



Executive Summary

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Executive Summary

AccuRx is a biotech company, incorporated and operating in GA. AccuRx is developing a differentiated technology to modulate the release behavior of drugs. Because our patent-protected technology allows careful optimization of drug formulations, key benefits to patients are realizable—i.e., safer and more efficacious prescription drugs. Current business focus is on two lucrative segments within ophthalmic market: *glaucoma and dry-eye syndrome*. AccuRx's one technology caters to both market needs. The next business focus is diabetic retinopathy, another attractive and fast-growing ophthalmic market segment. Management expertise and experience in ophthalmics; encouraging results; collaborations with GA Tech and Emory Eye Center; and prospective customer leads have placed us on a fast-track to success.

Problem: Customer Pain Points

Our customers are pharmaceutical companies active in ophthalmic markets—e.g., Alcon-Novartis; Allergan, Pfizer, etc. Glaucoma therapy currently is done with eye drops which have poor efficacy (~ 5%), requiring 1-3 instillations per day. A significant problem with such frequent dosing is potentially enhanced toxicity and poor patient compliance. The dry-eye market is filled with me-too saline drops which provide only temporary relief. Both these market segments stand to significantly gain from controlled drug release technologies that provide better efficacy and convenient dosing regimen, with greatly mitigated side-effects. A persistent pain routinely felt by our customers is significant (up to 80%) business loss to generics when blockbuster drug patents expire.

AccuRx's Solution

Instead of yet another eye drop that runs off the eye immediately after instillation, AccuRx offers a differentiated technology—a gel depot formed in situ at the lower cul-de-sac of the eye—to prolong the drug residence time. For glaucoma, this technology leads to a convenient dosing regimen (2-3 times a week vs. 1-3 times a day), simultaneously providing higher patient compliance and better therapeutic index (i.e., higher efficacy with lower toxicity). For dry-eye, the same gel technology provides all-day comfort versus temporary relief provided by me-too salines. In both cases, AccuRx's solution will be positioned to disrupt the market, rather than sustain it with incrementally improved products. When our technology is applied to reformulate the drugs facing patent expiry such as latanoprost (in *Xalatan*[®]) cyclosporine (in *Restasis*[®]), the generic onslaught can be mitigated, producing more revenue from these blockbuster drugs. Our technology also has the potential to increase the success rate of ophthalmic drug candidates in the pipeline, which may otherwise fail due to low efficacy and/or high toxicity.

Market Focus

AccuRx is targeting the ophthalmic market, which is currently valued at ~\$10 billion globally. Driven by the increasing pool of aging population with higher life expectancy, global ophthalmic market is projected to grow at a compounded annual rate of 13%. Within this market, we are focused on two lucrative segments: glaucoma, which affects ~ 3 million Americans; and dry eye syndrome, which affects ~ 40 million Americans. Together, they dominate the entire ophthalmic market, which is ~\$ 6 billion. Based on the demand and competitive product offerings, AccuRx plans to capture ~ \$1.2 billion of this market. While glaucoma is treated only with prescription eye drops, dry eye syndrome is treated with one prescription and several over-the-counter (OTC) eye drops. AccuRx's differentiated technology targets both market segments, of which dry eye will be faster market entry due to: the relative ease of technology development; simplified FDA approval; and our disruptive marketing strategy. Our business strategy thus gets a greater leverage of R&D resources, leading to faster market penetration, with a good potential for early return on investment.

Technology Description

AccuRx's technology is based on a temperature sensitive polymer that rapidly forms a transparent gel depot when instilled on eye. The bio-friendly polymer also exhibits high tissue-adhesion, promoting good contact with eye surface. The proprietary hydrogel system has specially been engineered to provide controlled release of active ingredients. Two formulations are under development: the dry-eye formulation contains a slowly releasing ingredient to provide all-day comfort, as opposed to the couple of minutes of relief typically provided by the saline eye drops currently in market; the glaucoma formulation targets a dosing regimen of twice a week topical administration by the patient, as opposed to the current usage of eye drops one to three times a day. We are in preclinical stage of technology development. Our technology is protected with in-licensed patents; a provisional patent is also being filed to protect ophthalmic applications. Diabetic retinopathy will use a different but related hydrogel-based technology.

Competition

AccuRx's competition is biotech companies providing ophthalmic drug delivery technologies. Analysis shows that our competitive advantage stems from the:

- *choice of market focus, the timing and the strategic fit of technology* with market demand—AccuRx is the only company focused on front-of-the-eye drug delivery in a market filled with just eye drops, versus our competitor's focus on implanted devices for back-of-the-eye diseases;
- *flexibility and versatility of our core technology* versus limited application potential of competitors' technologies; and
- *high competitive entry barrier* due to strong patent portfolio, management team expertise and first mover advantage.

Business Model

AccuRx's business model is simple: develop and license innovative technologies to pharmaceutical companies having significant ophthalmic market presence. To increase the odds of success and to get to market faster, we plan to partner with prospective customers as early as possible in the technology development phase. We have the requirements and contacts, and plan to bring customers aboard within a year of funding. Because of no direct involvement in the development and approval of the drug itself, our business model keeps the:

- R&D cost down;
- failure probability and liability low;
- time to market fast; and
- the return on investment quick.

Team

The management team consists of four seasoned entrepreneurs with startup track record in biopharmaceutical area; subject matter expertise; and over 100 years of combined experience:

Balu Balasubramanian, Ph.D.—CEO: Polymer chemistry expertise; drug development, manufacturing and regulatory experience. Balu was senior director of R&D for CytRx, a GA biopharmaceutical company that went public.

Sai Kumar, Ph.D.—President & CTO: Biomaterials expertise and ophthalmic and biomedical device experience. Sai was Global Head of Materials Science in Ciba Vision-Novartis prior to starting this venture. He has also owned and operated a small biotech company in MI.

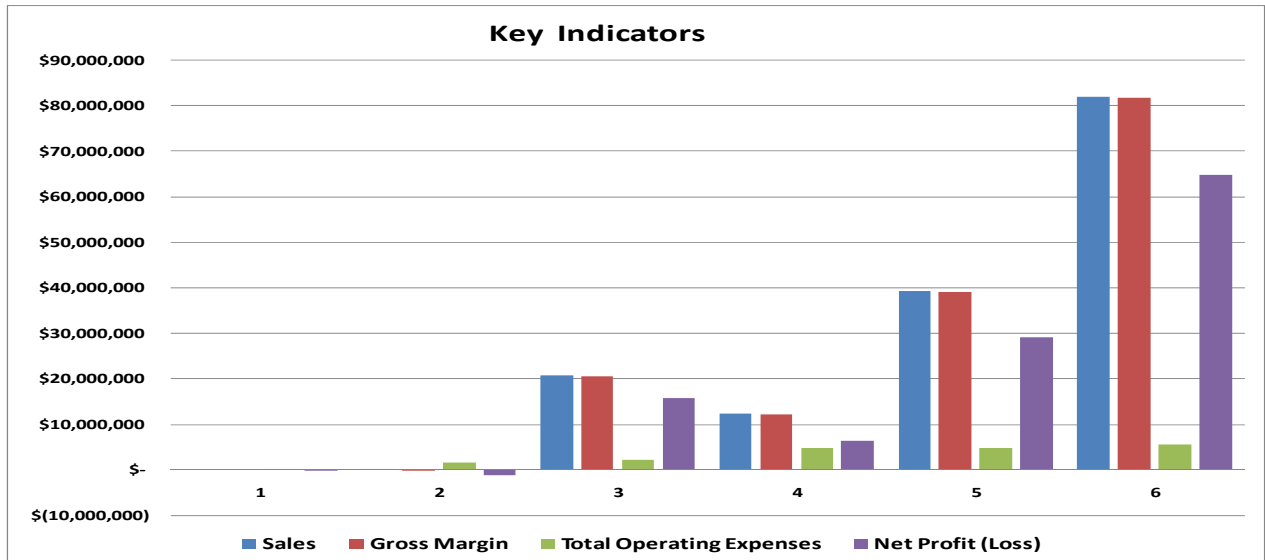
Shaker Reddy, M.S.—COO: Analytical Chemistry expertise; Shaker was President and CEO of Accura laboratories which was acquired by Xenco Laboratories.

Giri Polavarapu, Ph.D.—SVP: Biology expertise; biotech startup experience.

AccuRx presently has two professional employees with Ph.D.; AccuRx also has retained a science and technology advisory team composed of renowned experts; industry veterans; and opinion leaders with ophthalmic and biopharmaceutical experience.

Financial Plan

Consistent with the business model and technology strategy, AccuRx’s revenue projection mainly has two tracks: a fast-track dry-eye technology licensing; and a steady-track scheduled licensing of glaucoma and other ocular delivery technologies. The operating plan seeks to keep the R&D cost and debt low. Seed funding of \$ 2 million realizes our financial goals. The key financial indicators are projected in the graph below. The key project deliverables and the target timeframes are also shown below. The net result of our business strategy is higher return on investment in a more reasonable, risk-balanced timeframe than our competition.



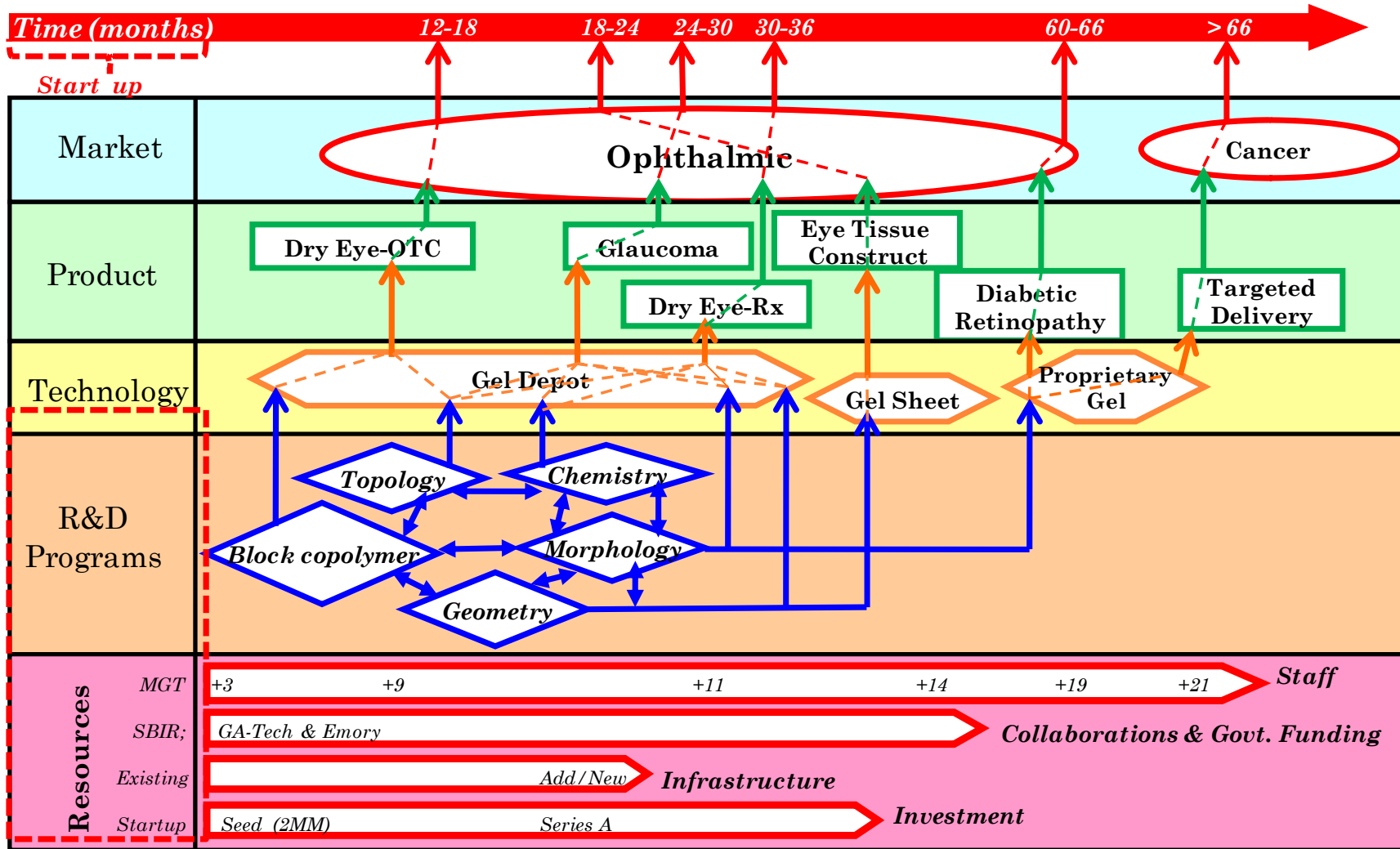
Projects	Deliverables	Timeframe	Comments
Dry Eye-OTC (12-18 months)	Optimized Formulation Proven Dog Model Proven Clinical Studies Biz Development	6-9 months 1-2 months 3-4 months 2-3 months	<i>One gel depot technology targets 3 products in stages. Dry Eye-OTC is rapid-to-market product, since it does not involve drug incorporation.</i>
Glaucoma (24-30 months)	Joint venture agreement <ul style="list-style-type: none"> Patented Technology Prototype Formulation In Vitro Proof-of-Concept Proven Animal Model Joint product development	9-12 months 15-18 months	<i>Detailed project plans are available for parallel execution of these 3 projects with \$ 2 MM seed funding. The resource allocation varies with time, balanced across the three projects, dictated by milestones. The diabetic retinopathy will be in R&D stage.</i>
Dry Eye-Rx	Similar to glaucoma project (run in parallel)		

Risk Assessment

Based on the current analysis of our position, we assess the overall risk to be *moderate*; the table below is a qualitative assessment on the key factors affecting the business risk:

Factor	Market	Technical	Competition	Financial
Risk	<i>Low</i>	<i>Low-Moderate</i>	<i>Moderate-High</i>	<i>Moderate-High</i>
Mitigation Strategy	<i>None; stay focused</i>	<i>Team expertise; focused innovation; IP strategy</i>	<i>Differentiation; disruptive innovation</i>	<i>Rapid time to market; viable business model</i>

AccuRx Business Roadmap



Note: R&D program theme is block copolymer hydrogel engineering using the four tuning knobs (see p10); products are launched in partnership with pharmaceutical companies; dotted red line denotes the startup phase (Jan 2008-current); and arrows show how the technology and products get to market at different points in time (given in months).