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## *Biotechnology*

## INITIATION REPORT

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## GENPREX, Inc. (GNPX) – Buy Rating & $3.0 Target

### An Emerging Gene Therapy Platform in Oncology & Diabetes

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*Genprex is a clinical company pioneering the development of gene-based therapies focused on oncology and diabetes. The oncology platform utilizes a non-viral Nanoparticle Delivery System (encapsulate plasmids that express tumor suppressor genes within lipid nanoparticles and intravenously administered). The diabetes technology is designed to work by transforming alpha cells in the pancreas into functional beta-like cells, which can produce insulin but are distinct enough from beta cells to evade the body's immune system.*

## Investment Highlights

**Lead Program in Oncology:** REQORSA Immunogene Therapy (GPX-001). REQORSA is a plasmid that expresses a tumor suppressor gene TUSC2, that is deleted early during lung cancer development. REQORSA appears to have a multimodal mechanism of action whereby it 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 modulates the immune response against cancer cells. REQORSA has been shown to be complementary with targeted drugs and immunotherapies.

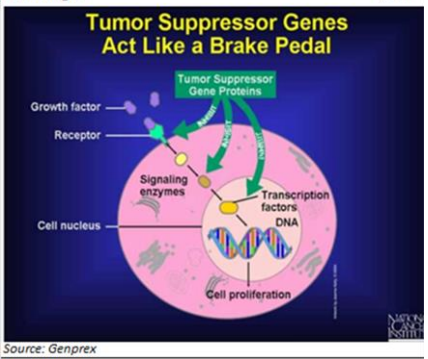
**Clinical Status:** REQORSA is currently enrolling clinical patients in two trials with a third coming. The trials are initially exploring its utility in NSCLC with a range of agents – standard of care. The Acclaim-1 clinical trial is evaluating a combination of REQORSA with Tagrisso in patients with late-stage NSCLC with activating epidermal growth factor receptor mutations, whose disease progressed after treatment. The first patient was dosed in Acclaim-1 in February 2022. A second trial, Acclaim-2 (first patient doses April 2022), is using a combination of REQORSA with Merck & Co.'s Keytruda in patients with late-stage NSCLC whose disease progressed after treatment with Keytruda. The FDA has granted Fast Track Designation for both trials. Accaim-3 is exploring REQORSA with Tecentriq in ES-SCLC patients.

**Diabetes Program:** The company has developed a gene therapy that is designed to transform alpha cells in the pancreas into functional beta-like cells, which can produce insulin but are distinct enough from beta cells to evade the body's immune system. The therapy utilizes a procedure in which an adeno-associated virus vector is endoscopically delivered to the pancreas to insert Pdx1 and MafA genes. GPX-002 for T1D uses a glucagon promoter in alpha cells. GPX-003 for T2D uses an insulin promoter in beta cells**. The planned phase 1 trial represents the first-ever gene therapy tested in humans for diabetes.** In vivo, preclinical studies (mice), have shown that GPX-002 restored normal blood glucose levels for an extended period. Research collaborators at the University of Pittsburgh plan to present data in non-human primates highlighting the therapeutic potential of Genprex's gene therapy for Type 1 diabetes at the 16th International Conference on Advanced Technologies & Treatments for Diabetes (ATTD 2023) being held February 22-25 in Berlin, Germany.

**Valuation:** We project our model out to 2033. We apply a 30% risk cut to our projected revenues in our product model in addition to our 30% risk rate applied in our Free Cash Flow to the Firm (FCFF), discounted EPS (dEPS), and Sum-of-the-Parts (SOP) models. We use a fully diluted out year share count assuming multiple raises. The result is equal-weighted and averaged and rounded to the nearest whole number to derive our 12-month projected price target of $3.00. We note that as the company established proof of concept as a result of clinical trial data, the risk rate (r) is reduced, and valuation rises.

**Risks to our thesis include:** 1. Regulatory Approvals; 2. Clinical Science 3. Adoption Rates 4. The competitive landscape. 5. Intellectual Capital 6. Dilution.

| | |
|---|---|
| Current Price | $1.34 |
| Price Target | $3.00 |




*Source: Genprex*

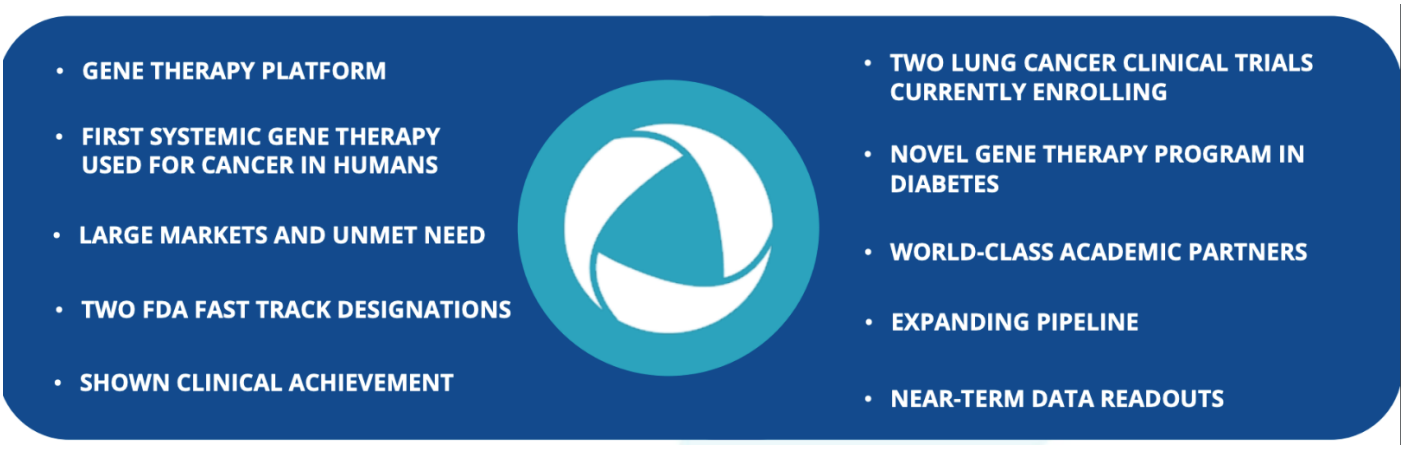
| Stock Data | | | |
|---|---|---|---|
| 52-Week Range | $0.97 | - | $2.67 |
| Shares Outstanding (mil.) | | | 48.0 |
| Market Capitalization (mil.) | | | $64 |
| Enterprise Value (mil.) | | | $39 |
| Debt to Capital | | | 0% |
| Book Value/Share | | | - |
| Price/Book | | | 1.5 |
| Average Three Months Trading Volume (K) | | | 33 |
| Insider Ownership | | | 4.9% |
| Institutional Ownership | | | 9.3% |
| Short interest (mil.) | | | 3.4% |
| Dividend / Yield | | | $0.00/0.0% |

**Company Description: (***adapted)***:** Genprex is a clinical-stage gene therapy company pioneering the development of gene-based therapies for large patient populations with unmet medical needs. The oncology platform utilizes a non-viral Nanoparticle Delivery System. Using this system, plasmids that express tumor suppressor genes are encapsulated within lipid nanoparticles and intravenously administered to the tumor cells. The idea is that the tumor suppressor genes express proteins that are missing or found in low quantities in the tumor cells. In essence, restoring the ability to stop the malignancy. The other program is in diabetes. Here the technology is designed to work by transforming alpha cells in the pancreas into functional beta-like cells, which can produce insulin but are distinct enough from beta cells to evade the body's immune system.

Their lead oncology drug candidate, REQORSA Immunogene Therapy, also sometimes referred to as GPX-001, initially is being developed in combination with top-selling cancer drugs to treat Non-Small Cell Lung Cancer ("NSCLC") and Small Cell Lung Cancer ("SCLC"). Genprex is enrolling one Phase 1/2 clinical trial in NSCLC along with a second Phase 1/2 clinical trial in NSCLC. The FDA has granted two Fast Track Designations, one for the use of REQORSA in the patient population targeted in each of these trials. In diabetes, Genprex is developing a gene therapy that is exclusively licensed from the University of Pittsburgh of the Commonwealth System of Higher Education for the treatment of Type 1 and Type 2 diabetes. This potential treatment is designed to work by transforming alpha cells in the pancreas into functional beta-like cells, which can produce insulin but are distinct enough from beta cells to evade the body's immune system.

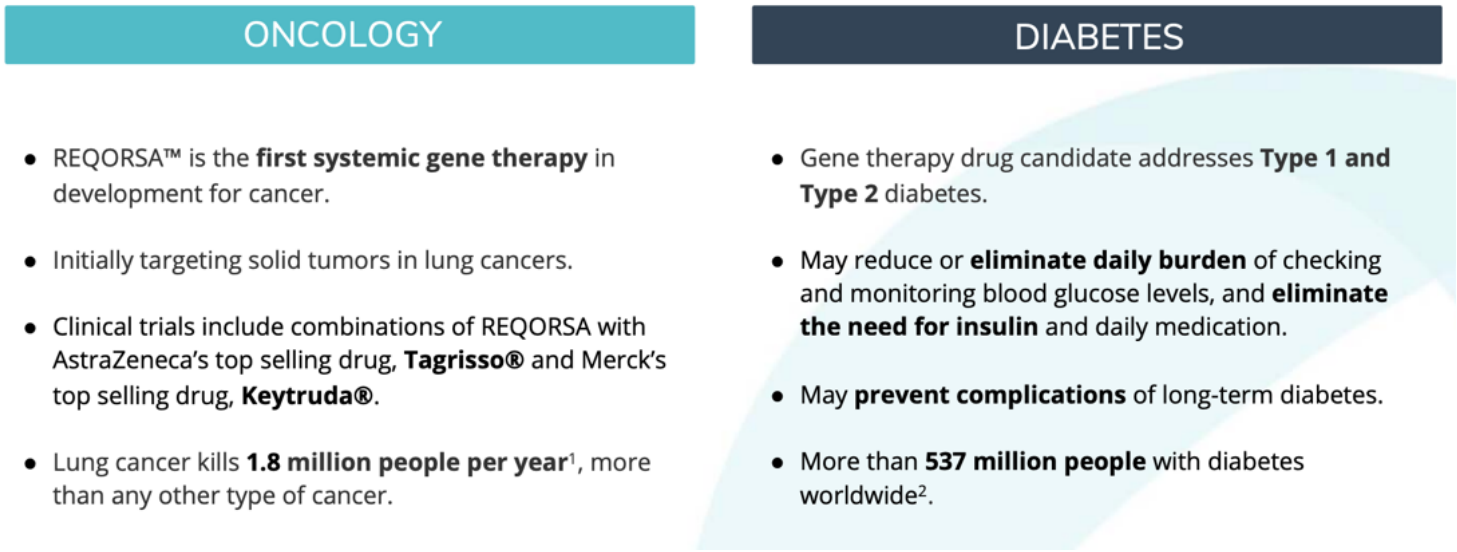
**Financials:** In the most recent reported quarter (Sept. 2022), the company has cash and equivalents of $ 25.5 million and showed a net loss of $6M in the period.

**Exhibit 1. What is Genprex?**



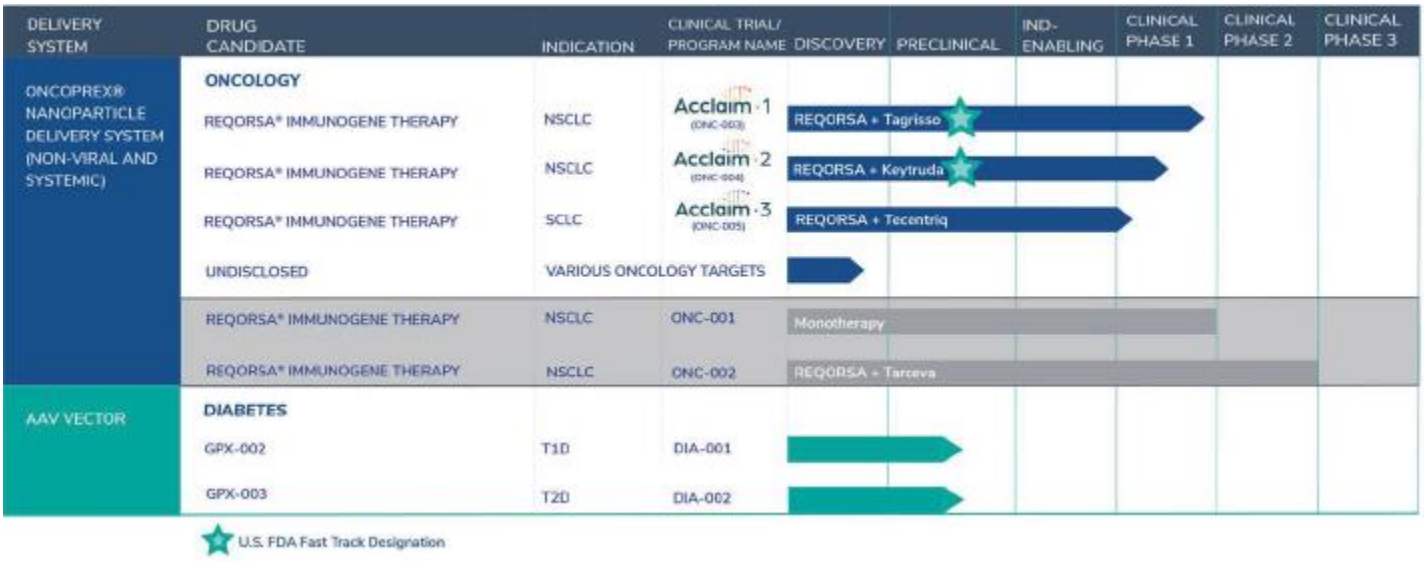

*Source: Genprex*

**Exhibit 2. Genprex is helping patients with limited treatment options**



*Source: Genprex*

**Exhibit 3. Research and development pipeline**




*Source: Genprex*

**The lead Program: REQORSA Immunogene Therapy or GPX-001.**

REQORSA is a plasmid that expresses a tumor suppressor gene named TUSC2. REQORSA appears to have a multimodal mechanism of action whereby it interrupts cell signaling pathways that cause replication and proliferation of cancer cells, re-establishes pathways for apoptosis, and modulates the immune response against cancer cells. REQORSA also has been shown to block mechanisms that create drug resistance and to be complementary with targeted drugs and immunotherapies.

Genprex is enrolling one Phase 1/2 clinical trial in NSCLC and a second Phase 1/2 clinical trial in NSCLC. The Acclaim-1 clinical trial is using a combination of REQORSA with Tagrisso in patients with late-stage NSCLC with activating epidermal growth factor receptor mutations, whose disease progressed after treatment with Tagrisso. The first patient was dosed in Acclaim-1 in February 2022. The Acclaim-2 clinical trial (enrolling patients), is using a combination of REQORSA with Keytruda in patients with late-stage NSCLC whose disease progressed after treatment with Keytruda. The FDA has granted two Fast Track Designations, one for use of REQORSA in the patient population targeted in each of these trials. A third trial, Accaim-3, is exploring REQORSA with Tecentriq in ES-SCLC patients.

The TUSC2 gene is one of a series of genes whose therapeutic use is covered by the company's licenses from The University of Texas MD Anderson Cancer Center. It is likely that the ONCOPREX Nanoparticle Delivery System may allow for the delivery of a number of cancer-fighting genes, alone or in combination with other cancer therapies, to combat multiple types of cancer and are in the early stages of discovery programs to identify early-stage candidates.

**Exhibit 4. Recent expansion to Small Cell Lung Cancer covers virtually the entire market**


*Source: Genprex*

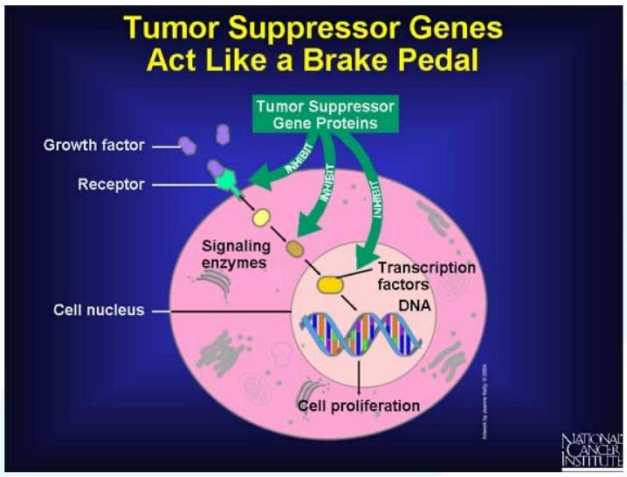
**How does it work?** TUSC2 is a multifunctional gene that plays a vital role in cancer suppression and normal cell regulation. Key TUSC2 anticancer mechanisms of action include the inactivation of multiple oncogenic kinases, the induction of apoptosis, the control of cell signaling and inflammation, and modulation of the immune system to fight cancer. REQORSA has also been shown to block mechanisms that create drug resistance. Normal TUSC2 function is often inactivated at the early onset of cancer development, making TUSC2 a potential target for all stages of cancer, including metastatic disease. The TUSC2 protein is reduced or absent in approximately 85% of lung cancers. In patients with NSCLC, the loss of TUSC2 expression has been associated with significantly worse overall survival than when TUSC2 expression is not impaired. 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 the activity of other proapoptotic effectors. Normally TUSC2 functions to mediate apoptosis in cancer cells through interaction with Apaf1 and also down-regulates multiple tyrosine kinases, 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 (overexpression) and its upstream activators, such as EGFR, have been associated with many forms of cancers.

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 receptor (EGFR in the figures), leading to cell cycle interruption and 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. 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.

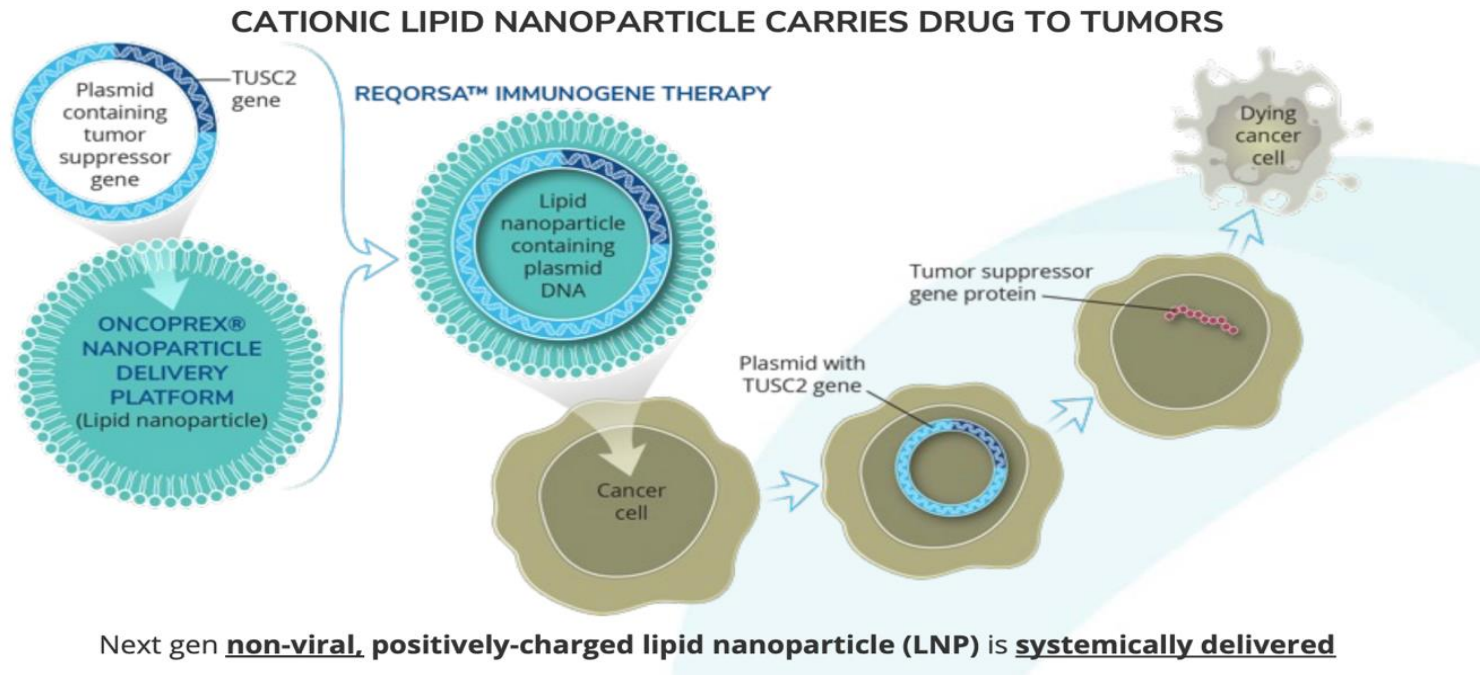
**Exhibit 5. Tumor suppressor genes deleted during cancer development**

- Tumor suppressor genes such as TUSC2 are deleted early during cancer development
- 80% of all non-small cell lung cancers express decreased amounts of TUSC2 tumor suppressor protein
- Loss or reduction of TUSC2 expression is associated with significantly reduced overall survival
- Led to the hypothesis that reintroduction of tumor suppressor genes may be a new method of treating cancer



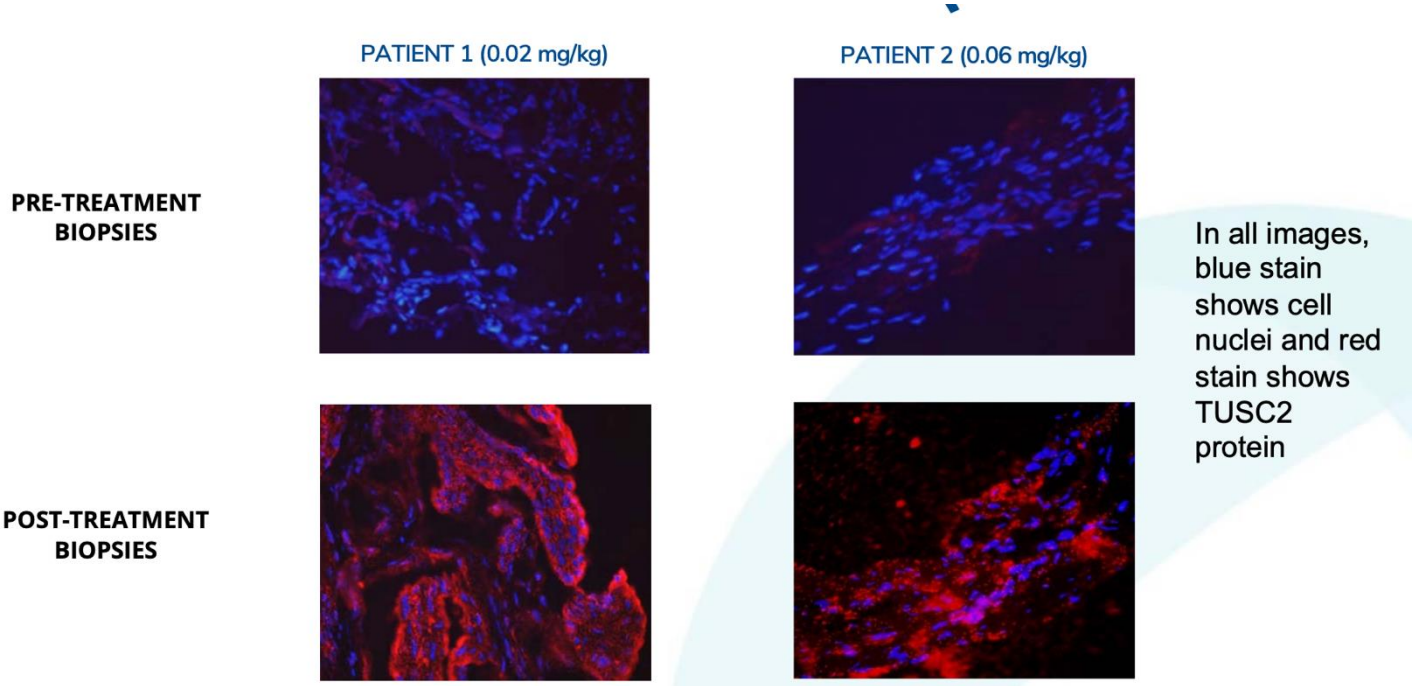

*Source: Genprex*

**Exhibit 6. Oncoprex NanoParticle Delivery System:** REQORSA utilizes the ONCOPREX Nanoparticle Delivery System to encapsulate the TUSC2 gene in positively charged nanoparticles that bind 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. The nanoparticles in our system differ significantly from liposomes historically used for drug delivery in that they are true particles encapsulating the therapeutic payload within a bilamellar lipid coat. The particle size is small enough to allow REQORSA to cross tight barriers in the lung but large enough to avoid accumulation or clearance in the liver, spleen, and kidney. The cationic (positive) charge of the nanoparticles targets cancer cells. A Phase 1 clinical trial showed that intravenous REQORSA therapy selectively and preferentially targeted tumor cells, resulting in anticancer activity. The nanoparticles are non-immunogenic, allowing repetitive therapeutic dosing and providing an extended half-life in the circulation.



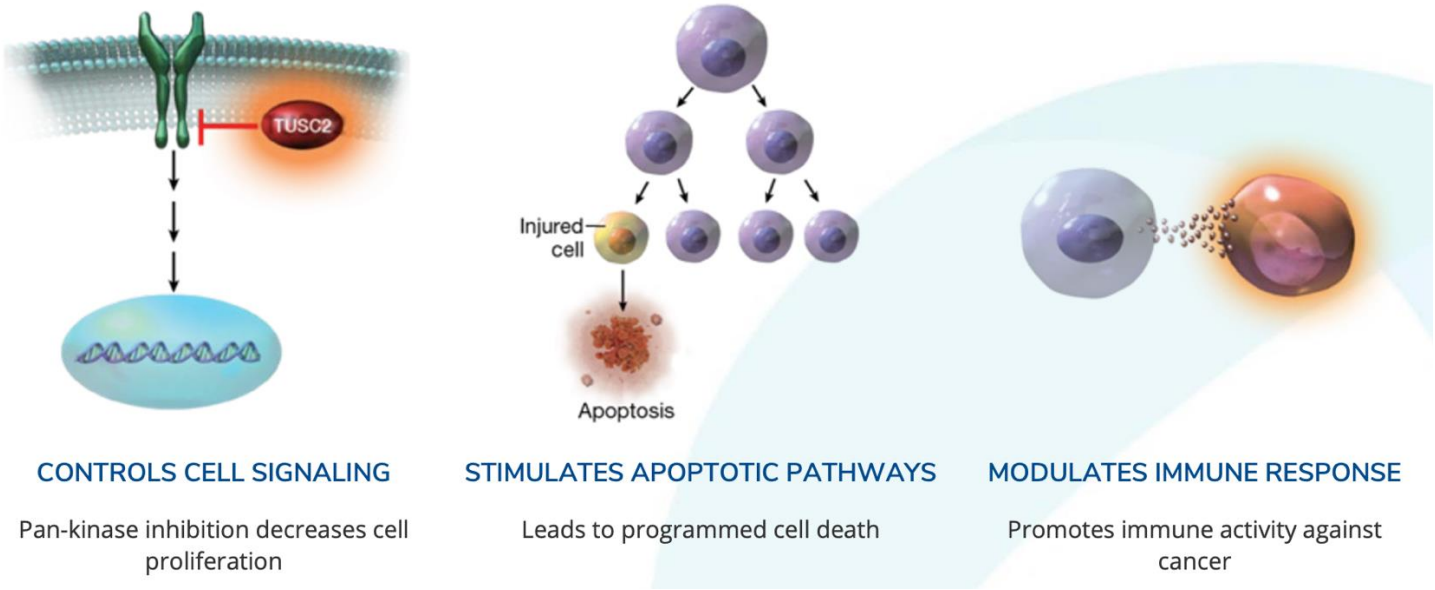

*Source: Genprex*

**Exhibit 7. Selective uptake of REQORSA**




*Source: Genprex*

**Exhibit 8. REQORSA targets cancer at the core**




*Source: Genprex*

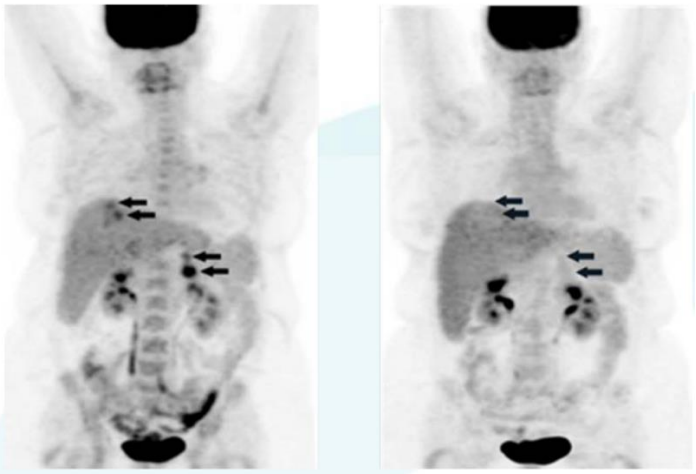
**Exhibit 9. REORSA monotherapy – ONC-001 Trial**

## DOSE ESCALATION STUDY

Explore toxicity and tolerability in patients.

Phase 1 monotherapy results:

- 31 Stage IV patients with at least 1 of 6 trial doses
- 23 patients evaluable
- Cancer growth halted in 5 of 23 patients
- Stable disease n=5; responses n=3
- Highest dose used was 0.09 mg/kg
- Well tolerated in patients



*Metabolic responses in late-stage metastatic lung cancer patient*

*Source: Genprex*

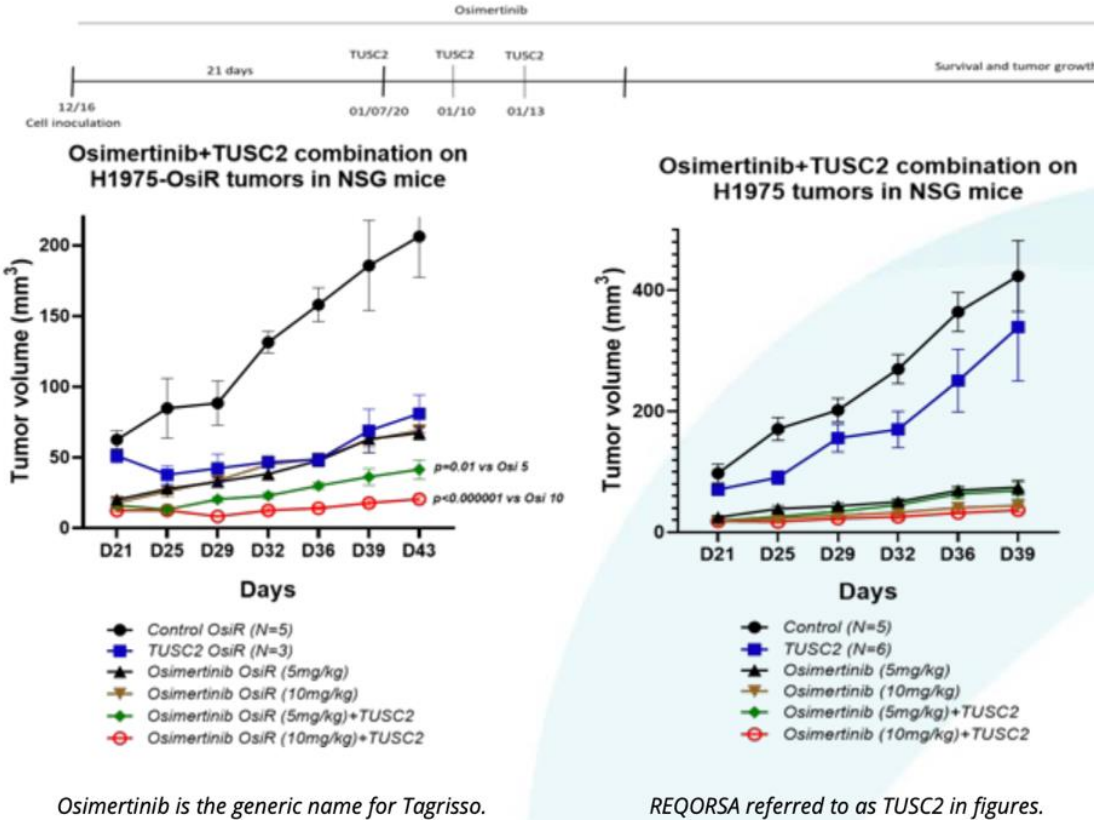
**Exhibit 10. REORSA + TARCEVA Combination**

### PHASE 2 DATA IN SUBJECTS WITH OR WITHOUT EGFR MUTATIONS

| PATIENT EGFR STATUS | RESPONSE | PRIOR THERAPY | PRIOR LINES OF THERAPY |
|---|---|---|---|
| Positive (exon 18+20) | Complete Response | Chemo | 3 |
| Negative | 24% regression Target Lesion | Chemo / anti-PD1 | 2 |
| Negative | 30% regression one Target Lesion<br>18% regression all Target Lesion | Chemo / anti-PD1 | 6 |
| Positive (exon 21) /<br>T790M Negative | Tumor Regression<br>Metabolic response *PET Scan* | Tarceva<br>*(10 cycles)* | 3 |
| Positive (exon 21) | Stable Disease | Tarceva<br>*(12 cycles)* | 2 |
| Negative | Stable Disease | Chemo | 2 |
| Negative | Stable Disease | Chemo | 4 |

*Source: Genprex*

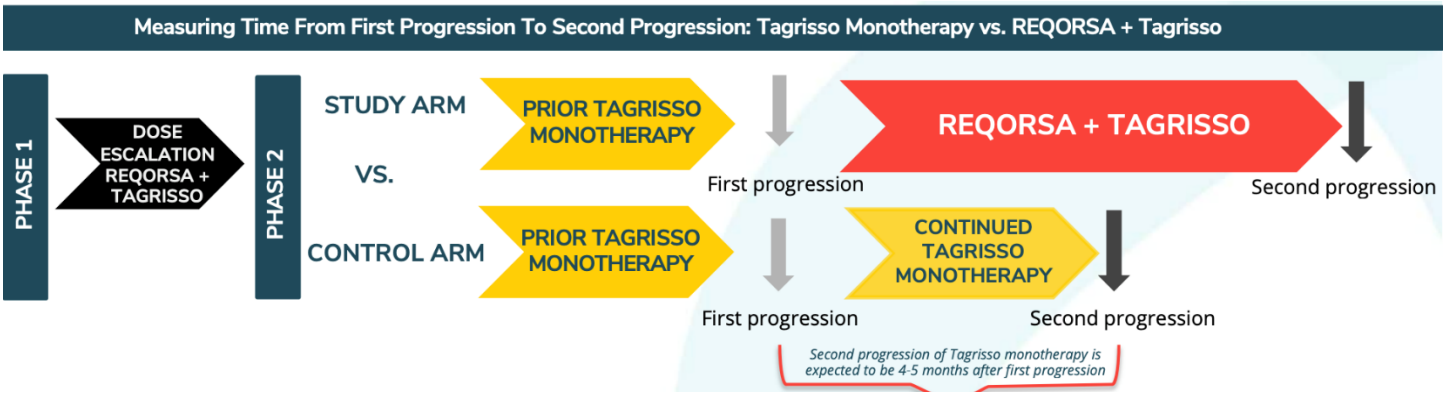
**Exhibit 11. REORSA + TAGRISSO reduce tumor growth in TAGRISSO-resistant tumors.** A preliminary analysis of the interim data from the Phase 2 portion of the ONC-002 trial supported our belief that REQORSA may provide medical benefit in several subpopulations of NSCLC patients for which there is an unmet medical need and may provide pathways for accelerated approval by the FDA. Data from the clinical trials, combined with preclinical data, provided the basis for our application for a Fast Track Designation, which was granted by FDA on January 14, 2020. In granting our Fast Track Designation, the FDA found that REQORSA may provide a benefit over existing therapies for patients whose tumors progress on Tagrisso. The FDA Fast Track Designation is for the use of REQORSA in combination with TKI Tagrisso for the treatment of NSCLC patients with EGFR mutations whose tumors progressed after treatment with Tagrisso. The Acclaim-1 clinical trial (a Phase 1/2 trial of REQORSA combined with Tagrisso) was initiated in June 2021.




*Osimertinib is the generic name for Tagrisso.* *REQORSA referred to as TUSC2 in figures.*

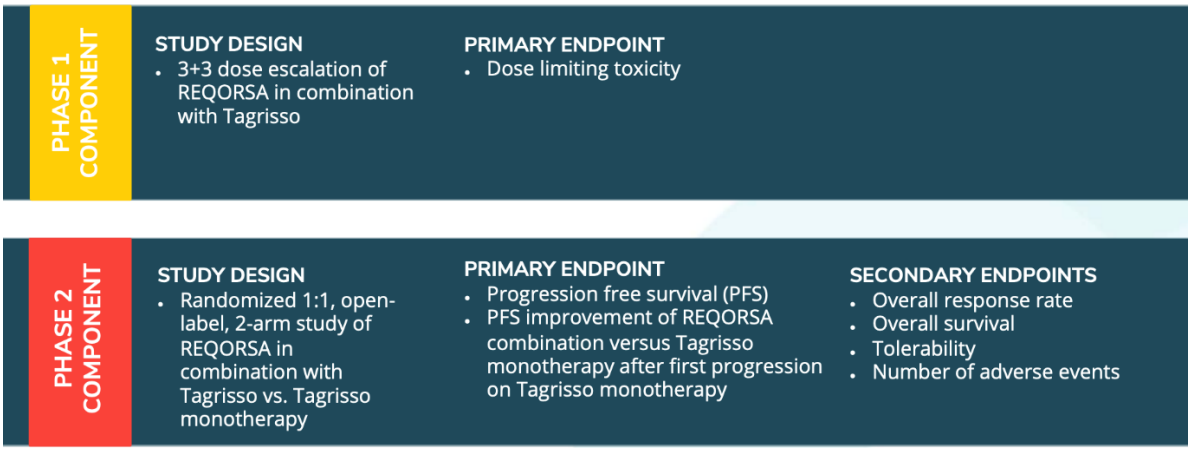
*Source: Genprex*

**Exhibit 12. Acclaim 1: REQORSA in combination with AstraZeneca's Tagrisso for NSCLC**




*Source: Genprex*

**Exhibit 13. Acclaim 1**

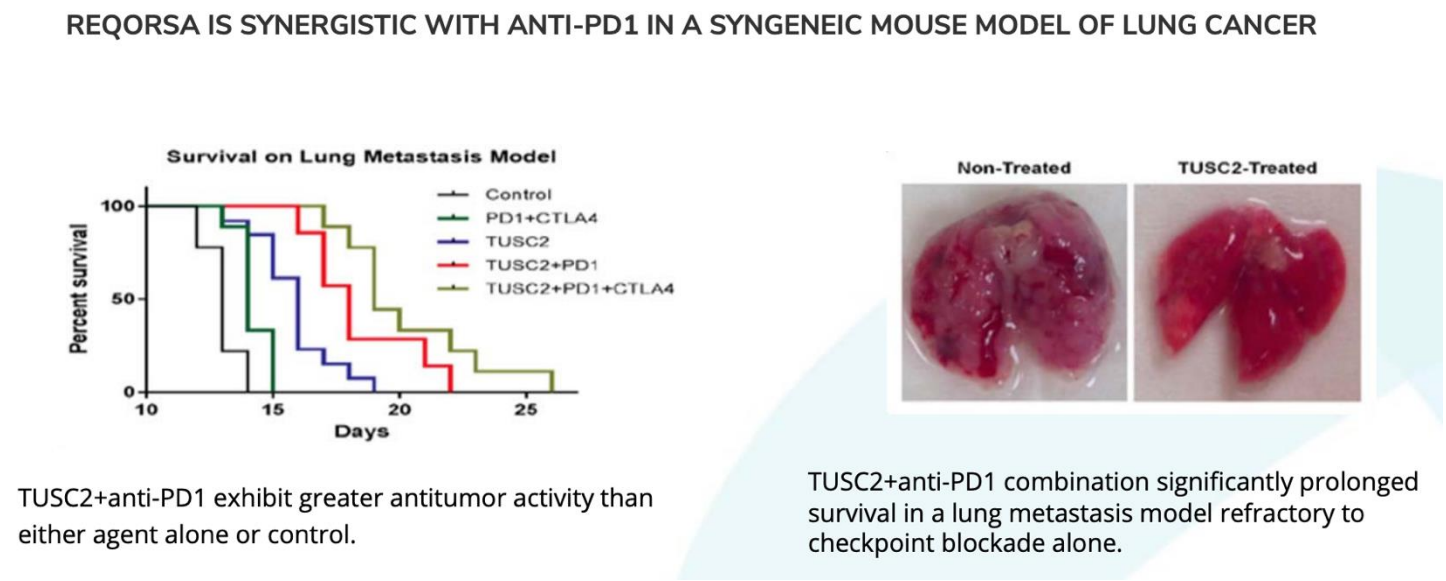



General Study Characteristics

- FDA Fast Track Designation
- Patients with advanced, EGFR mutant NSCLC whose disease progressed after Tagrisso
- ~15 U.S. sites
- ~92 patients
    - Phase 1: 9-18 patients – Cohort 1 Complete
    - Phase 2: 72 patients
- Interim analysis at 25 events (i.e., disease progression or death)
- Expect to complete Phase 1 by year-end 2022

*Source: Genprex*

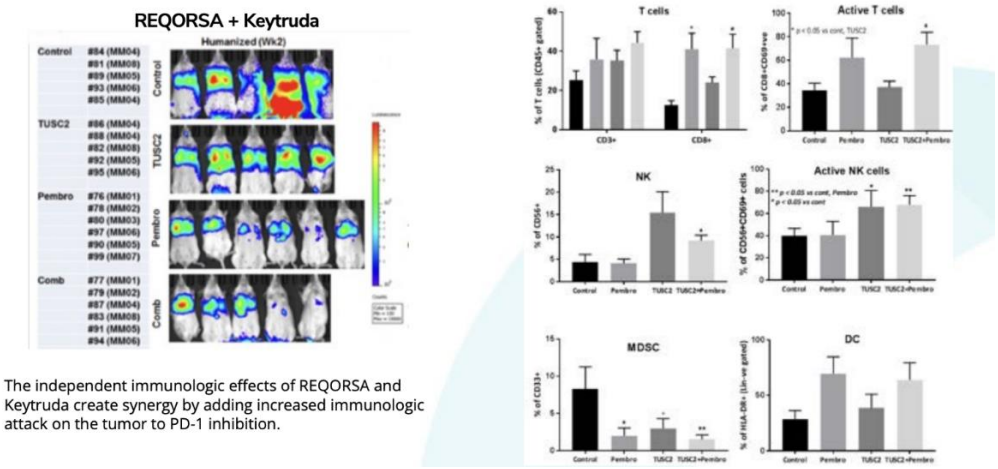
**Exhibit 14. REQORSA shows synergy with immunotherapies**




*Source: Genprex*

**Exhibit 15. REQORSA modulates the immune system**

REQORSA IS SYNERGISTIC WITH ANTI-PD1 IN A HUMANIZED MOUSE MODEL OF LUNG CANCER

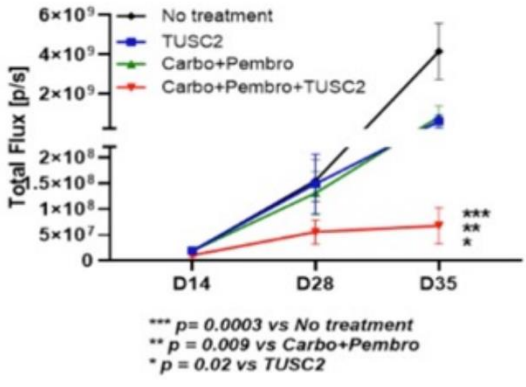


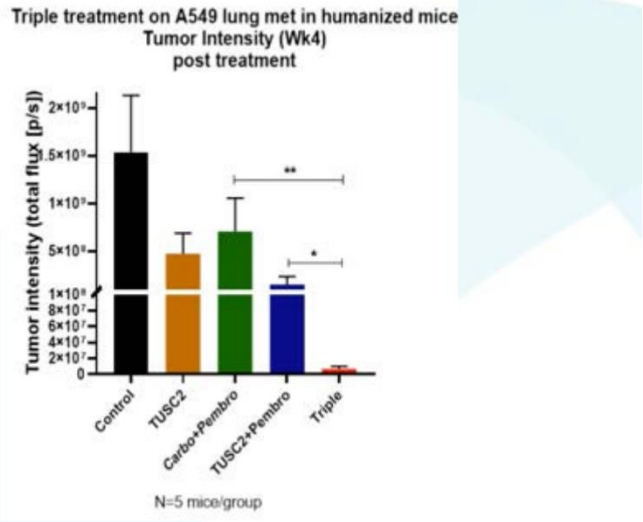

*Source: Genprex*

**Exhibit 16. AACR 21: REQORSA may enhance the first-line standard of care:** Researchers at MD Anderson Cancer Center have conducted preclinical studies evaluating REQORSA® in combination with anti-PD1 checkpoint inhibitors, including Keytruda. Positive and encouraging data indicate that REQORSA is synergistic with immunotherapies. In April 2019, MD Anderson presented positive preclinical data for the combination of TUSC2 with pembrolizumab, demonstrating that TUSC2 combined with checkpoint blockade was more effective than checkpoint blockade alone in increasing the survival of mice with human immune cells that had metastatic lung cancer. In November 2019, MD Anderson presented positive preclinical data for the combination of TUSC2, pembrolizumab, and chemotherapy for the treatment of some of the most resistant metastatic lung cancers. This study found that the combination of TUSC2 increases the effectiveness of pembrolizumab and chemotherapy and, thus, may improve on the first-line standard of care for lung cancer. In May 2020, the company entered into a worldwide, exclusive license agreement with The Board of Regents of the University of Texas System on behalf of MD Anderson for the use of TUSC2 in combination with immunotherapies, including Keytruda and also for the use of TUSC2 in a three-drug combination of TUSC2, immunotherapy, and chemotherapy. In December 2021, Genprex received Fast Track Designation from the FDA for the 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 March 2022, Genprex opened the Acclaim-2 clinical trial for patient enrollment, a Phase 1/2 clinical trial of REQORSA combined with Keytruda.

**REQORSA + Keytruda + Chemo**

- REQORSA enhances the efficacy of chemo-immunotherapy on KL-mutant lung metastases in humanized mice.
- Triple combination demonstrated strong antitumor efficacy and induced robust antitumor immunity in KRAS-LKB1 (KL)-mutant NSCLC in clinically relevant humanized mice models.

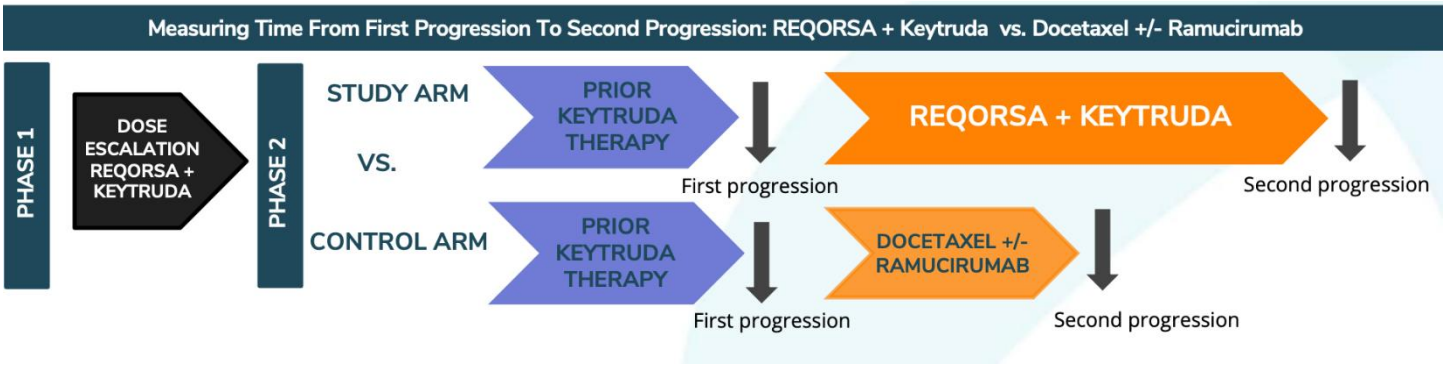



*Source: Genprex*

**Exhibit 17. Acclaim 2:** REQORSA is being evaluated in combination with Keytruda for NSCL. The Acclaim-2 trial is a Phase 1/2 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. The Company anticipates enrolling patients at approximately 15 clinical sites and estimates that the Phase 1 portion of the Acclaim-2 trial will enroll up to 30 patients, and the Phase 2 portion will enroll approximately 126 patients. Patients enrolled in the Phase 2 portion of the study will be randomized 2:1 to either REQORSA and Keytruda combination therapy or to chemotherapy (docetaxel with or without ramucirumab). Patients will be treated until disease progression or unacceptable toxicity is experienced. Patients must have histologically confirmed unresectable stage III or IV NSCLC (any histology) with radiological progression on Keytruda and an ECOG performance status of 0 to 1.

Genprex updated the status of the trial (Jan. 2023) as follows: The trial is currently enrolling and treating patients in the dose escalation portion of the Phase *1/2* (Acclaim-2) study. As stated above, the Acclaim-2 trial uses a combination of REQORSA and Keytruda in patients with late-stage non-small cell lung cancer whose disease has progressed after treatment with Keytruda. The dose escalation portion of Phase 1 of the study is expected to be completed by the end of 2023. The company plans to then evaluate 12 more patients at the maximum tolerated dose – MTD, or recommended Phase *2* dose RP2D to expand the safety profile. The FDA has granted Fast Track Designation for the Acclaim-2 treatment combination of REQORSA and Keytruda in NSCLC patients who have progressed after Keytruda.

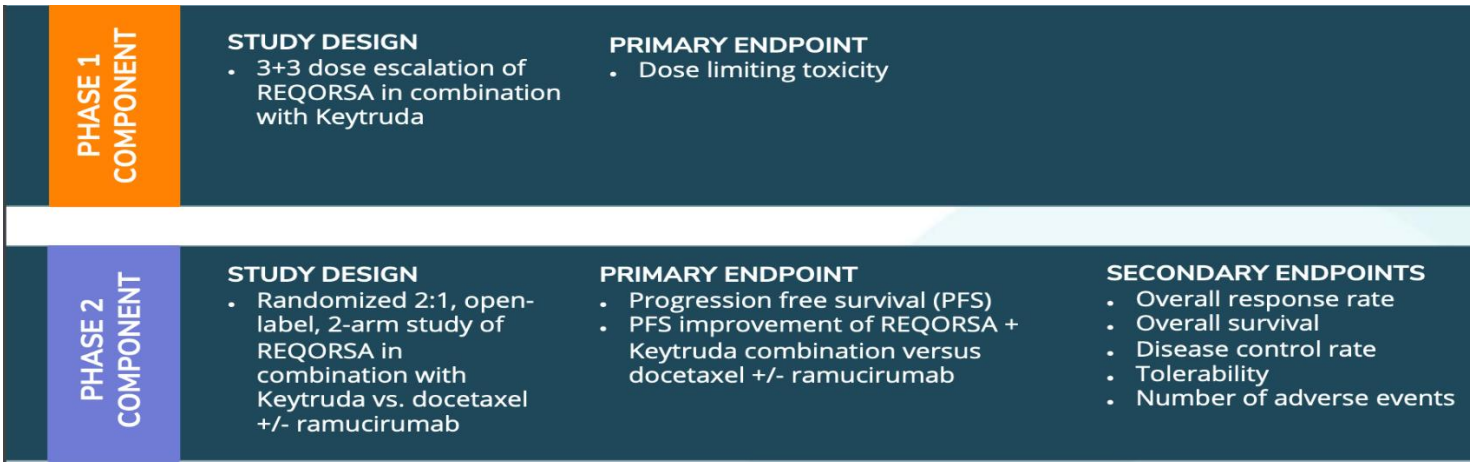



General study characteristics:

- FDA Fast Track Designation (received December 2021)
- Patients with advanced NSCLC whose disease progressed after treatment with Keytruda
- ~10 U.S. sites
- ~156 patients
    - Phase 1: Up to 30 patients
    - Phase 2: 126 patients
- Interim analysis at 50 events (i.e., disease progression or death)
- Expect to complete Phase 1 by mid-2023

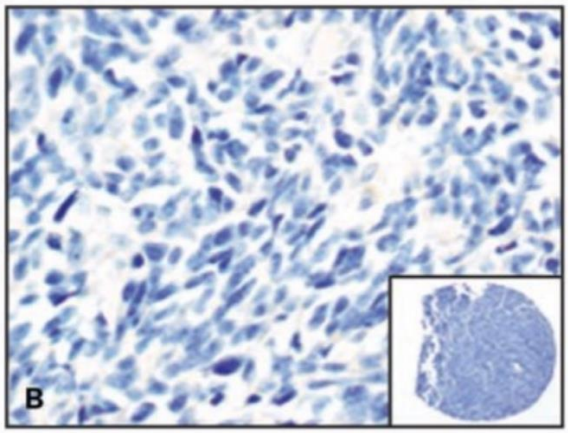
*Source: Genprex*

**Exhibit 18. Acclaim 2**




*Source: Genprex*

**Exhibit 19. REQORSA in small cell lung cancer**




Small cell lung cancer with negative TUSC2 expression.

Targeting **Small Cell Lung Cancer** (in addition to NSCLC) allows Genprex to address virtually the **entire lung cancer market.**

**Small Cell Lung Cancer:**

- Consistently has low TUSC2 protein levels
- Documented to often have deletion of one TUSC2 gene allele
- Extensive stage SCLC has very poor prognosis – a median PFS of 5.2 months

Another clinical opportunity to combine REQORSA with checkpoint inhibitors

*Source: Genprex*

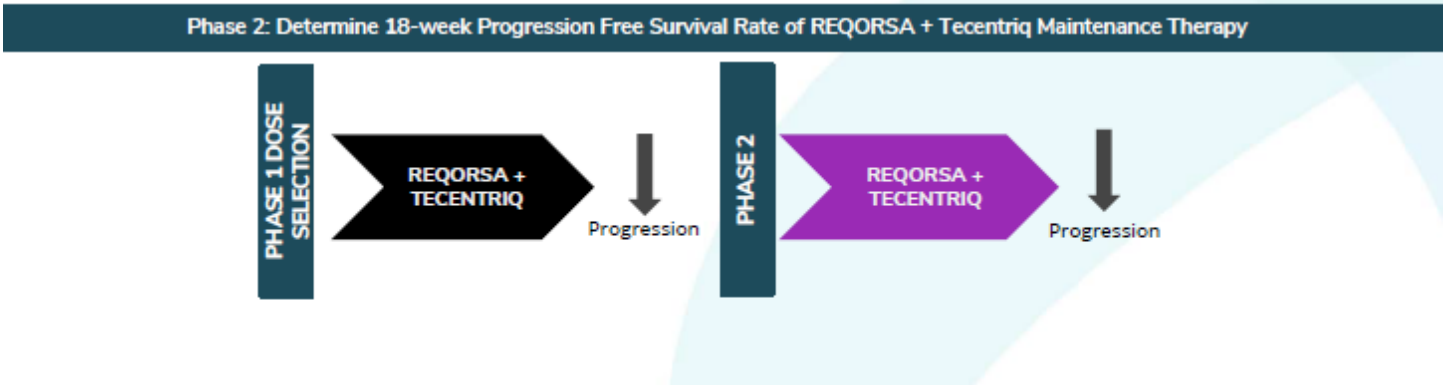
**Exhibit 20. ACLAIM 3:** In Q422 Genprex filed with the FDA the protocol for a P1/2 "Acclaim-3" trial using a combination of REQORSA and Tecentriq as maintenance therapy in patients with extensive stage small cell lung cancer ("ES-SCLC") who did not develop tumor progression after receiving Tecentriq and chemotherapy. The first patient is expected to be treated by 3Q23. The company anticipates enrolling patients at approximately 10 U.S. clinical sites and estimate that the Phase 1 escalation portion of the Acclaim-3 trial could enroll up to 12 patients, and the Phase 2 portion may enroll approximately 50 patients. Patients are to be treated with REQORSA and Tecentriq until disease progression or unacceptable toxicity is experienced. The primary endpoint of the Phase 1 escalation portion is to determine the maximum tolerated dose or recommended Phase 2 dose and the Phase 2 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.

GENERAL STUDY CHARACTERISTICS

- Patients with ES-SCLC who did not develop tumor progression after receiving Tecentriq and chemotherapy
- ~10 U.S. sites
- ~62 patients
  - Phase 1: Up to 12 patients
  - Phase 2: ~50 patients
- Expect to dose First Patient in Phase 1 Dose Escalation by end of Q3 2023
- Phase 2 futility analysis after 25th patient enrolled and treated reaches 18 weeks of follow up

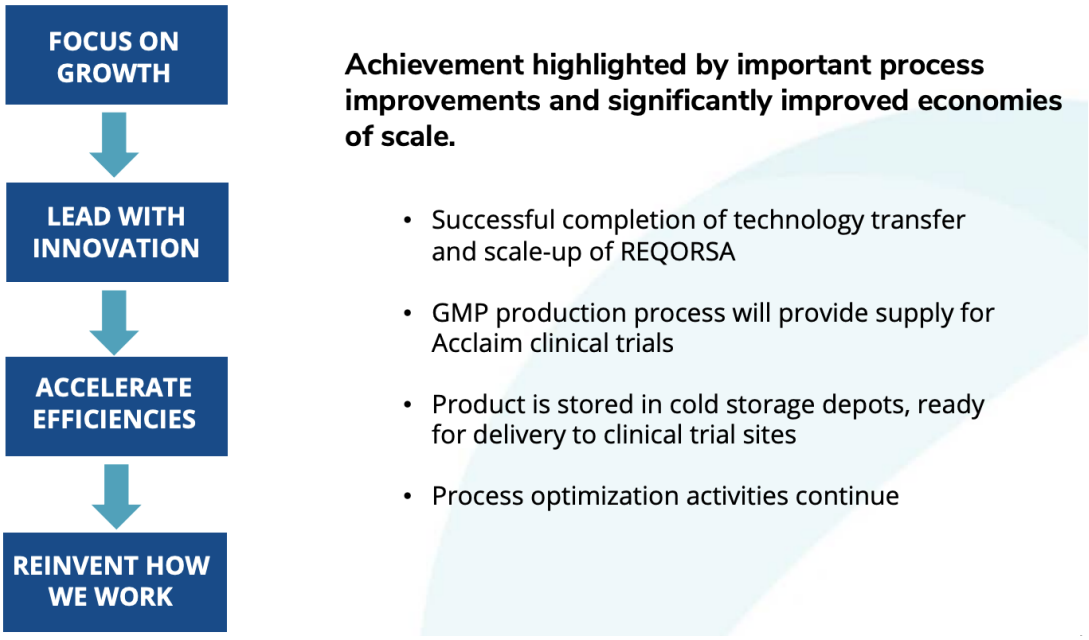
Acclaim · 3

REQORSA in combination with Genentech, Inc.'s Tecentriq for SCLC




*Source: Genprex*

**Exhibit 21. Scaled-up clinical-grade manufacturing positions company for success in lung cancer therapeutics market**




*Source: Genprex*

**Exhibit 22. Diabetes Program.** The goal of the program is to successfully reprogram beta cells to become “like” alpha cells. The therapy utilizes a novel infusion process that uses an endoscope to deliver an AAV vector with a glucagon promoter to deliver the Pdx1 + MafA (PM) genes to the pancreas. The goal is to transform alpha cells in the pancreas into functional beta-like cells, which can then produce insulin but are distinct enough from beta cells to evade the body’s immune system.

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. While the release products of the beta cell inhibit alpha cell function, the alpha cell releases factors that are stimulatory for beta cell function and increase glucose-stimulated insulin secretion.

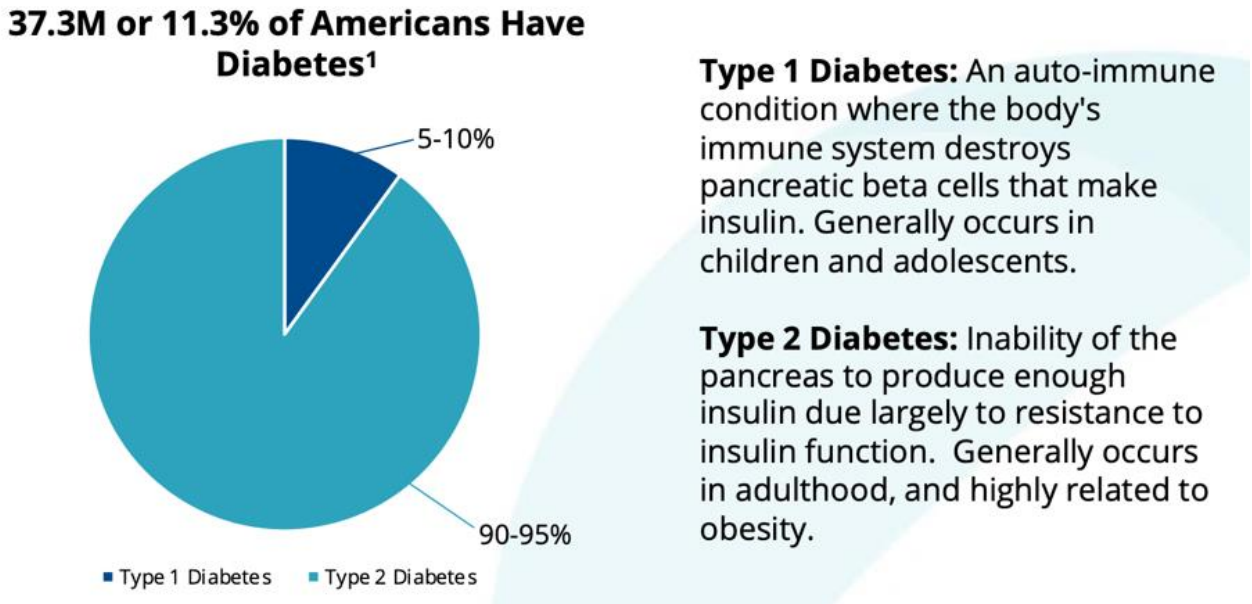
In people with Type 1 diabetes, however, beta cells are destroyed by the immune system and no longer secrete insulin, leading to an absolute deficit of insulin. Type 2 diabetes is due to "insulin resistance," an initial resistance of the body's cells to obey the direction of insulin. To overcome this 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 of 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 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 drugs 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 the quality of life, but none of these advances is 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 Byetta®, Trulicity®, 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.** Genprex licensed a gene therapy asset from the University of Pittsburgh, GPX-002. GPX-002 is believed able to restore the function of beta cells that are destroyed by the immune system and overcome further destruction of insulin-producing cells. This technology infuses adeno-associated virus carrying Pdx1 and MafA gene expression cassettes through the pancreatic duct to reprogram alpha cells into functional beta-like cells, which can produce insulin but are distinct enough from beta cells to evade the body's immune system. In Preclinical Studies, GPX-002 was tested, in vivo, in mice and nonhuman primates. In studies in non-obese diabetic mice, a model of Type 1 autoimmune diabetes, the gene therapy approach restored normal blood glucose levels for an extended period of time, typically around four months. According to the researchers, the duration of restored blood glucose levels in mice could potentially translate to decades in humans. If successful, this gene therapy could eliminate the need for insulin replacement therapy for diabetic patients.

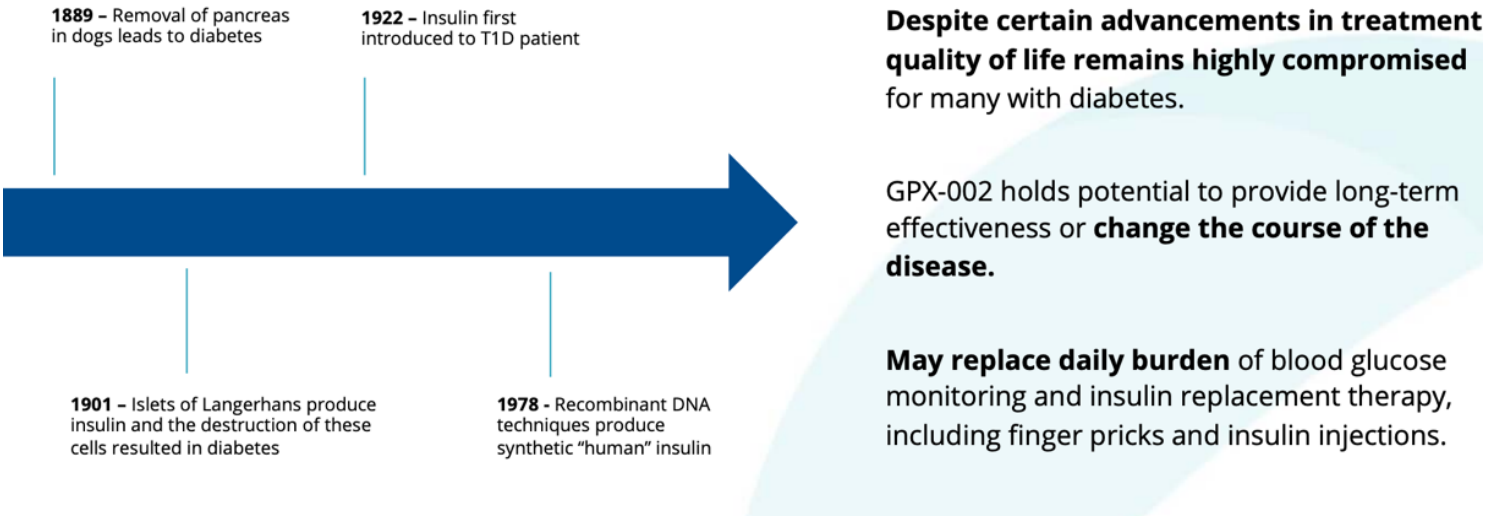



*Source: Genprex*

**Exhibit 23. Diabetes: A global epidemic**

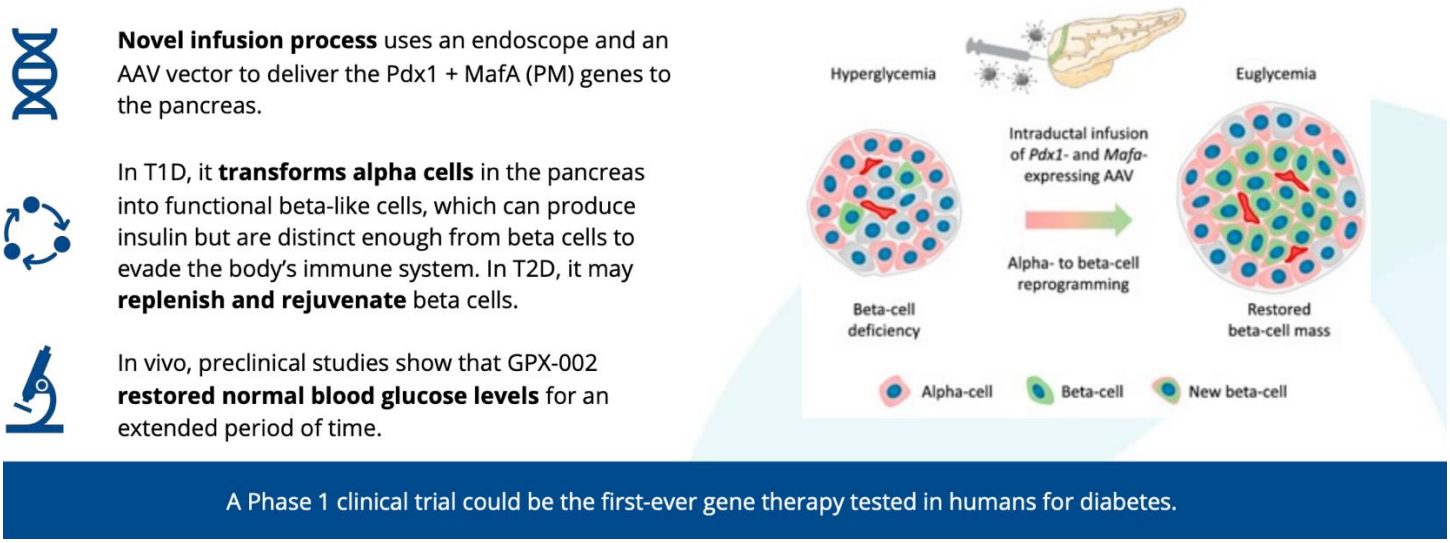

*Source: Genprex*

**Exhibit 24. Diabetic patients are in need of advanced therapy**



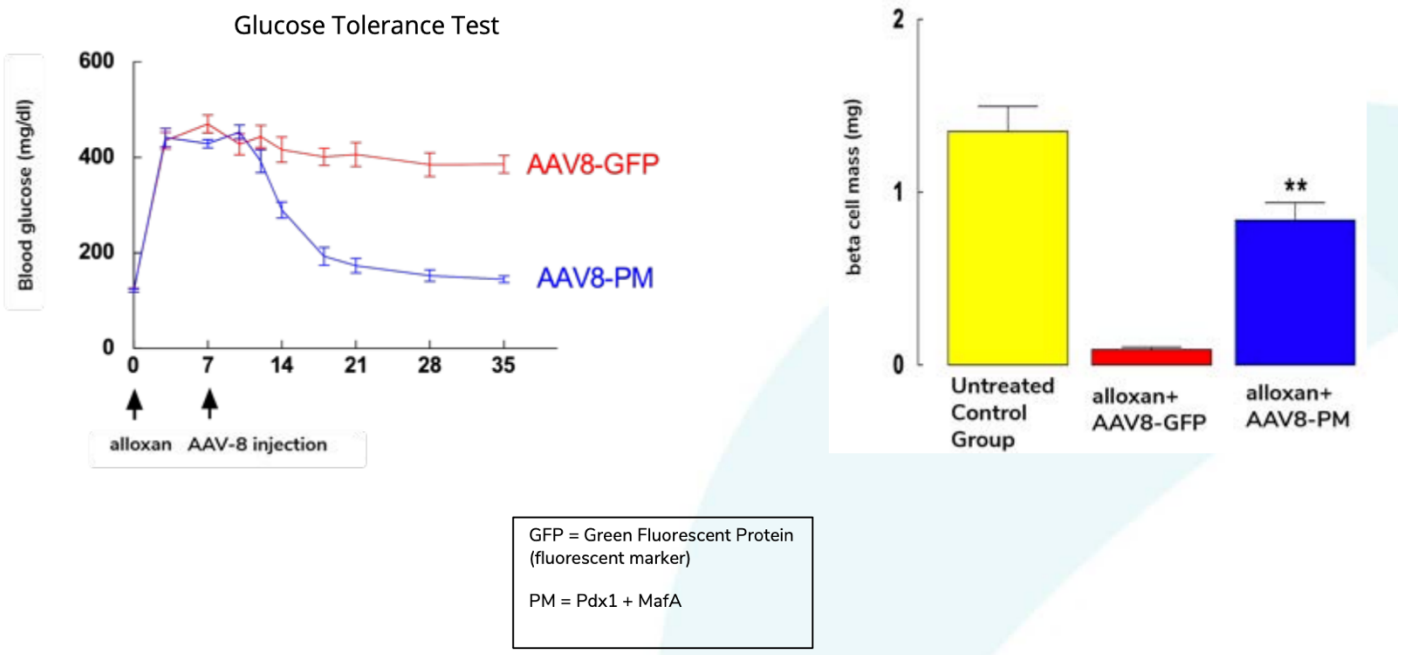

*Source: Genprex*

**Exhibit 25. GPX-002 replenishes levels of insulin:** GPX-002 is comprised of an infusion process that uses an endoscope and an adeno-associated virus (AAV) vector with a glucagon promoter to deliver Pdx1 and MafA genes to the pancreas. The genes express proteins that transform alpha cells in the pancreas into functional beta-like cells, which can produce insulin but are distinct enough from beta cells to evade the body's immune system. GPX-002 has been tested in vivo in mice and nonhuman primates. Earlier studies in diabetic mouse models showed that an earlier version of GPX-002 restored normal blood glucose levels for an extended period of time, typically around four months. It is believed that the duration of restored blood glucose levels in mice could translate to decades in humans. This gene therapy could not only become a new treatment option for millions of diabetes patients who need insulin replacement therapy, but it holds the potential to provide long-term effectiveness or may even be a cure for diabetic patients.



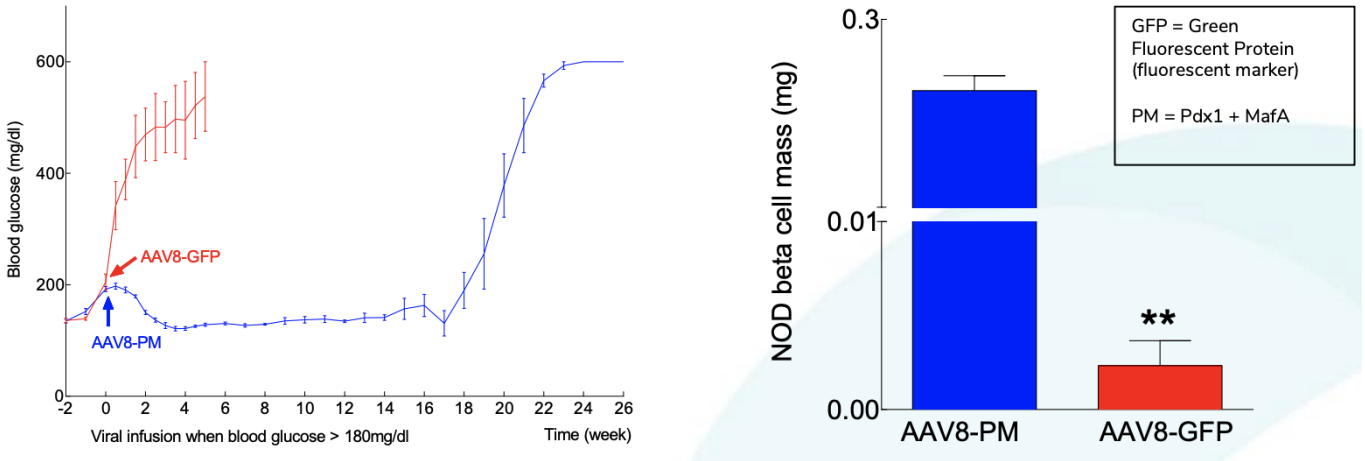

*Source: Genprex*

**Exhibit 26. GPX-002 reverse drug-induced diabetes in mice**




*Source: Genprex*

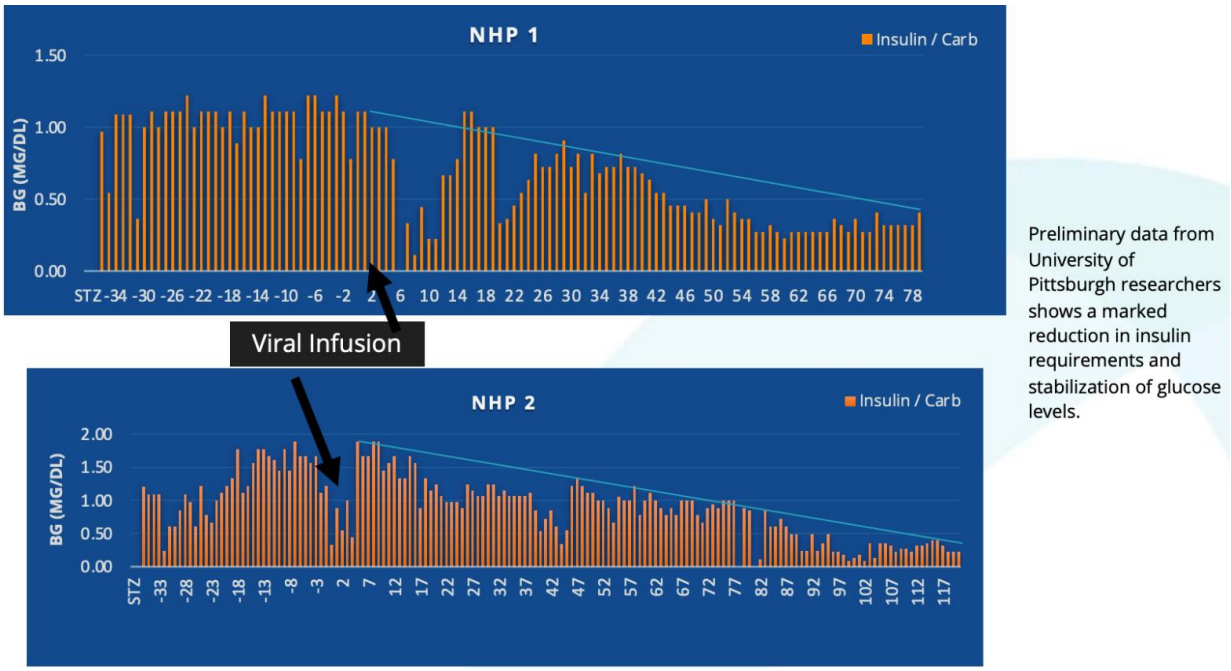
**Exhibit 27. GPX-002 restored blood glucose in T1D mouse model for four months**




- One week in a mouse tends to correlate to about one year in humans
- The average age of onset in Non-Obese Diabetic (NOD) mice is 14 weeks of age
- Coincidentally, the average age of onset of juvenile diabetes in humans is 14 years old
- The duration of restored blood glucose levels in mice could potentially translate to decades in humans.

*Source: Genprex*

**Exhibit 28. GPX-002 reduces insulin requirements in nonhuman primate model of T1D**



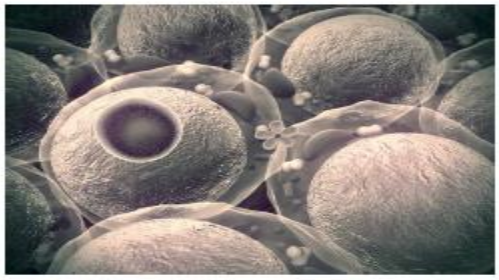

*Source: Genprex*

**Research collaborators at the University of Pittsburgh plan to present preclinical data highlighting the therapeutic potential of Genprex's gene therapy for Type 1 diabetes at the 16th International Conference on Advanced Technologies & Treatments for Diabetes (ATTD 2023) being held February 22-25 in Berlin, Germany and online.**

**Presentation Details:** Abstract Number: 203; Abstract Title: Pancreatic Intraductal Infusion of Adeno-Associated Virus To Treat Nonhuman Primates in a Toxin-Induced Diabetes Model. Format: Oral Presentation. Presenter: Ranjeet Kalsi, DO, representing the laboratory of George Gittes, MD, Professor of Surgery and Pediatrics and Chief of the Division of Pediatric Surgery, University of Pittsburgh School of Medicine. Time/Date: 1:45 pm Central European Standard Time on Saturday, February 25, 2023

The abstract will be made available on the ATTD conference website at https://attd.kenes.com

**Exhibit 29. GPX-003 rejuvenates and replenishes beta cells in T2D.** GPX-003 is believed to work by rejuvenating diminished beta cells to increase insulin expression by introducing transcription factors controlled by an insulin promoter. GPX-003 is based on the same general gene therapy approach under Genprex's original license that is comprised of a novel infusion process that uses an endoscope and an adeno-associated virus (AAV) vector to deliver Pdx1 and MafA genes directly to the pancreas.



- T2D stresses beta cells and their insulin production.
- GPX-003 is designed to replenish and rejuvenate beta cells and insulin production.
- Uses an endoscope and an AAV vector to deliver the Pdx1 + MafA (PM) genes to the pancreas with an insulin promoter.
- Sponsored Research Agreement supports ongoing non-human primate studies in T2D.
- Opportunity to lead disease modifying approach to treat this epidemic.

*Source: Genprex*

**Exhibit 30. Achievements, upcoming milestones, Trial Timelines**


*Source: Genprex*

**Intellectual Property:** The United States Patent and Trademark Office (USPTO) has granted Genprex U.S. Patent No: 11,278,592 B2. The patent covers methods of using REQORSATM Immunogene Therapy in conjunction with immune checkpoint inhibitors, through 2038.

**Valuation:** Our valuation for Genprex is based on revenue projections out to 2033. We know that the markets the company is pursuing in diabetes and Oncology are blockbuster in size, and the therapies are still in the early stages of development. To adjust for this, we apply a 30% risk cut in our therapeutic models. The subsequent revenues are then fed into our income statement. To the income statement metrics, we then model a target valuation. We assume the company does raise additional capital, and as such, our valuation math is based on 2033 fully diluted share count. Our valuation models include Free Cash Flow to the Firm (FCFF), discounted EPS (dEPS), and Sum-of-the-Parts (SOP) and use a 30% discount rate. This is in addition to the 30% risk cut in our revenue models. We select 30% for micro-capitalized growth companies, and this represents our highest risk rate. The result of these three models is then equal-weighted and averaged, and rounded to the nearest whole number to provide a 12-month target price. We note that as the company establishes proof of concept, from trial data, the risk rate (r) is lowered, resulting in a higher valuation. As such, understanding the timeline around data releases, the data becomes important as it is likely to have a significant impact on the valuation of the company.

## Exhibit 31. Free Cash Flow Model

| | | |
|---|---|---|
| | Average | $ 3 |

| | | |
|---|---|---|
| | Price Target | $ 3 |
| | Year | 2023 |

**DCF Valuation Using FCF (mln):**

| units ('000) | | | 2022E | 2023E | 2024E | 2025E | 2026E | 2027E | 2028E | 2029E | 2030E | 2030E | 2030E | 2030E |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| EBIT | | | (23,427) | (26,041) | (29,081) | (32,707) | (37,037) | (42,210) | (48,396) | (42,915) | 97,507 | 346,706 | 645,891 | 1,945,062 |
| Tax Rate | | | 0% | 0% | 0% | 0% | 0% | 0% | 0% | 0% | 10% | 15% | 20% | 36% |
| EBIT(1-t) | | | (23,427) | (26,041) | (29,081) | (32,707) | (37,037) | (42,210) | (48,396) | (42,915) | 87,757 | 294,700 | 516,713 | 1,244,840 |
| CapEx | | | | | | | | | | | | | | |
| Depreciation | | | | | | | | | | | | | | |
| Change in NWC | | | | | | | | | | | | | | |
| FCF | | | (23,427) | (26,041) | (29,081) | (32,707) | (37,037) | (42,210) | (48,396) | (42,915) | 87,757 | 294,700 | 516,713 | 1,244,840 |
| PV of FCF | | | (30,455) | (26,041) | (22,370) | (19,353) | (16,858) | (14,779) | (13,034) | (8,891) | 13,985 | 36,127 | 48,726 | 90,298 |
| Discount Rate | | 30% | | | | | | | | | | | | |
| Long Term Growth Rate | | 1% | | | | | | | | | | | | |
| Terminal Cash Flow | | 4,335,476 | | | | | | | | | | | | |
| Terminal Value YE2030 | | 314,487 | | | | | | | | | | | | |
| NPV | | 382,298 | | | | | | | | | | | | |
| NPV-Debt | | - | | | | | | | | | | | | |
| Shares out (thousands) | | 152,284 | 2033E | | | | | | | | | | | |
| NPV Per Share | $ | 2.51 | | | | | | | | | | | | |

*Source: Dawson James estimates*

## Exhibit 32. Discounted EPS Model

| | | |
|---|---|---|
| Current Year | | 2023 |
| Year of EPS | | 2033 |
| Earnings Multiple | | 5 |
| Discount Factor | | 30% |
| Selected Year EPS | $ | 8.17 |
| NPV | $ | 2.96 |

Source: Dawson James estimates

| | Discount Rate and Earnings Multiple Varies, Year is Constant 2033 EPS | | | | | |
|---|---|---|---|---|---|---|
| Earnings Multiple | 3.0 | 5% | 10% | 15% | 20% | 25% | 30% |
| | **5** | **$25.09** | $15.76 | $10.10 | $6.60 | $4.39 | $ 2.96 |
| | **10** | $50.18 | $31.52 | $20.21 | $13.20 | $8.78 | $ 5.93 |
| | **15** | $75.28 | $47.27 | $30.31 | $19.80 | $13.17 | $ 8.89 |
| | **20** | $100.37 | $63.03 | $40.41 | $26.40 | $17.55 | $ 11.86 |
| | **25** | $125.46 | $78.79 | $50.52 | $33.01 | $21.94 | $ 14.82 |
| | **30** | $150.55 | $94.55 | $60.62 | $39.61 | $26.33 | $ 17.79 |
| | **35** | $175.64 | $110.31 | $70.72 | $46.21 | $30.72 | $ 20.75 |
| | **40** | $200.74 | $126.06 | $80.82 | $52.81 | $35.11 | $ 23.72 |

*Source: Dawson James estimates*

## Exhibit 33. Sum-of-the-Parts Model

| **Genprex** | LT Gr | Discount Rate | Yrs. to Mkt Peak | % Success | Peak Sales MM's | Term Val |
|---|---|---|---|---|---|---|
| Oncology | 1% | 30% | 7 | 30% | $1,000 | $3,448 |
| NPV | | | | | | $0.87 |
| Diabetes | 1% | 30% | 7 | 30% | $1,000 | $3,448 |
| NPV | | | | | | $0.87 |
| Technology Platform & Pipeline | 1% | 30% | 7 | 30% | $1,000 | $3,448 |
| NPV | | | | | | $0.87 |
| Net Margin | | | | | | 80% |
| MM Shrs OS (2033E) | | | | | | 152 |
| Total | | | | | | $2.60 |

*Source: Dawson James estimates*

**Risks to our thesis include** 1. Regulatory Approvals; 2. Clinical Science 3. Adoption Rates 4. The competitive landscape 5. Intellectual Capital 6. Dilution.

- **Regulatory Approvals**. The company's products require regulatory approvals, and there can be no assurances that the requirements to achieve these approvals can be met.
- **Clinical Science:** The company will need to demonstrate to its "sophisticated" clients (cardiologists) that the product works and is comparable to the existing standard of care.
- **Adoption Rates**: There are no assurances that our projected market share can be met. A combination of factors from pricing and reimbursement to competitive performance are expected to be key factors in driving users to select the product for their practices, patients, and the emergency room setting.
- **The Competitive Landscape & IP**. The company does have intellectual property and knows how to protect the utility of its devices and software; however, we expect that the technology cycle will be competitive, and the company may face competition from well-financed competitors who are already in position in the target markets.
- **Dilution**: The company is likely to incur losses for the foreseeable future until it is able to generate sufficient revenue from product sales. Our model assumes a rising share count. There can be no assurances that the company can successfully raise the capital required to execute its business strategy.

## Exhibit 34. Income Statement

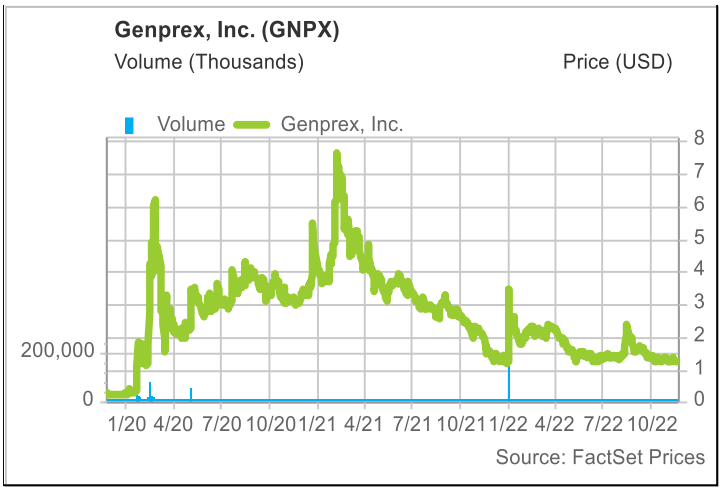
| GENPREX: Income Statement ('000s) | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 000 .: YE December 31 | 2022E | 1Q23E | 2Q23E | 3Q23E | 4Q23E | 2023E | 1Q24E | 2Q24E | 3Q24E | 4Q24E | 2024E | 2025E | 2026E | 2027E | 2028E | 2029E | 2030E | 2031E | 2032E | 2033E |
| **Product sales** | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | | | | |
| Oncology | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | 75,000 | 200,000 | 350,000 | 1,000,000 |
| Diabetes | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | 75,000 | 200,000 | 350,000 | 1,000,000 |
| **Total Product Sales** | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | 150,000 | 400,000 | 700,000 | 2,000,000 |
| **Costs and Expenses:** | | | | | | | | | | | | | | | | | | | | |
| COGS | | | | | | | | | | | | | | | | | 45,000 | 112,000 | 175,000 | 500,000 |
| COGS % | | | | | | | | | | | | | | | | | 30% | 28% | 25% | 25% |
| Depreciation | | | | | | | | | | | | | | | | | | | | |
| Research and Development | 12,191 | 3,511 | 3,657 | 3,657 | 3,804 | 14,629 | 4,213 | 4,389 | 4,389 | 4,564 | 17,555 | 21,066 | 25,280 | 30,336 | 36,403 | 29,122 | 27,666 | 28,219 | 28,784 | 29,359 |
| General and Administrative | 11,298 | 2,739 | 2,853 | 2,853 | 2,967 | 11,411 | 2,766 | 2,881 | 2,881 | 2,997 | 11,526 | 11,641 | 11,757 | 11,875 | 11,993 | 13,793 | 24,827 | 25,075 | 25,326 | 25,579 |
| **Total Operating Expenses** | 23,490 | 6,250 | 6,510 | 6,510 | 6,771 | 26,041 | 6,979 | 7,270 | 7,270 | 7,561 | 29,081 | 32,707 | 37,037 | 42,210 | 48,396 | 42,915 | 52,493 | 53,294 | 54,109 | 54,938 |
| Loss from Operations | (23,490) | (6,250) | (6,510) | (6,510) | (6,771) | (26,041) | (6,979) | (7,270) | (7,270) | (7,561) | (29,081) | (32,707) | (37,037) | (42,210) | (48,396) | (42,915) | 97,507 | 346,706 | 645,891 | 1,945,062 |
| **Other Expense** | | | | | | | | | | | | | | | | | | | | |
| Interest Income | 63 | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| **Total Other Expense** | 63 | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| **Net Loss** | (23,427) | (6,250) | (6,510) | (6,510) | (6,771) | (26,041) | (6,979) | (7,270) | (7,270) | (7,561) | (29,081) | (32,707) | (37,037) | (42,210) | (48,396) | (42,915) | 97,507 | 346,706 | 645,891 | 1,945,062 |
| | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | 9,751 | 52,006 | 129,178 | 700,222 |
| Tax Rate | 0% | 0% | 0% | 0% | 0% | 0% | 0% | 0% | 0% | 0% | 0% | 0% | 0% | 0% | 0% | 0% | 10% | 15% | 20% | 36% |
| **GAAP Net Income (loss)** | (23,427) | (6,250) | (6,510) | (6,510) | (6,771) | (26,041) | (6,979) | (7,270) | (7,270) | (7,561) | (29,081) | (32,707) | (37,037) | (42,210) | (48,396) | (42,915) | 87,757 | 294,700 | 516,713 | 1,244,840 |
| | | | | | | | | | | | | | | | | | | | | |
| **GAAP-EPS** | (0.49) | (0.10) | (0.11) | (0.11) | (0.11) | (0.43) | (0.09) | (0.09) | (0.09) | (0.10) | (0.38) | (0.38) | (0.38) | (0.39) | (0.43) | (0.38) | 0.77 | 2.57 | 4.48 | 10.76 |
| GAAP EPS (dil) | (0.49) | (0.09) | (0.09) | (0.09) | (0.09) | (0.37) | (0.07) | (0.07) | (0.07) | (0.07) | (0.28) | (0.28) | (0.28) | (0.29) | (0.32) | (0.29) | 0.58 | 1.95 | 3.41 | 8.17 |
| Wgtd Avg Shrs (Bas) ' 000 | 47,948 | 59,866 | 60,464 | 61,069 | 61,679 | 60,769 | 76,741 | 76,818 | 76,895 | 76,972 | 76,856 | 87,179 | 97,544 | 109,196 | 113,394 | 113,848 | 114,305 | 114,762 | 115,222 | 115,684 |
| Wgtd Avg Shrs (Dil) '000 | 47,948 | 69,866 | 70,564 | 71,270 | 71,983 | 70,920 | 102,054 | 102,157 | 102,259 | 102,361 | 102,208 | 117,640 | 133,133 | 144,928 | 149,270 | 149,868 | 150,468 | 151,071 | 151,676 | 152,284 |

*Source: Dawson James estimates, company reports*

Companies mentioned in this report:

**Important Disclosures:**

**Price Chart:**




Price target and ratings changes over the past three years:
Initiated – Buy – January 30, 2023 – Price Target $3.00

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**Ratings Definitions:**

1) **Buy**: The analyst believes the price of the stock will appreciate and produce a total return of at least 20% over the next 12-18 months.
2) **Neutral**: The analyst believes the price of the stock is fairly valued for the next 12-18 months.
3) **Sell**: The analyst believes the price of the stock will decline by at least 20% over the next 12-18 months and should be sold.

The following chart reflects the range of current research report ratings for all companies, followed by the analysts of the Firm. The chart also reflects the research report ratings relating to those companies for which the Firm has performed investment banking services.

Current as of 30-Jan-23

| | Company Coverage | | Investment Banking | |
|---|---|---|---|---|
| **Ratings Distribution** | # of Companies | % of Total | # of Companies | % of Totals |
| Market Outperform (Buy) | 23 | 70% | 1 | 4% |
| Market Perform (Neutral) | 9 | 27% | 2 | 22% |
| Market Underperform (Sell) | 1 | 3% | 0 | 0% |
| Total | 33 | 100% | 3 | 9% |

**Analyst Certification:**

The analyst(s) whose name appears on this research report certifies that 1) all of the views expressed in this report accurately reflect his (their) personal views about any and all of the subject securities or issuers discussed; and 2) no part of the research analyst's compensation was, is, or will be directly or indirectly related to the specific recommendations or views expressed by the research analyst in this research report; and 3) all Dawson James employees, including the analyst(s) responsible for preparing this research report, may be eligible to receive non-product or service-specific monetary bonus compensation that is based upon various factors, including total revenues of Dawson James and its affiliates as well as a portion of the proceeds from a broad pool of investment vehicles consisting of components of the compensation generated by investment banking activities, including but not limited to shares of stock and/or warrants, which may or may not include the securities referenced in this report.