FIG Therapeutics Inc.
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Stamford, CT 06906

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Industry: Biotechnology

Management
Ariel Yusupov, MS (Physiology and Biophysics) – Founder, CEO

Scientific Advisory Board
Dr. Mark N. Stein, MD
Associate Professor of Medical Oncology (Prostate Cancer), Columbia University

Dr. Matthew Dallos, MD –
Genitourinary Medical Oncologist, MSKCC

Dr. Moshe Ornstein, MD –
Genitourinary Medical Oncologist, Cleveland Clinic

Dr. Jenny Zilberberg, PhD
Head of Research, Imvax, Inc.

Number of Employees: 1

Finance:

Accounting/Tax:
EisnerAmper LLP

Funding to Date:
Founder: $10k
Angel Investors: $50k

Financing Sought: $400k
For:
- Pilot Studies
- R&D
- IP
- Operating Costs
- Overhead

IP: Wilson Sonsini

Legal: Orrick LLP

Business Description / Company Background*:*
FIG (Factor Induced Gene) Therapeutics is an early-stage biotechnology company that has developed a gene therapy that utilizes overexpressed transcription factors in cancer to drive a multimodal immunotherapy. Our Stealth Gene Therapy™ is an intratumorally delivered, lipid-nanoparticle encapsulated, polynucleotide that recruits cancer-causing transcription factors to drive a proprietary cocktail of genes that both induce anti-tumor immune cell infiltration and inhibit the immunosuppressive tumor microenvironment (TME). Our current focus is on the treatment of high-risk localized prostate cancer, where over 50% of patients have cancer recurrence after first line therapy. We are concurrently utilizing our Stealth Gene Therapy™ platform technology for development of therapeutics for other cancers.

Market Opportunity / Unmet Need:
Most cancers are driven by over-expression of key transcription factors (TFs). Naturally, inhibiting these TFs is the top therapeutic strategy for medical therapy. Although this approach works at first, resistance quickly develops within 1-2 years leading to more aggressive disease. Prostate cancer—the #1 cancer in men—is driven by the androgen receptor (AR). Although prostatectomy and radiation are the standard treatment for localized prostate cancer, over 50% of patients with high-risk localized disease (33K per year) have cancer recurrence following standard therapy and receive direct and indirect AR-inhibition therapy (castration therapy). Despite significant side effects and inducing resistance within 11 months to 2 years, these AR-inhibitory drugs generate over $20 billion in yearly revenue. Harnessing the immune system to kill cancer cells has long been sought as a therapeutics strategy which can avoid resistance seen with TF-inhibitors. Cancer, however, is a master immune evader. The *immunosuppressive tumor microenvironment* is the reason why many immunotherapies against solid tumors (CAR-T, neoantigen cancer vaccines, cytokine therapy, etc.) have failed and will keep failing, unless addressed.

Products / Services – Launched & Pipeline:
FIG Therapeutics has developed a solution to both problems. Rather than inhibit the cancer-causing transcription factors (TFs) and induce resistance, we harness their function: to transcribe genes. We have developed a proprietary polynucleotide that encodes promoter/enhancer sequences customized to multiple cancers which recruit cancer-causing TFs to drive a cocktail of genes. These genes not only recruit potent anti-tumor immune cells, but also modify the immunosuppressive tumor microenvironment intra- and extracellularly. We hijack the cancer cell and transform it from an immune evader into an immunotherapy machine that trains the immune system to kill cancer cells locally and wherever they may be hiding. Most importantly, since the therapy is driven by TFs elevated in cancer, we can promiscuously inject the entire tissue and get cancer-specificity despite non-specific delivery. Our therapy, which will be intratumorally delivered with MRI or ultrasound guidance on a weekly/biweekly basis as a neoadjuvant therapy prior to tumor resection. allows for the delay or potential elimination of the need for TF inhibitors (i.e. castration therapy). This will not only prevent development of resistance and more aggressive disease but will also improve quality of life for patients. Although our current focus for proof-of-concept is high-risk localized prostate cancer, we are utilizing our platform technology to concurrently develop similar constructs for melanoma, breast, and pancreatic cancers.

Commercial / Technical Milestones:
We have recently submitted a non-dilutive NIH SBIR Phase I grant for $400k, closely collaborating with an elite SBIR grant writing firm (BBC). Given that our grant closely aligns with a Notice of Special Interest (NOT-AI-24-007), we believe there is a high chance of success for issuance this coming December. We have already established relationships with Genscript, Acuitas Therapeutics, and Aldeveron to develop key reagents for our preclinical development. All plasmid designs and steps necessary for our lead selection—from our contract with BioInc incubator to quotes from multiple CROs—have been completed. We also have a patent in process that covers virtually every indication and variant of our therapeutic. The single green light we are waiting for prior to full speed execution is completion of our pre-seed funding round.

Competition/Competitive Advantage/ Customer Benefits:
There are currently no competitors who take advantage of over-expressed transcription factors to drive a cancer-specific, immunosuppressive tumor microenvironment neutralizing, multimodal therapeutic. The competitors in the prostate cancer arena have mainly focused on strategies that inhibit the androgen receptor. There are also no currently approved prostate cancer drugs in the neoadjuvant setting. If successful, at minimum, our therapy would become the standard of care for patients prior to surgical tumor resection or radiation to either delay or eliminate cancer recurrence. In addition, our therapy has the potential to improve the efficacy of countless other immunotherapies (approved and in development), from CAR-T cell therapies to bispecific T cell engagers to monoclonal antibodies, in the treatment of solid tumors. Pluvicto, a recently approved drug that increases progression-free-survival by only 6 months, is considered a future blockbuster. We believe we can do even better.

Financial Forecast
The company is currently raising a $400k pre-seed round to cover lead selection and IP strategy. An $8.5m seed round is planned in 2025 to cover IND-enabling efficacy/tox studies and analytical development. In addition, the company is taking advantage of non-dilutive capital with a $400k Phase I SBIR grant this year with plans to apply for a $2m Phase II SBIR grant in 2026. Our Series A round, which will fund our clinical trials, is expected in 2026.