Genprex, Inc.
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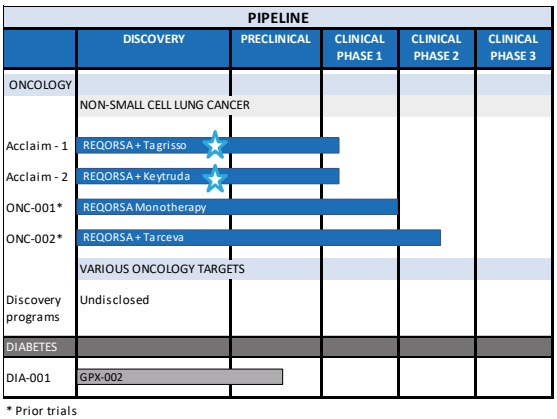
Ticker (Exchange)	GNPX-NASDAQ
Recent Price (06/23/2022)	$1.31
52-week Range	$1.17 - $3.89
Shares Outstanding	47.9 mm
Market Capitalization	$62.7 mm
Average 10-day volume	114,100
Insider Ownership +>5%	10.5%
Institutional Ownership	13%
EPS (Qtr. ended 03/31/22)	($0.12)
Employees	17

GNPX (NASDAQ) One-year Stock Chart



* Prior trials
★ U.S. FDA Fast Track Designation

COMPANY DESCRIPTION

Genprex, Inc. ("Genprex" or "the Company") is a clinical-stage **gene therapy†** company focused on developing life-changing treatments for patients with cancer and diabetes. The Company's oncology program employs its proprietary, non-viral ONCOPREX® Nanoparticle Delivery System, which encapsulates the gene-expressing **plasmids** using lipid **nanoparticles**. The resulting product is administered intravenously, where it is taken up by tumor cells that express deficient proteins. Genprex's lead product candidate, REQORSA™ Immunogene Therapy (quaratusugene ozeplasmid), is being evaluated to treat **non-small cell lung cancer (NSCLC)** in combination with two leading cancer drugs to potentially improve their benefits—Merck & Company's Keytruda® (pembrolizumab) and AstraZeneca's Tagrisso® (osimertinib). The active ingredient in REQORSA is the **TUSC2 gene**, a tumor suppressor gene, which has inhibitory actions on cancer cell growth. Genprex is also evaluating a gene therapy, GPX-002, for Type 1 and Type 2 diabetes, which 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.

KEY POINTS

- REQORSA, being evaluated in two Phase 1/2 clinical trials (Acclaim-1 and Acclaim-2), is the first systemically delivered gene therapy being used for cancer in humans that can be combined with top-selling cancer drugs to potentially improve their benefits.
- Genprex has received two U.S. Food and Drug Administration (FDA) Fast Track Designations (FTD) for REQORSA: (1) REQORSA in combination with AstraZeneca's Tagrisso for NSCLC patients with **Epidermal Growth Factor Receptor (EFGR)** mutations whose tumors progressed after treatment with Tagrisso; and (2) REQORSA in combination with Merck & Co's Keytruda for NSCLC patients whose disease progressed after treatment with Keytruda.
- REQORSA has a multimodal mechanism of action that has been shown to (1) interrupt cell signaling pathways that cause replication and proliferation of cancer cells; (2) re-establish pathways for apoptosis, or programmed cell death, in cancer cells; and (3) modulate the immune response against cancer cells.
- Lung cancer was the leading cause of cancer deaths worldwide in 2020, with over 2.2 million new cases and 1.8 million deaths. In 2022, approximately 236,740 new cases of lung cancer are expected to be diagnosed in the U.S. and 130,180 people will die from the disease.
- Genprex employs a team of executives and advisors with widespread expertise in the pharmaceutical and biotechnology industries, as well as research and clinical experts from preeminent medical and academic institutions around the world.
- The Company is focused on pursuing pharmaceutical partnerships and collaborations with its programs and seeks to expand and strengthen its global intellectual property portfolio.
- As of March 31, 2022, Genprex's cash position was $34.6 million.

Genprex

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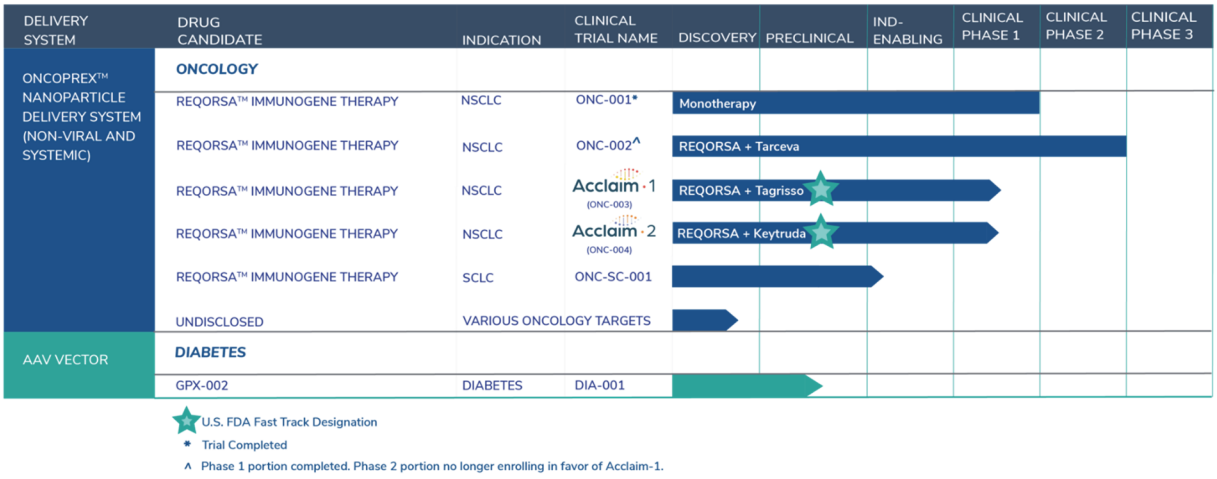
Executive Overview

Genprex, Inc. ("Genprex" or "the Company") is a clinical-stage gene therapy company focused on developing life-changing treatments for patients with cancer and diabetes. The Company's technologies are designed to administer disease-fighting genes to provide new therapies for sizeable patient populations who have limited options. Genprex works with world-class institutions and collaborators to develop its drug candidates to expand its pipeline of gene therapies with the purpose of providing novel treatment approaches.

The Company's lead product candidate, REQORSA Immunogene Therapy, is targeting patients with non-small cell lung cancer (NSCLC) as well as small cell lung cancer (SCLC). Genprex is exploring how REQORSA may be administered with targeted therapies and immunotherapies in other solid tumors, and is researching how other cancer fighting genes can be applied using its ONCOPREX Nanoparticle Delivery System. The Company is further developing its pre-clinical diabetes candidate, GPX-002, 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. Figure 1 summaries the Company's product development pipeline, followed by brief summarizes of each product candidate. Greater details are provided within the Core Story section (pages 13-37).

Figure 1
PIPELINE



Source: Genprex, Inc.

ONCOPREX® Nanoparticle Delivery System

Genprex's oncology program utilizes its unique, proprietary, non-viral ONCOPREX® Nanoparticle Delivery System, which may be the first systemic gene therapy delivery platform used for cancer in humans. ONCOPREX encapsulates the gene-expressing plasmids using lipid nanoparticles, which produces a product that is then administered intravenously, to be taken up by tumor cells that express proteins that are deficient. This platform, originally developed through collaborative research between a major cancer research center located in Houston, Texas, and the National Institutes of Health, has been optimized to work with Genprex's product candidate, REQORSA™ Immunogene Therapy.

REQORSA™ Immunogene Therapy (quaratusugene ozeplasmid)

The Company's lead product candidate, REQORSA Immunogene Therapy, is being evaluated as a treatment for patients with NSCLC. The active agent in REQORSA is a TUSC2 gene expressing plasmid encapsulated in a DOTAP cholesterol nanoparticle. TUSC2 is a tumor suppressor gene, which has both tumor killing (via **apoptosis**) and **immunomodulatory** effects. REQORSA has a multimodal mechanism of action that has been shown to (1) interrupt cell signaling pathways that cause replication and proliferation of cancer cells; (2) re-establish pathways for apoptosis, or programmed cell death, in cancer cells; and (3) modulate the immune response against cancer cells. REQORSA has also been shown to block mechanisms that create drug resistance.

In 2020, the U.S. Food and Drug Administration (FDA) granted Fast Track Designation (FTD) to REQORSA for NSCLC in combination therapy with AstraZeneca's Tagrisso® (osimertinib) for patients with Epidermal Growth Factor Receptor (EFGR) mutations whose tumors progressed after treatment with Tagrisso. In 2021, AstraZeneca's Tagrisso generated over $5 billion in global gross sales and is AstraZeneca's highest grossing product.

Additionally, in 2021, the FDA granted FTD for REQORSA for NSCLC in combination therapy with Merck & Co's Keytruda® (pembrolizumab) for patients whose disease progressed after treatment with Keytruda. In 2021, Merck's Keytruda generated more than $17 billion in worldwide sales and is Merck's highest grossing product as a standard of care in non-EGFR mutated NSLC.

With Genprex's FTDs for combination with Tagrisso's status as the current standard of care in EGFR-mutated NSCL, and Keytruda's status as a standard of care in non-EGFR mutated NSCLC, Genprex believes these regulatory pathways may position Genprex favorably within the $18 billion global lung cancer market. The global market for NSCLC treatments is expected to reach $48.7 billion by 2026. Figure 2 provides a summary of Genprex's key lead program for NSCLC.

Figure 2
LEAD PROGRAM: NON-SMALL CELL LUNG CANCER (recent expansion into small cell lung cancer)

84%	Most common lung cancer NSCLC represents the majority of all lung cancers	**$5 billion+**	Tagrisso 2021 sales AstraZeneca's highest grossing product
2 million	Worldwide cases More than two million cases per year worldwide	**$17 billion+**	Keytruda 2021 sales Merck's highest grossing product
236K	More than 236,000 new cases per year in the U.S.	**$48.7 billion+**	Global Market Global market is projected to grow from $18.3 billion in 2018 to $48.7 billion by 2026

Source: Genprex, Inc.

Acclaim Clinical Trials

Acclaim-1

In June 2021, Genprex initiated the Acclaim-1 clinical trial, a Phase 1/2 clinical trial of REQORSA combined with AstraZeneca's Tagrisso for NSCLC. In granting Genprex FTD, the FDA found that REQORSA may provide a benefit over existing therapies for patients whose tumors progress on AstraZeneca's Tagrisso. The FTD is for use of REQORSA in combination with Tagrisso to treat NSCLC patients with EGFR mutations whose tumors progressed after treatment with Tagrisso. Genprex believes that the FTD may provide a clearly defined pathway toward FDA approval of the combination of REQORSA with Tagrisso.

Acclaim-2

In March 2022, Genprex opened the Acclaim-2 clinical trial for patient enrollment, a Phase 1/2 clinical trial of REQORSA combined with Merck & Company's Keytruda to treat advanced NSCLC patients whose tumors progressed after treatment with Keytruda. In April 2022, the first patient was treated in the Acclaim-2 clinical trial. The Company expects the Phase 1 portion of the Acclaim-2 trial to enroll up to 30 patients in a dose escalation study to determine the maximum tolerated dose of combining REQORSA and Keytruda. The Phase 2 portion of the study is expected to enroll approximately 126 patients to be randomized 2:1 to receive either REQORSA and Keytruda combination therapy or docetaxel with or without ramucirumab. The primary endpoint of the Phase 2 portion of the trial is **progression-free survival** (defined as time from randomization to progression or death). An interim analysis will be performed after 50 events. Genprex expects to complete the Phase 1 portion of Acclaim-2 by the end of the first quarter of 2023.

GPX-002

Genprex's diabetes gene therapy (also referred to as GPX-002), was developed by lead researcher Dr. George Gittes (biography page 9) at the Rangos Research Center at the University of Pittsburgh Medical Center (UPMC) Children's Hospital. This preclinical candidate 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. The therapy employs a procedure in which an adeno-associated virus vector delivers Pdx1 and MafA genes to the pancreas.

Intellectual Property

Genprex currently holds a worldwide, exclusive license to 18 issued patents and 18 pending patent applications for technologies that were developed in-house, by researchers at the National Cancer Institute, MD Anderson Cancer Center, the University of Texas Southwestern Medical Center, and the University of Pittsburgh. These patents comprise various therapeutic, diagnostic, technical, and processing claims relating to REQORSA and the ONCOPREX Nanoparticle Delivery System and diabetes technologies. Genprex has further received trademark registrations for the trademarks GENPREX and ONCOPREX and has filed a trademark application for the drug name REQORSA.

Corporate History and Recent Financing

Genprex was founded in 2009 and since 2018 has traded on the Nasdaq under the symbol GNPX. The Company has headquarters in Austin, Texas and employs 17 individuals. In February 2021, Genprex announced that it had entered into securities purchase agreements with two healthcare-dedicated institutional investors for the purchase and sale of 4,000,000 shares of its common stock at a purchase price of $6.25 per share in a registered direct offering priced at-the-market under Nasdaq rules. No warrants were issued in connection with the transaction.

Company Leadership

Genprex employs a team of executives and has retained advisors with widespread expertise within the pharmaceutical and biotechnology industries, as well as other research and clinical experts at preeminent medical and academic institutions around the world. Biographies of these key individuals are provided in the accompanying section.

Management Team

Rodney Varner, Chairman, President and Chief Executive Officer (CEO)

Rodney Varner is a co-founder of Genprex and has served as its chief executive officer (CEO) and chairman of the board of directors since August 2012. Mr. Varner also currently serves as its president. He formerly served as its secretary. Mr. Varner served as a partner of the law firm Wilson & Varner, LLP, since 1991. He has more than thirty-five years of legal experience with large and small law firms and as outside general counsel of a Nasdaq-listed company. Mr. Varner has represented for-profit and non-profit companies at the board of directors or senior management levels in a wide variety of contractual, business, tax, and securities matters, including technology transfers, licensing, collaboration and research agreements, clinical trial contracts, pharmaceutical and biologics manufacturing and process development contracts, state and federal grants, including NIH and SBA grants, corporate governance and fiduciary issues, and real estate matters. He served as counsel in company formation, mergers and acquisitions, capital raising, other business transactions, protection of trade secrets and other intellectual property, real estate, and business litigation. Mr. Varner is a member of the State Bar of Texas and has been admitted to practice before the United States Court of Appeals for the Fifth Circuit and the United States Tax Court. He has been a registered securities representative and founder of a company that is a licensed securities broker-dealer. Mr. Varner received his BBA with high honors from Texas A&M University and a JD degree from The University of Texas School of Law.

Catherine Vaczy, Executive Vice President, General Counsel, Chief Strategy Officer and Secretary

Catherine Vaczy joined Genprex in 2020 and has more than 20 years of experience as a founder and senior executive of life science companies, serving as a strategic partner and business and legal advisor to senior leadership teams and boards. Most recently, she has provided strategic advisory services to early stage biotechnology companies. In 2005, Ms. Vaczy co-founded and served for ten years on the senior leadership team of NeoStem, Inc. (now Caladrius Biosciences), a Nasdaq-listed clinical stage biotechnology company that combined a leading cell and gene therapy process development and manufacturing organization (sold to Hitachi Chemical) with a development pipeline of cell therapy products. Prior to that, she was an early employee and served on the senior leadership team of ImClone Systems Incorporated (sold to Eli Lily and Company), a pioneer in targeted cancer therapy, where she was instrumental in forging important strategic alliances, including a transformative $1 billion co-development deal for the Company's blockbuster drug, Erbitux. Earlier in her career, Ms. Vaczy was a practicing attorney in a nationally recognized law firm representing early stage life science and other technology companies. Ms. Vaczy received a BA degree from Boston College and a JD degree from St. John's University School of Law.

Ryan Confer, MS, Chief Financial Officer (CFO)

Ryan Confer has served as Genprex's chief financial officer (CFO) since September 2016. From December 2013 through September 2016, he served as its chief operating and financial officer, and from June 2011 to December 2013 as its business manager. Mr. Confer has served in a variety of strategic, operations, and finance capacities since the Company's inception in 2009, both as a consultant through his own firm, Confer Capital, Inc., and as an employee. Mr. Confer has more than ten years of entrepreneurial experience in planning, launching, developing, and growing emerging technology companies. He has served in c-level and vice president roles for a variety early-stage technology companies since 2008. Most notably, Mr. Confer served as VP of customer experience and then later as VP of strategy for KaiNexus, Inc., an emerging technology company that develops continuous improvement software. Prior to his entrepreneurial experiences, Mr. Confer served as a business development consultant for the University of

Texas at Austin's IC2 Institute, an international thinktank and incubator, where he focused on evaluating the commercialization potential of nascent technologies in emerging growth markets. From 2006 to 2009, Mr. Confer served as a portfolio manager for a $500 million early-stage technology investment fund. Mr. Confer holds a BS in finance and legal studies from Bloomsburg University of Pennsylvania and an MS in technology commercialization from the McCombs School of Business at the University of Texas at Austin.

Mark Berger, M.D., Chief Medical Officer

Dr. Mark Berger is a senior executive with 25 years of biotech and pharmaceutical company experience in the development of oncology therapeutics. Prior to joining Genprex in September 2021, Dr. Berger served as chief medical officer for Actinium Pharmaceuticals, Inc., where he was responsible for clinical strategy and development of radioisotope-labeled antibodies for therapy in oncology. Before that, he was senior vice president-clinical research at Kadmon Corporation, where he led all aspects of the company's new drug development, including clinical trial design and management of the oncology programs in non-small cell lung cancer and breast cancer, among others. Prior to that, Dr. Berger was Chief Medical Officer of Deciphera Pharmaceuticals. Prior to Deciphera, he was vice president for clinical development at Gemin X Pharmaceuticals, where he led the clinical strategy, design, and management of clinical trials for two novel oncology agents. Before that, Dr. Berger served as Group Director, Medicine Development Centre-Oncology for GlaxoSmithKline. Dr. Berger began his career in drug development at Wyeth Research, where he led the planning and execution of the pivotal Phase 2 trial for Mylotarg, which was the first antibody targeted chemotherapy agent. Dr. Berger holds a B.A. in biology from Wesleyan University and a M.D. from the University of Virginia School of Medicine. He did his Hematology/Oncology fellowship at the University of Pennsylvania, where he was an Assistant Professor of Medicine, and also was a Research Fellow at the Ludwig Institute for Cancer Research and the Imperial Cancer Research Fund, both in London. Dr. Berger is board certified in internal medicine, hematology, and medical oncology.

Thomas Gallagher, Esq., Senior Vice President of Intellectual Property and Licensing

Thomas Gallagher joined Genprex as the Company's Senior Vice President of Intellectual Property and Licensing in 2020. Mr. Gallagher has extensive experience in the area of biotechnology intellectual property (IP) law, business development, and licensing transactions with industry and academic institutions. He has more than 20 years of experience as an IP attorney. Prior to joining Genprex, Mr. Gallagher served as Principal at the Fenagh Group, an IP and licensing consultancy, providing clients in the healthcare sector with guidance on all aspects of patent and trademark portfolio management, IP due diligence, freedom-to-operate analysis, and related transactional work. He has also served as Senior Vice President of Intellectual Property and Licensing at Kadmon Corporation, LLC, a biopharmaceutical company based in Manhattan. Prior to joining Kadmon, he served as in-house IP counsel at Neostem, Inc. (now Caladrius Biosciences, Inc.), a company focused on stem cell biology. Previously, Mr. Gallagher held several positions at ImClone Systems Incorporated, most recently as Vice President of Intellectual Property and Licensing. While at ImClone, he was responsible for all aspects of IP and led the IP function in multiple due diligence undertakings by major pharmaceutical companies, which resulted in a $2 billion strategic investment, the highest-valued biotech deal ever at the time, and the eventual sale of the company to Eli Lilly and Company for $6.5 billion. Mr. Gallagher is experienced in both patent prosecution and litigation, as well as IP issues relating to business development and licensing matters. His patent litigation experience includes European litigation and opposition proceedings. In addition to a law degree, Mr. Gallagher holds a master's degree in molecular biology. Before becoming an attorney, Mr. Gallagher worked as a molecular biologist in France, Spain, and the U.S.

Hemant Kumar, PhD, CPM, EMBA, Chief Manufacturing and Technology Officer

Dr. Hemant Kumar is a recognized global expert in Chemistry, Manufacture and Controls (CMC) Technical Development and GMP manufacturing. Prior to joining Genprex in September 2021, Dr. Kumar was vice president, global head of manufacturing, supply chain, and strategy for Arcturus Therapeutics, Inc. Prior to that, Dr. Kumar was vice president of CMC Technical Development and Manufacturing Operations at Oncoimmune Therapeutics, Inc., a private company that was acquired by Merck & Co. during his tenure there. Before that, he was vice president, head of global process sciences and clinical manufacturing operations at Rentscher BioPharma, SE. Previous to that, Dr. Kumar was with Anaptysbio, Inc., where he served as senior vice president, head of global CMC, Technical

Development and Manufacturing Operations. Before that, Dr. Kumar held senior level positions of increasing manufacturing and technical operations leadership in global biopharmaceutical companies, including Merck & Co., Inc., Sanofi Genzyme, Inc., Lonza Biologics, Inc., Sanofi Pasteur, Janssen Biotech (a Johnson & Johnson company), and Wyeth Lederle Vaccines, Inc. Dr. Kumar earned a PhD in Biochemistry at J.N. Medical College, Aligarth India through a collaboration with the U.S. National Institute of Health (NIH). He holds a graduate certificate in Project Management from Lehigh University. Dr. Kumar has conducted postdoctoral and research scientist fellowships at Yale University School of Medicine's Howard Hughes Research Center and at the University of Rhode Island and the Center for Disease Control and Prevention's Center for Infectious Diseases. He holds professional affiliations with the American Chemical Society, American Association for the Advancement of Science, American Society for Microbiology, and the International Society of Pharmaceutical Engineers.

David M. Schloss, Senior Vice President of Human Resources

David Schloss has more than 25 years of experience as a human resources executive and employment attorney in life sciences with a focus on biotech, cell and gene therapy, and healthcare technology in both the public and private sectors. He served as VP, human resources with GlaxoSmithKline before moving on to lead HR for multiple small to mid-size companies, including ImClone Systems, Eurand Pharmaceuticals, OraPharma, Caladrius Biosciences, and Teladoc Health, helping to take each through dramatic growth and evolution. Mr. Schloss has also served as Principal with DMS HR Consulting, LLC, where he worked with life sciences companies to deliver HR and business strategies that lead to profitable growth and value creation. Mr. Schloss' focus has been to help organizations navigate the most challenging elements of human resources, which define their culture and values. Additionally, he has served as Of Counsel with Porzio Bromberg & Newman, where, as a member of the firm's employment law team, he worked with clients to deliver HR and business strategies to senior management, offering advice and counsel in compensation, benefits, talent acquisition and development, organizational design, employee relations, and HR compliance. Mr. Schloss holds a BA degree from Clark University and a JD degree from The University of Miami School of Law and is a member of the Pennsylvania Bar Association.

William E. Gannon, Jr., MD, MBA, Vice President of Regulatory Affairs

Dr. William Gannon joined Genprex as the Company's Vice President of Regulatory Affairs. Dr. Gannon brings more than 30 years of experience in the biotech and pharmaceutical industries to the Company, with expertise in clinical development, regulatory affairs, and commercialization of products, and a strong background in oncology and gene therapy. He is responsible for managing the Company's regulatory affairs for its upcoming clinical trials, and also serves as the Medical Monitor, interfacing with medical personnel at trial sites and assisting with FDA communication throughout the clinical trials. Dr. Gannon has held several executive roles at various biotech, pharmaceutical, and medical device companies, overseeing regulatory affairs, both U.S. and international, for filings, meetings, submissions, and approvals. He has served on the Institutional Review Board (IRB), Board of Directors, and Clinical Advisory Board of several organizations and is an active member of research and professional affiliations, including the AdvaMed (Advance Medical Technology Association), the Drug Information Association, the Regulatory Affairs Professional Society, and the American Academy of Pharmaceutical Physicians and Investigators.

Board of Directors

Rodney Varner, Chairman, President and Chief Executive Officer (CEO)

Biography on page 6.

James E. Rothman, PhD, Strategic Advisor to the Board of Directors

Dr. Rothman is an internationally renowned scientist. He was awarded the 2013 Nobel Prize in medicine and has received numerous other honors, including the Lasker Basic Research Award. Dr. Rothman is also a biopharmaceutical company founder, life science industry executive, and prestigious academic leader. He served as chief scientist and executive committee member at GE Healthcare, a $15 billion unit of General Electric Corporation. Prior to the acquisition of Amersham Biosciences PLC by GE Healthcare, Dr. Rothman served as chief scientist at

Amersham. His distinguished academic career includes endowed chairs at Memorial Sloan-Kettering Cancer Center, where he served as vice-chair of the Sloan-Kettering Institute; Columbia University's College of Physicians and Surgeons; and Yale University, where he is currently professor and chair of cell biology and executive director for high throughput cell biology. He is a member of the National Academy of Sciences, a member of the Institute of Medicine of the National Academy of Sciences, and fellow of the American Academy of Arts and Sciences.

Brent Longnecker, Board Director

Brent Longnecker has more than 30 years of experience in corporate governance, executive compensation, and risk management consulting for public, private, and non-profit organizations. Mr. Longnecker built one of the country's leading privately-held executive compensation and corporate governance consultancies, serving both domestic and international markets. He has deep expertise in healthcare, energy, real estate, manufacturing, and financial companies, regularly consulting with boards of directors, CEOs, key executives, and advisors in many major industries. He is a prolific author on the subjects of executive compensation and corporate governance.

Jose A. Moreno Toscano, Board Director

Jose Moreno Toscano brings to Genprex over 20 years of experience in the pharmaceutical and biotechnology industries, building, developing, and transforming organizations. Mr. Toscano has a successful track record of identifying and capitalizing on opportunities to drive exponential revenue growth and market expansion, revitalizing underperforming operations and establishing foundations for successful start-up operations. His experience includes strategic planning, corporate restructuring, business development, M&A, investor relations, and general management.

William Wilson, Jr., Board Director

William Wilson, Jr. has more than 40 years of experience as an attorney, with legal experience spanning healthcare regulation, biotechnology, clinical trial management, nursing home licensing and regulation, physician accreditation, securities, corporate governance, and contractual matters. He previously served as Judge of the 250th District Court of Travis County, Texas, where he presided over civil litigation, as well as Assistant District Attorney for Dallas County, Texas.

Scientific Advisory Board (SAB)

Jack A. Roth, MD, FACS, SAB Chairman

Dr. Jack Roth is the Chairman of Genprex's SAB. Dr. Roth is an internationally renowned cancer expert and oncology pioneer. He is Professor and Distinguished Chair of Thoracic Surgery, Professor of Molecular and Cellular Oncology, Director of the Keck Center for Innovative Cancer Therapies, and Chief of Section of Thoracic Molecular Oncology at The University of Texas MD Anderson Cancer Center. Dr. Roth is a prolific inventor and the author of more than 600 peer reviewed publications. He is a pioneer in the clinical use of DNA as a therapeutic agent. He is the first clinical investigator approved by the FDA and NIH-RAC to conduct direct patient gene therapy clinical trials. Dr. Roth has over 20 years of experience in developing new cancer therapeutics for commercial application and is an inventor of Genprex's key IP.

George K. Gittes, MD, SAB Board Member

Dr. George Gittes serves as the Chief of Pediatric Surgery and Surgeon-in-Chief Emeritus at the UPMC Children's Hospital of Pittsburgh. In addition, he was appointed Director of the Richard King Mellon Foundation Institute for Pediatric Research and Co-Scientific director at UPMC Children's Hospital in 2018. Prior to UPMC, Dr. Gittes served as the Director of Surgical Research at Children's Mercy Hospital in Kansas City and held the Thomas M. Holder and Keith W. Ashcraft Chair in Pediatric Surgical Research. During his time in Kansas City, he also was elected to the position of President of the Society of University of Surgeons.

Pasi Antero Jänne, MD, PhD, SAB Board Member

Dr. Pasi Antero Jänne is an Associate Professor of Medicine at Harvard Medical School and a clinician at Dana-Farber Cancer Institute Lowe Center for Thoracic Oncology. Dr. Jänne is a leading researcher in medical oncology and lung cancer and is Co-Leader of the Lung Cancer Program at Dana-Farber Harvard Cancer Center. His research includes the study of epidermal growth factor receptor (EGFR) mutations in non-small cell lung cancer (NSCLC) and their impact on the efficacy of EGFR-targeted therapeutic agents, as well as mechanisms of sensitivity and resistance targeted cancer therapies.

Tony S.K. Mok, MD, FRCP, SAB Board Member

Dr. Tony S.K. Mok is a professor in the Department of Clinical Oncology at the Chinese University of Hong Kong in Prince of Wales Hospital in Hong Kong. Dr. Mok formerly served as President of the International Association for the Study of Lung Cancer (IASLC), Vice-Secretary General of the Chinese Society of Clinical Oncology (CSCO), and Co-Founder of the Lung Cancer Research Group, a multicenter organization serving the Asian-Pacific region.

George Simon, MD, FACS, SAB Board Member

Dr. George Simon is a Professor of Medicine and Section Chief, Translational Research, Department of Thoracic/Head and Neck Medical Oncology, Division of Cancer Medicine at The University of Texas MD Anderson Cancer Center, where his principal focus includes translational research in lung cancer to predict the most effective therapeutic options based upon a tumor's molecular profile.

Clinical Advisory Board (CAB)

Andrew B. Becker, MD, PhD, Clinical Advisory Board Member

Dr. Andrew Becker is President and Founder of Becker Pharmaceutical Consulting, a market research, competitive intelligence and strategic planning consulting firm that provides analytic and strategy services to companies ranging from small biotechnology and medical device companies up to large multinational pharmaceutical companies on a global basis. Dr. Becker received both his medical degree and PhD in Molecular Pharmacology from Stanford University. At Stanford, Dr. Becker's research focused on signaling pathways for the insulin and IGF-1 receptors, deciphering the structure and function of the insulin degrading enzyme and its role in insulin processing.

Michael Morse, MD, MHS, FACP, Clinical Advisory Board Member

Dr. Michael Morse is a Professor of Medicine in the Division of Medical Oncology and Professor in the Department of Surgery at Duke University Medical Center, Durham, NC. His clinical expertise includes management of gastrointestinal malignancies, including colon, hepatobiliary, gastroesophageal, and pancreatic cancer. His research expertise includes the development of targeted therapies, including immunotherapies for cancer. He has published extensively on topics in cancer immunotherapy, targeted therapies and gastrointestinal malignancies, including textbooks on Cancer Vaccines and Liver Tumors. Dr. Morse is Editor for Current Opinions in Biologic Therapies. He has been the principal investigator of a number of investigator-initiated and industry-supported Phase 1 and 2 clinical trials of cancer immunotherapy and therapies for gastrointestinal malignancies. He is a member of the American Association of Cancer Research, the American Society of Clinical Oncology, the American Society for Clinical Investigation, American College of Physicians, and the Society for the Immunotherapy of Cancer.

Col. George E. Peoples, MD, FACS, Clinical Advisory Board Member

Dr. George Peoples served 30 years of active duty as a surgeon and research scientist in the military. He is the founder and director of the Cancer Vaccine Development Program (CVDP), which has been focused on the discovery, development, and clinical testing of cancer vaccines for more than 20 years. Four of the program's cancer vaccines have been licensed for commercial development. Dr. Peoples currently serves as the CEO of Cancer Insight, LLC, CVDP's commercial counterpart, which is a boutique cancer immunotherapy Contract Research Organization (CRO) conducting multiple Phase 1 and 2 clinical trials. He also serves as Professor of Surgery at the Uniformed Services University of the Health Sciences and Professor (adjunct) of Surgical Oncology at MD Anderson Cancer Center (MDACC). Dr. Peoples is the past Chair of the Cancer Care Program, San Antonio Military Medical Center and the past Military Director of the United States Military Cancer Institute. He is a graduate of the United States Military Academy, West Point and the Johns Hopkins School of Medicine. Dr. Peoples completed his surgical training at Harvard's Brigham and Women's Hospital and a surgical oncology fellowship at MDACC.

Intellectual Property

Genprex seeks to obtain, maintain, and enforce patent protection for its products, formulations, processes, methods, and other proprietary technologies, as well as preserve its trade secrets as the Company operates without infringing on the proprietary rights of other parties, both within the U.S. as well as around the world. The Company actively pursues the broadest intellectual property (IP) protection available for its products, proprietary information, and technology through a combination of contractual arrangements and patents.

The Company currently holds a worldwide exclusive license to 18 issued patents and 18 pending patent applications for technologies developed in-house or by researchers at the National Cancer Institute, MD Anderson, The University of Texas Southwestern Medical Center, and the University of Pittsburgh. These patents comprise various therapeutic, diagnostic, technical, and processing claims relating to REQORSA™ and the ONCOPREX® Nanoparticle Delivery System and for diabetes technologies. Genprex has further received trademark registrations for the trademarks GENPREX and ONCOPREX and has filed a trademark application for the drug name REQORSA.

LICENSE AGREEMENTS

MD Anderson

On May 4, 2020, Genprex entered into an exclusive worldwide license agreement with MD Anderson (amended on March 3, 2021, see below) relating to a portfolio of 16 patent applications and related technology for the treatment of cancer using the Company's lead drug candidate and immunotherapies. The agreement granted the Company worldwide, exclusive license to certain licensed intellectual property and technology, including the use of chemotherapy in combination with TUSC2 therapy for treating cancer. As part of the agreement, Genprex is required to make certain payments to MD Anderson, including an upfront license fee, annual maintenance fees ranging from the low five figures to low six figures, milestone payments aggregating up to a maximum of $6,150,000, and royalty payments.

In May 2021, Genprex entered into an amendment to their May 2020 License Agreement that granted the Company an exclusive worldwide license to an additional portfolio of six patents and one patent application and related technology. The newly licensed IP includes methods for treating non-small cell lung cancer (NSCLC) by administration of a TUSC2 therapeutic in conjunction with EGFR inhibitors or other anti-cancer therapies. A TUSC2 gene-expressing plasmid is the active agent in REQORSA immunogene therapy, Genprex's lead drug candidate.

In addition, the Company's ONCOPREX and REQORSA technologies are exclusively licensed pursuant to a 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, between MD Anderson and Introgen Therapeutics, Inc. Introgen sublicensed its rights under the MD Anderson License Agreement to Introgen Research Institute, Inc. (IRI). IRI is a Texas-based technology company formed by Rodney Varner, the Company's President and Chairman of the Board (biography on page 6). On April 13, 2009, IRI assigned its rights under the Sublicense Agreement to Genprex.

University of Pittsburgh

On February 11, 2020, Genprex entered into an exclusive license agreement with the University of Pittsburgh for patented gene therapy technologies relating to the potential treatment of Type 1 and Type 2 diabetes. The agreement provides the Company 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. As consideration for the license agreement, Genprex agreed to pay the University of Pittsburgh an initial license fee, as well as annual maintenance fees, and royalties beginning with the first commercial sale of the licensed technology, and milestone payments in the aggregate amount of up to $3,975,000.

Core Story

CANCER OVERVIEW

Cancer is a major burden and leading cause of death worldwide, accounting for nearly 10 million deaths in 2020, or nearly one in six deaths. The most common cancers are lung, breast, colon and rectum, and prostate cancers. Approximately one-third of deaths from cancer are due to tobacco use, high body mass index (BMI), alcohol consumption, low fruit and vegetable intake, and lack of physical activity. Cancer-causing infections, such as human papillomavirus (HPV) and hepatitis, are responsible for approximately 30% of cancer cases in low- and lower-middle-income countries. In 2020, there were an estimated 18.1 million cancer cases around the world. Of these, 9.3 million cases were in men and 8.8 million in women. As the population continues to age, cancer is expected to remain a significant health problem as the leading cause of death and the most important barrier to increasing life expectancy.

In the U.S., approximately 1.9 million new cancer cases are expected to be diagnosed in 2022, with this estimate excluding basal cell and squamous cell skin cancers, which are not required to be reported to cancer registries, and carcinoma in situ (noninvasive cancer), except for urinary bladder. As shown in Figure 3 (which illustrates both leading sites of new cancer cases and well as cancer deaths), cancers of the lung, colon and rectum, breast, and prostate are the most common types with the highest mortalities, with approximately 609,360 deaths expected in the U.S. in 2022, or roughly 1,670 deaths per day. Cancer is the second most common cause of death in the U.S., exceeded only by heart disease. Due to the significant improvements in treating and preventing cardiovascular disease, cancer is soon expected to become the number one cause of death in the U.S.

Figure 3

LEADING SITES OF NEW CANCER CASES AND DEATHS, 2022 ESTIMATES

Estimated New Cases

Male			Female		
Prostate	268,490	27%	Breast	287,850	31%
Lung & bronchus	117,910	12%	Lung & bronchus	118,830	13%
Colon & rectum	80,690	8%	Colon & rectum	70,340	8%
Urinary bladder	61,700	6%	Uterine corpus	65,950	7%
Melanoma of the skin	57,180	6%	Melanoma of the skin	42,600	5%
Kidney & renal pelvis	50,290	5%	Non-Hodgkin lymphoma	36,350	4%
Non-Hodgkin lymphoma	44,120	4%	Thyroid	31,940	3%
Oral cavity & pharynx	38,700	4%	Pancreas	29,240	3%
Leukemia	35,810	4%	Kidney & renal pelvis	28,710	3%
Pancreas	32,970	3%	Leukemia	24,840	3%
All sites	**983,160**		**All sites**	**934,870**	

Estimated Deaths

Male			Female		
Lung & bronchus	68,820	21%	Lung & bronchus	61,360	21%
Prostate	34,500	11%	Breast	43,250	15%
Colon & rectum	28,400	9%	Colon & rectum	24,180	8%
Pancreas	25,970	8%	Pancreas	23,860	8%
Liver & intrahepatic bile duct	20,420	6%	Ovary	12,810	4%
Leukemia	14,020	4%	Uterine corpus	12,550	4%
Esophagus	13,250	4%	Liver & intrahepatic bile duct	10,100	4%
Urinary bladder	12,120	4%	Leukemia	9,980	3%
Non-Hodgkin lymphoma	11,700	4%	Non-Hodgkin lymphoma	8,550	3%
Brain & other nervous system	10,710	3%	Brain & other nervous system	7,570	3%
All sites	**322,090**		**All sites**	**287,270**	

Estimates are rounded to the nearest 10, and cases exclude basal cell and squamous cell skin cancers and in situ carcinoma except urinary bladder. Estimates do not include Puerto Rico or other US territories. Ranking is based on modeled projections and may differ from the most recent observed data.

Source: American Cancer Society., Surveillance and Health Equity Science.

Cancer also represents a significant economic burden. In 2019, the national patient economic burden associated with cancer care was $21.09 billion, comprised of patient out-of-pocket costs of $16.22 billion and patient time costs of $4.87 billion. Patient time costs reflect the value of time that patients spend traveling to and from healthcare, waiting for care, and receiving care.

Among adults aged 65 years and older who had Medicare coverage, average annualized net out-of-pocket costs for medical services and prescription drugs, across all cancer sites, were highest in the initial phase of care, defined as the first 12 months following diagnosis ($2,200 and $243, respectively), and the end-of-life phase, defined as the 12 months before death ($3,823 and $448, respectively), and lowest in the continuing phase, the months between the initial and end-of-life phases ($466 and $127, respectively). Across all cancer sites, average annualized net patient out-of-pocket costs for medical services in the initial and end-of-life phases of care were lowest for patients originally diagnosed with localized disease compared with more advanced stage disease. Costs are expected to increase as new (often more costly) treatments are adopted as standards of care (Source: U.S. National Institutes of Health's National Cancer Institute).

Lung Cancer: New Cases and Deaths

As shown in Figure 3 (page 13), in 2022, approximately 236,740 new cases of lung cancer will be diagnosed in the U.S. and 130,180 people will die from the disease. The majority of lung cancers are classified as either non-small cell lung cancer (NSCLC; 82%) or small cell lung cancer (SCLC; 14%). Incidence of lung cancer has been decreasing since the mid-1980s in men, but only since the mid-2000s in women due to the differences between genders of smoking uptake and cessation. Specifically, from 2009 to 2018, the rate decreased by 2.8% per year in men and by 1.4% per year in women. Mortality rates for patients with lung cancer rates have declined in men by 56% since 1990 and in women by 32% since 2002 due primarily to reductions in smoking, with the pace accelerating in recent years stemming from significant advances in treating NSCLC. For example, from 2015 to 2019, the rate decreased by about 5% per year in men and 4% per year in women.

The most important risk factor for developing lung cancer remains cigarette smoking, with roughly 80% of lung cancer deaths in the U.S. due to smoking. An individual's risk increases with both quantity and duration of smoking. Cigar and pipe smoking also increase a person's risk, as well as exposure to radon gas (which is released from soil and can accumulate in indoor air and is the second-leading cause of lung cancer in the U.S.). Additional reasons that are linked to a higher risk of lung cancer include exposure to secondhand smoke (2.7% of new cases, the equivalent of about 6,400 in 2022), asbestos (predominantly among people who smoke), certain metals (chromium, cadmium, arsenic), certain organic chemicals, radiation, air pollution, as well as diesel exhaust. Furthermore, there are particular occupational exposures that increase ones risk of developing lung cancer, which include rubber manufacturing, paving, roofing, painting, and chimney sweeping. Screening for lung cancer with **low-dose spiral computed tomography (LDCT)** has been shown to reduce lung cancer mortality.

Symptoms of lung cancer do not typically appear until the cancer is advanced and can include persistent cough, sputum streaked with blood, chest pain, a hoarse voice, worsening shortness of breath, and recurrent pneumonia or bronchitis. Treatment is based on whether the tumor is NSCLC or SCLC, as well as its stage and molecular characteristics. For early-stage NSCLC, surgery is the standard treatment for otherwise healthy individuals, at times with other treatments such as chemotherapy, targeted drugs, immunotherapy, and/or radiation therapy. Advanced-stage NSCLC is typically treated with chemotherapy, targeted drugs, and/or immunotherapy. Early-stage SCLC is usually treated with chemotherapy, alone or combined with radiation. Radiation to the brain (prophylactic cranial radiation) is perhaps given in early-stage SCLC to reduce the risk of brain metastases, though not in every case.

Due to limited benefit gains from current therapies, Genprex believes there is a significant unmet medical need for new NSCLC and SCLC treatments and that REQORSA may be appropriate for the majority of lung cancer patients.

Cancer and Genetic Mutations

Cancer results from genetic mutations. Mutations that progress to cancer frequently appear in two major classes of genes: oncogenes, which are involved in functions such as **signal transduction** and **transcription**; and **tumor suppressor genes**, which play a role in governing cell proliferation by regulating transcription. Transduction is the process by which chemical and physical signals are transmitted through cells. Transcription is the process by which a cell's DNA sequence is copied to make RNA molecules, which then plays a role in protein expression. In normal cells, mutations in oncogenes are discovered and targeted for elimination by tumor suppressor genes. In cancer cells, the oncogene mutations may overwhelm the natural tumor suppression processes, or those tumor suppression processes may be diminished or absent altogether.

Functional alterations due to mutations in oncogenes or tumor suppressor genes may result in the abnormal and uncontrolled growth patterns that are characteristic of cancer. These genetic alterations enable such malignant growth by affecting signal transduction pathways and transcription, consequently inhibiting normal growth signaling in the cell, avoiding the natural process of apoptosis, evading the immune system's response to cancer, and inducing **angiogenesis**—the formation of new blood vessels. The most common genetic modifications present in NSCLC are in tumor suppressor genes, against which few targeted small molecule drugs (traditionally regarded as the backbone of traditional medicine) have been created.

Another genetic condition associated with lung cancer is the overexpression of EGFRs and mutations of **kinases**. Kinases are enzymes that play an important role in signal transduction through the modification of proteins by adding or taking away phosphate groups (called **dephosphorylation**) to change the proteins' function. When two EGFR transmembrane proteins are brought to proximity on the cell membrane surface (**dimerize**), either through a ligand or binding molecule, that binds to the extracellular receptor, or through some other process, the intracellular protein-kinase domains can **autophosphorylate**, and activate downstream processes, including cell signaling pathways that can lead to either cell cycle arrest or cell growth and proliferation. EGFRs and kinases 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 or failing to turn the switch "off," leading to the loss of cell control.

Cancer and the Immune System

Cancer can also spread when the natural immune functions within the body are compromised, including by the cancer cells themselves. **PD-1 (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 protein/receptor expressed on the surface of cancer and other cells. The binding of PD-1 to PD-L1 has been thought to contribute to cancer cells' ability to evade the body's immune response. PD-1 and similar molecules are called **immune checkpoints** since they can impede the normal immune response, for example by blocking the T cells from attacking the cancer cells. In many cancers, PD-L1 receptors are up-regulated. Significant research is now being performed within the field of immuno-oncology to uncover drugs or antibodies that could block PD-L1 and similar receptors. It is possible 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** may be able to inhibit cancer cells from inactivating T cells.

Current Treatment of NSCLC

The standard treatment for most NSCLC patients is chemotherapy. Since 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 side effects. A subcategory of NSCLC patients carry one or both of two EGFR mutations, referred to as exon 19 deletion and exon 21 substitution, which make their tumors sensitive to **tyrosine kinase inhibitors (EGFR TKIs)**. Since EGFR is often overexpressed in lung tumors, it has become a preferred therapeutic target for pharmaceutical companies. Several pharmacological and biological approaches, including EGFR TKIs, have been specifically created to block activated EGFR for cancer therapy. The class of drugs functioning as protein kinase inhibitors (KIs) encompasses the majority of targeted therapies for lung cancer, responsible for majority of use and sales. Of the KIs, the EGFR TKI drugs are the most common, with drugs targeting EGFR kinases leading the sector growth. Several EGFR TKI therapies are marketed commercially, including: Tagrisso, Tarceva, Iressa, and Gilotrif.

Roughly 7% of NSCLC patients of North American and European descent and 30% 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 consequently "EGFR negative" and are not optimal candidates for EGFR TKIs. However, while EGFR TKIs are most effective in patients who *have* an activating EGFR mutation and are therefore described as "EGFR positive," they are significantly less effective in overall NSCLC populations and are largely not effective in patients without an activating EGFR mutation.

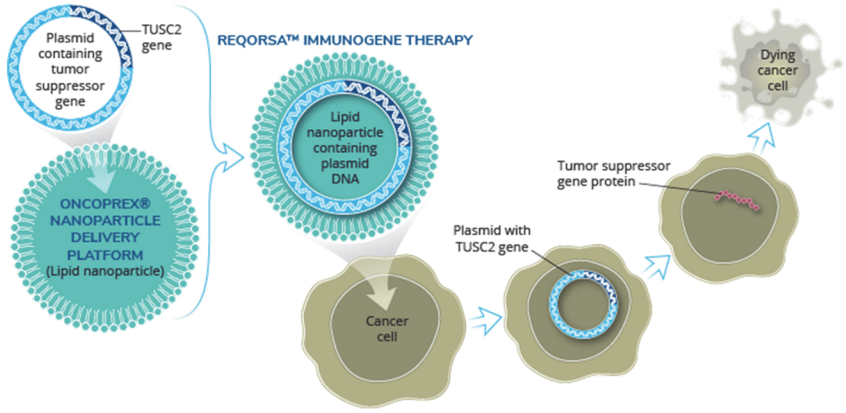
As well, even with those patients who are EGFR positive and benefit from EGFR TKI therapy, virtually all eventually become resistant to and ultimately no longer respond to EGFR TKI therapy, resulting in disease progression. For example, according to the FLAURA study (a Phase III trial pitting the third-generation EGFR–tyrosine kinase inhibitor osimertinib against gefitinib or erlotinib for the first-line treatment of EGFR mutation-positive advanced non-small-cell lung cancer) sponsored by AstraZeneca, the median time to tumor progression for lung cancer patients on Tagrisso is nearly 18 months. Furthermore, clinical trials have shown that combining EGFR TKIs with conventional chemotherapy does not increase survival for lung cancer patients.

GENPREX TECHNOLOGY AND PIPELINE CANDIDATES

ONCOPREX® Nanoparticle Delivery System

Genprex's immunogene therapy platform consists of anti-cancer gene expressing DNA plasmids contained in non-viral lipid nanoparticles delivered intravenously. The Company's lead drug candidate, REQORSA, employs the Company's ONCOPREX® Nanoparticle Delivery System (depicted in Figure 4) to encapsulate the TUSC2 gene in positively charged nanoparticles that bind to actively replicating (and therefore negatively charged) cancer cells, and then enters 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 Genprex's system differ considerably from liposomes used in the past for drug delivery since 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 target cancer cells and direct nanoparticle fusion avoids target cell endocytosis.

Figure 4
NON-VIRAL DELIVERY OF TUMOR SUPPRESSOR GENE



Source: Genprex, Inc.

The ONCOPREX Nanoparticle Delivery System is a non-viral delivery system. The majority of gene therapies rely on viral based delivery systems, where 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 additional cells (not only the targeted cells containing mutated genes). If this were to happen, healthy cells may be damaged causing other illness or diseases. The ONCOPREX Nanoparticle Delivery System is intended to deliver tumor suppressor genes, which are encapsulated in lipid nanoparticles. The nanoparticles are then administered intravenously and taken up by tumor cells, where the encapsulated gene is translated to express proteins that are missing or depleted in cancer cells.

Genprex has treated more than 50 NSCLC patients in clinical trials with REQORSA, the Company's lead drug candidate that uses the ONCOPREX Nanoparticle Delivery System to deliver the TUSC2 gene. A Phase 1 clinical trial revealed that systemic, intravenous therapy using the ONCOPREX Nanoparticle Delivery System was shown to target tumor cells selectively and preferentially, resulting in clinically significant anticancer activity. The nanoparticles are non-immunogenic, allowing repetitive therapeutic dosing and providing extended half-life in the circulation. REQORSA has been developed using the ONCOPREX Nanoparticle Delivery System to deliver the functioning TUSC2 gene to cancer cells while minimizing their uptake by normal tissue. Tumor biopsy studies conducted at MD Anderson demonstrated the uptake of TUSC2 in tumor cells of three patients after REQORSA treatment, which was 10 to 33 times the uptake in normal cells and was well tolerated in humans with over 50 study patients.

Preclinical Data Shows Potential for Genprex's ONCOPREX® Nanoparticle Delivery System in Treating Colon Cancer

Genprex announced in January 2022 that its collaborators published positive preclinical data for the use of the Company's ONCOPREX® Nanoparticle Delivery System for delivery of a FAS DNA plasmid in treating metastatic colorectal cancer. Published in the journal *Cancers*, the preclinical study found that tumor selective ONCOPREX nanoparticles carrying FAS DNA plasmids suppress human colon tumor growth *in vivo* in mouse models, potentially suggesting that this may be an effective therapy for human colorectal cancer. With this data, Genprex may expand its oncology programs to explore use of its delivery system for other therapeutic genes, alone or in combination with other approved cancer therapies, to provide new approaches for patients with serious medical conditions.

REQORSA™ Immunogene Therapy

Genprex's REQORSA Immunogene Therapy has been developed to: (1) interrupt cell signaling pathways that cause replication and proliferation of cancer cells, (2) target and kill cancer cells via receptor pathways, and (3) stimulate the natural immune responses against cancer. As an immunogene therapy that combines features of gene therapy and immunotherapy, REQORSA up-regulates TUSC2 expression in the cell, increasing the anti-tumor immune cell population and down-regulating PD-L1 receptors, potentially boosting the immune response to cancer.

REQORSA consists of the TUSC2 gene expressing plasmid encapsulated in a non-viral nanoparticle made from lipid molecules (the Company's ONCOPREX Nanoparticle Delivery System, described on page 17) with a positive electrical charge. REQORSA is injected intravenously and specifically targets cancer cells. Cancer cells have elevated metabolism compared to healthy cells and because of this, are negatively charged (versus healthy cells, which are positively charged, or charge neutral). REQORSA has been developed to deliver the functioning TUSC2 gene to cancer cells while minimizing their uptake by normal tissue. Genprex believes that REQORSA—unlike other gene therapies that either need to be delivered directly into tumors or require cells to be removed from the body, re-engineered, and then reinserted into the body—is the first systemic gene therapy to be used for cancer in human clinical trials.

REQORSA has been shown to have a multimodal mechanism of action whereby it interrupts cell signaling pathways that cause replication and proliferation of cancer cells, re-establishing pathways for programmed cell death (apoptosis) in cancer cells, and modulating the immune response against cancer cells. It has also been shown to block mechanisms that create drug resistance.

As a **pan-kinase inhibitor,** REQORSA has been shown to simultaneously inhibit the EGFR and Protein kinase B (also known as AKT) oncogenic kinase pathways *in vitro* and *in vivo*. Once the cancer cell takes up the nanoparticles containing the TUSC2 expressing plasmid, it is reprogrammed to die. Resistance to targeted drugs and checkpoint inhibitors develop through activation of alternate bypass pathways. For example, when PD-1 is blocked, the TIM-3 checkpoint is up-regulated. Genprex believes that REQORSA's multimodal activity may be able to block emerging bypass pathways, potentially lowering the chance for developing drug resistance.

Many approved cancer therapeutics target only single molecules or a single specific genetic abnormality related to driving the proliferation and survival of cancer cells. REQORSA, in contrast, has been developed to work by targeting several molecules within the cancer cell to interrupt cell signaling pathways that cause replication and proliferation of cancer cells, to target and kill cancer cells, to block mechanisms that create drug resistance, and to stimulate the natural immune response.

Preclinical and clinical data indicates that REQORSA is well tolerated and may be effective alone or in combination with targeted small molecule therapies. Preclinical data indicates that REQORSA may also be effective with immunotherapies, and in a three-drug combination with immunotherapy and chemotherapy. By enabling the action of both drugs, a greater population of patients may benefit from these therapies.

Second Fast Track Designation (FTD)

In January 2022, Genprex announced that the U.S. FDA had granted Fast Track Designation (FTD) to REQORSA in combination with Merck & Co's Keytruda® in patients with histologically-confirmed unresectable stage III or IV NSCLC whose disease progressed after treatment with Keytruda. The Company previously received its first FTD for REQORSA in combination with AstraZeneca PLC's Tagrisso® in patients with histologically confirmed unresectable stage III or IV NSCLC, with EGFR mutations that progressed after treatment with Tagrisso.

Fast track designation (FTD) provides a company with opportunities to have more frequent engagement with the FDA to discuss the drug candidate's development plan as well as provide potential eligibility for priority review (which has a six-month review timeline). The FDA may award FTD if it determines that non-clinical or clinical data demonstrate the potential for a drug to address unmet medical needs for a serious or life-threatening disease or condition. This establishment is intended to facilitate development and expedite review of such medications so that if approved, the product is able to reach the market expeditiously. FTD recipients may also be entitled to accelerated approval or rolling review of the recipient's Biologics License Application (BLA) if other qualifying criteria are met. As well, FTD product candidates may be eligible for priority review if supported by clinical data at the time of BLA submission.

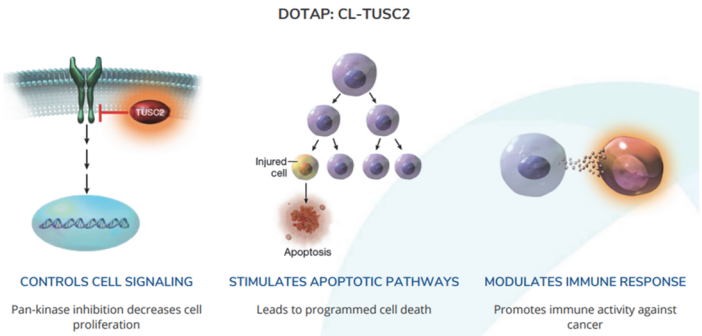
Enrollment Opened and First Patient Treated in Phase 1/2 Acclaim-2 Clinical Trial of REQORSA™ Immunogene Therapy in Combination with Keytruda® to Treat NSCLC

In March 2022, Genprex announced the opening for patient enrollment, and in April, 2022, treated the first patient in its Acclaim-2 clinical trial, its open-label, multi-center Phase 1/2 clinical trial evaluating REQORSA Immunogene Therapy in combination with Keytruda (pembrolizumab) in patients with late-stage NSCLC whose disease progressed after treatment with Keytruda. These are important milestones in the Company's clinical development program for REQORSA as Genprex continues to engage with respected clinical trial sites to build patient enrollment and provide hope to lung cancer patients who need new treatment options.

TUSC2 (the Active Agent in REQORSA™)

TUSC2 is a multifunctional gene that plays a vital role in cancer suppression and normal cell regulation. Key TUSC2 anti-cancer 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, as shown in Figure 5. REQORSA has been shown to block mechanisms that create drug resistance. Genprex's data shows that REQORSA, in combination with both EGFR TKIs and with immunotherapies, achieves results that are more favorable than results achieved with either REQORSA or other such therapies alone, and could make those drugs effective for patients who would not otherwise benefit from them.

Figure 5
REQORSA™ TARGETS CANCER AT ITS CORE



Source: Genprex, Inc.

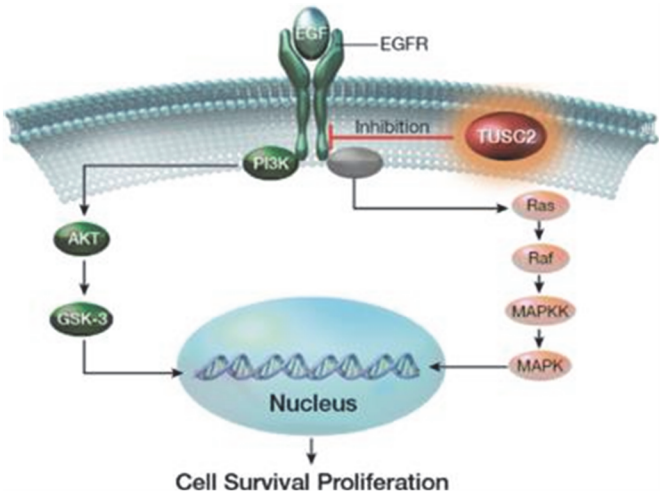
Normal TUSC2 function is inactivated at the early onset of cancer development, making TUSC2 a potential target for all stages of cancer, including metastatic disease. The TUSC2 protein is reduced or absent in approximately 85% of lung cancers. In patients with NSCLC, the loss of TUSC2 expression has 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* and by up-regulating activity of other proapoptotic effectors. Normal TUSC2 function mediates apoptosis in cancer cells through interaction with Apaf1 and down-regulates multiple tyrosine kinases, including EGFR, AKT, platelet-derived growth factor receptor (PDGFR), c-Kit, and c-Abl. TUSC2 mediates apoptosis in cancer cells but not normal cells through its interaction with Apaf1 and down-regulates tyrosine kinases, including EGFR, PDGFR, c-Kit, and c-Abl.

In normal cells, the proteins involved in the PI3K/AKT pathway (also called the mTOR pathway), in which 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, play an important role in cellular function and cellular trafficking. These proteins are frequently found to be abnormally active in cancers, causing cells to lose their ability to control cell growth, proliferation, and differentiation. Therefore, mutations in PI3K (overexpression) and its upstream receptors, EGFR, have been associated with many forms of cancers.

Likewise, 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 proinflammatory factors. Figure 6 shows how 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.

Figure 6
PAN-KINASE INHIBITION BY TUSC2

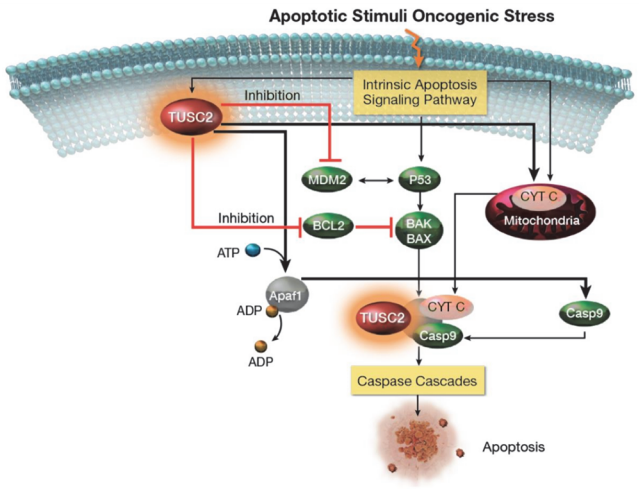


Source: Genprex, Inc.

Figure 7 (page 21) shows that under stress conditions, such as oncogenic stress, cells go through a regulated process of programmed cell death, also known as apoptosis, to control cell development and replication. The TUSC2 protein interacts via various apoptotic signaling pathways to stimulate programmed cell death via the release of **caspases** (enzymes that play a significant role in apoptosis).

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

Figure 7
STIMULATION OF APOPTOTIC SIGNALING BY TUSC2



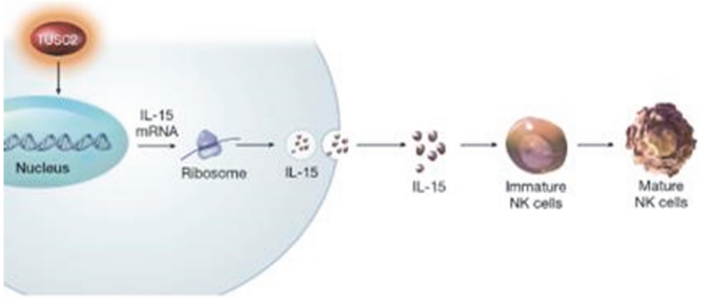
Source: Genprex, Inc.

TUSC2 and the Immune Response

Beyond its pro-apoptotic cytotoxicity and tyrosine kinase inhibitory activity, TUSC2 enhances the immune response to cancer. Data from preclinical studies have demonstrated a therapeutic 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. As well, TUSC2 has been found to down-regulate PD-L1 receptors on the surface of cancer cells. By inducing tumor cell apoptosis, TUSC2 increases antigen release and presentation, promoting an enhanced antitumor response in the presence of other immune regulators.

An important part of the natural immune system, NK cells 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 through the up-regulation and interplay of receptors, including checkpoint inhibitors, such as PD-1 and PD-L1. Figure 8 illustrates how TUSC2 has been found to stimulate the release of interleukin-15 (IL-15), resulting in up-regulation of mature NK cells that circulate and target cancer cells.

Figure 8
MODULATION BY TUSC2 OF THE IMMUNE RESPONSE TO CANCER



Source: Genprex, Inc.

REQORSA Background

TUSC2 was discovered through a lung cancer research consortium, including two major cancer research centers located in Texas, along with the National Cancer Institute (NCI). The Company's technology and R&D 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. Genprex holds a worldwide, exclusive license from a major cancer research center based in Houston, Texas, to patents covering the therapeutic use of TUSC2 and other genes that have been shown to have cancer fighting properties, along with a number of related technologies, including 18 issued patents and 18 pending patent applications (described on page 12). The rights Genprex has obtained pursuant to its 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 (IP) was developed under a funding agreement between the cancer research center and the U.S. government.

REQORSA Approach

Genprex's lead product candidate, REQORSA, is being developed as a potential treatment for NSCLC. Clinical and preclinical data indicate that when combined with EGFR TKIs, such as Tagrisso, Tarceva, and Iressa, REQORSA provides a synergistic effect that could also benefit the larger population of NSCLC patients who are EGFR negative (meaning they are not expected to benefit from EGFR TKI drugs alone). Company data show that REQORSA may re-sensitize EGFR positive patients who become resistant to, and therefore no longer benefit from, EGFR TKIs alone. Consequently, REQORSA may (1) significantly expand the benefit of EGFR TKIs to the majority of patients who do not have EGFR activating mutations, and (2) extend the usefulness and benefit of EGFR TKIs for the population of NSCLC patients who are EGFR positive, but whose tumors progress on EGFR TKIs.

Preclinical and clinical data support Genprex's belief that REQORSA may provide medical benefit in several subpopulations of NSCLC patients for which there is an unmet medical need, and served as the basis for FTDs from the FDA. In granting the Company's first FTD, in January, 2020, the FDA found that REQORSA may provide a benefit over existing therapies for patients whose tumors progress on Tagrisso. The first FTD from the U.S. FDA is for use of the combination of REQORSA with Tagrisso to treat NSCLC patients with EGFR mutations whose tumors progressed following treatment with Tagrisso.

Pre-clinical data has also shown that REQORSA augments the immune response to cancer. Data from preclinical studies demonstrated a therapeutic benefit from the combination of TUSC2 and anti-PD-1 antibody and a key role for TUSC2 in regulating immune cell subpopulations, including cytokines, NK cells, and T lymphocytes. TUSC2 has also been found to downregulate PD-L1 receptors on the surface of cancer cells. This data supported Genprex's second FTD for use of REQORSA combined with Keytruda in late stage lung cancer patients whose disease progressed on Keytruda.

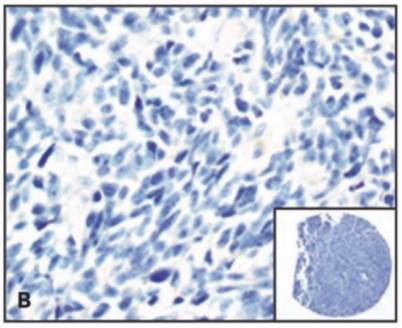
Importantly, the manufacturers of the marketed drugs were not involved in any of Genprex's clinical or preclinical studies. In the studies involving marketed drugs, the drugs were administered simultaneously with REQORSA without being modified and the antibodies used in Genprex's preclinical studies that did not use the marketed drugs were the non-humanized equivalent to marketed drugs.

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

Expanded Pipeline to Include SCLC

Genprex announced in January 2022 that it had expanded its oncology research and development pipeline to include small cell lung cancer (SCLC), as shown in Figure 9, as an additional disease indication for REQORSA™—an indication that represents approximately 10% to 14% of the lung cancer market (while REQORSA's initial target indication of non-small cell lung cancer (NSCLC) represents approximately 84% of the lung cancer market). Similar to NSCLC, SCLC regularly has low TUSC2 protein levels and is recorded to often have deletion of one TUSC2 gene **allele**. Extensive SCLC has a very poor prognosis with a median progression free survival of 5.2 months. Expanding the therapeutic indications targeted by REQORSA to include SCLC may provide Genprex with another important clinical opportunity to combine REQORSA with SCLC therapies, including checkpoint inhibitors.

Figure 9
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, Inc.

Preclinical Data at AACR 2021

Encouraging preclinical data on the combination of REQORSA and Tagrisso (osimertinib) were presented by Genprex collaborators at the 2021 American Association of Clinical Research (AACR) annual meeting, showing that REQORSA and Tagrisso had a synergistic antitumor effect in EGFR mutant Tagrisso-resistant NSCLC tumor xenograft models. Researchers in the preclinical study developed an osimertinib-resistant H1975-OsiR isogenic cell line through continuous exposure to osimertinib. Xenograft tumors from both H1975-parental and H1975-OsiR cells were grown in NSG mice and were treated with osimertinib. The combination of REQORSA and osimertinib showed a strong antitumor effect versus single agent treatment groups against H1975-OsiR tumors.

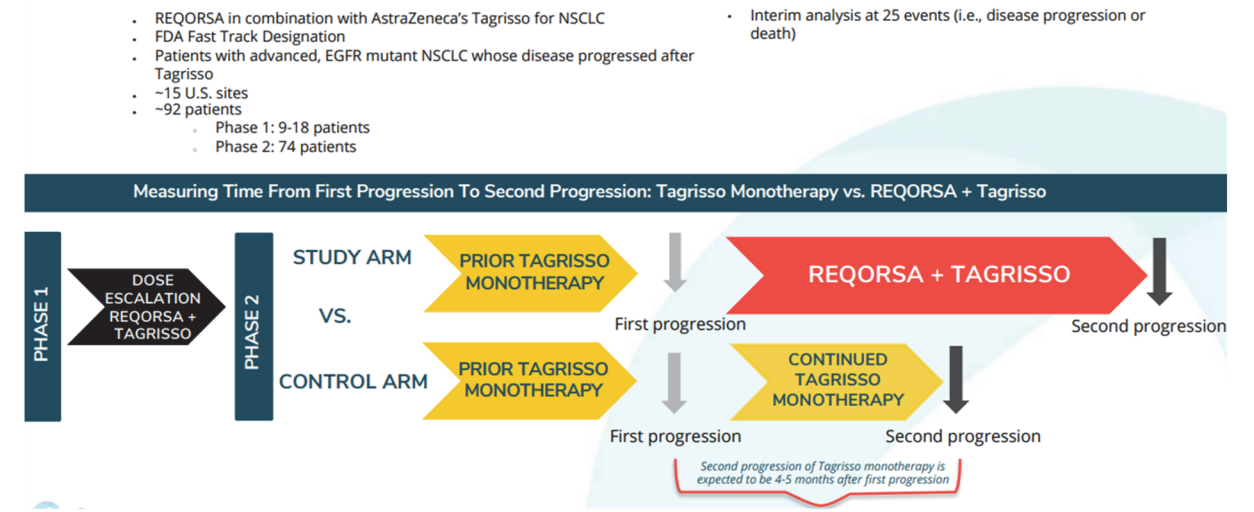
Acclaim-1

In 2020, Genprex received FTD from the U.S. FDA for treating the Acclaim-1 patient population. With this FTD, clinical and preclinical data have provided the basis for the Company's development strategy for REQORSA and its use in treating NSCLC. The Acclaim-1 clinical trial is an open-label, multi-center Phase 1/2 clinical trial evaluating REQORSA in combination with Tagrisso in patients with late-stage NSCLC with activating EGFR mutations whose disease progressed after treatment with Tagrisso.

The Company expects the Phase 1 portion of the Acclaim-1 trial to enroll up to 18 patients at three clinical sites and for the Phase 2 portion to enroll approximately 74 patients (a 1:1 ratio of REQORSA and Tagrisso combination therapy versus AstraZeneca's Tagrisso monotherapy) at up to 15 clinical sites. The first part of the Phase 1/2 clinical trial will be a dose escalation study. The primary endpoint of the Phase 2 portion is progression-free survival, which is defined as time from randomization after first progression on Tagrisso, to first event (second progression) or death. An interim analysis will be performed at 25 events.

The Acclaim-1 trial offers a unique opportunity to transform cancer care for patients with advanced lung cancer who have EGFR mutations that are no longer responsive to standard targeted therapies. Figure 10 summarizes the characteristics of the Acclaim-1 study.

Figure 10
ACCLAIM-1: GENERAL STUDY CHARACTERISTICS



Source: Genprex, Inc.

First Patient Dosed in Phase 1/2 Acclaim-1 Clinical Trial of REQORSA™ Immunogene Therapy in Combination with Tagrisso® to Treat NSCLC

In March 2022, the Company announced that the first patient was dosed in the Acclaim-1 clinical trial. REQORSA has the potential to improve the response to current targeted therapies, such as Tagrisso, for this study patient population.

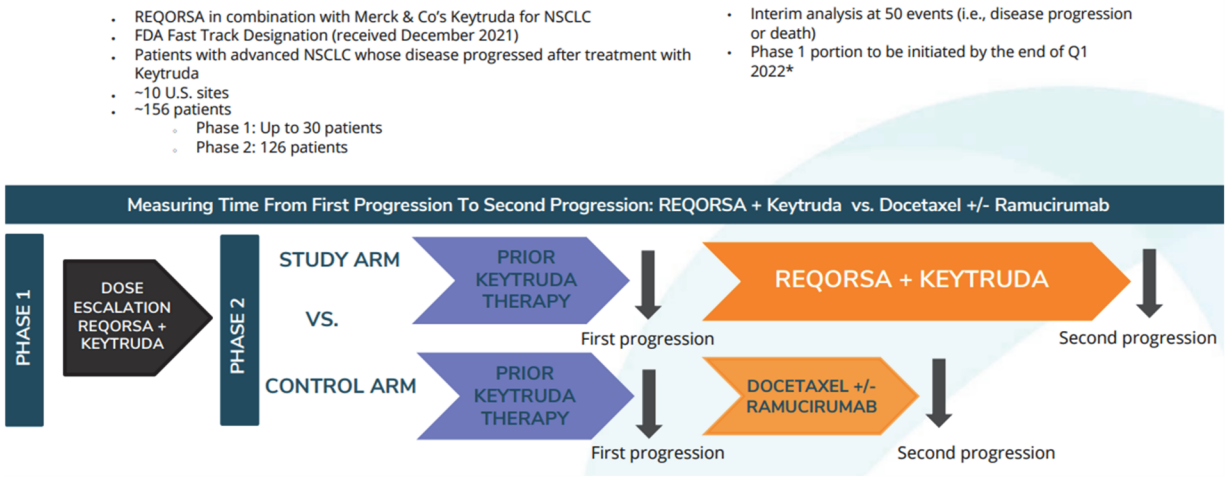
Acclaim-2

In April 2022, the Company treated the first patient in its Acclaim-2 clinical trial for treating NSCLC. In December 2021, Genprex received FTD from the U.S. FDA for treating the Acclaim-2 patient population. The Acclaim-2 trial is a Phase 1/2 clinical trial combining REQORSA with Keytruda in patients whose disease has progressed on Keytruda. The Company plans to conduct the Acclaim-2 clinical trial in approximately 15 sites with about 156 patients. The final protocol is subject to change based on input from investigators. Figure 11 (page 25) summarizes the general study characteristics of the Acclaim-2 clinical trial.

In 2019, preclinical data was presented by Genprex's academic collaborators relating to the combination of TUSC2, the active agent in 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 human immune cells (humanized mice) that had metastatic lung cancer. The researchers also presented preclinical data in 2019 for the combination of TUSC2, Keytruda, and chemotherapy to treat some of the most resistant metastatic lung cancers. This study found that the addition of TUSC2 demonstrates synergy with Keytruda and chemotherapy, and consequently, may improve on first-line standard of care for lung cancer. In May 2020, Genprex entered into a worldwide, exclusive license agreement with the major cancer research center that conducted this pre-clinical research to use TUSC2 in combination with immunotherapies, including Keytruda, as well as the use of TUSC2 in a three-drug combination of TUSC2, immunotherapy, and chemotherapy.

Figure 11

ACCLAIM-2: GENERAL STUDY CHARACTERISTICS



Source: Genprex, Inc.

ONC-001: REQORSA™ Phase 1 Monotherapy Dose Escalation Study (completed)

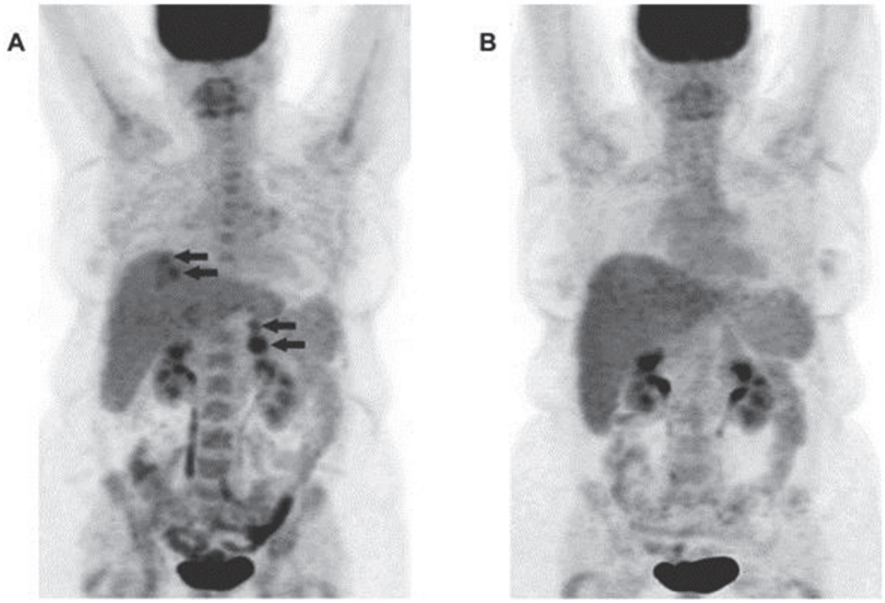
In 2012, academic researchers completed a Phase 1 clinical trial of REQORSA as a monotherapy. The primary objective of the REQORSA Monotherapy Trial was to assess the toxicity of REQORSA administered intravenously and to determine the maximum tolerated dose (MTD) and recommended Phase 2 dose of REQORSA alone. Secondary objectives were to assess the expression of TUSC2 following intravenous delivery of REQORSA in tumor biopsies and to assess the anticancer activity of REQORSA. This trial showed that REQORSA was well tolerated and established the MTD and the therapeutic dosage for REQORSA at 0.06 mg/kg administered every 21 days. 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. As well, pre- and post-treatment patient biopsies demonstrated that intravenous REQORSA selectively and preferentially targeted patients' cancer cells, suggesting that clinical anti-cancer activity was mediated by TUSC2.

In the Phase 1 Monotherapy Trial, REQORSA was injected intravenously in Stage IV (metastatic) lung cancer patients who had received traditional platinum combination chemotherapy but still showed tumor progression at the time of entry into the study; 31 subjects were treated at six dose levels and 70% of subjects had received two or more prior chemotherapy regimens. The only serious adverse events, defined as grade 3, 4, or 5 events under the Common Terminology Criteria for Adverse Events published by the U.S. Department of Health and Human Services, 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. Twenty-three subjects received two or more doses, of whom five subjects, or 22% of the 23 subjects, achieved disease control for periods ranging from 2.6 months to 10.8 months. The median disease control period for these subjects was 5.0 months (95% CI: 2.0-7.6), while the other 18 subjects' cancer progressed during the Phase 1 Monotherapy Trial. Disease control for cancer therapies is defined under the **Response Evaluation Criteria in Solid Tumors (RECIST)** as Complete Response (CR) + Partial Response (PR) + Stable Disease (SD)>8weeks). 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) 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 dose—all showing decreased metabolic activity in the tumor with no changes in size or number of metastases by computed tomography (CT) imaging.

Figure 12 shows the PET scan of this subject performed after the fourth dose. 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 Figure 12. Illustration A shows the pretreatment PET scan. The dose of Fluorodeoxyglucose (18F) was 8.8mCi. Illustration B shows the post treatment PET scan performed 20 days following the fourth dose of REQORSA. The dose of Fluorodeoxyglucose (18F) was 9.0mCi. All scans were performed within a 60 to 90 minute window after injection. This individual survived after subsequent therapy more than seven years after the final treatment with REQORSA without evidence of cancer progression in the responding sites (to Genprex's knowledge).

Figure 12
METABOLIC TUMOR RESPONSE IN A METASTATIC LUNG CANCER SUBJECT



Source: Genprex, Inc.

ONC-002: Phase 1/2 Trial Combining REQORSA with Tarceva (Phase 1 portion completed; Phase 2 portion no longer enrolling in favor of conducting Acclaim-1)

Phase 1

The Phase 1 Monotherapy Trial demonstrated that REQORSA was well tolerated, that high levels of TUSC2 expression were 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, Genprex began a Phase 1/2 trial combining REQORSA with Tarceva in patients with Stage IV (metastatic) or recurrent NSCLC that is not potentially curable by radiotherapy or surgery, whether or not they have received prior chemotherapy and whether or not they have an activating EGFR mutation. Enrollment in the Phase 1 portion of the Phase 1/2 Combination Tarceva Trial commenced in 2014.

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 (0.045mg/kg)	
(2)	Tarceva (100 mg/day) + REQORSA (0.06mg/kg)	
(3)	Tarceva (150 mg/day) + REQORSA (0.045mg/kg)	
(4)	Tarceva (150 mg/day) + REQORSA (0.06mg/kg)	

Similar to the Phase 1 Monotherapy Trial, subjects received a pre-treatment regimen of oral and intravenous dexamethasone and diphenhydramine to reduce 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). Consequently, three additional subjects were treated at this dose level (six subjects total)—none of whom suffered 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); thus, an additional three subjects were treated at this dose level (six subjects total). No additional subjects suffered a DLT. At dose level 4, there were no DLTs; thus dose level 4 was determined to be the MTD. Once the MTD for the study treatment combination was determined in the Phase 1 portion of the Phase 1/2 Combination Tarceva Trial to be Dose Level 4, accrual proceeded with 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 to the Phase 2 portion, three subjects in the Phase 1 portion of the Phase 1/2 Combination Tarceva Trial who were treated at the MTD were included in the Phase 2 portion of the study.

Four patients in the Phase 1 portion of the study had stable disease ranging from 12 weeks to 36 weeks. The following observations from Genprex's preclinical studies and from the Phase 1 portion of the Phase 1/2 Combination Tarceva Trial provided the rationale for proceeding with the Phase 2 portion of the study:

- TUSC2 inhibits a variety of tyrosine kinases, including EGFR, PDGFR, c-kit, and c-abl;
- expression of TUSC2 in NSCLC cells combined with EGFR TKIs is complementary *in vitro* and *in vivo*;
- intravenous administration of a nanoparticle encapsulated TUSC2 expression plasmid effectively delivers TUSC2 to distant tumor sites and mediates an anti-tumor effect in orthotopic human lung cancer xenograft models; and
- when the TUSC2-nanoparticle is combined with an EGFR TKI, the suppression of tumor growth in mouse xenograft models is synergistic.

Phase 2

The Phase 2 portion of the Phase 1/2 Combination Tarceva Trial was designed to include subjects treated with the combination of REQORSA and Tarceva at the MTD 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 is defined under the RECIST as Complete Response (CR) + Partial Response (PR); disease control rate is defined under the RECIST criteria as Complete Response (CR) + Partial Response (PR) + Stable Disease (SD) > 8 weeks.

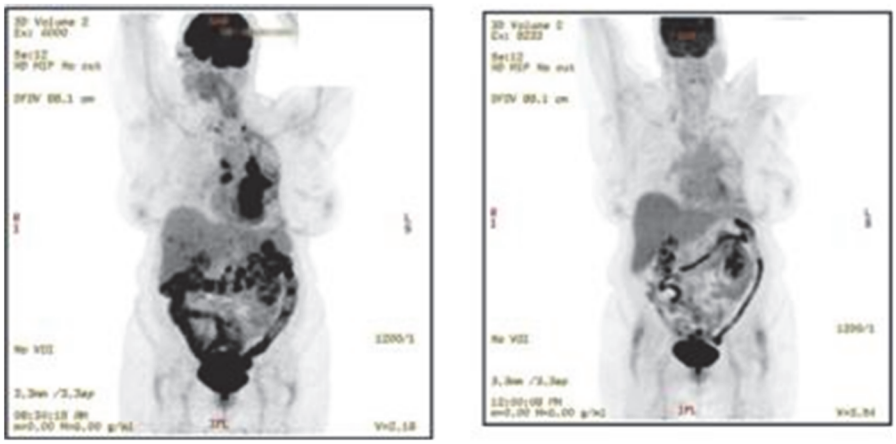
Enrollment criteria for the Phase 2 portion were identical to those in Phase 1. The first subject enrolled in the Phase 2 portion began Tarceva on Day 8, and subsequently every other enrolled subject began Tarceva on Day 8. The rationale for delaying Tarceva was to allow exploratory analyses of potential differential effects of REQORSA alone and in combination with Tarceva on downstream pathway activation and potential biomarkers of Tarceva resistance. 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 allowed in the protocol 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) and nine were evaluable for response under the trial protocol as they received two or more cycles of treatment. None of the 10 subjects treated in the Phase 2 portion of the Phase 1/2 Combination Tarceva Trial suffered a DLT. Interim results from the Phase 2 portion for the 9 evaluable patients show that:

- One patient had a response for a study response rate of 11%; this response was a CR;
- Four patients had tumor regression;
- The median response duration for all patients (the median time between when response is first noted to the time when cancer progression is observed) was three months; and
- Disease control rate for the nine patients was 78%.

The patient with the CR, a 58-year-old female, upon enrollment in the study had metastatic NSCLC status following 6 cycles of pemetrexed and carboplatin and two cycles of maintenance pemetrexed with cancer progression. The patient's tumor has EGFR exon 18 and 20 missense mutations, which are not sensitive to Tarceva. Figure 13 illustrates that this patient had disappearance of both the lung primary tumor and the lung, liver, and lymph node metastases.

Figure 13
SUBJECT WITH RECIST COMPLETE RESPONSE



Source: Genprex, Inc.

Genprex is no longer enrolling the Phase 2 portion of the Phase 1/2 Combination Tarceva Trial as it is focused on conducting Acclaim-1 (detailed on pages 23-24). The response rate and disease control rate in the Phase 2 portion of the Phase 1/2 Combination Tarceva Trial significantly exceeded 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.

A total of 585 patients were enrolled in that Phase 2b/3 clinical trial, whose primary endpoint was overall survival and whose secondary endpoints were progression-free survival, RECIST response, quality of life, and safety. 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). The Phase 2 portion of Genprex's Phase 1/2 trial was not blinded and was designed to treat NSCLC subjects regardless of EGFR status. Figure 14 summarizes interim data from the Phase 2 portion of the Phase 1/2 Combination Tarceva Trial for subjects with and without EGFR mutations.

Figure 14
REQORSA + TARCEVA COMBINATION PHASE 2 PRELIMINARY 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 18% regression all Target Lesion	Chemo / anti-PD1	6
Positive (exon 21) / T790M Negative	Tumor Regression Metabolic response *PET Scan*	Tarceva *(10 cycles)*	3
Positive (exon 21)	Stable Disease	Tarceva *(12 cycles)*	2
Negative	Stable Disease	Chemo	2
Negative	Stable Disease	Chemo	4

Source: Genprex, Inc.

REQORSA Preclinical Studies Support Genprex's Conduct of Acclaim-1

REQORSA and Tyrosine Kinases

Genprex collaborators conducted preclinical research showing that REQORSA alone blocked the activation of the c-Abl tyrosine kinase. A number of other studies 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, Tagrisso, MK2206, and others. Researchers investigated the use of REQORSA combined with commercially available EGFR TKI drugs Tarceva and Iressa, and conducted preclinical *in vitro* and *in vivo* studies combining REQORSA with these drugs in a variety of human lung cancer cell lines, including cancers with activating EGFR mutations and EGFR mutation negative cancers. Lung cancers known to have intrinsic and acquired resistance to Tarceva therapy were also studied, as well as Kras-related and other cancers.

Studies in xenograft animal models showed that REQORSA and either Tarceva or Iressa showed synergistic anti-cancer effects, superior to either agent used alone, in both EGFR mutation negative cancers (generally not candidates for Tarceva) and in EGFR mutation positive cancers (optimal candidates for Tarceva), including cancers known to be resistant to Tarceva therapy. The addition of REQORSA to either Tarceva or Iressa overcame drug-induced resistance by simultaneously inactivating EGFR and AKT signaling pathways and by inducing apoptosis in Tarceva- or Iressa-resistant cancers with EGFR mutations and with EGFR mutation-negative cancers.

In one study, researchers tested the combination of Tarceva and REQORSA against five human NSCLC cell lines: H1299, H322, A549, H460, and H1975, the latter of which has the L858R and T790M EGFR mutations and is highly resistant to Tarceva. Results showed that the combination of REQORSA and Tarceva significantly reduced NSCLC colony formation beyond the effect of Tarceva, REQORSA, or controls alone ($p<0.01$ at both 1 and 2.3 uM concentrations for all cell lines). The cooperative interaction between Tarceva and REQORSA was confirmed *in vivo* using a lung colony formation metastases model in nu/nu mice with A549 human lung cancer cells injected in the tail vein. Mice were treated with the combination of REQORSA and Tarceva and various controls, including empty nanovesicles, Tarceva alone, REQORSA alone, and other controls.

The greatest reduction in lung colonies occurred in the REQORSA with Tarceva combination (90% reduction), which was reduced compared to all control groups ($p<0.0005$). In terms of total tumor nodules, the cooperative effect is greater than 0.9999. P-value is the probability that the difference between two data sets was due to chance. The smaller the p-value, the more likely the differences are not due to chance alone. In most cases, if the p-value is less than or equal to 0.05, the outcome is considered statistically significant. The FDA's evidentiary standard of efficacy generally relies on a p-value that is less than or equal to 0.05.

REQORSA and TUSC2 Deficient and Tarceva or Iressa Resistant Cell Lines

Genprex collaborators 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 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 as 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 benefit from REQORSA with Tarceva combination therapy. These data also suggest that NSCLC patients without an activating EGFR mutation (generally unresponsive to Tarceva) may benefit from REQORSA with Tarceva combination therapy.

TUSC2 and Tumor Sensitivity

In another study, academic researchers analyzed the effects of TUSC2 re-expression on the sensitivity of tumor cells to the AKT inhibitor MK2206 *in vitro* and in mice. The AKT pathway is an important intracellular, converging positive regulator of apoptosis. AKT stimulates apoptosis and is frequently dysregulated in cancers; this has been associated with reduced sensitivity to anti-tumor drugs. The study showed that the combination of TUSC2 transfection with MK2206 treatment suppressed tumor cell viability *in vitro* and effectively inhibited xenograft tumor growth *in vivo* more effectively than either agent alone.

Preclinical Studies of TUSC2 in the Immune Response to Cancer Support Acclaim-2

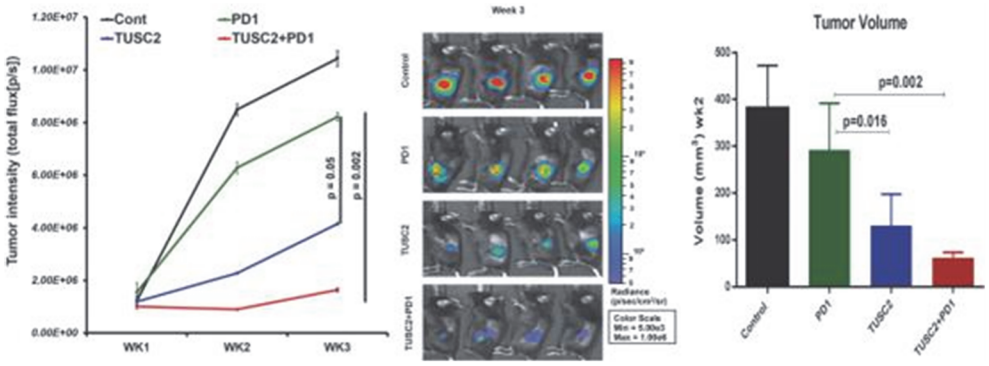
Previous research has shown that TUSC2 regulates cytokine expression *in vitro*. Cytokines are proteins that stimulate inflammation as part of the immune response. Stable expression of TUSC2 in H1299 NSCLC cells altered expression of a wide spectrum of cytokines, including IL2, IL7, IL8 and 10, GM-CSF and PDGF-beta. TUSC2 is a positive regulator of innate immunity via regulation of IL-15 expression. IL-15 induces NK cell differentiation. The systemic effect of the TUSC2 and anti-PD1 antibody combination was examined in two immunocompetent, syngeneic mouse models of Kras and p53 mutant lung cancer. C57BL/6 mice were subcutaneously injected with murine adenocarcinoma lung carcinoma CMT/167-luc cells (KrasG12V mutation). CMT/167 cells do not express TUSC2. Tumors from untreated mice, isotype antibody control, or those treated with anti-PD1 were used as controls. 344SQ (KrasG12D allele and a knock-in Trp53R172HÄG allele) adenocarcinomas, which metastasize to the lung in 126S2 mice, were also used.

When tumors reached 50-100 mm3, mice were either injected intravenously with DOTAP:cholesterol (DC)-TUSC2 complex alone (at a dose of 25 “g of plasmid DNA and 10 nmol DC, every 48 hours for three injections), or (DC)-TUSC2 complex combined with anti-PD1 antibody (250 “g for four injections) alone or combined with anti-CTLA4 (100ug for three injections). Tumor growth and development was monitored by scoring *ex-vivo* luminescence using the IVIS Imaging System 200 Series. All tumor measurements were blinded to treatment and results were analyzed independently by biostatisticians.

Preclinical Study Showed that the TUSC2 and Anti-PD1 Combination Cooperatively Inhibits Growth of CMT/167 Lung Adenocarcinomas

Mouse experiments demonstrated combined treatment with TUSC2 and anti-PD1 antibody superior to anti-PD1 alone in five independent experiments in two different tumor models. Results of a representative experiment are shown in Figure 15. By week three, the reduction in tumor image intensity by the combination of TUSC2 and anti-PD1 and TUSC2, anti-PD1, plus anti-CTLA4 was greater than the reduction with TUSC2 alone, anti-PD1 combined with anti-CTLA4, or the isotype control. Spleens and blood were collected for immunological analysis profiling by multicolor flow cytometry. Immune profiling panels were designed to evaluate response and major changes of specific regulatory innate and adaptive immune cells to TUSC2 or anti-PD1 treatment in peripheral blood and spleen.

Figure 15
PRECLINICAL STUDY SHOWING EFFECT OF TUSC2 ANTI-PD1 COMBO ON T LYMPHOCYTES



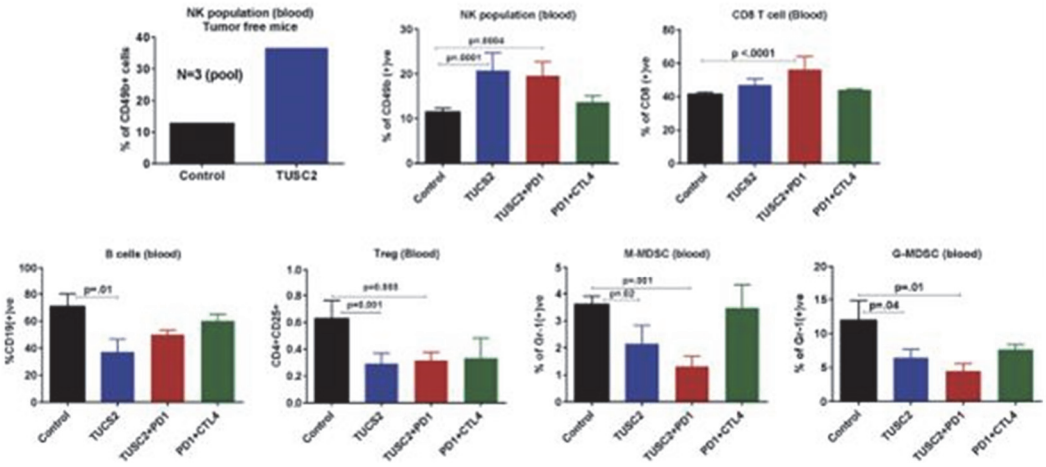
Source: Genprex, Inc.

Preclinical Study Showing the Effect of the TUSC2 and Anti-PD1 Combination on T Lymphocytes

The population of NK cells, cytotoxic lymphocytes critical to innate immune function, was assessed in **peripheral blood mononuclear cells (PBMCs)** in tumor-bearing mice treated with anti-PD1, TUSC2 alone, and the combination. As shown in Figure 16 (page 32), the NK cell population increased strongly in the TUSC2 alone and TUSC2+PD1 groups, correlating with tumor regression. Anti-PD1 alone had no effect on NK cell proliferation. Tumor free mice without mutations that lead to metastasis were injected intravenously with TUSC2, causing a threefold up-regulation of NK cells in the peripheral blood of TUSC2 injected mice versus non-injected mice. CD8 T cells, which are cytotoxic T cells (CTL) for tumor killing, act as a prognostic marker of tumor regression. Increased numbers of CTL were found in the TUSC2 and TUSC2+PD1 groups compared to that of the control group, which directly correlated with the anti-tumor effect. Lower levels of CD62L expression on T lymphocytes in TUSC2 treated mice suggests that TUSC2 regulates T cell activation. Moreover, TUSC2 induced down-regulation of regulatory T cells (Treg, CD4+CD25+). TUSC2 was shown to down-regulate checkpoint markers, such as PD-1, CTLA-4, Tim-3, and LAG-3.

Figure 16
EFFECT OF TUSC2 WITH ANTI-PD1 ON IMMUNE CELL POPULATIONS IN PERIPHERAL BLOOD (LARGE)

Effect of TUSC2 alone or in combination with anti-PD1 on immune cell populations in peripheral blood. Multi-color flow cytometry showed that TUSC2 significantly upregulated NK and cytotoxic T cells, and downregulated regulatory T cells, myeloid-derived suppressor cells (MDSCs), and B lymphocytes in tumor-bearing mice. The plot at the upper left shows that TUSC2 upregulated NK cells by 3-fold in tumor-free mice. All analyses were done 2 weeks after tumor cell implantation.



Source: Genprex, Inc.

Preclinical Study Showing that TUSC2 Immunogene Therapy is Synergistic with Anti-PD1 in Lung Cancer Syngeneic Mouse Models

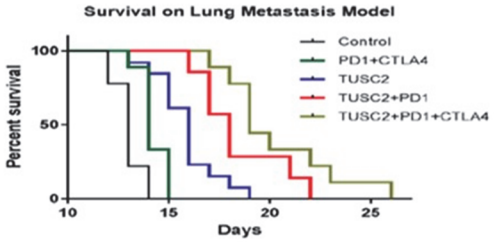
Based on the prolonged responses that were observed in TUSC2 clinical trials, suggesting that TUSC2 may modulate the immune response, and on the fact that checkpoint blockade immunotherapy against PD1 and PD-L1 has yielded durable antitumor activity in a subset of NSCLC patients, Genprex collaborators conducted a preclinical study to investigate the immune response to TUSC2 in immune cell populations and the synergistic antitumor effect of TUSC2 in combination with anti-PD1 checkpoint blockade in syngeneic mouse NSCLC models. Two Kras-mutant syngeneic mouse models were used to explore the effect of TUSC2+anti-PD1 (+/- anti-CTLA-4) on immune cells infiltration into the tumor micro-environment. Activating Kras mutations are the most common driver mutations in lung adenocarcinomas. Lung cancer with mutant Kras has a poor prognosis, is often resistant to conventional therapy, and readily becomes resistant to targeted therapies with kinase inhibitors. Studies by researchers (not at MD Anderson) have found that PD1 expression was highly associated with the presence of Kras mutations and that PD-L1 expression was elevated in premalignant Kras-mutant cells, suggesting that Kras mutation may affect the function of the PD1/PD-L1 immune checkpoint pathway.

The first syngeneic mouse model used a murine lung carcinoma cell line CMT/167-luc with a Kras G12V mutation and a low level of TUSC2 expression, implanted subcutaneously in C57BL/6 mice. The second syngeneic mouse model optimized an aggressive experimental metastatic lung cancer model using 129SvE mice injected with SQ344 lung cancer cells, which contained KrasG12D allele. The SQ344 tumor model was found to be less sensitive to anti-PD1 single agent treatment.

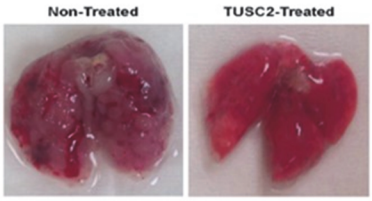
Figure 17 (page 33) shows results of this preclinical study in which anti-PD-1, TUSC2, and anti-CTLA-4 treatments were administered in the SQ344 metastatic lung tumor mouse model. The graph on the left shows the survival of the mice with the lung tumor cells treated with (a) no treatment, (b) a combination of anti-PD-1 and anti-CTLA-4, (c) TUSC2 alone, (d) a combination of TUSC2 and anti-PD-1, and (e) a combination of TUSC2, anti-PD-1 and anti-CTLA-4. The image on the right shows samples of untreated lung tissue and lung tissue treated with TUSC2.

Figure 17

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



TUSC2+anti-PD1 exhibit greater antitumor activity than either agent alone or control.



TUSC2+anti-PD1 combination significantly prolonged survival in a lung metastasis model refractory to checkpoint blockade alone.

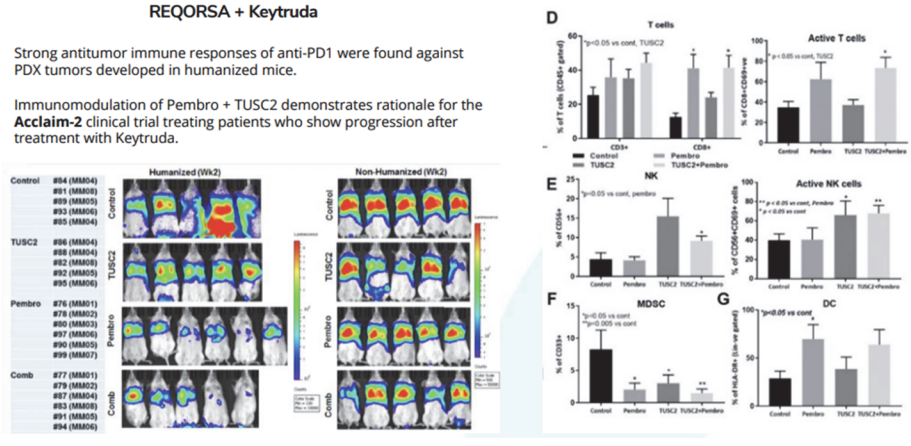
Source: Genprex, Inc.

Preclinical Studies Show TUSC 2 Immunogene Therapy is Synergistic with Anti-PD1 in Lung Cancer Humanized Mouse Models

Results of a preclinical study combining anti-PD1 with TUSC2 immunogene therapy showed strong antitumor immune responses of anti-PD-1 against PDX (patient derived xenograft) tumors developed in humanized mice. Additionally, TUSC2 plus anti-PD1 plus a chemotherapy combination resulted in metastasis regression significantly greater than either TUSC2 immunogene therapy alone or anti-PD1 plus chemotherapy, as shown in Figure 18.

Figure 18

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



Source: Genprex, Inc.

Discovery Programs

ONCOPREX® Nanoparticle Delivery System as a Platform

Genprex believes that its ONCOPREX Nanoparticle Delivery System may be applicable to delivering a range of therapeutic and prophylactic plasmid DNA constructs and show efficacy in cancers beyond NSCLC. The manufacturing methods that have been developed for REQORSA have been optimized and may be useful for a wide array of disease treatments. Clinical data from the use of REQORSA has shown that the ONCOPREX Nanoparticle Delivery System is well tolerated in humans and can be delivered at high therapeutic doses.

Rights to Other Tumor Suppressor Genes

Genprex has licensed rights to a group of candidate tumor suppressor genes, including 101F6, NPRL2, CACNA2D2, PL6, BLU, RASSF1, HYAL 1, and HYAL2, in addition to tumor suppressor gene, TUSC2—all of which are located in a sub-region of human chromosome 3 (known as 3p21.3). Using a number of techniques, Genprex collaborators have identified these genes as potentially having cancer-fighting characteristics. Researchers have subsequently conducted a number of preclinical studies on some of these genes, particularly 101F6 and NPRL2, as well as TUSC2, both alone and in combination with other compounds, in order to assess their actual effects on NSCLC. Under Genprex's Sponsored Research Agreement with MD Anderson, the Company plans to continue to support research into the cancer-fighting properties of these and other genes in the 3p21.3 sub-region.

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

DIABETES OVERVIEW

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

In the U.S., more than 37 million people have diabetes, with 1 in 5 unaware that they have the condition. Approximately 96 million U.S. adults (over a third of the U.S. population) has prediabetes and more than 8 in 10 of these individuals are unaware that they are prediabetic https://www.cdc.gov/diabetes/basics/prediabetes.html. Diabetes is the seventh leading cause of death in the U.S. (though this may be underreported). Type 2 diabetes accounts for approximately 90% to 95% of all diagnosed cases of diabetes; Type 1 diabetes accounts for approximately 5-10% of all cases. In the past 20 years, the number of adults diagnosed with diabetes has more than doubled as the American population has aged and become more overweight or obese, with the prevalence of this chronic disease continuing to rise.

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 vital 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, 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 slow, and over time the compensation of insulin resistance disappears, which leads to blood glucose levels increasing.

Current Treatments for Diabetes

Improvements in diabetes treatment have helped better manage the disease for many patients. However, in spite of patients' best attempts, managing diabetes continues to be a challenge due to the fact that insulin therapy is not an ideal means by which to mimic the body's biological function. Insulin is currently the primary means to treat Type 1 diabetes patients, with the majority of progress stemming from enhanced drug delivery along with improved methods for measuring blood glucose levels. An array of drug release technologies have allowed for rapid-acting, intermediate-acting, and long-acting insulin injections that provide from one to 24 hours of treatment. As well, enhancements in needles, continuous delivery ports, and inhalation technologies have enabled patients to better manage their disease and perhaps improve their quality of life; however, none of these innovations have proven to be disease modifying. Patients with Type 2 diabetes are advised to use diet and exercise to manage their condition. When the lifestyle changes alone do not control the disease, patients may be prescribed a variety of medications that help alter how the body manages blood sugar levels. For instance, 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. Insulin injections may be needed if these oral medications, along with diet and exercise, do not lower blood sugar levels enough. Importantly, while offering improvements for Type 2 diabetes patients, these treatments (including insulin replacement therapy) do not affect the underlying cause of the disease.

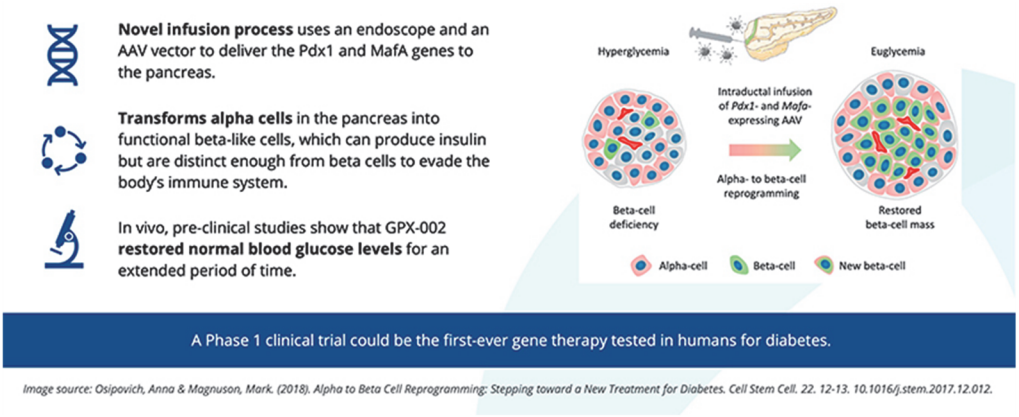
GPX-002

Genprex has licensed a pre-clinical gene therapy from the University of Pittsburgh to restore the function of beta cells that are destroyed by the immune system and overcome further destruction of insulin-producing cells. This technology, called GPX-002, 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. GPX-002 may replace the daily burden of blood glucose monitoring and insulin replacement therapy, including finger pricks and insulin injections. This technology holds the potential to provide long-term effectiveness, or may even be a cure, for diabetic patients.

Preclinical Studies

GPX-002 has been 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 about four months). According to the researchers, the duration of restored blood glucose levels in mice could translate to decades in humans, where if proven successful, this gene therapy could eliminate the need for insulin replacement therapy for diabetic patients. Researchers are continuing to conduct preclinical studies in diabetic primates. Once sufficient preclinical data has been generated, Genprex expects to begin a Phase 1 clinical trial in diabetic patients, which could be the first gene therapy to be ever tested in humans for diabetes. Figure 19 summarizes key attributes of Genprex's GPX-002.

Figure 19
GPX-002 REPLENISHES LEVELS OF INSULIN, REPROGRAMS, AND RESTORES CELL FUNCTION



Source: Genprex, Inc.

Received Inaugural "License of the Year" Award from University of Pittsburgh Innovation Institute

In February 2020, Genprex signed an exclusive license agreement with the University of Pittsburgh for an innovative gene therapy technology developed by lead researcher, George Gittes, M.D. (biography on page 9) at the Rangos Research Center at the University of Pittsburgh Medical Center Children's Hospital. In April 2021, the Company announced that it had been selected to receive the inaugural "License of the Year" award from the University of Pittsburgh Innovation Institute (UPII) in recognition of the advances made with its license from University of Pittsburgh toward progressing the development of its gene therapy for diabetes.

Process Development and Manufacturing

Genprex is preparing for commercial readiness of REQORSA through the development of an integrated supply chain network of vendors. The Company has developed a robust manufacturing process through years of process development activities that they continue to improve with the development and expansion of technologies in the nascent gene therapy sector.

REQORSA is an immunogene therapy with two main components. The active agent is a DNA plasmid encoding the TUSC2 protein. The plasmid is encapsulated by non-viral DOTAP cholesterol lipid nanoparticles. This system of encapsulating DNA plasmid in non-viral lipid nanoparticles is referred to by Genprex as its ONCOPREX Nanoparticle Delivery System. Each of these two components currently is manufactured by separate third-party contract development and manufacturing organizations (CDMOs) and then transported to another CDMO for final drug formulation (Figure 20).

Figure 20
SCALED-UP CLINICAL GRADE MANUFACTURING

Source: Genprex, Inc.

Genprex does not currently have the internal infrastructure or facilities to manufacture REQORSA or any other product candidate for use in the conduct of its trials or for commercial supply. It's strategy could change in the future and the Company could choose to develop its own infrastructure. Where other gene therapy agents need to be prepared individually for each patient or require viral vectors for gene delivery, REQORSA utilizes the ONCOPREX Nanoparticle Delivery System and has been shown to be scalable at **current Good Manufacturing Practices (cGMP)** and can be stored for approximately six to eight months for later use.

The Company continues to work to identify new manufacturing technologies and approaches to improve manufacturing processes and shelf life and expects this to increase REQORSA's shelf life to 12 to 18 months as well as achieve other process improvements. Successful tech transfer of REQORSA from MD Anderson, where it was previously manufactured, to a CDMO has been achieved as well as scale-up of the Company's clinical grade manufacturing production in accordance with cGMP. The clinical grade production is being used to supply Genprex's Acclaim-1 and Acclaim-2 clinical trials, with the Company managing its manufacturing arrangements with its CDMO vendors through various agreements.

Milestones

Completed Milestones

- ***Successfully completed technology transfer and scale-up of REQORSA***. Genprex recently completed the manufacturing and has scaled up clinical grade production of REQORSA to supply drug product for its upcoming Acclaim-1 and Acclaim-2 clinical trials.

- ***Opened patient enrollment for its Acclaim-2 clinical trial.*** In March 2022, the Company opened patient enrollment for its Acclaim-2 clinical trial, the open-label, multi-center Phase 1/2 clinical trial evaluating REQORSA in combination with Keytruda® (pembrolizumab) in patients with late-stage NSCLC whose disease progressed after treatment with Keytruda. Genprex expects to begin screening patients in the very near term for their eligibility to participate in the trial.

- ***Received the second Fast Track Designation (FTD) from the U.S. FDA for the combination of REQORSA + Keytruda.*** In December 2022, the U.S. FDA granted FTD to REQORSA in combination with Keytruda in patients with histologically-confirmed unresectable Stage III or IV NSCLC whose disease progressed after treatment with Keytruda.

- ***First patient dosed in the Acclaim-1 clinical trial.*** In February 2022, the first patient was dosed in the Acclaim-1 clinical trial, an open-label, multi-center Phase 1/2 clinical trial evaluating REQORSA in combination with Tagrisso® (osimertinib) in patients with late-NSCLC whose disease progressed after treatment with Tagrisso.

- ***Reported preclinical data for REQORSA in combination with targeted therapies and immunotherapies.*** Genprex reported that preclinical studies have shown increased numbers of immune cells in a tumor, improving the killing effect after inhibition of the PD-1/PD-L1 checkpoint interaction. REQORSA may also be shown to reduce the expression of PD-L1 by the tumor (leading to the FTD from the FDA).

- ***Received centralized Institutional Review Board (IRB) approval for its Acclaim-1 clinical trial.*** In May 2021, the Company received centralized IRB approval of the clinical trial protocol for its Acclaim-1 clinical trial in NSCLC. The purpose of IRB review is to assure that appropriate steps are taken to protect the rights and welfare of individuals participating as subjects in clinical research.

- ***Entered into license amendment with a major cancer research center in Houston, Texas, in-licensing additional technologies and expanding its intellectual property (IP) portfolio.*** In March 2021, Genprex entered into an amendment to the Patent and Technology License Agreement dated May 4, 2020. License Amendment grants the Company a worldwide, exclusive, sublicensable license to an additional portfolio of six patents and one patent application and related technology for methods of 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.

- ***Added small cell lung cancer to preclinical pipeline.*** In January 2022, Genprex expanded its oncology R&D pipeline to include small cell lung cancer (SCLC) as an additional disease indication for REQORSA.

- ***Sold an aggregate of 4,000,000 shares of its common stock for a purchase price of $6.25 per share.*** In February 2021, Genprex sold an aggregate of 4,000,000 shares of its common stock for a purchase price of $6.25 per share in a registered direct offering, receiving net proceeds of approximately $23.2 million after deducting estimated offering expenses.

Potential Milestones Over Next 12-24 Months

- Complete Phase 1 portion of Acclaim-1 by the end of 2022 and generate data showing the synergistic effects that REQORSA combined with EGFR-TKI inhibitors can have in patients.
- Complete Phase 1 portion of Acclaim-2 by the end of the first quarter of 2023, generating data showing the synergistic effects that REQORSA combined with immunotherapies can have in patients.
- Announce interim data from the Acclaim clinical trials.
- Initiate clinical trial for combination of REQORSA and immunotherapy in Small Cell Lung Cancer.
- Report preclinical data related to the Company's Sponsored Research Agreements and from ongoing preclinical studies of GPX-002.
- Explore new cancer indications.
- Continue to expand pipeline and platform technologies.
- Pursue pharmaceutical partnerships and collaborate with partners on its programs.
- Continue to expand and strengthen global intellectual property portfolio.

Investment Highlights

- ***Genprex, Inc. is a clinical-stage gene therapy company focused on developing life-changing therapies for patients with cancer and diabetes***. The Company's technologies are designed to administer disease-fighting genes to provide new treatments for large patient populations with limited options. Genprex is working with world-class institutions and collaborators to develop drug candidates to advance its pipeline of gene therapies using novel treatment approaches.

- ***The Company's oncology program employs its proprietary, non-viral ONCOPREX® Nanoparticle Delivery System, which the Company believes is the first systemic gene therapy delivery platform used to treat cancer in human clinical trials.*** ONCOPREX encapsulates the gene-expressing plasmids using lipid nanoparticles, with the resulting product dispensed intravenously, where it is then taken up by tumor cells that express deficient proteins. This avoids intertumoral administration and allows the drug to circulate throughout the body, entering cancer cells in the main tumor and distant sites.

- ***Genprex's lead product candidate, REQORSA™ Immunogene Therapy, is being evaluated as a treatment for non-small cell lung cancer (NSCLC).*** REQORSA has a multimodal mechanism of action that has been shown to (1) interrupt cell signaling pathways that cause replication and proliferation of cancer cells; (2) re-establish pathways for apoptosis, or programmed cell death, in cancer cells; and (3) modulate the immune response against cancer cells. REQORSA has also been shown to block mechanisms that create drug resistance.

- ***In 2020, the U.S. Food and Drug Administration (FDA) granted Fast Track Designation (FTD) to REQORSA for NSCLC in combination therapy with AstraZeneca's Tagrisso® (osimertinib) for patients whose tumors progressed after treatment with Tagrisso***.

    - In June 2021, Genprex initiated the Phase 1/2 Acclaim-1 study testing REQORSA in combination with Tagrisso. This strategy combines an EGFR drug that stops signals for tumor growth with the gene that signals tumor suppression and cell death. The study has a planned enrollment of about 92 patients at 15 clinical sites.

- ***In 2021, the U.S. FDA granted FTD for REQORSA for NSCLC in combination therapy with Merck & Co's Keytruda® (pembrolizumab) for patients whose disease progressed after treatment with Keytruda.*** The designation permits the Company to increase its engagement with the FDA concerning the drug data and requirements for development, as well as provides for the potential of an accelerated or rolling review, with a 6-month timeframe (versus the standard 10-month review).

    - In March 2022, the Company opened patient enrollment of its Acclaim-2 clinical trial, its open-label, multi-center Phase 1/2 clinical trial evaluating REQORSA in combination with Keytruda® in patients with late-stage NSCLC whose disease progressed after treatment with Keytruda. The first patient was dosed in April 2022. This trial could determine safety, tolerability, and improvement over checkpoint inhibitor immunotherapy alone. The Company expects to begin screening patients in the very near term for their eligibility to participate in the trial.

- ***According to the World Health Organization (WHO), in 2020 lung cancer was the leading cause of cancer deaths worldwide, causing more deaths than colorectal, breast, liver or stomach cancers, with 2.2 million new lung cancer cases and 1.8 million deaths worldwide***. In 2022, roughly 236,740 new cases of lung cancer are expected to be diagnosed in the U.S. and 130,180 people will die from the disease, with NSCLC representing 84% of all lung cancers and the five-year survival rate for patients with NSCLC with distant spread being 7%.

- ***Despite advances in surgical techniques, radiation therapy, and systemic therapy, the outlook for patients with lung cancer has improved more slowly than many other cancers over the last 50 years, indicating a significant unmet medical need***. Lung cancer mortality rate remains high, with localized stage patients displaying a 57% 5-year survival prognosis and those patients diagnosed in the distant stage showing a 5-year survival rate of only 5%.

- ***REQORSA delivers TUSC2, a gene with suppressive actions on pathways for cancer growth and tumor survival, as well as increases in the immune response against cancer***. TUSC2 has actions that restore regulatory controls lost in cancer mutations, block certain pathways of cancer growth signaling, and promote pathways of cell death. The behaviors as a suppressor gene and an immune stimulator have given it the name "immunogene therapy."

- ***Preclinical studies that led to the FTD demonstrated that REQORSA has effects on the immune system that stimulate populations of T-cells and decrease expression of a surface receptor that help cancer cells avoid the immune system (PD-L1), demonstrating possible synergies with Keytruda***.

- ***Genprex's diabetes program (GPX-002) holds promise as a way to replace the beta cells with insulin-producing cells that will evade that immunologic attack.*** The candidate works well in mice, which have the same mechanisms to control insulin as humans. A Phase 1 clinical trial could be the first gene therapy tested in humans for diabetes.

- ***The Company recently announced that it is expanding its research to include small cell lung cancer (SCLC) as well as NSCLC***. Out of the estimated 235,000 patients that are diagnosed each year in the U.S., an estimated 10% to 15% have SCLC and greater than 85% have NSCLC.

- ***Genprex currently holds a worldwide, exclusive license to 18 issued patents and 18 pending patent applications for technologies developed in-house, at the NCI, at MD Anderson, The University of Texas Southwestern Medical Center and the University of Pittsburgh.*** These patents comprise various therapeutic, diagnostic, technical, and processing claims relating to REQORSA, the ONCOPREX Nanoparticle Delivery System and diabetes technologies.

- ***With a strong balance sheet of $34.6 million in cash as of March 31, 2022 and expert clinical trial management led by Chief Medical Officer and industry veteran Mark Berger, MD who joined Genprex in September 2021 (biography on page 7), Genprex believes that the Company is well positioned to advance its Acclaim-1 and Acclaim-2 clinical trials.***

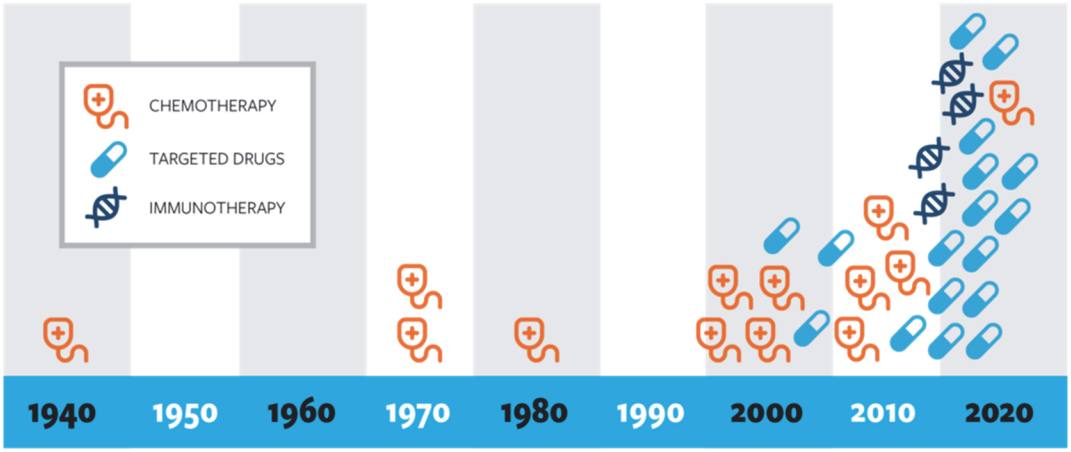
Competition

The biotechnology and pharmaceutical industries are intensely competitive and subject to rapid and significant technological change. As Genprex continues to develop and eventually commercialize its product candidates, it may encounter competition from other domestic and international pharmaceutical companies, biotechnology companies, and generic drug companies marketing or developing therapeutic treatments for the same indications the Company is targeting. Potential competitors also include academic institutions, government agencies, and other public and private research organizations that seek to develop novel therapeutic treatments for these conditions. In addition, the Company believes that smaller or early-stage companies may prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

Genprex's lead product candidate is intended to treat non-small-cell lung cancer (NSCLC). Currently, there are a number of drugs approved and in development to treat lung cancer, with current treatment options including chemotherapy, surgery, targeted therapies, radiation therapy, and immunotherapy. The pace of FDA approvals for lung cancer treatments has been accelerating, as shown in Figure 21, with 21 new diagnostic or treatment therapies and products approved since the beginning of 2020 (Source: Lung Cancer Research Foundation's FDA Approvals in Lung Cancer Treatment).

Figure 21

FDA APPROVALS IN LUNG CANCER TREATMENT



Source: Lung Cancer Research Foundation.

Despite advances in surgical techniques, radiation therapy, and systemic therapy, the outlook for patients with lung cancer has improved more slowly than many other cancers over the last 50 years, indicating a significant unmet medical need. Lung cancer mortality rate remains high, with localized stage patients displaying a 57% 5-year survival prognosis and those patients diagnosed in the distant stage showing a 5-year survival rate of only 5% (Sources: American Cancer Society's Cancer Facts & Figures, 2020).

Nevertheless, recent advances in the fields of immuno-oncology and precision medicine, as well as an increased understanding of NSCLC biology, have led to significant improvements in clinical outcome in metastatic NSCLC. Genprex believes that these new advancements in chemotherapies, targeted therapies, and immunotherapies represent the biggest competitive positions in the developing market. Accordingly, the list of companies presented in this Competition section is not intended to be an exhaustive collection of the Company's competitors. However, it is believed to be a sample of the type of competition that Genprex may face as it strives to commercialize its technologies and product candidates.

POTENTIAL COMPETITORS

AbbVie Inc. (ABBV-NASDAQ)

AbbVie is a global pharmaceutical company focused on developing innovative therapeutic products across several areas, including immunology, oncology, neuroscience, eye care, virology, women's health, and gastroenterology. The company's pipeline includes Telisotuzumab vedotin (ABBV-399), an antibody drug conjugate (ADC) for the treatment of NSCLC (Phase II); ABBV-011, a targeted ADC being investigated to treat SCLC (Phase I); and Veliparib (ABT-888) a Phase III candidate being investigated to treat BRCA breast cancer and ovarian cancer. The company was incorporated in 2012 and is headquartered in North Chicago, Illinois.

Amgen Inc. (AMGN-NASDAQ)

Amgen is a global biotechnology company focused on inflammation, oncology/hematology, bone health, cardiovascular disease, nephrology, and neuroscience areas. The company's products include LUMAKRAS™ (sotorasib) for the treatment of adult patients with some forms of metastatic NSCLC. The indication was approved in June 2021 under accelerated approval based on overall response rate (ORR) and duration of response (DOR). LUMAKRAS™ is also in Phase II trials for the treatment of advanced NSCLC, as well as Phase I and Phase II development for the treatment of NSCLC as monotherapy and in combination with other therapies, including a collaboration agreement with Verastem, Inc. to evaluate VS-6766 in combination with LUMAKRAS™. Amgen's pipeline also includes Tarlatamab (formerly AMG 757) to treat SCLC (Phase II), Acapatamab (formerly AMG 160) for the treatment of NSCLC (Phase I), and AMG 119 for the treatment of SCLC (Phase I). Amgen was incorporated in 1980 and is headquartered in Thousand Oaks, California.

AstraZeneca plc (AZN-NASDAQ)

AstraZeneca is a global, science-led biopharmaceutical company that focuses on the discovery, development, and commercialization of prescription medicines in oncology, rare diseases, and biopharmaceuticals, including cardiovascular, renal and metabolism, and respiratory and immunology. The company's products include IMFINZI® to treat some types of unresectable Stage III NSCLC, as well as a combination therapy for first-line treatment of extensive-stage SCLC; IRESSA® for the first-line treatment of patients with metastatic NSCLC; and TAGRISSO®, as adjuvant therapy after tumor resection for NSCLC as well as a first-line treatment of some types of metastatic NSCLC. AstraZeneca's pipeline additionally includes multiple Phase II and III trials evaluating IMFINZI® and TAGRISSO® for the first line treatment of NSCLC (as monotherapy or in combination with other therapeutics). AstraZeneca was incorporated in 1992 and is headquartered in Cambridge, the United Kingdom.

Eli Lilly and Company (LLY-NASDAQ)

Eli Lilly and Company discovers, develops, and markets human pharmaceuticals worldwide. The company's lung cancer therapeutics include Alimta® (in combination or as a single agent) for patients with various forms of NSCLC; Cyramza®, in combination with other agents for the treatment of some forms of metastatic NSCLC, Retevmo® for metastatic NSCLC, and Tyvyt® for relapsed or refractory classic Hodgkin's lymph and non-squamous NSCLC. Furthermore, Eli Lilly's pipeline includes LY3342901 (sintilimab), in combination with pemetrexed and platinum chemotherapy, in collaboration with Innovent for the first-line treatment of nonsquamous NSCLC (in regulatory review) and LY3527723 (Selpercatinib) for advanced or metastatic, treatment-naïve NSCLC (Phase III). Eli Lilly and Company was founded in 1876 and is headquartered in Indianapolis, Indiana.

Genentech (part of Roche Holding AG [ROG.SW-EBS])

Genentech is a leading biotechnology company that discovers, develops, manufactures, and commercializes medicines to treat patients with serious and life-threatening medical conditions. The company's products include TARCEVA® (erlotinib), ALECENSA® (alectinib), and GAVRETO® (pralsetinib), for the treatment of different types of metastatic NSCLC. In addition, Genentech's pipeline includes Entrectinib, in Phase II studies for NSCLC, and Tiragolumab in Phase I studies for NSCLC and Phase III studies for SCLC (the later managed by Roche). A member of the Roche Group, Genentech has headquarters in South San Francisco, California.

Iovance Biotherapeutics, Inc. (IOVA-NASDAQ)

Iovance Biotherapeutics is a clinical-stage biotechnology company focused on developing and commercializing tumor infiltrating lymphocyte (TIL) cancer immunotherapies to harness the power of a patient's immune system to eradicate cancer cells. The company's clinical pipeline includes two Phase II programs investigating its product candidate Tumor Infiltrating Lymphocytes (TIL) LN-145 for NSCLC, as well as a couple of Phase II programs investigating LN-146 in combination with other compounds for the treatment of NSCLC. Headquartered in San Carlos, California, the Company was formerly known as Lion Biotechnologies, Inc. and changed its name to Iovance Biotherapeutics, Inc. in June 2017.

Merck & Co., Inc. (MRK-NASDAQ)

Merck & Co., Inc. operates as a healthcare company worldwide. It operates through two segments, Pharmaceutical and Animal Health. The Pharmaceutical segment offers human health pharmaceutical products in the areas of oncology, hospital acute care, immunology, neuroscience, virology, cardiovascular, and diabetes, as well as vaccine products. The company's pipeline includes vibostolimab+pembrolizumab (MK-7684A), Pembrolizumab subcutaneous (MK-3475), LYNPARZA® (MK-7339), and LENVIMA® (MK-7902), all in Phase III development for NSCLC; as well as TUKYSA® (MK-7119), zilovertamab vedotin (MK-2140), ladiratuzumab vedotin (MK-6440), MK-4830, favezelimab (MK-4280), quavonlimab (MK-1308), MK-0482, LENVIMA® (MK-7902), and MK-5890 (with Keytruda), all in Phase II development for NSCLC. Merck & Co. was founded in 1891 and is headquartered in Kenilworth, New Jersey.

Mirati Therapeutics, Inc. (MRTX-NASDAQ)

Mirati Therapeutics is a clinical-stage oncology company developing product candidates to address the genetic and immunological promoters of cancer. The company develops Adagrasib (MRTX849), in Phase II/III clinical trial for treating NSCL both as monotherapy as well as in combination with other compounds; Sitravatinib, in a Phase III clinical trial for the treatment of NSCL; and MRTX1133 in preclinical studies for NSCLC. Mirati has a collaboration and license agreement with BeiGene, Ltd. to develop, manufacture, and commercialize sitravatinib. Mirati was founded in 1995 and is headquartered in San Diego, California.

Novartis AG (NVS-NYSE)

Novartis AG researches, develops, manufactures, and markets healthcare products through two operational entities: Innovative Medicines and Sandoz. The Innovative Medicines segment contains ophthalmology, neuroscience, immunology, hepatology, dermatology, respiratory, cardiovascular, renal, and metabolism medicine products. Novartis' product lines include TABRECTA® (capmatinib) indicated for the treatment of adult patients with metastatic NSCLC under accelerated approval with a Phase III confirmatory trial on-going for both monotherapy and combination therapy (under code INC280). The company also offers ZYKADIA® (ceritinib) indicated for the treatment of metastatic NSCLC, as well as HYCAMTIN® (topotecan) indicated for treatment of SCLC. Novartis' NSCLC-related pipeline includes ACZ885 (Canakinumab) (Phase III), JDQ443 (Phase III), and VDT482 (tislelizumab) (Phase III). The company was incorporated in 1996 and is headquartered in Basel, Switzerland.

Takeda Pharmaceutical Company Limited (TAK-NYSE)

Takeda is a global R&D-driven biopharmaceutical company developing therapeutic products in the areas of oncology, gastroenterology, neuroscience, and rare genetics and hematology, as well targeted R&D efforts in plasma-derived therapies and vaccines. The company's products include ALUNBRIG® (Brigatinib) and EXKIVITY® (Mobocertinib), both agents indicated for the treatment of some forms of metastatic NSCLC. The later was approved under accelerated approval based on overall response rate and duration of response and is currently undergoing Phase III confirmatory trial. Takeda's pipeline also includes CABOMETYX® (Cabozantinib), in Phase III studies for the treatment of metastatic NSCLC (being developed in Japan in collaboration with Exelixis, Inc. [EXEL-NASDAQ]). Takeda was founded in 1781 and is headquartered in Tokyo, Japan.

Turning Point Therapeutics, Inc. (TPTX-NASDAQ)

Turning Point Therapeutics, a clinical-stage precision oncology biopharmaceutical company, is engaged in designing and developing therapies that target genetic drivers of cancer. The company has developed a pipeline of tyrosine kinase inhibitors (TKIs) that target genetic drivers of cancer. Lead drug candidate, Repotrectinib, is being evaluated in an ongoing late-stage clinical trial, called TRIDENT-1, for the treatment of patients with some form of advanced NSCLC and solid tumors. Turning Point's pipeline also includes TPX-0131, in Phase I/II FORGE-1 study for patients with advanced or metastatic pretreated NSCLC. Turning Point Therapeutics was founded in 2013 and is headquartered in San Diego, California.

Historical Financial Results

Figures 22, 23, and 24 provide Genprex, Inc.'s Statements of Operations, Balance Sheets, and Statements of Cash Flows for the quarters ended March 31, 2022 and 2021.

Figure 22
STATEMENTS OF OPERATIONS

	Three Months Ended March 31,	
	2022	**2021**
Revenues	$ —	$ —
Cost and expenses:		
Depreciation	6,730	6,242
Research and development	1,860,837	2,169,143
General and administrative	3,855,796	4,316,310
Total costs and expenses	5,723,363	6,491,695
Operating loss	(5,723,363)	(6,491,695)
Interest income	879	1,982
Net loss	(5,722,484)	(6,489,713)
Net loss per share—basic and diluted	($0.12)	($0.14)
Weighted average number of common shares— basic and diluted	47,879,597	45,546,106

Source: Genprex, Inc.

Figure 23

BALANCE SHEETS

	March 31, 2022	December 31, 2021
	(unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	$ 34,555,337	$ 38,628,876
Accounts receivable	$ 32,171	—
Prepaid expenses and other	$ 1,115,601	$ 511,348
Total current assets	$ 35,703,109	$ 39,140,224
Property and equipment, net	$ 41,878	$ 48,608
Other assets:		
Security deposits	$ 10,000	$ 8,691
Supplies	$ 3,010,243	$ 3,022,403
Intellectual property, net	$ 644,201	$ 642,360
Total other assets	$ 3,664,444	$ 3,673,454
Total assets	$ 39,409,431	$ 42,862,286
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,252,978	$ 973,195
Other current liabilities	$ 1,131,839	$ 612,100
Total current liabilities	$ 2,384,817	$ 1,585,295
Stockholders' equity:		
Preferred stock $0.001 par value: 10,000,000 shares authorized; no shares issued and outstanding	—	—
Common stock $0.001 par value: 200,000,000 shares authorized; 47,879,708 and 47,874,708 shares issued and outstanding at March 31, 2022, and December 31, 2021, respectively	$ 47,879	$ 47,874
Additional paid-in capital	$ 120,717,072	$ 119,246,970
Accumulated deficit	$ (83,740,337)	$ (78,017,853)
Total stockholders' equity	$ 37,024,614	$ 41,276,991
Total liabilities and stockholders' equity	$ 39,409,431	$ 42,862,286

Source: Genprex, Inc.

Figure 24

STATEMENTS OF CASH FLOWS

	Three Months Ended March 31,	
	2022	2021
Cash flows from operating activities:		
Net loss	$ (5,722,484)	$ (6,489,713)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	$ 6,730	6,242
Share based compensation	$ 1,470,107	671,738
Changes in operating assets and liabilities:		
Accounts receivable	$ (32,171)	—
Prepaid expenses and other	$ (605,561)	187,282
Accounts payable	$ 279,783	146,493
Other current liabilities	$ 519,739	12,676
Net cash used in operating activities	$ (4,083,857)	(5,465,282)
Cash flows from investing activities:		
Additions to property and equipment	$ —	(91,701)
Additions to intellectual property	$ (1,841)	(9,071)
Reductions (additions) to research and development supplies	$ 12,160	(9,258)
Net cash provided (used) by investing activities	$ 10,319	(110,030)
Cash flows from financing activities:		
Proceeds from issuances of stock	$ —	25,324,330
Net cash provided by financing activities	$ —	25,324,330
Net decrease (increase) in cash and cash equivalents	$ (4,073,539)	19,749,018
Cash and cash equivalents, beginning of period	$ 38,628,876	27,319,685
Cash and cash equivalents, end of period	$ 34,555,337	$ 47,068,703

Source: Genprex, Inc.

Recent Events

June 2, 2022—Genprex, Inc. announced the Company's participation in the following upcoming investor and industry conferences to be held in June 2022: LD Micro Invitational (June 7-9) and BIO International Convention (June 13-16).

May 19, 2022—Announced that its President and Chief Executive Officer, Rodney Varner, will be providing a virtual overview of the Company's gene therapies for cancer and diabetes to investors at the following conference in May 2022.

May 9, 2022—Announced that its Chief Medical Officer, Mark Berger, M.D., will be featured as an expert panelist at the 33rd Annual Cancer Progress Conference, taking place virtually May 10-12, 2022.

May 5, 2022—Announced that it has issued a shareholder letter and corporate update outlining the Company's recent progress in its clinical development programs and key milestones and achievements for 2022 and beyond.

April 18, 2022—Announced that its executive leaders will be providing an overview of the Company's gene therapies for cancer and diabetes to investors and industry professionals at investor and industry conferences in April 2022.

March 31, 2022—Announced the opening for patient enrollment of its Acclaim-2 clinical trial. Acclaim-2 is an open-label, multi-center Phase 1/2 clinical trial evaluating the Company's lead drug candidate, REQORSA™ Immunogene Therapy, in combination with Keytruda® (pembrolizumab) in patients with late-stage non-small cell lung cancer (NSCLC) whose disease progressed after treatment with Keytruda. In 2021, Genprex received U.S. Food and Drug Administration's (FDA) Fast Track Designation for the treatment of the Acclaim-1 patient population.

March 23, 2022—Announced that its President and Chief Executive Officer, Rodney Varner, will provide an overview of the Company's gene therapies for cancer and diabetes to investors at the 2022 BIO Europe Spring Investor Conference.

March 2, 2022—Announced that the first patient was dosed in the Acclaim-1 clinical trial, an open-label, multi-center Phase 1/2 clinical trial evaluating the Company's lead drug candidate, REQORSA™ Immunogene Therapy, in combination with Tagrisso® (osimertinib) in patients with late-stage non-small cell lung cancer (NSCLC) whose disease progressed after treatment with Tagrisso. In 2020, Genprex received U.S. Food and Drug Administration's (FDA) Fast Track Designation for treatment of the Acclaim-1 patient population.

February 9, 2022—Announced that its President and Chief Executive Officer, Rodney Varner, will provide an overview of the Company's gene therapies for cancer and diabetes to investors at the 2022 BIO CEO and Investor Conference and at the 2022 Diamond Equity Research Conference.

January 27, 2022—Announced that its collaborators published positive preclinical data for the use of Genprex's ONCOPREX® Nanoparticle Delivery System for delivery of a FAS DNA plasmid to treat metastatic colorectal cancer. Published in the journal *Cancers*, the preclinical study found that tumor selective ONCOPREX nanoparticles carrying FAS DNA plasmids suppress human colon tumor growth *in vivo* in mouse models, indicating that this may be an effective therapy for human colorectal cancer.

January 5, 2022—Announced its participation in upcoming investor and healthcare conferences to be held in January 2022. Genprex's President and Chief Executive Officer, Rodney Varner, and the Company's Chief Medical Officer, Mark Berger, MD will lead the Company's presentations.

January 4, 2022—Announced that it had expanded its oncology research and development pipeline to include small cell lung cancer (SCLC) as an additional disease indication for its lead drug candidate, REQORSA™ Immunogene Therapy. SCLC represents approximately 10% to 15% of the lung cancer market, while REQORSA's initial target indication of non-small cell lung cancer (NSCLC) represents over 85% of the lung cancer market.

January 3, 2022—Announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track Designation (FTD) for the Company's lead drug candidate, REQORSA™ Immunogene Therapy, in combination with Merck & Co's Keytruda® in patients with histologically-confirmed unresectable stage III or IV NSCLC whose disease progressed after treatment with Keytruda.

November 16, 2021—Announced that its President and Chief Executive Officer, Rodney Varner, will be presenting in November with CEO Roadshow to provide a company overview of its novel gene therapies in cancer and diabetes to investors.

September 28, 2021—Announced that the Company has strengthened its leadership team with the appointments of Mark S. Berger, M.D. to the newly-created position of Chief Medical Officer and Hemant Kumar, Ph.D., CPM, EMBA to the newly-created position of Chief Manufacturing and Technology Officer. Drs. Berger and Kumar will report to Rodney Varner, Chief Executive Officer of Genprex.

September 20, 2021—Announced that its President and Chief Executive Officer, Rodney Varner, will be participating in two investor conferences in September 2021.

July 20, 2021—Announced that its President and Chief Executive Officer, Rodney Varner, will be participating in a webinar series with CEO Roadshow to provide a company overview to investors on a monthly basis from July through September 2021.

June 23, 2021—Announced that the U.S. FDA has reviewed and confirmed all comments have been addressed regarding the Company's clinical trial protocol for the Acclaim-1 clinical trial, an open-label, multi-center Phase 1/2 clinical trial evaluating the Company's lead drug candidate, REQORSA™ Immunogene Therapy, in combination with AstraZeneca's Tagrisso® in patients with late-stage NSCLC whose disease progressed after treatment with Tagrisso. In January 2020, Genprex received FDA Fast Track Designation for the Acclaim-1 patient population.

May 19, 2021—Announced that it will participate in in Noble Capital Markets' Virtual Roadshow Series, presented by Channelchek on May 20, 2021.

May 10, 2021—Announced that it will participate in investor conferences in the month of May, with presentations led by the Company's President and Chief Executive Officer, Rodney Varner.

May 6, 2021—Announced that the Company and a major cancer research center in Houston, Texas, in March 2021, entered into an amendment to their May 2020 License Agreement to grant to Genprex an exclusive worldwide license to an additional portfolio of six patents and one patent application and related technology. The Newly Licensed IP includes methods for treating NSCLC by administration of a TUSC2 therapeutic in conjunction with EGFR inhibitors or other anti-cancer therapies, in patients who are predicted to be responsive to TUSC2 therapy. A TUSC2 gene-expressing plasmid is the active agent in REQORSA™ Immunogene Therapy.

May 5, 2021—Announced that the Company has received centralized Institutional Review Board (IRB) approval of the clinical trial protocol for its upcoming Acclaim-1 clinical trial in NSCLC. Acclaim-1 is an open-label, multi-center Phase 1/2 clinical trial that combines the Company's lead drug candidate, REQORSA™ Immunogene Therapy, with AstraZeneca's Tagrisso® (osimertinib) in patients with late-stage NSCLC with mutated epidermal growth factor receptors (EGFRs), whose disease progressed after treatment with Tagrisso.

May 4, 2021—Announced it has commenced clinical trial site recruitment for its upcoming Acclaim-2 clinical trial for the treatment of NSCLC.

April 21, 2021—Announced that its President and Chief Executive Officer, Rodney Varner, will be participating in a webinar series with CEO Roadshow to provide a company overview to investors on a weekly basis from April 22 through June 10, 2021.

April 20, 2021—Announced that the Company has been selected to receive the inaugural "License of the Year" award from the University of Pittsburgh Innovation Institute (UPII) in recognition of the advances made with its license from University of Pittsburgh toward progressing the development of its gene therapy for diabetes.

April 12, 2021—Announced that its collaborators presented positive preclinical data for the combination of TUSC2 Immunogene Therapy (REQORSA™) in combination with chemotherapy and immunotherapies for the treatment of NSCLC. Collaborators also presented positive preclinical data for the use of REQORSA in combination with targeted therapies for the treatment of NSCLC. These data were presented in two presentations at the 2021 American Association of Cancer Research (AACR) annual meeting. The TUSC2 gene is a tumor suppressor gene and is the active agent in REQORSA.

April 5, 2021—Announced that its then Executive Vice President and Chief Operating Officer, Michael Redman, will present at the annual Cell & Gene Meeting on the Mediterranean, which will take place virtually April 6-9, 2021.

March 30, 2021—Announced that preclinical data of its TUSC2 immunogene therapy (REQORSA™) in combination with chemotherapy and immunotherapies, as well as in combination with targeted therapies to overcome resistance to osimertinib, for the treatment of non-small cell lung cancer (NSCLC), will be featured in two presentations at the upcoming annual meeting of the American Association for Cancer Research (AACR 21) taking place virtually from April 9-14, 2021.

March 24, 2021—Announced that it will present at the Spring 2021 Oncology Investor Conference on March 29, 2021. Genprex's President and Chief Executive Officer, Rodney Varner, will deliver a virtual company overview to investors, including its novel gene therapies for non-small cell lung cancer and diabetes.

March 1, 2021—Announced that it will participate in investor conferences in the month of March, with presentations led by the Company's President and Chief Executive Officer, Rodney Varner.

February 9, 2021—Announced it has entered into securities purchase agreements with two healthcare-dedicated institutional investors for the purchase and sale of 4,000,000 shares of its common stock at a purchase price of $6.25 per share in a registered direct offering priced at-the-market under Nasdaq rules. No warrants will be issued in connection with the transaction. The closing of the offering is expected to occur on or about February 11, 2021, subject to the satisfaction of customary closing conditions.

February 8, 2021—Announced the formation of a Clinical Advisory Board (CAB) to support its oncology and diabetes development programs. Comprised of preeminent clinical specialists, the CAB will lead and advise Genprex as it advances its REQORSA™ Immunogene Therapy program, including its Acclaim clinical trials in NSCLC and its preclinical diabetes gene therapy program. Some of the members also serve in additional roles at the Company.

February 4, 2021—Announced that it joins with millions of healthcare advocates around the world in support of World Cancer Day in order to raise awareness, elevate the public understanding of the global cancer burden, promote greater equity and ensure that cancer control continues to be a priority in the world health and development agenda.

Risks and Disclosures

This Executive Informational Overview® (EIO) has been prepared by Crystal Research Associates, LLC ("CRA") based upon information that has not been independently verified. Statements contained in this EIO regarding matters that are not historical facts are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. These and other risks and uncertainties are described more fully under the caption "Risk Factors" in the Company's annual report on form 10-K for the year ended December 31, 2021 and other filings and reports with the United States Securities and Exchange Commission that may be filed in the future. These risks and uncertainties are not exhaustive.

The content of this report with respect to Genprex has been compiled from information available to the public released by the Company through news releases, Annual Reports, and U.S. Securities and Exchange Commission (SEC) filings made by the Company. Genprex is solely responsible for the accuracy of this information. Information as to other companies has been prepared from publicly available information and has not been independently verified by Genprex or CRA. Certain summaries of activities and outcomes have been condensed to aid the reader in gaining a general understanding. CRA assumes no responsibility to update the information contained in this report. In addition, for year one of its agreement, CRA has been compensated by the Company in cash of thirty-nine thousand five hundred dollars for its services in creating this report and for quarterly updates.

Investors should carefully consider the risks and information about Genprex's business, as summarized below and further detailed in the Company's 2021 Annual Report on Form 10-K as filed with the Securities and Exchange Commission. Investors should not interpret the order in which considerations are presented in this or other filings as an indication of their relative importance. In addition, the risks and uncertainties overviewed in Genprex's SEC filings are not the only risks that the Company faces. Additional risks and uncertainties not presently known to Genprex or that it currently believes to be immaterial may also adversely affect the Company's business. If any of such risks and uncertainties develops into an actual event, Genprex's business, financial condition, and results of operations could be materially and adversely affected, and the trading price of the Company's shares could decline.

This report is published solely for information purposes and is not to be construed as an offer to sell or the solicitation of an offer to buy any security in any state. Past performance does not guarantee future performance.

RISK FACTOR SUMMARY

Genprex's business is subject to significant risks and uncertainties that make an investment in it speculative and risky. Below is summarized what are likely to be the principal risk factors but these risks are not the only ones the Company may face, and investors should carefully review and consider the full discussion of the Company's risk factors in the section titled "Risk Factors," together with the other information in the Company's Annual Report on Form 10-K. If any of the following risks actually occurs (or if any of those listed elsewhere in the Company's Annual Report on Form 10-K occur), Genprex's business, reputation, financial condition, results of operations, revenue, and future prospects could be seriously harmed. Additional risks and uncertainties that the Company is unaware of, or that Genprex currently believes is not material, may also become important factors that adversely affect its business.

Risks Related to Company Operations and Need for Additional Capital

- Genprex will require substantial additional funding, which may not be available to the Company on acceptable terms, or at all, and, if not so available, may require Genprex to delay, limit, reduce, or cease its operations.

- Genprex has never been profitable, has no products approved for commercial sale, and to date has not generated any revenue from product sales. As a result, the Company's ability to reduce its losses and reach profitability is unproven, and the Company may never achieve or sustain profitability.

- Genprex has a limited operating history and expects a number of factors to cause its operating results to fluctuate on an annual basis, which may make it difficult to predict the Company's future performance.

- The Company's ability to utilize net operating loss carryforwards may be limited, resulting in income taxes sooner than currently anticipated.

- U.S. federal income tax reform could adversely affect Genprex.

Risks Related to Development and Commercialization of the Company's Current and Future Product Candidates

- Genprex's success depends greatly on the success of its development of REQORSA for the treatment of NSCLC and SCLC, and other product candidates, including GPX-002 for the treatment of diabetes.

- If the Company is unable to secure contract manufacturers with capabilities to produce the products that they require, Genprex could experience delays in conducting its planned clinical trials.

- Negative public opinion and increased regulatory scrutiny of gene therapy and genetic research may damage public perception of the Company's current and potential product candidates or adversely affect its ability to conduct business or obtain regulatory approvals for 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 the Company and delay or limit its ability to obtain regulatory approval for REQORSA and other current or future product candidates.

- Fast track designation of Genprex's 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 the Company's product candidates.

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

- REQORSA™, GPX-002, and any other product candidate that the Company advances through clinical trials may not have favorable results in later clinical trials or receive regulatory approval. Even if Genprex completes the necessary clinical trials, the Company cannot predict when, or if, it will obtain regulatory approval to commercialize its product candidates, and the approval may be for a narrower indication than the Company seeks.

- Even if Genprex obtains regulatory approval of its 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 Genprex for uninsured liabilities, or such claim exceeds the Company's insurance coverage, it could be forced to pay substantial damage awards that could materially harm Genprex's business.

- Security breaches and other disruptions could compromise Genprex's information and expose the Company to liability, which would cause its business and reputation to suffer.

- Genprex's business has been adversely affected by the ongoing coronavirus pandemic, which has delayed and may continue to delay its clinical trials and has disrupted and may continue to disrupt the supply chain and may have other adverse effects on its business and operations.

- The Company faces competition from other biotechnology and pharmaceutical companies and its operating results will suffer if they fail to compete effectively.

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

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

- Even if Genprex obtains regulatory approval for its product candidates, these products will remain subject to regulatory oversight.

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

- Genprex 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. The Company's 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 the Company's other current or future product candidates, if approved, which could make it difficult for Genprex to sell REQORSA, GPX-002, and 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 used or delay or prevent the regulatory approval of the Company's current and potential product candidates.

- Healthcare legislative reform measures may have a material adverse effect on Genprex's business and results of operations.

- The Company is subject to a variety of risks associated with international operations, which could materially adversely affect its business.

- If Genprex fails to comply with environmental, health, and safety laws and regulations, the Company could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of its business.

Risks Related to the Company's Dependence on Third Parties

- Genprex may not be successful in establishing and maintaining development and commercialization collaborations, which could adversely affect its ability to develop current and future product candidates and the Company's financial condition and operating results could be adversely affected.

- The Company relies, in part, and expects to continue to rely, in part, on third parties to conduct, supervise, and monitor its clinical trials, and if these third parties perform in an unsatisfactory manner, it may harm Genprex's business.

- Genprex relies, and expects to continue to rely, on third parties to distribute, manufacture, and perform release testing for its 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, the Company may not be able to obtain regulatory approvals for its product candidates.

- The Company has 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 Genprex's business, financial condition, and results of operations.

Risks Related to the Company's Intellectual Property

- If Genprex fails to comply with obligations pursuant to its license agreements, the Company could lose intellectual property and other rights that are important to its business.

- The intellectual property rights the Company has licensed from MD Anderson and the UP are subject to the rights of the U.S. government.

- If the Company is unable to protect its intellectual property rights or if its intellectual property rights are inadequate for its technology and product candidates, Genprex's competitive position could be harmed.

- Third-party claims of intellectual property infringement may prevent or delay the Company's development and commercialization efforts.

- Genprex may not be successful in obtaining or maintaining necessary rights to product components and processes for its 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 the Company's intellectual property.

- Reliance on third parties may require Genprex to share its trade secrets, which increases the possibility that a competitor will discover them or that the Company's trade secrets will be misappropriated or disclosed.

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

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

- Issued patents covering the Company's product candidates could be found invalid or unenforceable if challenged in court.

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

- Genprex may be subject to claims challenging the inventorship or ownership of its patents and other intellectual property.

- Changes in U.S. patent law could diminish the value of patents in general, thereby impairing Genprex's ability to protect its products.

- The Company has not yet registered the trademark for REQORSA™, and failure to secure such registration could adversely affect its business.

- Genprex may not be able to protect its intellectual property rights throughout the world.

Risks Related to Employee Matters and Managing Growth

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

- The Company may not be able to manage its business effectively if they are unable to attract and retain key personnel and consultants.

- Genprex may use its 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 the Company engages in future acquisitions or strategic partnerships, this may increase its capital requirements, dilute its stockholders, cause it to incur debt or assume contingent liabilities, and subject it to other risks.

Risks Related to Genprex's Securities

- The market price of the Company's common stock may be highly volatile, and investors may lose all or part of his/her investment.

- An active, liquid, and orderly market for Genprex's common stock may not be sustained, and investors may not be able to sell his/her common stock.

- Genprex is currently listed on The Nasdaq Capital Market. If they are unable to maintain listing of the Company's securities on Nasdaq or any stock exchange, the Company's stock price could be adversely affected and the liquidity of its stock and its ability to obtain financing could be impaired and it may be more difficult for Company stockholders to sell their securities.

- Unstable market and economic conditions may have serious adverse consequences on the Company's business, financial condition, and stock price.

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

- Genprex has no intention of declaring dividends in the foreseeable future.

- The Company is an emerging growth company and cannot be certain if the reduced reporting requirements applicable to emerging growth companies will make its common stock less attractive to investors.

- Sales of a substantial number of shares of the Company's common stock in the public market could cause its stock price to fall.

- Future sales and issuances of Genprex's securities could result in additional dilution of the percentage ownership of its stockholders and could cause the Company's share price to fall.

- Certain provisions in the Company's organizational documents could enable Genprex's board of directors to prevent or delay a change of control.

- Genprex's Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws contains 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 the Company or its 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 Genprex's management will be required to devote substantial time to compliance matters.

- Business disruptions could seriously harm the Company's future revenue and financial condition and increase its costs and expenses.

- Genprex may be at risk of securities class action litigation.

Glossary

Allele—One of two or more alternative versions of a gene found at a given site on a chromosome. Alleles may occur in pairs, or there may be multiple alleles affecting the expression (phenotype) of a particular trait.

Alpha cells—Endocrine cells in the pancreatic islets of the pancreas. They make up to 20% of the human islet cells synthesizing and secreting the peptide hormone glucagon, which elevates the glucose levels in the blood.

Angiogenesis—The development of new blood vessels.

Apoptosis—The death of cells which occur as a normal and controlled part of an organism's growth or development.

Autophosphorylate—A type of post-translational modification of proteins essential in cell signaling. It is a biochemical process in which a phosphate is added to a protein kinase by the action of the protein kinase itself.

Beta-like cells—Beta cells are a type of cell found in pancreatic islets that synthesize and secrete insulin and amylin. The autoimmune-mediated destruction of insulin producing beta cells in the pancreas is a key element of Type 1 diabetes. Generation of functional insulin-producing beta-like cells, either through transplantation or differentiation of human stem cells, is a key area of research for the effective treatment of diabetes.

Caspases—A family of enzymes playing essential roles in programmed cell death.

Cationic—A cationic material has a net positive charge.

Checkpoint inhibitor—A type of drug that blocks immune proteins called checkpoints. Checkpoint inhibitor therapy is a form of cancer immunotherapy. The therapy targets immune checkpoints, key regulators of the immune system that when stimulated can dampen the immune response to a stimulus. Some cancers can protect themselves from attack by stimulating immune checkpoint targets.

Current Good Manufacturing Practices (cGMP)—The regulations provided by the U.S. Food and Drug Administration (FDA) that guide the design, monitoring, and maintenance of manufacturing facilities and processes involved in the production of pharmaceutical products, medical devices, food and beverages, and dietary supplements.

Dephosphorylation—The removal of a phosphate group from an organic compound. It is a reversible post-translational modification involved in the activation and deactivation of enzymes.

Diabetes Mellitus—A disease in which the body's ability to produce or respond to the hormone insulin is impaired, resulting in abnormal metabolism of carbohydrates and elevated levels of glucose in the blood and urine.

Dimerize—To combine with a similar molecule to form a dimer (a molecule composed of two identical molecules linked together).

Endocytosis—A cellular process by which cells absorb external material by engulfing it with the cell membrane.

Epidermal Growth Factor Receptor (EFGR)—A protein found on certain types of cells that bind to a substance called epidermal growth factor and is involved in cell signaling pathways that control cell division. Mutations in the EGFR gene can cause EFGR proteins to be made in higher-than-normal amounts on some types of cancer cells, causing cancer cells to divide more rapidly. Drugs that block EFGR proteins are being used in the treatment of some types of cancer.

Gene Therapy—A medical approach that treats or prevents disease by correcting the underlying genetic problem. It refers to the treatment of disease by repairing or reconstructing missing or defective genes in order to correct genetic disorders.

Hypophosphatemia—Refers to low level of phosphorous (phosphate) in the blood. Symptoms may include muscle weakness, trouble breathing, and loss of appetite, and in serious cases even respiratory or heart failure, seizure, or coma.

Immune checkpoints—Regulators of the immune system. These pathways are crucial for self-tolerance, which prevents the immune system from attacking cells indiscriminately. However, some cancers can protect themselves from attack by stimulating immune checkpoint targets.

Immunomodulatory—A substance that stimulates or suppresses the immune system and may help the body fight cancer, infection, or other diseases.

Kinases—An enzyme that catalyzes the transfer of a phosphate group from ATP to a specified molecule, a process called phosphorylation.

Low-dose spiral computed tomography (LDCT)—A procedure that uses a computer linked to an x-ray machine that gives off a very low dose of radiation to make a series of detailed pictures of areas inside the body to create 3-D views of tissues and organs. Low-dose CT scan is recommended as a screening test for adults who have a high risk of developing lung cancer based on their age and smoking history.

Nanoparticles—Usually refers to a particle of matter that is between 1 and 100 nanometers in diameter.

Non-small cell lung cancer (NSCLC)—A group of lung cancers named for the kinds of cells found in the cancer. The three main types of NSCLC are adenocarcinoma (most common), squamous cell carcinoma, and large cell carcinoma. Non-small cell lung cancer is the most common of the two main types of lung cancer (NSCLC and small cell lung cancer).

Pan-kinase inhibitor—A pharmaceutical drug that inhibits kinases, enzymes responsible for the activation of many proteins by adding a phosphate group to the protein (phosphorylation), a step that these compounds inhibit.

PD-1 (Programmed Death-1)—A protein found on the surface of T cells (a type of immune cell) that helps keep the body's immune responses in check and is vital for the physiologic regulation of the immune system. When PD-1 is bound to another protein called PD-L1, it helps keep T cells from killing other cells, including cancer cells. Some anticancer drugs, called immune checkpoint inhibitors, are used to block PD-1. When this protein is blocked, the "brakes" on the immune system are released and the ability of T cells to kill cancer cells is increased.

Peripheral blood mononuclear cells (PBMCs)—A diverse mixture of highly specialized immune blood cells having a round nucleus. These cells consist of lymphocytes (T cells, B cells, NK cells) and monocytes.

Plasmids—A small, often circular segment of DNA independent of the chromosomes and capable of replication, occurring in bacteria and yeast. They are often used in recombinant DNA procedures to transfer genetic material from one cell to another.

Positron emission tomography (PET) imaging—A functional imaging technique that uses radioactive substances known as radiotracers to visualize and measure changes in metabolic processes, and in other physiological activities including blood flow, regional chemical composition, and absorption.

Progression-free survival—The length of time during and after the treatment of a disease, such as cancer, that a patient lives with the disease but it does not get worse.

Response Evaluation Criteria in Solid Tumors (RECIST)—A set of published rules that define when tumors in cancer patients improve, stay the same, or worsen during treatment.

Signal Transduction—Also known as cell signaling, is the transmission of molecular signals from a cell's exterior to its interior, initiated by cell-surface receptors. Signals received by cells must be transmitted effectively into the cell to ensure an appropriate cellular response. Cells that have abnormal signaling molecules may become cancer cells.

Transcription—The process by which a cell copies a segment of DNA into RNA. This RNA copy, called messenger RNA (mRNA), carries the genetic information needed to make proteins from the DNA in the nucleus of the cell to the cytoplasm, where proteins are made.

Tumor Suppressor Genes—Also known as an anti-oncogene, is a gene that regulates a cell during cell division and replication. If the cell grows uncontrollably, it will result in cancer. When a tumor suppressor gene is mutated, it results in a loss or reduction in its function.

TUSC2 gene—A gene that encodes the Tumor suppressor candidate 2 (TUSC2) protein. This gene is a highly conserved lung cancer candidate gene. Evidence to date indicates that TUSC2 behaves as a tumor suppressor in lung cancer.

Tyrosine Kinase Inhibitors (EGFR TKIs)—A substance that blocks the action of the EGFR proteins, which are a part of many cell functions, including cell signaling, growth, and division. These proteins may be too active or found at high levels in some types of cancer cells and blocking them may help keep cancer cells from growing.

Intentionally Blank

About Our Firm: For the past two decades, Crystal Research Associates, LLC has successfully articulated the exceptional stories of small- and mid-cap companies to the Wall Street investor community. Our methods are well-established and diverse, from compiling and disseminating objective, factual information for both institutional and retail investor audiences to capitalizing on our expansive line of targeted distribution channels, which include industry-leading financial data and information providers. Our distribution efforts are accompanied by the use of prominent social media channels and by strategic and targeted appearances on national news programs and print media.

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