PRELIMINARY ROUND 1

BITTER PILL TO SWALLOW

-Dr. B. S. Patil and Prof. Ashwini Parab

PharmaNova Inc., is a biotechnology company based in Cambridge, Massachusetts, United States of America. The Company was founded by Dr. Schumer in 2008. The Company was found for advancement of biologics and molecular therapies targeting autoimmune disorders. In 2022, PharmaNova developed a proprietary AI platform called *BioSage* that could predict plant-based compound efficacy with 87% accuracy.

PharmaNova Inc. focused on biologics for autoimmune diseases. Their first major success was a monoclonal antibody for rheumatoid arthritis in 2013. With rising demand for sustainable therapies, PharmaNova Inc. began exploring plant-based compounds. Their search led them to BioVeda's research on hemidesmus indicus (Anantamul).

BioVeda Labs, a Pharmacognosist and Ayurvedic Researcher Lab is situated at Marcel, Goa, India. The Company was founded by Dr. Iyer. Inspired by the grandmother's herbal remedies and her own research into plant-based medicine, she launched BioVeda Labs in 1995 to modernize traditional Indian healing systems. The Lab maintains an herbarium with over 500 species and consults village healers for insights.

BioVeda began as a modest lab focused on standardizing Ayurvedic formulations. Its early work on *Tulsi* and *Ashwagandha* earned recognition from India's Ministry of AYUSH. In 2010, it expanded its phytochemical research, partnering with universities to catalogue over 300 indigenous plants. BioVeda launched its first patented herbal anti-inflammatory gel in 2012, which became a bestseller in Southeast Asia. In 2014 the Lab built a GMP-certified manufacturing facility and began exporting to Europe. The company's R&D division developed *PhytoScan*, a proprietary tool for analyzing plant compound interactions. In 2015, BioVeda's presentation at the Geneva Biotech Summit caught the attention of PharmaNova, sparking the first conversations about collaboration.

Both Companies entered into a strategic partnership to co-develop a novel drug for diabetes derived from an indigenous medicinal plant. The Joint Development and Investment Agreement (JDIA) to co-develop the medicine "Glycora" provided.

Stages of the Research and collaboration-

Stage I: Preclinical Research

This stage began in the year 2016. The stage was related to initial research, which was called the Pre-clinical Research Stage.

Conducted by: BioVeda (India)

Funding: $2 million from PharmaNova (USA)

The BioVeda agreed on the Identification of antidiabetic plants and checking the potency of each identified plant. It focused on integration of traditional Indian medicinal knowledge with modern medical discoveries and laboratory-based studies to assess biological activity, toxicity, and pharmacological potential before human trials.

PharmaNova invested $2M immediately in January 2016 to support BioVeda's discovery efforts. Being the leading company in pharmacy, it reserved the right to conduct a half-yearly audit to trace the use of funds and retained supervisory control through surprise inspections and auditing. The terms of investment included a directive for BioVeda to submit the quarterly progress report. It also gave access to BioSage, an AI platform to analyse compound efficacy and optimise selection.

Stage II: Clinical Trials (Phase I & II)

Stage II was initiated immediately after completion of Stage I in record time. This stage was divided into two phases, I and II, starting from 2019.

Conducted in: India

Supervision: Jointly by BioVeda and PharmaNova

Funding: $5 million from PharmaNova

The **BioVeda** was to identify the process for refined extraction and standardisation methods. The party has to utilise its specific number of trained professionals and scientists to apply Ayurvedic principles to the synergistic blending of compounds as well as to manufacture pilot batches at its Marcel facility for PharmaNova's testing.

Once this part of the task is completed, the party has to make an application to conduct a Clinical Trial to the Drug Controller General of India. Ethical Committee Approval, Clinical Research Organisation Advertising and Outreach for volunteers by contacting

hospitals and private clinics, Registration for recruiting volunteers, entering into participation Agreements with volunteers for the Clinical Trial Consent.

The PharmaNova simulated molecular interactions, designed delivery formats (capsules, gels, nano emulsions) using predictive modelling and conducted toxicology studies in USA labs. It co-filed international patents for formulation and delivery mechanisms and supervised the clinical trial stage. Additionally, the party invested $5 million into the research activity in June 2019 and continues to hold a supervisory role over the research project.

Phase I (in Stage II)

BioVeda began the Clinical trial in Goa. It aimed at assessing the safety, tolerability, and optimal dosage range to examine how the drug is absorbed, metabolized and excreted. It also checked the side effects and safe dosage levels. This phase had a trial conducted on 20-100 healthy volunteer patients.

In February 2020, during the quarterly audit, PharmaNova identified that the required number of scientists, laboratory personnel, and coders were not employed by BioVeda, and the same was not even brought to the notice of PharmaNova. PharmaNova claimed it was a breach of contract and issued a legal notice to BioVeda to terminate the contract. In July 2020, the dispute between PharmaNova and BioVeda was resolved through mediation, and the parties rejoined to continue with the research project. In Jan 2021, preclinical data showed promising antidiabetic medicine with minimal toxicity.

Phase II (in Stage II)

This phase evaluated the effectiveness and further assessed safety by measuring the therapeutic effect of the drug. It also monitored and compared the short-term side effects of different dosages. This phase was trialled on 100-300 volunteers with targeted conditions.

PharmaNova transferred 5 million dollars to BioVeda in February 2022 for Stage II. Accordingly, BioVeda began Phase II trials in Goa. However, in May 2023, BioVeda modified dosage levels and patient inclusion criteria, citing local ethics committee recommendations. PharmaNova alleged that these changes were made without their prior written consent, which was necessary as per the terms of the Contract. PharmaNova even claimed that earlier, BioVeda had already altered the terms of the contract unilaterally by

not appointing the required number of persons as per contractual terms. In June 2024, two trial participants reported moderate adverse reactions. BioVeda submitted a report to Indian regulators but delayed sharing it with PharmaNova. Further, in July 2025, PharmaNova discovered that BioVeda diverted 1.2 million dollars to a parallel project. BioVeda claimed that COVID-19 complications had led to new types of diseases, and new challenges have emerged as the COVID-19 vaccination has altered the immune system of the human body. Hence, there was a need to redesign the drug based on new developments and so claimed this was within its discretionary R&D budget under the JDIA.

Annoyed by the irresponsible attitude of BioVeda of constantly taking unilateral decisions and ignoring the terms of JDIA, in Aug 2025, PharmaNova issued a breach notice to BioVeda and suspended all future funding. BioVeda halted the trials and threatened PharmaNova with litigation for reputational harm, actual damages, consequential losses, and opportunity costs.

Because of all the complications, research progress was halted.

The following are the pending processes:

Stage III: Regulatory Approval & Commercialization (Phase III)

This is the final stage of the research. Reaching this stage would be considered an achievement. From here onwards, the speculations and doubts will give way to confidence and assurance. This stage had to commence in November 2025 and had to complete in a duration of five years, but due to the dispute that arose between the parties this stage did not commence.

Following were the responsibilities of both the parties in stage III-

Lead: PharmaNova (Global marketing)

Rights Retained by BioVeda: South Asia

Funding: $10 million from PharmaNova

Phase III

This phase had to check the effectiveness of the drug and monitor adverse reactions of the drug and compare them with standard treatments by providing comprehensive data for regulatory approval, detecting rare side effects, and establishing the risk-benefit ratio.

BioVeda in this phase, had to conduct the trial on 1000-3000 patients across the cities of India.

Stage IV: Post-Marketing Surveillance

Role of BioVeda

It was the responsibility of BioVeda to Monitor long-term safety and effectiveness through its Ayurvedic clinics and rural outreach, track patient feedback, lifestyle compatibility, and rare side effects using its PhytoScan Clinical module. It assesses quality of life improvements and supports holistic integration.

Role of PharmaNova

It was the responsibility of PharmaNova to oversee global safety reporting and pharmacovigilance using its BioSage AI platform. It conducts cost-effectiveness studies, manages regulatory updates and uses real-world data to guide future product enhancements and lifecycle strategies.

Phase IV

This phase focuses on post-marketing surveillance to assess the long-term safety and effectiveness of the medicine after approval. It focuses on monitoring the real-world use of the drug, detecting long-term or rare adverse effects, and evaluating cost-effectiveness and impact on quality of life.

The time and money spent on this drug are too huge to ignore. The litigation in court created jitters among both parties. The Government of India is also hopeful about the effectiveness of the drug. India, being the Capital of the world's Diabetes, felt this would be the invention of the century. The Government of India sent its minister to broker a deal between the parties. Keeping the interests of society and the State in mind, BioVeda invited PharmaNova to mediation at Lex Infinitum, VMSCL, Panjim, Goa.