Numiera Therapeutics

Company Description: Numiera Therapeutics is a pharmaceutical company, developing small-molecule drugs for oncology indications.
Problem: Our primary disease indication is glioblastoma (GBM), which is the most common form of primary malignant brain tumor. GBM carries a dire prognosis and few therapeutic options. Standard-Of-Care treatment comprises surgical resection of the tumor, radiotherapy, and the chemotherapeutic drug temozolomide. Together, these existing therapies only minimally slow the course of this disease, with a median survival time of approximately 15 months post-diagnosis. There is currently no second-line therapy.
Solution: Our unique solution involves targeting metabolism, or how the cancer cells make enough energy to grow. While cancers were previously thought to rely on sugars to make energy, we have found that GBM (and some other cancer cells) rely on fatty acids to fuel their malignant growth. Our small-molecule drug, a CPT1 inhibitor, targets the rate-limiting step in this key metabolic pathway.

Company Name:
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Basic Details:
Founded In: Oct 2023 Registered In: Delaware

Funding History and Deal Terms:
Private Investment: $307,000 (safe note)
Committed Funds: $250,000 (awarded grant)
Now Seeking Seed: $8,000,000 (equity)

Use of funds: IND submission, drug manufacture, early phase investigator initiated clinical trial, and further developing intellectual property

Financials:
Burn Rate: $17,000/month (current)
Cash Flow Positive in: Year 2030 (anticipated)

Market Size:
SAM: $4.7B annually, based on the following report: https://finance.yahoo.com/news/glioma-treatment-industry-report-projected-143900536.html
Estimated Reach: 20% SAM/80% SOM By Year: 2032

Team:
Izi Stoll, PhD – CEO/Co-Founder (Also Scientific Director, Western Institute for Advanced Study)
Josh Pan, PhD MBA – Co-Founder (Now Chief Business Devel Officer, Landmark BioVentures)
Gordon Beck, PhD – Corporate Strategy Advisor (previously served as Executive Director of Global Business Development at Roche)
Karl Nicholls, CPA – Financial Strategy Advisor (previously served as Director of Financial Planning and Analysis at Covidien)
Megan Halloran, PhD – Comms Director (Also Comms Director, Western Institute for Advanced Study)
John Nieland, PhD – Scientific Advisor (Also Head of Molecular Pharmacology at Aalborg University)
Patrick Wen, MD – Clinical Consultant (Also Director of Neuro Oncology at Dana Farber Cancer Institute)
Vicki Abbas, RN – Clin Trial Ops Advisor (Previously Exec Director of Clinical Ops at Nivalis and Sinopsys)
Dustin Key, MA – Data Mgment Advisor (Previously Programmer Analyst at Kaiser Permanente Research Institute and Group Health Research Institute)

Technology

- Our initial discovery was awarded by the Society for Neuro Oncology in 2016.
- We now have a full IND-enabling dataset on our lead candidate drug, including dose exploration studies showing safety in 226 human subjects.
- Several other labs have independently replicated our preclinical efficacy data.
- The FDA has recognized the clinical potential of this product by awarding us orphan drug designation, in both glioblastoma and low-grade glioma.

Defensibility

- We have secured orphan drug designation on our lead candidate drug, providing seven years of market exclusivity after FDA approval.
- We have filed a patent on a drug combination and diagnostic kit, to expand into multiple cancer indications through a quick 505(b)2 regulatory pathway.
- The development of additional CPT1 inhibitors will allow us to further improve targeting and secure composition of matter patents.

Business Model

Our SOM is 34,000 patients in US + EU, where orphan drug designation applies. We expect to ramp from 20% to 80% coverage over four years post-approval. With a price point similar to comparator product temozolomide (Wasserfallen et al. *Neuro Oncol* 2005), we estimate a price point of $50K/patient/year and total sales of $7.5B over a seven-year post-approval market exclusivity period.

Go-To-Market Strategy

The Society for Neuro Oncology (SNO) links oncology therapeutics companies with clinicians. New treatments are readily adopted by the clinical community, and patient advocacy groups support marketing efforts through sponsorships. Medicare and private insurers typically cover oncology drugs under a J code, and this coverage will be negotiated alongside approval and product launch.

Competitive Landscape

Temozolomide/Temodar (Merck) – Standard-Of-Care for any grade of glioma (DNA alkylating agent - serious side effects - gives patients 2-3 extra months)
Bevacizumab/Avastin (Genentech) – Approved for multiple cancer indications (VEGF inhibitor - may control swelling - has no effect on GBM patient survival)
Paxalisib (Kazia's PI3K inhibitor), Regorafenib (Bayer's RTK inhibitor), + VAL083 (Kintara's DNA chemo drug) recently failed clinical trials (reported at SNO2024).

Competitive Advantages

- Specific targeting of a key metabolic vulnerability in cancer cells
- Passes the blood brain barrier and has a functional effect in animal models
- Easy-to-manufacture small molecule drug with high margin + affordable cost
- Improved preclinical models are expected to better predict clinical outcomes
- Orphan designation provides significant incentives + quicker path to approval

Exit Strategy

Acquisition at Phase II/III (2027): Our preferred exit strategy is acquisition by a large pharmaceutical firm, who can handle sales and distribution at the scale required. A number of companies will have blockbuster oncology drugs losing patent protection in the coming years, and are seeking pipelines. Possible acquirers include Merck, Novartis, Abbvie, Eli Lilly and Bristol Myers Squibb.