|  |  |  |  |
| --- | --- | --- | --- |
| **Problem and Its Financial Impact** | **Included** | **Missing** | **N/A** |
| What is the problem? Why does it matter? Why solve it now? |  |  |  |
| What is the estimated number of people experiencing the problem? How will this change in the future? |  |  |  |
| What are the estimated individual or US/global system costs associated with the problem today? How will these costs change in the future if the problem isn't solved? |  |  |  |
| Who are the key stakeholders associated with this problem? What are their motivations or potential objections to adopt your solution? |  |  |  |
| **Comments** |

|  |  |  |  |
| --- | --- | --- | --- |
| **Solution**  | **Included** | **Missing** | **N/A** |
| What is the solution?  |  |  |  |
| What is the basic description of the scientific hypothesis and mechanism of action? Is it first in class or best in class? Is it a single asset or a platform?Has dosing and administration been determined?What are the specific benefits or outcomes that will be claimed? |  |  |  |
| What is the current development stage(s)? |  |  |  |
| What are the primary development milestones on a timeline - the history and the future? Make sure to include items associated with formulation/product development, toxicology/biocompatibility, regulatory, manufacturing, launch, etc.  |  |  |  |
| What are the key decision points and timelines for different indications or label claims?  |  |  |  |
| Will a diagnostic be required to drive adoption/use of the solution? |  |  |  |
| Is there safety and efficacy data? If so, what are the results? |  |  |  |
| **Comments** |

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| --- | --- | --- | --- |
| **Regulatory**  | **Included** | **Missing** | **N/A** |
| What is the primary regulatory pathway and timeline?  |  |  |  |
| Have there been discussions with regulators? Is there an orphan designation? Will there be an expedited regulatory review? |  |  |  |
| Medical devices: If 510(k), have you identified a predicate? What is the predicate, product classification, and outcomes claims? Will clinical studies be required? |  |  |  |
| **Comments** |

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| --- | --- | --- | --- |
| **Intellectual Property** | **Included** | **Missing** | **N/A** |
| What are the patents and other intellectual property (IP)? |  |  |  |
| Does the company own the rights to the assets and IP? |  |  |  |
| Have the rights to the assets and IP been negotiated and legally documented? Are there any terms that will make financing the IP difficult (ex. royalty rates, approval rights, etc.)? |  |  |  |
| Has there been research or evaluation for the potential of patent infringement(s) of other existing products? |  |  |  |
| What is the patent/IP protection strategy? Does the firm have IP counsel? |  |  |  |
| Medical devices: Is there a prototype? |  |  |  |
| **Comments** |

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| **Software** | **Included** | **Missing** | **N/A** |
| Is there a clear description of the use case(s) for the software? |  |  |  |
| Does the software collect patient data? Is it HIPAA compliant? |  |  |  |
| Will the software require its own separate regulatory pathway independent to the solution? Have conversations with the regulators been initiated? How does the timeline parallel the primary solution’s regulatory timeline? |  |  |  |
| Has the CSQ/QMS package been created? Does the package adhere to current global data protection and privacy requirements? Does it include cybersecurity protections? Has the software been validated?  |  |  |  |
| Does the company have an employee training system with documentation? |  |  |  |
| From a revenue standpoint, will the software be bundled with the solution or will there be a separate charge/subscription?  |  |  |  |
| Subscription: Are there one-time fees associated with on-boarding new customers? If so, have these been identified as a separate revenue line item? |  |  |  |
| Subscription: Are there computer system integration requirements?  |  |  |  |
| Subscription: Are there existing reimbursement codes that could be used for the software subscription? What are they? |  |  |  |
| Subscription: What are the current vs post raise SaaS metrics: ARR/MRR/one-time, growth rate (%), growth margin (%), CAC payback in months, gross revenue retention rate (%), and net revenue retention rate (%).  |  |  |  |
| **Comments** |

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| **Formulation and Manufacturing** | **Included** | **Missing** | **N/A** |
| Has the solution’s formulation/product design been finalized? |  |  |  |
| What is the mode of administration? How has this mode been validated by the market? |  |  |  |
| How will the solution be manufactured? Have potential manufacturing partners been identified? |  |  |  |
| Will the manufacturing be contracted out? If so, have manufacturing partners been identified? Has the scope of work been negotiated? Have contracts been executed? Is there a feasible scale-up plan? |  |  |  |
| Are there any aspects associated with the manufacturing of the solution patentable?  |  |  |  |
| Medical device: What is the stage on the design process map? Has QMS been established? |  |  |  |
| **Comments** |

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| **Sales and Marketing** | **Included** | **Missing** | **N/A** |
| What is the USD size of the target market(s) (US/OUS)? |  |  |  |
| Who is the target customer that will get benefit from the solution? Has there been any customer discovery work? What were the results and testimonies? |  |  |  |
| Are customers engaged in the development of the solution? |  |  |  |
| How will the solution be adopted/accepted?  |  |  |  |
| Is there a go-to-market plan? |  |  |  |
| Who are the stakeholders that will influence adoption?  |  |  |  |
| What is the pricing and reimbursement strategy? |  |  |  |
| Will the entity paying for the solution be the one to use the solution? |  |  |  |
| Are there existing codes to charge for the use of this device? What are they? If not, does it need one or what is the progress toward establishing a new code? |  |  |  |
| **Comments** |

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| **Competition** | **Included** | **Missing** | **N/A** |
| What are the current products **on market** to solve this problem? How does the solution compare?  |  |  |  |
| What are the products **in development** by trial phase to solve this problem? How does the solution compare? |  |  |  |
| What market or scientific evidence supports the current and ongoing investment and research activities? |  |  |  |
| What adjacent markets exist? Are they a threat or an opportunity? |  |  |  |
| **Comments** |

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| **Co-development Partners and Strategics**  | **Included** | **Missing** | **N/A** |
| Who are the co-development partners? What are their commitments and responsibilities? How are they being compensated? |  |  |  |
| Who are the strategics in this therapeutic area and adjacent markets?  |  |  |  |
| What is the status of the discussions with strategics? What exit opportunities have been discussed? Have discussions included in-licensing opportunities and possible acquisition? Do any of the strategics have material control or influence over the adoption and use of the solution? Have they provided specific feedback or suggestions about the development timeline? |  |  |  |
| What are the market comps for an acquisition or IPO? |  |  |  |
| **Comments** |

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| **Publications and Presentations**  | **Included** | **Missing** | **N/A** |
| Is there a publication strategy?  |  |  |  |
| Are there publications about this research?  |  |  |  |
| What is the schedule for presentations and posters at scientific conferences?  |  |  |  |
| How are KOLs and other though leaders involved? How are they being compensated? |  |  |  |
| **Comments** |

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| --- | --- | --- | --- |
| **Team** | **Included** | **Missing** | **N/A** |
| Do they have relevant technical and business expertise to run the business? |  |  |  |
| If they have advisors, do the advisors have the right skills to grow/ scale a venture? |  |  |  |
| What does the composition of the board of directors look like? Does it include leaders who are adequate to guide and support the company at its current stage? |  |  |  |
| Is there a team gap? Is there an explanation or plan to fill the gap? |  |  |  |
| How are the founders committed to the venture? |  |  |  |
| **Comments** |

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| --- | --- | --- | --- |
| **Financial Status** | **Included** | **Missing** | **N/A** |
| Is there any revenue? What is generating this revenue? |  |  |  |
| How has research been funded to this point?  |  |  |  |
| Has non-dilutive funding been received? If so, how much and from whom? |  |  |  |
| Is there a pro forma available showing the financials of the past 12 months and a forecast of the financials for the next 36 months? |  |  |  |
| What is the current vs post raise monthly burn rate? What is the current vs post raise runway in months? |  |  |  |
| Have the COGs been estimated? |  |  |  |
| Are the leadership’s compensation package comparable to current market rates (eg salary, benefits, equity/stock options, etc.)? |  |  |  |
| What does the cap table look like? Are there notable investors that participated in previous rounds? |  |  |  |
| Are the founders/leadership team invested (employee options or cash equity)?  |  |  |  |
| Are any of the investors recognized as active board members? |  |  |  |
| Is there equity set aside for incentivizing the leadership team and employees? |  |  |  |
| **Comments** |

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| --- | --- | --- | --- |
| **Funding Request**  | **Included** | **Missing** | **N/A** |
| What is this funding request? (eg Type, Amount, instrument, terms) |  |  |  |
| How will this funding be used? How long of a runway does this funding provide? |  |  |  |
| What milestones will be completed with this new funding? |  |  |  |
| How much more money will be required to reach each subsequent milestone and ultimately to complete development and launch the solution?  |  |  |  |
| Who else has committed to the round or is engaged in diligence? |  |  |  |
| **Comments** |