

REGENERX PHARMACEUTICALS

Opportunity

Fast, affordable, broad reaching drug development is a vision that sharply contrasts with the current state of the pharmaceutical industry.

On average, it takes 15 years and costs \$1 billion to bring one new drug to market, and 99% of drugs fail due to toxicity. Companies focus on profitable markets, neglecting > 24,000 diseases. At the current rate of discovery it will take over 300 years for the number of drugs to double.

Finding new drug uses is a safe, rapid, and proven shortcut to profits. Consider Viagra.

Because the medical profiles of existing drugs are known, new clinical uses can rapidly and inexpensively be patented and reintroduced as profitable new treatments. Costly safety trials are unnecessary for drugs already FDA approved. Existing safety data prevents unforeseen side-effects that create legal risk, as seen with the recalled arthritis drug Vioxx. Pfizer patented Viagra in 1991 to treat hypertension. During 1994 clinical trials Viagra-treated patients experienced reversal of erectile dysfunction. Pfizer patented this use in 1996 and won FDA approval in 1998. Pfizer saved time and money because Viagra's safety was established.

Despite the promise of finding new uses for existing drugs, a comprehensive collection of the 9,990 approved drugs does not yet exist.

Current drug collections cover < 20% of medicines. The discovery of drugs like Viagra suggests many new treatments will be found if all of pharmacologic space is systematically screened

Market Opportunity

RegenRx Pharmaceuticals reduces the cost and time for drug discovery.

"RegenRx" discovers new uses for existing drugs and re-introduces them to the market. We are collecting all 9,900 drugs ever used in medicine and are identifying new uses for infectious diseases, diabetic eye degeneration, and cancer. Because our collection is FDA approved we bypass safety and toxicity clinical trials which are costly and time consuming.

Product Service Offering and Business Model

RegenRx discovers new uses for existing, FDA-approved drugs and re-introduces them to the market. We leverage exclusive rights to patent-protected disease models developed at Johns Hopkins Medicine. These models are important in identifying new uses for existing drugs, as they are highly predictive of the drugs' action in humans.

- **Drug development (product):** RegenRx is assembling a robust pipeline of repurposed drugs that target profitable disease markets. Citraconazole, RegenRx's flagship product, targets inappropriate blood vessel formation in tumor metastasis and age-related macular degeneration, \$16.8 billion and \$1.6 billion markets, respectively.
- **Contract screening (service):** To generate cash flow from the first operating year, RegenRx will offer a drug screening service based on proprietary disease models in-licensed from Johns Hopkins to pharmaceutical companies. This will allow customers to repurpose their failed drug candidates.
- **Grants:** RegenRx will pursue non-dilutive grants from charitable organizations such as the Gates Foundation and NIH to pursue drug discovery for neglected diseases like malaria.

Customer profile

RegenRx will develop our drugs drug with an interest in partnering with large-scale pharmaceutical firms with the resources to assist us in late stage clinical development, regulatory approval, and postapproval marketing. Through industry contacts, we discussed our discovery platform and pipeline with executives at Pfizer, AstraZeneca, CombinatoRx, and AsymetRx, who expressed interest in licensing arrangements. Once drugs are licensed, inventors are typically entitled to milestone payments as candidates progress through various stages of clinical development and approval. RegenRx will pursue clinical development activities using this royalty model.

PRIMARY CONTACT INFORMATION

Curtis Chong
E: cchong@jhmi.edu
T: 202-255-9256

COMPANY PROFILE

Category

Biotechnology

Industry

Pharmaceuticals

Stage of Development

Ready for Phase II clinical trials

Team

Curtis Chong, MD/PhD candidate
Ankit Mahadevia, MD/MBA
candidate

Market Overview and competing technologies

Two of our competitors, CombinatoRx and GeneLogic, raised \$183 and \$248 million, respectively through IPOs and are now publicly traded companies with established mutual fund investors. Both of their drug libraries are 50% smaller than the one assembled by the RegenRx team. Worldwide, the market for diabetic eye degeneration and tumor metastasis encompasses 500 million people and is growing at 4%/year. Compared to competitor drugs, citraconazole has several advantages, the key being oral, outpatient dosing:

Drug	Revenue/market size	Dosing	Mechanism
Citraconazole	<u>Oncology:</u> \$850 million (assumes 5% market penetration) <u>Age-related macular degeneration:</u> \$400 million (25% market penetration)	Daily oral dosing can be done at home	Inhibits sterol metabolism in endothelial cells
Avastin (Genentech)	\$360 million colon and breast cancer (2004)	Intravenous dosing must be done biweekly in hospital chemotherapy centers	Protein therapeutic inhibits endothelial cell growth signals
Macugen (Eyeteck)	\$150 million for macular degeneration (2005)	Eye injections every two weeks	RNA-based therapeutic inhibits endothelial cells

Description of Science

To demonstrate initial proof of concept, the management team, with the supervision of RegenRx's scientific advisors, identified 7 promising drug candidates for treating malaria, cancer, and diabetic eye degeneration. We published these results in *Nature Chemical Biology* and *The Journal of Medicinal Chemistry*, receiving international press coverage. Two new drug targets and seven new applications of existing medicines are being patented.

Members of RegenRx's management team discovered two components of a common antifungal drug (citraconazole) inhibit blood vessel growth, which play a major role in tumor metastasis and macular degeneration. Results of this research, which included extensive animal testing, were published in a prominent scientific journal. The potential market for these disease areas is predicted to grow by 20%/year with the aging population.

Overview of Intellectual Property

RegenRx is closing the rights to all intellectual property necessary for commercialization of citraconazole. The method of use patents for this discovery allows exclusive rights to apply for US Food and Drug Administration approval, market the drug, and create new dosing regimens.

Regulatory Status

We plan to file an investigational new drug application with the FDA.

Insurance Coverage

Once a new use for an existing drug is FDA-approved it is eligible for Medicare/Medicaid reimbursement. Most private insurance carriers follow Medicare/Medicaid.

RegenRx Financials

	Year 0	Year 1	Year 2	Year 3	Year 4
Income					
VC Paid in	1,320,000		0	0	0
Licensing agreements	250,000	500,000	1,750,000	2,000,000	2,500,000
Grants	300,000	600,000	1,200,000	1,500,000	2,100,000
Contract screening	100,000	600,000	500,000	1,000,000	1,500,000
Net Royalties	0	250,000	2,000,000	5,000,000	10,000,000
Total income	1,970,000	1,950,000	5,450,000	9,500,000	16,100,000
Expenses					
Fixed cost					
Salaries	150,000	300,000	500,000	750,000	1,000,000
Rent	100,000	100,000	100,000	100,000	100,000
Advisory boards	20,000	40,000	60,000	80,000	80,000
Marketing	20,000	100,000	200,000	200,000	200,000
Website	5,000	20,000	20,000	20,000	20,000
Accounting fees	10,000	20,000	20,000	20,000	20,000
Overhead	10,000	20,000	20,000	20,000	20,000
Variable costs					
Licensing disease models	200,000	400,000	600,000	600,000	600,000
Research	500,000	500,000	1,500,000	2,000,000	2,500,000
Equipment	300,000	300,000	500,000	500,000	500,000
Legal/patent fees	200,000	500,000	1,000,000	1,000,000	1,000,000
Total Expenses	1,515,000	2,300,000	4,520,000	5,290,000	6,040,000
Cash flow	455,000	-350,000	930,000	4,210,000	10,060,000