Taking Drugs from the Lab to your Nightstand

Last week, we discussed how rational drug design can hasten the discovery process and lower its cost. Today, we talk about the challenges that biotech startups face in taking these new drugs to market.

Often, drugs are borne from a university research lab, funded largely by government grants, such as from the National Institutes of Health (NIH). When a marketable drug emerges from the lab, it goes through a **tech transfer** process.

Tracing the journey from lab to marketplace, we follow the story of Drs. Nazneen Dewji and Jonathon Singer as they discover a molecule with potential for treating Alzheimer's disease and create the company Cenna Biosciences.

About Alzheimer's Disease (AD)

Over 1 in 10 people over 65 suffer from Alzheimer's, rising to 1 in 2 over the age of 90, affecting over 8 million people today. The disease is marked by cognitive degeneration and memory loss. Many families experience the emotional devastation of slowly watching their parents fade away. Currently, there is no safe and effective treatment.

Since the effects of amyloid plaques, which are implicated in the disease, are irreversible, there is a large market for a preventative drug. Currently, most Alzheimer's drugs inhibit gamma and beta-secretases, which affect 50-60 other chemical process in the brain.

Taking a drug with such a large off-target effect is not sustainable in the long run, says Dewji. What patients need is a preventative drug for the brain the "same way that you take statins for heart disease."

In the Lab: Discovering the Drug and Tech Transfer

In 1996, Dewji and Singer began researching pre-senelins, large molecules associated with amyloid beta reduction. They noticed that certain peptide groups prevented amyloid beta from forming. Over time, they narrowed down the peptide group to their most promising peptide, P8, with over 50% reduction in amyloid beta.

In the case of Dewji and Singer, their path to business followed the typical tech transfer process. In 2005, when their research became viable in industry, the University of California San Diego granted them exclusive license to the patent, allowing them to turn their research into a business opportunity.

Out of the Lab: Funding and FDA Approval

After receiving exclusive license, Dewji and Singer started Cenna Biosciences in 2006. The company is entirely owned by the two founders who invested $646,000 of their own money and raised $13.5 million, mostly in non-diluting NIH grants.

Currently in the process of seeking investigational drug application (IND) approval from the FDA, they have an added tailwind of a recent change at the NIH, that recently fast-tracked testing using biomarkers. They optimistically hope for 5 years between IND approval and reaching the market, hoping to partner with a major pharmaceutical company to assist with Phase II (small) and Phase III (large) human trials and marketing.

Deciding when to partner is a large and difficult decision for researchers. If they partner too early, the original researchers get diluted and receive a smaller payout for over 20 years of research. Most profit would go to the pharmaceutical company. If they partner too late, they run the risk of investing hundreds of thousands of their own money - into a drug that might not pass clinical trials or that might not succeed in the marketplace. For scale, a Phase III human trial for AD can cost over $200 million.

Dewji anticipates some trouble taking peptide drugs to market, since they cannot be ingested orally in pill form. Instead it will likely be administered via a nasal spray, allowing the drug to pass directly to the brain through the blood-brain barrier.

Either way it plays out, we can surely be grateful for the scientists doing the basic research that brings new therapies to light for many suffering people alive today and in the future.

Wrapping It Up: Drug Design in Medicine

The pharmaceutical industry is currently in the classical trial-and-error approach, passing along the high cost of experimentation in drug development to patients. Nanobiotechnology merges physics and biology, opening the doors for physics-based rational drug design. Many biotech startups then take these drugs to market.

What is Compassionate Technologies?

Each Sunday we deliver to your doorstep an inspirational and educational piece describing a certain trend in technology and business.

We go from small to large throughout the year. This month focuses on Drug Design in Medicine, progressing up to topics in robotics, artificial intelligence, environmental and then space technologies.

Each month has four parts:

1st Sunday: Trends
2nd Sunday: Research
3rd Sunday: Technology
4th Sunday: Business

To keep our doors open, fund interviews with top scientists and industry players, and to continue hosting local events, we charge $150 per year for 52 print weeklies.

While we're getting started, I'm doing free deliveries in my neighborhood for the month of June. Please enjoy and consider joining me on this journey!

Kindly yours,

Thoughts?

Email me at olivia@compassionate-technologies.org
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"Around here we don't look backwards for very long. We keep moving forward, opening new doors, and doing new things, because we're curious... and curiosity keeps leading us down new paths."
- Walt Disney, Film Producer, 1901-1966