

Renova™ Therapeutics: Creating transformational gene and peptide therapies that treat the most prevalent diseases to restore health and renew life

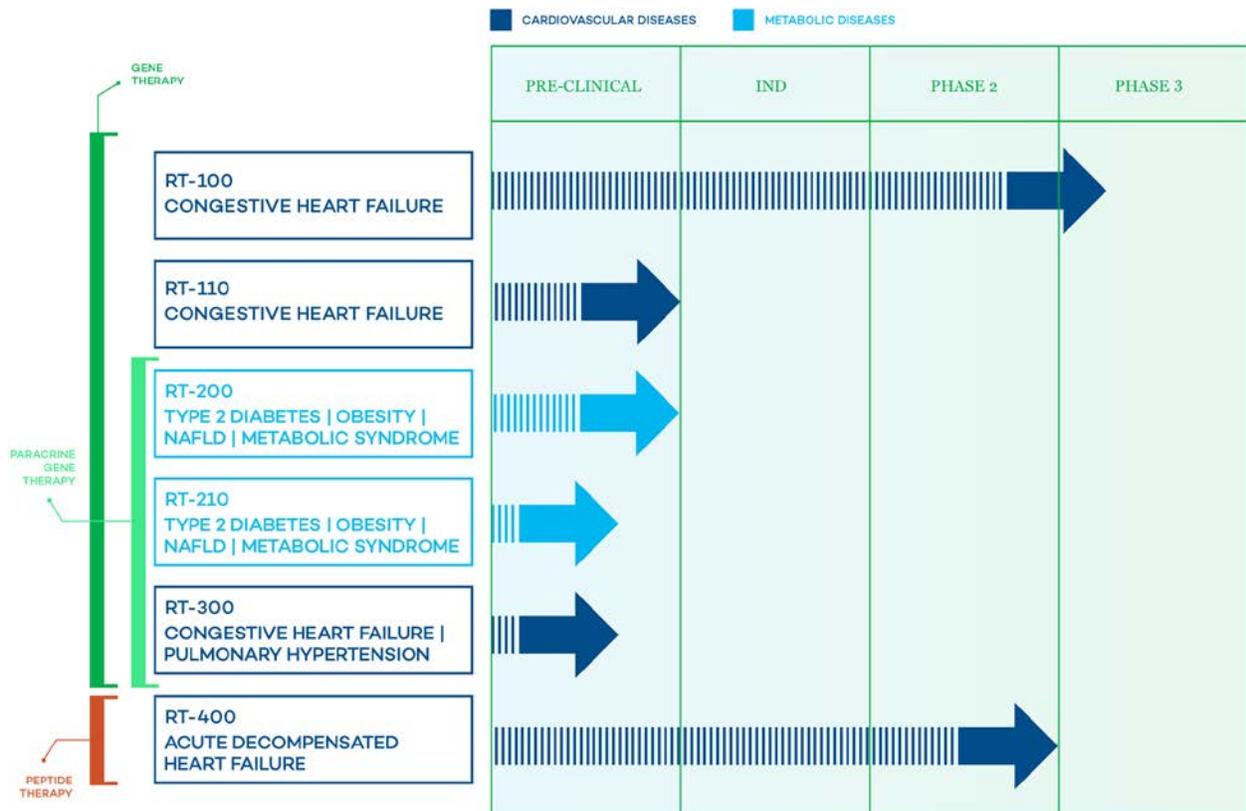
OVERVIEW

Founded in 2009 by biotech pioneers, Renova Therapeutics is working to create a portfolio of definitive gene and peptide therapies to restore health to people suffering from cardiovascular and metabolic diseases, including congestive heart failure (28 million patients worldwide) and type 2 diabetes (380 million patients worldwide).

Renova Therapeutics’ investigational therapies are based on carefully validated and proprietary research into disease mechanisms and the founders’ nearly 50 combined years of work in the gene therapy field. This experience forms the basis of the company’s efforts to generate an entirely original platform of therapeutics and delivery systems that may provide durable, lifelong treatments for chronic diseases.

PRODUCT PIPELINE

The first indications the company is pursuing are gene therapies for congestive heart failure (CHF) and type 2 diabetes, two debilitating chronic diseases that pose an unsustainable burden on the lives of patients and their families, on medical practitioners, and on economies crippled by health care costs. Along with one-time gene therapies, Renova Therapeutics is also developing peptide therapies for the periods in which CHF patients are hospitalized for acute decompensated heart failure.



PRODUCT CANDIDATE FOCUS: RT-100 FOR CONGESTIVE HEART FAILURE

- Novel, single-dose gene therapy delivers the therapeutic gene AC6 directly to heart tissue in a routine outpatient procedure
- Phase 2 clinical trial published in [JAMA Cardiology](#): **RT-100 safely increased function of the failing heart beyond optimal heart failure therapy**
- Two endpoints showed differences between the two highest doses of AC6 (combined) versus placebo:
 - Increased left ventricular (LV) peak $-dP/dt$
 - Increased LV ejection fraction in participants with non-ischemic HF
- Symptoms of heart failure were reduced 12 weeks after therapy in the AC6-treated group but not in placebo subjects
- Morbidity and mortality – key safety measures in the trial – showed:
 - During the one-year study period, there were no CHF-related deaths among the 42 patients treated with the gene therapy.
 - The rate of CHF-related hospitalization was substantially lower in RT-100 patients compared to those receiving placebo.
- **Next up: Phase 3 clinical trial of RT-100 – known as FLOURISH – to begin in H2 2017**

PRODUCT CANDIDATE FOCUS: RT-200 FOR TYPE 2 DIABETES

- IV-injected, single-dose gene therapy designed to provide substantially improved, sustained outcomes in type 2 diabetes patients by normalizing blood glucose
- Delivered through a single intravenous injection
- In proof-of-concept studies, **after type 2 diabetes was established in animal models, a single dose of the RT-200 gene therapy normalized these animals**
- Preclinical studies published in [JCI Insight](#): Mice treated with urocortin 2 metabolized glucose more efficiently than the control group, showed reduced weight gain, improved glucose tolerance and reduced fatty infiltration of the liver
- Preventative therapy: In similar protocols in which animals were dosed initially prior to being fed a high-fat diet, treated animals did not develop type 2 diabetes in their lifetime
- RT-200 has the potential to circumvent the need for daily insulin injections
- **Next up: Completing preclinical studies and entering first clinical trial in 2018**

PRODUCT CANDIDATE FOCUS: RT-400 FOR ACUTE DECOMPENSATED HEART FAILURE

- Human peptide stresscopin infusion for periods in which heart failure patients are hospitalized for Acute Decompensated Heart Failure, delivered by continuous IV infusion
- Phase 2 clinical trials with heart failure patients: **short IV infusions of human stresscopin safely increased cardiac index in a dose- and plasma-concentration-dependent manner** without adversely affecting heart rate, systolic blood pressure or cardiac rhythm
- Renova Therapeutics acquired exclusive license to stresscopin and stresscopin program IND file from Janssen; plans to advance clinical development of RT-400 to pivotal trials
- Acute clinical study will be both fast to execute and quicker to market, allowing RT-400 to drive revenue that contributes to early company profitability
- **Next up: Entering pivotal trial in 2018**

MARKET OPPORTUNITY: CONGESTIVE HEART FAILURE

6 MILLION PATIENTS IN THE US, 28 MILLION PATIENTS WORLDWIDE*

- Congestive heart failure (CHF) is a progressive and fatal chronic disease characterized by the inability of the heart to pump sufficient blood to meet the body's demands.
- CHF can be caused by many conditions that damage the heart muscle, including heart attacks, infections, alcohol or drug abuse, as well as high blood pressure, valve disease, thyroid disease, kidney disease, diabetes, or heart defects present at birth. People with severe CHF may need a mechanical heart pump (LVAD) or a heart transplant.
- Current treatment options for CHF patients have, at best, slowed the progression or minimized symptoms. At present, there are no definitive treatments that can restore heart function, with the exception of heart transplants, which are limited in availability.

Reduced ejection fraction	Preserved ejection fraction
US: 3 million patients	US: 3 million patients
Worldwide: 14 million patients	Worldwide: 14 million patients
Mortality worse than most cancers: 50% of patients are dead within 5 years of diagnosis	
US: Most frequent cause of hospitalization for people 65+	
2012: Annual cost of heart failure in the US was \$31 billion	
By 2030: Estimated annual cost will rise to \$70 billion	

*Source: American Heart Association

MARKET OPPORTUNITY: TYPE 2 DIABETES

28 MILLION PATIENTS IN THE US, 380 MILLION PATIENTS WORLDWIDE**

- Type 2 diabetes is by far the most common form of diabetes, accounting for ~90% of all diabetes. It renders the body unable to regulate blood sugar levels, resulting in a range of problems, including heart disease, kidney failure, blindness, and the loss of toes and fingers to nerve damage.
- The cause of type 2 diabetes: Genetics and lifestyle both play roles, and the risk of having type 2 diabetes increases as one gets older. This chronic condition has been linked to obesity, genetic risk factors and inactivity.
- Managing type 2 diabetes varies but often includes medication and insulin therapy.

US: 28 million patients
Worldwide: approx. 380 million patients (approx. 90% of all diabetes)
No known cure; in 2012: 1.5 million deaths directly caused by diabetes
By 2030: WHO projects diabetes will be 7 th -leading cause of death in the world, affecting 10% of the world's population
Direct annual global cost of diabetes is \$827 billion
US: Average medical expenditures of about \$13,700 per year per patient – 2.3x higher than for those without diabetes
2012: Annual cost of Type 2 Diabetes in the US was \$245 billion – a 41% increase from \$174 billion in 2007

**Source: International Diabetes Federation

THE FOUNDERS

H. Kirk Hammond, M.D. Dr. Hammond, a professor of medicine at the University of California, San Diego, and cardiologist at the Veterans Affairs San Diego Healthcare System, has authored more than 100 peer-reviewed publications related to cardiovascular research and is the inventor on seven issued patents. His lab has received continuous NIH funding for a number of years, including two consecutive Program Project Grants in cardiovascular gene transfer. Dr. Hammond received his M.D. from Indiana University and is board certified in internal medicine and cardiovascular diseases.

Jack W. Reich, Ph.D. Dr. Reich has extensive experience in the field of gene therapy. He was a co-founder of the first gene therapy company, Viagene, which was acquired by Chiron. He went on to found Collateral Therapeutics, the first gene therapy company focused on cardiovascular disease, later acquired by Schering AG. Dr. Reich received a B.A. in Biology from Washington and Jefferson College, a B.S. in Pharmacy from Creighton University, an M.S. in Hospital Pharmacy Administration from Temple University and a Ph.D. in Pharmaceuticals – International Pharmaceutical Administration from Temple University.

Craig Andrews. Mr. Andrews practiced corporate law at the international law firm of DLA Piper LLP. He has more than 30 years of experience representing private and public companies, venture capitalists and entrepreneurs, and has an extensive background in the biotechnology industry. He was a co-founder of Collateral Therapeutics. Mr. Andrews holds a B.A. in Political Science and Economics from the University of California, Los Angeles and a J.D. from the University of Michigan.

THE EXECUTIVE TEAM

Jack W. Reich, Ph.D., CEO and Co-Founder.

Roy Cosan, President. Mr. Cosan is a 32-year veteran of Johnson & Johnson (J&J), where he was VP of New Product Development and, in that role, launched a \$billion+ product for schizophrenia, as well as a leading treatment for dementia. He was also a VP with the J&J Development Corporation, the venture capital arm of J&J, where he invested in 19 companies and was a director on 11 boards. He holds a B.B.A. with a concentration in marketing from Western Michigan University.

Catherine Bovenizer, Chief Financial Officer. Ms. Bovenizer, CPA, has 20 years of experience in financial management for a variety of public and closely held biotech and software companies. Most recently, Ms. Bovenizer was VP of Finance and Chief Accounting Officer at Apricus Biosciences. Prior to Apricus, she held roles of increasing responsibility at Ambit Biosciences, Senomyx, Ligand Pharmaceuticals and GeneFormatics. Ms. Bovenizer graduated magna cum laude from Claremont McKenna College with a B.A. in Economics, Accounting and Literature.

Richard McCloskey, M.D., Executive Vice President, Clinical Development. Dr. 'Mac' McCloskey is author of more than 100 peer-reviewed papers and editorials as well as three books. He has directed registration trials for Hoffman LaRoche and Centocor and was VP of Scientific Affairs at Johnson & Johnson Development Corporation as well as a scientific adviser to Endo Pharmaceuticals. Dr. McCloskey received a master's in microbiology and an M.D. from the University of Rochester and completed his medical training at Duke University and the National Institutes of Health. He is an emeritus fellow of the American College of Physicians.

Jennifer Spinella, MT (ASCP), RAC, Executive Vice President, Regulatory Affairs & Quality Assurance. Ms. Spinella has more than 20 years of hands-on regulatory experience. Most recently, she was VP of Regulatory Affairs and Quality Assurance for Rare Disease Therapeutics, Inc. Ms. Spinella has held multiple VP- and director-level regulatory positions at various companies. She spent eight years as a neonatal biochemist at St. Joseph's Hospital and Medical Center in Phoenix, AZ. Ms. Spinella earned her B.S. in Medical Technology from the University of Nebraska College of Medicine. She obtained her Regulatory Affairs Certificate (RAC) from the Regulatory Affairs Professional Society in 2000.

Waldemar Radziszewski, M.D., Ph.D., Executive Vice President, Translational Research. Before joining Renova Therapeutics, Dr. Radziszewski served as Vice President, Immunology Development Unit, and Site Head, Biopharmaceuticals Clinical Development, at Sandoz. He spent 18 years in various senior leadership positions within Merck Research Laboratories and later Johnson & Johnson companies, including Janssen Research & Development, managing clinical operations and multiple early- and late-stage clinical development projects with small molecules, therapeutic proteins and peptides in diverse therapeutic areas. Dr. Radziszewski received both his M.D. and his Ph.D. from Nicolas Copernicus Academy of Medicine in Krakow, Poland, now known as Jagiellonian University Medical College in Krakow.

Peter Gengo, Ph.D., Vice President, Preclinical Research and Pharmacology. An accomplished biochemical analytical pharmacologist with extensive knowledge of drug discovery and early drug development, Dr. Gengo has more than 30 years of research and leadership experience, most recently in the Cardiovascular & Metabolic Disease unit at Merck & Co. Dr. Gengo also spent several years with Johnson & Johnson companies, including Janssen Pharmaceuticals as Scientific Director and Research Fellow. Dr. Gengo earned his Ph.D. at the University of Buffalo, graduating summa cum laude. He graduated magna cum laude from the State University of New York with a B.S. in Biology. He received a Medical Technology Degree & License (MT, ASCP) at the School of Medical Technology at Rochester General Hospital in Rochester, NY.

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