

## CASE STUDY

# Guiding an Entrepreneur Through the Complex Process of Drug Development: A Cannabis Case Study

## OVERVIEW

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There are more than 160 'rare' cannabinoids that have been isolated from cannabis and hemp. Except for the THC variants, a majority are not psychoactive and, in many cases, they are therapeutic. The effects they produce have potential for use in many branches of medicine, but exploration and development were long hindered by the fact that use of cannabis was illicit until recently. However, with a more tolerant attitude toward cannabis and its derivatives and increasing scientific knowledge of its potential utilities, laws to control its distribution and consumption have relaxed, as seen in the 'Farm Bill' of 2018. Now more companies are embarking on the process of bringing these molecules to market as ethical pharmaceuticals.

That's good news for the patients who could benefit from the drugs that might result, but finding a viable, commercially feasible path to market remains a challenge for the would-be drug makers.

Recently an entrepreneur who had been involved in the cannabinoid space came to TBG in hopes of turning his early success into an FDA-approved drug or drugs. The client's goal had merit, but there were several hurdles. Among the many challenges was the lack of drug development experience within the entrepreneur's company. The client recognized that pursuing the path to an ethical pharmaceutical was beyond his team's expertise and so reached out to TBG.

### Key Takeaway

Successful drug development is a complex and costly process. Insightful application of knowledge in science, regulatory affairs, business, and marketing is essential. It also helps to be resourceful, creative, committed, and collaborative. TBG delivered on all criteria to position its ambitious client for success.

## KEY SERVICES & DELIVERABLES


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- Market analysis and market size estimate
- Regulatory strategy
- Intellectual property protection planning
- Competitive landscape analysis
- Go-to-market strategy
- Business plan development
- SWOT analysis of products and technology under consideration
- Detailed budget projections with likely value inflection points
- Project timing, milestones, and Gantt Chart development.
- Comprehensive presentation for prospective investors



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## THE CHALLENGE

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As is often the case for those new to drug development, there were far more questions to answer and difficulties to surmount than the entrepreneur and his team had anticipated. TBG had the challenge of earning the trust of people who were new to the drug development space and so had a limited foundation for assessing the advice TBG provided. There was also a meeting with potential investors looming for the client. They would need answers, solutions, a multi-part plan of action, and a buttoned-up presentation within 6 weeks where a typical timeline for such deliverables would be months.

## THE DETAILS

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- The client: An entrepreneur from another closely allied industry who had no experience in drug development but had seen the therapeutic benefits of cannabinoids in action and believed there was an opportunity for the development of ethical pharmaceuticals.
- The client had not considered the competitive landscape, neither from an ethical pharmaceutical perspective or how the novel molecules could best be positioned for success.
- To make any future drug commercially viable, its development would need to include a patented element or proprietary process to protect the drug maker's intellectual property.
- The client needed a valuation of his company in order to bring in investors. A critical meeting in which he would need to make the case for his vision was already scheduled.

## THE SOLUTION

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The TBG team quickly marshalled its diverse resources to create a plan for meeting the client's several needs and objectives within the time allotted. A core team of four consultants took on responsibility for success.

To build trust and move ahead as quickly as possible, the team instituted multiple daily meetings and phone calls with the client's team, seven days per week.

Due to the client's inexperience with ethical pharmaceutical regulations and requirements, the TBG team needed to provide an accelerated learning curve. TBG consultants took the time at every turn to thoroughly explain issues and concepts that were new to the client, confirm their understanding, and redirect the company where appropriate.

## THE RESULT

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In working with TBG, the client found not only the insight and advice needed, but also a supportive, collaborative team of professionals who were willing to go above and beyond to deliver an entire business plan, including clinical, regulatory, commercial, and manufacturing strategies, in record time.

