ABSTRACT

An Analyst's Guide to Patents

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Currently, Baylor Angel Network analysts and angels alike handle patent diligence without a simple framework to evaluate the patent component of an early-stage company. I aim to provide a concise, useful guide to help analysts rigorously and objectively evaluate companies that depend on patent protection. In sum, I recommend that the analyst should understand the stages of the patent(s), ask strategic questions to clarify the quality and depth of protection, and understand patent value in its broader context. Patents are primarily valuable when the company creates value within the patent's boundaries and inasmuch as the company has the practical ability to defend its patent rights. In addition to the patent overview, significant analysis has been completed on specific, confidential, medical device startups. Example analysis (anonymized to protect sensitive information) is included in the appendix and constitutes much of the work that went into the thesis project.

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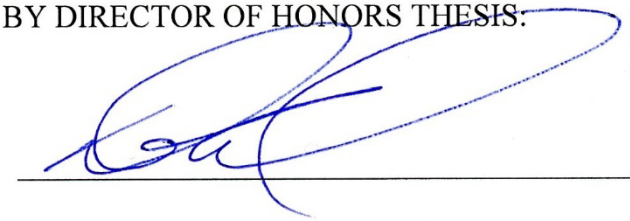

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# AN ANALYST'S GUIDE TO PATENTS

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By

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The Baylor Angel Network would not exist without our exceptional faculty, especially Dr. Bill Petty, Steven Diedrich, and David Reid, my advisor. They have shaped this transformational program in phenomenal ways. My work would not be possible without their support.

The program has grown due to the excellent work of analysts who came before. I want to thank each of these leaders for their hard work in building the network and passing the torch to each new class of analysts. Their efforts made this project possible.

# CHAPTER ONE

## Introduction

The Baylor Angel Network (BAN) began with a fortuitous conversation on the golf course and has grown into a thriving angel network and student experience. BAN is a network of accredited investors aided by a team of student analysts who screen potential investments.

In an average angel network, many, if not most, of the entrepreneurs who apply for funding are invited to pitch to the network. Interested angels lead due diligence after the pitch themselves or in smaller groups. In contrast, BAN, assigns student analysts to screen companies before they present. With the help of angel mentors, students analyze business models, competitive landscapes, financial statements, management teams, potential investment returns, and growth projections. The goal of the analysis is to preliminarily assess the overall potential of the companies. As such, students gain hands-on experience, driven by the highly professional environment and the real financial risk of early-stage investment opportunities.[1]

At the end of the screening process, the screening committee invites four companies, on average, to pitch. By the time entrepreneurs present, the analysts and mentors have vetted the deal and written a concise, analytical deliverable for the network.

After pitch day, BAN operates like most angel networks. Investors lead due diligence on their own, without student involvement. Still, the program is unique for its in-

[1] BAN's screening committee makes all decisions about which companies will be invited to pitch. The student analysts do not make investment recommendations.

depth screening process prior to the pitch, which provides substantial value to the investors. Among students, the program is known to be an educational, hands-on experience like none other, guided by mentors with decades of industry expertise.

### *BAN Student Practicum*

Each year, 8-10 juniors are chosen to be the next class of analysts. Over the next three semesters, the analysts have the privilege to work alongside experienced angel mentors. They learn how to preliminarily analyze early-stage startups, how to handle themselves professionally, and how to manage their time during fast-paced screening cycles. Analysts are mentored by angel investors and senior analysts, developing relationships that open the door for new opportunities. The BAN process lasts about a month for each round of entrepreneur applications. The cycle is structured around three events: Subjective Meeting, Objective Meeting, and Presentation Day.

#### *Student Process: Subjective*

On Day 1 of the cycle, the analyst receives her company assignments. She starts researching the company and reaches out to mentors to schedule internal calls. For this phase of research, the analyst digs into everything she can find, seeking to uncover any potential trouble areas. Prior to the internal call, she sifts through any information she can find on the company, market, and exit potential to identify strengths and weaknesses. If the analyst can address the simple questions ahead of time, she can ask strategic questions of the angel.

During the call, an experienced angel mentor listens to the analyst's initial appraisal, offers their perspective, and asks questions. The mentor is often experienced in

the industry, so he helps the student gauge the severity of any issues. The student returns to finalize her subjective analysis deliverable (see Appendix A) and prepare for her external call with the entrepreneur.

*The Subjective Analysis Deliverable*

The goal of this deliverable is to survey the entire field and identify any potential trouble areas. The subjective analysis foreshadows the objective analysis; the identified trouble areas will become focus areas in the second phase of analysis.

Every company is solving a problem, and the analyst must identify who is willing to pay for the solution. Once the value proposition and business model are clearly laid out, the analyst can evaluate their performance in light of competition and market trends. In summary, the subjective document is designed to encourage thorough preliminary analysis as the analyst identifies the primary issue to dig into during the objective analysis.

*The Subjective Meeting*

Mid-cycle, the analysts convene with their reports for the subjective meeting. This time is set aside to give each lead analyst feedback and insights on their company from the rest of the analyst team. Every student presents their company's strengths and weaknesses, and other analysts offer thoughts or ask questions from their own experience. The analysts come away with insights from the group and new questions to answer.

*Student Process: Objective*

After the subjective meeting, the analyst hosts an external call where she digs into the key topics with the entrepreneur. The call is often short. To make the best use of the time, the analyst focuses on topics that are best answered on a call, not email. Often, the

entrepreneur will reveal information during the call that changes the analyst's and angel's entire outlooks on the company. The entrepreneur uses this time to demonstrate her capability, to express the mission of the company, and to persuade BAN that they are the best team for the job. On the other hand, this call is also the analyst's opportunity to think on her feet. The analyst learns when to dig in further and when to be satisfied with an answer from the angel mentor. This call is the moment to ask "The Five Whys" to deeply probe the most important question.

Often, after the external call, the analyst's entire take on the company shifts. The analyst must think nimbly and evaluate the company without bias throughout the screening process. As she completes the objective analysis, the mentors and analyst decide if they will suggest to the screening committee that the company should be invited to pitch, should re-apply in a future round, or should be declined.

*The Objective Analysis Deliverable*

The objective analysis report (see Appendix B) is the final major deliverable of the BAN process. The analyst must identify the crucial issue and include all pertinent information. The document is concise, dense, and clear. Writing the objective requires thorough analysis of the key questions identified in the subjective phase.

The objective analysis includes an Excel component to visualize and analyze investor ownership, potential returns, and revenue projections. The model consists of financial projections, where the analyst identifies revenue drivers; a capitalization table; a return model; and a sensitivity analysis of returns. For more detail, see the explanatory paragraphs in Appendix C.

This phase of analysis often requires evaluation of unit economics data, financial projections, and growth plans as predicted by the entrepreneur. Often, the objective analysis will boil down to these basic questions: How does the entrepreneur plan to achieve their next goal? Are they capable? Unit economics provide invaluable insight into this question. For revenue-generating companies, key metrics based on unit economics reveal whether the company is trending towards success or failure.

The objective deliverable is designed to communicate the key issues. During a company's pitch, the entrepreneur will share all positive news. The analyst needs to present the problems, pre-empting the investors' preliminary questions and providing an evaluation in the objective analysis.

*The Objective Meeting and Screening Call*

The objective meeting takes place two weeks before Presentation Day. Before discussing potential "invite" companies, analysts quickly present the rest of the companies. Each analyst identifies one to three reasons for their rejection, demonstrating their understanding of the core problem. Then, for each potential "invite," the lead analysts explain the people, opportunity, context, and deal quality. With that background, the analysts evaluate and rank the cohort of companies, finalizing their list of suggestions for the screening committee. At this point, analysts tie up loose ends in their conversations with the entrepreneur and make final edits to their objective deliverable.

When the screening committee convenes, the analysts present all companies, highlighting suggested invites based on their preliminary analysis. Angel mentors give comments on each company before the committee discusses and votes on which companies to invite.

After the screening committee makes their decision, each analyst calls their entrepreneur. These calls require careful preparation and quick thinking. The student analyst must always behave professionally, carefully deliver difficult feedback, and be prepared to answer questions. The analysts aim to provide valuable feedback to every entrepreneur that goes through the screening process, even if they are not invited to pitch. For those that are selected, the analyst has the privilege of explaining the screening committee's rationale and inviting them to present in two weeks.

*Presentation Day*

Presentation Day, the culmination of the cycle, takes place on a Friday morning on Baylor's campus. Thirty to fifty investors and guests convene in Waco (or on Zoom) and four entrepreneur teams prepare to pitch. Historically, angels and entrepreneurs all convened in person, but with the recent transition online for the pandemic setting, BAN has added the option to attend virtually. The director and analysts have found ways to maintain personal connections, despite the distance.

Each analyst knows their role to make the day run smoothly. Over the course of the day, some analysts host their entrepreneur, making sure that their needs are met, that they are prepared for the pitch, and that they are aware of questions previously raised by investors. The other analysts handle logistics, making sure the angels are comfortable and that the day runs without a hitch. When they are not working, analysts are networking. Presentation Day is an opportunity for analysts to meet angels outside the deal mentoring process, and angels look forward to engaging with students.

After the pitches conclude and the entrepreneurs depart, the investors discuss the opportunities, and analysts observe. Analysts highlight this time as the most educational

hour of the entire cycle. Investors ask different questions than the analysts initially think to ask. They focus their energy where it matters, which is often the team, potential returns, and the one fatal flaw. Their focus can shock the green analyst who spent days evaluating competition and understanding the market. Since the analyst has identified the key issues in their objective deliverable, the investors hone in on the essence of the company: what, exactly, are they doing, and how will it make money?

After Presentation Day, investors soft commit their interest in the company, if any, and move forward into member-led diligence. The analyst role has ended, so students have a few weeks to focus on classes and other priorities. Soon, the cycle will start again, with a new industry, new team, and new questions to ask. A BAN analyst always has more to learn.

*Patent Analysis*

Through my semesters in the program, I focused on medical device companies. One of BAN's founders told me early on that, often, BAN members did not know how to deal with patents. I saw that firsthand. Medical device companies primarily hedge against competition through patent protection. However, the analyst does little more than look at their patent protection and check a mental box. As a result, the analyst rarely understands the efficacy of the patent protection or what major pitfalls might be around the corner.

As I progressed through the BAN cycles, I saw companies approach patents differently; some requested NDAs to protect their information while others flippantly planned to file "soon." Both seemed incorrect, but I lacked the context to articulate it. For once, my mentors were not as knowledgeable about intellectual property as they were

experts on market strategy and reimbursement. We clearly needed guidance to understand the nuanced patent environment.

However, I did not realize how crucial this guide would be until I looked into a company that had applied to BAN a few years back and returned for funding. This was a medical device company who depended heavily on IP for their innovative hospital tool design. The CMO, who owned all IP, had abandoned the company, leaving the rest of the team without a product. Then, he sued the company for infringement on his patent and nearly drove the company bankrupt. BAN had not invested when they had the choice before, but I began to wonder if that analyst had realized the risks of their IP strategy.

As I explored the issue, I learned that our angels frequently did not do much more diligence on patents after Presentation Day either. I spoke with venture capital firms that were in the habit of leaving patent evaluation to the very last step of their diligence because they outsourced it to a high-cost legal firm. Companies applying for funding from BAN are too early-stage to merit outsourcing legal analysis. The responsibility falls to the analyst and angel mentor. As such, this project is intended to provide a concise, useful guide to help analysts and angels evaluate companies with patent protection.

# CHAPTER TWO

## An Analyst's Guide to Evaluating Patents

The *Analyst's Guide* is designed for use as a reference. This chapter provides a high-level overview of key questions, general context, and stage-specific insights. Some key questions should be asked directly of the entrepreneur, but many can be answered through thoughtful analysis of the company, their patent material, and their competition. The Context and Red Flags sections help the analyst identify and assess problem areas by understanding themes from the experience of previous analysts. The analyst should identify relevant topics and reference the subsequent chapter to find more detailed information. Most of the general context, especially regarding patent history, strategy, and value generation, is contained in Chapter 3. To best use the *Guide*, the analyst should reference those sections as needed.

## Patents 101: How to Evaluate

Analyzing the whole of relevant prior art and claim quality of a patent would be ideal, but that is rarely necessary for angel-stage deals. Instead, answer five key questions:

1. **What have they patented?**
    a. What is a patent, and how do patents work?
    b. Is the material patentable?
    c. Does their patent cover the **key value drivers** of their product?
    d. How could a competitor work around the patent to solve the same problem?
    e. Is it likely to be granted or be defensible?
2. **What stage is their patent protection?**
    a. See the next page for specific questions and context for each stage.
3. **Who has control over the IP?**
4. **Who is their IP lawyer?**
    a. Who drafted their IP, and what are their credentials?
    b. This question serves a proxy to understand the quality of their claims.
5. **How will their IP generate returns?**
    a. **What patent protection do competitors have?**
    b. Have they done a Freedom-to-Operate Analysis?
    c. **Is their IP Clean? (**Is there risk of lawsuits?)
    d. How valuable/useful is patent protection in this industry?
    e. Is there acquisition potential?
    f. How does the IP fit into their broader strategy?

**This two-page guide gives a high-level overview of context and questions to use in answering these key questions. The following pages offer more in-depth additional questions and insights, especially in patent strategy and risk.**

**Red Flags:**[2]

- Poorly drafted claims are unlikely to survive the examination process.
    - Poor claims are difficult to identify without experience.
    - As a proxy, know the quality of their patent lawyer. (Do they litigate?)
- Third-party claims to the IP ownership introduce major risk.
    - Estranged inventors can destroy a company by exercising ownership rights.
- Lack of IP when the invention has already been publicly disclosed means that the company must file an application in the next few months, within their one-year grace period to file a US patent application.
    - They have invalidated any potential international protection by disclosing before filing an application.

[2] This is by no means an exhaustive list. Think carefully, especially about information revealed by the five key questions, to identify additional issues.

**Key Insights:**

- Pay attention to claim length
  - Detailed claims limit patent coverage and may result in the patent not holding up in court[3]
- Not all inventions are patentable, especially in programming and diagnostics.[4]
- Design patents are rarely worth anything.[4]
- Inventorship/ownership disputes are common in startups.[5]
- Waco is the patent capital of the US. Over 20% of U.S. patent cases are heard in Waco by Judge Albright.

**How does a patent work?**

- Patents grant the **right to prevent** someone from making or selling an invention.
  - They do **not** give the right to create.
- Patent value is realized by **work**.
  - Think of patents like a fence around land; **the asset only gives returns if you farm it.**
- Protecting patent value in court is expensive and time-consuming.
  - The goal of the patent is primarily to deter lawsuits and competition.

**Key Patent Statistics**

**10%** of patents account for **80-90%** of returns.

**In 2020,**

**175,000** provisional apps filed

**653,000** non-provisional apps filed

**399,000** patents granted

**Value and Key Questions by Stage**

**To-Be-Filed**

- Public disclosure (to you) before filing means they cannot file internationally.
- They have no patent protection.
- **Why have you not filed yet?**

**Provisional Patent Application**

- The patent has a priority date, which is better than nothing!
- Provisionals are little more than nothing.
- **Have you done an FTO Analysis?**
- **When will you file your non-provisional?**

**Non-Provisional Application**

- At this point, the patent is being examined [torn apart] by the USPTO (Patent Office).
- The patent is often publicly available. Patents publish 18 months after their priority date.
- **Who is your IP lawyer?**
- **How deep is your moat?**

**Granted or Issued Patent**

- Congratulations, a real patent!
- Monopoly protection has been granted.
- Patents can still be revoked; majority are not.
- **Do competitors have patents in this space as well? What do they look like?**

**Continuation-in-Part Application**

- Priority dates will vary, so pay attention.
- Companies can keep early priority dates for part of the invention and still innovate.
- **What components were patented earliest?**

**Licensed Patent**

- The patent has been granted to Company A, who has a right to use the IP, so Company B must pay royalties to operate in that space.
- Nonexclusive license can be a red flag.
- **Are the terms set?**
- **Is the license exclusive?**

[3] See Question 4 – Who is their IP Lawyer? in Chapter Three
[4] See Question 1 – What is a Patent? in Chapter Three
[5] See Question 3 – Who owns the IP? in Chapter Three

CHAPTER THREE

In-Depth Resource

This chapter is designed both to be read and used as a reference. The first section, *Supporting Details*, walks through specific aspects of the patent evaluation process by key question. The rest of the chapter expands upon each of those questions in order. Throughout the chapter, **boldface text indicates essential points**, so special attention should be paid to it.

*Supporting Details, organized by Key Question:*

1. What have they patented?
2. What stage is their patent protection?
3. Who has control over the IP?
4. Who is their IP lawyer?
5. How will their IP generate returns?

*1. What have they patented?* [6]

Inventions must meet four requirements to be patented.[7]

- Patentable: while this seems obvious, laws of nature, natural phenomena, and abstract ideas are not patentable[8]

[6] The ability to patent an invention is a constitutional right, granted in Article I, Section 8, Clause 8. This means the federal government has jurisdiction over patent law.
[7] 35 U.S.C. § 102
[8] *Mayo v Prometheus, Diamond v. Diehr*

- The courts' goal is to "distinguish patents that claim the 'buildin[g] block[s]' of human ingenuity" from inventions that build upon them.[9]
- **For material to be patentable, it must pass the two-step "Mayo test."**
    1. Does the claim cover unpatentable material (law of nature, etc.)?
    2. Does any part of the claim cover a patent-eligible application of that concept (an 'inventive concept')? [10]
- Natural phenomena (Example in footnote[11])
    - Natural phenomena can be subtle in medical devices and diagnostics.
- Laws of nature
- Abstract ideas (Example in footnote[12])
    - Notably, abstract ideas include computer algorithms, which are considered 'building blocks' of innovation.
    - Be cautious if the patent seems to cover a big-picture concept.

- Novel: must not have been publicly disclosed.

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[9] *Alice Corp v. CLS Bank Int'l*

[10] www.uspto.gov/web/offices/pac/mpep/s2106.html

[11] *Ariosa Diagnostics, Inc. v. Sequenom*
Sequenom had patented a method for detecting a particular type of DNA (cffDNA) to diagnose fetal characteristics. The patent was declared invalid because "the only subject matter new and useful was the discovery of the presence of cffDNA," saying that the method just detected a natural phenomenon. Useful resource: https://www.ipwatchdog.com/2019/04/14/patent-eligibility-of-medical-diagnostics-inventions-where-are-we-now-and-where-is-there-to-go/id=108263/

[12] *CardioNet, LLC v. InfoBionic, Inc.*
The Federal Circuit recently decided claims for a cardiac monitoring system were patent-eligible. It was highly debated because the claims arguably covered the basic concept of using electrodes to monitor the heart. Allowing a patent for this claim would give them excessive monopoly power over cardiac monitoring. The claims were accepted because they covered a "specific means or method that improve[d]" the technology, instead of just the basic concept.

    - **Talks with investors/manufacturers can (and do) count as public disclosures.**
    - The US has a one-year grace period after the first public disclosure, but international patents **do not** have a grace period.[13]
- Useful: must be specific, substantial, and have credible use. (rarely an issue)
    - Requirement is designed to block someone from patenting without cause.
- Nonobvious: must not be obvious to someone "skilled in the art."
    - Prior art, or evidence that the invention was obvious or existed prior to the patent filing, can and does invalidate patents.

Three major types of patents; startups are likely to work with utility patents.

- Utility patent: covers a process and/or machine
- Design patent: covers the aesthetic appearance of an item
    - **DESIGN PATENTS ARE NOT WORTH A STARTUP'S EFFORT.**
    - Design patents are identifiable by the letter "D" at the end of their patent number.
    - They cover nuances of the aesthetic and are **very** easy to work around.
    - If a company has a design patent, **question why they paid money for it.**
- Plant patent: covers asexually reproduced non-tubers

Four Types of Utility Patents[14]

- Composition of Matter: often, chemicals that make up a novel compound.
- Process: method of making or using the invention.

[13] 35 U.S.C. § 102(b)(1)
[14] 35 U.S.C. § 101

    - While process patents are valuable, they are easier to work around than, for example, a composition of matter patent.
- Machine: the typical invention but requires multiple moving parts.
- Article of Manufacture: the typical invention without moving parts.

Highlighted Components of a Patent:

- Classification – useful to scan for prior art in the classification.[15]
- Specification – written description of the invention; required in every patent[16]
- **Claims – define the scope of protection;** contained in the specification.
- Drawings – illustrate the invention and are helpful to understand the specification.

Patent Statistics, as context.

- Patent Filings in 2020[17]
    - 175,000 provisional applications
    - 653,000 non-provisional app.
    - 251,000 patents abandoned.
    - 1,037,219 patents pending
    - 399,000 patents issued.
    - About 5,000 lawsuits filed[18]
- Patent Returns
    - Top 10% of patents account for 80-90% of total returns (in 2000).[19]

[15] 35 U.S.C. § 8
[16] 35 U.S.C. § 112
[17] USPTO FY 2020.
[18] Unified Patents. "2020 Litigation Annual Report."
[19] Bessen and Meurer. "Lessons on Patent Policy."

    - More than half of all patents are not renewed by their ten-year anniversary.[20]
        - Technological advancement, resulting in obsolete patents, is likely a major driver, although entrepreneurial failure could contribute.
- USPTO receives 650,000+ patent applications annually. Most are non-provisional utility patents.
- Maintenance fees are due at 3.5, 7.5, and 11.5 years and in total, cost under $5,000.

*2. What stage is their patent protection?*

**Key Takeaway:** Patents introduce substantial risk until they are granted, and even then, could be subject to further investigation and revocation.[21]

- Early priority date, or date of filing, defines who receives the patent.

Application to be filed

- **Goal**: none.
- This is the riskiest stage of the application process.
- The company needs to be cautious about public disclosures of any kind and may be inclined to request NDAs or hesitate to share information about their invention.
- The company has **no patent protection whatsoever** before filing.
    - They also have no evidence that they are pursuing patent protection.
- **Key Questions:**
    - When do you intend to file your patent?

[20] Allison et al. "Valuable Patents."
[21] Somaya. "Patent Strategy and Management."

- **Why have you not filed yet?**
- Have you performed a freedom-to-operate analysis?

Provisional Patent Application[22]

- **Goal**: get the earliest possible priority date at the lowest cost.
- **Provisional patent applications are cheaper and faster to file than non-provisional applications.**
- Filing a provisional patent application decides the "priority date," or date that the application was filed, which is important because the US is a *first-to-file* country when it comes to granting patents.
- They are also ***not* examined** (challenged by patent office) **against the existing patent landscape.**
  - Provisional patent applications can very well duplicate existing patents and could undergo meaningful change, with major financial implications.
  - **Provisional patent applications have no guarantee of being approved or even defensible.**
- If, in development, the invention changes enough that the provisional patent application's specification no longer covers it, the provisional patent application gives no protection. Any public disclosures of the new invention count as such.
  - Entrepreneurs who are still designing their invention should be careful about the timing of their application.
- **Provisional patent applications show that an entrepreneur has put time and money into obtaining a patent, but they have little value otherwise.**

[22] 35. U.S.C. § 111(b)

- The application is not examined by the USPTO and does not usually hold significant commercial value. It is essentially a placeholder to allow the company to file a non-provisional patent application within a year to keep the early priority date.

- **Key Questions:**
  - Did you perform a Freedom-to-Operate analysis before filing your provisional patent?
  - When do you intend to file your non-provisional application? Do you intend to seek international patent protection?
  - Who is your IP lawyer?

Patent Cooperation Treaty (PCT) Application[23]

- **Goal**: gain international patent protection and postpone filing of non-provisional
- **There is no such thing as a worldwide patent**. Companies must apply for patent protection in each country after filing a PCT.
- International patents have no grace period: any public disclosure before filing can invalidate the patent.
  - Also true for EPO (European Patent Office) – must apply in each country.
  - **Other companies' patent strategies can provide important insights into which countries are important in the industry.**
  - Top five to consider: US, China, Japan, Korea, Europe

[23] 35 U.S.C. § 351

- **Filing a PCT application is another way to delay the non-provisional patent application while maintaining the same priority date.**
    - The PCT application, filed after the provisional, can give the inventor **30 months** between priority date and filing of non-provisional patent.
    - Pros and cons: while the PCT allows for more innovation, this tactic may also delay patent issuance.
    - The PCT also prolongs "pending" status, which is valued lower than issued patents.

Non-Provisional Patent Application[24]

- **Goal**: receive patent protection for the claims of their invention.
- Non-provisional patent applications are made public 18 months after the priority date, so they are often public before the patent is granted.
    - **This means you can access their patent and look at it yourself.**
- During the non-provisional patent application process, the patent is **examined** before approval.
    - The patent examiner often rejects the patent application based on prior art claims (essentially, saying someone else has already patented it)
    - Then, a negotiation of sorts takes place where the inventor often cuts out or reduces the scope of certain claims to satisfy the examiner's requirements. They go back and forth for a bit, and **the patent coverage can be significantly modified**.
    - The patent is either allowed (granted) or abandoned.

[24] 35 U.S.C. § 111(a)

- The USPTO takes 23 months, on average, to approve or deny a patent.[25]
- Overall, at this stage, the patent has the potential to be approved.
    - However, it has not been approved, and investors do not know where the company is in their examination process.
    - There is **no guarantee** that the patent will be granted, let alone granted with similar claims to what was filed.
- **Key Questions:**
    - When did you file your non-provisional patent application?
    - Did you perform a freedom-to-operate analysis?
    - **Who is your IP lawyer?**
    - **How strong of a moat does your patent create?**
    - What do the claims cover, exactly?

Granted/Issued Patent

- **Goal**: defend and commercialize technology within the patent space
- Granted patents are public, examined, and defensible.
    - Granted patents can be rescinded if a litigator cites conflicting prior art, which is why a thorough freedom-to-operate analysis is so important.
    - **Granted patents do not guarantee success.**
        - Patent value, as noted below, stems from the work of the company.
        - Patent infringement requires money and time to defend, and startups are low on those resources.

[25] FY 2020 USPTO

- Once the patent is granted and follow-on patents can be generated, it is important to know who gets IP for adaptations made during manufacturing.
    - Without protection, the manufacturer has the right to file for patents over adaptations they invented ("reduced to practice") in the process of creating the original invention.
    - Rarely, this results in the manufacturer holding the only invention that can be commercialized.
- More prior art is a good thing, since it can mean that the examiner was more thorough, and the patent is less likely to be revoked.
    - In 2020, the USPTO lengthened examination times, which should reduce the number of patents improperly granted.
- **Key Questions:**
    - Does the company own the patent?
    - Do you anticipate any IP-related lawsuits?
    - Who owns IP related to marginal improvements during manufacturing?
    - How strong of a moat does your patent create? What does it cover?

Continuation-in-Part Application (CIP)

- This application involves the addition of new subject matter not sufficiently disclosed in the parent application.
- Earlier subject matter will have the same priority date and all new material will have a later priority date.
- Continuation and divisional applications are similar; they have the same specification as the original application, so they keep the original priority date.

- **Key Questions:**
    - What component has the earliest priority date?
    - Why was the continuation not included in the initial filing?
    - Has the continuation patent been issued? Has the prior patent been issued?

Licensed Patent

- **Goal**: Commercialize existing technology patented by another party.
- An exclusive patent license can be stronger than a patent application, especially a provisional patent application, since the protection exists and terms are set.
- Terms can vary greatly, so know what they are and how they benefit the entrepreneur and patent owner.
- **Nonexclusive licenses could mean competitors could potentially use the same technology.**
- **Key Questions:**
    - Is your license exclusive?
    - What are your terms?

*3. Who has control over the IP?*

Patents give the owner **the right to prevent someone from making/selling an invention.**

- Notably, they do **not** give the owner the right to *create* said invention.
    - Existing patents may cover key elements, and if so, the inventor of the new patent must license the existing patent(s).
    - **Subordinate patents** are filed despite an existing patent covering the base material and are perfectly legal, so long as the existing patent is licensed.

- **The *owner* has rights to the patent.**[26]
    - Rights include the rights to profit, license, and prosecute.
    - Companies are never automatically the owner.
    - The inventor, who applies for and receives the patent, can transfer ownership by "assigning" the patent to the company.

Employee agreements should be in place to ensure IP created by employees is assigned to the company, and employees should file to assign the patent as well.

- The phrasing must be specific (present tense "I will" for a future assignment) to stand up in court. This is worth verifying if employee innovation is key to the company's strategy.
- **Check assignment.uspto.gov to make sure the IP is company-owned.**
    - A patent that says "assigned to [company]" on the first page may not actually be company-owned.

Ownership/inventorship disputes are common in startups.

- Manufacturers who might improve the product should be contractually signing over all IP as well, like the employees.

As a rule of thumb, **inventorship is a fact. Ownership is a choice.**

*4. Who is their IP Lawyer?*

**Patent value stems from how claims are written and handled.**

- For an analyst, claim quality is difficult to gauge, so we ask, "Who is your IP Lawyer?"

[26] 35 U.S.C. 261

- **Most IP lawyers never step foot in a courtroom.** IP lawyers are required to have a technical background (engineering, medical), so it is not surprising that most of these lawyers are not inclined to litigate. This is especially true of in-house patent lawyers.
- **Litigating patent lawyers know how to write claims that will stand up in court:** broad claims that cover key elements of the invention and will block infringement.

If another company infringes on a patent, the patent owner may sue. **The practical, legal value of a patent is that it acts as a deterrent to infringement.**

- **Key idea:** patents give you the right to defend the space; they do not defend space for you.
- To be successful, the company needs **money** (millions) **and time** (years) for litigation.
    - Without resources and expertise, startup companies **cannot reasonably expect to defend** against patent infringement.
- Company profits are difficult to recover.
    - Lost profit lawsuits require that a company be able to prove four *Panduit* factors: (1) demand for patented product (2) absence of acceptable non-infringing substitutes (3) manufacturing and marketing capability to exploit the demand (4) amount of profit the owner would have made.[27]
    - Unsurprisingly, startups with highly speculative markets struggle to win lost profit damages.

[27] *Panduit Corp. v. Stahlin. Bros Fibre Works, Inc*

- Reasonable royalty damages are more common and easier to recover.
    - Of those who receive damages, 60% receive only reasonable royalties.
- Biotech, Pharmaceuticals, and Medical Devices are the most active industries in patent infringement lawsuits and have highest damage awards.
    - Success rate is about 40% for companies that do not settle.

*5. How will their IP generate returns?*

In analyzing patent strategy, the analyst should consider how the patent fits into the overall strategy of the company.

- Some companies, especially medical devices or pharmaceuticals, intend to be acquired before they begin commercialization.
    - For these companies, the value of their patent and its potential market makes up much of their acquisition value, so the defensibility of their patent and quality of their invention is key.
- For others, a patent defends their invention, but they intend to either IPO or exit after demonstrating commercial success.
    - These companies will need to focus more on their customer and branding strategy since their value will be based on their customer base as well as the quality of the invention and its IP protection.
- Patents are intended to protect innovation by granting a short-term monopoly to the inventor.

    - As a result, the entrepreneur should be focused on maximizing returns during their patent lifetime.
    - However, to maximize overall returns, an entrepreneur would ideally generate a strong brand following as well to last past the patent duration.
        - This is not a common strategy in medical device companies, but it is seen in B2C, D2C, and B2B firms.

- **Key Takeaway:** How does the patent add value to the firm? How does the entrepreneur plan to generate value within *and* around the patent space?

Research shows that companies whose patents are granted on their first application are significantly more successful (sales, employees, VC funding, bank loans) than companies whose patents are not. **Patents are valuable outside their legal ramifications.**[28]

- Patent protection increases startup valuation and access to capital.
- Patent protection, especially for inexperienced entrepreneurs, demonstrates capability to external parties.

Patents can be valuable in multiple company contexts.

- **Key idea:** Most of a patent's value comes from the company's work to develop and sell the technology, not from the patent itself. **Patents do not auto-generate value.**
- A company with a single patent is often particularly valuable because of the expertise of its company executives, who know how to use it.
- A company with a platform of IP surrounding a key concept is competitively effective.

[28] Farre-Mensa et al. "What is a Patent Worth?"

- IP with licensing potential can bring in additional revenue, but only if it is not the company's main value generator.
- IP already in the market is ideal since value is being realized and can be more easily quantified.

Some patents are more valuable (effective) than others.

- For example, in a pharmaceutical company, a patent on a small molecule is much stronger than a patent on the process of manufacturing the small molecule. The patent on the process is equally valid, but it is a lot easier to produce a new process that accomplishes the same goal than to produce a new molecule.

Patent Strategy - **Filing**

- Provisional patent applications are a cheaper way to claim an earlier priority date, and in the US, the priority date decides who has priority on the invention.
    - After the priority date, the entrepreneur can also speak about the invention without worrying about public disclosure to investors.
- However, provisional patent applications are only as good as their claims, which need to be well-written and cover the invention as it needs to be defended.
    - For example, writing claims that cover functionality, not just implementation, will have better patent coverage in the long run.
- Filing a Continuation-in-Part application results in a new priority date for additional components. If those components are essential elements, the new priority date can render the provisional application valueless.
- Sheer length is another method to get a patent granted; applications with up to 20,000 claims, tens of thousands of pages in length, are being filed.[29]

Patent Strategy - **Timing**[29]

- Patent filings can be intentionally accelerated or delayed.
    - Accelerated search and examination requests will speed the granting process. They are sometimes used for a company's primary patent or for a patent in a highly innovative industry.
    - Provisional and/or PCT applications can delay the process, which gives the entrepreneur more time to raise money or continue to develop the invention.

Patent Strategy - **International**

- International patents are useful for companies where competitors manufacture products, countries with large target markets, and countries with key distribution channels.
- Important countries for medical device IP include the US, Europe, Japan, China, and Brazil.
- As an early-stage venture, the entrepreneur should be thinking long-term and seeking to protect their invention wherever needed.
- **Key Question:** How does international patent protection affect the company's future cash flows?

Alternate Patent Strategy

- Entrepreneurs often aim to maximize monopoly power through commercialization of their invention.
- However, firms file patents for additional reasons.[29]

[29] Süzeroğlu-Melchiors et al, "Friend or Foe?"

    - Blocking: Patenting the space to increase competitor cost and increase uncertainty.
    - Exploiting: Filing a broad, powerful patent that is not as immediately valuable for licensing or acquisition.
    - Securing: Quickly filing a specific patent to get protection for a niche innovation as fast as possible.
- In addition, some firms are simply "patent trolls."
    - These entities, known as Patent Assertion Entities (PAEs), buy patents from inert owners and use the patents to sue other operators for patent infringement.
    - PAE-targeted firms make up 56% of defendants in IP cases[30]
- Patent strategy can change dramatically depending on the relative value of the patent to the company and on their competitive landscape.
- **Key Question:** How much value does patent protection add?

The most valuable patents can be discerned by identifying traits of those patents sued most frequently: patents that are new, domestically originated, that cite more prior art, are filed by individuals/small companies, and are in mechanical, computer, or medical device industries.[31]

[30] Feng and Jaravel. "Crafting Intellectual Property Rights."
[31] Allison et al. "Valuable Patents."

# CHAPTER FOUR

## An Analyst's Tips for Healthcare Companies

This chapter is designed as a reference for analysts working on their first medical device companies. Through my time in the Baylor Angel Network, I have had the privilege of learning from many mentors and senior analysts. A few key themes and resources have emerged over these semesters, and I highlight those here.

**Do not be afraid to use scientific literature!** Great source for market size or treatment landscapes.

- Google Scholar: Search "[disease] epidemiology" to get population data.
    - Search "[disease] treatments" to understand how well alternate treatments work.
    - Search "[disease] review" to get a meta-analysis where scientists have reviewed the literature for you.

*Insurance Reimbursement*

- Reimbursement is challenging to understand, but it is crucial for a go-to-market strategy.
    - **Doctors want to make money** on a product (be reimbursed for more than cost).
    - Patients want insurance to cover as much as possible.
- Products designed for the elderly or patients with kidney failure (ESRD) are universally covered by Medicare, so Medicare approval is the make-it-or-break it.

- **Most companies will shoot for Medicare approval before targeting individual players in the highly fragmented private insurance market.**
- Other products often use Medicare pricing as a benchmark.
    - Codes are used to standardize billing across providers (doctors) and insurers.
        - HCPCS (Level II) codes refer to specific types of products.
        - CPT (HCPCS Level I) codes refer to procedures.
    - "Fee schedule" is the menu of prices for various product/procedure codes.
    - Medicare prices some HCPCS codes. To find out, go to https://www.cms.gov/medicare/physician-fee-schedule/search.
        - Prices calculated by multiplying the RVU (relative value unit – specific to the device/procedure), the GPCI (geographic adjustor), and a constant conversion factor (accounts for inflation, in dollars).
    - Companies can use "miscellaneous codes," or generic codes, to be reimbursed by CMS (Medicare) and potentially by other insurers immediately upon FDA clearance/approval.
    - They can also file for their own code, but it takes time.

*FDA Terminology – Medical Devices*

- Medical devices are grouped into classes based on intended use and indications for use.
    - A scalpel meant for general use is a Class I device, but it becomes a Class III device when marketed and intended for eye surgery (a specific indication).

- Pre-submission meeting – a meeting when the FDA tells the company what class their device will fall under. This meeting mitigates **substantial** risk. **Companies that have not had their "pre-sub" meeting yet should have exceptionally good reasons for it.**
- Class I devices – devices with minimal risk of harm.
    - FDA approval for Class I devices is easy to achieve.
    - 47% of medical devices are Class I (example: tongue depressors, casts).
    - **95% of Class I devices are exempt from the regulatory process.**
- Class II – most medical devices; receive FDA clearance by de novo or 510(k) pathways.
    - De novo clearance: Unique, novel devices must file a "de novo" application.
        - **This designation indicates a unique competitive positioning.**
        - De novos are not common; they must prove safety and efficacy.
        - **De novo devices, since they are granted FDA approval, not just clearance, can be a significant asset.**
    - 510(k) clearance demonstrates that a device is "substantially equivalent" to an existing, legally marketed device.
        - Some, but few, 510(k)s require clinical data to support clearance.
        - Many companies will do clinical trials regardless so they can market their device with efficacy data.
    - 43% of medical devices are Class II, including catheters and pregnancy tests.

- Class III – devices that sustain or support life, are implanted, or present potential unreasonable risk of illness or injury.
    - PMA (pre-market approval) applications are required for Class III devices.
        - PMA applications require evidence from human clinical trials.
        - **Clinical trials are expensive. Many Class III device companies will seek to be acquired instead of funding their clinical trials.**
    - 10% of medical devices are Class III, including implantable pacemakers, breast implants, or casings for arteriovenous fistulas.

*FDA Terminology – Pharmaceuticals*

- **Only 10% of drugs who pass the IND mark will be approved.**
- Small Molecule (chemical compound that can be created in a lab)
    - IND – permission from the FDA to begin preclinical trials, granted after successful animal data established.
        - Phase I trials aim to establish safety of the drug. Small, low dose.
        - Phase II trials show safety and efficacy. Doses escalate; ideal dose found.
        - Phase III trials demonstrate efficacy and safety and are expensive.
        - Many startups are acquired after successful Phase II trials by major players who can afford Phase III trials.
    - NDA [ANDA]
        - After successfully completing Phase III trials, companies will submit an NDA, or a new drug application.
        - Generics can apply for an ANDA after the original patent expires.

    - PDUFA date
        - The PDUFA date is the deadline by which the FDA must review the NDA.
    - Commercialization, which follows a successful PDUFA date, is an expensive, complex beast, which is another reason that major players who are experienced in commercialization often acquire startups early.
- Biologics (antibody, vaccine – anything that is made in a living cell)
    - Identical except that an NDA is called a BLA, or biologics license application.

# CHAPTER FIVE

## Reflection

Patents are key to the success of many companies that have been screened by BAN analysts. With patent protection, an entrepreneur has permission to sue infringers on their invention, but more importantly, the company has an asset that they can strategically use to generate value. Companies file patent applications in countries with large markets or manufacturer presence to prepare for future growths. They file provisional patent applications early to get the best priority date and allow themselves to publicly disclose their invention. Non-provisional patent applications are the key step in generating the patent asset, and although they still provide no real protection, they demonstrate that the company has finalized their design and has submitted the patent for examination. These strategic uses of the patent are more practical and productive than the two most common assumptions: that a patent is a revenue-driving asset in and of itself or that a patent is only useful to sue infringers.

Patents can be valuable even beyond their commercial context, through sheer statistics, trading potential, or acquisition value. Some see patents as a lottery, knowing one in a million will be the moneymaker. They continually design, create, and develop, assuming that one will succeed in a big way. This strategy is particularly common in industries like pharmaceuticals, where the best commercialization strategy cannot overcome the failings of an ineffective drug. The empirical literature shows that pharmaceutical and medical device patents are more likely to be litigated, which is an indicator of strategic value. However, these same patents are less likely to be renewed, showing that a high proportion simply do not work. This lottery strategy is the justification

behind the high price tag of many medical treatments; every successful treatment must pay for the R&D of ten failed treatments.

Alternatively, other companies collect patents more like trading cards. A company with this strategy will file multiple patents that they use to bargain with competitors in the same space. This strategy uses patents as a form of defense. They will trade an unused patent for the right to work within their ideal space. Lastly, companies know that patents have acquisition value. Acquirers are willing to pay a premium to ensure that their competitors do not have access to the patented technology, especially within highly concentrated industries. This last strategy is the most common for medical device companies in the BAN process. As analysts are investigating patent defensibility, they need to discern how the company intends to use the patent. The analyst should focus on the crowdedness of the space, the defensibility of their idea, and their intent for their patents.

Obtaining, protecting, and capitalizing on the patent is challenging, and the analyst must account for the risk. A company that has filed any sort of application has no guarantee that the patent will be granted. If it is granted, the examination process could radically change the space covered by the patent claims. In addition, defending patent protection in court requires capital and time to cover litigation costs. Legal costs can easily kill a cash-strapped startup. Lastly, patents are not inherently valuable. The company usually must design, market, and launch the product before they can realize the value of their IP. A good analyst realizes that a quality patent is hard to come by, but defensible patent protection is worth the risk.

*Reflections on Specific Companies*

Over the semesters, I screened seven medical device companies that depended on patent protection, and each of those companies shaped this project in a different way.

The first medical device company I screened had patent protection in the US and EU for their main product, an orthopedic screw. However, another startup was developing a nearly identical screw in Europe, and they had their own patent in the EU. I read both companies' patents in detail, and they seemed eerily similar. On the external call, the entrepreneur verified my findings; in fact, the European company was selling somewhat of a knock-off of their screw. However, because my company had patent protection in the US and the EU, the entrepreneur claimed that this competitor would not be an issue. Unfortunately, in this situation, the competitor's patent limited their market size for an already limited subset of surgeries. If it had not been for my experienced angel mentor, I would have had to take the entrepreneur at their word. Later, I would discover that the American company sued the European company for infringement. They needed to regain European market share and were forced to spend valuable time and money to do so. However, at the time, I could not discern between an invaluable patent and a worthless one. I began to investigate what made a patent defensible, and in what situations patents were genuinely valuable.

Months later, I screened a catheter company that had barely filed their provisional patent application. This company was so early-stage that they had not finalized their design, had not had a pre-submission meeting, and were not interested in sharing the details of the provisional patent application without an NDA. I learned that although they had filed an application, they had not finalized their design and were not sure what, exactly, the patent

needed to defend. Companies file to get the earliest possible filing date, but they run the risk of filing too early. If their specification doesn't cover the final product, their early filing is worse than nothing, because they have publicly disclosed an invention without any protection. As this company demonstrated, patents must be general enough to mark out the company's IP territory, but specific enough to carve out their own space in the sea of prior art. Drafting patents is an art, which is why the analyst needs to know the company's patent lawyer and evaluate their experience as a proxy for the patent quality. The analyst cannot assume that every patent is written to cover the device in its final form.

Most recently, I worked with a medical device company that required two patents. The first patent covered the concept of disinfecting a specific tubing with a spacer, and it would be licensed from a university. The second would be the disinfecting device itself, and it was not yet filed. The second would be owned by the company after filing. Four questions needed to be answered: (1) which patent was more important, if either; (2) when the second patent would be filed; (3) what the terms for the license were; and (4) how unique the idea and the design were in reality. These questions introduced substantial risk into the deal. Even though the company was a first-mover in a massive, sleepy market and was led by strong entrepreneurs and mentors, the company received very little investment. Without a filed patent application, the investor could only trust that the entrepreneur would achieve the protection needed to commercialize the product.

### *Final Thoughts*

Understanding patent strategy is particularly important for medical device companies, but these principles apply for any company that depends on patents to hedge against protection. For all intellectual property, protection is valuable only to the degree

that the company builds value around it. The protection is more valuable at later stages of development as the risk decreases. The firm must time their filing correctly to maximize the length of patent term, streamline funding efforts, and write claims that cover the essential elements of the final device. The guides in Chapters 2-4 are intended to direct an analyst's thought process as they preliminarily assess a patent. With direction, analysis of patent protection can become a useful element of the analyst's comprehensive company analysis.

During my years in BAN, I learned far more than how to build Excel models. BAN is the ideal program to teach a student how to handle themselves in stressful, professional situations, how to understand "enough" of an endlessly nuanced company, and how to manage time when thirty-hour days would not be enough. Any BAN analyst would say that they work so hard for BAN because we are working for the investor and the entrepreneur, not for our own gain. We give up free time, weekends, and sleep because if we do our job well, we can connect a capable entrepreneur with the investor who will invest the capital they need to succeed. Because BAN is real-world and hands-on, analysts get their first taste of real work. We provide a service that others need, generating real value for both the entrepreneur and the investor. Wise mentors, driven peers, thoughtful senior analysts, and curious junior analysts leave the program better than they found it as they connect strong companies with investors to seek stellar exits.

# APPENDICES

APPENDIX A

Subjective Analysis

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**Sample Data: All names and financial data are fictitious and any resemblance to an existing company is purely coincidental.**

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## OsteoSynth Therapeutics

Analyst: Rachel Elequin

Mentor: Dr. David Reid

| | |
|---|---|
| Entrepreneur: | Dr. George Matthews, Dr. Sachin Shah |
| Location: | San Diego, CA |
| Founded: | July 2018 |
| Convertible Debt Raise Amount: | $2.0MM |
| Capacity Remaining: | $1.3MM |
| Deal Structure: | Convertible Debt |
| Valuation Cap: | $7.0MM |
| Series A Raise: | $4.0MM |
| Series A Post-Money Valuation: | $15.0MM |
| Series A Year: | 2023 |
| Convertible Debt Interest: | 8% |
| Convertible Debt Discount: | 20% |
| Potential Ownership: | 11.7% |

## Team

*Entrepreneur's background? Past start-up or industry experience? Strengths and weaknesses? Team's ability to exit the business?*

Team:

- Sean Astin, MD: Co-Founder, President and CEO

- *Industry experience – leader in orthopaedic med devices, specifically in screw and plating area - and MBA*
- Long career in medical devices, working up to President of ConMed from initial position as a product developer for orthopedic plates (same niche as OsteoSynth, different product)
- MBA from University of Pittsburgh
- MD from University of Pittsburgh, BS in Biology from Howard Payne University

- Billy Boyd, MBA: CMO
  - *Industry experience – orthopedic research*
  - CMO of Pittsburgh Foundation for Orthopaedic Advancement – increases awareness of orthopaedic research.
  - Director of Research in Dept of Orthopaedic Surgery – University of Pittsburgh
  - MD from University of Pittsburgh
  - BS – Oregon State in Biology
- Dominic Monaghan: CCO
  - *Industry experience – orthopaedic med devices*
  - 4y to current - President of Biologics Consulting – Med device consulting
  - 4y - past CEO of orthopedics company, recently stepped down.
  - Advisor for multiple small startups, no exits
  - Experience in Stryker, DePuy Synthes
  - MS – University of Indiana in Biomedical Engineering

- BS – University of Omaha in Electrical Engineering

- Ian Holm, MBA: Co-Founder, COO
  - *Industry experience – biomedical engineering – and MBA*
  - MBA from University of Pittsburg
  - BA from University Houston in Biomedical Engineering
  - 11y at OsteoSynth – 6y Full-time
  - ~15y total experience in Med-Device or Hospital settings as engineer, IT, and administrator

Board of Directors, in addition to above:

- Aidan Turner: Director
  - *30 years industry experience – medical device executive – two **exits***
  - 4y- Consultant – startups/small businesses
  - 13y- Founder, K2M– **sold** to Stryker in 2018.
  - 9y - VP at Medtronic
  - 8y- Founder, Instent Inc – **sold** to Medtronic in 1996.
  - BBA in Accounting from Baylor University

- Dean O'Gorman: Observer
  - *Experienced in Medical Investments – unsure of involvement.*
  - 15y – Chief Ventures Officer for UT SW
  - 7y – Associate director of BusDev and Equity
  - 15y – clinical and lab research work
  - MA from UChicago in Zoology
  - BA from University of Indiana in Biology

*Questions for Entrepreneur or Mentor:*

- Practicing medical doctors? People who have used the product?
- Who is full-time?
- Can you tell me the story of discovering this idea, creating the product, and bringing it to market?
- Are you personally invested? Is anyone else on the team?
- Do you plan to make key hires in the next few years?
- What is your board involvement?
- What are your salary costs?

*Analyst's Opinion:*

I am concerned to not see a practicing medical doctor on the team or a particularly significant amount of customer feedback happening from surgeons who have used it. The main employee (CMO) seems all-in but was a researching medical doctor and not a practicing doctor. I want to see a lot more customer (surgeon) interaction with this company. They do have exit experience on the board, which is good, but no exit experience in the c-suite. A lot of these guys are from med-device companies, but all seem to have a higher-focus other job except for Holm and Monaghan. The team is strong in experience and expertise, but none are actively involved in medical practices or have exit experience. The board fills in some holes.

## Fatal Flaw and Feasibility

*Fatal flaw? Can the company survive without meeting projections? What will kill this deal or make it a homerun?*

- The company has not demonstrated that the screw fulfills substantial market need.
    - Mentor would like to see data demonstrating decreased failure rate in bone healing when these screws are used.
    - Clinical data in general has not been provided.
    - High price tag requires high value add to the product in order to switch.
    - Normal competitors, the average screw, inherently cheaper due to lack of innovative polymer
- If this deal is something doctors want and need, it is great - very different from competitors' offerings.
    - Zimmer-Biomet screw that claims most of market share.
    - Very similar screw from startup
    - Regular screws

*Questions for Entrepreneur or Mentor:*

- How do doctors know this screw will fix the micromotion problem? What data have you generated?
- How do your prices compare to competitors?
- Is there additional cost to patients or provider when they use this product? Is it recognized by insurance?
- What do you believe is the biggest value add of your product to a surgeon?
- What is the response of KOLs who discover the product? What sort of market traction will you get from each doctor?
- How many screws, on average, are used per surgery? What is your revenue per surgery, on average?

- What does your average sale look like?
- Do you sell primarily screws or screw/plate systems?

*Analyst's Opinion:*

If the market sees that this screw can eliminate all nonunions/failed healings, this screw has potential to help heal with very good science. However, I am not convinced that the failure rate and degree to which this screw eliminates the failure rate justifies switching screws and paying a higher cost. If OsteoSynth can provide significant data to demonstrate that their product solves the problem and that the solution applies to a large percentage of the surgeries happening in this space, this deal will become very interesting.

## Market

*Who is the target customer? Size of target market? Accessible market? What is the go-to-market strategy? Cost of customer acquisition?*

- Future Market Insights (source) Bone Screw System Market (pub 7/2019)
    - Exceed $1.96B by 2028
    - 45% titanium
    - 6.5% growth rate
    - Market led by lower extremity segment – caused by osteoporosis.
    - Market drivers of growth – more cases undergoing surgery and increasing geriatric population.
    - Stainless steel – readily available and cheaper – expected to be most commonly used.
    - North American market expected to grow 7.1% annually.

- Global Market Insights (source) Bone Screw System Market (pub 2019)
- Future Market Insights (source) Bone Screw Market System (pub 6/18)
    - Market worth $1.04B at end of 2018 and expected to grow at CAGR of 6.5% over next ten years.
    - North American segment - $0.25B in 2017 and expected to keep growing at 7.1% annually.
    - Stainless steel has majority of market share - $441.4MM market size but their segment is expected to grow fastest.
    - Primary end users – 66% hospitals, then outpatient, then clinics
- IBISWorld – Orthopedics Products Manufacturing
    - $10.6B Total Revenue – 2019
    - 1.7% growth 2014-2019, 1.7% growth 2019-2024
    - 5.0% profit margins
    - Important drivers – rising elderly population.
- IBISWorld – Surgical Instrument Manufacturing (May 2019)
    - $40.8B 2019 Revenue
    - 0.6% Annual growth 2014-2019, 1.6% annual growth 2019-2024
    - Supporters: aging population, obesity trends
    - High competition, high imports
    - Low revenue growth, lots of people with private health insurance
        - Why is this an issue??
    - Weird industry situation because of healthcare regulations shifting so much recently.

- Orthopedic instruments and implants - $7.91B (19.4% of market)
- Major market drivers:
  - Number of adults 65+ - increasing (2019 est. 54.2MM)
  - Number of people with private health insurance (more likely to use healthcare services) – increasing (1.3% annually)
  - World price of steel – declining, so more likely to buy steel products.
  - Trade-Weighted Index – strength of US Dollar against imports. Decreasing, so dollar is less powerful, imports are more expensive, and companies are incentivized to buy in-country.
  - Federal funding for Medicare and Medicaid – reimbursement rate fluctuation is a potential threat, but increased healthcare coverage means increased spending on healthcare.
- Disposable income expected to grow 1.5% annually over next five years – increased need of surgeries for old/overweight and increased income to spend on elective surgeries (rip, coronavirus)
- Mature industry
- Buyers: hospitals and other treatment centers/wholesalers (distributors?)
- Lots of international activity
- Most companies use third-party distributor.

- When are these surgeries done?
  - Open Reduction Internal Fixation – plates and screws, normally
    - Done when fracture is at/near the joint, where bone would not heal right with only casting/splinting.

        - Rigid fixation – enables direct bone healing (primary) because no micromovement – risk of nonunion.
    - Closed Reduction Internal Fixation – nails, wires, pins.
        - Long bones or elbow fractures in children – enables secondary healing (callus formation)

    Internal fixation in general – reduces non-union/delayed union or malunion.

    When you need it – displaced intra-articular fracture, axial/angular instability, mal-reduction (interposed soft tissue), multiple traumas.

- Wikipedia Internal Fixation
    - ORIF techniques used in serious fractures – comminuted or displaced fractures or where bone would otherwise not heal correctly.
    - Most people do not need it – Hopkins medical.
- Schwoebel statistics (legal) source
    - 6.3 million fractures annually in US
    - 1998 – most fractures requiring hospitalizations were hip (330k), ankle (102k), tibia (68k)
    - 8.6 million visits to orthopedic surgeons in 1998
- source - healthgrades.com 670,000 surgeries every year to repair broken bones.
- Use a LOT of screws per surgery.

*Questions for Entrepreneur or Mentor:*

- Who is your target customer? Who are you marketing to?
- What demographics make up the majority of the trauma market? How much will your company grow from the increase in the geriatric population?

- Are you familiar with MicroTech Innovations, in Germany, who is working on an extremely similar screw? How is your technology different and how will it retain market share in the face of a screw that functions similarly?
- What is your go-to market strategy?
- Does your screw work better with strong bone or weak bone? How well does it work for elderly patients?
- Are there specific surgeries that are better for this type of improved healing? What percentage of breaks will your screw be able to treat? How many?

*Analyst's Opinion:*

Are these surgeries necessary? If they are not essential, they are subject to greater market fluctuations. The market seems favorable (minus COVID-19) with drivers like increasingly aging populations and the obesity epidemic increasing the numbers of surgeries happening. The supplies that OsteoSynth is using are more affordable and widely used, so their cost structures for the metal should ride along with major market turns. I am concerned that I do not know anything about their distribution plan except that they are targeting key doctors to market, and I would like to see a lot from them about how they are going to grow and scale effectively and get those large customer bases. There are many broken bones annually, and the margins are high for these sorts of products, meaning the market is fairly large. However, I would say we are overestimating the market because only a small percentage of breaks require surgery and these screws, while they can probably be used in all surgeries that would use screws, may not be optimal for all surgeries. In a sentence: I am concerned that the market is not big enough.

## Industry and Competition

*Who is the competition? Barriers to entry? Competitive Advantage? Does the company have strategic differentiation? What is the industry growth? Is this good timing for the opportunity?*

- Screws are used more than any other type of implant for internal fixation.
- Key current tenant of orthopedic fixation: bone heals better if the fracture fragments are pressed firmly together.
    - Static – compression produced by fixation device alone.
    - Dynamic – body weight or muscle forces produce additional compression.
    - Do these differences apply in different bones? Or with different screws?
- Types of screws:
    - Cortical – grooved throughout – for harder bone.
    - Cancellous – smooth top, grooved bottom – for softer bone. (lag screw)
    - Cannulated screw – has channel in middle and can be placed more accurately.
    - Topless screws, screws with different threads (resulting in interfragmental compression)
- Solutions to the micromotion problem:
    - Unicortical – short screw, locked on the near side.
        - Torsion means that the screw can kind of wiggle on the inside.
        - I am not seeing much of these.
    - Bicortical – long screw, locked on both sides – very still.
    - Far cortex locking – long screw, locked on the far side.

        - Not as much micromotion inside but wiggles on the near side, next to the plate

- Fracture = break, in common vernacular, I think
- Major competitor – Zimmer Biomet MotionLoc – smaller diameter in near cortex
    - This screw needs radiologists to confirm that the screw tip has completely engaged the far cortex because the motion comes from the slightly-smaller-than-the-hole screw in the near cortex
    - Because the whole value of this screw is in the flexibility, also must be very careful to put it in squarely in the center.
    - Must be detailed and accurate, but procedure is the same.
    - Retains strength while reducing stiffness.
    - Reducing stress
    - Diathesis or metathesis – can mix and match.
    - Delayed unions and nonunions
    - Stiffness has been decreased, which allows for better screw function – stiffness was decreased only at the plate/bone interaction, not within the bone with MotionLoc technology – is that what you want?
    - Movement occurs between plate and bone.
    - 
- Major competitor – MicroTech Innovations
    - starting clinical work in 2020 with their Variable Fixation Locking Screw (VFLS) which is very similar and possibly superior to OsteoSynth's screw.

- CE markings,[32] ISO certified[33].
- seem to be moving ahead into clinical trials.
- EUROPE-based and planning to stay there for a while.
- MicroTech patent
- Dissertation with screw research: https://www.zora.uzh.ch/id/eprint/174361/1/174361.pdf - page 19 has summaries on each of the types of screws. Written by MicroTech associate.
- 
- *This industry is notably quite globalized.*

- Mostly normal screw with locking head (here for the picture for comparative analysis) 5mm standard locking screw from DePuy Synthes
  - 
- Screw costs
  - Foot and ankle screws below $300 per screw – most expensive ~$1000 (these are cannulated) from Arthrex.
- Differentiation – pin-sleeve design allows micromotion.
  - Same – locking head.
  - Same - Full-length threads
  - Motion from: pin-sleeve design allowing micromotion.

[32] CE Markings are given when a device conforms to health, safety, and protection standards within the European Economic Area.
[33] ISO Certification refers to the International Organization for Standardization (ISO), who are an independent, non-governmental group that set manufacturing and documentation standards for quality assurance.

- Pin and sleeve laser welded together.
- Cobalt Chromium Molybdenum alloy
- Self-tapping screw tip – although instructed to pre-drill hole.
- 

- Prices:
  - Small Fragment Locking Plate Instrument Set - $670 (no screws, but lots of other supplies) source
  - Locking Screw Premium Box - $556.20 (for animals, presumably?) source
  - Alibaba – Screw pricing from $5/screw to $60 – made in China.
  - India (various) – screw pricing from $1-5 dollars source source source
- Things to include in competitive analysis for objective: value proposition, method of locking, percent cases applicable for, burden on surgeons, amount stiffness reduced.
- FDA Regulation:
  - Cleared:
    - 510(k) for Forearm
    - Special 510(k) - Distal Fibula
  - Not yet filed: 2021
    - LTF for Proximal Humerus
    - 510(k)/Special 510(k) for Distal Humerus
  - Not yet filed: 2022
    - LTF for Distal Tibia
    - 510(k) for Proximal Tibia

    - Not yet filed: 2023
        - 510(k) for Clavicle
        - Special 510(k) or LTF for Volar (wrist)
- Patents:
    - Orthopedic fixation device with smaller diameter in near cortex
        - Multiple iterations of the Dynamic Locking Screw
        - Filed 2007 – US 8,398,690 – Granted 2013
        - Filed 2012 – US 9,510,879 - Granted 2016
        - Filed 2011 – US 8,740,955 – Granted 2014
        - Filed 2005 – US 8,197,523 – Granted 2012, filed by another company?
        - Filed 2012 – US 8,317,846 – Granted 2012, still held by another company?
- MicroTech has a strong patent – bone screw having innovative proximal shaft portion filed 2001 and granted.
- Looked into articles on deck – cannot access any of those without paying $30 each. Asking entrepreneur for evidence that these screws actually solve the problem.

*Questions for Entrepreneur or Mentor:*

- Who is your target customer? Who are you marketing to?
- Would you explain why particular products are only applicable to certain subsets of orthopedics? Why are products like Clavicle applicable to so many industries but the others are not?
- What FDA Class is your product?

- Would you explain what traits in the product allow you to file an LTF instead of a 510(k) or Special 510(k)?
- How do you set your price? (90% avg screw markup)
- What does an average sale look like for your company?
- When are you going to file for the Distal Humerus' 510(k)?
- How long does it take the polymer head to resorb?
- What types of surgeries are these screws used in? How commonly would they be used if everyone in the world adopted them?
- Are there occasions where it is better to use a combination of DLS and normal locking screws, or just to use the locking screws?
- How many 510(k)s have you filed? How many do you expect to have to?
- Why are there quote marks around the 0 of "0 complications" on your summary slide?

*Analyst's Opinion:*

The orthopedic screw industry is large, with many options available. This is a new issue and a new solution. The big market alternatives were released within the last ten years (and one was recalled), and the other startup competitor, with an identical product, is a few years behind OsteoSynth. I am concerned that this screw is too niche, and that its use will not be widespread enough to support this entire business. However, the market is large, the markup is huge, and the industry is definitely interested in a product like this at this time. This company's offerings are very different from anything else offered on the market right now.

## Scalability

*Does the company have milestones? Are there additional SKUs/contracts/retailers? Do economies of scale exist?*

- Incredible number of existing SKUs because of screws
    - Length
    - DLS (Dynamic Locking Screw) vs regular fully threaded or partially threaded.
    - Compression plates
    - Different bones
    - Currently selling – hardware:
        - Screws: 33 DLS Locking, 33 normal locking, 33 non-locking cortex, 25 non-locking cancellous fully threaded, 25 non-locking cancellous partially threaded
        - Plates: 3 straight locking compression plates
    - Coming soon:
        - 9 distal fibula LCP, 4 distal tibia LCP, 7 proximal humerus LCP
- If they succeed in making this screw a staple in the market, this is simply scalable to additional markets by developing different plates, from my understanding.
- Also, good target for strategic because most of their pieces can be replaced by common screws that anyone sells, but the important parts are the DLS technology specifically – companies that have already developed different platings could easily expand offerings.
- Not seeing anything regarding distributors in their plan to grow

- Plan for Distribution:
    - Target Key Opinion Leaders in Trauma – well-known surgeons who will effectively act ask reps? – in tertiary care centers.
    - Target KOL in Trauma and subspecialty ortho in tertiary care, community centers, select surgicenters.
    - Target all ortho doctors everywhere – tertiary, community, surgicenters.

*Questions for Entrepreneur or Mentor:*

- Would you walk us through the next five years of your company?
- Would you walk us through the distribution timeline on your deck, with an idea of when each of these milestones would be achieved?
- Do you have relationships with distributors? Do you intend to grow them? What role do you see distributors playing for your company?
- How do you get into new markets and sell your product to key opinion leaders?
- What is your reasoning behind the shift into external fixators and hip fixators in 2023?
- What is your go-to market channel?
- Why did you choose to target KOLs?
- Where do you see this company in 5 years? In 10?

*Analyst's Opinion:*

The company's ability to scale is dependent on how much surgeons want this screw. If the market is big enough and orthopedic surgeons truly see the value in this screw, which I have been convinced is present, the product will scale simply. I have a lot of questions about their distribution channels, because if they are targeting individual doctors, it does

not seem efficient. I want to know why they are not using distributors or contract manufacturers to promote this product.

## Financial Projections

*What are the assumptions? Does the model make sense? Is sales growth believable? What is the burn rate? Do they consider cash on hand? When will they need to raise additional capital?*

- **Current burn rate: $132k/month or $1.6M/year**
    - Payroll: $45k/month or $537k/year
    - R&D: $54k/month or $648k/year
    - Regulatory: $1.75k/month or $20k/year
    - Legal and IP: $4k/month or $48k/year
    - Rent: $5.3k/month or $64k/year
    - Misc.: $1.3k/month or $16k/year
- **18-month runway**
- Assumed Seed close in 2021, Series A close in 2022, and Series B close in 2023.
    - Financial projections list $15MM Series B, Deck says $20MM Series B.
- Assume increase #patients/orthopedist significantly over time.
    - 60 patients/one orthopedic network in Y1
    - 510 patients/one orthopedic network in Y2
    - 2800 patients/three orthopedists in Y3 (1400 patients/orthopedic network)
    - 7900 patients/six orthopedists in Y4 (1320 patients/orthopedic network)

    - 16800 patients/twelve orthopedists in Y5 (1400 patients/orthopedic network)
- Assume exponential growth in number of orthopedists over time.
    - 1 Y1, 1 Y2, 2 Y3, 6 Y4, 12 Y5
- Assume FDA clearance in 2023 and successful clinical trials alongside FDA clearance.
- Economies of scale built into model – achieved at Year 3 of manufacturing, which seems early.
- Steady $600k in salaries after Y3, but early G&A costs do not match the salary burn rate.

*Questions for Entrepreneur or Mentor:*

- Why do you anticipate increasing your number of patients per orthopedic network so drastically through year 4?
- Have you had any communication with the FDA thus far for this device?
- What are your R&D expenses? What are your salary expenses?
- Who is taking a salary?

*Analyst's Opinion:*

Payroll is high. Burn rate is high, but that is to be expected with med device companies, and they seem to have budgeted for it. I am not particularly keen with the near-equivalent payroll and R&D budget, especially when it looked like the founders were only tangentially involved in the business.

## Deal Structure

*Is there a lead investor? Are the terms set? What are the terms? Is there a board seat available?*

- Previous raise - $2MM in Convertible Debt from angel investors
- Current raise - $2MM in Convertible Debt, $1.3MM remaining.
    - 8% interest
    - 20% discount
    - 24-month maturity
    - Valuation cap: $7MM
    - IRR: 87%
- Future raise - $4.0MM Equity from VC firms
    - Valuation: $15MM
    - Year: 2022
    - IRR: 159%
- Anticipated Series B - $15MM
    - Estimated Valuation: $50MM.
    - Year: 2025
    - IRR: 92%

*Questions for Entrepreneur or Mentor:*

- What are the terms of the convertible note? Are they set?
- What is the use of funds for this raise?
- What is your valuation? How did you arrive at this number?
- Are the terms set? Is there a lead investor for this round?
- Why are you raising a convertible note?

- Is there a board seat available for a lead investor?

*Analyst's Opinion:*

Very little information was included, and a thorough analysis will be done once anything involving current valuations or full financials are known.

## Exit Opportunity

*How does the entrepreneur view the exit opportunity? Do they have particular companies or strategies in mind? Is there M&A activity in the industry?*

- Ample M&A activity in the industry
- Notably: in contrast to the deck, I cannot find evidence of Zimmer-Biomet acquiring the MotionLoc technology – instead, in 2010, Zimmer was seeing clinical trial success with the technology
- Medical devices multiples:
    - McKinsey – 21.3x EBITDA general medical devices (May 2019)
    - source - the healthcare investor - EBITDA multiples ranging from 10s to teens (April 2019)
- Strategic acquisitions:
    - Make sense in other major ortho manufacturers who can quickly manufacture this screw.
        - Similar in material to average screws
        - 20 major transactions in 2019 as of October
    - DePuy Synthes (JNJ)

        - Had previous interest in the micromotion problem – their screw was recalled a few years ago.
        - Acquired by JNJ this year, so would be well-timed to buy a complimentary screw around when OsteoSynth is ready for an exit.
    - Stryker
        - Major orthopedic manufacturer and significant acquisition presence – biggest seller of drills
    - Smith & Nephew
        - Recent acquisitions in the joint reconstruction business
        - Joint reconstruction is potentially relevant to OsteoSynth's screws.
    - Contract manufacturers
        - Consistently lower cost and high returns – could manufacture the screws cheaply and efficiently to increase margins but would not innovate further.
- Financial:
    - PE firms based on high CFs.
- Medartis is trading at 3x revenue.
- Globus is trading at 5x revenue.
- Stryker is trading at 4.5x revenue.
- Wright Medical acquired by Stryker for 6x revenue.
- Vilex acquired OrthoPediatrics for 5x revenue.
- Invuity acquired by Stryker for 5x revenue.

*Questions for Entrepreneur or Mentor:*

- What do you see being the most likely exit potential for your company?
- What milestones would you like to hit before looking at exits?
- How much additional funding will your company require before it is ready to be acquired?
- Have you had conversations with potential acquirers?

*Analyst's Opinion:*

The MedTech industry continues to see high levels of M&A. OsteoSynth's products can be easily manufactured using supply chains already present in most large companies, and the synergies of selling a company's own plating systems with OsteoSynth's DLS screws could be high. Companies such as Stryker and DePuy Synthes (JNJ) could both reasonably look into acquiring OsteoSynth to complement their current product offerings, since the only other significant micromotion-giving screw is owned by Zimmer-Biomet.

APPENDIX B

Objective Analysis – Presentation

**Sample Data: All names and financial data are fictitious and any resemblance to an existing company is purely coincidental.**


Figure 1: Title Page and Invite Recommendation

## Deal Overview

Baylor Angel Network

*OsteoSynth has $1.3MM remaining in its $2MM convertible note and intends to raise their Series A raise by early next year*

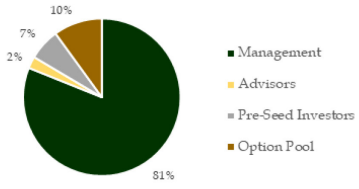
### TOPLINE

- Raise Amount: $2MM
- Capacity: $1.3MM
  - Committed Capital: $725k
- Potential BAN Ownership after conversion upon Series A raise: 11.7%
- Financing Structure: Convertible Note
- Stage: Seed

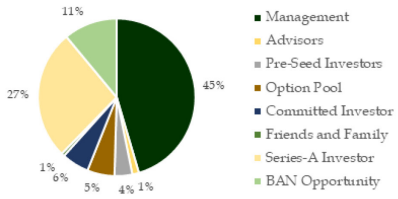
### KEY TERMS

- Discount: 20%
- Valuation Cap: $7.0MM
- Maturity: 24 Months after investment
- Interest: 8%
- Series A Raise: $4MM on a $15MM post-money
  - Forecasted for 2021

### PRE-MONEY OWNERSHIP




### POST-MONEY OWNERSHIP[1]




1: Assuming that BAN fills remaining capacity. Assuming that convertible notes convert at Valuation Caps.

Figure 2: Deal Overview

## Business Overview

Baylor Angel Network

*OsteoSynth sells a screw that theoretically reduces the failure (nonunion/ malunion) rates of orthopedic surgeries that require plating and screw systems.*

### PROFILE

- OsteoSynth is an orthopedic company selling screws with an innovative pin-and-sleeve design
- The screw is bicortical, meaning it locks into both the hard edges of bone, and has a locking head
- Screw pictured: 
- Current surgeries have a risk of nonunion, which is when the bones are so securely held by the plate and screw that they forget to heal
- OsteoSynth's screw allows micromotion to trigger healing while still holding the plate and bone in place in a macro sense
- Founded in 2018 by Sean Astin, who has decades of medical device experience and brought the patents to the team, OsteoSynth has been granted five patents since 2005 for its DLS screw
- They are currently in the forearm plating market, with plans to launch their first ankle and upper-arm plating systems with this raise
- The company plans to apply for FDA clearance repeatedly, for each system, over the next four years

### STRENGTHS

- Post-Revenue with forearm plating system
- Team is experienced in orthopedic device industry
- Competition does not offer a satisfactory solution to mitigate the increased risk of nonunion in weak or compromised bone
- DLS Screw, OsteoSynth's main value proposition, can be easily sold with any plating system from Osteo, so it can solve this problem all over the body

### FLAWS

- Due to high R&D and long timelines, the team may need further raises to get to an acquisition, which would dilute ownership
- The overall screw market (TAM) is large, but the surgeries that OsteoSynth benefits (SAM) make up only a small percentage
- High burn rates and expensive development mean the company requires large amounts of cash to get to an acquisition event

Figure 3: Business Overview

## Market Landscape

Baylor Angel Network

*The orthopedic screw market is expected to grow with the geriatric population and obesity epidemic. However, the OsteoSynth screw applies only to select surgeries, further segmenting the market.*

### TARGET MARKET

- The orthopedic bone and screw market is large, but the DLS screw primarily benefits compromised/ weak bone and patients who don't heal well
- TAM: $1.04B[1] in 2018 - Bone Screw and Plate market
  - SAM: Surgeries at high risk of failure[2]
    - Failure rates: 25% D. Femur, 15% D. Tibia, 8% P. Tibia, 6% P. Humerus, and lower
  - Highly globalized industry
  - Estimated 6.5% CAGR[1]

### BARRIERS TO ENTRY

- OsteoSynth must convince surgeons that the failure rate of these surgeries is high enough to pay a premium for their innovative screw
- Current solutions either eliminate micromotion completely, increasing risk of nonunion (no-healing) or encourage micromotion within bone, which harms the bone's interior and creates large holes
- IP defends plates, but not screw
- FDA approval required for every new system.

### GO-TO-MARKET STRATEGY

- Primary Market Channel: Key Opinion Leaders
- Market Strategy:
  - Connect with Key Opinion Leaders (KOLs) – orthopedic trauma surgeons
  - KOLs work with hospitals' Value Analysis Committees to bring the DLS screw system in-hospital
  - OsteoSynth contracts independent sales reps to restock surgery kits after use
- Market acquisition driven by surgeons, not patients

### OUTLOOK

- Demand will continue to grow:
  - Growing geriatric population, who are most at-risk for falls and have the highest surgery failure rates, benefit specifically from this screw
  - Trauma surgeries are not elective, so demand is less subject to market forces
  - Competition to solve this problem is weak
- IP in both US and EU will protect the screw's design, its major competitive edge, which is a strong hedge against competition

Sources: [1]Future Market Insights, 2018 [2]Management estimate: 1.6% market share by 2025

Figure 4: Market Landscape

## Head-to-Head Comparison

Baylor Angel Network

*OsteoSynth's product is well-designed to optimize healing. The screw has not yet demonstrated market success or been clinically proven but is the best solution scientifically.*

| PRODUCT | SCREW DESIGN | VALUE PROPOSITION | MAJOR DRAWBACKS |
|---|---|---|---|
| Zimmer-Biomet MotionLoc Screw | ▪ Far-unicortical screw with locking head  | ▪ Allows micromotion<br>▪ Currently only screw allowing micromotion on the market | ▪ Micromotion in bone's near cortex enlarges screw hole<br>▪ Constant micromotion |
| Biomech Innovations Variable Fixation Locking Screw | ▪ MotionLoc ^ that delays micromotion with polymer  | ▪ Fixes weakness of MotionLoc: by optimally delaying micromotion | ▪ Micromotion in bone's near cortex enlarges screw hole<br>▪ Likely patent conflicts in US |
| Average Locking Screw | ▪ Bicortical, threaded head that locks into plate  | ▪ Superior in weak/compromised bone and near joints<br>▪ Most common | ▪ Lack of micromotion increases risk of nonunion |
| Average Non-Locking Screw | ▪ Bicortical, smooth head  | ▪ Variable angle – allows surgeon more flexibility<br>▪ Cheapest option, oldest option | ▪ Not secure enough for weak/compromised bone |
| OsteoSynth **Tx** Dynamic Locking Screw | ▪ Pin-and-sleeve design, bicortical, locking head  | ▪ Micromotion within screw<br>▪ Bicortical design is better for weak/compromised bone | ▪ Constant micromotion<br>▪ Priced higher than what hospitals pay for avg screws |

Note: OsteoSynth surgery kit sold at the price hospitals are already paying for plates and normal screws. DLS screws are 3x the price of regular screws while the rest of the kit is sold at market price.

Figure 5: Head-to-Head Comparison

## Team

Baylor Angel Network

*The team is experienced in the medical device industry and has exit experience on the board; there are no practicing or previously practicing medical doctors*

**MANAGEMENT TEAM**

- Sean Astin, MD, MBA: Co-Founder, President ,CEO
  - Past President at ConMed – 25 years of experience with orthopedic device company
  - MD, MBA from University of Pittsburgh
- Billy Boyd, MBA: CMO
  - CMO of Pittsburgh Foundation for Orthopaedic Advancement (research)
  - Director of Research in Dept of Orthopaedic Surgery – University of Pittsburgh
- Dominic Monaghan: CCO
  - President of Biologics, Medical Device Consulting
  - Past CEO of orthopedics company
  - Experience in Stryker, DePuy Synthes
- Ian Holm, MBA: Co-Founder, COO
  - 15 years of experience in Med-Device or Hospital settings as engineer, IT, and administrator
  - MBA from University of Pittsburg
  - BA from UHouston in Biomedical Engineering
  - 11y at OsteoSynth – 6y Full-time

**BOARD OF DIRECTORS**

- Aidan Turner: Director
  - 30 years industry experience with two exits
  - Currently runs a consulting business for startups and small businesses
  - Founder of K2M, which sold to Stryker in 2018
  - Past VP at Medtronic
  - CFO for Instent Inc, which sold to Medtronic in 1996
  - BBA in Accounting from Baylor University
- Dean O'Gorman: Observer
  - Chief Ventures Officer for UT SW
  - Expert in Health Investments
  - Advisor for multiple health-directed VCs or funds, especially one that invested in OsteoSynth last round

Figure 6: Team

## Funding and Scale

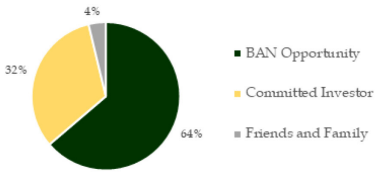
Baylor Angel Network

*OsteoSynth will launch their ankle plating system, significantly more valuable to surgeons than their current offerings, and scale with that product*

**PLAN TO SCALE**

- With this raise, OsteoSynth will file their Distal Fibula plating system with the FDA (Special 510(k)).
- Four months after funding - Distal Fibula (*ankle*) plating system launched and in hospitals
- Also in 2021 – file Proximal Humerus (*arm*) plating system with FDA (LTF) and launch Proximal Humerus system
  - Notably, existing ankle systems have some of the highest failure rates (Distal Tibia, 15% per Khalsa et al), increasing DLS value
- Also intend to hire VP of Sales to increase the number of hospitals in their network
  - Ankle plating system is significantly more valuable to surgeons than current forearm offerings, because of the ankle's higher risk of nonunion and the larger volume of ankle surgeries
  - Increased value of DLS system will drive number of hospitals interested in this technology

**SOURCES**




**USES**

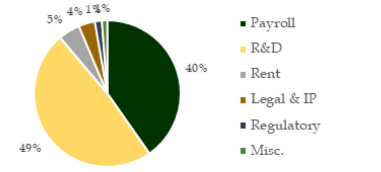



Figure 7: Funding and Scale

## Financial Projections

Baylor Angel Network

*Management predicts massive growth in revenue for 2021 as the ankle plating systems are released and sales efforts are increased.*

**MANAGEMENT MODEL**

| in 000s | 2017A | 2018A | 2019E | 2020E | 2021E | 2022E | 2023E | 2024E | 2025E |
|---|---|---|---|---|---|---|---|---|---|
| Sales | $0.0 | $0.0 | $0.0 | $0.0 | $319.0 | $2,959.0 | $16,478.0 | $46,145.0 | $98,945.0 |
| Orthopedic Networks | | | | | 1 | 1 | 2 | 6 | 12 |
| Surgeries | | | | | 60 | 510 | 2800 | 7900 | 16800 |
| *% Growth* | | *n/a* | *n/a* | *n/a* | *n/a* | *828%* | *457%* | *180%* | *114%* |
| (-) Cost of Goods Sold | ($0.0) | ($0.0) | ($0.0) | ($0.0) | ($151.2) | ($1,166.4) | ($4,849.2) | ($13,597.2) | ($29,149.2) |
| Gross Profit | $0.0 | $0.0 | $0.0 | $0.0 | $167.8 | $1,792.6 | $11,628.8 | $32,547.8 | $69,795.8 |
| *Gross Margin* | *n/a* | *n/a* | *n/a* | *n/a* | *53%* | *61%* | *71%* | *71%* | *71%* |
| (-) SG&A | ($9.6) | ($15.6) | ($1,188.0) | ($1,824.0) | ($3,024.0) | ($5,208.0) | ($6,312.0) | ($11,832.0) | ($13,008.0) |
| **EBITDA** | **($9.6)** | **($15.6)** | **($1,188.0)** | **($1,824.0)** | **($2,856.2)** | **($3,415.4)** | **$5,316.8** | **$20,715.8** | **$56,787.8** |
| *EBITDA Margin* | *n/a* | *n/a* | *n/a* | *n/a* | *n/a* | *n/a* | *32%* | *45%* | *57%* |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| Sales | $0 | $0 | $0 | $0 | $319 | $2,959 | $16,478 | $46,145 | $98,945 |
| EBITDA | ($10) | ($16) | ($1,188) | ($1,824) | ($2,856) | ($3,415) | $5,317 | $20,716 | $56,788 |

Figure 8: Financial Projections

## Financial Drivers and Assumptions

Baylor Angel Network

*Release of ankle plates expected to drive revenue up by 830% after past year while expenses are driven by low R&D, COGS, and high accrued salaries.*

**REVENUE DRIVERS & ASSUMPTIONS**

- Ankle products (Distal Fibula and Proximal Humerus) to be released in 2021
  - High volume of ankle and arm surgeries
  - High risk of non/malunion means higher value of using DLS screw
- Revenue depends on successful acquisition of large orthopedic networks, prior to Medicare coverage
- Over four years, intend to release plating systems for seven different areas of the body

**COST DRIVERS & ASSUMPTIONS**

- Research and Development costs average 17% of overall expenses
  - New products are very similar to previously released products, so require less FDA approval
- COGS assume economies of scale as sales and production increase; margins increase to 70% in Y6
- Salaries are high, but employees are not paid in full until device is commercialized

**MANAGEMENT FORECAST OVERVIEW - $ IN 000s**

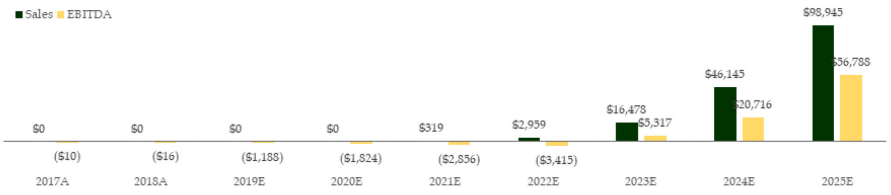
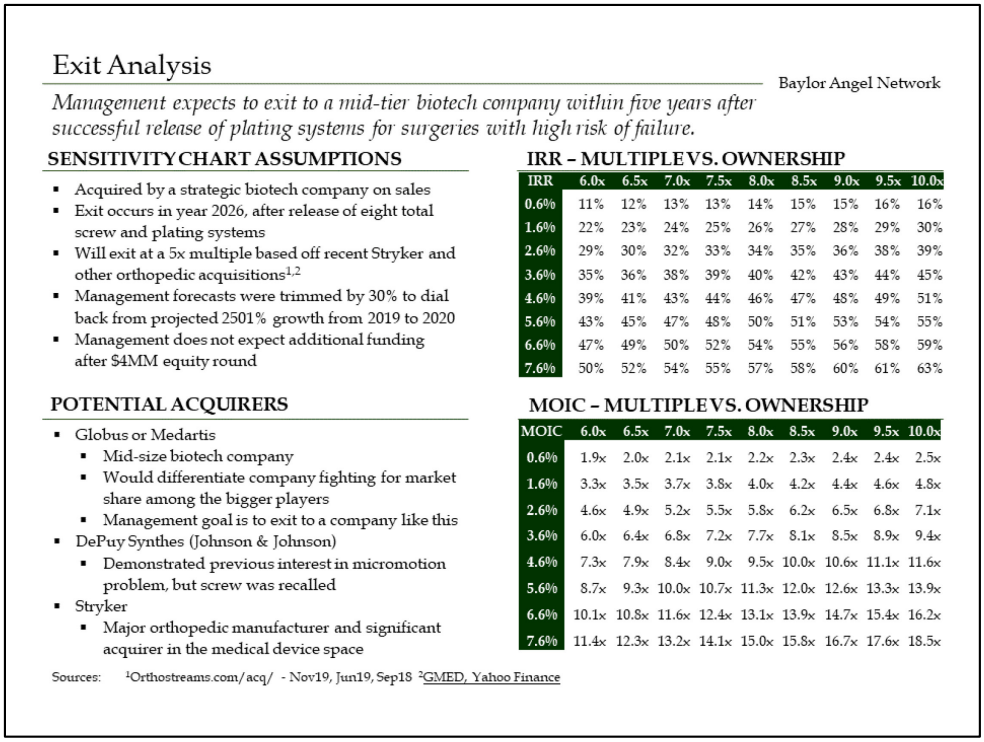



Figure 9: Financial Drivers and Assumptions



## Exit Analysis

Baylor Angel Network

*Management expects to exit to a mid-tier biotech company within five years after successful release of plating systems for surgeries with high risk of failure.*

### SENSITIVITY CHART ASSUMPTIONS

- Acquired by a strategic biotech company on sales
- Exit occurs in year 2026, after release of eight total screw and plating systems
- Will exit at a 5x multiple based off recent Stryker and other orthopedic acquisitions[1,2]
- Management forecasts were trimmed by 30% to dial back from projected 2501% growth from 2019 to 2020
- Management does not expect additional funding after $4MM equity round

### POTENTIAL ACQUIRERS

- Globus or Medartis
  - Mid-size biotech company
  - Would differentiate company fighting for market share among the bigger players
  - Management goal is to exit to a company like this
- DePuy Synthes (Johnson & Johnson)
  - Demonstrated previous interest in micromotion problem, but screw was recalled
- Stryker
  - Major orthopedic manufacturer and significant acquirer in the medical device space

### IRR – MULTIPLE VS. OWNERSHIP

| IRR | 6.0x | 6.5x | 7.0x | 7.5x | 8.0x | 8.5x | 9.0x | 9.5x | 10.0x |
|---|---|---|---|---|---|---|---|---|---|
| 0.6% | 11% | 12% | 13% | 13% | 14% | 15% | 15% | 16% | 16% |
| 1.6% | 22% | 23% | 24% | 25% | 26% | 27% | 28% | 29% | 30% |
| 2.6% | 29% | 30% | 32% | 33% | 34% | 35% | 36% | 38% | 39% |
| 3.6% | 35% | 36% | 38% | 39% | 40% | 42% | 43% | 44% | 45% |
| 4.6% | 39% | 41% | 43% | 44% | 46% | 47% | 48% | 49% | 51% |
| 5.6% | 43% | 45% | 47% | 48% | 50% | 51% | 53% | 54% | 55% |
| 6.6% | 47% | 49% | 50% | 52% | 54% | 55% | 56% | 58% | 59% |
| 7.6% | 50% | 52% | 54% | 55% | 57% | 58% | 60% | 61% | 63% |

### MOIC – MULTIPLE VS. OWNERSHIP

| MOIC | 6.0x | 6.5x | 7.0x | 7.5x | 8.0x | 8.5x | 9.0x | 9.5x | 10.0x |
|---|---|---|---|---|---|---|---|---|---|
| 0.6% | 1.9x | 2.0x | 2.1x | 2.1x | 2.2x | 2.3x | 2.4x | 2.4x | 2.5x |
| 1.6% | 3.3x | 3.5x | 3.7x | 3.8x | 4.0x | 4.2x | 4.4x | 4.6x | 4.8x |
| 2.6% | 4.6x | 4.9x | 5.2x | 5.5x | 5.8x | 6.2x | 6.5x | 6.8x | 7.1x |
| 3.6% | 6.0x | 6.4x | 6.8x | 7.2x | 7.7x | 8.1x | 8.5x | 8.9x | 9.4x |
| 4.6% | 7.3x | 7.9x | 8.4x | 9.0x | 9.5x | 10.0x | 10.6x | 11.1x | 11.6x |
| 5.6% | 8.7x | 9.3x | 10.0x | 10.7x | 11.3x | 12.0x | 12.6x | 13.3x | 13.9x |
| 6.6% | 10.1x | 10.8x | 11.6x | 12.4x | 13.1x | 13.9x | 14.7x | 15.4x | 16.2x |
| 7.6% | 11.4x | 12.3x | 13.2x | 14.1x | 15.0x | 15.8x | 16.7x | 17.6x | 18.5x |

Sources: [1]Orthostreams.com/acq/ - Nov19, Jun19, Sep18 [2]GMED, Yahoo Finance

Figure 10: Exit Analysis

# APPENDIX C

## Objective Analysis – Spreadsheet

**Sample Data: All names and financial data are fictitious and any resemblance to an existing company is purely coincidental.**

The objective analysis is summed up in the presentation in Appendix C, but the data underlying all graphs and tables comes from Excel work. For each model, I explain the purpose of that component. First, the Financial Projections model inputs management's estimates to visualize Revenue and EBITDA growth. The analyst looks at revenue drivers to understand how the company plans to scale. Often, they will cut revenues by 30-50% to arrive at reasonable growth rates, based on unit economics.

| | |
|---|---|
| Last Historical | 2018 |
| First Estimate Date | 2020 |
| Last Projection Year | 2026 |
| Maximum Growth | 1,000.0% |

*Management Model*

| in 000s | 2018A | 2019A | 2020E | 2021E | 2022E | 2023E | 2024E | 2025E | 2026E |
|---|---|---|---|---|---|---|---|---|---|
| Sales | $0.0 | $0.0 | $0.0 | $0.0 | $319.0 | $2,959.0 | $16,478.0 | $46,145.0 | $98,945.0 |
| Orthopedic Networks | | | | | 1 | 1 | 2 | 6 | 12 |
| Patients | | | | | 60 | 510 | 2,800 | 7,900 | 16,800 |
| *% Growth* | | *0%* | *0%* | *0%* | *ND* | *828%* | *457%* | *180%* | *114%* |
| (-) Cost of Goods Sold | (0.0) | (0.0) | (0.0) | (0.0) | (151.2) | (1,166.4) | (4,849.2) | (13,597.2) | (29,149.2) |
| Gross Profit | 0.0 | 0.0 | 0.0 | 0.0 | 167.8 | 1,792.6 | 11,628.8 | 32,547.8 | 69,795.8 |
| *Gross Margin* | *2%* | *2%* | *2%* | *2%* | *53%* | *61%* | *71%* | *71%* | *71%* |
| (-) SG&A | (9.6) | (15.6) | (1,188.0) | (1,824.0) | (3,024.0) | (5,208.0) | (6,312.0) | (11,832.0) | (13,008.0) |
| **EBITDA** | **($9.6)** | **($15.6)** | **($1,188.0)** | **($1,824.0)** | **($2,856.2)** | **($3,415.4)** | **$5,316.8** | **$20,715.8** | **$56,787.8** |
| *EBITDA Margin* | *0%* | *0%* | *0%* | *0%* | *0%* | *0%* | *32%* | *45%* | *57%* |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| Sales | $0 | $0 | $0 | $0 | $319 | $2,959 | $16,478 | $46,145 | $98,945 |
| EBITDA | ($10) | ($16) | ($1,188) | ($1,824) | ($2,856) | ($3,415) | $5,317 | $20,716 | $56,788 |

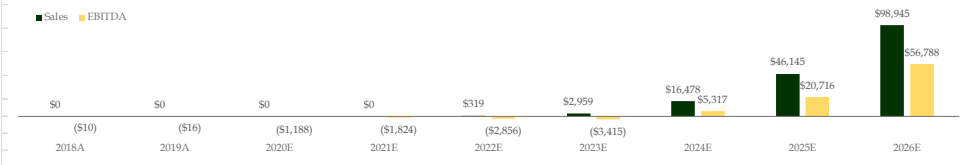


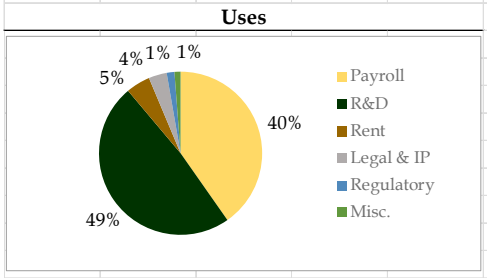

Figure 11: Financial Projections Model

The Sources graph provides a clear visualization of how much is remaining in the raise. The Uses graph illustrates where investor funds will be allocated, which is crucial to an investor who is handing capital to an entrepreneur with the intent of growing their business. This graph is highly scrutinized if most of the funds are not going toward R&D or Marketing efforts. For example, this Uses graph shows 40% of the raise going towards payroll, which is acceptable, but not desirable.

| Uses | |
|---|---|
| Payroll | $805 |
| R&D | $972 |
| Rent | $96 |
| Legal & IP | $72 |
| Regulatory | $31 |
| Misc. | $24 |
| Use 7 | $0 |
| Use 8 | $0 |
| Use 9 | $0 |
| Total | $2,000 |
| | =SUM(E3:E11) |

| Equality | |
|---|---|
| Check | TRUE |
| | =E12=L12 |

| Sources | |
|---|---|
| BAN Opportunity | $1,275 |
| Committed Investor | $650 |
| Friends and Family | $75 |
| Investor D | $0 |
| Investor E | $0 |
| Investor F | $0 |
| Investor G | $0 |
| Investor H | $0 |
| Investor I | $0 |
| Total | $2,000 |
| | =SUM(L3:L11) |



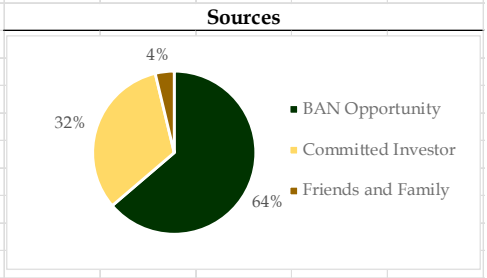




Figure 12: Sources and Uses

The capitalization table model calculates ownership by identifying share prices and ownership percentages for key parties. The convertible note model, shown here, applies when the entrepreneur is offering a debt instrument that will convert into equity upon completing a qualified "priced round." I reworked this model to correctly account for management dilution and model the correct share prices. To do so, I added the "Previous Shares (000s)" cell and backed into the algebraic calculation required to find price per share for each party. I also set the "Convert at Cap?" cell to convert automatically to the lowest price between the investor's capped share price and discounted share price.

| Pre-Money | | | |
|---|---|---|---|
| Entity | Shares | % Ownership | |
| Management | 5,000,000 | 81.1% | =G5/$G$9 |
| Advisors | 150,000 | 2.4% | =G6/$G$9 |
| Pre-Seed Investors | 400,000 | 6.5% | =G7/$G$9 |
| Option Pool | 616,000 | 10.0% | =G8/$G$9 |
| **Total** | **6,166,000** | **100.0%** | =G9/$G$9 |

| Sources | | |
|---|---|---|
| Entity | Investment | |
| BAN Opportunity | $1,275 | ='Sources & Uses'!L3 |
| Committed Investor | $725 | =SUM('Sources & Uses'!L4:L5) |
| Total | $2,000 | =SUM(H15:H16) |

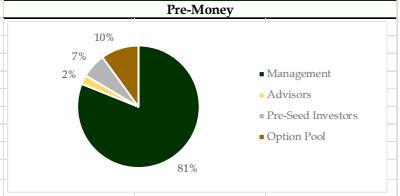
| Scenario 2: Convertible Note | | |
|---|---|---|
| BAN Opportunity | 10.4% | =INDEX($H$42:$H$48,MATCH($F$22,F42:F48,0)) |
| BAN Initial Investment | $1,275.0 | =+$D$5 |
| Total Shares Out | 10,810,519 | =+G49 |
| | | |
| Note Size: | $2,000.0 | =H17 |
| Discount: | 20% | |
| Interest Rate: | 8% | |
| Valuation Cap: | $7,000 | |
| Convert at Cap? | Yes | =+IF(Previous_Shares>(Seed_Shares__Cap-Series_A_Valuation)*(1-Valuation_Cap),0,1) |
| Previous Shares (000s) | 6,166 | =G9/1000 |
| Series-A Raise | $4,000.0 | |
| Series-A Valuation | $15,000 | |
| Seed Shares (if Cap, 000s) | 1,762 | =Note_Size/(Valuation_Cap/Previous_Shares) |
| Seed Ownership | 16.3% | =IF(Convert_at_Cap?=0,Note_Size/(1-Discount)/Series_A_Valuation,Seed_Shares__Cap/(Seed_Shares__Cap+Previous_Shares)*(1-Series_A_Ownership)) |
| Series A Ownership | 26.7% | =Series_A_Raise/(Series_A_Valuation) |
| Previous Ownership | 57.0% | =IF(Convert_at_Cap?=1,Previous_Shares/((Seed_Shares_Cap+Previous_Shares)/(1-Series_A_Ownership)),Previous_Shares/(Seed_Shares__Cap+Previous_Shares)*(1-Series_A_Ownership)) |

| Post-Money | | | |
|---|---|---|---|
| Entity | Shares | % Ownership | |
| Management | 5,000,000 | 46.3% | =+G42/$G$49 |
| Advisors | 150,000 | 1.4% | =+G43/$G$49 |
| Pre-Seed Investors | 400,000 | 3.7% | =+G44/$G$49 |
| Option Pool | 616,000 | 5.7% | =+G45/$G$49 |
| Committed Investor | 638,621 | 5.9% | =+H16/$H$17*$H$35 |
| Series-A Investor | 2,882,805 | 26.7% | =+H36 |
| BAN Opportunity | 1,123,093 | 10.4% | =+H15/$H$17*$H$35 |
| **Total** | **10,810,519** | **100.0%** | =SUM(H42:H48) |

| Post-Money | | |
|---|---|---|
| Entity | Shares | % Ownership |
| Management | 5,000,000 | 46.3% |
| Advisors | 150,000 | 1.4% |
| Pre-Seed Investors | 400,000 | 3.7% |
| Option Pool | 616,000 | 5.7% |
| Committed Investor | 638,621 | 5.9% |
| Series-A Investor | 2,882,805 | 26.7% |
| BAN Opportunity | 1,123,093 | 10.4% |
| **Total** | **10,810,519** | **100.0%** |

Charts

Pre-Money




Post-Money

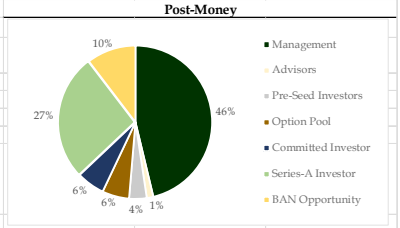



Figure 13: Capitalization Table

The Return Model calculates IRR, internal rate of return, and MOIC, multiple of invested capital. The Pro Forma considers dilutions from future raises, which I also amended when working through the Convertible Note model, and considers liquidation preference. Liquidation preferences often only come into play with Preferred Stocks or some Common Stock priced rounds, not with Convertible Notes. The Equity Build considers the Face Value of investment, or the investment and all accrued interest, as well as the Pro Rata distribution of funds to calculate the value of BAN's equity at exit.

| Exit Assumptions | |
|---|---|
| Exit Year | 2026 |
| Risking Factor | 0.3 |
| Metric | Sales |
| Multiple | 5.0x |
| BAN Ownership | 7.6% |

| Equity Build | |
|---|---|
| Exit Year EBITDA | $29,683.5 |
| (x) Exit Multiple | 5.0x |
| Implied Exit Value | $148,417.5 |
| (-) Debt | (100.0) |
| (+) Cash | 100.0 |
| Implied Equity Value | $148,417.5 |

| BAN Return | |
|---|---|
| IRR | 46% |
| MOIC | 9.6x |

| Investment Assumptions | |
|---|---|
| Year Investment Made | 2020 |
| Initial Investment | 1275 |

| BAN Equity Build | |
|---|---|
| BAN Face Value | $1,377.0 |
| (+) BAN Pro-Rata | 10,905.3 |
| BAN Total Distr. | $12,282.3 |

*Projections*

| | 2018A | 2019A | 2020E | 2021E | 2022E | 2023E | 2024E | 2025E | 2026E |
|---|---|---|---|---|---|---|---|---|---|
| Sales | $0 | $0 | $0 | $0 | $319 | $2,959 | $16,478 | $46,145 | $98,945 |
| EBITDA | ($10) | ($16) | ($1,188) | ($1,824) | ($2,856) | ($3,415) | $5,317 | $20,716 | $56,788 |

*Pro-Forma Ownership*

| Year | Future Fundings | Amount | Post - Money | % Dilution | PF Shares | BAN Ownership |
|---|---|---|---|---|---|---|
| 2020 | Post-Inv. | $1,275.0 | | | 10,810,519 | 10.4% |
| 2023 | Funding 1 | $4,000.0 | $15,000.0 | 26.7% | 14,741,617 | 7.6% |
| 2024 | Funding 2 | 0.0 | 0.0 | 0.0% | 14,741,617 | 7.6% |
| 2025 | Funding 3 | 0.0 | 0.0 | 0.0% | 14,741,617 | 7.6% |
| 2026 | Funding 4 | 0.0 | 0.0 | 0.0% | 14,741,617 | 7.6% |

| Investor | Liq. Pref. | Shares Owned | Ownership | Liq. Pref. |
|---|---|---|---|---|
| BAN | 1 | 1,123,093 | 7.6% | 1275 |
| Funding 1 | 1 | 3,931,098 | 26.7% | 4000 |
| Funding 2 | 1 | 0 | 0.0% | 0 |
| Funding 3 | 1 | 0 | 0.0% | 0 |
| Funding 4 | 1 | 0 | 0.0% | 0 |
| *Total Shares at Exit* | | *14,741,617* | | |

| | |
|---|---|
| BAN Original Shares | 1,123,093 |
| Conv. Note Toggle | Yes |
| Interest Rate | 8% |
| Next Round | 2021 |

Figure 14: Return Model

The Sensitivity Analyses, shown below, show sensitivities if the investor does not fully invest or if the company is not as successful and exits at a lower multiple than the analyst has estimated. The sensitivities show the dependency of the company's IRR on specific drivers, including percent ownership, exit timeline, and exit multiple.

**Sensitivities**

| *Sensitivity* | IRR | Exit Multiple | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | 3.0x | 3.5x | 4.0x | 4.5x | 5.0x | 5.5x | 6.0x | 6.5x | 7.0x |
| BAN Ownership | 4.1% | 25% | 27% | 30% | 32% | 34% | 35% | 37% | 39% | 40% |
| | 4.6% | 27% | 29% | 32% | 34% | 36% | 38% | 39% | 41% | 43% |
| | 5.1% | 28% | 31% | 33% | 36% | 38% | 40% | 41% | 43% | 45% |
| | 5.6% | 30% | 33% | 35% | 37% | 40% | 42% | 43% | 45% | 47% |
| | 6.1% | 31% | 34% | 37% | 39% | 41% | 43% | 45% | 47% | 49% |
| | 6.6% | 33% | 36% | 38% | 41% | 43% | 45% | 47% | 49% | 50% |
| | 7.1% | 34% | 37% | 40% | 42% | 44% | 47% | 49% | 50% | 52% |
| | 7.6% | 35% | 38% | 41% | 44% | 46% | 48% | 50% | 52% | 54% |

| *Sensitivity* | MOIC | Exit Multiple | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | 3.0x | 3.5x | 4.0x | 4.5x | 5.0x | 5.5x | 6.0x | 6.5x | 7.0x |
| BAN Ownership | 4.1% | 3.8x | 4.3x | 4.7x | 5.2x | 5.7x | 6.2x | 6.7x | 7.1x | 7.6x |
| | 4.6% | 4.1x | 4.7x | 5.2x | 5.7x | 6.3x | 6.8x | 7.3x | 7.9x | 8.4x |
| | 5.1% | 4.4x | 5.0x | 5.6x | 6.2x | 6.8x | 7.4x | 8.0x | 8.6x | 9.2x |
| | 5.6% | 4.8x | 5.4x | 6.1x | 6.7x | 7.4x | 8.0x | 8.7x | 9.3x | 10.0x |
| | 6.1% | 5.1x | 5.8x | 6.5x | 7.2x | 7.9x | 8.7x | 9.4x | 10.1x | 10.8x |
| | 6.6% | 5.4x | 6.2x | 7.0x | 7.7x | 8.5x | 9.3x | 10.1x | 10.8x | 11.6x |
| | 7.1% | 5.8x | 6.6x | 7.4x | 8.2x | 9.1x | 9.9x | 10.7x | 11.6x | 12.4x |
| | 7.6% | 6.1x | 7.0x | 7.9x | 8.7x | 9.6x | 10.5x | 11.4x | 12.3x | 13.2x |

| *Sensitivity* | IRR | Exit Multiple | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | 3.0x | 3.5x | 4.0x | 4.5x | 5.0x | 5.5x | 6.0x | 6.5x | 7.0x |
| Exit Year | 2023 | NEG | NEG | NEG | 0.1% | 1.0% | 1.8% | 2.7% | 3.5% | 4.3% |
| | 2024 | 13.4% | 15.8% | 18.1% | 20.3% | 22.4% | 24.3% | 26.2% | 28.0% | 29.7% |
| | 2025 | 26.6% | 29.6% | 32.4% | 35.0% | 37.4% | 39.7% | 41.8% | 43.8% | 45.7% |
| | 2026 | 35.1% | 38.2% | 41.0% | 43.5% | 45.9% | 48.0% | 50.0% | 51.9% | 53.7% |

| *Sensitivity* | MOIC | Exit Multiple | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | 3.0x | 3.5x | 4.0x | 4.5x | 5.0x | 5.5x | 6.0x | 6.5x | 7.0x |
| Exit Year | 2023 | 0.9x | 1.0x | 1.0x | 1.0x | 1.0x | 1.1x | 1.1x | 1.1x | 1.1x |
| | 2024 | 1.7x | 1.8x | 1.9x | 2.1x | 2.2x | 2.4x | 2.5x | 2.7x | 2.8x |
| | 2025 | 3.2x | 3.7x | 4.1x | 4.5x | 4.9x | 5.3x | 5.7x | 6.1x | 6.6x |
| | 2026 | 6.1x | 7.0x | 7.9x | 8.7x | 9.6x | 11x | 11x | 12x | 13x |

Figure 15: Sensitivity Analysis

# APPENDIX D

## Additional Resources

Glossary:

*Claims* – define the scope of patent protection and are the most essential element of a patent.

- Claims use technical language to describe the technology.
- Claims must be clear enough that one "skilled in the art" would be able to identify potential patent infringement.

*Infringement* – occurs when Person B is actively profiting off material covered by Person A's IP.

- Infringement does not occur when an inventor knowingly or unknowingly files an application over material that has already been patented.
- Subordinate patents do not infringe on the dominant patent because they must pay licensing fees or otherwise contract with the dominant patent to use that IP.

*Freedom to Operate (FTO) Analysis/Search* – validates that the patent has white space to operate in (is not infringing or subordinate to an existing patent).

- The search checks that no non-expired patents or pending, published patent applications are operating over the same IP.
- Some inventors strategically do not do FTOs. When filing the application, an inventor must list any and all prior art (s)he knows. The examiner will notice any art listed, but may not see non-listed art. If the inventor lists fewer, because (s)he

did a weak FTO and did not see many, the examiner may be more likely to grant the patent as it is.

*Priority Date* – the date a patent is filed.

- US is a first-to-file country, so the application with the earlier priority date wins.
- Public disclosures can only be made in the 12 months prior to the priority date without invalidating the patent, and public disclosures can only be made after the priority date to avoid invalidating international patents.

*Prior art* – any evidence that the invention is not novel.

- Prior art does not need to be commercialized or physically exist, but it can have been.
- Patent examiners will compare the patent application closely to the prior art and cut claims that may already be covered by existing patents.
- Existing prior art can invalidate a patent, even after it is granted.

*Public disclosure* - any non-confidential communication of the patent's materials

- Public disclosure before the first application date (priority date) can invalidate international applications.
- The US has a one-year grace period, but failing to file 12 months after the first public disclosure results in the same invalidation.
- **Talking to manufacturers and investors can *(and does)* count as public disclosure.**

*White space* – area within a field that is not already covered by patent protection.

- The goal is to draft new patents in white space that previous patents do not cover.

- If a patent modifies another inventor's idea, that idea can be patented, **but it can only be commercialized if the earlier patent is licensed.**

*Key Patent Resources:*

- USPTO Assignment database to check who owns a company's patents https://assignment.uspto.gov/patent/index.html#/patent/search
- Google Patents to see publicly disclosed patents. https://patents.google.com/
- Google Scholar to investigate similar inventions and the scientific literature around it. https://scholar.google.com/

# APPENDIX E

## Patent Exhibit[34]

Analyzing patent protection requires an understanding of the patent itself. An example patent, already granted, follows. This commentary highlights areas of note to help familiarize the analyst with an example patent.

The granted patent below, Patent No. US 8,740,955 B2, is assigned to Zimmer, Inc. This means that Zimmer, Inc., not the inventor, has ownership rights to the invention and to all commercial value. On the first page, we can identify key details: it was invented by Bottlang et al, granted on June 3, 2014, filed as a continuation-in-part of a previous patent, and submitted for a PCT application. See Chapter 3 for implications of each of these details. The publication classification, also on the first page, provides a starting place to find prior art or related patents.

Next, this patent, and most medical device patents, will include drawings. On the third page, Figure 2 provides a helpful image of a cross-section of the bone with the screw in place. Further images show the plating system and how the screw functions in the bone. For context, the product is designed to create micromotion on the head-side of the bone. In addition to their importance for IP protection, patents are a helpful resource to understand the product without any marketing flair.

Figure 19 shows the motion of the screw, demonstrating material difference between their product and competitive patents as well as showing how their product

[34] Note: The patent referenced is US 8,740,955 B2, invented by Bottlang et al and owned by Zimmer, Inc. It has not been directly included in this thesis because it is a publicly-available document owned by Zimmer, Inc. When this project is given to analysts, the thesis is attached.

improves upon known concepts. Considering the uncertainty regarding ineligibility, especially within medical devices (see Chapter 3), this graph is included strategically.

The specification makes up most of the patent. The drawings are helpful to illustrate confusing wording in the summary. However, detailed descriptions of the drawings do not need to be read in detail unless it can clear up confusion elsewhere.

Notably, the claims do not begin until the end (in Line 53 of Column 17), which is common. Claims are very specifically worded and can be challenging to read. For example, a claim that reads "System 1 consisting of A, B, and C" has starkly different implications than one that reads "System 1 including A, B, and C." The former means that the patent covers a system with only A, B, and C, while the latter covers a system with A, B, C, and other elements as desired. As a result, if you must read the claims, find a guide to clarify the terminology. It is key to note that since claims define the scope of coverage, they are the most important component of the patent. The majority of the patent provides context, illustrates the device, discusses data regarding the screw's function, and discusses nuances of the design, but the claims determine the value.

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