans for healthcare professionals, and elements to assure a product's safe use ("ETASU"). An ETASU can include, but is not limited to, special training or certification for prescribing or dispensing the product, dispensing the product only under certain circumstances, special monitoring, and the use of patient-specific registries. If the FDA concludes that a REMS is needed, the sponsor of the BLA must submit a proposed REMS; the FDA will not approve the BLA without a REMS, if required.

Before approving a BLA, the FDA will typically inspect the facilities at which the product is manufactured. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in substantial compliance with GMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving a BLA, the FDA will typically inspect one or more clinical sites, to assure that the clinical trials were conducted in compliance with GCP requirements. In addition, the FDA may inspect one or more sites where animal studies were conducted to confirm compliance with GLP requirements. To assure GMP, GCP and GLP compliance, an applicant must incur significant expenditure of time, money, and effort in the areas of training, record keeping, production, and quality control.

Notwithstanding the submission of relevant data and information, the FDA may ultimately decide that the BLA does not satisfy its regulatory criteria for approval and deny approval. Data obtained from clinical trials are not always conclusive and the FDA may interpret data differently from how we interpret the same data. If the agency decides not to approve the BLA in its present form, the FDA will issue a complete response letter that usually describes all of the specific deficiencies in the BLA identified by the FDA. The deficiencies identified may be minor, for example, requiring labeling changes, or major, for example, requiring additional clinical trials. Additionally, the complete response letter may include recommended actions that the applicant might take to place the application in a condition for approval. If a complete response letter is issued, the applicant may resubmit the BLA, addressing all of the deficiencies identified in the letter, withdraw the application, or request a hearing.

If a product candidate receives regulatory approval, the FDA will issue an approval letter. The approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings, or precautions be included in the product labeling. The FDA may impose restrictions and conditions on product distribution, prescribing, or dispensing in the form of a risk management plan, or otherwise limit the scope of any approval. In addition, the FDA may require post marketing clinical trials, sometimes referred to as Phase 4 clinical trials, designed to assess further a biological product's safety and effectiveness, and testing and surveillance programs to monitor the safety of approved products that have been commercialized.

Expedited Development and Review Programs

The FDA has four programs in place intended to facilitate and expedite development and review of new drugs and biologics intended to address unmet medical needs in the treatment of serious or life-threatening conditions. These are Fast Track Designation, Breakthrough Therapy Designation, Accelerated Approval Program, and Priority Review Designation.

The Fast Track program is intended to expedite or facilitate the process for reviewing a new product if it is intended for the treatment of a serious or life-threatening disease or condition, and it demonstrates the potential to address unmet medical needs for such a disease or condition. Fast Track Designation applies to the combination of the product and the specific indication for which it is being studied. The sponsor of a new drug or biologic may request the FDA to designate the drug or biologic as a Fast Track product at any time during the clinical development of the product. Unique to a Fast Track product, the FDA may consider for review sections of the marketing application on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the application, the FDA agrees to accept sections of the application and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the application.

A product can receive Breakthrough Therapy Designation if it is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that it may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. A Breakthrough Therapy Designation conveys all of the features of Fast Track Designation in addition to more intensive FDA guidance on an efficient development program, organizational commitment involving senior managers, and eligibility for priority review. Specifically, the FDA intends to expedite the development and review of a Breakthrough Therapy by, where appropriate, intensively involving senior managers and experienced review staff in a proactive collaborative, cross-disciplinary review. Where appropriate, the FDA also intends to assign a cross-disciplinary project lead for the review team to facilitate an efficient review of the development program. The FDA notes that a compressed drug development program still must generate adequate data to demonstrate that the drug or biologic meets the statutory standard for approval. Omitting components of the development program that are necessary for such a determination can significantly delay, or even preclude, marketing approval.

Breakthrough Therapy Designation indicates that preliminary clinical evidence demonstrates the drug may have substantial improvement on one or more clinically significant endpoints over available therapy. Breakthrough Therapy Designation intensifies FDA involvement to ensure an efficient drug development program and is an organizational commitment from the FDA to involve its senior managers. A sponsor receiving Breakthrough Therapy Designation has up to six months after receiving the Breakthrough Therapy Designation to request an Initial Comprehensive Multidisciplinary meeting to discuss the drug development program. This initial meeting is a Type B meeting, used to discuss the overarching, high-level plan for drug development. These discussions include topics such as planned clinical trials and endpoints, any resizing or adaptations to the trials, plans for expediting the manufacturing development strategy and studies that potentially could be completed after approval. When Breakthrough Therapy Designation has been granted, the FDA is encouraged to meet regularly with the sponsor and subsequent meetings are considered Type B meetings and are established based on the needs of the program.

The FDA may grant accelerated approval under its Accelerated Approval Program to a product candidate for a serious or life-threatening condition upon a determination that the product candidate has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or an effect on a clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. Accelerated approval is contingent on a sponsor's agreement to conduct at least one adequate and well-controlled additional post-approval trial to verify and describe the product's clinical benefit. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product.

Fast Track Designation, Breakthrough Therapy Designation, RMAT, and Accelerated Approval do not change the standards for approval but may expedite the development process. Additionally, Fast Track Designation or Breakthrough Therapy Designation may be withdrawn by the FDA if the FDA believes that the designation is no longer supported by data emerging in the clinical trial process, including considering any new drug or biologic approvals that address the unmet medical need.

An application for a product candidate may be eligible to obtain Priority Review Designation if it is intended to treat a serious condition and, if approved, would provide a significant improvement in safety or effectiveness. The FDA will attempt to direct additional resources to the evaluation of an application for a new product designated for priority review in an effort to facilitate the review. A Priority Review Designation means FDA's goal is to take action on the marketing application within six months (compared to ten months under standard review) of the 60-day filing date. Priority Review Designation does not change the standards for approval but may expedite the review process.

Orphan Designation and Exclusivity

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biologic intended to treat a rare disease or condition, defined as a disease or condition with a patient population of fewer than 200,000 individuals in the United States, or a patient population greater than 200,000 individuals in the United States and when there is no reasonable expectation that the cost of developing and making available the drug or biologic in the United States will be recovered from sales in the United States for that drug or biologic. Orphan drug designation must be requested before submitting a BLA or NDA. After the FDA grants orphan drug designation, the generic identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA.

If a product that has orphan drug designation subsequently receives the first FDA approval for a particular active ingredient for the disease for which it has such designation, the product is entitled to orphan product marketing exclusivity, which means that the FDA may not approve any other applications, including a full BLA, to market the same biologic for the same use or indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity or if FDA finds that the holder of the orphan drug exclusivity has not shown that it can assure the availability of sufficient quantities of the orphan drug to meet the needs of patients with the disease or condition for which the drug was designated. Orphan drug exclusivity does not prevent the FDA from approving a different drug or biologic for the same disease or condition, or the same drug or biologic for a different disease or condition. Among the other benefits of orphan drug designation are tax credits for certain research and a waiver of the BLA or NDA application user fee.

A designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation. In addition, orphan drug exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or, as noted above, if the second applicant demonstrates that its product is clinically superior to the approved product with orphan exclusivity or the manufacturer of the approved product is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition.

Post-Approval Requirements

Once a BLA is approved, maintaining post-approval compliance with applicable federal, state, and local statutes and regulations requires the expenditure of substantial time and financial resources. Manufacturers and other entities involved in the manufacture and distribution of approved products are required to register the establishments where the approved products are made with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with GMP and other laws. Rigorous and extensive FDA regulation of products continues after approval, particularly with respect to GMP. We rely, and expect to continue to rely, on third parties for the production and distribution of clinical and commercial quantities of any products that we may commercialize. Manufacturers of our products are required to comply with applicable requirements in the GMP regulations, including quality control and quality assurance and maintenance of records and documentation. Other post-approval requirements include reporting of GMP deviations that may affect the identity, potency, purity and overall safety of a distributed product, record-keeping requirements, reporting of adverse effects, reporting updated safety and efficacy information, and complying with electronic record and signature requirements. After a BLA is approved, the product also may be subject to official lot release. As part of the manufacturing process, the manufacturer is required to perform certain tests on each lot of the product before it is released for distribution. If the product is subject to official release by the FDA, the manufacturer submits samples of each lot of product to the FDA together with a release protocol showing a summary of the history of manufacture of the lot and the results of all of the manufacturer's tests performed on the lot. The FDA also may perform certain confirmatory tests on lots of some products before releasing the lots for distribution by the manufacturer. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain GMP compliance. Discovery of problems with a product after approval may result in restrictions on a product, manufacturer, or holder of an approved BLA, including withdrawal of the product from the market. In addition, changes to the manufacturing process or facility generally require prior FDA approval before being implemented. Other types of changes to the approved product, such as adding new indications and additional labeling claims, are also subject to further FDA review and approval.

We also must comply with the FDA's advertising and promotion requirements, such as those related to direct-to-consumer advertising, the prohibition on promoting products for uses or in patient populations that are not described in the product's approved labeling (known as "off-label use"), industry-sponsored scientific and educational activities, and promotional activities involving the internet. Discovery of previously unknown problems or the failure to comply with the applicable regulatory requirements may result in restrictions on the marketing of a product or withdrawal of the product from the market as well as possible civil or criminal sanctions.

Failure to comply with the applicable U.S. requirements after approval may subject an applicant or manufacturer to administrative or judicial civil or criminal sanctions and adverse publicity. FDA sanctions could include refusal to approve pending applications, withdrawal of an approval, clinical hold, warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, mandated corrective advertising or communications with doctors, debarment, restitution, disgorgement of profits, or civil or criminal penalties.

U.S. Patent Term Restoration

Depending upon the timing, duration, and specifics of the FDA approval of the use of our current and potential product candidates, some of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984 ("Hatch-Waxman Amendments"). The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent term restoration period is generally one-half the time between the effective date of an IND and the submission date of a BLA plus the time between the submission date of a BLA and the approval of that application. Only one patent applicable to an approved biological product is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. The U.S. Patent and Trademark Office, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration.

Biosimilars and Exclusivity

The Biologics Price Competition and Innovation Act of 2009 ("BPCIA") created an abbreviated approval pathway for biological products shown to be highly similar to, or interchangeable with, an FDA-licensed reference biological product. The FDA has issued several guidance documents outlining an approach to review and approval of biosimilars.

Biosimilarity, which requires that there be no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency, can be shown through analytical studies, animal studies, and a clinical study or studies. Interchangeability requires that a product is biosimilar to the reference product and the product must demonstrate that it can be expected to produce the same clinical results as the reference product in any given patient and, for products that are administered multiple times to an individual, the biologic and the reference biologic may be alternated or switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic.

The BPCIA includes, among other provisions:

- A 12-year exclusivity period from the date of first licensure, or BLA approval, of the reference product, during which approval of a 351(k) application referencing that product may not be made effective;
- A four-year exclusivity period from the date of first licensure of the reference product, during which a 351(k) application referencing that product may not be submitted; and
- An exclusivity period for certain biological products that have been approved through the 351(k) pathway as interchangeable biosimilars.

The BPCIA also establishes procedures for identifying and resolving patent disputes involving applications submitted under section 351(k) of the PHSA.

The BPCIA is complex and its interpretation and implementation by the FDA remains unpredictable. In addition, government proposals have sought to reduce the 12-year reference product exclusivity period. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. As a result, the ultimate effect, implementation, and meaning of the BPCIA is subject to uncertainty.

Disclosure of Clinical Trial Information

Sponsors of clinical trials of FDA-regulated products, including biological products, are required to register and disclose certain clinical trial information on the website www.clinicaltrials.gov. Information related to the product, patient population, phase of investigation, trial sites and investigators, and other aspects of a clinical trial are then made public as part of the registration. Sponsors are also obligated to disclose the results of their clinical trials after completion. Disclosure of the results of clinical trials can be delayed in certain circumstances for up to two years after the date of completion of the trial. Competitors may use this publicly available information to gain knowledge regarding the progress of clinical development programs as well as clinical trial design.

Pediatric Information

Under the Pediatric Research Equity Act ("PREA"), BLAs or supplements to BLAs must contain data to assess the safety and effectiveness of the biological product for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the biological product is safe and effective. The FDA may grant full or partial waivers, or deferrals, for submission of data. Unless otherwise required by regulation, PREA does not apply to any biological product with orphan product designation except a product with a new active ingredient that is a molecularly targeted cancer product intended for the treatment of an adult cancer and directed at a molecular target determined by FDA to be substantially relevant to the growth or progression of a pediatric cancer that is subject to a BLA submitted on or after August 18, 2020.

The Best Pharmaceuticals for Children Act ("BPCA") provides a six-month extension of any non-patent exclusivity for a biologic if certain conditions are met. Conditions for exclusivity include the FDA's determination that information relating to the use of a new drug or biologic in the pediatric population may produce health benefits in that population, the FDA making a written request for pediatric studies, and the applicant agreeing to perform, and reporting on, the requested studies within the statutory timeframe. Applications under the BPCA are treated as priority applications, with all of the benefits that designation confers.

Additional U.S. Regulation

In the United States, our activities are potentially subject to regulation by various federal, state and local authorities in addition to the FDA, including but not limited to, the Centers for Medicare and Medicaid Services ("CMS"), other divisions of the U.S. Department of Health and Human Services, for instance the Office of Inspector General, the U.S. Department of Justice ("DOJ"), and individual U.S. Attorney offices within the DOJ, and state and local governments. For example, sales, marketing and scientific/educational grant programs must comply with the anti-fraud and abuse provisions of the Social Security Act, the false claims laws, the physician payment transparency laws, the privacy and security provisions of the Health Insurance Portability and Accountability Act ("HIPAA"), as amended by the Health Information Technology for Economic and Clinical Health Act ("HITECH") and similar state laws, each as amended.

In addition to the foregoing, state and federal laws regarding environmental protection and hazardous substances, including the Occupational Safety and Health Act, the Resource Conservancy and Recovery Act and the Toxic Substances Control Act, may affect our business. These and other laws govern our use, handling and disposal of various biological, chemical, and radioactive substances used in, and wastes generated by, our operations. If our operations result in contamination of the environment or expose individuals to hazardous substances, we could be liable for damages and governmental fines.

Federal and State Fraud and Abuse, Privacy and Transparency Laws

Federal and state fraud and abuse laws, which generally will not be applicable to us or our current and potential product candidates unless and until we obtain FDA marketing approval for any of our current and potential product candidates, include, among others, anti-kickback statutes, the False Claims Act and related stated state and federal laws, the Stark Law and related state and federal laws, transparency laws, privacy and regulation regarding providing drug samples, sales and marketing activities and our relationships with customers and payors as follows.

The federal Anti-Kickback Statute prohibits, among other things, individuals and entities from knowingly and willfully offering, paying, soliciting, or receiving any remuneration, directly or indirectly, overtly or covertly, to induce or in return for purchasing, leasing, recommending, ordering, or arranging for the purchase, lease, recommendation or order of any health care item or service reimbursable, in whole or in part, under Medicare, Medicaid, or other federally financed healthcare programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand and prescribers, purchasers, and formulary managers on the other. Although there are a number of statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution, the exemptions and safe harbors are drawn narrowly, and practices that involve remuneration that may be alleged to be intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exemption or safe harbor. Additionally, the intent standard under the Anti-Kickback Statute was amended by the Affordable Care Act to a stricter standard such that a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. Further, the Affordable Care Act codified case law that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act.

HIPAA created additional federal criminal statutes that prohibit, among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud or to obtain, by means of false or fraudulent pretenses, representations or promises, any money or property owned by, or under the control or custody of, any healthcare benefit program, including private third-party payers, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up by trick, scheme or device, a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

Federal false claims and civil monetary penalties laws, including the federal civil False Claims Act, prohibit, among other things, any person or entity from knowingly presenting, or causing to be presented, a false, fictitious or fraudulent claim for payment to, or approval by, the federal government, or knowingly making, using, or causing to be made or used, a false statement to get a false claim paid. Several pharmaceutical and other health care companies have been prosecuted under these laws for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. Other companies have been prosecuted for causing false claims to be submitted because of the company's marketing of the product for unapproved, and thus non-reimbursable, uses.

The majority of states also have statutes or regulations similar to the federal Anti-Kickback Statute and false claims laws, which apply to items and services, reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payer.

We may also be subject to data privacy and security regulations by both the federal government and the states in which we conduct our business. HIPAA, as amended by HITECH, and their respective implementing regulations, including the final Omnibus Rule published in 2013, imposes requirements on certain types of entities, including mandatory contractual terms, relating to the privacy, security, and transmission of individually identifiable health information. Among other things, HITECH makes HIPAA's security standards and certain privacy standards directly applicable to business associates, which are independent contractors or agents of covered entities that create, receive, maintain or transmit protected health information in connection with providing a service for or on behalf of a covered entity. HITECH also created four new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions. In addition, many state laws govern the privacy and security of health information in specified circumstances, many of which differ from each other and from HIPAA in significant ways and may not have the same requirements, thus complicating compliance efforts.

Additionally, the federal Physician Payments Sunshine Act and its implementing regulations require that certain manufacturers of drugs, devices, biological and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with certain exceptions, annually report to CMS information related to certain payments or other transfers of value made or distributed to physicians, physician assistants, certain types of advanced practice nurses and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of, the physicians and teaching hospitals and to report annually certain ownership and investment interests held by physicians and their immediate family members. Failure to submit timely, accurately, and completely the required information may result in civil monetary penalties of up to an aggregate of $150,000 per year and up to an aggregate of $1 million per year for "knowing failures." Certain states also mandate implementation of compliance programs, impose restrictions on pharmaceutical manufacturer marketing practices, and/or require the tracking and reporting of gifts, compensation, and other remuneration to healthcare providers and entities.

Because of the breadth of these laws and the narrowness of the exceptions and safe harbors, it is possible that some of our business activities could be subject to challenge under one or more of such laws. Such a challenge could have a material adverse effect on our business, financial condition, and results of operations. If our operations are found to be in violation of any of these or any other health regulatory laws that may apply to us, we may be subject to, without limitation, significant penalties, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgement, individual imprisonment, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

In addition, as part of the sales and marketing process, pharmaceutical companies frequently provide samples of approved products to physicians. This practice is regulated by the FDA and other governmental authorities, including, in particular, requirements concerning record keeping and control procedures. Any failure to comply with the regulations may result in significant criminal and civil penalties as well as damage to our credibility in the marketplace.

Coverage and Reimbursement

In many of the markets where we may do business in the future, the prices of pharmaceutical products are subject to direct price controls (by law) and to reimbursement programs with varying price control mechanisms. In the United States, significant uncertainty exists as to the coverage and reimbursement status of any product candidates for which we obtain product approval. Often private payers follow the coverage and reimbursement decisions of the Medicare program, and it is difficult to predict how CMS may decide to cover and reimburse approved products, especially novel products, and those determinations are subject to change.

Moreover, the process for determining whether a third-party payer will provide coverage for a drug product may be separate from the process for setting the price of a drug product or for establishing the reimbursement rate that such a payer will pay for the drug product. Third-party payers may limit coverage to specific products on an approved list, also known as a formulary, which might not include all of the FDA-approved drugs for a particular indication. A decision by a third-party payer not to cover our current and potential product candidates could reduce physician utilization of our products once approved. A payer's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Further, one payer's determination to provide coverage for a drug product does not assure that other payers will also provide coverage for the drug product. Coverage and reimbursement for new products can differ significantly from payer to payer. As a result, the coverage determination process will require us to provide scientific and clinical support for the use of our products to each payer separately and will be a time-consuming process. Additionally, third-party reimbursement may not be available or may not be adequate to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development.

Federal, state and local governments in the United States and foreign governments continue to consider legislation to limit the growth of healthcare costs, including the cost of prescription drugs. Specifically, there have been several recent U.S. Congressional inquiries and proposed federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. Future legislation could limit payments for pharmaceuticals such as the drug candidates that we are developing.

Different pricing and reimbursement schemes exist in other countries. In the EU, governments influence the price of drug products through their pricing and reimbursement rules and control of national health care systems that fund a large part of the cost of those products to consumers. Some jurisdictions operate systems under which products may be marketed only after a reimbursement price has been agreed. To obtain reimbursement or pricing approval, some of these countries may require the completion of studies or analyses of clinical trials that compare the cost-effectiveness of a particular product candidate to currently available therapies. Other member states allow companies to set their own prices for medicines, but exert cost controls in other ways, including but not limited to, placing revenue caps on product sales, providing reimbursement for only a subset of eligible patients, mandating price negotiations after a set period of time, or mandating that prices not exceed an average basket of prices in other countries. The downward pressure on health care costs in general, particularly treatments, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, European governments may periodically review and decrease prices based on factors, including, but not limited to, years-on-market, price in other countries, competitive entry, new clinical data, lack of supporting clinical data, or other factors.

The marketability of any product candidates for which we or our collaborators receive regulatory approval for commercial sale may suffer if the government and third-party payers fail to provide adequate coverage and reimbursement. In addition, an emphasis on cost containment measures in the United States has increased and we expect will continue to increase the pressure on pharmaceutical pricing. Third-party payers are increasingly challenging the prices charged for medical products and services, examining the medical necessity and reviewing the cost-effectiveness of drugs, medical devices and medical services, in addition to questioning safety and efficacy. If these third-party payers do not consider our products to be cost-effective compared to other available therapies, they may not cover our products after FDA approval or, if they do, the level of payment may not be sufficient to allow us to sell our products at a profit. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we or our collaborators receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Legislative and Regulatory Changes, Including Health Care Reform

The laws and regulation that affect our business are subject to change from time to time, and entirely new laws and regulations are sometimes adopted. In particular, healthcare reforms that have been adopted, and that may be adopted in the future, could result in further reductions in coverage and levels of reimbursement for pharmaceutical products, increases in rebates payable under U.S. government rebate programs and additional downward pressure on pharmaceutical product prices. In 2022, President Biden signed the Inflation Reduction Act, which, among other things, contains a provision that authorizes CMS to negotiate a "maximum fair price" for a limited number of high-cost, single-source drugs each year, and another provision that requires drug companies to pay rebates to Medicare if prices rise faster than inflation. It is unclear to what extent these and other statutory, regulatory, and administrative initiatives will be enacted and implemented in future years.

Environmental Regulation

In addition to the foregoing, state and federal laws regarding environmental protection and hazardous substances, including the Occupational Safety and Health Act, the Resource Conservancy and Recovery Act and the Toxic Substances Control Act, may affect our business. These and other laws govern our use, handling and disposal of various biological, chemical, and radioactive substances used in, and wastes generated by, our operations. If our operations result in contamination of the environment or expose individuals to hazardous substances, we could be liable for damages and governmental fines.

U.S. Foreign Corrupt Practices Act and Similar International Laws

The U.S. Foreign Corrupt Practices Act, to which we are subject, prohibits corporations and individuals from engaging in certain activities to obtain or retain business or to influence a person working in an official capacity. It is illegal to pay, offer to pay or authorize the payment of anything of value to any foreign government official, government staff member, political party, or political candidate in an attempt to obtain or retain business or to influence otherwise a person working in an official capacity.

Other countries, including a number of EU member states, have laws of similar application, including anti-bribery or anti-corruption laws such as the UK Bribery Act. The UK Bribery Act prohibits giving, offering, or promising bribes to any person, as well as requesting, agreeing to receive, or accepting bribes from any person. Under the UK Bribery Act, a company that carries on a business or part of a business in the United Kingdom may be held liable for bribes given, offered or promised to any person in any country by employees or other persons associated with the company in order to obtain or retain business or a business advantage for the company. Liability under the UK Bribery Act is strict, but a defense of having in place adequate procedures designed to prevent bribery is available.

Government Regulation Outside of the United States

In addition to regulations in the United States, we will be subject to a variety of regulations in other jurisdictions governing, among other things, clinical trials and any commercial sales and distribution of our products. Because biologically sourced raw materials are subject to unique contamination risks, their use may be subjected to different types of restrictions in different countries.

Whether or not we obtain FDA approval for a product, we must obtain the required approvals from regulatory authorities in foreign countries prior to the commencement of clinical trials or marketing of the product in those countries. Certain countries outside of the United States have a similar process that requires the submission of a clinical trial application equivalent to an IND prior to the commencement of human clinical trials. In the European Union, for example, a clinical trial authorization, or CTA, must be submitted to each country's national health authority and an independent ethics committee, much like the FDA and the IRB, respectively. Once the CTA is approved in accordance with a country's requirements, clinical trials may start.

The requirements and process governing the conduct of clinical trials, product licensing, manufacturing, sales and marketing, pricing, and reimbursement vary from country to country. In all cases, the clinical trials are to be conducted in accordance with GCP, applicable regulatory requirements, and the ethical principles that have their origin in the Declaration of Helsinki.

If we fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension, or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution in those countries.

Employees and Human Capital

As of March 15, 2026, we had 13 total employees, all of which were full-time. We are not a party to any collective bargaining agreements. We believe that we maintain good relations with our employees. Our employees are highly skilled, with many holding advanced degrees and having experience in drug development. We anticipate that the number of employees will remain approximately at this level throughout this year even as we progress our product pipeline.

We believe that our success depends in large part on our ability to attract and retain experienced and skilled employees. We endeavor to provide competitive compensation and benefits packages that reflect the highly competitive nature of our industry, as well as opportunities for professional development which are designed to attract, engage, retain and reward talented individuals who possess the skills necessary to support our business objectives, assist in the achievement of our strategic goals and increase stockholder value. We employ a pay for performance philosophy. Annual salary increases, promotional opportunities, incentive bonuses and stock-based compensation awards are available to all employees and are based on merit and include individual and corporate performance factors, subject to available financing.

As a clinical stage gene therapy company focused on transforming the lives of patients battling cancer and diabetes, we are committed to providing an environment of mutual respect and equal opportunity. We value our talented and diverse workforce, which we believe contributes to our long-term success. We take pride in supporting an open culture where we respect our colleagues, value their health and well-being and foster personal and professional growth and development. We believe that our business benefits from the different perspectives that our workforce brings.

Corporate Information and Available Information.

We were incorporated in Delaware in April 2009. Our principal executive offices are located at 3300 Bee Cave Road, #650-227, Austin, TX 78746, and our telephone number is (877) 774-4679.

Our website address is *www.genprex.com*. On our website, investors can obtain, free of charge, copies of our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, our Code of Business Conduct and Ethics, including disclosure related to any amendments or waivers thereto, other reports and any amendments thereto filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act of 1934, as amended, as soon as reasonably practicable after we file such material electronically with, or furnish it to, the Securities and Exchange Commission ("SEC"). None of the information posted on our website is incorporated by reference into this Annual Report on Form 10-K. Additionally, the SEC maintains an internet site that contains reports, proxy and information statements and other information regarding us and other issuers that file electronically with the SEC. The address of the SEC's website is *www.sec.gov*. The information contained in the SEC's website is not intended to be a part of this filing.

We have proprietary rights to a number of trademarks, including GENPREX, ONCOPREX, CONVERGEN and REQORSA, that are used in this Annual Report on Form 10-K. Solely for convenience, the trademarks and trade names in this Annual Report on Form 10-K are generally referred to without the ® or ™ symbols, but such references should not be construed as any indicator that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto. All other trademarks, trade names and service marks appearing in this Annual Report on Form 10-K are the property of their respective owners.

RISK FACTOR SUMMARY

Our business is subject to significant risks and uncertainties that make an investment in us speculative and risky. Below we summarize what we believe are the principal risk factors but these risks are not the only ones we face, and you should carefully review and consider the full discussion of our risk factors in the section titled "Risk Factors," together with the other information in this Annual Report on Form 10-K. If any of the following risks actually occurs (or if any of those listed elsewhere in this Annual Report on Form 10-K occur), our business, reputation, financial condition, results of operations, revenue, and future prospects could be seriously harmed. Additional risks and uncertainties that we are unaware of, or that we currently believe are not material, may also become important factors that adversely affect our business. Except as required by the federal securities laws, we undertake no obligation to update or revise any risk factor, whether as a result of new information, future events or otherwise.

Risks Related to Our Operations and Need for Additional Capital

- We will require substantial additional funding, which may not be available to us on acceptable terms, or at all, and, if not so available, may require us to delay, limit, reduce or cease our operations.
- Our recurring losses from operations have raised substantial doubt regarding our ability to continue as a going concern.
- We have never been profitable, we have no products approved for commercial sale, and to date we have not generated any revenue from product sales. As a result, our ability to reduce our losses and reach profitability is unproven, and we may never achieve or sustain profitability.
- We have a limited operating history and we expect a number of factors to cause our operating results to fluctuate on an annual basis, which may make it difficult to predict our future performance.
- Our ability to utilize our net operating loss carryforwards may be limited, resulting in income taxes sooner than currently anticipated.

Risks Related to Development and Commercialization of Our Current and Future Product Candidates

- Our success depends greatly on the success of our development of REQORSA for the treatment of NSCLC and SCLC, and our other product candidates, including GPX-002 for the treatment of diabetes.
- The biopharmaceutical industry is subject to extensive regulatory obligations and policies that may be subject to change, including due to judicial challenges.
- If we are unable to secure contract manufacturers with capabilities to produce the products that we require, we could experience delays in conducting our planned clinical trials.
- Negative public opinion and increased regulatory scrutiny of gene therapy and genetic research may damage public perception of our current and potential product candidates or adversely affect our ability to conduct our business or obtain regulatory approvals for our current and potential product candidates.
- Conducting successful clinical studies may require the enrollment of large numbers of patients, and suitable patients may be difficult to identify and recruit.
- Delays in the commencement, enrollment and completion of clinical trials could result in increased costs to us and delay or limit our ability to obtain regulatory approval for REQORSA and other current or future product candidates.
- Fast track designation of our products by FDA and designation under any other FDA expedited development program may not actually lead to a faster development or regulatory review or approval process, nor will it assure FDA approval of our product candidates.
- We may not be able to obtain or maintain orphan drug designation or exclusivity for our product candidates.
- A product candidate can fail at any stage of preclinical and clinical development.
- REQORSA®, GPX-002, and any other product candidate we advance through clinical trials may not have favorable results in later clinical trials or receive regulatory approval. Even if we complete the necessary clinical trials, we cannot predict when, or if, we will obtain regulatory approval to commercialize our product candidates, and the approval may be for a narrower indication than we seek.
- Even if we obtain regulatory approval of our current and future product candidates, the products may not gain market acceptance among physicians, patients, hospitals, treatment centers, third-party payors and others in the medical community.
- REQORSA®, GPX-002, and other current or future product candidates may have undesirable side effects that may delay or prevent marketing approval, or, if approval is received, require them to be taken off the market, require them to include safety warnings or otherwise limit their sales.
- If a product liability claim is successfully brought against us for uninsured liabilities, or such claim exceeds our insurance coverage, we could be forced to pay substantial damage awards that could materially harm our business.

- Security breaches and other disruptions could compromise our information and expose us to liability, which would cause our business and reputation to suffer.
- We face risks related to health epidemics and outbreaks or other widespread health crises which could significantly disrupt our preclinical studies and clinical trials. Any future disease outbreak, epidemic or pandemic, could disrupt our clinical trials and supply chain and materially adversely affect our business and operations.
- We face competition from other biotechnology and pharmaceutical companies, particularly those that are gene therapy companies, and our operating results will suffer if we fail to compete effectively.

Risks Related to Regulatory Approval and Marketing of Our Current and Future Product Candidates and Other Legal Compliance Matters

- We cannot provide assurance that REQORSA, GPX-002, or any of our other current or future product candidates will receive regulatory approval, and without regulatory approval we will not be able to market them.
- Even if we obtain regulatory approval for our product candidates, our products will remain subject to regulatory oversight.
- If the FDA does not find the manufacturing facilities of our current or future contract manufacturers acceptable for commercial production, we may not be able to commercialize REQORSA, GPX-002, or any of our other current or future product candidates.
- We may be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws and other federal and state healthcare laws, and the failure to comply with such laws could result in substantial penalties. Our employees, independent contractors, consultants, principal investigators, CROs, commercial partners and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.
- Coverage and reimbursement may be limited or unavailable in certain market segments for REQORSA, GPX-002, and our other current or future product candidates, if approved, which could make it difficult for us to sell REQORSA, GPX-002, and our other current or future product candidates profitably.
- Concerns about gene therapy, genetic testing, and genetic research could result in new and/or additional government regulations and requirements that restrict or prohibit the processes we use or delay or prevent the regulatory approval of our current and potential product candidates.
- Healthcare legislative reform measures may have a material adverse effect on our business and results of operations.
- We are subject to a variety of risks associated with international operations which could materially adversely affect our business.
- If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.

Risks Related to Our Dependence on Third Parties

- We may not be successful in establishing and maintaining development and commercialization collaborations, which could adversely affect our ability to develop our current and future product candidates and our financial condition and operating results could be adversely affected.
- We rely, in part, and expect to continue to rely, in part, on third parties to conduct, supervise and monitor our clinical trials, and if these third parties perform in an unsatisfactory manner, it may harm our business.
- Changes in the U.S. political and regulatory environment could affect availability of government funding that we or our third party collaborators may rely on, which could negatively impact the development of our product candidates.
- We rely, and expect to continue to rely, on third parties to distribute, manufacture and perform release testing for our current and future product candidates and other key materials and if such third parties do not carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approvals for our product candidates.
- We have completed and may in the future complete related party transactions that were not and may not be conducted on an arm’s length basis.
- Disruptions in the global economy and supply chains may have a material adverse effect on our business, financial condition and results of operations.

Risks Related to Our Intellectual Property

- If we fail to comply with obligations pursuant to our license agreements, we could lose intellectual property and other rights that are important to our business; if we fail to obtain licenses to advance our research and development that may be required we may be unable to develop the affected product exclusively, on acceptable terms or at all.
- The intellectual property rights we have licensed from MD Anderson and the University of Pittsburgh are subject to the rights of the U.S. government.
- If we are unable to protect our intellectual property rights or if our intellectual property rights are inadequate for our technology and product candidates, our competitive position could be harmed.
- Third-party claims of intellectual property infringement may prevent or delay our development and commercialization efforts.
- We may not be successful in obtaining or maintaining necessary rights to product components and processes for our development pipeline through acquisitions and in-licenses.
- Confidentiality agreements with employees and others may not adequately prevent disclosure of trade secrets and other proprietary information and may not adequately protect our intellectual property.
- Our reliance on third parties may require us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.
- We may be involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time-consuming and unsuccessful.
- Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.
- Issued patents covering our product candidates could be found invalid or unenforceable if challenged in court.
- We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties or that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.
- We may be subject to claims challenging the inventorship or ownership of our patents and other intellectual property.
- Changes in U.S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our products.
- We have in the past and may again in the future have trademark applications in the United States and/or certain other countries, and failure to secure these registrations could adversely affect our business; additionally, we may need to enforce our trademark rights against third parties and expend significant resources to enforce such rights against infringement.
- We may not be able to protect our intellectual property rights throughout the world.

Risks Related to Employee Matters and Managing Growth

- We have no sales, marketing or distribution experience and we will have to invest significant resources to develop those capabilities or enter into acceptable third-party sales and marketing arrangements.
- We may not be able to manage our business effectively if we are unable to attract and retain key personnel and consultants.
- We may use our financial and human resources to pursue a particular research program or product candidate and fail to capitalize on programs or product candidates that may be more profitable or for which there is a greater likelihood of success.
- If we engage in future acquisitions or strategic partnerships, this may increase our capital requirements, dilute our stockholders, cause us to incur debt or assume contingent liabilities, and subject us to other risks.

Risks Related to our Securities

- The market price of our common stock may be highly volatile, and you may lose all or part of your investment.
- An active, liquid and orderly market for our common stock may not be sustained, and you may not be able to sell your common stock.
- We are currently listed on The Nasdaq Capital Market. If we fail to maintain compliance with the continued listing requirements of Nasdaq, our common stock may be delisted and the price of our common stock and our ability to access the capital markets could be negatively impacted.
- Unstable market and economic conditions may have serious adverse consequences on our business, financial condition and stock price.
- Failure to maintain effective internal control over our financial reporting in accordance with Section 404 of the Sarbanes-Oxley Act of 2002, as amended ("Sarbanes-Oxley Act") could cause our financial reports to be inaccurate.
- We have no intention of declaring dividends in the foreseeable future.
- Sales of a substantial number of shares of our common stock in the public market could cause our stock price to fall.
- Future sales and issuances of our securities could result in additional dilution of the percentage ownership of our stockholders and could cause our share price to fall.
- If securities or industry analysts do not publish research or reports about us, or if they adversely change their recommendations regarding our common stock, then our stock price and trading volume could decline.
- Certain provisions in our organizational documents could enable our board of directors to prevent or delay a change of control.
- Our Amended and Restated Certificate of Incorporation, as amended, and Amended and Restated Bylaws, as amended, contain an exclusive forum provision with respect to certain actions which may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable and discourage lawsuits against us or our current or former directors or officers and/or stockholders in such capacity.

General Risk Factors

- Obligations associated with being a public company in the United States are expensive and time-consuming, and our management will be required to devote substantial time to compliance matters.
- Business disruptions could seriously harm our future revenue and financial condition and increase our costs and expenses.
- We may be at risk of securities class action litigation.

Item 1A. Risk Factors.

An investment in our common stock involves a high degree of risk. You should carefully consider the following risk factors and the other information in this Annual Report on Form 10-K before investing in our common stock. Our business and results of operations could be seriously harmed by any of the following risks. The risks set out below are not the only risks we face. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition and/or operating results. If any of the following events occur, our business, financial condition and results of operations could be materially adversely affected. In such case, the value and trading price of our common stock could decline, and you may lose all or part of your investment. Except as required by the federal securities laws, we undertake no obligation to update or revise any risk factor, whether as a result of new information, future events or otherwise.

Risks Related to Our Operations and Need for Additional Capital

We will require substantial additional funding, which may not be available to us on acceptable terms, or at all, and, if not so available, may require us to delay, limit, reduce or cease our operations.

We are using the proceeds from our sales of securities to advance REQORSA through clinical development, and to advance our other preclinical development programs as well as for other corporate purposes. Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is expensive. We will require substantial additional future capital to complete clinical development and commercialize REQORSA and for preclinical and clinical development and commercialization of our gene therapy for diabetes, GPX-002, and our other product candidates. If the FDA requires that we perform additional preclinical studies or clinical trials beyond what we currently anticipate, our expenses will further increase beyond what we currently expect and the anticipated timing of any potential approval of REQORSA, GPX-002, and our other current or future product candidates would likely be delayed. Furthermore, there can be no assurance that the costs to obtain regulatory approval of these product candidates will not increase.

We will continue to require substantial additional capital to continue our preclinical and clinical development and commercialization readiness activities. Because successful development of our current and potential product candidates is uncertain, we are unable to estimate the actual amount of funding we will require to complete research and development and commercialize our current and future product candidates.

The amount and timing of our future funding requirements will depend on many factors, including, but not limited to:

- the progress, costs, results and timing of our preclinical development and clinical trials for REQORSA, GPX-002, and other current or future product candidates;
- the outcome, costs and timing of seeking and obtaining FDA and any other regulatory approvals;
- the ability of third parties to deliver materials and provide services for us;
- the costs associated with securing and establishing commercialization and manufacturing capabilities;
- market acceptance of our current and future product candidates;
- the costs of acquiring, licensing or investing in businesses, products, product candidates and technologies;
- our ability to obtain, maintain, expand and enforce intellectual property rights for our products and product candidates, including the amount and timing of any payments we may be required to make, or that we may receive, in connection with the licensing, filing, prosecution, defense and enforcement of any patents or other intellectual property rights;
- our need and ability to hire additional management and scientific and medical personnel;
- the effect of competing drug candidates and new product approvals;
- our need to implement additional internal systems and infrastructure, including financial and reporting systems and enhancement of internal controls to address the material weaknesses we have identified as described in Part II, Item 9A of this Annual Report on Form 10-K; and
- the economic and other terms, timing of and success of our existing licensing arrangements and any collaboration, licensing or other arrangements into which we may enter in the future.

Some of these factors are outside of our control. Although we expect that our existing cash will be sufficient to fund our current operations and planned clinical trial activities into the second quarter of 2027, this period could be shortened if there are any significant increases in planned spending on current or additional development programs or more rapid progress of these development programs than anticipated. Furthermore, we believe that our existing capital will not be sufficient to enable us to complete the development and commercialization of REQORSA, GPX-002, and our other current or future product candidates. Accordingly, we expect that we will need to raise additional funds in the future.

We have raised and may continue to raise capital through a variety of sources that may be available to us.

On December 13, 2023, we entered into an At The Market ("ATM") Offering Agreement (the "ATM Agreement") with H.C. Wainwright & Co., LLC, serving as agent ("H.C. Wainwright" or the "Agent") with respect to an at-the-market offering program under which we may offer and sell through the Agent, from time to time at our sole discretion, up to such number or dollar amount of shares of our common stock (the "Shares") as registered on the prospectus supplement covering the ATM offering, as may be amended or supplemented from time to time. We have agreed to pay the Agent a commission equal to three percent (3%) of the gross sales proceeds of any Shares sold through the Agent under the ATM Agreement, and also have provided the Agent with customary indemnification and contribution rights. As of December 31, 2025, we had sold 1,602,490 Shares for net proceeds to us totaling approximately $10.8 million through the Agent under the ATM Agreement. From January 1, 2026 through the date of filing of this Annual Report on Form 10-K, we have sold 5,714,798 Shares for net proceeds to us totaling approximately $13.3 million through the Agent under the ATM Agreement. Immediately prior to filing this Annual Report on Form 10-K, we were eligible to rely on General Instruction I.B.1 to Form S-3 and were not subject to the sales limitations of General Instruction I.B.6 to Form S-3. In connection with our filing of this Annual Report on Form 10-K, we were again required to retest our eligibility to rely on General Instruction I.B.1 of Form S-3 and because the aggregate market value of our outstanding common stock held by non-affiliates ("public float") was less than $75 million, as of the date of filing this Annual Report on Form 10-K we are again subject to the sales limitations of General Instruction I.B.6 to Form S-3. Under these so-called "baby shelf" limitations, we may utilize Form S-3 (including our current shelf Registration Statement on Form S-3 (File No. 333-271386), or any new or successor shelf Registration Statement on Form S-3 of the Company) to conduct primary offerings (excluding our ATM) only to the extent securities sold during any period of 12 calendar months immediately prior to, and including, the sale is equivalent to no more than one-third (1/3) of our public float. So long as we remain subject to this "baby shelf" sales limitation, our ability to utilize Form S-3, for offerings other than our ATM, and/or to access the capital markets to conduct other primary offerings of securities will be constrained.

In addition, on June 11, 2025, we entered into an equity line of credit ("ELOC") purchase agreement (the "Purchase Agreement") with Lincoln Park Capital Fund, LLC ("Lincoln Park"), pursuant to which Lincoln Park committed to purchase up to $12.5 million in shares of our common stock (subject to certain conditions and limitations contained in the Purchase Agreement) from time to time at our sole discretion over the 24-month term of the Purchase Agreement (the "2025 ELOC Facility"). Sales of shares of common stock to Lincoln Park under the Purchase Agreement will depend on a variety of factors to be determined by us from time to time, including, among others, market conditions, the trading price of the common stock and our determination as to the appropriate sources of funding for our operations. During the twelve months ended December 31, 2025, we (i) issued 23,737 shares of common stock to Lincoln Park with a value of $365,550 as commitment shares pursuant to the 2025 ELOC Facility, which was expensed as incurred, and (ii) sold 749,130 shares of common stock to Lincoln Park as purchase shares for aggregate net proceeds of approximately $5.3 million under the 2025 ELOC Facility.

We may seek additional funding through a combination of equity offerings, drawdowns on our ATM pursuant to our ATM Agreement with H.C. Wainwright as Agent and/or through other third-party ATM agreements in the future, sales pursuant to our 2025 ELOC Facility, debt financings, government or other third-party funding, commercialization, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements, some of which may require us to relinquish rights to some of our technologies or product candidates or otherwise agree to terms unfavorable to us. Additional funding may not be available to us on acceptable terms, if at all. In addition, the terms of any financing may adversely affect the holdings or the rights of our stockholders. Any new equity securities we issue could have rights, preferences, and privileges superior to those of holders of our existing capital stock. In addition, the issuance of additional shares by us may cause the market price of our shares to decline and result in dilution to our stockholders. Any debt financing secured by us in the future could involve restrictive covenants relating to our capital-raising activities and other financial and operational matters, which may make it more difficult for us to obtain additional capital and to pursue business opportunities.

If we are unable to obtain funding on a timely basis, we may be required to significantly curtail one or more of our preclinical or clinical development programs, our ability to continue to support our business growth and to respond to business challenges could be significantly limited, and we may be required to curtail or cease operations. Accordingly, our business may fail, in which case you would lose the entire amount of your investment in our securities.

Our recurring losses from operations have raised substantial doubt regarding our ability to continue as a going concern.

We have recognized recurring losses, and as of December 31, 2025, had an accumulated deficit of approximately $171.0 million. We anticipate operating losses to continue for the foreseeable future due to, among other things expenses related to ongoing activities to research, develop and commercialize our product candidates. We expect the cash and cash equivalents of approximately $7.83 million at December 31, 2025 to be insufficient to meet our operating and capital requirements at least 12 months from the filing of this Annual Report on Form 10-K. Based on our current cash, we estimate that we will be able to fund our expenditure requirements for our current operations and planned clinical trial activities into the second quarter of 2027. Our forecast of the period of time through which our current financial resources will be adequate to support our operations and the costs to support our general and administrative and research and development activities are forward-looking statements and involve risks and uncertainties. The consolidated financial statements do not include any adjustments that might be necessary should we be unable to continue as a going concern.

Although we believe our current cash will be able to fund our expenditure requirements for our current operations and planned clinical trial activities into the second quarter of 2027, our ability to continue as a going concern is dependent on our ability to raise additional working capital through public or private equity or debt financings or other sources, which may include collaborations with third parties as well as disciplined cash spending. Should we be unable to raise sufficient additional capital, we may be required to undertake cost-cutting measures including delaying or discontinuing certain clinical activities, and we may be required to curtail or cease operations. The sale of equity and convertible debt securities may result in dilution to our stockholders and certain of those securities may have rights senior to those of our common stock. If we raise additional funds through the issuance of preferred stock, convertible debt securities or other debt financing, these securities or other debt could contain covenants that would restrict our operations. Any other third-party funding arrangement could require us to relinquish valuable rights.

The source, timing and availability of any future financing will depend principally upon market conditions, and, more specifically, on the progress of our clinical development programs. Funding may not be available when needed, at all, or on terms acceptable to us. Lack of necessary funds may require us, among other things, to delay, scale back or eliminate some or all of our planned clinical trials. These factors among others create a substantial doubt about our ability to continue as a going concern.

We have never been profitable, we have no products approved for commercial sale, and to date we have not generated any revenue from product sales. As a result, our ability to reduce our losses and reach profitability is unproven, and we may never achieve or sustain profitability.

We have never been profitable and do not expect to be profitable in the foreseeable future. We have not yet submitted any drug candidates for approval by regulatory authorities in the United States or elsewhere. From our inception on April 1, 2009, to December 31, 2025, we incurred an accumulated deficit of approximately $171.0 million. We incurred net losses of approximately $16.2 million and approximately $21.1 million for the years ended December 31, 2025 and 2024, respectively.

To date, we have devoted most of our financial resources to our corporate overhead and research and development, including our preclinical development activities, manufacturing processes and clinical trials. We have not generated any revenues from product sales. We expect to continue to incur losses for the foreseeable future, and we expect these losses to increase as we continue our development of, and seek regulatory approvals for, our current and potential product candidates, prepare for and begin the commercialization of any approved products, and add infrastructure and personnel to support our continuing product development efforts. We anticipate that any such losses could be significant for the next several years. If REQORSA, GPX-002, or any of our other current or future product candidates fail in clinical trials or do not gain regulatory approval, or if our drug candidates do not achieve market acceptance, we may never become profitable. These net losses and negative cash flows have had, and will continue to have, an adverse effect on our stockholders' equity and working capital.

Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses or if, or when, we will be able to achieve profitability. In addition, our expenses could increase if we are required by the FDA to perform studies or trials in addition to those currently expected, or if there are any delays in completing our clinical trials or the development of any of our drug candidates. The amount of future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenues.

We have a limited operating history and we expect a number of factors to cause our operating results to fluctuate on an annual basis, which may make it difficult to predict our future performance.

We are a clinical stage company with a limited operating history. Our operations to date have been limited to conducting clinical and preclinical research and development. We have not yet obtained any regulatory approvals for any of our drug candidates. Consequently, any predictions made about our future success or viability may not be accurate. Our operating results are expected to significantly fluctuate from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. Factors relating to our business that may contribute to these fluctuations include:

- any delays in regulatory review and approval (assuming that our data support approval) of our current and future product candidates in clinical development, including our ability to receive approval from the FDA for REQORSA or GPX-002;
- delays in the commencement, enrollment and timing of clinical trials;
- the success of our current and future product candidates through all phases of preclinical and clinical development, including the ability of our third-party suppliers or manufacturers to supply or manufacture our products on a timely, consistent basis in a manner sufficient and appropriate as is commensurate to meet our clinical trial timing, courses of treatment, and other requisite fulfillment considerations necessary to adequately advance our development programs;
- potential side effects of our current and future product candidates that could delay or prevent approval or cause an approved drug to be taken off the market;
- our ability to obtain additional funding to develop our current and future product candidates;
- our identification and development of additional drug candidates beyond REQORSA, GPX-002, and our other current product candidates;
- competition from existing products or new products or product candidates that continue to emerge;
- the ability of patients or healthcare providers to obtain coverage or sufficient reimbursement for our products;
- our ability to adhere to clinical trial requirements directly or with third parties such as contract research organizations ("CROs");
- our dependency on third-party suppliers or manufacturers to manufacture our key ingredients and/or raw materials, products and/or product components and successfully carry out a sustainable, reproducible and scalable manufacturing process in accordance with specifications or applicable regulations;
- our ability to establish or maintain collaborations, licensing, sponsored research or other arrangements, particularly with MD Anderson and UP and otherwise relating to REQORSA, and GPX-002;
- our ability to defend against any challenges to our intellectual property including claims of patent infringement;
- our ability to enforce our intellectual property rights against potential competitors;

- our ability to secure additional intellectual property protection for our product candidates and associated technologies as may be required or desirable as the development of the product candidates progresses;
- our ability to attract and retain key personnel to manage our business effectively; and
- potential product liability claims.

Our ability to utilize our net operating loss carryforwards may be limited, resulting in income taxes sooner than currently anticipated.

As of December 31, 2025, we had federal net operating loss carryforwards ("NOLs") of approximately $117.5 million for federal income tax purposes of which approximately $1.3 million will begin to expire in 2030 and approximately $107.9 million can be carried forward indefinitely. These NOLs may be used to offset future taxable income, to the extent we generate any taxable income, and thereby reduce or eliminate our future federal income taxes otherwise payable. Section 382 of the Internal Revenue Code of 1986, as amended (the "Code"), imposes limitations on a corporation's ability to utilize NOLs if it experiences an ownership change as defined in Section 382. In general terms, an ownership change may result from transactions increasing the ownership of certain stockholders in the stock of a corporation by more than 50% over a three-year period. In the event that an ownership change has occurred, or were to occur, utilization of our NOLs would be subject to an annual limitation under Section 382 determined by multiplying the value of our stock at the time of the ownership change by the applicable long-term tax-exempt rate as defined in the Code. Any unused annual limitation may be carried over to later years. We may be found to have experienced an ownership change under Section 382 as a result of events in the past or the issuance of shares of common stock in the future. If so, the use of our NOLs, or a portion thereof, against our future taxable income may be subject to an annual limitation under Section 382, which may result in expiration of a portion of our NOLs before utilization.

The utilization of our NOLs may also be limited under state laws. In addition, under the 2017 Tax Cuts and Jobs Act (the "TCJA"), tax losses generated in taxable years beginning after December 31, 2017 may be utilized to offset no more than 80% of taxable income annually. This change may require us to pay federal income taxes in future years despite generating a loss for federal income tax purposes. There is also a risk that due to regulatory changes, such as suspensions on the use of NOLs, or other unforeseen reasons, our existing NOLs could expire or otherwise be unavailable to offset future income tax liabilities. For these reasons, we may not be able to realize a tax benefit from the use of our NOLs, whether or not we attain profitability.

Risks Related to Development and Commercialization of Our Current and Future Product Candidates

Our success depends greatly on the success of our development of REQORSA for the treatment of NSCLC and SCLC, and our other product candidates, including GPX-002 for the treatment of diabetes.

At this time, we are actively pursuing the development of REQORSA for NSCLC through our Acclaim-1 clinical trial and for SCLC through our Acclaim-3 clinical trial, which are both currently enrolling patients. We are also pursuing the development of preclinical gene therapy GPX-002 for Type 1 and Type 2 diabetes, as well as earlier discovery programs. In particular, we are dependent on the success of REQORSA and GPX-002. We cannot provide you any assurance that we will be able to successfully advance REQORSA, GPX-002 or any of our other current or future product candidates through the development process, or that any development problems we experience in the future will not cause significant delays or unanticipated costs, or that such development problems can be solved. For example, as previously announced in August 2024, based on a number of factors, including enrollment challenges and delays due to competition for investigators and eligible patients with numerous other trials involving the same patient population, we decided to cease enrollment of new patients in the Acclaim-2 trial (which involved a combination of REQORSA and Merck & Co.'s Keytruda® (*pembrolizumab*) in patients with late-stage NSCLC whose disease has progressed after treatment with Keytruda) to prioritize our resources and focus on the other two Acclaim trials in SCLC and NSCLC, respectively. We may also experience delays in the development of a sustainable, reproducible and scalable manufacturing process or transferring that process to commercial partners, or developing or validating product release assays in a timely manner, which may prevent us from completing our clinical trials or commercializing our products on a timely or profitable basis, if at all. Immunotherapy, gene therapy and biopharmaceutical product development are highly speculative undertakings and involve a substantial degree of uncertainty. Because REQORSA, GPX-002 and our other current product candidates are based upon novel technology, it is difficult to predict whether, either as stand-alone therapies or in combination with other drugs, they will show consistently favorable results and to predict the time and cost of their development and of subsequently obtaining regulatory approval. We believe only a few gene therapy products have been approved in the United States or Europe. We have found it difficult to enroll patients in our clinical studies in the past, have experienced certain difficulties in enrolling patients in our current trials and may continue to find it difficult in the future, which could delay or prevent clinical studies of REQORSA or other current or future product candidates. Examples of such difficulties include the Acclaim-2 trial noted above and also for Acclaim-1, which as previously announced in August 2024, we decided to limit our enrollment efforts moving forward to patients who received only prior

Tagrisso treatment and cease enrollment of the second cohort (patients who received prior Tagrisso treatment and chemotherapy) due to slow enrollment, resource prioritization and to focus on the patients for whom REQORSA is most likely to show a benefit. We may encounter other delays in our preclinical or clinical studies, or we may fail to demonstrate safety and efficacy to the satisfaction of FDA and other regulatory authorities. We may not be successful in our efforts to identify or discover additional product candidates, or to develop product candidates that we have identified.

In addition, the clinical trial requirements of the FDA, the European Commission, the European Medicines Agency ("EMA"), the competent authorities of the Member States of the European Union ("EU") and other regulatory authorities and the criteria these regulators use to determine the safety and efficacy of a product candidate vary substantially according to the type, complexity, novelty and intended use and market of such product candidates. The regulatory approval process for novel product candidates such as ours can be more expensive and take longer than for other, better known or more extensively studied product candidates. Even if we are successful in developing product candidates, it is difficult to determine how long it will take or how much it will cost to obtain regulatory approvals for these product candidates in either the United States or the EU, or how long it will take to commercialize any other products for which we receive marketing approval. In addition, any future marketing authorization granted by the European Commission may not be indicative of what the FDA may require for approval and vice versa.

The biopharmaceutical industry is subject to extensive regulatory obligations and policies that may be subject to change, including due to judicial challenges.

The U. S. biopharmaceutical industry is highly regulated and subject to frequent and substantial changes, including as a result of new judicial or government actions. Legislative and regulatory agendas as they relate to the biopharmaceutical industry are currently uncertain. Changes in the regulatory approval process, or substantial reductions in the personnel who oversee that process, could affect our ability to obtain regulatory approval for our product candidates or the timeline in which we can obtain that approval. We and our current and future third party collaborators may rely on government programs or agencies, such as the National Institutes for Health ("NIH"), as a source of grant funding for scientific research relevant to our product candidates. Funding from government agencies such as the NIH can fluctuate and is subject to the political process, which is often unpredictable. Reductions in NIH grants to us or our third party collaborators may adversely impact our ability to develop our existing product candidates and our ability to identify new product candidates. In addition, on June 28, 2024, the U.S. Supreme Court issued an opinion holding that courts reviewing agency action pursuant to the Administrative Procedure Act (APA) "must exercise their independent judgment" and "may not defer to an agency interpretation of the law simply because a statute is ambiguous." The decision could have a significant impact on how lower courts evaluate challenges to agency interpretations of law, including those by the FDA and other agencies with significant oversight of the biopharmaceutical industry. The new framework may increase both the frequency of such challenges and their odds of success by eliminating one way in which the government previously prevailed in such cases. As a result, significant regulatory policies could be subject to increased litigation and judicial scrutiny. We cannot predict how other future federal or state legislative or administrative changes relating to healthcare reform or the biopharmaceutical industry, or the regulatory agencies that oversee the biopharmaceutical industry, will affect our business.

If we are unable to secure contract manufacturers with capabilities to produce the products that we require, we could experience delays in conducting our planned clinical trials.

Manufacturing REQORSA involves several manufacturing steps. Historically, part of our manufacturing process was conducted in manufacturing facilities at MD Anderson. We have transferred all of the steps of our manufacturing process to CDMOs and scaled-up clinical production in order to supply our Acclaim-1 and Acclaim-3 clinical trials. We also are preparing for commercial readiness for REQORSA through the development of an integrated supply chain network of manufacturing vendors and continue to work to identify cutting edge manufacturing technologies to optimize manufacturing processes and shelf life. With the advancement of the development of GPX-002, we also are working to optimize the manufacture of this product candidate and to source high quality and integrated vendors capable of producing it in accordance with GMP. Although we have contracted with CDMOs to produce our products, no assurance can be given that such CDMOs will be able to continue to produce the products that we require. In addition, the tremendous growth in the gene therapy sector has created increasing demand for the services of CDMOs with gene therapy capabilities which may impact our ability to schedule production runs of our products or product components to meet our needs on a timely basis. Furthermore, manufacturing gene-based therapies is complex and highly regulated and a CDMO with which we have contracted may fail to produce our products or product components timely or in accordance with our specifications or applicable regulations. We have experienced a variety of these challenges to varying degrees in connection with performance by our CDMOs, which have resulted in delays in our Acclaim clinical trials in the past. Additionally, our CDMOs may get acquired or change ownership structure, enter into new lines of business or depart existing lines of business, or go out of business altogether; all of which could require us to find new CDMOs and adversely affect our business. Changing our current or future contract manufacturers may be difficult and could be costly, which could result in our inability to manufacture our clinical product

candidates and a delay in the development of our clinical product candidate. Further, in order to maintain our development timelines, any changes to, or the addition of a new, third-party contract manufacturers may result in our incurring higher costs to manufacture our clinical product candidates. Any delay in the availability of product supply or product component supply could result in a delay in our clinical trials, including our Acclaim-1 and Acclaim-3 clinical trials as well as the commencement of clinical trials for GPX-002.

Negative public opinion and increased regulatory scrutiny of gene therapy and genetic research may damage public perception of our current and potential product candidates or adversely affect our ability to conduct our business or obtain regulatory approvals for our current and potential product candidates.

Public perception may be influenced by claims that gene therapy is unsafe, and gene therapy may not gain the acceptance of the public or the medical community. In particular, our success will depend upon physicians prescribing treatments that involve the use of our product candidates in lieu of, or in addition to, existing treatments with which they are already familiar and for which greater clinical data may be available. More restrictive government regulations or negative public opinion would have a negative effect on our business or financial condition and may delay or impair the development and commercialization of our current and potential product candidates or demand for any products we may develop. Adverse events in our clinical trials, even if not ultimately attributable to our current and potential product candidates, and the resulting publicity could lead to increased governmental regulation, unfavorable public perception, potential regulatory delays in the testing or approval of our potential product candidates, stricter labeling requirements for those product candidates that are approved and a decrease in demand for any such product candidates. Concern about the environmental spread of our product, whether real or anticipated, could also hinder the commercialization of our products.

Prior to receiving REQORSA in our Acclaim-1 clinical trial, patients are required to undergo genetic screening to detect EGFR mutations. Genetic testing has raised concerns regarding the appropriate utilization and the confidentiality of information provided by genetic testing. Genetic tests for assessing a person's likelihood of developing a chronic disease have focused public attention on the need to protect the privacy of genetic information. Genetic testing information is also subject to significant restrictions under both federal and state law. For example, concerns have been expressed that insurance carriers and employers may use these tests to discriminate on the basis of genetic information, resulting in barriers to the acceptance of genetic tests by consumers. This could lead to governmental authorities restricting genetic testing or calling for limits on or regulating the use of genetic testing, particularly for diseases for which there is no known cure. Any of the foregoing could decrease demand for REQORSA or our other product candidates.

Conducting successful clinical studies may require the enrollment of large numbers of patients, and suitable patients may be difficult to identify and recruit.

Patient enrollment in clinical trials and completion of patient participation and follow-up depends on many factors, including the size of the patient population; the nature of the trial protocol; the attractiveness of, or the discomforts and risks associated with, the treatments received by enrolled subjects; the availability of appropriate clinical trial investigators; support staff; and proximity of patients to clinical sites; ability to comply with the eligibility and exclusion criteria for participation in the clinical trial; and patient compliance. For example, patients may be discouraged from enrolling in our clinical trials if the trial protocol requires them to undergo extensive post-treatment procedures or follow-up to assess the safety and effectiveness of our product candidates or if they determine that the treatments received under the trial protocols are not attractive or involve unacceptable risks or discomforts. Patients may also not participate in our clinical trials if they choose to participate in contemporaneous clinical trials of competitive products.

In addition, our ability to successfully initiate, enroll and complete clinical trials in any foreign country is subject to numerous risks of conducting business in foreign countries, including:

- difficulty in establishing or managing relationships with CROs and physicians;
- different standards for the conduct of clinical trials;
- our inability to locate qualified local consultants, physicians and partners; and
- the potential burden of complying with a variety of foreign laws, medical standards and regulatory requirements, including the regulation of pharmaceutical and biotechnology products and treatments.

If we have difficulty enrolling a sufficient number of patients to conduct our clinical trials as planned, such as we have experienced with the Acclaim-2 clinical trial for example, we may need to delay, limit or terminate ongoing or planned clinical trials, any of which would have an adverse effect on our business.

Delays in the commencement, enrollment and completion of clinical trials could result in increased costs to us and delay or limit our ability to obtain regulatory approval for REQORSA and other current or future product candidates.

Clinical development is very expensive and can take many years. Delays in the commencement, enrollment and/or completion of our Acclaim-1 and Acclaim-3 clinical trials or any future clinical trials could increase our product development costs or delay or limit the regulatory approval of REQORSA or other product candidates. We have experienced delays in opening our clinical sites for our Acclaim-1 and Acclaim-2 trials in the past; for example, there was a delay with Acclaim-2 due to competition for investigators and eligible patients with numerous other trials involving the same patient population. We do not know and cannot predict whether future trials or studies of other current or future product candidates, including later stages of our Acclaim trials, and any for GPX-002, will begin as planned, if at all, and we do not know and cannot predict whether our Acclaim-1 and Acclaim-3 clinical trials or any future trials or studies of other current or future product candidates will be completed on schedule, if at all. The start or end of a clinical study may be delayed or halted due to regulatory requirements, changes in the proposed regulatory approval pathway for a drug candidate, manufacturing challenges, including delays or shortages in available raw materials required to manufacture the drug product, required clinical trial administrative actions, slower than anticipated patient enrollment, changing standards of care, availability or prevalence of use of a comparative drug or required prior therapy, clinical outcomes or financial constraints. For instance, delays or difficulties in patient enrollment or difficulties in retaining trial participants can result in increased costs, longer development times or termination of a clinical trial, such as the Acclaim-2 program. Clinical trials of a new product candidate require the enrollment of a sufficient number of patients, including patients who are suffering from the disease the product candidate is intended to treat and who meet other eligibility criteria, such as mutation of the EGFR which is required for the Acclaim-1 trial and is present in a minority of NSCLC patients. Rates of patient enrollment are affected by many factors, including the size of the patient population, the eligibility criteria for the clinical trial, which include the age and condition of the patients and the stage and severity of disease, the nature of the protocol, the proximity of patients to clinical sites and the availability of effective treatments and/or availability of other investigational treatment options for the relevant disease. We have initiated our Acclaim-1 and Acclaim-3 clinical trials pursuant to an existing IND. We have previously filed with the FDA amendments to our IND consisting of an updated chemistry, manufacturing and controls section, and the protocol for the respective clinical trial. We cannot be sure that issues will not arise in the future in connection with potential subsequent amendments or otherwise that might result in the FDA imposing a clinical hold which could result in the delay of any of these clinical trials. For GPX-002 we have not yet filed an IND and cannot predict all of the challenges and issues that may arise in connection with the preparation and filing of an IND, or whether this IND will be filed at all.

Fast track designation of our products by FDA and designation under any other FDA expedited development program may not actually lead to a faster development or regulatory review or approval process, nor will it assure FDA approval of our product candidates.

REQORSA has received three fast track designations from the FDA. We may in the future seek additional fast track designations for our products and/or request breakthrough therapy designation, accelerated approval or priority review of applications for approval. FDA has broad discretion whether or not to grant these designations and requests, so even if we believe a particular product candidate is eligible for these designations, we cannot assure you that the FDA will grant them. Even with fast track designation and other FDA expedited development programs, we may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may withdraw fast track designation and other expedited program designations if it believes that the requirements of the program are no longer met.

We may not be able to obtain or maintain orphan drug designation or exclusivity for our product candidates.

In August 2023, the FDA granted Orphan Drug Designation to REQORSA for the treatment of SCLC. Upon receipt of regulatory approval, orphan drug status will provide us with seven years of market exclusivity in the United States under the Orphan Drug Act. We may seek other orphan drug designations in the future in the United States and in the European Union for our product candidates. However, there is no guarantee that the FDA will grant orphan drug designation for any of our other drug candidates for any future indication, which would make us ineligible for the additional exclusivity and other benefits of orphan drug designation for those other drug candidates in the future. Moreover, there can be no assurance that another company also holding orphan drug designation for the same indication or which may receive orphan drug designation in the future will not receive approval prior to us, in which case our competitor would have the benefit of the seven years of market exclusivity, and we would be unable to commercialize our product for the same indication until the expiration of such seven-year period. Even if we are the first to obtain approval for the orphan drug indication, there are circumstances under which a competing product may be approved for the same indication during our seven-year period of exclusivity.

Under the Orphan Drug Act, the FDA may grant orphan drug designation to a drug intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making a drug available in the Unites States for this type of disease or condition will be recovered from sales of the product. Orphan drug designation must be requested before submitting an NDA or BLA. After the FDA grants orphan drug designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan designation does not convey any advantage in or shorten the duration of regulatory review and approval process. In addition to the potential period of exclusivity, orphan designation makes a company eligible for grant funding of up to $400,000 per year for four years to defray costs of clinical trial expenses, tax credits for clinical research expenses and potential exemption from the FDA application user fee.

If a product that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan drug exclusivity, which means the FDA may not approve any other applications to market the same drug for the same indication for seven years, except in limited circumstances, such as (i) the drug's orphan designation is revoked; (ii) its marketing approval is withdrawn; (iii) the orphan exclusivity holder consents to the approval of another applicant's product; (iv) the orphan exclusivity holder is unable to assure the availability of a sufficient quantity of drug; or (v) a showing of clinical superiority to the product with orphan exclusivity by a competitor product. If a drug designated as an orphan product receives marketing approval for an indication broader than what is designated, it may not be entitled to orphan drug exclusivity. There can be no assurance that we will receive orphan drug designation for any of our drug candidates for any additional indications, if we elect to seek such designation. Even if orphan designation is granted it may be withdrawn by the FDA for non-compliance with regulations.

A product candidate can fail at any stage of preclinical and clinical development.

The historical failure rate for product candidates is high due to scientific feasibility, safety, efficacy, changing standards of medical care and other variables. The results from preclinical testing or early clinical trials of a product candidate may not predict the results that will be obtained in later phase clinical trials of the product candidate. We, the FDA or other applicable regulatory authorities may suspend clinical trials of a product candidate at any time for various reasons, including, but not limited to, a belief that subjects participating in such trials are being exposed to unacceptable health risks or adverse side effects, or other adverse initial experiences or findings. We may not have the financial resources to continue development of, or to enter into collaborations for, a product candidate if we experience any problems or other unforeseen events that delay or prevent regulatory approval of, or our ability to commercialize, product candidates, including:

- inability to obtain sufficient funds required for clinical development;
- inability to reach agreements on acceptable terms with current or prospective vendors, CROs and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different vendors, CROs and trial sites;
- negative or inconclusive results from our clinical studies or the clinical studies of others for product candidates similar to ours, leading to a decision or requirement to conduct additional preclinical testing or clinical trials or abandon a program;
- serious and unexpected side effects experienced by subjects in our clinical trials or by individuals using drugs similar to our current and future product candidates;
- conditions imposed by the FDA or comparable foreign authorities regarding the scope or design of our clinical trials;
- unexpected results from preclinical testing and development;
- inability or delays in enrolling research subjects in clinical trials;
- high drop-out rates and high fail rates of research subjects;
- inadequate supply or quality of product candidate components or materials or other supplies necessary for the conduct of preclinical or clinical testing;
- greater than anticipated clinical trial costs;
- poor effectiveness of our current and potential product candidates during clinical trials; or
- unfavorable FDA or other regulatory agency inspection and review of a clinical trial site or vendor.

REQORSA®, GPX-002, and any other product candidate we advance through clinical trials may not have favorable results in later clinical trials or receive regulatory approval. Even if we complete the necessary clinical trials, we cannot predict when, or if, we will obtain regulatory approval to commercialize our product candidates, and the approval may be for a narrower indication than we seek.

Clinical failure can occur at any stage of our clinical development. Clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or nonclinical studies. In addition, data obtained from trials and studies are susceptible to varying interpretations, and regulators may not interpret our data as favorably as we do, which may delay, limit or prevent regulatory approval. Additionally, our partners, clients, other vendors, and/or other stakeholders may not agree with our interpretation(s) of data obtained from our clinical trials, which could potentially cause a variety of issues, including, but not limited to, delays, the necessity for additional studies and analyses, dependence on third-party validation, and/or other unforeseen challenges. Success in preclinical studies and early clinical trials does not ensure that subsequent clinical trials will generate the same or similar results or otherwise provide adequate data to demonstrate the efficacy and safety of a product candidate. Later-stage clinical trials could differ in significant ways from early-stage clinical trials, including changes to inclusion and exclusion criteria, efficacy endpoints, dosing regimen and statistical design. For example, the small number of patients in our completed Phase 1 Monotherapy clinical trial of REQORSA and the Phase 1/2 Combination Tarceva trial may make the results of these trials less predictive of the outcome of later clinical trials. In addition, although we observed encouraging clinical activity in the Phase 1 Monotherapy and Phase 1/2 Combination Tarceva trial, the primary objectives of the Phase 1 Monotherapy Trial and the Phase 1 portion of the Phase 1/2 Combination Tarceva trial were safety and MTD and not to demonstrate efficacy. The assessments of clinical activity from these clinical trials, some of which were not pre-specified, may not be predictive of the results of later clinical trials of REQORSA. Furthermore, safety events may be observed in later trials that alter the anticipated risk-benefit profiles of REQORSA or other product candidates.

In addition, the design of a clinical trial can determine whether its results will support approval of a product and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced. We may be unable to design and execute a clinical trial to support regulatory approval. Further, clinical trials of potential products often reveal that it is not practical or feasible to continue development efforts.

We do not know whether any clinical trials we conduct will demonstrate the consistent or adequate efficacy and safety that would be required to obtain regulatory approval and market any products. If REQORSA, GPX-002 or other current or future product candidates are found to be unsafe or lack efficacy, we will not be able to obtain regulatory approval for it and our business would be harmed. If we are unable to bring REQORSA, GPX-002 or other product candidates to market, or acquire other products that are on the market or can be developed, our ability to create stockholder value will be limited.

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. 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.

Even if we obtain regulatory approval of our current and future product candidates, the products may not gain market acceptance among physicians, patients, hospitals, treatment centers, third-party payors and others in the medical community.

Ethical, social and legal concerns about gene therapy and genetic research could result in additional regulations restricting or prohibiting the products and processes we may use. Even with the requisite approvals, the commercial success of REQORSA, GPX-002 and any of our other current or future product candidates will depend in part on the medical community, patients, and third-party payors accepting gene therapy products in general, and our current and future product candidates in particular, as medically useful, cost-effective and safe. Any product that we bring to the market may not gain market acceptance by physicians, patients, hospitals, treatment centers, third-party payors and others in the medical community. If these products do not achieve an adequate level of acceptance, we may not generate significant product revenue and may not become profitable. The degree of market acceptance of these product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the clinical indications for which our current and potential product candidates are approved;
- physicians, hospitals, treatment centers and patients considering our product candidates as a safe and effective treatment;
- the potential and perceived advantages of our product candidates (or the currently approved products used in combination therapy with our product candidates) over alternative treatments;
- the prevalence and severity of any side effects;
- product labeling or product insert requirements of the FDA or other regulatory authorities;
- limitations or warnings contained in the labeling approved by the FDA;
- the timing of market introduction of our product candidates as well as competitive products and/or changes in the standard of care for the indications we are targeting with our product candidates or the currently approved products used in combination therapy with our product candidates no longer being considered standard of care;
- the cost of treatment – both in absolute terms and in relation to alternative treatments;
- the availability of coverage, reimbursement and pricing by third-party payors and government authorities and the adequacy thereof;
- the willingness of patients to pay out-of-pocket in the absence of coverage by third-party payors, including government authorities;
- the willingness, ability and availability of healthcare providers that can comply with the transportation, handling, and temperature-controlled storage requirements associated with our product candidates;
- relative convenience and ease of administration, including as compared to alternative treatments and competitive therapies; and
- the effectiveness of our sales and marketing efforts, which are subject to various limitations under applicable law.

Our efforts to educate the medical community and third-party payors about the benefits of our product candidates may require significant resources and may never be successful.

REQORSA®, GPX-002, and other current or future product candidates may have undesirable side effects that may delay or prevent marketing approval, or, if approval is received, require them to be taken off the market, require them to include safety warnings or otherwise limit their sales.

Undesirable side effects for REQORSA, GPX-002, or any of our other current or future product candidates could arise either during clinical development or, if approved, after the approved product has been marketed. A showing that REQORSA, GPX-002, or any of our other current or future product candidates cause undesirable or unacceptable side effects could interrupt, delay or halt clinical trials and result in the failure to obtain or suspension or termination of marketing approval from the FDA and other regulatory authorities, or result in marketing approval from the FDA and other regulatory authorities only with restrictive label warnings.

If REQORSA, GPX-002, or any of our other current or future product candidates receives marketing approval and we or others later identify undesirable or unacceptable side effects caused by such products:

- regulatory authorities may require the addition of labeling statements, specific warnings, a contraindication or field alerts to physicians and pharmacies;
- we may be required to change instructions regarding the way the product is administered, conduct additional clinical trials or change the labeling of the product;
- we may be subject to limitations on how we may promote the product;
- sales of the product may decrease significantly;
- regulatory authorities may require us to take our approved product off the market;
- we may be subject to litigation or product liability claims; and
- our reputation may suffer.

Any of these events could prevent us or our potential future collaborators from achieving or maintaining market acceptance of our products or could substantially increase commercialization costs and expenses, which in turn could delay or prevent us from generating revenues from the sale of our products.

If a product liability claim is successfully brought against us for uninsured liabilities, or such claim exceeds our insurance coverage, we could be forced to pay substantial damage awards that could materially harm our business.

The use of any of our existing or future product candidates in clinical trials and the sale of any approved pharmaceutical products may expose us to significant product liability claims. We currently carry product liability insurance relating to our clinical trials only. Such insurance coverage may not protect us against any or all of the product liability claims that may be brought against us in the future. We may not be able to acquire or maintain adequate product liability insurance coverage at a commercially reasonable cost or in sufficient amounts or scope to protect us against potential losses. In the event a product liability claim is brought against us, we may be required to pay legal and other expenses to defend the claim, as well as uncovered damage awards resulting from a claim brought successfully against us. In the event our product candidate is approved for sale by the FDA or other regulatory agency and commercialized, we may need to substantially increase the amount of our product liability coverage. Defending any product liability claim or claims could require us to expend significant financial and managerial resources, which could have an adverse effect on our business.

Security breaches and other disruptions could compromise our information and expose us to liability, which would cause our business and reputation to suffer.

In the ordinary course of our business, we collect and store sensitive data, including intellectual property, our proprietary business information and that of our suppliers and business partners, as well as personally identifiable information of clinical trial participants and employees. Similarly, our CROs, contractors and consultants possess certain of our sensitive data. The secure maintenance of this information is critical to our operations and business strategy.

Despite the implementation of security measures, our internal computer systems and those of our CROs, CMOs, and other contractors and consultants are vulnerable to damage from cyberattacks, malicious intrusion, computer viruses, unauthorized access, loss of data privacy, natural disasters, terrorism, war and telecommunication, electrical failures or other significant disruption. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our drug development programs and commercialization efforts. For example, the loss of clinical study data from completed or ongoing clinical studies for any of our drug candidates could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of or damage to our data or applications or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development or commercialization of our drug candidates could be delayed.

While we have not experienced any such event to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our independent drug development programs. For example, the loss of clinical trial data from ongoing or future clinical trials for any of our product candidates could result in delays in regulatory approval efforts and significantly increase costs to recover or reproduce the data. Our information security systems are also subject to laws and regulations requiring that we take measures to protect the privacy and security of certain information we gather and use in our business. For example, HIPAA and its implementing regulations impose, among other requirements, certain regulatory and contractual requirements regarding the privacy and security of personal health information. In addition to HIPAA, numerous other federal, state, and international laws, including, without limitation, state security breach notification laws, state health information privacy laws and federal and state consumer protection laws, govern the collection, use, disclosure and storage of personal information. To the extent that any disruption or security breach were to result in a loss of or damage to data or applications, or inappropriate disclosure of confidential or proprietary information or personal health information, we could incur substantial liability, our reputation would be damaged, and the further development of our product candidates could be delayed.

We face risks related to health epidemics and outbreaks or other widespread health crises which could significantly disrupt our preclinical studies and clinical trials. Any future disease outbreak, epidemic or pandemic, could disrupt our clinical trials and supply chain and materially adversely affect our business and operations.

Disease outbreaks, epidemics and pandemics in regions where we have concentrations of clinical trial sites and other business operations, could adversely affect our business, including by causing significant disruptions in our operations and/or in the operations of manufacturers and CROs upon whom we rely. Disease outbreaks, epidemics and pandemics may have negative impacts on our ability to initiate new clinical trial sites, enroll new patients and maintain existing patients who are participating in clinical trials, which may result in increased clinical trial costs, longer timelines and delays in our ability to obtain regulatory approvals of our product candidates, if at all. For example, patient enrollment and recruitment could be delayed due to local clinical trial site protocols designed to protect staff and patients from certain outbreaks, which could delay the expected timelines for data readouts of our preclinical studies and clinical trials. Additionally, general supply chain issues may be exacerbated during disease outbreaks, epidemics or pandemics and may also impact the ability of our clinical trial sites to obtain basic medical supplies used in our trials in a timely fashion, if at all. Moreover, the extent to which disease outbreaks, epidemics and pandemics may impact our business, results of operations and financial position will depend on future developments, which are highly uncertain and cannot be predicted with confidence. New health epidemics or pandemics may emerge that result in similar or more severe disruptions to our business. A future disease outbreak, epidemic or pandemic adversely affects our business, financial condition, results of operations and growth prospects.

The impacts of a potential new epidemic or pandemic could pose the risk that we or our employees, suppliers, customers and others may be restricted or prevented from conducting business activities for indefinite or intermittent periods of time, including as a result of employee health and safety concerns, shutdowns, shelter in place orders, travel restrictions and other actions and restrictions that may be prudent or required by governmental authorities. This could disrupt our ability to operate our business, including producing drug product and administering our preclinical and clinical studies. In addition, fluctuations in demand and other implications associated with such widespread health crisis could result in certain supply chain constraints and challenges in the broader markets and economy generally, which could impact our business and supply sources, including our CDMOs.

We face competition from other biotechnology and pharmaceutical companies, particularly those that are gene therapy companies, and our operating results will suffer if we fail to compete effectively.

The biotechnology and pharmaceutical industries are intensely competitive and subject to rapid and significant technological change. This is particularly so in the fast-growing gene therapy space. We face competition from domestic and international competitors including major multinational pharmaceutical and biotechnology companies, specialty pharmaceutical and generic drug companies, academic institutions, government agencies and other public and private research institutions. Many of our competitors have greater financial and other resources, such as larger research and development staff and more experienced marketing and manufacturing organizations than we do. Large pharmaceutical companies, in particular, have extensive experience in clinical testing, obtaining regulatory approvals, recruiting patients and manufacturing pharmaceutical products. These companies also have significantly greater research, sales and marketing capabilities and collaborative arrangements in our target markets with leading companies and research institutions. Established pharmaceutical companies may also invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make the product candidates that we develop obsolete. As a result of these factors, our competitors may succeed in obtaining patent protection and/or FDA or other regulatory approval or in discovering, developing and commercializing drugs for the indications that we are targeting before we do or may develop drugs that are deemed to be more effective or gain greater market acceptance than ours. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies.

If our competitors market products that are more effective, safer or less expensive than our future products, or if the current standard of care to which we are comparing our future products changes, or if the drug that we are combining our future products with is no longer considered to be standard of care, or if our competitors' product candidates reach the market sooner than our future products, if any, we may not achieve commercial success. In addition, because of our limited resources, it may be difficult for us to stay abreast of the rapid changes in all technologies that are or may become competitive with ours. If we fail to stay at the forefront of technological change, we may be unable to compete effectively. Technological advances or products developed by our competitors may render our technologies or product candidates obsolete, less competitive or not economical.

Risks Related to Regulatory Approval and Marketing of Our Current and Future Product Candidates and Other Legal Compliance Matters

We cannot provide assurance that REQORSA, GPX-002, or any of our other current or future product candidates will receive regulatory approval, and without regulatory approval we will not be able to market them.

Our business currently depends largely on the successful development and commercialization of REQORSA, GPX-002, and our other current product candidates. Our ability to generate revenue related to product sales will depend on the successful development and regulatory approval of REQORSA for the treatment of cancer and/or GPX-002 for diabetes. Even if we complete the necessary clinical studies, we cannot predict when or if we will obtain regulatory approval to commercialize a product candidate. Further, even if we obtain regulatory approval, it may only apply to a narrower indication than we expect and our products will remain subject to regulatory scrutiny.

We currently have no products approved for sale and we cannot guarantee that we will ever have marketable products. The development of a product candidate and issues relating to its approval and marketing are subject to extensive regulation by the FDA in the United States and regulatory authorities in other countries, with regulations differing from country to country. We are not permitted to market our product candidates in the United States until we receive approval of a BLA from the FDA. We have not submitted any marketing applications for any of our current and potential product candidates.

BLAs must include extensive preclinical and clinical data and supporting information to establish the product candidate's safety and effectiveness for each desired indication. BLAs must also include significant information regarding the chemistry, manufacturing and controls for the product. Obtaining approval of a BLA is a lengthy, expensive and uncertain process, and we may not be successful in obtaining approval. The FDA review processes can take years to complete, and approval is never guaranteed. If we submit a BLA to the FDA, the FDA must decide whether to file the BLA or refuse to file it. We cannot be certain that any submissions will be filed and reviewed by the FDA. In addition, regulators in other jurisdictions have their own procedures for approval of product candidates.

The FDA or regulators in other jurisdictions could delay, limit or deny approval of a product candidate for many reasons, including because they:

- may not deem our product candidate to be safe and effective;
- determine that the product candidate does not have an acceptable benefit-risk profile;
- determine in the case of a BLA seeking accelerated approval that the BLA does not provide evidence that the product candidate represents a meaningful advantage over available therapies;
- determine that the results on our primary endpoints are not clinically meaningful;
- may not agree that the data collected from preclinical studies and clinical trials are acceptable or sufficient to support the approval of a BLA or other submission or to obtain regulatory approval, and may impose requirements for additional preclinical studies or clinical trials;
- may determine that adverse events experienced by participants in our clinical trials represent an unacceptable level of risk;
- may determine that population studied in the clinical trial may not be sufficiently broad or representative to assure safety in the full population for which we seek approval;
- may disagree regarding the formulation or the specifications of our product candidates;
- may not approve the manufacturing processes associated with our product candidate or may determine that a manufacturing facility does not have an acceptable compliance status; or
- may change approval policies or adopt new regulations.

Even if a product is approved, the FDA may limit the indications for which the product may be marketed, require extensive warnings on the product labeling or require expensive and time-consuming clinical trials or reporting as conditions of approval. Regulatory authorities in countries outside of the United States also have requirements for approval of drug candidates with which we must comply prior to marketing in those countries. Obtaining regulatory approval for marketing of a product candidate in one country does not ensure that we will be able to obtain regulatory approval in any other country. Furthermore, regulatory approval for any of our future product candidates may be withdrawn after approval.

If we are unable to obtain approval from the FDA or other regulatory agencies for REQORSA, GPX-002, or our other current or future product candidates, or if, subsequent to approval, we are unable to successfully commercialize REQORSA, GPX-002, or our other current or future product candidates, we will not be able to generate sufficient revenue to become profitable or to continue our operations.

In addition, the clinical trial requirements of the FDA, the EMA, and other regulatory agencies and the criteria these regulators use to determine the safety and efficacy of a product candidate vary substantially according to the type, complexity, novelty and intended use and market of the potential products. The regulatory approval process for novel product candidates such as ours can be more expensive and take longer than for other, better known or extensively studied pharmaceutical or other product candidates.

Regulatory requirements governing gene therapy products have changed frequently and may continue to change in the future. Additionally, before a clinical trial can begin, an independent Institutional Review Board and an Institutional Biosafety Committee have to review the proposed clinical trial to assess the safety of the study. In addition, adverse developments in clinical trials of gene therapy products conducted by others may cause the FDA or other regulatory bodies to change the requirements for performing studies or for obtaining approval of any of our current and potential product candidates. The regulatory changes discussed herein as well as other existing and future regulatory developments may cause unexpected delays and challenges for companies seeking approval of gene therapy products, like REQORSA, GPX-002, and our other current or future product candidates.

These regulatory review committees and advisory groups, and the new guidelines they promulgate, may lengthen the regulatory review process, require us to perform additional studies, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of our current and potential product candidates or lead to significant post-approval limitations or restrictions. As we advance our current and potential product candidates, we will be required to consult with these regulatory and advisory groups and comply with applicable guidelines. Any delay or failure to obtain, or unexpected costs in obtaining, the regulatory approval necessary to bring a potential product to market could decrease our ability to generate sufficient revenue to maintain our business.

Even if we obtain regulatory approval for our product candidates, 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 the specific obligations imposed as a condition for marketing authorization by equivalent authorities in a foreign jurisdiction, particularly by the European Commission, 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 BLA is obligated to monitor and report adverse events and any failure of a product to meet the specifications in the BLA. The holder of an approved 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 ("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 the EU, any future advertising and promotion of our products will be subject to EU laws governing promotion of medicinal products, interactions with physicians, misleading and comparative advertising and unfair commercial practices. In addition, other legislation adopted by individual EU Member States may apply to the advertising and promotion of medicinal products. These laws may limit or restrict the advertising and promotion of our products to the general public and may impose limitations on our promotional activities with health care professionals. These laws require that promotional materials and advertising for medicinal products are consistent with the product's Summary of Product Characteristics ("SmPC") as approved by the competent authorities. The SmPC is the document that provides information to physicians concerning the safe and effective use of the medicinal product. It forms an intrinsic and integral part of the marketing authorization granted for the medicinal product. Promotion of a medicinal product that does not comport with the SmPC is considered to constitute off-label promotion, which is prohibited in the EU. The applicable laws at EU level and in the individual EU Member States also prohibit the direct-to-consumer advertising of prescription-only medicinal products. Violations of the rules governing the promotion of medicinal products in the EU could be penalized by administrative measures, fines and imprisonment.

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 FDA and other regulatory authorities for compliance with cGMP, requirements and adherence to commitments made in the 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 disagree with the promotion, marketing or labeling of that 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 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 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.

If the FDA does not find the manufacturing facilities of our current or future contract manufacturers acceptable for commercial production, we may not be able to commercialize REQORSA, GPX-002, or any of our other current or future product candidates.

We do not have the internal infrastructure or facilities to manufacture REQORSA ourselves, or earlier stage GPX-002 which is in preclinical development, or any other current or future product candidate, and intend to rely on CDMOs for clinical trial needs and commercial supply. However, our strategy could change in the future and we could choose to develop such infrastructure. We do not have agreements for all of the steps relating to the ongoing supply of REQORSA or any of our other product candidates, and we may not be able to reach agreements with these or other contract manufacturers for sufficient supplies to complete clinical development and commercialize REQORSA or any of our other product candidates, if any of them are approved. The manufacture of gene therapy products is complex, and for CDMOs with whom we have agreements, there is no guarantee that they will be able to perform as required on a timely, consistent basis under the applicable governing agreement. Additionally, the facilities used by our contract manufacturers to manufacture product candidates must be the subject of a satisfactory inspection before the FDA approves the product candidate manufactured at that facility. We are completely dependent on our third-party manufacturers for compliance with the requirements of U.S. and non-U.S. regulators for the manufacture of our finished products. If our manufacturers cannot successfully manufacture materials that conform to our specifications and the FDA's cGMP standards and other requirements of any governmental agency to whose jurisdiction, we are subject, our product candidates will not be approved or, if already approved, may be subject to recalls. Reliance on third-party manufacturers entails risks including:

- the possibility that we are unable to enter into manufacturing agreements with third parties to manufacture our product candidates on acceptable terms;
- the possibility that our contract manufacturers may breach the terms of their manufacturing agreements with us;
- the possibility that our contract manufacturers may experience failures in product production; and
- the possibility of termination or nonrenewal of any manufacturing agreement we may enter into.

Any of these factors could cause the delay of approval or commercialization of our product candidates, cause us to incur higher costs or prevent us from commercializing our product candidates successfully. Furthermore, if our product candidates are approved for commercialization and our contract manufacturers fail to deliver the required commercial quantities of finished product on a timely basis at commercially reasonable prices, we would likely be unable to meet demand for our products and could lose potential revenue. It may take several years to establish an alternative source of supply for our product candidates and to have any such new source approved by the government agencies that regulate our products.

We may be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws and other federal and state healthcare laws, and the failure to comply with such laws could result in substantial penalties. Our employees, independent contractors, consultants, principal investigators, CROs, commercial partners and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

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. 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 Anti-Kickback Statute. Enforcement agencies also continue to pursue novel theories of liability under these laws. Government agencies have 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 types of programs have resulted in significant civil and criminal settlements.

We are exposed to the risk of fraud, misconduct or other illegal activity by our employees, independent contractors, consultants, principal investigators, CROs, commercial partners and vendors. Misconduct by these parties could include intentional, reckless and/or negligent conduct that fails to: comply with the laws of the FDA and similar foreign regulatory bodies; provide true, complete and accurate information to the FDA and similar foreign regulatory bodies; comply with manufacturing standards we have established; comply with federal and state data privacy, security, fraud and abuse and other healthcare laws and regulations in the United States and similar foreign fraudulent misconduct laws; or report financial information or data accurately or to disclose unauthorized activities to us. If we obtain FDA approval for any of our product candidates and begin commercializing those products in the United States, our potential exposure under such laws would increase significantly, and our costs associated with compliance with such laws would likely also increase. These laws may impact, among other things, our current activities with principal investigators and research patients, as well as proposed and future sales, marketing and education programs and interactions with physicians and other health care providers. In particular, the promotion, sales and marketing of healthcare items and services, as well as certain 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 may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, including off-label uses of our products, structuring and commission(s), certain customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use or misrepresentation of information obtained in the course of patient recruitment for clinical trials, creating fraudulent data in our preclinical studies or clinical trials or illegal misappropriation of drug product, which could result in regulatory sanctions and cause serious harm to our reputation. Additionally, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. 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, including the imposition of fines or other sanctions. The laws that may affect our ability to operate include, but are not limited to:

- the Federal Anti-Kickback Statute, which prohibits, among other things, individuals and entities from knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- federal civil and criminal false claims laws and civil monetary penalty laws, including the civil False Claims Act, which impose criminal and civil penalties, through government, civil whistleblower or qui tam actions, on individuals and entities for, among other things, knowingly presenting, or causing to be presented, claims for payment or approval from Medicare, Medicaid, or other third-party payors that are false, fictitious or fraudulent, or knowingly making, using or causing to be made or used, a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. In addition, the government may assert that a claim including items and services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act;
- HIPAA imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud or to obtain any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private), willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false, fictitious or fraudulent statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters;

- HIPAA, as amended by HITECH and their respective implementing regulations, which impose requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses, as well as their respective business associates that perform services for them that involve the creation, use, maintenance or disclosure of, individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization;
- the federal physician payment transparency requirements, sometimes referred to as the "Physician Payments Sunshine Act," created under the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (the Affordable Care Act) and its implementing regulations, which require certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the United States Department of Health and Human Services information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members;
- the U.S. FDCA, which prohibits, among other things, the adulteration or misbranding of drugs;
- the Foreign Corrupt Practices Act and similar worldwide anti-bribery laws, which generally prohibit companies and their intermediaries from making improper payments to non-U.S. officials for the purpose of obtaining or retaining business;
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; and
- state and foreign equivalents of each of the healthcare laws described above, among others, some of which may be broader in scope and may apply regardless of the payor.

It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent inappropriate conduct may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. Efforts to ensure that our business arrangements will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental and enforcement authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and 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, including the imposition of civil, criminal and administrative penalties, damages, disgorgement, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. In addition, the approval and commercialization of any of our current and potential product candidates outside the United States will also likely subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws.

Coverage and reimbursement may be limited or unavailable in certain market segments for REQORSA, GPX-002, and our other current or future product candidates, if approved, which could make it difficult for us to sell REQORSA, GPX-002, and our other current or future product candidates profitably.

The commercial success of any current or future product candidate will depend upon the degree of market acceptance by physicians, patients, insurance companies and other third-party payors, and others in the medical community. Even if we obtain approval to commercialize our current and potential product candidates outside of the United States, a variety of risks associated with international operations could materially affect our business. Due to the novel nature of our technology, we face uncertainty related to pricing and reimbursement for our current and potential product candidates. The insurance coverage and reimbursement status of newly approved products is uncertain. Failure to obtain or maintain adequate coverage and reimbursement for new or current products could limit our ability to market those products and decrease our ability to generate revenue. If market opportunities for our current and potential product candidates are smaller than we believe they are, our revenues may be adversely affected and our business may suffer.

Successful sales of our products, if our current and potential product candidates are approved, depend on the availability of coverage and adequate reimbursement from third-party payors. In addition, because our current and potential product candidates represent new approaches to the treatment of cancer and diabetes, we cannot be sure that coverage and reimbursement will be available for, or accurately estimate the potential revenue from, our current and potential product candidates. Patients who are provided medical treatment for their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Coverage and adequate reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors are critical to new product acceptance.

Government authorities and other third-party payors, such as private health insurers and health maintenance organizations, decide which drugs and treatments they will cover and the amount of reimbursement. Coverage and reimbursement by a third-party payor may depend upon a number of factors, including, but not limited to, the third-party payor's determination that use of a product is:

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

In the United States, no uniform policy of coverage and reimbursement for products exists among third-party payors, and coverage and reimbursement for products can differ significantly from payor to payor. As a result, obtaining coverage and reimbursement approval of a product from a government or other third-party payor is a time-consuming and costly process that could require us to provide to each payor supporting scientific, clinical and cost-effectiveness data for the use of our products and to justify the level of coverage and reimbursement relative to other therapies, with no assurance that coverage and adequate reimbursement will be obtained. Third party payors may also have difficulty in determining the appropriate coverage of REQORSA and our other current and future product candidates that are combination products, if approved, due to the fact that they are combination products that include another drug. To the extent there are any delays in determining such coverage or inadequate coverage and reimbursement for all aspects of our combination therapies, it would adversely affect the market acceptance, demand and use of our current and potential product candidates. Any denial in coverage or reduction in reimbursement from Medicare or other government programs may result in a similar denial or reduction in payments from private payors, which may adversely affect our future profitability.

We intend to seek approval to market our product candidates in both the United States and in selected foreign jurisdictions. If we obtain approval in one or more foreign jurisdictions for our product candidates, we will be subject to rules and regulations in those jurisdictions. In some foreign countries, particularly those in the European Union, the pricing of biologics is subject to governmental control and other market regulations which could put pressure on the pricing and usage of our current and potential product candidates. In these countries, pricing negotiations with governmental authorities can take considerable time after obtaining marketing approval of a product candidate. In addition, market acceptance and sales of our current and potential product candidates will depend significantly on the availability of coverage and adequate reimbursement from third-party payors for our current and potential product candidates and may be affected by existing and future health care reform measures.

Concerns about gene therapy, genetic testing, and genetic research could result in new and/or additional government regulations and requirements that restrict or prohibit the processes we use or delay or prevent the regulatory approval of our current and potential product candidates.

Ethical, social, and legal concerns about gene therapy, genetic testing, and genetic research could result in additional regulations restricting or prohibiting the processes we may use. Federal and state agencies, congressional committees and foreign governments have expressed interest in further regulating biotechnology. More restrictive regulations or claims that our products are unsafe or pose a hazard could prevent us from commercializing any products. New government requirements may be established that could delay or prevent regulatory approval of our current and potential product candidates. It is impossible to predict whether legislative changes will be enacted, regulations, policies, or guidance changed, or interpretations by agencies or courts changed, or what the impact of such changes, if any, may be.

Healthcare legislative reform measures may have a material adverse effect on our business and results of operations.

Third-party payors, whether domestic or foreign, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. In both the United States and certain foreign jurisdictions, there have been a number of legislative and regulatory changes to the health care system that could affect our ability to sell our products profitably. In particular the Affordable Care Act and its implementing regulations, among other things, subjected biological products to potential competition by lower-cost biosimilars, revised the methodology by which rebates owed by manufacturers to the state and federal government for covered outpatient drugs and certain biologics, including our current and potential product candidates, under the Medicaid Drug Rebate Program are calculated, increased the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program, extended the Medicaid Drug Rebate program to utilization of prescriptions of individuals enrolled in Medicaid managed care organizations, subjected manufacturers to new annual fees and taxes for certain branded prescription drugs, and provided incentives to programs that increase the federal government's comparative effectiveness research.

More recently, other legislative changes that affect the pharmaceutical industry have been proposed and adopted in the United States since the Affordable Care Act was enacted. For example, the Inflation Reduction Act of 2022 included, among other things, a provision that authorizes CMS to negotiate a "maximum fair price" for a limited number of high-cost, single-source drugs every year, and another provision that requires drug companies to pay rebates to Medicare if prices rise faster than inflation. In addition, various states have adopted or are considering adopting laws that require pharmaceutical companies to provide notice prior to raising prices and to justify price increases. We expect that additional healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, and in turn could significantly reduce the projected value of certain development projects and reduce our profitability.

There have been, and likely will continue to be, legislative, executive and regulatory proposals at the foreign, federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. We cannot predict the initiatives that may be adopted in the future. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare and/or impose price controls may adversely affect:

- the demand for our current and potential product candidates, if we obtain regulatory approval;
- our ability to set a price that we believe is fair for our products;
- our ability to generate revenue and achieve or maintain profitability;
- the level of taxes that we are required to pay; and
- the availability of capital.

We are subject to a variety of risks associated with international operations which could materially adversely affect our business.

We anticipate that we will be subject to additional risks in commercializing our product candidates outside the United States, including the following, any one or combination of which could have a material adverse effect on our business:

- different regulatory requirements for approval of product candidates in foreign countries;
- reduced protection for intellectual property rights;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- compliance with international data privacy laws, including GDPR;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geopolitical actions, including war and terrorism or natural disasters including earthquakes, typhoons, floods, fires and medical epidemics.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.

We may become subject to federal, state, local, and foreign laws and regulations governing the use, manufacture, storage, handling and disposal of hazardous materials and certain waste products, including numerous environmental, health and safety laws and regulations, such as those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations may in the future involve the use of hazardous materials, including chemicals and biological materials. Our operations may also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties. In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations may also result in substantial fines, penalties or other sanctions.

Risks Related to Our Dependence on Third Parties

We may not be successful in establishing and maintaining development and commercialization collaborations, which could adversely affect our ability to develop our current and future product candidates and our financial condition and operating results could be adversely affected.

Because developing pharmaceutical products, conducting preclinical studies and clinical trials, obtaining regulatory approval, establishing manufacturing capabilities and marketing approved products are expensive, we have and may continue to enter into collaborations with companies that have the required expertise. Additionally, if any of our product candidates receive marketing approval, we may enter into sales and marketing arrangements with third parties. If we are unable to enter into arrangements on acceptable terms, or at all, we may be unable to effectively market and sell our products in our target markets. We expect to face competition in engaging collaborators. We may not be successful in our efforts to establish and implement collaborations or other alternative arrangements for the development of our current and potential product candidates.

When we collaborate with a third party for development and commercialization of a product candidate, we can expect to relinquish some or all of the control over the timing and future success of that product candidate to such third party.

One or more of our collaboration partners may not devote sufficient resources to the development and commercialization of our product candidates or may otherwise fail in these efforts. The terms of any collaboration or other arrangement that we establish may contain provisions that are not favorable to us. In addition, any collaboration that we enter into may not be successful in the development and commercialization of our product candidates. In some cases, we may be responsible for continuing preclinical and initial clinical development of a product candidate or research program under a collaboration arrangement, and the payment we receive from our collaboration partner may be insufficient to cover the cost of such development. If we are unable to reach agreements with suitable collaborators for our product candidates, we may face increased costs, we may be forced to limit the number of our product candidates we can commercially develop or the territories in which we commercialize them. As a result, we may be unable to commercialize products or programs if we are unable to engage a suitable collaborator, which may have a material adverse effect on our operating results and financial condition.

We rely, in part, and expect to continue to rely, in part, on third parties to conduct, supervise and monitor our clinical trials, and if these third parties perform in an unsatisfactory manner, it may harm our business.

We rely in part on CROs and clinical trial sites to ensure our preclinical studies and our clinical trials are conducted properly and on time. While we have or will have agreements governing their activities, we may have limited influence over their actual performance because we control only certain aspects of our CROs' activities. Nevertheless, we are responsible for ensuring that each of our preclinical studies and clinical trials is conducted in accordance with the applicable protocol and legal, regulatory and scientific standards, and our reliance on the CROs does not relieve us of our regulatory responsibilities. These CROs may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other drug development activities that could harm our competitive position.

We and our CROs are required to comply with good laboratory practices ("GLPs") for the completion of preclinical laboratory tests and animal studies and good clinical practices ("GCPs") for conducting, recording and reporting the results of clinical trials to assure that the data and reported results are credible and accurate and that the rights, integrity and confidentiality of clinical trial participants are protected. The FDA enforces these GLPs and GCPs through periodic inspections of study sponsors, principal investigators and clinical trial sites. If we or our CROs fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable, and the FDA may require us to perform additional clinical trials before approving any marketing applications. In addition, our ongoing and future clinical trials will require a sufficient number of test subjects to evaluate the safety and effectiveness of our current and potential product candidates. Accordingly, if our CROs fail to comply with applicable regulations or fail to recruit a sufficient number of patients, we may be required to repeat such clinical trials, which would delay the regulatory approval process.

If our CROs do not successfully carry out their contractual duties or obligations, fail to meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to their failure to adhere to our clinical protocols or regulatory requirements, or for any other reasons, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. As a result, our financial results and the commercial prospects may be harmed, our costs could increase and our ability to generate revenues could be limited or delayed.

Changes in the U.S. political and regulatory environment could affect availability of government funding that we or our third party collaborators may rely on, which could negatively impact the development of our product candidates.

We and our current and future third party collaborators may rely on government programs or agencies, such as the NIH, as a source of grant funding for scientific research relevant to our product candidates. Funding from government agencies such as the NIH can fluctuate and is subject to the political process, which is often unpredictable. For example, on February 7, 2025, the NIH issued Notice Number NOT-OD-25-068, a guidance document pronouncing that funding in NIH grants to cover certain indirect costs would be capped at 15% for existing and future grant recipients, a rate that is substantially lower than the existing rates. As of February 2026, it remains uncertain how indirect costs will be handled in NIH grants. Reductions in NIH grants to us and our third party collaborators may adversely impact our ability to develop our existing product candidates and our ability to identify new product candidates.

We rely, and expect to continue to rely, on third parties to distribute, manufacture and perform release testing for our current and future product candidates and other key materials and if such third parties do not carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approvals for our product candidates.

We rely, and expect to continue to rely on third-party CDMOs to produce REQORSA and expect to do so with GPX-002 and other current and future product candidates and other key materials and on third-party contract testing organizations, or CTOs, for the establishment and performance of validated product release assays. Additionally, any CDMO may not have specific experience producing our product candidates at commercial levels and may not achieve the necessary regulatory approvals or produce our products at the quality, quantities, locations and timing needed to support commercialization. We do not have full control of these CDMOs, and they may prioritize other customers or be unable to provide us with enough manufacturing capacity to meet our objectives. We may change our manufacturing process, and there can be no guarantee that the regulatory authorities will approve any new process in a timely manner, or ever. Also, as a consequence of the manufacturing change, there may be a requirement to conduct additional preclinical safety or efficacy studies, develop new manufacturing and release assays and/or repeat all or part of the ascending dose safety study in animals or humans. Regulatory requirements ultimately imposed could adversely affect our ability to test, manufacture or market products.

Historically, part of our manufacturing process was conducted in manufacturing facilities at MD Anderson. We have completed the technology transfer from MD Anderson to experienced commercial contract development and manufacturing organizations and have scaled-up clinical production of REQORSA appropriate for our Acclaim-1 and Acclaim-3 clinical trials. For our diabetes program, we have also completed the technology transfer from our academic collaborators at the University of Pittsburgh to an integrated network of CDMOs and other vendors. As we advance the development of the diabetes program, we continue the work to optimize the manufacture of the product candidate and to source high quality and integrated vendors capable of producing it in accordance with GMP. No assurance can be given that such contract manufacturers will be able to, and will receive all approvals to, produce product sufficient for all of our preclinical and clinical trial needs moving forward or for commercialization. Additionally, our contract manufacturers may get acquired or change ownership structure, enter into new lines of business or depart existing lines of business, or go out of business altogether; all of which could require us to find new contract manufacturers and adversely affect our business. In accordance with cGMPs, changing manufacturers may require the re-validation of manufacturing processes and procedures, and may require further preclinical studies or clinical trials to show comparability between the materials produced by different manufacturers. Changing our contract manufacturers may be difficult and could be costly if we do make such a change, which could result in our inability to manufacture our product candidates and a delay in the development of our product candidates and their commercial sale, should they be approved. Further, in order to maintain our development timelines in the event of a change in a third-party contract manufacturer, we may incur higher costs to manufacture our product candidates. There can be no guarantee that the regulatory authorities will approve any new process in a timely manner or ever. Regulatory requirements ultimately imposed could adversely affect our ability to test, manufacture or market products.

In connection with our manufacturing activities, we may encounter technical or scientific issues related to manufacturing or development that we may be unable to resolve in a timely manner or with available funds. Further, we have not fully completed the characterization and validation activities necessary for commercial and regulatory approvals. If our manufacturing and testing partners do not enable such regulatory approvals, our commercialization efforts may be harmed. If such third-party manufacturers are unable to produce REQORSA, GPX-002, or other product candidates in the necessary quantities, or in compliance with cGMP or in compliance with pertinent regulatory requirements, and within our planned time frame and cost parameters, the development and sales of our products, if approved, would be materially harmed. The manufacturing processes used by our contract manufacturers to manufacture product candidates must be approved by the FDA as part of our BLA package and the facilities used by our contract manufacturers must maintain a compliance status acceptable to the FDA pursuant to inspections that will be conducted after we submit our BLA to the FDA. Although we provide specifications, we do not control the manufacturing process of, and are completely dependent on, our contract

manufacturing partners for compliance with cGMPs for the manufacture of our product candidates. If our CDMOs cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or other regulatory agencies, we will not be able to secure and/or maintain regulatory approval covering their manufacturing facilities. In addition, we have limited control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly affect our ability to develop, obtain regulatory approval for or market our future product candidates, if approved. In addition, any failure to achieve and maintain compliance with these laws, regulations and standards could subject us to the risk that we may have to suspend the manufacturing of our current and future product candidates or that obtained approvals could be revoked, which would adversely affect our business and reputation.

In addition, any significant disruption in our supplier relationships could harm our business. We source key materials, devices and equipment from third parties, either directly through agreements with suppliers or indirectly through our manufacturers who have agreements with suppliers. There is a small number of suppliers for certain key materials and components that are used to manufacture our current and future product candidates. Such suppliers may not sell these key materials to our manufacturers at the times or quantities we need them or on commercially reasonable terms. We may not have any control over the process or timing of the acquisition of these key materials by our manufacturers.

We also expect to rely on other third parties to store and distribute our products for our clinical trials. Any performance failure on the part of these third parties could delay clinical development or marketing approval of our current and future product candidates or commercialization of our products, if approved, producing additional losses and depriving us of potential product revenue.

We have completed and may in the future complete related party transactions that were not and may not be conducted on an arm's length basis.

If we are successful in commercializing REQORSA, our lead drug candidate, we will owe IRI a 1% royalty of our product sales. REQORSA is based upon patents and related technology covered by the 1994 MD Anderson License Agreement, under which we have rights to patents covering use of various genes, including the TUSC2 gene, for treatment of cancer, as well as know-how and related intellectual property. In 2007, the 1994 MD Anderson License Agreement was sublicensed by Introgen to IRI and in 2009 this sublicense was assigned by IRI to us, and we granted back to IRI a nonexclusive, royalty-free license to use and practice the licensed technology for non-commercial research purposes. As consideration for this assignment, we agreed to assume all of IRI's obligations to MD Anderson under the 1994 MD Anderson License Agreement, including ongoing patent-related expenses and royalty obligations. IRI also agreed in 2011, pursuant to the 2011 IRI Collaboration Agreement, to provide additional technology licensing opportunities and services to us in return for monthly payments and our obligation to pay to IRI a royalty of 1% on sales of products licensed to us under the 1994 MD Anderson License Agreement. We also granted a non-exclusive, royalty-free sublicense to IRI in 2011 for non-commercial research purposes. IRI's obligations to provide additional technology licensing opportunities and services to us, and our obligation to make monthly payments to IRI, were terminated in 2012; however, our obligation to pay the 1% royalty to IRI upon sales of products licensed to us under the 1994 MD Anderson License Agreement is ongoing. This royalty obligation continues for 21 years after the later of the termination of the 1994 MD Anderson License Agreement and the termination of the sublicense assigned by IRI to us. IRI was controlled by Rodney Varner, our former President, Chief Executive Officer and Chairman of our Board of Directors, and IRI is currently controlled by trusts for the benefit of Mr. Varner's descendants.

Disruptions in the global economy and supply chains may have a material adverse effect on our business, financial condition and results of operations.

Disruptions to the global economy have previously impeded, and may continue to impede global supply chains, resulting in longer lead times and also increased critical component costs and freight expenses. We have previously experienced this impact most notably in the past in our manufacturing operations due to the delay in our ability to acquire raw materials for our drug product, although we are no longer experiencing these delays. Future delays have the potential to impact the timing of the conduct of our clinical trials. We have taken steps to minimize the impact of these increased costs by working closely with our suppliers and locating redundant or comparable sources. Despite the actions we have undertaken to minimize the impacts from disruptions to the global economy, there can be no assurances that unforeseen future disruptions to the global supply chain, including the threat and risk of recently enacted and potential new or changes to cross-border tariffs, the potential adoption and expansion of trade restrictions or the occurrence or intensification of trade wars and inflationary pressures, will not have a material adverse effect on our business, financial condition and results of operations.

Risks Related to Our Intellectual Property

If we fail to comply with obligations pursuant to our license agreements, we could lose intellectual property and other rights that are important to our business; if we fail to obtain licenses to advance our research and development that may be required we may be unable to develop the affected product exclusively, on acceptable terms or at all.

Pursuant to the 1994 MD Anderson License Agreement and subsequent Amendments thereto, as well as the 2020 MD Anderson License Agreement and subsequent Amendments thereto, we hold worldwide, exclusive license rights to certain inventions covering the therapeutic use of TUSC2 and other genes and polypeptides that have been shown to have cancer fighting properties, as well as a number of related technologies. In addition, pursuant to the New UP License Agreement, UP granted us a worldwide, exclusive license to certain licensed technology, and a worldwide, non-exclusive license to use certain related know-how, all related to diabetes gene therapy. We also have entered into license agreements with other universities and third parties for various technologies which are currently in early research and development within our discovery program, including but not limited to the University of Michigan, New York University and the University of Texas Health Sciences Center at Houston. In addition, we expect to enter into additional license agreements in the future. Our existing and future license agreements may impose various payment and other obligations on us. If we fail to comply with our obligations under these agreements, our licensors may have the right to terminate our licenses, in which event we would not be able to market products covered by the patents of such licenses.

Moreover, in the event we need to obtain licenses from third parties to advance our research and development or allow commercialization of our product candidates, including additional technology that may be required or advisable to advance REQORSA or GPX-002, we may fail to obtain any of such licenses at a reasonable cost or on reasonable terms, if at all. In that event, we may be required to expend significant time and resources to develop or license replacement technology. If we are unable to develop or license replacement technology, we may be unable to develop or commercialize the affected product candidates, which could harm our business significantly. We cannot provide any assurances that third-party patents do not exist which might be enforced against our current product candidates or future products, resulting in either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties and/or other forms of compensation to third parties. Specifically, mice and NHP studies for which we have disclosed data relating to our diabetes program includes a technology to which we do not have exclusive rights, though we expect, but are not guaranteed, that we will have exclusive rights to the final product(s) developed under this program.

In certain cases, patent prosecution of our licensed technology may be controlled solely by the licensor. If our licensors fail to obtain and maintain patent or other protection for the proprietary intellectual property we license from them, we could lose our ability to capitalize on the intellectual property or our exclusivity with respect to those rights may be compromised, and our competitors could market competing products using the subject technology. Licensing intellectual property is of critical importance to our business and involves complex legal, business and scientific issues and is complicated by the rapid pace of scientific discovery in our industry. Disputes may arise regarding intellectual property subject to a licensing agreement, including, but not limited to:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which our technology and processes infringe intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patent and other rights under our collaborative development relationships;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and
- the priority of invention of patented technology.

If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates.

The intellectual property rights we have licensed from MD Anderson and the University of Pittsburgh are subject to the rights of the U.S. government.

The rights we have obtained pursuant to our license agreements with MD Anderson and UP are made subject to the rights of the U.S. government to the extent that the technology covered by the licensed intellectual property was developed under a funding agreement between such institution and the U.S. government. Additionally, to the extent there is any conflict between our license agreement and applicable laws or regulations, applicable laws and regulations will prevail. Similarly, to the extent there is any conflict between our license agreement with one of these institutions and the institution's funding agreement with the U.S. government, the terms of the funding agreement will prevail. Some, and possibly all, of our licensed intellectual property rights have been developed in the course of research funded by the U.S. government. As a result, the U.S. government may have certain rights to intellectual property embodied in our current or future products pursuant to the Bayh-Dole Act of 1980. Government rights in certain inventions developed under a government-funded program include a non-exclusive, non-transferable, irrevocable worldwide license to use inventions for any governmental purpose. In addition, the U.S. government has the right to require us, or an assignee or sublicensee to such inventions, to grant licenses to any of these inventions to a third party if the U.S. government determines that adequate steps have not been taken to commercialize the invention, that government action is necessary to meet public health or safety needs, that government action is necessary to meet requirements for public use under federal regulations, or the right to use or sell such inventions is exclusively licensed to an entity within the U.S. and substantially manufactured outside the U.S. without the U.S. government's prior approval. Additionally, we may be restricted from granting exclusive licenses for the right to use or sell our inventions created pursuant to such agreements unless the licensee agrees to additional restrictions (e.g., manufacturing substantially all of the invention in the U.S.). The U.S. government also has the right to take title to these inventions if our licensors failed to disclose the invention to the government in a timely manner and/or failed to file an application to register the intellectual property within specified time limits. In addition, the U.S. government may acquire title in any country in which a patent application is not filed within specified time limits. Furthermore, certain inventions are subject to transfer restrictions during the term of these agreements and for a period thereafter, including sales of products or components, transfers to foreign subsidiaries for the purpose of the relevant agreements, and transfers to certain foreign third parties. If any of our intellectual property becomes subject to any of the rights or remedies available to the U.S. government or third parties pursuant to the Bayh-Dole Act of 1980, this could impair the value of our intellectual property and could adversely affect our business.

If we are unable to protect our intellectual property rights or if our intellectual property rights are inadequate for our technology and product candidates, our competitive position could be harmed.

Our commercial success will depend in part on our ability and the ability of our licensors to obtain and maintain patent and other intellectual property protection in the United States and other countries with respect to our proprietary technology and products. We rely on trade secret, patent, copyright and trademark laws, and confidentiality, licensing and other agreements with employees and third parties, all of which offer only limited protection. We seek to protect our proprietary position by filing and prosecuting patent applications in the United States and abroad related to our novel technologies and products that are important to our business.

The patent positions of biotechnology and pharmaceutical companies generally are highly uncertain, involve complex legal and factual questions and have in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our patents, including those patent rights licensed to us by third parties, are highly uncertain. The steps we or our licensors have taken to protect our proprietary rights may not be adequate to preclude misappropriation of our proprietary information or infringement of our intellectual property rights, both inside and outside of the United States. Further, the examination process may require us or our licensors to narrow the claims for our pending patent applications, which may limit the scope of patent protection that may be obtained if these applications issue. The rights already granted under any of our currently issued patents or those licensed to us and those that may be granted under future issued patents may not provide us with the proprietary protection or competitive advantages we are seeking. If we or our licensors are unable to obtain and maintain patent protection for our technology and products, or if the scope of the patent protection obtained is not sufficient, our competitors could develop and commercialize technology and products similar or superior to ours, and our ability to successfully commercialize our technology and products may be adversely affected. It is also possible that we or our licensors will fail to identify patentable aspects of inventions made in the course of our development and commercialization. It is also possible that as research and development progresses, the direction of our intellectual property strategy and patent portfolio will change, resulting in strategic business decisions to allow certain patents or patent applications to be abandoned or lapse.

With respect to patent rights, we do not know whether any of the pending patent applications relating to any of our current and future product candidates will result in the issuance of patents that effectively protect our technology or products, or if any of our licensors' issued patents will effectively prevent others from commercializing competitive technologies and products. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing or in some cases not at all, until they are issued as a patent. Therefore, we cannot be certain that we or our licensors were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or that we or our licensors were the first to file for patent protection of such inventions.

Our pending applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications. Because the issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, issued patents that we have licensed from third parties may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in the loss of patent protection, the narrowing of claims in such patents or the invalidity or unenforceability of such patents, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection for our technology and products. Protecting against the unauthorized use of our or our licensor's patented technology, trademarks and other intellectual property rights is expensive, difficult and may in some cases not be possible. In some cases, it may be difficult or impossible to detect third-party infringement or misappropriation of our intellectual property rights, even in relation to issued patent claims, and proving any such infringement may be even more difficult.

Third-party claims of intellectual property infringement may prevent or delay our development and commercialization efforts.

Our commercial success depends in part on our avoiding infringement of the patents and proprietary rights of third parties. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, oppositions and other post grant proceedings before the United States Patent and Trademark Office ("USPTO") and corresponding foreign patent offices. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are pursuing development candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our current and future product candidates may be subject to claims of infringement of the patent rights of third parties.

Third parties may in the future assert that we are employing their proprietary technology without authorization. There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that our product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of any of our product candidates, or any final product itself, the holders of any such patents may be able to block our ability to develop and commercialize such product candidate until such patents expire unless we obtained a license under the applicable patents, which license may not be available on acceptable terms, if at all.

Parties making claims against us may obtain injunctive or other equitable relief, which may hinder our ability to further develop and commercialize one or more of our product candidates. Defense of these claims, regardless of their merit, may involve substantial litigation expense and diversion of our management's attention. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, pay royalties, redesign our infringing products or obtain one or more licenses from third parties, which licenses may not be on acceptable terms or require substantial time and monetary expenditure.

We may not be successful in obtaining or maintaining necessary rights to product components and processes for our development pipeline through acquisitions and in-licenses.

At present, we believe that we have the necessary rights to the intellectual property, through licenses or other rights from third parties to develop our product candidates. Because our programs may involve additional product candidates that may require the use of proprietary rights held by third parties, the growth of our business may depend in part on our ability to acquire, in-license or use these proprietary rights. In addition, our product candidates may require specific formulations to work effectively and efficiently and these rights may be held by others. We may be unable to acquire or in-license any compositions, methods of use, processes or other third-party intellectual property rights from third parties on reasonable terms, if at all. The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies are also pursuing strategies to license or acquire third-party intellectual property rights that we may consider attractive. These established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities.

If we are unable to successfully obtain rights to required third-party intellectual property, our business, financial condition and prospects for growth could suffer.

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

We rely on trade secrets to protect our proprietary technologies, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. We rely in part on confidentiality agreements with our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to protect our trade secrets and other proprietary information. These agreements may not effectively prevent disclosure of confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. In addition, others may independently discover our trade secrets and proprietary information. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights, and failure to obtain or maintain trade secret protection could adversely affect our competitive business position.

Our reliance on third parties may require us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.

Because we rely on and intend to continue to rely on third parties to manufacture our current and future product candidates, and because we collaborate with various organizations and academic institutions on the advancement of our product candidates, we must, at times, share trade secrets with them. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, collaborative research agreements, consulting agreements or other similar agreements with our manufacturers, collaborators, advisors, employees and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, such as trade secrets. Despite the contractual provisions of such agreements, the need to share trade secrets and other confidential information increases the risk that such trade secrets may become known by our competitors, may be inadvertently incorporated into the technology of others, may be used inappropriately to create new inventions or may be disclosed or used in violation of such agreements.

Our academic collaborators typically have rights to publish data, provided that we are notified in advance and may delay publication for a specified time in order to secure our intellectual property rights arising from the collaboration. In other cases, publication rights are controlled exclusively by us, although in some cases we may share these rights with other parties. We may also conduct joint research and development programs that may require us to share trade secrets under the terms of research and development partnerships or similar agreements. Despite our efforts to protect our trade secrets, our competitors may discover our trade secrets through breach of these agreements, independent development or publication of information including our trade secrets in cases where we do not have proprietary or otherwise protected rights at the time of publication. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's discovery of our trade secrets or other unauthorized use or disclosure may impair our competitive position and have a material adverse effect on our business.

We may be involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time-consuming and unsuccessful.

Competitors may infringe our patents or the patents of our licensors. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent is not valid, is unenforceable and/or is not infringed, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not issuing.

Inter Partes Review ("IPR") and Post-Grant Review ("PGR") proceedings, among others, provoked by third parties or brought by us may be used to determine the validity of inventions with respect to our patents or patent applications or those of our licensors. An unfavorable outcome could invalidate licensed intellectual property or require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Our defense of IPR and/or PGR proceedings, for example, may fail and, even if successful, may result in substantial costs and distract our management and other employees. We may not be able to prevent, alone or with our licensors, misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also 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 material adverse effect on the price of our common stock.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or applications will be due to be paid to the USPTO and various governmental patent agencies outside of the United States in several stages over the lifetime of the patents and/or applications. We rely on our licensors' outside counsel, as well as our outside counsel, to pay these fees due to the various patent agencies. The USPTO and various non-U.S. governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. Although an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, our competitors might be able to enter the market which would have a material adverse effect on our business.

Issued patents covering our product candidates could be found invalid or unenforceable if challenged in court.

If we or one of our licensing partners, including MD Anderson or UP, initiate legal proceedings against a third party to enforce a patent covering one of our product candidates, the defendant could counterclaim that the patent covering our product candidate is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post grant review and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). Such proceedings could result in revocation or amendment to our patents in such a way that they no longer cover our current and potential product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our current and potential product candidates. Such a loss of patent protection would have a material adverse impact on our business.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties or that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

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

We may be subject to claims challenging the inventorship or ownership of our patents and other intellectual property.

We may be subject to claims that former employees, collaborators or other third parties have an ownership interest in our patents or other intellectual property. We may have potential ownership disputes arising, for example, from conflicting obligations of consultants, collaborators or others who are involved in developing our current and potential product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship or ownership. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

Changes in U.S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our products.

The United States has enacted and is currently implementing wide-ranging patent reform legislation. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

We have in the past and may again in the future have trademark applications in the United States and/or certain other countries, and failure to secure these registrations could adversely affect our business; additionally, we may need to enforce our trademark rights against third parties and expend significant resources to enforce such rights against infringement.

We have obtained trademark registrations in the United States for GENPREX, ONCOPREX and REQORSA, we have a pending application in the United States for the trademark CONVERGEN, and we may in the future have pending trademark applications in the United States and/or certain other countries. During trademark registration proceedings, our application may be rejected. Although we would be given an opportunity to respond to the rejection of a trademark application, we may be unable to overcome such rejection. In addition, with respect to the USPTO and comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademark, and our trademark may not survive such proceedings. Additionally, we may need to enforce our trademark rights against third parties and expend significant additional resources to enforce such rights against infringement. Moreover, any name we propose to use with our current and potential product candidates in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. The FDA typically conducts a review of proposed product names, including an evaluation of the potential for confusion with other product names. If the FDA objects to any of our proposed proprietary product names, we may be required to expend significant additional resources in an effort to identify a suitable substitute name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA.

We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting and defending patents with respect to product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Risks Related to Employee Matters and Managing Growth

We have no sales, marketing or distribution experience and we will have to invest significant resources to develop those capabilities or enter into acceptable third-party sales and marketing arrangements.

We have no sales, marketing or distribution experience. To develop sales, distribution and marketing capabilities, we will have to invest significant amounts of financial and management resources, some of which will need to be committed prior to any confirmation that our product candidates will be approved by the FDA. For product candidates for which we decide to perform sales, marketing and distribution functions ourselves or through third parties, we could face a number of additional risks, including that we or our third-party sales collaborators may not be able to build and maintain an effective marketing or sales force, and we may experience difficulty in managing the growth of our organization. If we use third parties to market and sell our products, we may have limited or no control over their sales, marketing and distribution activities on which our future revenues may depend.

We may not be able to manage our business effectively if we are unable to attract and retain key personnel and consultants.

As of March 15, 2026, we had 13 total employees, all of which were full-time. As we advance our product candidates through preclinical studies and clinical trials, we will need to increase our clinical trial management, product development, manufacturing, regulatory, and administrative headcount to manage these programs. In addition, to meet our obligations as a public company, we may need to increase our general and administrative capabilities. We may not be able to attract or retain qualified personnel and consultants due to the intense competition for qualified personnel and consultants among biotechnology, pharmaceutical and other businesses. If we are not able to attract and retain necessary personnel and consultants to accomplish our business objectives, we may experience constraints that will significantly impede the achievement of our development objectives, our ability to raise additional capital and our ability to implement our business strategy.

We are highly dependent on the development, manufacturing, regulatory, commercialization and business development expertise of our management team, key employees and consultants. Any of our executive officers or key employees or consultants may terminate their employment or engagement with us at any time. If we lose one or more of our executive officers or key employees or consultants, our ability to implement our business strategy successfully could be seriously harmed. Replacing executive officers, key employees and consultants may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to develop, gain regulatory approval of and commercialize products successfully. Competition to hire and retain employees and consultants from this limited pool is intense, and we may be unable to hire, train, retain or motivate these additional key personnel and consultants. Our failure to retain key personnel or consultants could materially harm our business.

In addition to our management team and key employees, we have scientific and clinical advisors and consultants who assist us in formulating our research, development and clinical strategies. These advisors are not our employees and may have commitments to, or consulting or advisory contracts with, other entities that may limit their availability to us and typically they will not enter into non-compete agreements with us. If a conflict of interest arises between their work for us and their work for another entity, we may lose their services. In addition, our advisors may have arrangements with other companies to assist those companies in developing products or technologies that may compete with ours.

We may use our financial and human resources to pursue a particular research program or product candidate and fail to capitalize on programs or product candidates that may be more profitable or for which there is a greater likelihood of success.

Because we have limited resources, we may forego or delay pursuit of opportunities with certain programs or product candidates or for indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on research and development programs for product candidates may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through strategic collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate, or we may allocate internal resources to a product candidate in a therapeutic area in which it would have been more advantageous to enter into a partnering arrangement.

If we engage in future acquisitions or strategic partnerships, this may increase our capital requirements, dilute our stockholders, cause us to incur debt or assume contingent liabilities, and subject us to other risks.

We may evaluate and enter into various acquisitions and strategic partnerships, including licensing or acquiring additional products, intellectual property rights, technologies, or businesses. Any potential acquisition or strategic partnership may entail numerous risks, including:

- increased operating expenses and cash requirements;
- the assumption of additional indebtedness or contingent liabilities;
- the issuance of our equity securities;
- assimilation of operations, intellectual property and products of an acquired company, including difficulties associated with integrating new personnel;
- difficulties in achieving anticipated cost savings, synergies, business opportunities, and growth prospects from any business combination;
- the diversion of our management's attention from our existing product programs and initiatives in pursuing such a strategic merger or acquisition;
- retention of key employees, the loss of key personnel, and uncertainties in our ability to maintain key business relationships;
- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing products or product candidates and marketing approvals; and
- our inability to generate revenue from acquired technology and/or products sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs.

Moreover, we may not be able to locate suitable acquisition opportunities and such inability could impair our ability to grow or obtain access to technology or products that may be important to the development of our business.

Risks Related to our Securities

The market price of our common stock may be highly volatile, and you may lose all or part of your investment.

The market price of our common stock has been volatile in the past and is likely to be volatile in the future. Our stock price could be subject to wide fluctuations in response to a variety of factors, including the following:

- inability to obtain additional funding;
- adverse results or delays in preclinical or clinical trials;
- reports of adverse events in other gene therapy products or clinical trials of such products;
- manufacturing and supply issues related to our existing or future products;
- any delay in filing an IND or BLA for our product candidates and any adverse development or perceived adverse development with respect to the FDA's review of that IND or BLA;
- failure to develop successfully and commercialize our product candidates;
- failure to maintain our existing strategic collaborations or enter into new collaborations;
- failure by us or our licensors and strategic collaboration partners to prosecute, maintain or enforce our intellectual property rights;
- changes in laws or regulations applicable to our products and product candidates;
- inability to obtain adequate product supply for our product candidates or inability to do so at acceptable prices;
- adverse regulatory decisions;
- introduction of new products, services or technologies by our competitors;
- failure to meet or exceed financial projections we may provide to the public;
- failure to meet or exceed the financial projections of the investment community;
- the perception of the pharmaceutical and biotechnology industries by the public, legislatures, regulators and the investment community;
- announcements of significant acquisitions, strategic partnerships, joint ventures, capital commitments or other material corporate transactions or events by us, our strategic collaboration partners or our competitors;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- additions or departures of key scientific or management personnel;
- significant lawsuits, including patent or stockholder litigation;
- changes in the market valuations of similar companies;
- sales of our common stock by us or our stockholders;
- trading volume of our common stock;
- material announcements or changes impacting our common stock or our capitalization, or the perception that such changes could occur; and
- general economic conditions in the United States and abroad; and other events or factors, many of which may be out of our control, including, but not limited to, pandemics, war, or other acts of God.

In addition, companies trading in the stock market in general, and The Nasdaq Capital Market in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance.

An active, liquid and orderly market for our common stock may not be sustained, and you may not be able to sell your common stock.

Our common stock trades on the Nasdaq Capital Market. We cannot assure you that an active trading market for our common stock will be sustained. The lack of an active market may impair your ability to sell the common stock at the time you wish to sell them or at a price that you consider reasonable. An inactive market may also impair our ability to raise capital by selling common stock and may impair our ability to acquire other businesses, applications or technologies using our common shares as consideration, which, in turn, could materially adversely affect our business.

We are currently listed on The Nasdaq Capital Market. If we fail to maintain compliance with the continued listing requirements of Nasdaq, our common stock may be delisted and the price of our common stock and our ability to access the capital markets could be negatively impacted.

Our common stock is currently listed for trading on Nasdaq. On February 7, 2025, we received a notice from the Listing Qualifications Staff (the "Staff") of the Nasdaq Stock Market LLC ("Nasdaq") indicating that we were not in compliance with the requirement under Nasdaq Listing Rule 5550(a)(2) to maintain a minimum bid price of $1.00 per share for continued listing on Nasdaq (the "Bid Price Requirement"). We were provided a compliance period of 180 calendar days from the date of the notice, or until August 6, 2025, to regain compliance with the Bid Price Requirement, pursuant to Nasdaq Listing Rule 5810(c)(3)(A). On August 12, 2025, we received a letter from Nasdaq indicating that, based upon our not having regained compliance with the Bid Price Requirement and our ineligibility for a second 180 calendar day compliance period, the Staff had determined to delist our securities from Nasdaq unless we timely request a hearing before the Nasdaq Hearings Panel (the "Panel"). Additionally, on August 19, 2025, we received a letter from the Nasdaq Staff indicating that we were not in compliance with the minimum stockholders' equity requirement for continued listing on the Nasdaq Capital Market, under Listing Rule 5550(b)(1) (the "Minimum Stockholders' Equity Rule"), because our stockholders' equity as reported in our Quarterly Report on Form 10-Q for the period ended June 30, 2025 was below the required minimum of $2.5 million, and because, as of August 19, 2025, we did not meet the alternative compliance standards relating to market value of listed securities or net income from continuing operations. The Staff indicated that this non-compliance with the Minimum Stockholders' Equity Rule served as an additional and separate basis for delisting our securities from Nasdaq.

In order to regain compliance with the Bid Price Requirement, effective October 21, 2025, we implemented a one-for-fifty (1:50) reverse stock split of our issued and outstanding common stock. On November 25, 2025, we were formally notified that the Panel determined that the Company had regained compliance with the Bid Price Requirement. However, the implementation of the reverse stock split could continue to negatively affect the price of our common stock. We cannot assure you that the market price of our common stock after the proposed reverse stock split will be maintained for any period of time or at any particular level. There is also the possibility that liquidity may be adversely affected by the reduced number of shares which are issued and outstanding after the reverse stock split is effected.

On January 7, 2026, we were formally notified (the "Compliance Notice") that the Panel determined that we had regained compliance with the Minimum Stockholders' Equity Rule. Pursuant to Nasdaq Listing Rule 5815(d)(4)(B), we will be subject to a mandatory panel monitor through January 7, 2027. If, within that one-year monitoring period, the Staff finds us again out of compliance with the Minimum Stockholders' Equity Rule that was the subject of the exception as previously granted by the Panel, notwithstanding Nasdaq Listing Rule 5810(c)(2), we will not be permitted to provide the Staff with a plan of compliance with respect to that deficiency and the Staff will not be permitted to grant additional time for us to regain compliance with respect to that deficiency, nor will we be afforded an applicable cure or compliance period pursuant to Nasdaq Listing Rule 5810(c)(3). Instead, the Staff will issue a Delist Determination Letter, and we will have an opportunity to request a new hearing with the initial Panel or a newly convened Hearings Panel if the initial Panel is unavailable. We will have the opportunity to present to the Hearings Panel as provided by Nasdaq Listing Rule 5815(d)(4)(C), and our securities may be at that time delisted from Nasdaq.

We must continue to satisfy and maintain compliance with Nasdaq's continued listing requirements, including, among other things, a minimum stockholders' equity of $2.5 million and a minimum closing bid price of $1.00 per share or risk delisting. In addition, Nasdaq has recently proposed a new listing rule that, if approved, would require listed companies to maintain a market value of listed securities of a minimum of $5 million, which as proposed would trigger immediate suspension and delisting in the event of failure to meet this requirement for 30 consecutive business days, bypassing typical grace periods and restricting appeal rights. If our common stock is delisted from Nasdaq, it could materially reduce the liquidity of our common stock and result in a corresponding material reduction in the price of our common stock as a result of the loss of market efficiencies associated with Nasdaq and the loss of federal preemption of state securities laws. In addition, delisting could harm our ability to raise capital through alternative financing sources on terms acceptable to us, or at all, and may result in the potential loss of confidence by investors, suppliers, contractual counterparties, and employees and fewer business development opportunities. If our common stock were delisted, it could be more difficult to buy or sell our common stock or to obtain accurate quotations, and the price of our common stock could suffer a material decline. Delisting could also impair our ability to raise capital on acceptable terms, if at all.

Unstable market and economic conditions may have serious adverse consequences on our business, financial condition and stock price.

Global credit and financial markets have experienced volatility and disruptions in past years, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates, concerns about medical epidemics, and uncertainty about economic stability. We cannot assure you that further deterioration in credit and financial markets and confidence in economic conditions will not occur. Our general business strategy may be adversely affected by any such economic downturn, volatile business environment or continued unpredictable and unstable market conditions. If the current equity and credit markets deteriorate, or do not improve, it may make any necessary debt or equity financing more difficult, more costly and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and stock price and could require us to delay or abandon clinical development plans. In addition, there is a risk that one or more of our current service providers, manufacturers and other partners may not survive difficult economic times, which could directly affect our ability to attain our operating goals on schedule and on budget.

Failure to maintain effective internal control over our financial reporting in accordance with Section 404 of the Sarbanes-Oxley Act of 2002, as amended ("Sarbanes-Oxley Act") could cause our financial reports to be inaccurate.

We are required pursuant to Section 404 of the Sarbanes-Oxley Act, or Section 404, to maintain internal control over financial reporting and to assess and report on the effectiveness of those controls. This assessment includes disclosure of any material weaknesses identified by our management in our internal control over financial reporting. Although we prepare our consolidated financial statements in accordance with accounting principles generally accepted in the United States, our internal accounting controls may not meet all standards applicable to companies with publicly traded securities. If we fail to implement any required improvements to our disclosure controls and procedures, we may be obligated to report control deficiencies, in which case we could become subject to regulatory sanction or investigation. Further, such an outcome could damage investor confidence in the accuracy and reliability of our consolidated financial statements.

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required or improved controls, or difficulties encountered in their implementation, could cause us to fail to meet our reporting obligations. We have designed, implemented and tested the internal control over financial reporting required to comply with this obligation, which was and is time consuming, costly, and complicated. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met.

Our management has concluded that our internal controls over financial reporting were, and continue to be, ineffective, and as of the year ended December 31, 2025 as a result of material weaknesses in our internal controls due to the lack of segregation of duties between accounting and other functions and the absence of sufficient depth of in-house accounting personnel with the ability to properly account for complex transactions. While management is working to remediate these material weaknesses, there is no assurance that such changes, when economically feasible and sustainable, will remediate the identified material weaknesses or that the controls will prevent or detect future material weaknesses. If we are not able to remediate the material weaknesses or maintain effective internal control over financial reporting, this could result in a material misstatement in our consolidated financial statements and a failure to meet our reporting and financial obligations, which could have a material adverse effect on our business.

We have no intention of declaring dividends in the foreseeable future.

We have never declared or paid cash dividends on our capital stock, and we do not currently anticipate declaring any dividends in the foreseeable future. We anticipate that we will retain all future earnings for the development, operation, and expansion of our business. Any future determination to declare dividends will be made at the discretion of our board of directors and will depend on, among other factors, our financial condition, operating results, capital requirements, contractual restrictions, general business conditions and other factors that our board of directors may deem relevant. Investors in our common stock should not expect to receive dividend income on their investment, and investors will be dependent on the appreciation of our common stock, if any, to earn a return on their investment.

Sales of a substantial number of shares of our common stock in the public market could cause our stock price to fall.

If our existing stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market, the market price of our common stock could decline. As of December 31, 2025, we had outstanding options to purchase an aggregate of 5,705 shares of our common stock at a weighted average exercise price of $6,081.93 per share and warrants to purchase an aggregate of 1,319,696 shares of our common stock at a weighted average exercise price of $24.40 per share. The exercise of such outstanding options and warrants will result in further dilution of your investment, even if there is no relationship between such sales and the performance of our business.

We are unable to predict the effect that sales may have on the market price of our common stock. If any shares of our common stock are sold, or if it is perceived that they will be sold, in the public market, the market price of our common stock could decline.

Future sales and issuances of our securities could result in additional dilution of the percentage ownership of our stockholders and could cause our share price to fall.

We expect that significant additional capital will be needed in the future to continue our planned operations, including research and development, increased marketing, hiring new personnel, commercializing our products, and continuing activities as an operating public company. To the extent we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution. We may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities or other equity securities in more than one transaction, investors may be materially diluted by subsequent sales. We may sell a substantial number of shares of our common stock pursuant to our existing ATM Agreement with H.C. Wainwright, pursuant to which we have the discretion to deliver placement notices to H.C. Wainwright at any time throughout the term of the ATM Agreement covering up to such number or dollar amount of shares of our common stock as registered on the prospectus supplement covering the ATM offering, as may be amended or supplemented from time to time; pursuant to such agreement, we have the discretion, subject to market demand, to vary the timing, prices, and quantity of shares sold, and there is no minimum or maximum sales price. Any sales of equity securities, whether pursuant to our existing ATM Agreement or other third-party ATM agreements in the future, or through our 2025 ELOC Facility with Lincoln Park, or otherwise, may also result in material dilution to our existing stockholders, and new investors could gain rights superior to our existing stockholders.

If securities or industry analysts do not publish research or reports about us, or if they adversely change their recommendations regarding our common stock, then our stock price and trading volume could decline.

The trading market for our common stock will be influenced by the research and reports that industry or securities analysts publish about us, our industry and our market. If no analyst elects to cover us and publish research or reports about us, the market for our common stock could be severely limited and our stock price could be adversely affected. In addition, if one or more analysts ceases coverage of us or fails to regularly publish reports on us, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline. If one or more analysts who elect to cover us issue negative reports or adversely change their recommendations regarding our common stock, our stock price could decline.

Certain provisions in our organizational documents could enable our board of directors to prevent or delay a change of control.

We are authorized to issue up to 10,000,000 shares of preferred stock, none of which are outstanding as of March 15, 2026. This preferred stock may be issued in one or more series, the terms of which may be determined at the time of issuance by our board of directors without further action by stockholders. The terms of any series of preferred stock may include voting rights (including the right to vote as a series on particular matters), preferences as to dividend, liquidation, conversion and redemption rights and sinking fund provisions. The issuance of any preferred stock could materially adversely affect the rights of the holders of our common stock, and therefore, reduce the value of our common stock. The ability of our board of directors to issue preferred stock also could have the effect of discouraging unsolicited acquisition proposals, thus adversely affecting the market price of our common stock.

In addition, our organizational documents contain provisions that may have the effect of discouraging, delaying or preventing a change of control of, or unsolicited acquisition proposals, that a stockholder might consider favorable. These include provisions:

- requiring at least 66-2/3% of the voting power of all of our then-outstanding shares of capital stock entitled to vote generally in the election of directors, voting together as a single class, for action by the stockholders to amend the Amended and Restated Bylaws, as amended;
- providing that the authorized number of directors may be changed only by resolution of the board of directors;
- providing that the directors may only be removed with cause and the affirmative vote of the holders of at least 66-2/3% of the voting power of all of our then outstanding shares of capital stock entitled to vote generally at the election of directors;
- providing that all vacancies, including newly created directorships, may, except as otherwise required by law, be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum;
- dividing our board of directors into three classes;
- requiring that any action to be taken by our stockholders must be effected at a duly called annual or special meeting of stockholders and not be taken by written consent;
- providing that stockholders seeking to present proposals before a meeting of stockholders or to nominate candidates for election as directors at a meeting of stockholders must provide notice in writing in a timely manner and also specify requirements as to the form and content of a stockholder's notice;
- that do not provide for cumulative voting rights (therefore allowing the holders of a majority of the shares of common stock entitled to vote in any election of directors to elect all of the directors standing for election, if they should so choose); and
- providing that special meetings of our stockholders may be called only by the Chairman of the board, our Chief Executive Officer or by the board of directors pursuant to a resolution adopted by a majority of the total number of authorized directors.

In addition, Delaware law makes it difficult for stockholders that recently have acquired a large interest in a corporation to cause the merger or acquisition of the corporation against the directors' wishes. Under Section 203 of the Delaware General Corporation Law, a Delaware corporation may not engage in any merger or other business combination with an interested stockholder for a period of three years following the date that the stockholder became an interested stockholder except in limited circumstances, including by approval of the corporation's board of directors.

Our Amended and Restated Certificate of Incorporation, as amended, and Amended and Restated Bylaws, as amended, contain an exclusive forum provision with respect to certain actions which may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable and discourage lawsuits against us or our current or former directors or officers and/or stockholders in such capacity.

Our Amended and Restated Certificate of Incorporation, as amended, as may be further amended from time to time, and Amended and Restated Bylaws, as amended, as may be further amended from time to time, provide that, unless we consent in writing to the selection of an alternative forum, the following actions must be brought solely and exclusively in the Court of Chancery of the State of Delaware (i) any derivative action or proceeding brought on behalf of us; (ii) any action asserting a claim of breach of a fiduciary duty owed by any director, officer or other employee of the Company to us or our stockholders; (iii) any action asserting a claim against us or any director or officer or other employee of the Company arising pursuant to any provision of the DGCL, our certificate of incorporation or our bylaws; or (iv) any action asserting a claim against us or any director or officer or other employee of the Company governed by the internal affairs doctrine. We believe that the exclusive forum provision may not apply to suits brought to enforce any liability or duty created by the Securities Act or the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction. We believe that to the extent that any such claims may be based upon federal law claims, Section 27 of the Exchange Act creates exclusive federal jurisdiction over all suits brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder. Furthermore, we believe that Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder. This choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers or other employees. Alternatively, if a court were to find the choice of forum provision contained in our Amended and Restated Certificate of Incorporation, as amended, or Amended and Restated Bylaws, as amended, to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could have a material adverse effect on our business, results of operations, and financial condition.

General Risk Factors

Obligations associated with being a public company in the United States are expensive and time-consuming, and our management will be required to devote substantial time to compliance matters.

As a publicly traded company we incur significant legal, accounting and other expenses. The obligations of being a public company in the United States require significant expenditures and places significant demands on our management and other personnel, including costs resulting from public company reporting obligations under the Securities Exchange Act of 1934, as amended ("Exchange Act") and the rules and regulations regarding corporate governance practices, including those under the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, and the listing requirements of The Nasdaq Capital Market. These rules require the establishment and maintenance of effective disclosure and financial controls and procedures, internal control over financial reporting and changes in corporate governance practices, among many other complex rules that are often difficult to implement, monitor and maintain compliance with. Further, in the event that in the future we were to no longer be eligible to qualify as a "smaller reporting company," and/or if we become subject to the requirements applicable to accelerated filers or large accelerated filers, including complying with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, our compliance burdens and expenses will further increase. In addition, and as a general matter, we expect the foregoing public company rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance. Our management and other personnel will need to devote a substantial amount of time to ensure that we comply with all of these requirements and to keep pace with new regulations, otherwise we may fall out of compliance and risk becoming subject to litigation or being delisted, among other potential consequences.

Business disruptions could seriously harm our future revenue and financial condition and increase our costs and expenses.

Our operations, and those of our CROs, contract manufacturers and other contractors, vendors and consultants, could be subject to power shortages, telecommunications failures, wildfires, water shortages, floods, earthquakes, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics and pandemics and other natural or man-made disasters or business interruptions. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. Our ability to obtain clinical supplies of our current and potential product candidates could be disrupted if the operations of our contract manufacturers are affected by a man-made or natural disaster or other business interruption.

In addition, the global macroeconomic environment could be negatively affected by, among other things, new pandemics, epidemics or other widespread health crises, instability in global economic markets, new or increased trade tariffs, imposed either by the U.S. government on foreign imports or foreign governments on U.S. exports, and trade disputes or "trade wars" with other countries, embargoes, trade restrictions, supply chain weaknesses, instability in the global credit markets, severely diminished liquidity and credit availability, interest and rate fluctuations and rising inflation, declines in consumer confidence, declines in economic growth, increases in unemployment rates, uncertainty about economic stability, instability in the geopolitical environment, the war between Russia and Ukraine and other political tensions, including in the Middle East, and foreign governmental debt concerns. In addition, future adverse developments with respect to specific financial institutions or the broader financial services industry may lead to market-wide liquidity shortages, impair the ability of market participants to access near-term working capital needs, and create additional market and economic uncertainty. There can be no assurance that any such continuing or future credit and financial market instability, liquidity shortages and a deterioration in confidence in economic conditions will not occur. Such challenges have caused, and may continue to cause, uncertainty and instability in local economies and in global financial markets, which could adversely affect our business, financial condition or results of operations. If these conditions continue to deteriorate or do not improve, it may make any necessary debt or equity financing more difficult to complete, more costly, and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance, and share price and could require us to delay or abandon development or commercialization plans.

We do not carry insurance for all categories of risk that our business may encounter. There can be no assurance that we will secure adequate insurance coverage or that any such insurance coverage will be sufficient to protect us from potential liability in the future. Any significant uninsured liability may require us to pay substantial amounts, which may adversely affect our financial position and results of operations.

We may be at risk of securities class action litigation.

We may be at risk of securities class action litigation. In the past, biotechnology and pharmaceutical companies have experienced significant stock price volatility, particularly when associated with binary events such as clinical trials and product approvals. If we face such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business and results in a decline in the market price of our common stock.

Item 1B. Unresolved Staff Comments.

None.

Item 1C. Cybersecurity.

Cybersecurity Risk Management

We, like other companies in our industry, face several cybersecurity risks in connection with our business. Our business strategy, results of operations, and financial condition have not, to date, been affected by risks from cybersecurity threats. During the reporting period, we have not experienced any material cyber incidents, nor have we experienced a series of immaterial incidents, which would require disclosure.

In the ordinary course of our business, we use, store and process data including data of our employees, partners, collaborators, and vendors. To effectively prevent, detect, and respond to cybersecurity threats, we maintain a cyber risk management program, which is comprised of a wide array of policies, standards, architecture, and processes. The cyber risk management program falls under the responsibility of our Chief Financial Officer, who has more than 15 years of experience, including cross-functional expertise in business operations and technology strategy. Under the guidance of our Chief Financial Officer, we develop, maintain, and evidence the policies, standards, and processes in a manner consistent with applicable legal requirements. We also utilize a variety of cybersecurity software from reputable vendors in cybersecurity.

We have implemented a cybersecurity risk management program that is designed to identify, assess, and mitigate risks from cybersecurity threats to this data and our systems and ensure the effectiveness of our security controls. Our cybersecurity risk management program is Systems and Organization Controls (SOC)-certified and incorporates a number of components, including information security program assessments, continuous monitoring of critical risks from cybersecurity threats using automated tools, including identity threat detection response systems and endpoint threat detection and response systems, internal audits, and employee training. We deploy a wide range of security tools across the environment, require multi-factor authentication, hold client data on a separate virtual private cloud (VPC), implement access control policies that further limit access to data within the systems, and maintain secured data back-up systems.

We periodically conduct internal audits and are consistently evaluating our cyber readiness. As a result, we have not identified any material cybersecurity risks and are continuously hardening our environment, systems and infrastructure to reduce our vulnerability to attack. Additionally, our program includes regular cybersecurity training for all employees.

For further information regarding cybersecurity risks, please refer to "Risk Factors – Risks Related to Development and Commercialization of Our Current and Future Product Candidates" and other risks described in the "Risk Factors" section of this Annual Report on Form 10-K.

Governance

Our board of directors is responsible for the oversight of cybersecurity risk management. The board of directors delegates oversight of the cybersecurity risk management program to the audit committee of the board of directors (the "Audit Committee"). Our Chief Financial Officer reports to the Audit Committee. The Audit Committee updates the board of directors on our cybersecurity risk management program, including any critical cybersecurity risks, ongoing cybersecurity initiatives and strategies, and applicable regulatory requirements and industry standards on an annual and as-needed basis.

Item 2. Properties.

Our principal offices are located at 3300 Bee Cave Road, #650-227, Austin, Texas 78746. We operate primarily as a virtual company, and we believe our current facilities and other facilities available to us are sufficient to meet our current needs and that suitable space will be available as and when needed. We do not own any real property.

Item 3. Legal Proceedings.

From time to time, we may be involved in legal proceedings that arise during the ordinary course of business. Although the results of legal proceedings cannot be predicted with certainty, we do not currently have any pending litigation to which we are a party or to which our property is subject that we believe to be material. Regardless of the outcome, litigation can be costly and time consuming, and it can divert management's attention from important business matters and initiatives, negatively impacting our overall operations.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

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

Market Information

Our common stock began trading on The Nasdaq Capital Market under the symbol "GNPX" on March 29, 2018. Prior to that date, there was no public trading market for our common stock.

Holders of Record

As of March 15, 2026, there were approximately 174 stockholders of record of our common stock. The actual number of stockholders is greater than this number of record holders and includes stockholders who are beneficial owners but whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust or by other entities.

Dividend Policy

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all available funds and any future earnings for use in the operation of our business and do not anticipate paying any dividends on our common stock in the foreseeable future. Any future determination to declare dividends will be made at the discretion of our board of directors and will depend on, among other factors, our financial condition, operating results, capital requirements, contractual restrictions, general business conditions and other factors that our board of directors may deem relevant.

Recent Sales of Unregistered Securities

For the quarter ended December 31, 2025, we issued and sold the following unregistered securities:

1) On October 1, 2025, we issued an aggregate of 100 shares of our common stock to a consultant in consideration of services during the three months ended December 31, 2025.

The foregoing issuance of securities was not registered under the Securities Act or the securities laws of any state, and the securities were offered and issued in reliance on the exemption from registration under the Securities Act afforded by Section 4(a)(2).

During the year ended December 31, 2025, there were no other unregistered sales of our securities except as previously reported in a Current Report on Form 8-K or a Quarterly Report on Form 10-Q.

Item 6. [Reserved]

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

This Management's Discussion and Analysis of Financial Condition and Results of Operations ("MD&A") contains certain forward-looking statements. Historical results may not indicate future performance. Our forward-looking statements reflect our current views about future events, are based on assumptions and are subject to known and unknown risks and uncertainties that could cause actual results to differ materially from those contemplated by these statements. Factors that may cause differences between actual results and those contemplated by forward- looking statements include, but are not limited to, those discussed in "Risk Factors." We undertake no obligation to publicly update or revise any forward-looking statements, including any changes that might result from any facts, events, or circumstances after the date hereof that may bear upon forward-looking statements. Furthermore, we cannot guarantee future results, events, levels of activity, performance, or achievements. All amounts in this report are in United States ("U.S.") dollars, unless otherwise noted.

Overview

We are a clinical stage gene therapy company pioneering the development of gene-based therapies for large patient populations with unmet medical needs. Our oncology platform utilizes our systemic, non-viral ONCOPREX® Delivery System which uses lipid-based nanoparticles in a lipoplex form to deliver tumor suppressor gene-expressing plasmids to cancer cells. The product is administered intravenously, where it is taken up by tumor cells that then express tumor suppressor proteins that were deficient in the tumor. Our diabetes technology is designed to work in Type 1 diabetes by transforming alpha cells in the pancreas into functional beta-like cells, which can produce insulin but may be distinct enough from beta cells to evade the body's immune system. In Type 2 diabetes, our technology is believed to work by replenishing and rejuvenating exhausted beta cells that make insulin.

Oncology Platform

Our lead oncology drug candidate, REQORSA® Gene Therapy (generic name: *quaratusugene ozeplasmid*), previously referred to as GPX-001, is initially being developed in combination with prominent, approved cancer drugs to treat Non-Small Cell Lung Cancer ("NSCLC") and Small Cell Lung Cancer ("SCLC"). REQORSA has multimodal effects on cancer cells. It harms the metabolism of cancer cells, which leads to reduced cancer cell growth. It has a mechanism of action whereby it decreases tumor glucose metabolism, interrupts cell signaling pathways that cause replication and proliferation of cancer cells, re-establishes pathways for apoptosis, or programmed cell death, in cancer cells, and increases the immune response against cancer cells. In preclinical studies, REQORSA has been shown to be complementary with targeted drugs and immunotherapies. Our strategy is to develop REQORSA in combination with currently approved therapies, and we believe REQORSA's unique attributes position it to provide treatments that improve on these current therapies for patients with NSCLC, SCLC, and possibly other cancers.

The TUSC2 gene, which is the key component of REQORSA and plays a vital role in cancer suppression and normal cell metabolism, is one of a series of genes on the short arm of Chromosome 3 whose therapeutic use is covered by our exclusive worldwide licenses from The University of Texas MD Anderson Cancer Center ("MD Anderson"). We believe that our ONCOPREX Delivery System allows for the delivery of a number of cancer-fighting tumor suppressor genes, alone or in combination with other cancer therapies, to combat multiple types of cancer and we are in early stages of discovery programs to identify other cancer candidates. In August 2022, we entered into a sponsored research agreement with MD Anderson to support further preclinical studies of TUSC2 and other tumor suppressor genes. As further described in the "Discovery Programs" section of "Part I, Item 1. Business" of this Annual Report on Form 10-K above, since not all patients respond to REQORSA, we have been collaborating with researchers at MD Anderson to identify biomarkers that might predict a strong positive or negative response to REQORSA in patients with lung cancer. This preclinical effort has led to the identification of two proteins whose expression appears to predict response to REQORSA. Validation in specimens from clinical trials will be needed to determine whether these potential biomarkers predict clinical response. We plan to test patient samples from our clinical trials for selected biomarkers to determine if sensitivities exist among our existing patient population in an effort to guide patient selection and improve clinical outcomes.

Acclaim – 1: We currently are enrolling and treating patients in the Phase 2a expansion portion of our Phase 1/2 Acclaim-1 clinical trial. The Acclaim-1 trial uses a combination of REQORSA and AstraZeneca's Tagrisso® (*osimertinib*) in patients with late-stage NSCLC that has activating epidermal growth factor receptor ("EGFR") mutations and progression on treatment with Tagrisso or Tagrisso-containing regimens. Following the May 2023 completion of the Phase 1 dose escalation portion of the study, the Acclaim-1 Safety Review Committee ("Acclaim-1 SRC") approved advancement from the Phase 1 dose escalation portion to the Phase 2a expansion portion of the study. Based on a review of safety data which showed no dose limiting toxicities ("DLTs"), the Acclaim-1 SRC determined the recommended Phase 2 dose ("RP2D") of REQORSA to be 0.12 mg/kg administered every 21 days. This was the highest dose level delivered in the Phase 1 portion of the study and is twice the highest dose level delivered in our prior clinical trial combining REQORSA

with Tarceva® (*erlotinib*) for the treatment of late-stage lung cancer. There were three patients out of the twelve originally enrolled in the Phase 1 dose escalation portion of the study who had prolonged progression-free survival ("PFS"). One patient attained a partial remission after the second course of REQORSA and Tagrisso and has maintained this response through 60 courses of treatment (approximately 42 months) and this patient continues to receive REQORSA and Tagrisso treatment to date. A second patient had stable disease without disease progression through 32 courses of treatment (approximately 24 months), but then had disease progression and REQORSA treatment was stopped. A third patient had stable disease without disease progression through 14 courses of treatment (approximately 10 months) before disease progression and is no longer receiving treatment. The results of the Phase 1 dose escalation portion of the study were published in *Clinical Lung Cancer*, a peer-reviewed journal covering various aspects of clinical and translational research of lung cancer, in January 2026. We opened the Phase 2a expansion portion of the study and enrolled and dosed the first patient in January 2024. The Phase 2a expansion portion of the trial is expected to enroll approximately 33 patients; all of whom have progressed on Tagrisso or Tagrisso-containing regimens. There will be an interim analysis following the treatment of 19 patients in the Phase 2a portion of the Acclaim-1 study. The Phase 2b randomized portion of the study, in which patients progressing on prior Tagrisso treatment will be randomized 1:1 to either REQORSA and Tagrisso combination therapy or to platinum-based chemotherapy, remains unchanged. We expect to complete the enrollment of the first 19 patients for interim analysis in the Phase 2a expansion portion of the study in the first half of 2026 and expect the interim analysis in the second half of 2026.

The Food and Drug Administration ("FDA") has granted Fast Track Designation for the Acclaim-1 treatment combination of REQORSA and Tagrisso in NSCLC patients who have progressed on Tagrisso treatment.

The Phase 2a expansion portion of the Acclaim-1 study provides us the advantage of early insight into drug effectiveness in defined and distinct patient populations at the maximum tolerated dose (the "MTD") or RP2D in order to better evaluate efficacy and increase the likelihood of a successful randomized Phase 2 trial which will follow the expansion portion of the study.

Acclaim – 2: The Acclaim-2 trial involved a combination of REQORSA and Merck & Co.'s Keytruda® (*pembrolizumab*) in patients with late-stage NSCLC whose disease has progressed after treatment with Keytruda. As previously announced in August 2024, based on a number of factors, including enrollment challenges and delays due to competition for investigators and eligible patients with numerous other trials involving the same patient population, we decided to cease enrollment of new patients in the Acclaim-2 trial to prioritize our resources and focus on the other two Acclaim trials in SCLC and NSCLC, respectively. There are no longer any patients receiving study treatment in the Acclaim-2 trial. Although the Acclaim-2 study in patients progressing on Keytruda containing regimens has been closed due to, among other factors, slow enrollment, we continue to believe that this combination could be beneficial.

Acclaim – 3: We are currently enrolling and treating patients in the Phase 2 expansion portion of our Phase 1/2 Acclaim-3 clinical trial. The Acclaim-3 clinical trial uses a combination of REQORSA and Genentech, Inc.'s Tecentriq® (*atezolizumab*) as maintenance therapy for patients with extensive stage small cell lung cancer ("ES-SCLC") who did not develop tumor progression after receiving Tecentriq and chemotherapy as initial standard treatment. Patients are treated with REQORSA and Tecentriq until disease progression or unacceptable toxicity is experienced. In December 2024, we announced that we had completed the Phase 1 dose escalation portion of the Acclaim-3 clinical trial. Based on full safety data, which showed no DLTs, the Acclaim-3 Safety Review Committee ("Acclaim-3 SRC") determined that the RP2D of REQORSA will be 0.12 mg/kg administered every 21 days, which was the highest dose level delivered in the Phase 1 portion of the trial, and approved the opening of the Phase 2 expansion portion of the trial. Although decreases in tumor size are not expected during maintenance therapy with atezolizumab alone, there were two patients out of the six enrolled in the Phase 1 dose escalation portion of the study who had marked decreases in measurable disease. We previously reported that the first patient treated in the Phase 1 dose escalation portion of the Acclaim-3 trial had a partial remission, which is defined as at least a thirty percent (30%) decrease in tumor size, from prior to the start of maintenance therapy to the time of the CT scan performed after two cycles of maintenance therapy. A CT scan performed after four cycles of maintenance therapy (three months), confirmed that the patient still had a 30% decrease in tumor size in measurable lesions; however, one lesion not previously measurable had grown in size, thus leading to a conclusion of disease progression at that time. Another patient in the Phase 1 dose escalation portion of the Acclaim-3 trial had a twenty-three percent (23%) decrease in tumor size from prior to the start of maintenance therapy to the time of the CT scan performed after two cycles of maintenance therapy. This patient received seven cycles of study therapy before progressing after 4.2 months. In addition, one patient in the Phase 1 dose escalation portion of the study achieved an unconfirmed partial remission after 24 cycles of therapy and continues to receive study treatment in the trial after more than 18 months. We anticipate that the Phase 2 expansion portion will enroll approximately 50 patients at approximately 10 to 15 U.S. sites. Patients will be treated with REQORSA and Tecentriq until disease progression or unacceptable toxicity is experienced. The primary endpoint of the Phase 2 portion is to determine the 18-week progression-free survival rate from the time of the start of maintenance therapy with REQORSA and Tecentriq in patients with ES-SCLC. Patients will also be followed for survival. A Phase 2 futility analysis will be performed after the

25th patient enrolled and treated reaches 18 weeks of follow up. We expect to complete enrollment of the first 25 patients for interim analysis in the Phase 2 expansion portion of the study in the first half of 2026 and expect the interim analysis in the second half of 2026.

The Acclaim-3 clinical trial has received FDA Fast Track Designation for this patient population and Acclaim-3 has also received an FDA Orphan Drug Designation.

Diabetes Gene Therapy

In diabetes, we have exclusively licensed from the University of Pittsburgh of the Commonwealth System of Higher Education ("University of Pittsburgh" or "UP") multiple technologies relating to the development of a gene therapy product for each of Type 1 and Type 2 diabetes. The same novel approach is used in each of Type 1 and Type 2 diabetes whereby an adeno-associated virus ("AAV") vector containing the Pdx1 and MafA genes is administered directly into the pancreatic duct. In humans, this can be done with a routine endoscopy procedure. Our diabetes product candidates are currently being evaluated and optimized in preclinical studies at the University of Pittsburgh. GPX-002 is being developed for the treatment of both Type 1 diabetes and Type 2 diabetes. GPX-002 for Type 1 diabetes is designed to work by transforming alpha cells in the pancreas into functional beta-like cells, which can produce insulin but may be distinct enough from beta cells to evade the body's immune system. In a similar approach, GPX-002 for Type 2 diabetes, where autoimmunity is not at play, is believed to work by replenishing and rejuvenating exhausted beta cells that make insulin. We are currently working with the University of Pittsburgh on species analyses for the animal models as well as other regulatory and clinical strategic planning, including the initiation of research in Type 2 diabetes animal models. In December 2025, we also executed on our strategic goal to submit a meeting request to the FDA by the end of the year to discuss the necessary Investigational New Drug ("IND")-enabling preclinical studies, an important step before potentially initiating clinical trials in humans. See the "Recent Developments" section in "Part I, Item 1. Business" of this Annual Report on Form 10-K above for more information on our meeting with the FDA which occurred in February 2026. In May 2025, following the completion of our August 2022 sponsored research agreement with UP, we entered into a new sponsored research agreement with UP to study Type 1 diabetes and Type 2 diabetes in animal models. The new sponsored research agreement also includes a revised research plan to encompass our most recent technologies to which we originally acquired exclusive rights from UP in July 2023 as amended and restated in the comprehensive New UP License Agreement in February 2025 (as defined and described below). These include a MafB promoter to drive expression of the Pdx1 and MafA transcription factors that can potentially be used for both Type 1 and Type 2 diabetes. See also "Note 7 – Commitments and Contingencies" to our consolidated financial statements included in this Annual Report on Form 10-K.

On February 17, 2025, we and the University of Pittsburgh entered into an amended and restated Exclusive License Agreement (the "New UP License Agreement"), which updated and consolidated into a single agreement our prior license agreements with UP. Pursuant to the New UP License Agreement, UP granted to us a worldwide, exclusive license for certain patents and related technology, collectively referred to as the "Licensed Technology," and a worldwide, non-exclusive license to use certain related know-how. The Licensed Technology covered by the New UP License Agreement is based on the same general gene therapy approach as covered under our prior license agreements with UP (less the previously-licensed macrophage technology), whereby an adeno-associated virus vector containing the Pdx1 and MafA genes is administered directly into the pancreatic duct. More specifically, the Licensed Technology covered by the New UP License Agreement is related to a gene therapy for both Type 1 diabetes and Type 2 diabetes using the genes of the Pdx1 and MafA transcription factors controlled by insulin, glucagon and MafB promoters.

In February 2023, our research collaborators at UP presented preclinical data in a non-human primate ("NHP") model of Type 1 diabetes highlighting the therapeutic potential of GPX-002 at the 16th International Conference on Advanced Technologies & Treatments for Diabetes (ATTD 2023) in Berlin, Germany. The statistically significant study results showed the treated animals had decreased insulin requirements, increased c-peptide levels, and improved glucose tolerance compared to baseline. In April 2023, we hosted a Key Opinion Leader virtual event entitled "Novel Gene Therapy to Treat Type 1 Diabetes," which discussed preclinical data reported at ATTD 2023 supporting gene therapy to treat Type 1 diabetes. In June 2025, our collaboration partners had two presentations at the 2025 American Diabetes Association ("ADA") 85th Scientific Sessions. Our research collaborators from UP were invited to give an oral presentation highlighting their work in NHP models of Type 1 diabetes. In addition, our contract development and manufacturing organization collaborators presented a poster on a non-viral lipid nanoparticle delivery system that would allow a patient to receive multiple treatments.

Convergen Biotech, Inc.

Additionally, in September 2024, we announced that we were considering various strategic alternatives and opportunities to enhance stockholder value, including evaluating ways to optimize our clinical and research programs and operational strategies, such as our intention to potentially transfer our diabetes clinical development program and our diabetes gene therapy assets into a new, initially wholly-owned subsidiary. In connection with this intended separation of the diabetes clinical development program, in February 2025, we announced that we had formed a wholly-owned subsidiary, Convergen Biotech, Inc. ("Convergen"), to implement this initial step of the reorganization and facilitate the separation of the diabetes program. If, and when, a potential separation is completed, Convergen will focus on developing and commercializing GPX-002. We plan to retain our oncology clinical development programs and other oncology pipeline assets.

Reverse Stock Splits

Effective as of February 2, 2024 and October 21, 2025, we effected reverse stock splits of our issued and outstanding shares of common stock, at respective ratios of one-for-forty (1:40) and one-for-fifty (1:50) (respectively referred to as the "2024 Reverse Stock Split" and "2025 Reverse Stock Split", and collectively, the "Reverse Stock Splits"). Our common stock continues to trade on The Nasdaq Capital Market under the same GNPX ticker following the Reverse Stock Splits, but following the 2025 Reverse Stock Split was assigned a new CUSIP number, 372446302. All share and per share amounts in this Annual Report on Form 10-K have been adjusted as appropriate to reflect the Reverse Stock Splits (see "Note 2 – Summary of Significant Accounting Policies" to our consolidated financial statements included in this Annual Report on Form 10-K).

Recently Issued Accounting Pronouncements

A description of recently issued accounting pronouncements that may potentially impact our financial position and results of operations is disclosed in Note 2 to our consolidated financial statements appearing in this Annual Report on Form 10-K.

Critical Accounting Policies and Significant Judgments and Estimates

Our consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States ("US GAAP"). The preparation of these consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the consolidated financial statements, and the reported amounts of expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

We believe that the following accounting policies and estimates are the most critical to aid in fully understanding and evaluating our reported financial results, and they require our most difficult, subjective or complex judgments, resulting from the need to make estimates about the effect of matters that are inherently uncertain**.**

Research and Development Costs

We record accrued expenses for costs invoiced from research and development activities conducted on our behalf by third-party service providers, which include the conduct of preclinical studies and clinical trials and contract research, manufacturing, and testing activities. We record the costs of research and development activities based upon the amount of services provided, and we include these costs in accrued liabilities in the balance sheets and within research and development expense in the statements of operations. These costs are a significant component of our research and development expenses. Purchased materials to be used in future research are valued at cost and capitalized and included in research and development supplies. The costs of materials that were acquired for a particular research and development activity and have no alternative future use are expensed in the period acquired.

We estimate the amount of work completed through discussions with internal personnel and external service providers as to the progress or stage of completion of the services and the agreed-upon fee to be paid for such services. We make significant judgments and estimates in determining the accrued balance in each reporting period. As actual costs become known, we adjust our accrued estimates. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed, the number of patients enrolled and the

rate of patient enrollment in any of our clinical trials may vary from our estimates and could result in our reporting amounts that are too high or too low in any particular period. Our accrued expenses are dependent, in part, upon the receipt of timely and accurate reporting from contract research organizations ("CROs") and other third-party service providers.

Income Taxes

Deferred tax assets or liabilities are recorded for temporary differences between financial statement and tax basis of assets and liabilities, using applicable rates in effect for the year in which the differences are expected to reverse. A valuation allowance is recorded if it is more likely than not that a deferred tax asset will not be realized. We have provided a full valuation allowance on our deferred tax assets, which primarily consist of cumulative net operating losses from April 1, 2009 (inception) to December 31, 2025. Due to our history of operating losses since inception and losses expected to be incurred in the foreseeable future, a full valuation allowance was considered necessary.

Impairment of Long-Lived Assets

Management evaluates long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount may not be realizable or at a minimum annually during the fourth quarter of the year. If an evaluation is required, the estimated future undiscounted cash flows associated with the asset are compared to the asset's carrying value to determine if an impairment of such asset is necessary. The effect of any impairment would be to expense the difference between the fair value of such asset and its carrying value based upon discounted cash flows.

Modification of Equity Classified Warrants

A change in the terms or conditions of a warrant is accounted for as a modification. For a warrant modification accounted for under ASC 815, the effect of a modification shall be measured as the difference between the fair value of the modified warrant over and the fair value of the original warrant immediately before its terms are modified, with each measured on the modification date. The accounting for any incremental fair value of the modified warrants over the original warrants is based on the specific facts and circumstances related to the modification. When a modification is directly attributable to an equity offering, the incremental change in fair value of the warrants is accounted for as an equity issuance cost. When a modification is directly attributable to a debt financing, the incremental change in fair value of the warrants is accounted for as a debt discount or debt issuance cost. For all other modifications, the incremental change in fair value is recognized as a deemed dividend.

Components of our Results of Operations and Financial Condition

Operating expenses

We classify our operating expenses into three categories: research and development, general and administrative, and depreciation.

Research and development. Research and development expenses consist primarily of:

- costs incurred to conduct research, such as the discovery and development of our current and potential product candidates;
- costs related to the production and storage of supplies for engineering purposes and storage and usage of clinical supplies, including waste created in the process of producing clinical materials, spoilage, and testing of clinical materials;
- costs related to the use of contract manufacturers, manufacturing consultants, testing organizations, cold-storage facilities, and logistics service providers;
- fees paid to clinical consultants, clinical trial sites and vendors, including CROs in conjunction with implementing and monitoring our clinical trials and acquiring and evaluating clinical trial data, including all related fees, such as patient screening fees, laboratory work, and statistical compilation and analysis;
- costs related to compliance with drug development regulatory requirements; and
- costs related to staffing and personnel associated with research and development activities, including wages, taxes, benefits, leases, overheads, supplies, and share-based compensation.

We recognize all research and development costs as they are incurred except those capitalized with alternative further use. Clinical trial costs, contract manufacturing and other development costs incurred by third-parties are expensed as the contracted work is performed.

We expect our research and development expenses to increase in the future as we (i) advance our current and future product candidates into and through clinical trials, (ii) transition some of our manufacturing activities to new vendors for a variety of reasons, such as to incorporate more advanced processes and scale production, including any additional work that has been or may be required to successfully adapt our process to these new processes, (iii) pursue regulatory approval of our current and potential product candidates in the United States and Europe, and (iv) expand our research programs to include new therapies and new therapy combinations. The process of conducting the necessary preclinical and clinical research to obtain regulatory approval is costly and time-consuming. The actual probability of success for our current and potential product candidates may be affected by a variety of factors including the quality of our current and potential product candidates, early clinical data, investment in our clinical program, competition, manufacturing capability and commercial viability, and limited contracted partners. We may never succeed in achieving regulatory approval for any of our current or future product candidates. As a result of the uncertainties discussed above, we are unable to determine the duration and completion costs of our research and development projects or when and to what extent we will generate revenue from the commercialization and sale of our product candidates, if at all. However, we continue to evaluate ways to optimize our clinical and research programs and operational strategies, as part of our ongoing prioritization initiative. Additionally, we are considering various strategic alternatives and opportunities to enhance stockholder value.

General and administrative. General and administrative expense consists of personnel related costs, which include administrative and executive salaries, as well as the costs of professional services, such as accounting and legal, travel, facilities, information technology and other administrative expenses. We expect our general and administrative expense to increase in future periods due to the anticipated growth of our business and related infrastructure as well as accounting, insurance, investor relations, legal, information technology, and other costs associated with being a public company.

Depreciation. Depreciation expense consists of depreciation from our fixed assets consisting of our property, equipment, and furniture. We depreciate our assets over their estimated useful life. We estimate furniture and computer and office equipment to have a five-year life.

Results of Operations

Comparison of the Years Ended December 31, 2025 and 2024

The following summarizes our results of operations for the years ended December 31, 2025 and 2024.

Research and Development Expense. Research and development ("R&D") expense was $9,428,720 for the year ended December 31, 2025 as compared to $10,535,446 for the year ended December 31, 2024. This decrease of $1,106,726, or 11%, is primarily due to (i) reduction in clinical and manufacturing expenses due to closing of the Acclaim-2 clinical trial, (ii) differences in enrollment of the Acclaim-1 and Acclaim-3 clinical trials during each of the periods, and (iv) expansion of expense reduction strategies by leadership to reduce R&D overheads and employee associated expenses that included reducing R&D staff from 9 employees at December 31, 2024 to 7 employees at December 31, 2025.

General and Administrative Expense. General and administrative ("G&A") expense for the year ended December 31, 2025 was $6,086,899 as compared to $10,632,028 for the year ended December 31, 2024, a decrease of $4,545,129, or 43%. This decrease was primarily due to (i) one-time charges associated with the separation with a former Company executive and changes in accounting policies that resulted in a non-cash expense of approximately $800,000 due to an adjustment of capitalized intellectual property during the year ended December 31, 2024, (ii) a significant reduction in share-based compensation for G&A personnel due to the timing and fair market value of equity awards, and (iii) expansion of expense reduction strategies by leadership to reduce travel expenses, the number of professional service providers and associated expenses, and G&A overheads.

Interest Income. Interest income was $26,900 and $63,574 for the years ended December 31, 2025 and 2024, respectively. This decrease of $36,674 was primarily due to lower cash balances held in interest bearing accounts for the year ended December 31, 2025 as compared to the prior year.

Interest Expense. There was no interest expense for the years ended December 31, 2025 and 2024 because we had no debt obligations. As of December 31, 2025, we had no outstanding debt.

Depreciation Expense. Depreciation expense was $0 and $6,693 for the years ended December 31, 2025 and 2024, respectively. The decrease of $6,693, or 100%, in depreciation was primarily due to the timing of purchases of computer equipment for employees and changes to accounting policies related to depreciation.

Net Loss. We had a net loss of $16,228,953, for the fiscal year ended December 31, 2025 compared to a net loss of $21,111,163 for the fiscal year ended December 31, 2024. The decrease of $4,882,210, or 23%, in net loss due to the implementation of expense reduction strategies by leadership in the starting in the year ended December 31, 2024 and continuing throughout the year ended December 31, 2025, which reduced travel expenses, the number of professional service providers and associated expenses, and reduced headcount and associated overhead of overall Company staff from 15 employees at December 31, 2024 to 13 employees at December 31, 2025.

Liquidity and Capital Resources

From inception through December 31, 2025, we have never generated revenue from product sales and have incurred net losses in each year. As of December 31, 2025, we had an accumulated deficit of $171,028,396. We have funded our operations primarily through the sale and issuance of capital stock.

For the year ended December 31, 2024, we (i) sold 153,701 shares of common stock for net proceeds of approximately $6.1 million pursuant to our 2023 ATM Facility (defined below), and (ii) completed a registered direct offering in which we sold (x) 3,300 shares of our common stock, (y) pre-funded warrants exercisable for up to an aggregate of 27,543 shares of our common stock ("March 2024 Pre-Funded Warrants"), and (z) warrants exercisable for up to an aggregate of 30,843 shares of our common stock ("March 2024 Common Warrants"), for net proceeds of approximately $5.9 million. In connection with the March 2024 registered direct offering, we amended certain existing warrants to reduce the exercise price and extend the term thereof. See also "Note 4 - Equity - Registered Direct Offering" to our consolidated financial statements included in this Annual Report on Form 10-K. As of December 31, 2024, all of the 27,543 March 2024 Pre-Funded Warrants had been exercised for shares of common stock.

For the year ended December 31, 2025, we sold (i) 1,602,490 shares of common stock for net proceeds of approximately $10.8 million pursuant to our 2023 ATM Facility, (ii) 772,867 shares of common stock (inclusive of the 23,737 commitment shares issued pursuant to the Purchase Agreement (as defined below)) for aggregate net proceeds of approximately $5.3 million, pursuant to our 2025 ELOC Facility (as defined below), (iii) completed a registered direct offering in which we sold (x) 243,622 shares of our common stock, and (y) warrants exercisable for up to an aggregate of 487,244 shares of our common stock ("October 2025 Private Warrant Shares I"), for net proceeds of approximately $2.5 million, and (iv) completed a registered direct offering in which we sold (x) 377,780 shares of our common stock, and (y) warrants exercisable for up to an aggregate of 755,560 shares of our common stock ("October 2025 Private Warrant Shares II"), for net proceeds of approximately $3.1 million. From January 1, 2026 through the date of filing of this Annual Report on Form 10-K, we sold 5,714,798 shares of common stock for aggregate net proceeds of approximately $13.3 million pursuant to our 2023 ATM Facility.

On June 11, 2025, we entered into an equity line of credit ("ELOC") purchase agreement, dated June 11, 2025 (the "Purchase Agreement"), with Lincoln Park Capital Fund, LLC ("Lincoln Park"), pursuant to which Lincoln Park committed to purchase from us up to $12.5 million in shares of our common stock (subject to certain conditions and limitations contained in the Purchase Agreement) from time to time at our sole discretion over the 24-month term of the Purchase Agreement (the "2025 ELOC Facility"). Sales of shares of common stock to Lincoln Park under the Purchase Agreement will depend on a variety of factors to be determined by us from time to time, including, among others, market conditions, the trading price of our common stock and our determination as to the appropriate sources of funding for our operations. See also "Note 1 – Description of Business and Basis of Presentation – Capital Requirements, Liquidity and Going Concern Considerations" and "Note 4 - Equity – Equity Line of Credit" to our consolidated financial statements included in this Annual Report on Form 10-K.

On December 13, 2023, we entered into an At The Market ("ATM") Offering Agreement (the "Sales Agreement") with H.C. Wainwright & Co., LLC, serving as agent (the "Agent") with respect to an at-the-market offering program (our "2023 ATM Facility") under which we may offer and sell through the Agent, from time to time at our sole discretion, up to such number or dollar amount of shares of our common stock (the "Shares") as registered on the prospectus supplement covering the 2023 ATM Facility offering, as may be amended or supplemented from time to time. We have agreed to pay the Agent a commission equal to three percent (3%) of the gross sales proceeds of any Shares sold through the Agent under the Sales Agreement, and also have provided the Agent with customary indemnification and contribution rights. Currently, we have registered $75 million of Shares to sell under the ATM, of which we have sold approximately $16.4 million and have approximately $58.6 million remaining unsold as of the date of filing of this Annual Report on Form 10-K. See also "Note 1 - Description of Business and Basis of Presentation - Capital Requirements, Liquidity and Going Concern Considerations" and "Note 4 - Equity - At-The-Market Offering" to our consolidated financial statements included in this Annual Report on Form 10-K.

As of December 31, 2025, we had $7,830,855 in cash. Subsequent to year-end 2025, we received net proceeds totaling approximately $13.3 million through the Agent pursuant to our 2023 ATM Facility.

We do not expect to generate revenue from product sales unless and until we successfully complete development of, obtain regulatory approval for and begin to commercialize one or more of our current or future product candidates, which we expect will take a number of years and which is subject to significant uncertainty. Accordingly, we anticipate that we will need to raise additional capital to fund our future operations, which include conducting our Acclaim-1 and Acclaim-3 clinical trials (of which both are currently enrolling) and completing preclinical work for potential other oncology candidates and completing preclinical work and conducting clinical trials for our diabetes program. We expect interim enrollment of the Phase 2a expansion portion of the Acclaim-1 trial to be completed in the first half of 2026. We expect interim enrollment in the Phase 2 dose expansion portion of the Acclaim-3 trial to be completed in the first half of 2026. Until such time as we can generate substantial revenue from product sales, if ever, we expect to finance our operating activities through a combination of equity offerings, drawdowns on our 2023 ATM Facility pursuant to our Sales Agreement with the Agent, sales pursuant to our 2025 ELOC Facility, and debt financings and we may seek to raise additional capital through strategic collaborations or transactions. However, we may be unable to raise additional funds or enter into such arrangements when needed on favorable terms, or at all, which would have a negative impact on our financial condition and could force us to delay, limit, reduce or terminate our research and development programs or commercialization efforts or grant rights to others to develop or market product candidates that we would otherwise prefer to develop and market ourselves. Failure to receive additional funding could cause us to curtail or cease our operations. Furthermore, even if we believe we have sufficient funds for our current or future operating plans, we may seek additional capital due to favorable market conditions or strategic considerations. As a result of the Company's recurring losses from operations and the need for additional financing to fund its operating and capital requirements, there is uncertainty regarding the Company's ability to maintain liquidity sufficient to operate its business effectively over the next 12 months, which raises substantial doubt as to the Company's ability to continue as a going concern.

Based on our current cash, we estimate that we will be able to fund our expenditure requirements for our current operations and planned clinical trial activities into the second quarter of 2027. We have based these estimates on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently plan due to incorrect assumptions or due to a decision to expand our activities beyond those currently planned. We have experienced delays in clinical trial enrollment as a result of competition for patients and previously experienced delays due to additional time required in connection with our transition to the new third party CDMO and the manufacture of final drug product. Delays in the conduct of our trials could result in utilizing our capital resources sooner without advancing our clinical trials as anticipated.

The following table sets forth the primary sources and uses of cash for the years ended December 31, 2025 and 2024:

	Years Ended December 31,	
	2025	**2024**
Net cash used in operating activities	$ (15,311,209)	$ (17,922,566)
Net cash provided by investing activities	—	774,644
Net cash provided by financing activities	21,540,404	12,011,953
Net increase (decrease) in cash and cash equivalents	6,229,195	(5,135,969)

Short Term Cash Requirements

We believe that our existing cash is sufficient to fund our expected short-term needs into the second quarter of 2027, but will need additional fundraising activities and cash on hand by such time. We currently have certain fixed cash obligations with respect to development of materials used in our clinical studies and payment obligations associated with our ongoing conduct and monitoring of our Acclaim clinical trials, and we expect that we will have insufficient cash to cover these requirements through fiscal year 2027 without raising additional working capital. The foregoing conditions raise substantial doubt regarding our ability to continue as a going concern for a period of one year after the date the consolidated financial statements included in this Annual Report are issued. Lack of necessary funds may require us, among other things, to delay, scale back or eliminate some or all of our ongoing and/or planned clinical trials, or research and development programs, or make changes to our operating plan, or curtail or cease operations.

Long Term Cash Requirements

We regularly evaluate our business plans and strategy. These evaluations often result in changes to our business plans and strategy, some of which may be material and significantly change our cash requirements. Ongoing business development activity may require us to use some of our liquidity for an acquisition, or additional capital to fund newly acquired operations. If we raise additional funds by issuing equity securities, our existing security holders will likely experience dilution; and the incurring of indebtedness would result in increased debt service obligations and could require us to agree to operating and financial covenants that could restrict operations.

Our future capital requirements depend on many factors, including, but not limited to:

- the costs and timing of our development activities and preclinical and clinical trials;
- the cost of manufacturing our existing and future products;
- the expenses needed to attract and retain skilled personnel;
- the costs associated with being a public company;
- the costs associated with additional business development or mergers and acquisitions activity, including acquisition-related costs, earn-outs or other contingent payments and costs of developing and commercializing any technologies to which we obtain rights;
- third-party costs associated with the development and commercialization of our existing and future products and the ability of our development partners to satisfy our requirements on a timely basis;
- the scope and terms of our business plans from time to time, and our ability to realize upon our business plans; and
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing possible patent claims, including litigation costs and the outcome of any such litigation.

Cash used in operating activities

Net cash used in operating activities was $15,311,209 and $17,922,566 for the years ended December 31, 2025 and 2024, respectively. The decrease of $2,611,357, or 15%, in net cash used in operating activities in 2025 was primarily due (i) the closing of the Acclaim-2 clinical trial and associated reductions in clinical and manufacturing related expenses, and (ii) the expansion of expense reduction strategies by leadership, which reduced travel expenses, the number of professional service providers and associated expenses, and reduced headcount and associated overhead of overall Company staff from 15 employees at December 31, 2024 to 13 employees at December 31, 2025.

Cash used in investing activities

Net cash provided by investing activities was $0 for the year ended December 31, 2025, compared to net cash used in investing activities of $774,644 for the year ended December 31, 2024, or a net change of $774,644. This difference in period-over-period net cash used in investing activities was primarily due to changes in accounting policy, for the year ended December 31, 2024, that reduced previously capitalized intellectual property.

Cash provided by financing activities

Net cash provided by financing activities was $21,540,404 and $12,011,953 for the years ended December 31, 2025 and 2024, respectively. The increase of $9,528,451, or 79%, in net cash provided by financing activities was primarily due to (i) differences in financing strategies used, (ii) differences in amounts raised by sales of our securities in capital raising activities, and (iii) differences in interest rates during the years ended December 31, 2025 and 2024, respectively.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

As a smaller reporting company, we are not required to provide the information called for by this item.

Item 8. Financial Statements and Supplementary Data.

The financial statements and supplementary data required by this item are included after Part IV of this Annual Report on Form 10-K beginning on page F-1.

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

Not applicable.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

As required by Rules 13a-15(b) and 15d-15(b) of the Exchange Act, our management with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2025. The term "disclosure controls and procedures" as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to a company's management, including its principal executive and principal financial officer (currently the same person following the passing of Mr. Varner, the Company's former President, Chief Executive Officer and Chairman of the Board of Directors, on May 7, 2024), as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of December 31, 2025, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were not effective due to material weaknesses in our internal control over financial reporting related to a lack of segregation of duties between accounting and other functions and the absence of sufficient depth of in-house accounting personnel with the ability to properly account for complex transactions.

Management's Report on Internal Control over Financial Reporting

Our principal executive officer and principal accounting and financial officer are responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rules 13a-15(f) and 15d-15(f). Management conducted an assessment of the effectiveness of our internal control over financial reporting as of December 31, 2025. In making this assessment, management used the criteria described in Internal Control-Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Our management concluded that our internal controls over financial reporting were, and continue to be, ineffective as of December 31, 2025 due to material weaknesses in our internal controls due to the lack of segregation of duties and insufficient depth of in-house accounting personnel.

It should be noted that any system of controls, however well designed and operated, can provide only reasonable and not absolute assurance that the objectives of the system are met. In addition, the design of any control system is based in part upon certain assumptions about the likelihood of certain events. Because of these and other inherent limitations of control systems, there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions, regardless of how remote.

In light of the material weaknesses described below, we performed additional analysis and other post-closing procedures to ensure our consolidated financial statements were prepared in accordance with generally accepted accounting principles. Accordingly, we believe that the consolidated financial statements included in this report fairly present, in all material respects, our financial condition, results of operations and cash flows for the periods presented.

During the year ended December 31, 2025 and as our operational activities increased, management determined and continues to determine that it does not have sufficient segregation of duties within its accounting functions nor does it have sufficient depth of in-house accounting personnel with the ability to properly account for complex transactions, which are basic internal controls. Due to our size, segregation of all conflicting duties may not always be possible and may not be economically feasible. However, to the extent possible, the initiation of transactions, the custody of assets and the recording of transactions should be performed by separate individuals. Our size and nature also do not allow for our accounting staff to have depth of expertise in all areas that might be desirable, such as expertise in accounting for a variety of complex transactions. Management evaluated the impact of our failure to maintain effective segregation of duties and sufficient depth of personnel on our assessment of our internal control over financial reporting and has concluded that these control deficiencies represent material weaknesses.

Remediation Plans

Management is actively engaged in remediation efforts to address the material weaknesses identified in management's evaluation of internal controls and procedures. The remediation efforts, which have been or are in the process of being implemented, are intended to address the identified material weaknesses and include:

- new accounting software, processes, and workflows to further segregate duties among limited accounting staff;
- specific review procedures, including the added involvement of our legal department to review certain accounting transactions following a given period in an effort to enhance accuracy of reporting;
- specific review procedures, including the added involvement of our manufacturing staff, to enhance controls associated with the tracking and reporting of inventory values in our supply chain;
- a formal Disclosure Committee that has oversight responsibility for the accuracy and timeliness of disclosures made by the Company through controls and procedures and the monitoring of their integrity and effectiveness;
- additional hiring of staff and development of accounting processes and policies to further segregate accounting responsibilities and increase the depth of our expertise in accounting for a variety of complex transactions; and
- additional training, testing, and certification of key accounting, finance, IT, and legal team members.

During the year ended December 31, 2025, we took actions to remediate the material weaknesses relating to our internal controls over financial reporting including:

- continued evaluation and documentation of policies, processes, and controls, both manual and automated;
- identification and implementation of improvements to information technology and security controls and supporting control documentation;
- evaluation of and updates to software workflows to further segregate duties, enhance accuracy of vendor billing, and ensure transparency and oversight from vendor or project managers, department leaders, legal team members, and finance team members;
- initiation and completion of training programs, testing, and certification for key employees related to enterprise risk management and general information technology controls; and
- hiring of specialized accounting consultants for advisement and evaluation of accounting for certain complex transactions.

As management continues to evaluate and work to improve its internal control over financial reporting, we may take additional measures to address control deficiencies, or we may modify certain of the remediation measures described above. While remediation efforts are active, management requires additional time to demonstrate the operating effectiveness of our remediation efforts. The material weaknesses cannot be considered remediated until the applicable remedial controls operate for a sufficient period of time and management has concluded, through testing, that these controls are operating effectively.

Changes in Internal Control over Financial Reporting

Except as described above, there were no changes in our internal control over financial reporting during the year ended December 31, 2025 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations of Disclosure Controls and Internal Control over Financial Reporting

Because of their inherent limitations, our disclosure controls and procedures and our internal control over financial reporting may not prevent material errors or fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. The effectiveness of our disclosure controls and procedures and our internal control over financial reporting is subject to risks, including that the controls may become inadequate because of changes in conditions or that the degree of compliance with our policies or procedures may deteriorate.

Item 9B. Other Information.

Rule 10b5-1 Trading Arrangements and Non-Rule 10b5-1 Trading Arrangements

During the fiscal quarter ended December 31, 2025, none of our officers or directors, as those terms are defined in Rule 16a-1(f), adopted or terminated a "Rule 10b5-1 trading arrangement" or a "non-Rule 10b5-1 trading arrangement," as those terms are defined in Item 408 of Regulation S-K.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The remaining information required by this Item 10, to the extent not set forth herein, is incorporated herein by reference to the information that will be contained in our definitive proxy statement (the "Proxy Statement") for the 2026 annual meeting of stockholders (the "Annual Meeting"), which is expected to be filed not later than 120 days after the end of our fiscal year ended December 31, 2025.

ETHICS CODE

We have adopted a written Code of Business Conduct and Ethics, or Ethics Code, that applies to all of our officers, directors and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. A current copy of our Ethics Code is available on our website at www.genprex.com/investors/corporate-governance. We may satisfy the disclosure requirement under Item 5.05 of Form 8-K regarding a substantive amendment to, or a waiver from, a provision of our Ethics Code that applies to our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions and that relates to any element of the code of ethics definition enumerated in paragraph (b) of Item 406 of the SEC's Regulation S-K, by posting such information on our website, www.genprex.com, or by filing a Form 8-K.

INSIDER TRADING POLICY

Our Company has an insider trading policy governing the purchase, sale and other dispositions of our Company's securities that applies to all Company personnel, including directors, officers, employees, other covered persons as well as the Company. We believe that our insider trading policy is reasonably designed to promote compliance with insider trading laws, rules and regulations, and listing standards applicable to the Company. A copy of our insider trading policy is filed as Exhibit 19.1 to this Form 10-K.

Item 11. Executive Compensation.

The information required by this Item 11 is incorporated herein by reference to the information that will be contained in our Proxy Statement for the Annual Meeting.

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

The information required by this Item 12 is incorporated herein by reference to the information that will be contained in our Proxy Statement for the Annual Meeting.

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

The information required by this Item 13 is incorporated herein by reference to the information that will be contained in our Proxy Statement for the Annual Meeting.

Item 14. Principal Accountant Fees and Services.

The information required by this Item 14 is incorporated herein by reference to the information that will be contained in our Proxy Statement for the Annual Meeting.

PART IV

Item 15. Exhibits and Financial Statement Schedules.

(a)(1) Financial statements.

The financial statements and supplementary data required by this item begin on page F-1.

(a)(2) Financial Statement Schedules.

All schedules are omitted because the required information is inapplicable or the information is presented in the financial statements and the related notes.

(a)(3) Exhibits.

EXHIBIT INDEX

Exhibit Number	Description of Exhibit
3.1	Amended and Restated Certificate of Incorporation of the Registrant, dated April 3, 2018, incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K filed on April 10, 2018.
3.2	Certificate of Amendment of the Amended and Restated Certificate of Incorporation, dated January 31, 2024, incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K filed on January 31, 2024.
3.3	Certificate of Amendment of the Amended and Restated Certificate of Incorporation, dated October 16, 2025, incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K filed on October 17, 2025.
3.4	Amended and Restated Bylaws of the Registrant, dated April 3, 2018, incorporated by reference to Exhibit 3.2 of the Registrant's Current Report on Form 8-K filed on April 10, 2018.
3.5	Amendment No. 1 to the Amended and Restated Bylaws of the Registrant, adopted and approved by the Registrant's Board of Directors on October 18, 2023, incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K filed on October 23, 2023.
3.6	Amendment No. 2 to the Amended and Restated Bylaws of the Registrant, adopted and approved by Registrant's Board of Directors on March 29, 2025, incorporated by reference to Exhibit 3.5 of the Registrant's Annual Report on Form 10-K filed on April 1, 2025.
4.1	Form of Common Stock Certificate of the Registrant, incorporated by reference to Exhibit 4.1 of the Registrant's Registration Statement on Form S-1 (File No. 333-219386), as amended, originally filed on July 21, 2017.
4.2	Warrant Agreement, dated November 3, 2016, issued to Viet Ly, incorporated by reference to Exhibit 4.6 of the Registrant's Registration Statement on Form S-1 (File No. 333-219386), as amended, originally filed on July 21, 2017.
4.3	Warrant Agreement, dated July 27, 2018, issued to Cancer Revolution, LLC, incorporated by reference to Exhibit 4.1 of the Registrant's Current Report on Form 8-K filed on August 6, 2018.
4.4	Warrant Agreement, dated July 27, 2018, issued to Inception Capital Management, LLC, incorporated by reference to Exhibit 4.2 of the Registrant's Current Report on Form 8-K filed on August 6, 2018.
4.5	Warrant Agreement, dated July 27, 2018, issued to Cancer Biotech, LLC, incorporated by reference to Exhibit 4.3 of the Registrant's Current Report on Form 8-K filed on August 6, 2018.
4.6	Form of Warrant, incorporated by reference to Exhibit 10.2 of the Registrant's Current Report on Form 8-K filed on November 22, 2019.
4.7	Warrant Agreement, dated April 24, 2020, issued to Cancer Revolution LLC, incorporated by reference to Exhibit 4.1 of the Registrant's Current Report on Form 8-K filed on April 28, 2020.
4.8	Warrant Agreement, dated August 10, 2020, issued to Capital City Technical Consulting, Inc., incorporated by reference to Exhibit 4.11 of the Registrant's Annual Report on Form 10-K filed on March 26, 2021.
4.9	Form of Securities Purchase Agreement, dated February 8, 2021, incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed on February 9, 2021.

Exhibit Number	Description of Exhibit
4.10	Warrant Agreement, dated February 10, 2021, issued to Bear Creek Capital LLC, incorporated by reference to Exhibit 4.1 of the Registrant's Quarterly Report on Form 10-Q filed on May 17, 2021.
4.11	Form of Warrant Agreement, dated as of July 1, 2021, incorporated by reference to Exhibit 10.1 of the Registrant's Quarterly Report on Form 10-Q filed on November 15, 2021.
4.12	Warrant Agreement, dated as of July 1, 2022, issued to Bear Creek LLC, incorporated by reference to Exhibit 10.2 of the Registrant's Quarterly Report on Form 10-Q filed on August 12, 2022.
4.13	Form of Warrant, dated March 1, 2023, incorporated by reference to Exhibit 4.1 of the Registrant's Current Report on Form 8-K filed on February 27, 2023.
4.14	Form of Warrant, incorporated by reference to Exhibit 4.1 of the Registrant's Current Report on Form 8-K filed on July 19, 2023.
4.15	Form of Placement Agent Warrant, incorporated by reference to Exhibit 4.2 of the Registrant's Current Report on Form 8-K filed on July 19, 2023.
4.16	Form of Pre-Funded Warrant, incorporated by reference to Exhibit 4.1 of the Registrant's Current Report on Form 8-K filed on March 20, 2024.
4.17	Form of Warrant, incorporated by reference to Exhibit 4.2 of the Registrant's Current Report on Form 8-K filed on March 20, 2024.
4.18	Form of Placement Agent Warrant, incorporated by reference to Exhibit 4.3 of the Registrant's Current Report on Form 8-K filed on March 20, 2024.
4.19	Form of Warrant Amendment Agreement, incorporated by reference to Exhibit 4.4 of the Registrant's Current Report on Form 8-K filed on March 20, 2024.
4.20	Form of First Private Warrant, incorporated by reference to Exhibit 4.1 of the Registrant's Current Report on Form 8-K filed on October 24, 2025.
4.21	Form of First Placement Agent Warrant, incorporated by reference to Exhibit 4.2 of the Registrant's Current Report on Form 8-K filed on October 24, 2025.
4.22	Form of Second Private Warrant, incorporated by reference to Exhibit 4.1 of the Registrant's Current Report on Form 8-K filed on October 29, 2025.
4.23	Form of Second Placement Agent Warrant, incorporated by reference to Exhibit 4.2 of the Registrant's Current Report on Form 8-K filed on October 29, 2025.
4.24*	Description of Registrant's Securities.

Exhibit Number	Description of Exhibit
10.1+	Form of Indemnity Agreement, by and between the Company and its directors and officers, dated as of May 17, 2022, incorporated by reference to Exhibit 10.1 of the Registrant's Quarterly Report on Form 10-Q filed on August 12, 2022.
10.2+	Registrant's 2009 Equity Incentive Plan, including Form of Notice of Stock Option Grant, and Form of Stock Option Agreement thereunder, incorporated by reference to Exhibit 10.2 of the Registrant's Registration Statement on Form S-1 (File No. 333-219386), as amended, originally filed on July 21, 2017.
10.3+	Genprex, Inc. Form of Inducement Grant, incorporated by reference to Exhibit 10.4 of the Registrant's Annual Report on Form 10-K filed on April 1, 2024.
10.4+	Genprex, Inc. 2018 Employee Stock Purchase Plan, dated April 3, 2018, incorporated by reference to Exhibit 10.4 of the Registrant's Annual Report on Form 10-K filed April 17, 2018.
10.5*+	Genprex, Inc. Amended and Restated Outside Director Compensation Policy, adopted March 9, 2026.
10.6	Patent and Technology License Agreement, dated July 20, 1994, by and between the Board of Regents of the University of Texas System, The University of Texas M.D. Anderson Cancer Center and Intron Therapeutics, Inc., incorporated by reference to Exhibit 10.6 of the Registrant's Registration Statement on Form S-1 (File No. 333-219386), as amended, originally filed on July 21, 2017.
10.7	Amendment No. 3 to Patent and Technology License Agreement, dated October 4, 2001, incorporated by reference to Exhibit 10.7 of the Registrant's Registration Statement on Form S-1 (File No. 333-219386), as amended, originally filed on July 21, 2017.
10.8	Technology Sublicense Agreement, dated March 7, 2007, by and between Introgen Therapeutics, Inc., and Introgen Research Institute, Inc., incorporated by reference to Exhibit 10.8 of the Registrant's Registration Statement on Form S-1 (File No. 333-219386), as amended, originally filed on July 21, 2017.
10.9	Assignment and Collaboration Agreement, dated April 13, 2009, by and between Gensolve, Inc. and the Registrant, incorporated by reference to Exhibit 10.9 of the Registrant's Registration Statement on Form S-1 (File No. 333-219386), as amended, originally filed on July 21, 2017.
10.10	Technology Sublicense Agreement, dated June 1, 2011, by and between the Registrant and Introgen Research Institute, Inc., incorporated by reference to Exhibit 10.12 of the Registrant's Registration Statement on Form S-1 (File No. 333-219386), as amended, originally filed on July 21, 2017.
10.11	Amended Collaboration and Assignment Agreement, dated July 1, 2011, by and between Introgen Research Institute, Inc. and the Registrant, incorporated by reference to Exhibit 10.13 of the Registrant's Registration Statement on Form S-1 (File No. 333-219386), as amended, originally filed on July 21, 2017.
10.12+	Executive Employment Agreement, dated April 13, 2018, by and between the Registrant and Rodney Varner, incorporated by reference to Exhibit 10.16 of the Registrant's Annual Report on Form 10-K filed on April 17, 2018.
10.13+	Executive Employment Agreement, dated April 13, 2018, by and between the Registrant and Ryan Confer, incorporated by reference to Exhibit 10.17 of the Registrant's Annual Report on Form 10-K filed on April 17. 2018.

Exhibit Number	Description of Exhibit
10.14+	First Amendment to Executive Employment Agreement, dated as of June 24, 2024, by and between Genprex, Inc. and Ryan M. Confer, incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed on June 24, 2024.
10.15	Form of Securities Purchase Agreement, dated November 20, 2019, incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed on November 22, 2019.
10.16	Exclusive License Agreement, dated February 11, 2020, by and between the Registrant and the University of Pittsburgh – Of the Commonwealth System of Higher Education, incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed on February 18, 2020.
10.17	Form of Securities Purchase Agreement, dated February 19, 2020, incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed on February 20, 2020.
10.18++	Patent and Technology License Agreement, dated May 4, 2020, by and between the Registrant and The University of Texas M.D. Anderson Cancer Center, incorporated by reference to Exhibit 10.9 of the Registrant's Quarterly Report on Form 10-Q filed on May 14, 2020.
10.19++	Amendment No. 1 to Patent and Technology License Agreement, dated March 3, 2021, by and between the Registrant and The University of Texas M.D. Anderson Cancer Center, incorporated by reference to Exhibit 10.29 of the Registrant's Annual Report on Form 10-K filed on March 26, 2021.
10.20+	Offer Letter, dated September 27, 2021, by and between the Registrant and Mark S. Berger, M.D., incorporated by reference to Exhibit 10.1 of the Registrant's Form 8-K filed on September 28, 2021.
10.21++	First Amendment to Exclusive License Agreement, dated August 17, 2022, by and between Genprex, Inc. and the University of Pittsburgh - Of the Commonwealth System of Higher Education, incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed on August 22, 2022.

Exhibit Number	Description of Exhibit
10.22++	Second Amendment to Exclusive License Agreement, dated November 3, 2022, by and between Genprex, Inc. and the University of Pittsburgh - Of the Commonwealth System of Higher Education, incorporated by reference to Exhibit 10.24 of the Registrant's Annual Report on Form 10-K filed on April 1, 2024.
10.23++	Exclusive License Agreement, dated November 22, 2022, by and between Genprex, Inc. and the University of Pittsburgh - Of the Commonwealth System of Higher Education, incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed on November 28, 2022.
10.24++	Exclusive License Agreement, dated December 29, 2022, by and between Genprex, Inc. and the University of Pittsburgh - Of the Commonwealth System of Higher Education, incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed on January 5, 2023.
10.25	Form of Securities Purchase Agreement, dated March 1, 2023, incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed on February 27, 2023.
10.26++	Exclusive License Agreement, dated July 14, 2023, by and between Genprex, Inc. and the University of Pittsburgh - Of the Commonwealth System of Higher Education, incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed on July 18, 2023.
10.27	Form of Securities Purchase Agreement, incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed on July 19, 2023.
10.28	At The Market Offering Agreement, dated December 13, 2023, by and between Genprex, Inc. and H.C. Wainwright & Co., LLC, incorporated by reference to Exhibit 1.1 of the Registrant's Current Report on Form 8-K filed on December 13, 2023.
10.29	Form of Securities Purchase Agreement, incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed on March 20, 2024.
10.30++	Exclusive License Agreement, dated February 17, 2025, by and between Genprex, Inc. and the University of Pittsburgh - Of the Commonwealth System of Higher Education, incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed on February 18, 2025.
10.31***	Purchase Agreement, dated June 11, 2025, by and between Genprex, Inc. and Lincoln Park Capital Fund, LLC, incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed on June 11, 2025.
10.32***	Registration Rights Agreement, dated June 11, 2025, by and between Genprex, Inc. and Lincoln Park Capital Fund, LLC, incorporated by reference to Exhibit 10.2 of the Registrant's Current Report on Form 8-K filed on June 11, 2025.
10.33+	Genprex, Inc. 2018 Equity Incentive Plan (As Amended and Restated Effective June 30, 2025), incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed on August 15, 2025.
10.34+	Form of Notice of Stock Option Grant and Stock Option Agreement, incorporated by reference to Exhibit 10.3 to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2023 filed on April 1, 2024.
10.35+	Form of Notice of Restricted Stock Award and Restricted Stock Agreement, incorporated by reference to Exhibit 10.3 to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2023 filed on April 1, 2024.
10.36+	Form of Notice of Restricted Stock Unit Award and Restricted Stock Unit Agreement, incorporated by reference to Exhibit 10.3 to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2023 filed on April 1, 2024.

Exhibit Number	Description of Exhibit
10.37+	Form of Employee Stock Option Grant Notice and Option Agreement, incorporated by reference to Exhibit 10.3 to the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2023 filed on April 1, 2024.
10.38	Form of Purchase Agreement, incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed on October 24, 2025.
10.39	Form of Purchase Agreement, incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed on October 29, 2025.
19.1	Genprex, Inc. Insider Trading Policy, incorporated by reference to Exhibit 19.1 of the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2024 filed on April 1, 2025.
21.1*	Subsidiaries of the Registrant.
23.1*	Consent of WithumSmith+Brown, PC, Independent Registered Public Accounting Firm.
31.1*	Certification of Chief Executive Officer Pursuant to Rules 13a-14(a) of the Securities Exchange Act, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Chief Financial Officer Pursuant to Rules 13a-14(a) of the Securities Exchange Act, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1 **	Certification of Chief Executive Officer and Chief Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
97.1 +	Genprex, Inc. Compensation Recovery Policy, incorporated by reference to Exhibit 97.1 of the Registrant's Annual Report on Form 10-K filed on April 1, 2024.
101.INS*	Inline XBRL Instance Document.
101.SCH*	Inline XBRL Taxonomy Extension Schema Document.
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document.
101.PRE*	Inline XBRL Taxonomy Extension Presentation Document.
104*	Cover Page Interactive Data File (Formatted as Inline XBRL and contained in Exhibit 101).

* Filed herewith.
** Furnished herewith.
*** Annexes, schedules and/or exhibits have been omitted pursuant to Item 601(a)(5) of Regulation S-K. The Company hereby agrees to furnish supplementally a copy of any omitted attachment to the SEC on a confidential basis upon request.
\+ Indicates management contract or compensatory plan.
++ Pursuant to Item 601(b)(10) of Regulation S-K, certain confidential portions of this exhibit were redacted by means of marking such portions with an asterisk because the identified confidential portions (i) are not material and (ii) the type that registrant treats as private or confidential.

Item 16. Form 10–K Summary.

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this annual report on Form 10-K to be signed on its behalf by the undersigned, thereunto duly authorized**.**

GENPREX, INC.

Date: March 30, 2026

By: /s/ Ryan M. Confer
Ryan M. Confer
President, Chief Executive Officer and
Chief Financial Officer
(Principal Executive Officer and
Principal Financial and Accounting Officer)

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

Signature	Title	Date
/s/ Ryan M. Confer Ryan M. Confer	President, Chief Executive Officer and Chief Financial Officer and Member of the Board of Directors *(Principal Executive Officer and Principal Financial and Accounting Officer)*	March 30, 2026
/s/ Brent M. Longnecker Brent M. Longnecker	Member of the Board of Directors	March 30, 2026
/s/ Jose Antonio Moreno Toscano Jose Antonio Moreno Toscano	Chairman of the Board of Directors	March 30, 2026
/s/ Will R. Wilson, Jr. Will R. Wilson, Jr.	Member of the Board of Directors	March 30, 2026

GENPREX, INC.
INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of
Genprex, Inc:

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Genprex, Inc., (the "Company") as of December 31, 2025 and 2024, and 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, 2025, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of Genprex, Inc., as of December 31, 2025 and 2024, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2025, in conformity accounting principles generally accepted in the United States of America.

Substantial Doubt About the Company's Ability to Continue as a Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has an accumulated deficit at December 31, 2025 and, since inception, has suffered significant operating losses and negative cash flows from operations that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

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

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Genprex, Inc., 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 entity's internal control over financial reporting. Accordingly, we express no such opinion.

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

Critical Audit Matters

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

Accounting for Accrued Research and Development Costs

Critical Audit Matter Description

The Company records accrued expenses for estimated costs of research and development activities conducted by third-party service providers, which include the conduct of preclinical studies and clinical trials, and contract manufacturing activities. The Company records the estimated costs of research and development activities based upon the estimated amount of services provided and included the costs incurred but not yet invoiced within other accrued liabilities in the consolidated balance sheet and within research and development expense in the consolidated statement of operations. These costs can be a significant component of the Company's research and development expenses.

The Company estimates the amount of work completed through discussions with internal personnel and external service providers as to the progress of the services and the agreed-upon fee to be paid for such services. The Company makes estimates in determining the accrued balance in each reporting period. Clinical trial-related contracts vary in duration, and may be for a fixed amount, based on the achievement of certain contingent events or deliverables, a variable amount based on actual costs incurred, capped at a certain limit, or contain a combination of these elements. Estimates include costs associated with services provided by contract organizations for preclinical and clinical development and manufacturing of the Company's product candidates. In the case of clinical trials, the Company relies on estimates of the progress of the clinical trials and related expenses incurred. As actual costs become known, the Company adjust its accrued estimates.

We identified accrued research and development costs as a critical audit matter given the estimation involved in accounting for accrued research and development costs, as well as the material weaknesses identified by the Company in its internal controls over financial reporting. This required extensive audit effort related to the estimation of accrued research and development costs.

How the Critical Audit Matter Was Addressed in the Audit

Our audit procedures related to accrued research and development costs included the following: we obtained an understanding through inquiries and walkthrough procedures and evaluated the design and implementation of controls over the estimation of accrued preclinical studies, clinical trials, and manufacturing expenses. We also read a sample of research, collaboration, and manufacturing agreements and contracts, as well as amendments thereto. We performed a retrospective review of accruals to determine the reasonableness of management's estimation process.

We also evaluated publicly available information (such as press releases and investor presentations) and board of directors' materials regarding the status of preclinical studies, clinical trials, and manufacturing activities. For a selection of agreements and contracts, we compared the amount of accrual at the end of the prior period to current year activity and evaluated the accuracy of the Company's estimation methodology.

For the selection of agreements, we obtained a written confirmation of the status of clinical trials and manufacturing from the Company's third-party service providers. We also made selections of specific amounts recognized as research and development expense as well as those recognized as accrued expenses to evaluate management's estimate of the vendor's progress.

/s/ WithumSmith+Brown, PC
We have served as Genprex, Inc.'s auditor since 2023.
East Brunswick, New Jersey
March 30, 2026
PCAOB ID Number 100

Genprex, Inc.

Consolidated Balance Sheets

	Year Ended December 31,	
	2025	**2024**
Assets		
Current assets:		
Cash and cash equivalents	$ 7,830,855	$ 1,601,660
Prepaid expenses and other	525,928	475,807
Total current assets	8,356,783	2,077,467
Property and equipment, net	—	—
Research and development supplies	1,802,228	2,046,858
Total non-current assets	1,802,228	2,046,858
Total assets	$ 10,159,011	$ 4,124,325
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 743,070	$ 1,074,295
Other current liabilities	1,431,565	1,429,875
Total current liabilities	2,174,635	2,504,170
Non-current liabilities:		
Derivative liabilities	22,500	—
Total liabilities	2,197,135	2,504,170
Commitments and contingencies (Note 7)		
Stockholders' equity:		
Preferred stock $0.001 par value: 10,000,000 shares authorized; no shares issued and outstanding at December 31, 2025 and December 31, 2024, respectively	—	—
Common stock $0.001 par value: 200,000,000 shares authorized; 3,291,488 and 217,234 shares issued and outstanding at December 31, 2025 and December 31, 2024, respectively	3,291	217
Additional paid-in capital	178,986,981	156,419,381
Accumulated deficit	(171,028,396)	(154,799,443)
Total stockholders' equity	7,961,876	1,620,155
Total liabilities and stockholders' equity	$ 10,159,011	$ 4,124,325

See accompanying notes to the consolidated financial statements.

Genprex, Inc.

Consolidated Statements of Operations

	Year Ended December 31,	
	2025	**2024**
Operating expenses:		
Depreciation	$ —	$ 6,693
Research and development	9,428,720	10,535,446
General and administrative	6,086,899	10,632,028
Total operating expenses	15,515,619	21,174,167
Operating loss	(15,515,619)	(21,174,167)
Other income	26,900	63,574
Other financing costs	(739,935)	—
Realized and unrealized loss	(299)	(570)
Net loss	(16,228,953)	(21,111,163)
Deemed dividend related to warrant modification	—	(277,119)
Net loss attributable to common stockholders	$(16,228,953)	$(21,388,282)
Net loss per share applicable to common stockholders — basic and diluted	$ (17.40)	$ (266.89)
Weighted average number of common shares — basic and diluted	932,730	80,139

See accompanying notes to the consolidated financial statements.

Genprex, Inc.

Consolidated Statements of Changes in Stockholders' Equity

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total
	Shares	Amount			
Balance at December 31, 2023	29,735	$ 30	$141,104,634	$(133,688,280)	$ 7,416,384
Issuance of common stock, pre-funded warrants, and warrants, net of issuance costs	184,544	184	12,011,769	—	12,011,953
Issuance of common stock for services	1,028	1	206,984	—	206,985
Company issued rounding of fractional shares of street name accounts for reverse stock split	1,294	1	(1)	—	—
RSUs conversion to common stock	633	1	(2)	—	(1)
Share-based compensation	—	—	3,095,997	—	3,095,997
Deemed dividend related to warrant modification	—	—	(277,119)	—	(277,119)
Warrant modification	—	—	277,119	—	277,119
Net loss	—	—	—	(21,111,163)	(21,111,163)
Balance at December 31, 2024	217,234	$ 217	$156,419,381	$(154,799,443)	$ 1,620,155
Issuance of common stock, pre-funded warrants, and warrants, net of issuance costs	2,996,759	2,997	22,254,842	—	22,257,839
Issuance of common stock for services	400	—	7,948	—	7,948
Company issued rounding of fractional shares of street name accounts for reverse stock split	75,310	75	(75)	—	—
RSUs conversion to common stock	1,785	2	(2)	—	—
Share-based compensation	—	—	304,887	—	304,887
Net loss	—	—	—	(16,228,953)	(16,228,953)
Balance at December 31, 2025	3,291,488	$ 3,291	$178,986,981	$(171,028,396)	$ 7,961,876

See accompanying notes to the consolidated financial statements.

Genprex, Inc.

Consolidated Statements of Cash Flows

	Year Ended December 31,	
	2025	**2024**
Cash flows from operating activities:		
Net loss	$(16,228,953)	$(21,111,163)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	—	6,693
Share-based compensation and issuance of stock for services	312,835	3,302,982
Non cash financing costs	739,935	—
Changes in operating assets and liabilities:		
Prepaid expenses and other	(50,120)	328,330
Research and development supplies	244,630	300,630
Accounts payable	(331,226)	(323,315)
Other current liabilities	1,690	(426,723)
Net cash used in operating activities	(15,311,209)	(17,922,566)
Cash flows from investing activities:		
Disposals of property and equipment	—	1,166
Reductions to intellectual property	—	773,478
Net cash provided by investing activities	—	774,644
Cash flows from financing activities:		
Net proceeds from issuances of common stock	21,540,404	12,011,953
Net cash provided by financing activities	21,540,404	12,011,953
Net increase (decrease) in cash and cash equivalents	6,229,195	(5,135,969)
Cash and cash equivalents, beginning of year	1,601,660	6,737,629
Cash and cash equivalents, end of year	$ 7,830,855	$ 1,601,660
Supplemental schedule of non-cash investing and financing activities:		
Deemed dividend related to warrant modification	$ -	$ (277,119)

See accompanying notes to the consolidated financial statements.

Note 1 – Description of Business and Basis of Presentation

Genprex, Inc. ("Genprex" or the "Company"), incorporated in Delaware in April 2008, is a clinical stage gene therapy company pioneering the development of gene-based therapies for large patient populations with unmet medical needs. The Company's oncology platform utilizes its systemic, non-viral ONCOPREX® Delivery System which uses lipid-based nanoparticles in a lipoplex form to deliver tumor suppressor gene-expressing plasmids to cancer cells. The product is administered intravenously, where it is taken up by tumor cells that then express tumor suppressor proteins that were deficient in the tumor. The Company's diabetes technology is designed to work in Type 1 diabetes by transforming alpha cells in the pancreas into functional beta-like cells, which can produce insulin but may be distinct enough from beta cells to evade the body's immune system. In Type 2 diabetes, the Company's technology is believed to work by replenishing and rejuvenating exhausted beta cells that make insulin.

Oncology Platform

Genprex's lead oncology drug candidate, REQORSA® Gene Therapy (generic name: *quaratusugene ozeplasmid*), previously referred to as GPX-001, is initially being developed in combination with prominent, approved cancer drugs to treat Non-Small Cell Lung Cancer ("NSCLC") and Small Cell Lung Cancer ("SCLC"). REQORSA has multimodal effects on cancer cells. It harms the metabolism of cancer cells, which leads to reduced cancer cell growth. It has a mechanism of action whereby it decreases tumor glucose metabolism, interrupts cell signaling pathways that cause replication and proliferation of cancer cells, re-establishes pathways for apoptosis, or programmed cell death, in cancer cells, and increases the immune response against cancer cells. In preclinical studies, REQORSA has been shown to be complementary with targeted drugs and immunotherapies. The Company's strategy is to develop REQORSA in combination with currently approved therapies, and the Company believes REQORSA's unique attributes position it to provide treatments that improve on these current therapies for patients with NSCLC, SCLC, and possibly other cancers.

The TUSC2 gene, which is the key component of REQORSA and plays a vital role in cancer suppression and normal cell metabolism, is one of a series of genes on the short arm of Chromosome 3 whose therapeutic use is covered by the Company's exclusive worldwide licenses from The University of Texas MD Anderson Cancer Center ("MD Anderson"). The Company believes that its ONCOPREX Delivery System allows for the delivery of a number of cancer-fighting tumor suppressor genes, alone or in combination with other cancer therapies, to combat multiple types of cancer and the Company is in early stages of discovery programs to identify other cancer candidates. In August 2022, the Company entered into a sponsored research agreement with MD Anderson to support further preclinical studies of TUSC2 and other tumor suppressor genes. As further described in the "Discovery Programs" section of "Part I, Item 1. Business" of this Annual Report on Form 10-K above, since not all patients respond to REQORSA, the Company has been collaborating with researchers at MD Anderson to identify biomarkers that might predict a strong positive or negative response to REQORSA in patients with lung cancer. This preclinical effort has led to the identification of two proteins whose expression appears to predict response to REQORSA. Validation in specimens from clinical trials will be needed to determine whether these potential biomarkers predict clinical response. The Company plans to test patient samples from our clinical trials for selected biomarkers to determine if sensitivities exist among the Company's existing patient population in an effort to guide patient selection and improve clinical outcomes.

Acclaim – 1: The Company currently is enrolling and treating patients in the Phase 2a expansion portion of its Phase 1/2 Acclaim-1 clinical trial. The Acclaim-1 trial uses a combination of REQORSA and AstraZeneca's Tagrisso® (*osimertinib*) in patients with late-stage NSCLC that has activating epidermal growth factor receptor ("EGFR") mutations and progression on treatment with Tagrisso or Tagrisso-containing regimens. Following the May 2023 completion of the Phase 1 dose escalation portion of the study, the Acclaim-1 Safety Review Committee ("Acclaim-1 SRC") approved advancement from the Phase 1 dose escalation portion to the Phase 2a expansion portion of the study. Based on a review of safety data which showed no dose limiting toxicities ("DLTs"), the Acclaim-1 SRC determined the recommended Phase 2 dose ("RP2D") of REQORSA to be 0.12 mg/kg administered every 21 days. This was the highest dose level delivered in the Phase 1 portion of the study and is twice the highest dose level delivered in the Company's prior clinical trial combining REQORSA with Tarceva® (*erlotinib*) for the treatment of late-stage lung cancer. There were three patients out of the twelve originally enrolled in the Phase 1 dose escalation portion of the study who had prolonged progression-free survival ("PFS"). One patient attained a partial remission after the second course of REQORSA and Tagrisso and has maintained this response

through 60 courses of treatment (approximately 42 months) and this patient continues to receive REQORSA and Tagrisso treatment to date. A second patient had stable disease without disease progression through 32 courses of treatment (approximately 24 months), but then had disease progression and REQORSA treatment was stopped. A third patient had stable disease without disease progression through 14 courses of treatment (approximately 10 months) before disease progression and is no longer receiving treatment. The results of the Phase 1 dose escalation portion of the study were published in *Clinical Lung Cancer*, a peer-reviewed journal covering various aspects of clinical and translational research of lung cancer, in January 2026. Genprex opened the Phase 2a expansion portion of the study and enrolled and dosed the first patient in January 2024. The Phase 2a expansion portion of the trial is expected to enroll approximately 33 patients; all of whom have progressed on Tagrisso or Tagrisso-containing regimens. There will be an interim analysis following the treatment of 19 patients in the Phase 2a portion of the Acclaim-1 study. The Phase 2b randomized portion of the study, in which patients progressing on prior Tagrisso treatment will be randomized 1:1 to either REQORSA and Tagrisso combination therapy or to platinum-based chemotherapy, remains unchanged. The Company expects to complete the enrollment of the first 19 patients for interim analysis in the Phase 2a expansion portion of the study in the first half of 2026 and expects the interim analysis in the second half of 2026.

The Food and Drug Administration ("FDA") has granted Fast Track Designation for the Acclaim-1 treatment combination of REQORSA and Tagrisso in NSCLC patients who have progressed on Tagrisso treatment.

The Phase 2a expansion portion of the Acclaim-1 study provides the Company the advantage of early insight into drug effectiveness in defined and distinct patient populations at the maximum tolerated dose (the "MTD") or RP2D in order to better evaluate efficacy and increase the likelihood of a successful randomized Phase 2 trial which will follow the expansion portion of the study.

Acclaim – 2: The Acclaim-2 trial involved a combination of REQORSA and Merck & Co.'s Keytruda® (*pembrolizumab*) in patients with late-stage NSCLC whose disease has progressed after treatment with Keytruda. As previously announced in August 2024, based on a number of factors, including enrollment challenges and delays due to competition for investigators and eligible patients with numerous other trials involving the same patient population, the Company decided to cease enrollment of new patients in the Acclaim-2 trial to prioritize its resources and focus on the other two Acclaim trials in SCLC and NSCLC, respectively. There are no longer any patients receiving study treatment in the Acclaim-2 trial. Although the Acclaim-2 study in patients progressing on Keytruda containing regimens has been closed due to, among other factors, slow enrollment, the Company continues to believe that this combination could be beneficial.

Acclaim – 3: The Company is currently enrolling and treating patients in the Phase 2 expansion portion of its Phase 1/2 Acclaim-3 clinical trial. The Acclaim-3 clinical trial uses a combination of REQORSA and Genentech, Inc.'s Tecentriq® (*atezolizumab*) as maintenance therapy for patients with extensive stage small cell lung cancer ("ES-SCLC") who did not develop tumor progression after receiving Tecentriq and chemotherapy as initial standard treatment. Patients are treated with REQORSA and Tecentriq until disease progression or unacceptable toxicity is experienced. In December 2024, the Company announced that it had completed the Phase 1 dose escalation portion of the Acclaim-3 clinical trial. Based on full safety data, which showed no DLTs, the Acclaim-3 Safety Review Committee ("Acclaim-3 SRC") determined that the RP2D of REQORSA will be 0.12 mg/kg administered every 21 days, which was the highest dose level delivered in the Phase 1 portion of the trial, and approved the opening of the Phase 2 expansion portion of the trial. Although decreases in tumor size are not expected during maintenance therapy with atezolizumab alone, there were two patients out of the six enrolled in the Phase 1 dose escalation portion of the study who had marked decreases in measurable disease. The Company previously reported that the first patient treated in the Phase 1 dose escalation portion of the Acclaim-3 trial had a partial remission, which is defined as at least a thirty percent (30%) decrease in tumor size, from prior to the start of maintenance therapy to the time of the CT scan performed after two cycles of maintenance therapy. A CT scan performed after four cycles of maintenance therapy (three months), confirmed that the patient still had a 30% decrease in tumor size in measurable lesions; however, one lesion not previously measurable had grown in size, thus leading to a conclusion of disease progression at that time. Another patient in the Phase 1 dose escalation portion of the Acclaim-3 trial had a twenty-three percent (23%) decrease in tumor size from prior to the start of maintenance therapy to the time of the CT scan performed after two cycles of maintenance therapy. This patient received seven cycles of study therapy before progressing after 4.2 months. In addition, one patient in the Phase 1 dose escalation portion of the study achieved an unconfirmed partial remission after 24 cycles of therapy and continues to receive study treatment in the trial after more than 18 months. The Company anticipates that the Phase 2 expansion portion will enroll approximately 50 patients at approximately 10 to 15 U.S. sites. Patients will be treated with REQORSA and Tecentriq until disease progression or unacceptable toxicity is experienced. The primary endpoint of the Phase 2 portion is to determine the 18-week progression-free survival rate from the time of the start of maintenance therapy with REQORSA and Tecentriq in patients with ES-SCLC. Patients will also be followed for survival. A Phase 2 futility analysis will be performed after the 25th patient enrolled and treated reaches 18 weeks of follow up. The Company expects to complete enrollment of the first 25 patients for interim analysis in the Phase 2 expansion portion of the study in the first half of 2026 and expects the interim analysis in the second half of 2026.

The Acclaim-3 clinical trial has received FDA Fast Track Designation for this patient population and Acclaim-3 has also received an FDA Orphan Drug Designation.

Diabetes Gene Therapy

In diabetes, Genprex has exclusively licensed from the University of Pittsburgh of the Commonwealth System of Higher Education ("University of Pittsburgh" or "UP") multiple technologies relating to the development of a gene therapy product for each of Type 1 and Type 2 diabetes. The same novel approach is used in each of Type 1 and Type 2 diabetes whereby an adeno-associated virus ("AAV") vector containing the Pdx1 and MafA genes is administered directly into the pancreatic duct. In humans, this can be done with a routine endoscopy procedure. The Company's diabetes product candidates are currently being evaluated and optimized in preclinical studies at the University of Pittsburgh. GPX-002 is being developed for the treatment of both Type 1 diabetes and Type 2 diabetes. GPX-002 for Type 1 diabetes is designed to work by transforming alpha cells in the pancreas into functional beta-like cells, which can produce insulin but may be distinct enough from beta cells to evade the body's immune system. In a similar approach, GPX-002 for Type 2 diabetes, where autoimmunity is not at play, is believed to work by replenishing and rejuvenating exhausted beta cells that make insulin. The Company is currently working with the University of Pittsburgh on species analyses for the animal models as well as other regulatory and clinical strategic planning, including the initiation of research in Type 2 diabetes animal models. In December 2025, the Company also executed on its strategic goal to submit a meeting request to the FDA by the end of the year to discuss the necessary Investigational New Drug ("IND")-enabling preclinical studies, an important step before potentially initiating clinical trials in humans. See the "Recent Developments" section of "Part I, Item 1. Business" of this Annual Report on Form 10-K above for more information on the Company's meeting with the FDA which occurred in February 2026. In May 2025, following the completion of the Company's August 2022 sponsored research agreement with UP, the Company entered into a new sponsored research agreement with UP to study Type 1 diabetes and Type 2 diabetes in animal models. The new sponsored research agreement also includes a revised research plan to encompass the Company's most recent technologies to which Genprex originally acquired exclusive rights from UP in July 2023 as amended and restated in the comprehensive New UP License Agreement in February 2025 (as defined and described below). These include a MafB promoter to drive expression of the Pdx1 and MafA transcription factors that can potentially be used for both Type 1 and Type 2 diabetes. See also "Note 7 – Commitments and Contingencies".

On February 17, 2025, the Company and the University of Pittsburgh entered into an amended and restated Exclusive License Agreement (the "New UP License Agreement"), which updated and consolidated into a single agreement the Company's prior license agreements with UP. Pursuant to the New UP License Agreement, UP granted to the Company a worldwide, exclusive license for certain patents and related technology, collectively referred to as the "Licensed Technology," and a worldwide, non-exclusive license to use certain related know-how. The Licensed Technology covered by the New UP License Agreement is based on the same general gene therapy approach as covered under the Company's prior license agreements with UP (less the previously-licensed macrophage technology), whereby an adeno-associated virus vector containing the Pdx1 and MafA genes is administered directly into the pancreatic duct. More specifically, the Licensed Technology covered by the New UP License Agreement is related to a gene therapy for both Type 1 diabetes and Type 2 diabetes using the genes of the Pdx1 and MafA transcription factors controlled by insulin, glucagon and MafB promoters.

In February 2023, the Company's research collaborators at UP presented preclinical data in a non-human primate ("NHP") model of Type 1 diabetes highlighting the therapeutic potential of GPX-002 at the 16th International Conference on Advanced Technologies & Treatments for Diabetes (ATTD 2023) in Berlin, Germany. The statistically significant study results showed the treated animals had decreased insulin requirements, increased c-peptide levels, and improved glucose tolerance compared to baseline. In April 2023, the Company hosted a Key Opinion Leader virtual event entitled "Novel Gene Therapy to Treat Type 1 Diabetes," which discussed preclinical data reported at ATTD 2023 supporting gene therapy to treat Type 1 diabetes. In June 2025, the Company's collaboration partners had two presentations at the 2025 American Diabetes Association ("ADA") 85th Scientific Sessions. The Company's research collaborators from UP were invited to give an oral presentation highlighting their work in NHP models of Type 1 diabetes. In addition, the Company's contract development and manufacturing organization collaborators presented a poster on a non-viral lipid nanoparticle delivery system that would allow a patient to receive multiple treatments.

Formation of Wholly Owned Subsidiary

On February 18, 2025, Genprex announced the formation of a wholly-owned subsidiary, Convergen Biotech, Inc. ("Convergen") in connection with a potential separation of the diabetes clinical development program. If, and when, a potential separation is completed, the Company would plan to transfer the diabetes program into Convergen in an effort to focus development and commercialization efforts separately from the Company's oncology program and other oncology pipeline assets.

Capital Requirements, Liquidity and Going Concern Considerations

The Company's consolidated financial statements are prepared in accordance with accounting principles generally accepted in the United States of America ("US GAAP") applicable to a going concern, which contemplates the realization of assets and liquidation of liabilities in the normal course of business. However, the Company has sustained substantial losses from operations since inception and has no current source of revenue. In addition, the Company has used, rather than provided, cash in its operations. Genprex expects to continue to incur significant expenditures to further clinical trials for the commercial development of its patents.

The Company recognizes that it must obtain additional capital resources to successfully commercialize its product candidates. To date, Genprex has received funding in the form of equity and debt, and the Company plans to seek additional funding in the future. However, no assurances can be given that it will be successful in raising additional capital. If the Company is not able to timely and successfully raise additional capital, the timing of its clinical trials, financial condition and results of operations may be materially and adversely affected. These consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts and classification of liabilities.

Genprex believes that its current cash and cash equivalents will be sufficient to fund expenditure requirements for its necessary operations and expected clinical trial activities into the second quarter of 2027. Genprex has based these estimates, however, on assumptions that may prove to be wrong, and could spend available financial resources much faster than it currently expects. The Company will need to raise additional funds to continue funding its development and operations. The Company plans to secure such additional funding and is evaluating various strategies to obtain additional financing, although the Company can give no assurance that its plans or strategies will be effectively implemented in such a way that they will sufficiently alleviate or mitigate the conditions and events noted above.

As a result of its recurring losses from operations and the need for additional financing to fund its operating and capital requirements, there is uncertainty regarding the Company's ability to maintain liquidity sufficient to operate its business effectively, which raises substantial doubt as to the Company's ability to continue as a going concern. These consolidated financial statements do not include any adjustments that might be necessary if Genprex is unable to continue as a going concern.

Note 2 – Summary of Significant Accounting Policies

Genprex's consolidated financial statements have been prepared in accordance with US GAAP. Accordingly, they do not include all the information and footnotes required by US GAAP for complete financial statements. In the Company's opinion, the consolidated financial statements include all adjustments (consisting of normal recurring accruals) necessary to make the consolidated financial statements not misleading. The results of operations for any interim periods are not necessarily indicative of results to be expected for the full year. A summary of the Company's significant accounting policies consistently applied in the preparation of the accompanying consolidated financial statements follows.

Principles of Consolidation

The accompanying consolidated financial statements, which include the accounts of the Company and its wholly-owned subsidiary, Convergen Biotech, Inc., have been prepared in accordance with US GAAP. All significant intercompany balances and transactions are eliminated in consolidation. As of December 31, 2025, Convergen Biotech, Inc. has yet to initiate operating activity.

Change in Accounting Principle

During the year ended December 31, 2024, the Company changed an accounting principle related to accounting treatment of intellectual property expenditures. Previously, the Company capitalized certain intellectual property costs associated with the filing or maintenance of specific patents, including application costs, filing fees, and patent prosecution, in accordance with Accounting Standards Codification ("ASC") 350-30. The Company voluntarily changed this accounting principle to expense, rather than capitalize, these intellectual property costs on the basis that the new treatment is favorable.

Reverse Stock Splits

On February 2, 2024, Genprex completed a 1-for-40 reverse stock split ("2024 Reverse Split") of its issued and outstanding shares of common stock. On October 21, 2025, Genprex completed a 1-for-50 reverse stock split ("2025 Reverse Split" and together with the 2024 Reverse Stock Split, the "Reverse Splits") of its issued and outstanding shares of common stock. The Reverse Splits did not change the number of authorized shares of common stock or par value of the common stock. All references in these consolidated financial statements to shares, share prices, exercise prices, and other per share information in all periods have been adjusted, on a retroactive basis, to reflect the Reverse Splits (See "Note 4 – Equity – Reverse Stock Splits").

Use of Estimates

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

Cash and Cash Equivalents

Genprex considers all highly liquid short-term investments with an initial maturity of three months or less to be cash equivalents. Any amounts of cash in financial institutions which exceed Federal Deposit Insurance Corporation ("FDIC") insured limits expose the Company to cash concentration risk. Genprex has cash in a money market account and had $7,580,820 and $1,351,625 in excess of FDIC insured limits of $250,000 at December 31, 2025 and 2024, respectively. Any loss incurred or a lack of access to such funds could have a significant adverse impact on the Company's financial condition, results of operations, and cash flows.

Net Loss Per Share

Basic net loss per share is calculated by dividing the net loss by the weighted-average number of shares of common stock outstanding for the period, without consideration for potential dilutive shares of common stock, which includes common stock equivalents consisting of (i) 5,705 unexercised options granted by the Company's board of directors and warrants to purchase shares of common stock, and (ii) 141,360 unvested restricted stock units to purchase shares of common stock granted by the Company's board of directors as of December 31, 2025.

Segments

Operating segments are defined as components of an entity for which separate discrete financial information is made available and that is regularly evaluated by the chief operating decision maker ("CODM") in making decisions regarding resource allocation and assessing performance. The Company's CODM is its Chief Executive Officer and the Company manages its operations as a single segment for the purposes of assessing performance and making operating decisions. The Company is focused on pioneering the discovery and development of gene therapies for use in patient populations with unmet medical needs. See "Note 8 – Segment Reporting" for additional disclosures related to segment reporting.

Fair Value of Financial Instruments

The carrying amounts reported in the balance sheets for cash, money-market savings account, accounts receivable, and accounts payables approximate fair value because of the immediate or short-term maturity of these financial instruments.

ASC 820, *Fair Value Measurements and Disclosures*, defines fair value, provides a consistent framework for measuring fair value under US GAAP and expands fair value financial statement disclosure requirements. ASC 820's valuation techniques are based on observable and unobservable inputs. Observable inputs reflect readily obtainable data from independent sources, while unobservable inputs reflect the Company's market assumptions. ASC 820 classifies these inputs into the following hierarchy:

Level 1: Quoted prices for identical instruments in active markets.

Level 2: Quoted prices for similar instruments in active markets; quoted prices for identical or similar instruments in markets that are not active; and model-derived valuations whose inputs are observable or whose significant value drivers are observable.

Level 3: Instruments with primarily unobservable value drivers.

Property and Equipment

Property and equipment are stated at cost less accumulated depreciation. Depreciation is calculated using the straight-line method over the estimated useful lives of the assets, which range from three to five years. Routine maintenance and repairs are charged to expense as incurred and major renovations or improvements are capitalized.

Research and Development Materials Costs

Research and development expenditures consist of costs incurred to conduct research, develop engineering materials for further study, and develop clinical strategies for current and future programs associated with the Company's preclinical and Phase 1/2 clinical trials. These expenditures are expensed in the period incurred and include payments to collaborative research partners, manufacturing partners and consultants, and clinical strategy partners, wages and associated employee benefits, facilities, and overhead costs.

Materials acquired to be used in clinical research, that have an alternative future use, are capitalized when the materials are acquired, and included in research and development supplies. These supplies are recognized as expense as they are consumed through use for testing or clinical activities, or have spoiled. The costs of materials that were acquired for a particular research and development activity and have no alternative future use are expensed in the period acquired.

Research and development supplies purchased and capitalized for future use were $1,802,228 and $2,046,858 at December 31, 2025 and 2024, respectively.

Intellectual Property

Intellectual property consists of legal and related costs associated with patents, trademarks, and other proprietary technology and rights developed, acquired, or licensed by Genprex. Costs related to filing and pursuing patent applications are expensed as incurred, as recoverability of such expenditures is uncertain. These patent-related legal costs are reported as a component of general and administrative expenses.

Accounting for Stock-Based Compensation

Genprex uses the fair value-based method of accounting for stock-based compensation for options granted to employees, independent consultants and contractors. The Company measures options granted at fair value determined as of the grant date and recognizes the expense over the periods in which the options vest or are expected to vest and related services are rendered based on the terms and conditions of the award. Generally, where the award only has a service condition, the requisite service period is the same as the vesting period.

Long-Lived Assets

Genprex reviews long-lived assets and certain identifiable intangibles held and used for possible impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. In evaluating the fair value and future benefits of its intangible assets, the Company performs an analysis of the anticipated undiscounted future net cash flow of the individual assets over the remaining amortization period. The Company recognizes an impairment loss if the carrying value of the asset exceeds the discounted expected future cash flows. During the years ended December 31, 2025 and 2024, there were no deemed impairments of the Company's long-lived assets.

Derivative Liability

The Company evaluates all features contained in financing agreements to determine if there are any embedded derivatives that require separate accounting from the underlying agreement under ASC 815, – *Derivatives and Hedging*. An embedded derivative that requires separation is accounted for as a separate asset or liability from the host agreement. The derivative asset or liability is accounted for at fair value, with changes in fair value recognized in the statements of operations within the other financing costs line item. The Company determined that certain features under the Equity Line of Credit (see Note 4 – Equity – Equity Line of Credit) qualified as an embedded derivative. The derivative liability is accounted for separately from the Equity Line of Credit Purchase Agreement and is accounted for at fair value. $22,500 has been recorded on the accompanying consolidated balance sheet as of December 31, 2025, related to this derivative liability.

Modification of Equity Classified Warrants

A change in the terms or conditions of a warrant is accounted for as a modification. For a warrant modification accounted for under ASC 815, the effect of a modification shall be measured as the difference between the fair value of the modified warrant over and the fair value of the original warrant immediately before its terms are modified, with each measured on the modification date. The accounting for any incremental fair value of the modified warrants over the original warrants is based on the specific facts and circumstances related to the modification. When a modification is directly attributable to an equity offering, the incremental change in fair value of the warrants is accounted for as an equity issuance cost. When a modification is directly attributable to a debt financing, the incremental change in fair value of the warrants is accounted for as a debt discount or debt issuance cost. For all other modifications, the incremental change in fair value is recognized as a deemed dividend. The Company recognized a modification of an equity classified warrant as a deemed dividend for the year ended December 31, 2024. There were no modifications of equity classified warrants during the year ended December 31, 2025.

Recent Accounting Developments

Accounting pronouncements issued but not effective until after December 31, 2025 are not expected to have a significant effect on the Company's financial condition, results of operations, or cash flows.

In December 2023, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures*, which modifies the rules on income tax disclosures to require disaggregated information about a reporting entity's effective tax rate reconciliation as well as information on income taxes paid. The standard is intended to benefit investors by providing more detailed income tax disclosures that would be useful in making capital allocation decisions. The guidance is effective for annual periods beginning after December 15, 2024, with early adoption permitted. The Company adopted the standard effective January 1, 2025 and there was no material impact to our consolidated financial statements.

In December 2025, the FASB issued ASU 2025-11, *Interim Reporting (Topic 270): Narrow-Scope Improvements*, which is intended to clarify the applicability of interim reporting guidance, the types of interim reporting and the form and content of interim GAAP financial statements. ASU 2025-11 will be effective for our fiscal year beginning on September 1, 2028 and we are currently evaluating the impact it may have on our interim condensed consolidated financial statements.

Note 3 – Intellectual Property

As of December 31, 2025, Genprex owned or had exclusive license agreements on 15 granted patents and 28 pending patent applications worldwide for technologies developed in-house or by researchers at the National Cancer Institute, New York University, The University of Texas MD Anderson Cancer Center, the University of Texas Southwestern Medical Center, the University of Texas Health Sciences Center at Houston, the University of Michigan, and the University of Pittsburgh. These patents comprise various therapeutic, diagnostic, technical and processing claims and costs are expensed as incurred. These license rights will be amortized on a straight-line basis over the estimated period of useful lives of the underlying patents or the license agreements.

University of Pittsburgh

On February 17, 2025, Genprex and the University of Pittsburgh entered into an amended and restated Exclusive License Agreement (the "New UP License Agreement") to update and consolidate, into a single agreement, prior license agreements and licensed technologies covered by the prior University of Pittsburgh agreements related to a gene therapy for both Type 1 diabetes and Type 2 diabetes using the genes of the Pdx1 and MafA transcription factors controlled by insulin, glucagon and MafB promoters. As of February 17, 2025, the New UP License Agreement effectuates the termination of, and amends, restates, replaces and supersedes in their entirety, the prior license agreements between Genprex and the University of Pittsburgh which were effective as of February 10, 2020 (as amended August 17, 2022 and November 3, 2022), December 29, 2022 and July 14, 2023. Genprex also terminated, effective February 17, 2025, a prior agreement with UP related to a license for macrophage technology dated November 22, 2022.

The University of Texas MD Anderson Cancer Center

On May 4, 2020, Genprex entered into an exclusive worldwide license agreement with The Board of Regents of the University of Texas System on behalf of MD Anderson relating to a portfolio of patent applications and related technology for the treatment of cancer using the Company's lead drug candidate and immunotherapies. See "Note 7 - Commitments and Contingencies - Commitments - MD Anderson" for information on additional agreements involving MD Anderson licensed rights and technologies.

University of Michigan

On November 11, 2024, Genprex and the Regents of the University of Michigan ("UM" or the "University of Michigan") entered into a Patent License Agreement ("UM License Agreement"), which granted Genprex a worldwide, exclusive license to the University of Michigan's patent rights in a co-owned patent application relating to the use of REQORSA in combination with ALK-inhibitors for the treatment of ALK-EML4 positive translocated lung cancer.

New York University

On April 25, 2025, Genprex and New York University ("NYU") entered into a License Agreement (the "NYU License Agreement"), which granted Genprex exclusive patent and commercial rights worldwide relating to Genprex's lead drug candidate REQORSA for the potential treatment of mesothelioma.

University of Texas Health Sciences Center at Houston

On May 2, 2025, Genprex and the Board of Regents of The University of Texas System on behalf of The University of Texas Health Sciences Center at Houston ("UTHealth Houston" or "UTH") entered into a Patent and Technology License Agreement (the "UTH License Agreement"), which granted Genprex exclusive patent and commercial rights worldwide relating to Genprex's lead drug candidate REQORSA for the potential treatment of glioblastoma.

Note 4 – Equity

Reverse Stock Splits

On February 2, 2024, Genprex completed a 1-for-40 Reverse Split of its issued and outstanding shares of common stock. The 2024 Reverse Split did not change the number of authorized shares of common stock or the par value of the common stock. All references in these consolidated financial statements to shares, share prices, exercise prices, and other per share information in all periods have been adjusted, on a retroactive basis, to reflect the 2024 Reverse Split.

On October 21, 2025, Genprex completed a 1-for-50 Reverse Split of its issued and outstanding shares of common stock. The 2025 Reverse Split did not change the number of authorized shares of common stock or the par value of the common stock. All references in these consolidated financial statements to shares, share prices, exercise prices, and other per share information in all periods have been adjusted, on a retroactive basis, to reflect the 2025 Reverse Split.

Registered Direct Offerings

On March 21, 2024, the Company completed a registered direct offering priced at the market under Nasdaq rules, in which the Company sold to an institutional investor an aggregate of (i) 3,300 shares of common stock, (ii) pre-funded warrants (the "March 2024 Pre-Funded Warrants") exercisable for up to an aggregate of 27,543 shares of common stock, and (iii) warrants (the "March 2024 Common Warrants") exercisable for up to an aggregate of 30,843 shares of common stock. The offering price for each share of common stock and accompanying March 2024 Common Warrant was $210.75, and the offering price for each March 2024 Pre-Funded Warrant and accompanying March 2024 Common Warrant was $210.75. The March 2024 Pre-Funded Warrants were exercisable immediately upon issuance at an exercise price of $0.005 per share and expired when exercised in full. The March 2024 Common Warrants are exercisable immediately upon issuance at an exercise price of $204.50 per share and will expire in five years from the date of issuance. The Company received net proceeds of approximately $5.9 million after commissions and expenses, excluding any proceeds received from any exercise of the March 2024 Common Warrants. In connection with the offering, the Company also amended certain existing warrants to purchase up to an aggregate of 3,886 shares of common stock that were previously issued to investors in March 2023 and July 2023, with exercise prices of $2,200.00 and $1,770.00 per share and expiration dates of March 1, 2028 and July 21, 2028 for $6.25 per amended warrant, such that the amended warrants have a reduced exercise price of $204.50 per share and an expiration date of five years from the closing of the March 2024 offering. As of December 31, 2024, all of the 27,543 March 2024 Pre-Funded Warrants had been exercised for shares of common stock.

On October 24, 2025, Genprex completed a registered direct offering priced at-the-market under Nasdaq rules (the "October 2025 Registered Direct Offering I"), pursuant to which the Company issued an aggregate of 243,622 shares of common stock at a purchase price of $11.21 per share. In a concurrent private placement (the "October 2025 Private Placement I", and together with the October 2025 Registered Direct Offering I, the "October 2025 Financing I"), the Company issued warrants (the "October 2025 Private Warrants I") exercisable for up to an aggregate of 487,244 shares of common stock (the "October 2025 Private Warrant Shares I") at an exercise price of $11.00 per share. The October 2025 Private Warrants I are exercisable immediately upon issuance and will expire on December 12, 2027. Also, the Company agreed to issue to H.C. Wainwright & Co., LLC (the "Placement Agent") or its designees warrants to purchase up to an aggregate of 14,617 shares of common stock. The warrants issued to the Placement Agent or its designees have substantially the same terms as the October 2025 Private Warrants I except that the warrants issued to the Placement Agent or its designees have an exercise price of $14.0125 per share and a termination date of December 12, 2027. The net proceeds of the October 2025 Financing I, after deducting the placement agent's fees and expenses and other estimated October 2025 Registered Direct Offering I expenses payable by the Company and excluding the net proceeds, if any, from the exercise of the October 2025 Private Warrants I, were approximately $2.5 million. Additionally, if the holders of October 2025 Private Warrants I exercise such warrants in full, the Company would receive additional gross proceeds of approximately $5.4 million.

On October 29, 2025, Genprex completed a registered direct offering priced at-the-market under Nasdaq rules (the "October 2025 Registered Direct Offering II"), pursuant to which the Company issued an aggregate of 377,780 shares of common stock at a purchase price of $9.00 per share. In a concurrent private placement (the "October 2025 Private Placement II", and together with the October 2025 Registered Direct Offering II, the "October 2025 Financing II"), the Company issued warrants (the "October 2025 Private Warrants II") exercisable for up to an aggregate of 755,560 shares of common stock (the "October 2025 Private Warrant Shares II") at an exercise price of $8.75 per share. The October 2025 Private Warrants II are exercisable immediately upon issuance and will expire on December 12, 2027. Also, the Company agreed to issue to H.C. Wainwright & Co., LLC (the "Placement Agent") or its designees warrants to purchase up to an aggregate of 22,667 shares of common stock. The warrants issued to the Placement Agent or its designees have substantially the same terms as the October 2025 Private Warrants II except that the warrants issued to the Placement Agent or its designees have an exercise price of $11.25 per share and a termination date of December 12, 2027. In addition, in connection with any future exercise of the October 2025 Private Warrants II, the Company has agreed to (A) pay the Placement Agent (i) a cash fee equal to 7.0% of the aggregate gross exercise price paid in cash with respect to the exercise of such warrants and (ii) a management fee equal to 1.0% of the aggregate gross exercise price paid in cash with respect to the exercise of such warrants and (B) issue to Placement Agent or its designees additional placement agent warrants to purchase that number of shares equal to 6.0% of the aggregate number of shares of common stock underlying such October 2025 Private Warrants II that have been exercised. The net proceeds of the October 2025 Financing II, after deducting the placement agent's fees and expenses and other estimated October 2025 Registered Direct Offering II expenses payable by the Company and excluding the net proceeds, if any, from the exercise of the October 2025 Private Warrants II, were approximately $3.1 million. Additionally, if the holders of October 2025 Private Warrants II exercise such warrants in full, the Company would receive additional net proceeds of approximately $6.1 million.

At-The Market Offering

On December 13, 2023, Genprex entered into an At The Market ("ATM") Offering Agreement (the "Sales Agreement") with H.C. Wainwright & Co., LLC, serving as agent (the "Agent") with respect to an at-the-market offering program (the "2023 ATM Facility") under which the Company may offer and sell through the Agent, from time to time at its sole discretion, up to such number or dollar amount of shares of its common stock (the "Shares") as registered on the prospectus supplement covering the 2023 ATM Facility offering, as may be amended or supplemented from time to time. Any Shares offered and sold pursuant to the Sales Agreement will be issued pursuant to the Company's currently effective shelf Registration Statement on Form S-3 (File No. 333-271386) filed with the SEC on April 21, 2023, which was declared effective on June 9, 2023, as may be amended or supplemented from time to time, or pursuant to any new or successor shelf Registration Statement of the Company. The Company has agreed to pay the Agent a commission equal to three percent (3%) of the gross sales proceeds of any Shares sold through the Agent under the Sales Agreement, and also have provided the Agent with customary indemnification and contribution rights. During the year ended December 31, 2025, the Company sold 1,602,490 shares of common stock for aggregate net proceeds of approximately $10.8 million under the 2023 ATM Facility.

See "Note 10 – Subsequent Events – 2023 ATM Facility" for a description of the Company's usage of the 2023 ATM Facility after December 31, 2025 resulting in net proceeds of approximately $13.3 million.

Equity Line of Credit

On June 11, 2025, Genprex entered into an equity line of credit ("ELOC") purchase agreement (the "Purchase Agreement") with Lincoln Park Capital Fund, LLC ("Lincoln Park"), pursuant to which Lincoln Park committed to purchase up to $12.5 million in shares of the Company's common stock (subject to certain conditions and limitations contained in the Purchase Agreement) from time to time at the Company's sole discretion over the 24-month term of the Purchase Agreement (the "2025 ELOC Facility"). Sales of shares of common stock to Lincoln Park under the Purchase Agreement will depend on a variety of factors to be determined by the Company from time to time, including, among others, market conditions, the trading price of the common stock and the Company's determination as to the appropriate sources of funding for its operations. Due to certain pricing and settlement provisions, the Purchase Agreement qualifies as a standby purchase equity agreement and includes an embedded put option and an embedded forward contract. Genprex will account for the Purchase Agreement as a derivative measured at fair value, with changes in fair value recognized in the statements of operations. The put option derivative liability is accounted for on a fair value basis under the provisions of ASC 815 – Derivatives and Hedging. The derivative associated with the Purchase Agreement was deemed de minimis at inception until the Company obtained stockholder approval to issue shares of common stock to Lincoln Park under the Purchase Agreement in excess of the Exchange Cap. The fair value of the ELOC Purchase Agreement contemplated future purchase decisions based on economic considerations and relevant stock issuance rules and limitations and has been determined using a Monte Carlo simulation. The fair value of the ELOC derivative liability was $22,500 at December 31, 2025.

The following table provides the carrying value and fair value of the ELOC derivative liability of the Company measured at fair value on a recurring basis as of December 31, 2025:

		Fair Value Measurement at December 31, 2025		
	Carrying Value	Level 1	Level 2	Level 3
Liabilities:				
Derivative liabilities	$ 22,500	$ —	$ —	$ 22,500
Totals liabilities measured and recorded at fair value	$ 22,500	$ —	$ —	$ 22,500

The following table provides quantitative information regarding fair value measurements inputs used with respect to the ELOC derivative liability, as of their respective measurement dates:

	December 31, 2025
Closing stock price:	$ 1.75
Volatility:	225.0%
Expected term (in years):	1.50
Risk-free rate:	3.5%

The Company expenses the difference between the discounted purchase price of the settled forward and the fair value of the shares on the date of settlement as a non-cash financing cost. During the year ended December 31, 2025, the Company (i) issued 23,737 shares of common stock to Lincoln Park with a value of $365,550 as commitment shares pursuant to the 2025 ELOC Facility, which was expensed as incurred, (ii) sold 749,130 shares of common stock to Lincoln Park as purchase shares for aggregate net proceeds of approximately $5.3 million under the 2025 ELOC Facility, and (iii) expensed $351,883 related to the difference between the discounted purchase price of the settled forward and the fair value of the shares on the date of settlement as a non-cash financing cost. From January 1, 2026 through the date of filing of this Annual Report on Form 10-K, the Company has not sold shares of common stock to Lincoln Park.

Stock Issuances

During the year ended December 31, 2025, the Company issued (i) 400 shares of common stock for services provided to the Company valued at $7,875 to the Chairman of its Scientific Advisory Board, (ii) 1,785 shares of common stock upon the vesting of restricted stock units ("RSUs") valued at $21,922 to Company executives, other employees, and non-employee service providers, (iii) 1,602,490 shares of common stock sold for aggregate net proceeds of approximately $10.8 million under the 2023 ATM Facility, (iv) 23,737 shares of common stock issued to Lincoln Park as commitment shares pursuant to the Company's 2025 ELOC Facility, and (v) 749,130 shares of common stock sold to Lincoln Park as purchase shares for aggregate net proceeds of approximately $5.3 million under the 2025 ELOC Facility.

During the year ended December 31, 2024, Genprex issued (i) 303 shares of common stock for services provided to the Company valued at $27,669 to the Chairman of its Scientific Advisory Board, (ii) 725 shares of common stock to service providers of the Company valued at $179,550, (iii) 633 shares of common stock upon the vesting of restricted stock units ("RSUs") valued at $96,524 to Company executives and employees, non-employee directors, and former Company executives (Mr. Varner and Ms. Vaczy) pursuant to the terms of employment and/or separation agreements, (iv) 1,294 shares of common stock due to fractional share rounding adjustments related to the Company's Reverse Split, (v) 3,300 shares of common stock sold for aggregate net proceeds of approximately $5.9 million associated with the Company's March 2024 offering, as described above, (vi) 153,701 shares of common stock sold for aggregate net proceeds of approximately $6.1 million under the Company's 2023 ATM Facility, as described above, and (vii) 27,543 shares of common stock upon the exercise of pre-funded warrants at a nominal price associated with the Company's March 2024 offering.

Preferred Stock

Genprex is authorized to issue 10,000,000 shares of preferred stock at a par value of $0.001 per share, none of which are outstanding at the years ended December 31, 2025 and 2024.

Common Stock

Genprex is authorized to issue 200,000,000 shares of common stock at a par value of $0.001 per share, all of which is voting common stock. There were 3,291,488 and 217,234 shares of common stock outstanding at the years ended December 31, 2025 and 2024, respectively.

Common Stock Purchase Warrants

Common stock purchase warrant activity for the years ended December 31, 2025 and 2024 respectively are as follows:

	2025		2024	
	Number of Warrants	Weighted Average Exercise Price	Number of Warrants	Weighted Average Exercise Price
Outstanding at January 1,	39,633	$ 503.75	6,938	$ 1,898.24
Warrants issued	1,280,088	9.71	60,238	112.81
Warrants exercised	—	—	27,543	0.01
Warrants cancelled or expired	25	7,620.00	—	—
Outstanding at December 31,	1,319,696	$ 24.40	39,633	$ 503.75

During the year ended December 31, 2025, and in connection with the registered direct offering, with an institutional investor, completed on October 24, 2025, the Company (i) issued warrants to purchase up to 487,244 shares of common stock, at an exercise price of $11.00 per share, (ii) issued warrants to purchase up to 14,617 shares of common stock to H.C. Wainwright & Co., LLC or its designees ("Placement Agent"), at an exercise price of $14.0125 per share, and in connection with the registered direct offering, with an institutional investor, completed on October 29, 2025, the Company (iii) issued warrants to purchase up to 755,560 shares of common stock, at an exercise price of $8.75 per share, (iv) issued warrants to purchase up to 22,667 shares of common stock to H.C. Wainwright & Co., LLC or its designees ("Placement Agent"), at an exercise price of $11.25 per share, and (v) canceled warrants to purchase up to 25 shares of common stock at a weighted average exercise price of $7,620.00. The Company did not record any share-based compensation related to warrants during the year ended December 31, 2025. The Company expects to record approximately $0.3 million of share-based compensation based on performance-based vesting in the future with respect to its warrants outstanding as of December 31, 2025.

During the year ended December 31, 2024, and in connection with the registered direct offering, with an institutional investor, completed on March 21, 2024, Genprex (i) issued pre-funded warrants to purchase up to an aggregate of 27,543 shares of common stock at a nominal exercise price of $0.01 per share, the remaining balance of the purchase price of each share of common stock associated with each pre-funded warrant net of the portion of the subscription price therefor paid at closing, (ii) issued warrants to purchase up to 30,843 shares of common stock, at an exercise price of $204.50 per share, (iii) issued warrants to purchase up to 1,852 shares of common stock to H.C. Wainwright & Co., LLC or its designees ("Placement Agent"), at an exercise price of $263.44 per share, (iv) amended existing warrants to purchase up to an aggregate of 3,885 shares of common stock that were previously issued to the same institutional investor in March 2023 and July 2023, such that the amended warrants have a reduced exercise price of $4.09 per share and an expiration date of five years from the closing of the March 2024 offering, and (v) issued 27,543 shares of common stock associated with the exercise of March 2024 Pre-Funded Warrants. During the year ended December 31, 2024, the Company recorded share-based compensation of $18,039 associated with the vesting and issuance of warrants.

As of December 31, 2025, Genprex had outstanding warrants to purchase 1,319,696 shares of common stock at a weighted average exercise price of $ 24.40 that have been issued to various consultants, investors, and placement agents of the Company. These warrants vest immediately or over periods ranging up to 12 months, are exercisable for a period of up to five years, enable the holders to purchase shares of the Company's common stock at exercise prices ranging from $8.75 to $14,440.00 per share and have per-share fair values ranging from $60.67 to $9,250.20, based on Black-Scholes-Merton pricing models. The following assumptions were used in calculation of fair market value of options via Black-Scholes-Merton pricing models for the years ended December 31, 2025 and 2024, respectively.

	Year Ended December 31, 2025	Year Ended December 31, 2024
Expected term (in years):	1.0	5.0
Risk-free rate:	3.58% - 3.70%	4.52%
Volatility:	131.34% - 131.39%	87.49%
Dividend yield:	0%	0%

Warrant Modifications

On March 21, 2024, the Company amended two warrants whereby, for both warrants, the exercise price was reduced to $204.50 per share and the maturity dates were extended to a term of five years. The value of these modifications were calculated using the Black-Scholes-Merton option pricing model based on the following weighted average assumptions:

	Post-modification	Pre-modification
Exercise Price	$ 204.50	$1,770.00 - $2,200.00
Expected term (in years):	5.0	4.00 - 4.50
Risk-free rate:	4.52%	4.99% - 5.35%
Volatility:	87.49%	83.42%
Dividend yield:	0%	0%

The incremental fair value attributable to the modified awards compared to the original awards immediately prior to the modification was calculated at $277,119, which was treated as a deemed dividend and is reflected as "Deemed dividend related to warrant modification" in the accompanying statement of operations.

2018 Equity Incentive Plan

The Company's board of directors and stockholders have approved and adopted the Genprex 2018 Equity Incentive Plan ("2018 Plan"), which became effective on the completion of the Company's IPO on April 3, 2018. The 2018 Plan provides for the grant of incentive stock options that are intended to qualify under Section 422 of the Internal Revenue Code of 1986, as amended ("ISOs"), nonstatutory stock options, stock appreciation rights, restricted stock awards, RSU awards, performance-based stock awards and performance-based cash awards. ISOs may be granted only to employees. All other awards may be granted to employees, including officers, and to the Company's non-employee directors and consultants.

A total of 2,080 shares of common stock were initially available under the 2018 Plan, plus a number of shares of common stock (not to exceed 1,314 shares) subject to outstanding awards under the Company's 2009 Equity Incentive Plan (the "2009 Plan") as of the IPO that expire, are forfeited or otherwise terminate or that are used to cover the exercise price or applicable tax withholdings. No further grants will be made under the 2009 Plan.

In addition, the number of shares of common stock reserved for issuance under the 2018 Plan automatically increases on January 1 of each year, since January 1, 2019, by 5% of the total number of shares of the Company's common stock outstanding on December 31 of the preceding calendar year, or a lesser number of shares determined by the Company's board of directors or a committee of the board of directors appointed to administer the 2018 Plan.

On August 15, 2025 at the 2025 Annual Meeting of Stockholders, the Company's stockholders approved the Company's amended and restated 2018 Plan (the "2018 Amended Plan"). The principal changes to the 2018 Plan implemented by the 2018 Amended Plan include amendments to (i) increase the number of shares of the Company's common stock authorized for issuance under the 2018 Plan by an additional 130,000 shares (subject to adjustment for stock splits, stock dividends and similar events), (ii) extend the term of the 2018 Plan to June 30, 2035 (the 10-year anniversary of the Board's adoption of the Amended Equity Plan) and (iii) remove provisions of the 2018 Plan that had been included to comply with the exception for the deductibility of "performance-based compensation" under Section 162(m) of the Internal Revenue Code of 1986, as amended, which was repealed by the Tax Cuts and Jobs Act of 2017. The 2018 Amended Plan became effective upon its approval by the Company's stockholders at the 2025 Annual Meeting.

On January 1, 2024 and 2025, the number of shares of common stock reserved for issuance under the 2018 Plan was increased by an aggregate of 1,486 and 10,861 shares, respectively. As of December 31, 2025, a total of 1,558 shares of common stock remained available for issuance for future awards under the 2018 Plan. Subsequent to the year ended December 31, 2025, an additional 164,574 shares of common stock became available for issuance for future awards under the 2018 Plan pursuant to the evergreen provision thereof.

2018 Employee Stock Purchase Plan

The Company's board of directors and stockholders approved and adopted the Genprex 2018 Employee Stock Purchase Plan ("ESPP"), which became effective on April 3, 2018. The ESPP has not yet been utilized as a benefit available to the Company's employees. The ESPP authorizes the issuance of 105 shares of common stock pursuant to purchase rights that may be granted to eligible employees. The number of shares of common stock reserved for issuance under the ESPP is automatically increased on January 1 of each calendar year, beginning on January 1, 2019, by 2% of the total number of shares of common stock outstanding on December 31 of the preceding calendar year, or a lesser number of shares determined by the administrator of the ESPP. In January 2025, the administrator of the ESPP determined not to increase the number of shares reserved for issuance under the ESPP for the 2025 fiscal year.

Stock Options

As of December 31, 2025, Genprex had outstanding stock options to purchase 5,705 shares of common stock that have been granted to various executives, other employees, directors, and independent contractors of the Company, including outstanding stock options to purchase 509 shares of common stock issued as inducement grants, outside of the 2018 Plan, associated with the hiring of new executives in 2021 and 2023. These options vest immediately or over periods ranging from 12 to 48 months, are exercisable for a period of up to ten years, and enable the holders to purchase shares of the Company's common stock at exercise prices ranging from $900.00 to $19,600.00 per share.

The Company did not issue stock options during the year ended December 31, 2025. During the year ended December 31, 2025, the Company cancelled stock options to purchase 1 share of common stock with an exercise price of $4,280.00 per share in connection with the termination of employees.

The Company did not issue stock options during the year ended December 31, 2024. During the year ended December 31, 2024, the Company cancelled stock options to purchase 44 shares of common stock with a weighted average exercise price of $2,515.00 in connection with the termination of employees.

The weighted average remaining contractual term for the outstanding options at December 31, 2025 and 2024 is 4.11 and 5.11 years, respectively.

Stock option activity for the years ended December 31, 2025 and 2024, respectively, is as follows:

	2025		2024	
	Number of Options	Weighted Average Exercise Price	Number of Options	Weighted Average Exercise Price
Outstanding at January 1,	5,706	$ 6,081.61	5,750	$ 6,054.32
Options granted	—	—	—	—
Options exercised	—	—	—	—
Options expired or cancelled	1	4,280.00	44	2,515.00
Outstanding at December 31,	5,705	$ 6,081.93	5,706	$ 6,081.61

Restricted Stock Units

During the year ended December 31, 2025, the Company (i) issued 141,600 RSUs to executives, other employees, and non-employee directors, (ii) cancelled 246 RSUs associated with the termination of employees, (iii) withheld 328 RSUs to cover taxes associated with the vesting of employee issued RSUs, and (iv) issued 1,790 shares of common stock associated with the vesting of RSUs to executives, other employees, and non-employee directors.

During the year ended December 31, 2024, the Company (i) issued 1,922 RSUs to executives, other employees, and non-employee directors, (ii) cancelled 9 RSUs associated with the termination of employees, (iii) withheld 202 RSUs to cover taxes associated with the vesting of employee issued RSUs, and (iv) issued 636 shares of common stock associated with the vesting of RSUs to executives, other employees, and non-employee directors.

A summary of the RSU activity under the 2018 Plan during the years ended December 31, 2025 and 2024, respectively, is presented below. These amounts include RSUs granted to executives, other employees, and board members.

	2025		2024	
	Number of Units	Weighted Average Grant Date Fair Value	Number of Units	Weighted Average Grant Date Fair Value
Outstanding at January 1,	2,124	$ 362.71	1,049	$ 2,977.29
Restricted stock units granted	141,600	2.24	1,922	—
Restricted stock units vested	1,790	362.28	636	2,767.74
Restricted stock units forfeited or cancelled	574	221.60	211	3,300.00
Outstanding at December 31,	141,360	$ 66.00	2,124	$ 362.71

Share-Based Compensation

In the year ended December 31, 2025, Genprex's total share-based compensation was approximately $0.30 million, consisting of $0.20 million and $0.10 million associated with G&A expense and R&D expense, respectively, which represents the vesting of options and warrants issued to service providers, executives, other employees, and board members of the Company. As of December 31, 2025, the Company's total compensation cost related to non-vested time-based stock option awards, RSUs, and warrants granted to executives, other employees, board members, and service providers and not yet recognized was approximately $0.32 million, consisting of $0.21 million and $0.12 million associated with G&A expense and R&D expense, respectively. Genprex expects to record this stock-based compensation expense over the next three years using a graded vesting method. As of December 31, 2025, the weighted average term over which these expenses are expected to be recognized is 1.06 years.

As of December 31, 2025, there are no performance-based stock option awards outstanding and one performance-based warrant outstanding issued to a service provider of the Company. Genprex's total compensation cost related to the non-vested performance-based warrant not yet recognized was approximately $300,000. The entirety of this warrant may be recognized and recorded upon the achievement of certain milestones.

In the year ended December 31, 2024, the Company's total share-based compensation was approximately $3.30 million, consisting of $2.80 million and $0.60 million associated with G&A expense and R&D expense, respectively, which represents the vesting of options and warrants issued to service providers, executives, other employees, and board members of the Company.

Note 5 - 401(k) Savings Plan Transactions

In 2022, Genprex established a defined-contribution savings plan under Section 401(k) of the Internal Revenue Code ("401(k) Plan") and established an employer matching program for participants in the 401(k) Plan. The 401(k) Plan covers all employees who meet defined minimum age and service requirements, and allows participants to defer a portion of their annual compensation on a pre-tax basis. Genprex incurred $90,901 and $125,731 of expense for matching contributions to the 401(k) Plan for the years ended December 31, 2025 and 2024, respectively.

Note 6 - Related Party Transactions

Introgen Research Institute

Introgen Research Institute ("IRI") is a Texas-based technology company formed by Rodney Varner, who prior to his passing in May 2024, was the Company's President, Chief Executive Officer and Chairman of the Board and who was IRI's sole officer. IRI is owned by trusts of which Mr. Varner's descendants are the sole beneficiaries. In April 2009, prior to Mr. Varner becoming an officer and director of Genprex in August 2012, the Company entered into an Assignment and Collaboration Agreement with IRI, providing Genprex with the exclusive right to commercialize a portfolio of intellectual property. This agreement was amended in 2011 to include additional sublicensing of additional intellectual property made available to IRI from MD Anderson (see "Note 7 – Commitments and Contingences – Commitments – MD Anderson"). There were no amounts incurred or due under this agreement at the years ended December 31, 2025 and 2024.

Note 7 - Commitments and Contingencies

Commitments

MD Anderson

In July 2018, Genprex entered into a two-year sponsored research agreement with MD Anderson to sponsor preclinical studies focused on the combination of REQORSA with an immunotherapy with a projected total cost of approximately $2 million. This agreement was extended beyond the original expiration date, expiring in May 2022 after giving effect to such extension. In August 2022, the Company entered into a three-year sponsored research agreement with MD Anderson ("August 2022 SRA") to sponsor preclinical studies focused on REQORSA and NPRL2 in oncology to resensitize NSCLC and SCLC to targeted therapies and immunotherapies with an initial projected total cost of approximately $2.9 million. On June 7, 2024, the Company amended the August 2022 SRA with MD Anderson to (i) extend the sponsored research program an additional six months, (ii) amend the quarterly budget from approximately $240,000 to $165,000 per quarter, and (iii) amend the total commitment from $2.9 million to approximately $2.75 million. The Company incurred approximately $828,505 and $811,540 of expense from this agreement during the years ended December 31, 2025 and 2024, respectively. As of December 31, 2025, the Company has paid approximately $2.43 million toward this $2.77 million commitment.

In 2011, the Company agreed to assume certain contractual and other obligations of IRI in consideration for the sublicense rights, expertise, and assistance associated with certain technologies and intellectual property originally licensed to another party under the 1994 License Agreement with MD Anderson ("Original MD Anderson License Agreement"). These technologies and intellectual property were later sublicensed to IRI (the "IRI Sublicense"). The Company also agreed to pay royalties of 1% on sales of certain licensed products for a period of 21 years following the termination of the later of the Original MD Anderson License Agreement and the IRI Sublicense. The Company assumed patent prosecution costs and an annual minimum royalty of $20,000 payable to the National Institutes of Health.

On March 3, 2021, the Company entered into an amendment (the "MD License Amendment") to the Patent and Technology License Agreement dated May 4, 2020, with MD Anderson. The MD License Amendment grants Genprex a worldwide, exclusive, sublicensable license to an additional portfolio of six patents and one patent application and related technology for methods for treating cancer by administration of a TUSC2 therapy in conjunction with EGFR inhibitors or other anti-cancer therapies in patients predicted to be responsive to TUSC2 therapy. Pursuant to the MD License Amendment, the Company agreed to (i) pay annual maintenance fees ranging from the mid five figures to the low six figures, (ii) total milestone payments of $6,150,000, (iii) a one-time fee in the mid five figures and (iv) certain patent-related expenses. The Company incurred approximately $155,000 and $50,000 of expense from this agreement during the years ended December 31, 2025 and 2024, respectively. As of December 31, 2025, Genprex has paid approximately $525,000 toward this commitment.

National Institutes of Health

Genprex has a royalty obligation to the National Institutes of Health ("NIH") to be paid upon the Company's receipt of FDA approval using NIH technology. The $240,000 contingent obligation which increases annually by $20,000 and is $400,000 and $380,000 for the years ended December 31, 2025 and 2024, respectively, will be recognized when the Company obtains regulatory approval (the event that triggers the payment obligation).

New York University

On April 25, 2025, the Company and NYU entered into the NYU License Agreement, which granted Genprex exclusive patent and commercial rights worldwide relating to Genprex's lead drug candidate REQORSA for the potential treatment of mesothelioma. Pursuant to the NYU License Agreement, Genprex agreed to pay: (i) an initial license fee of $5,000, (ii) annual license fees of $35,000 for the first and second year anniversaries, $25,000 for the third anniversary and $50,000 for the fourth year and each subsequent year following the fourth anniversary of the agreement thereafter, (iii) running low single digit percentage royalties ranging from 1% to 2% of net sales, (iv) certain potential technical milestone payments through regulatory approval up to an aggregate of approximately $400,000, and (v) certain patent-related expenses. The Company incurred approximately $5,000 of expense from this agreement during the year ended December 31, 2025. As of December 31, 2025, Genprex has paid approximately $5,000 toward this commitment.

University of Michigan

On November 11, 2024, the Company and the University of Michigan entered into the UM License Agreement, which granted Genprex a worldwide, exclusive license to the University of Michigan's patent rights in a co-owned patent application relating to the use of REQORSA in combination with ALK-inhibitors for the treatment of ALK-EML4 positive translocated lung cancer. Genprex agreed to pay: (i) an initial license issue fee of $30,000, (ii) running low single digit percentage royalties ranging from 1% to 3% of net sales, (iii) minimum annual royalties in a fixed cash amount of $15,000 for 2025 and 2026, and $30,000 for 2027 and each year thereafter during the term of the UM License Agreement, (iv) a tiered double digit percentage share of non-royalty sublicense income ranging from 10% to 40%, and (v) certain potential clinical milestone payments through FDA regulatory approval up to an aggregate of approximately $350,000 in addition to certain potential commercial sales milestones. The Company incurred approximately $15,000 and $15,000 of expense from this agreement during the years ended December 31, 2025 and 2024, respectively. As of December 31, 2025, Genprex has paid approximately $30,000 toward this commitment.

University of Pittsburgh

Pursuant to the New UP License Agreement dated February 17, 2025, by and between Genprex and the University of Pittsburgh, Genprex agreed to pay (i) an initial licensing fee of $10,000, (ii) annual maintenance fees of $65,000 for the first, second and third years, and $120,000 for the fourth year and each subsequent year following the fourth anniversary of the agreement thereafter until the anniversary prior to the year of the first commercial sale, (iii) royalties ranging from 1.5% to 3% of net sales of licensed technologies, (iv) an annual minimum royalty payment of $250,000 per year beginning in the year of the first commercial sale of licensed technology, (v) a share of non-royalty sublicense income of 20%, and (vi) an aggregate of $4,825,000 in milestone payments related to the usage of the licensed technologies to potentially treat Type 1 and Type 2 diabetes. Unless earlier terminated pursuant to its terms, the agreement expires upon the later of (i) 20 years after the first commercial sale of the licensed technology thereunder and (ii) expiration of the last valid claim under the patent rights. In connection with the New UP License Agreement, the Company incurred $15,000 and $0 of expense from this agreement for the years ended December 31, 2025 and 2024, respectively. As of December 31, 2025, Genprex has paid approximately $15,000 toward this commitment.

UTHealth Houston

On May 2, 2025, the Company and UTHealth Houston entered into the UTH License Agreement, which granted Genprex exclusive patent and commercial rights worldwide relating to Genprex's lead drug candidate REQORSA for the potential treatment of glioblastoma. Pursuant to the UTH License Agreement, Genprex agreed to pay (i) an initial license issue fee of $10,000 along with additional, staggered upfront license fees totaling another $40,000 and an annual license management fee of $3,000, (ii) running low single digit percentage royalties ranging from 0.10% to 0.25% of net product sales, (iii) minimum annual royalty of $25,000 beginning after the first year in which royalties obligations commence pursuant to the UTH License Agreement, (iv) certain potential clinical and regulatory milestone payments through FDA and international regulatory approvals up to an aggregate of approximately $360,000, and (v) certain patent-related expenses. The Company incurred approximately $10,000 of expense from this agreement during the year ended December 31, 2025. As of December 31, 2025, Genprex has paid approximately $10,000 toward this commitment.

Contract Development and Manufacturing Organization

Genprex entered into a three-year development services agreement in July 2022, amended in each of January 2023 and March 2023, with a contract development and manufacturing organization ("CDMO") to manufacture good manufacturing practices ("GMP") grade materials for use in the Company's clinical trials with a projected total cost at inception of approximately $4.5 million. On April 2, 2024, the Company was informed by the CDMO that the CDMO was ceasing certain manufacturing operations subject to the development services agreement. On June 30, 2024, the development services agreement was terminated by mutual agreement and the CDMO returned $1.3 million to the Company and no additional commitments are obligated or owed by the Company. The Company incurred no expense from this agreement during either of the years ended December 31, 2025 and 2024.

Contingencies

From time to time, the Company may become subject to threatened and/or asserted claims arising in the ordinary course of its business. The Company is not aware of any matters, either individually or in the aggregate, that are reasonably likely to have a material impact on its financial condition, results of operations or liquidity.

Note 8 – Segment Reporting

Operating segments are defined as components of an entity for which separate discrete financial information is made available and that is regularly evaluated by the CODM in making decisions regarding resource allocation and assessing performance. The Company manages its operations as a single segment (the "Segment") for the purposes of assessing performance and making operating decisions. The CODM of the Segment is the Company's Chief Executive Officer. The Segment is focused on pioneering the discovery and development of gene therapies for use in patient populations with unmet medical needs. The accounting policies for the Segment are the same as those described in Note 2, Summary of Significant Accounting Policies. The CODM assesses the performance of the Segment and decides how to allocate resources based on net loss that is reported on the statements of operations and comprehensive loss. Further, the following represents information about segment loss and significant segment expenses:

	Year Ended December 31,	
	2025	2024
Revenues	$ —	$ —
Less:		
Clinical and regulatory	6,785,848	7,809,750
Manufacturing	1,258,765	1,658,373
Research	1,281,852	483,927
General and administrative support	5,872,327	7,877,622
Non-cash expenses[(1)]	316,827	3,344,495
Other income	26,900	63,574
Plus:		
Other financing costs	(739,935)	—
Realized and unrealized loss	(299)	(570)
Segment and net loss	$ 16,228,953	$ 21,111,163

(1) Inclusive of $0.3 million and $3.3 million of stock-based compensation expense for the years ended December 31, 2025 and 2024, respectively, and $0 and $6,693 of depreciation and amortization expense for the years ended December 31, 2025 and 2024, respectively.

Note 9 – Income Taxes

Components of income tax expense for the years ended December 31, 2025 and 2024, respectively, are as follows:

	December 31, 2025	December 31, 2024
Current Tax Expense (Benefit):		
Federal	$ —	$ —
State	—	2,650
Total	$ —	$ 2,650
Deferred Tax Expense (Benefit):		
Federal	—	—
State	—	—
Total	—	—
Total Provision for Income Taxes	$ —	$ 2,650

The total provision for income taxes for the year ended December 31, 2024, was accounted for in the Consolidated Statement of Operations within General and Administrative Expenses.

Temporary differences between financial statement carrying amount and tax basis of assets and liabilities that give rise to significant portions of the deferred tax assets and liabilities at December 31, 2025 and 2024, respectively, are as follows:

	December 31, 2025	December 31, 2024
Deferred tax assets:		
Intangible Assets - R&D Expenses	$ 3,950,937	$ 5,298,509
Accrued Expenses	446,430	529,639
Tax Credits	728,701	728,701
Stock Compensation Expense	1,106,464	1,302,638
Net Operating Losses	24,756,877	20,215,112
Other	59,820	87,089
Total Deferred Income Tax Assets	31,049,229	28,161,688
Deferred Income Tax Liabilities:		
Fixed Assets	—	—
Prepaid Expenses	(473,475)	(537,405)
Lease - Right of Use	—	—
Total Deferred Income Tax Liabilities	(473,475)	(537,405)
Less Valuation Allowance	(30,575,754)	(27,624,283)
Net Deferred Income Tax Asset	$ —	$ —

For the years ended December 31, 2025 and 2024, the Company recorded pre-tax book losses of approximately $16.2 million and approximately $21.1 million, respectively.

At December 31, 2025 and 2024, the Company had federal net operating losses of approximately $117.5 million and approximately $95.2 million, respectively. Net deferred tax assets are mainly comprised of temporary differences between financial statement carrying amount and tax basis of assets and liabilities.

In assessing the ability to realize the deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent on the generation of future taxable income during the period in which these temporary differences become deductible. Management considers the projected future taxable income and prudent and feasible tax planning strategies in making this assessment. As of December 31, 2025 and 2024, valuation allowances of approximately $30.6 million and approximately $27.6 million have been recorded, respectively.

The Company has federal research and development ("R&D") credit carryforwards of $0.8 million which will begin to expire in 2037.

	Year Ended December 31, 2025			Year Ended December 31, 2024*		
	Amounts	Adjusted	Rate	Amounts	Adjusted	Rate
U.S. Statutory Tax Rate	$ (16,228,953)	$ (3,408,080)	21.00%	$ (21,388,282)	$ (4,491,539)	21.00%
State and Local Income Taxes, Net of Federal Income Tax Effect	—	—	0.00%	—	(23,612)	0.11%
Foreign Tax Effects	—	—	—	—	—	—
Effect of Changes in Tax Laws or Rates Enacted in the Current Period	—	—	0.00%	(73,178)	(73,178)	0.34%
Effect of Cross-Border Tax Laws	—	—	—		—	—
Tax Credits	—	—	0.00%	706,150	706,150	(3.30)%
Change in Valuation Allowances	—	$ 2,946,220	(18.15)%	—	4,203,531	(19.65)%
Nontaxable or Nondeductible Items	—	$ 189,910	(1.17)%	2,251,326	472,778	(2.21)%
Changes in Unrecognized Tax Benefits	—	—	—	—	—	—
Other Adjustments	—	—	—	—	—	—
Prior Year True-Ups	—	$ (8,368)	0.05%	—	(791,480)	3.70%
Share-based compensation	—	$ 280,318	(1.73)%	—	—	—
Income tax expense and effective income tax rate	$ (16,228,953)	$ —	0.00%	$ (18,503,984)	$ 2,650	(0.01)%

* While the underlying tax effects remain unchanged from the prior year, certain reconciling items have been reallocated consistent with the required ASU 2023-09 disclosure.

Effective January 1, 2009 the Company adopted ASC 740-10, the provision formerly FASB Interpretation No. 48, "Accounting for Uncertainty in Income Taxes," ("FIN48") and began evaluating tax positions utilizing a two-step process. The first step is to determine whether it is more-likely-than-not that a tax position will be sustained upon examination based on the technical merits of the position. The second step is to measure the benefit to be recorded from tax positions that meet the more-likely-than-not recognition threshold by determining the largest amount of tax benefit that is greater than 50% likely of being realized upon ultimate settlement and recognizing that amount in the consolidated financial statements.

The following table reflects changes in the gross unrecognized tax benefits:

	December 31, 2025	December 31, 2024
Unrecognized tax benefits at beginning of period	$ (80,967)	$ (159,428)
Gross increases – tax positions in current period	—	—
Gross decreases – tax positions in prior period	—	78,461
Settlements	—	—
Lapse of Statute of Limitations	—	—
Unrecognized tax benefits at end of period	$ (80,967)	$ (80,967)

The Company classifies uncertain tax positions as non-current unrecognized tax liabilities unless expected to be paid within one year or otherwise directly related to an existing deferred tax asset, in which case the uncertain tax position is recorded as an offset to the asset on the balance sheets. As of December 31, 2025 and 2024, $80,967 of the Company's gross unrecognized tax benefits were recorded as a reduction of the related deferred tax assets.

Note 10 – Subsequent Events

The Company has evaluated subsequent events through the filing of this Annual Report on Form 10-K and determined that there have been no recognized subsequent events that have occurred that would require adjustments to the Company's disclosures in the consolidated financial statements. The following are nonrecognized subsequent events through the filing of this Annual Report on Form 10-K.

Reserves of 2018 Equity Incentive Plan and 2018 Employee Stock Purchase Plan

On January 1, 2026, the total shares of common stock reserved under the 2018 Plan increased by 164,574 shares pursuant to the "evergreen" provision of the 2018 Plan. On December 22, 2025, the Company's board of directors determined that no additional shares would be reserved during the 2026 fiscal year for the ESPP given that no shares have yet been issued under the ESPP.

Share Issuances

From January 1, 2026 through the date of filing of this Annual Report on Form 10-K, Genprex issued (i) 5,000 shares of common stock to the Chairman of the Company's Scientific Advisory Board in consideration for services, and (ii) 33,570 shares of common stock upon the vesting of restricted stock units ("RSUs") valued at $67,015 to Company executives and other employees.

2023 ATM Facility

From January 1, 2026 through the date of filing of this Annual Report on Form 10-K, Genprex has sold 5,714,798 shares of its common stock for aggregate net proceeds to the Company totaling approximately $13.3 million under the 2023 ATM Facility.

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