

Answers to Frequently Asked Investor Questions

1) What does the company do?

Sollievo is a pharmaceutical start-up company located in Southern California. Sollievo is positioned to disrupt the \$500 million global injectable benzodiazepine (sedative) market by introducing a fast-acting, consistent, intramuscularly (I.M.) administered product.

2) What is unique about the company?

The company, founded in February 2018, is a virtual company consisting of the CEO and part-time CFO. All work is done through contractors and consultants. The company was founded and is being led by a 40-year pharmaceutical and medical device executive with industry-relevant experience.

3) What big problem does it solve?

Workplace violence in the emergency department is a growing and dangerous problem. The cost of treating patients and hospital staff injured at work is a significant burden to hospital budgets. The Sollievo product does not require an IV line and is ideally suited to address this problem.

Also, as a follow-on indication, the product will be the drug of choice for treating status epilepticus, especially outside of the hospital setting. In these and other indications, the product satisfies the need to have a rapid onset of action when minutes matter.

4) How big is the market opportunity? Plan?

Injectable Benzodiazepine Market (million)			Projected Sollievo Revenue (million)	
	2019	2027	2023	2027
WW	\$486	\$624	\$29	\$272
Target Market US & Top 5 EU	\$268	\$348		

The \$272 million projected revenue in 2027 is a combination of a conservative estimate of market share (30% by units) and a function of premium pricing over the competitive products—also, new products, indications, and geographical expansion fuel the rapid growth of Provisa.

8) What motivates the founders, and how are they showing their commitment to the business?

The founder retired as President of a Medical Device company after 15 years and was ready for the challenge of creating a start-up. The founder devotes full-time effort to the company and has personally funded the company with \$1.0 million to date.

9) How do you plan to scale the team in the next 12 months?

Over the next 12 months, there is no plan to scale the team. Outside resources cover every key position required to develop and submit the 505(b)(2) NDA to the FDA.

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In year 3, depending on the marketing partner, it is anticipated that up to 5 additional FTEs will be needed, including product manager, sales, and marketing support.

10)What is the actual addressable market?

See #4, \$268A million in 2019, and \$348 million in 2027. Sollievo's first markets are the U.S. and the 5 top markets in Europe (UK, France, Germany, Spain, and Italy). By 2025 Sollievo will geographically expand to Japan, Australia, and New Zealand.

11)What percentage of the market do you plan to get over what period of time?

Over five years, Sollievo projected revenue would grow from \$29 million in 2023 to \$272 million in 2027. This growth is a combination of a conservative estimate of market share (30% by units) and a premium pricing over the competitive products—also, new products, indications, and geographical expansion fuel the rapid growth of Proviza.

12)Why does your company have high growth potential?

The product meets a large unmet need that leads to robust uptake. There have been no new products developed for I.M. indications in this market in the last 30 years.

13)Why do users care about your product or service?

More rapid sedation of acutely aggressive and agitated patients in hospitals and emergency departments correlates to a direct reduction in injury risk to both patients and staff. The savings to hospitals by reducing just one or two workplace injuries are significant and drives the acceptance of a premium price over the competitors.

Also, providing a rapid treatment for status epilepticus without the need for an IV will ultimately save the lives of people with epilepsy, particularly those in the elderly population.

14)What are the major product milestones?

Scale-up of drug and product	Q1 2021
Complete Clinical trials	November 2021
File US NDA	February 2022
Approval of US NDA	June 2023

15)What are the key differentiated features of your product or service?

Advantages of the ProDZP Formulation

	ProDZP	DIAZEPAM	LORAZEPAM
Onset of Action	10 minutes	30-60 minutes	20-40 minutes
Does not contain alcohol and/or propylene glycol in formulation	Yes	No	No
Eliminates residual pain after initial injection	Yes	No	No
Unlimited mixing with other CNS drugs	Yes	No	No
No dilution prior to IV use	Yes	Yes	No
Does not requires refrigeration	Yes	Yes	No
Premium Pricing ¹	Yes	No	No

¹Sollievo US Payer and HPD Qualitative Research Findings, Medical Marketing Economics (MME) April 2020

16)What have you learned from early versions of the product or service?

Since 1990, the French military nerve gas antidote has contained the drug. The proof of concept was demonstrated in 2010 in a pharmacokinetic trial in volunteers. The study showed the speed of absorption of the diazepam prodrug.

17)Can you provide a demonstration of the product or service?

Published proof-of-concept paper with the following data:

Comparison of Diazepam and ProDZP after Intramuscular Injection

Parameter	Diazepam (DZP)	Sollievo Proviza	Interpretation
Time to maximum DZP blood level	1.5 hours (0.5-96)	0.75 hours (0.5-1.0)	ProDZP gets into bloodstream 50% faster and with more consistent absorption
Maximum DZP Blood Level	148 ng/mL	230 ng/mL	ProDZP peak concentration in the blood is 55% greater

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18) What are the two or three key features you plan to add?

A veterinary formulation for sedating dogs and cats for exams and procedures
Expanding the indications to include status epilepticus
Introduction of an autoinjector product for home use

19) Who are your company's competitors?

The competitors include generic manufacturers of Diazepam, Lorazepam, and Midazolam. In the U.S., the largest supplier of these products is Hospira, a subsidiary of Pfizer, Inc.

20) What will give your company a competitive advantage?

See answer #15. The main competitive advantage is the rapid onset of sedation

21) What benefits does your competition have over you?

Established drug products, lower cost

22) Compared to your competition, how do you compete with respect to price, features, and performance?

Significant improvement in the performance over competitors, which translates into a premium price of 3-4 times the generic drugs' cost. The viability of the price premium was confirmed in a market research study with 3rd party payors and Hospital Pharmacy Directors (study completed April 2020),

23) How does the company market or plan to market its products or services?

The product will be sold via a partnership with a leading marketing, sales, and distribution company that is established in the marketing channels that provide these types of products to hospitals and clinics

24) What is the cost of a customer acquisition?

The acquisition price is \$150 for a package of 10 individual doses.

25) What early traction does the company have (sales, traffic to the company's website, app downloads, etc., as relevant).

A complete social media campaign is launched in addition to the company's website, <http://sollievopharm.com>.

26) How can the early traction be accelerated?

- a) Select strong marketing partner six months before product approval to prepare for commercial launch
- b) Presentation of product clinical data 6-12 months before approval at major medical conferences
- c) Garner formulary approvals at large hospitals 3 months before approval

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27)What have been the principal reasons for the early traction?

Although there is no early traction available for sales, a survey of 50 emergency medicine board-certified physicians indicated the following:

After viewing the product profile, 76% said they would prescribe Proviza if available today. The survey also revealed that Proviza would be prescribed for the majority (60%) of acute aggression cases in the emergency department.

This indicates both the desire to prescribe the drug and supports the case for rapid conversion to the new product.

28)What do you see as the principal risks to the business?

The company has mitigated the development, commercial and regulatory risks. Therefore, the path to approval is primarily execution risk and time for FDA approval.

Execution risk is mitigated by the Founder/CEO's experience and selection of top contractors with many years of developing pharmaceutical products that have been approved by the FDA.

Regulatory risk is mitigated by having a pre-development meeting held with the FDA in October 2019. This product's development and approval path is short and less costly than developing a totally new drug.

29)What legal risks do you have?

None

30)Do you have any regulatory risks?

Regulatory risk is mitigated by having a pre-IND meeting held with the FDA in October 2019. This product's development and approval path is short and less costly than developing a totally new drug.

Also, the U.S. and Canada produce both the drug and the final product. This eliminates the need for the FDA to inspect overseas facilities, which can significantly delay approval. Also, there is no risk of a future inspection of the foreign manufacturer that can result in product shortages.

31)Are there any product liability risks?

At the time of approval, Sollievo will have standard product liability insurance. Product liability risks for a product of this nature are low.

32)What key intellectual property does the company have (patents, patents pending, copyrights, trade secrets, trademarks, domain names)?

The company has filed two provisional patents that protect the product's formulation, which contributes to its rapid absorption. A second provisional patent protects the novel manufacturing process for the drug. Both patents, when issued, will present substantial barriers to competitors. A third provisional will be submitted to cover a low-cost novel subcutaneous delivery system for treating seizures out of the hospital.

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33)What comfort do you have that the company's intellectual property does not violate the rights of a third party?

Sollievo has completed two major patent and literature searches which have not revealed any conflicts. Also, the drug is off-patent, and there is no freedom to operate issues regarding manufacturing and use the drug.

34)How was the company's intellectual property developed?

The provisional formulation patent was done exclusively by the founder, while the drug manufacturer developed the drug manufacturing process patent. Sollievo retains exclusive rights to this I.P. The filing of additional patents is expected as development continues.

35)Would any prior employers of a team member have a potential claim to the company's intellectual property? No

36)What are the company's three-year projections?

The total development cost FDA approval is \$10 million

37)What are the key assumptions underlying your projections?

The \$272million projected revenue in 2027 is a combination of a conservative estimate of market share (30% of the addressable market) and a function of premium pricing over the competitive products.

Projected Sollievo Revenue (million)

2023	2027
\$29	\$272

38)How much equity and debt has the company raised; what is the capitalization structure?

Currently, the company is 100% owned by the founder. After Series A, the founder percentage is projected to be 45 -50%.

39)What future equity or debt financing will be necessary?

\$1.0 million convertible debt October 2020

\$5 million Series A equity round November December through March 2021

\$4 million Series B equity round Q1 2022

40)How much of a stock option pool is being set aside for employees?

At the time of the closing of Series A, the stock option pool will be 15%

41)How much burn will occur until the company gets to profitability?

\$10 million to get to FDA approval plus \$3 million for commercial readiness and launch. The financial projections anticipate the Proviza launch in the U.S. in Q2 2023 and cash flow positive by Q4 2023

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42)What are the key metrics that the management team focuses on?

Initiation of the animal studies	Q1 2021
Scale-up of drug and product	Q2 2021
Completion of clinical studies	Q4, 2021
Submission to the FDA	Q1 2022
Integration of Marketing Partner	October 2022

43)How much is being raised in this round?

\$5 million in a Series A equity round

44)What is the company's desired pre-money valuation?

\$11 million

45)What is the planned use of proceeds from this round?

Produce the registration batches of drug and product to support NDA submission

Complete limited animal safety studies

Provide data package to out-license the veterinary rights to a significant veterinary health company

Establish a quality management system

Complete a pharmacokinetic study in volunteers

Initiate the efficacy study in 100 subjects suffering from alcohol withdrawal symptoms