ProViZiGen, LLC 160 Convent Ave at 140th st Steinman Hall T313 NY 10031

Jui Chaugule www.provizigen.com jui.chaugule@provizigen.com

Industry: Biotech

Management:

Jin Montclare, PhD- Founder, CEO Jui Chaugule, PhD-Head of research

Scientific Advisory Board:

CJ Liu, Ph.D. – Professor, Orthopaedics & Rehabilitation, Yale University Robert Schneider, Ph.D. – Professor, Microbiology and Molecular Pathogenesis, NYU Langone Philip Leucht, M.D., Ph.D. – Orthopedic Trauma Surgery, NYU Langone Health

Priya Katyal, Ph.D. – Associate Director, NHPRR

Number of Employees: 2

Finance:

Accounting/Tax: Funding to Date: \$800,000 Financing Sought: \$8M For: Pilot Studies R&D IP Operating Costs Overhead

IP (seeking): Protection for new formulation.

Legal: seeking

Business Description / Company Background:

ProViZiGen is an innovative biotechnology company dedicated to developing the first disease-modifying treatment for osteoarthritis (OA). Founded by Dr. Jin Montclare, a renowned Professor of Biomedical Engineering at NYU Tandon School of Engineering, the company takes a holistic, protein-engineering approach to tackle OA. By focusing on halting and reversing the progression of OA, ProViZiGen aims to address a significant unmet medical need, moving beyond merely managing symptoms to offering a potential cure.

Market Opportunity / Unmet Need:

Osteoarthritis, affecting 13% of the global population, leads to chronic joint pain and disability. An alarming 54% of OA patients require joint replacement within 13 years of diagnosis. Current treatments only offer temporary symptom relief without addressing disease progression. The US OA market is valued at \$30 billion with a compound annual growth rate (CAGR) of 5.76%. Within this market, post-traumatic osteoarthritis (PTOA) is valued at \$11.79 billion, while chronic pain from generalized OA exceeds \$42.5 billion, representing significant market opportunities.

Products / Services – Launched & Pipeline:

ProViZiGen's flagship product, HydroGEN, combines two breakthrough protein technologies: A thermoresponsive protein hydrogel that is liquid at lower temperatures and forms a gel at body temperature, and an anti-inflammatory therapeutic protein that reduces inflammation and promotes cartilage repair. This injectable combination therapy provides immediate mechanical benefits and long-lasting therapeutic effects via a one-time, minimally invasive injection. Preclinical data from rabbit studies demonstrate significant cartilage regeneration and improved bone quality within eight weeks of a single treatment. Currently, we are working towards reformulating the product for human use.

Commercial / Technical Milestones:

Achieved: Successful proof-of-concept in rabbit studies demonstrating cartilage regeneration and improved bone quality; sustained release of therapeutic protein over 30 days. Pending: 2025-2026: Reformulation for human use and IP development; 2028: Preclinical studies; 2031: IND filing; 2033: Phase I trials; 2034: Phase II trials; 2037: Phase III trials and potential market approval.

Competition / Competitive Advantages / Customer Benefits:

Current treatments (Synartro, Arthrex, Synvisc One, Cytonics) are costly (\$600-\$10,000 per treatment) and require repeated administration every 6-12 months with limited efficacy. HydroGEN's advantages include single injection vs. competitors' multiple treatments; disease modification potential rather than symptom management; cartilage regeneration capabilities; applicability across multiple joint types; and proven OA reversal in rabbit models within 8 weeks.

Financial Forecast:

We will scale business in two steps - first to VA hospitals and later to surgeons in orthopedic hospitals. The pricing model for our current product is based on competition and is priced at \$22,000. NYU Langone treated about 9637 patients in 2022. Based on this, our revenue is estimated to \$212 M per year once launched.

	2025	2026	2027	2028	2029
Revenue (\$k)	0	0	0	0	0
R&D (\$K)	650	850	800	2,400	2,000
Operating Expenses (\$K)	100	100	120	200	300
Salary Expenses (\$K)	50	50	80	200	200
Net Income (\$K)	(800)	(1,000)	(1,000)	(2,800)	(2,500)

